FDA FVM Microbiology Program Review

Results of Microbiology Research Personnel Interviews

Final
July 31, 2014

Contract No. HHSF223201210011B
BPA No. 10

TABLE OF CONTENTS

ES. EXECUTIVE SUMMARY 1
ES.1. Key Findings 1

1.0. INTRODUCTION 6
1.1. Purpose 6
1.2. Interview Process 6

2.0. INTERVIEWEE RESPONSES BY QUESTIONS 8
2.1. Science Questions 8
2.1.1. Question 1 8
2.1.2. Question 2 9
2.1.3. Question 3 10
2.1.4. Question 4 12
2.1.5. Question 5 13
2.1.6. Question 6 15
2.1.7. Question 7 18
2.1.8. Question 8 18
2.1.9. Question 9 21
2.1.10. Question 10 22
2.1.11. Question 11 23
2.2. Organizational Management 24
2.2.1. Question 12 24
2.2.2. Question 13 26
2.2.3. Question 14. 28
2.2.4. Question 15. 30
2.3. Collaboration/Communication 30
2.3.1. Question 16 30
2.3.2. Question 17. 32
2.3.3. Question 18 34
2.3.4. Question 19 35
2.3.5. Question 20 37
2.3.6. Question 21 38
2.4. Expertise/Training 39
2.4.1. Question 22 39
2.4.2. Question 23 40
2.4.3. Question 24 42
2.4.4. Question 25 42
2.4.5. Question 26 43

APPENDICES

APPENDIX A: REVIEW QUESTIONS A-1
APPENDIX B: COMPOSITION BY OFFICE OF INTERVIEWEES B-1
APPENDIX C: INTERVIEWEE OBSERVATIONS C-1

Acronyms used in this report:

Additional acronyms are defined within the document where they arise. The document also includes commonly used acronyms (e.g., IT) or those considered to be in common use within FDA (e.g., BAM, names of other centers or offices) that are not defined.

AOAC: Association of Analytical Communities
ASM: American Society for Microbiology
AST: Antibiotic susceptibility testing
BC: Branch Chief
BSL: Biological Safety Level
CD: Center Director
COI: Conflict of interest
CORE: Coordinated Outbreak Response and Evaluation Network
CPK1: College Park; used for both the location and personnel working therein
CSO/RD: Chief Science Officer/Research Director
DD: Division Director
DDSO: Deputy Director for Scientific Operations
ELISA: Enzyme-linked immunosorbent assay
ERO: Expected research outcome
FERN: Food Emergency Response Laboratory Network
FSMA: Food Safety Modernization Act
GFN: Global Foodborne Infections Network
GIMS: Genomic Information Management System
GMI: Global Microbial Identifier
GMP: Good manufacturing practices
IAFP: International Association for Food Protection
IBRCC: Interagency Botulism Research Coordinating Committee
ICLN: Integrated Consortium of Laboratory Networks
IAFP: International Association for Food Protection
IFSH: Institute for Food Safety and Health
IFT: Institute of Food Technology
IIT: Illinois Institute of Technology
ISO: International Organization for Standardization
ISSC: Interstate Shellfish Sanitation Conference
JIFSAN: Joint Institute for Food Safety and Applied Nutrition
LIMS: Laboratory Information Management System
LRN: Laboratory response network
MB: Microbiology
MOU: Memorandum of Understanding
NCBI: National Center for Biotechnology Information
NCNPR: National Center for Natural Products Research
NCTR: National Center for Toxicological Research
OD: Office Director
ORISE: Oak Ridge Institute for Science and Education
PCR: Polymerase chain reaction

PEG array: Poly(ethylene glycol) array
PFGE: Pulsed field gel electrophoresis
PI: Principal investigator
PMAP: Performance Management Appraisal Program
qPCR: Quantitative Real-Time PCR
RAC: Research Area Coordinator
SME: Subject matter expert
SRA: Sequence Read Archive
SSA: Senior Science Advisor
UMD: University of Maryland
Vet-LRN: Veterinary Laboratory Investigation and Response Network
WGS: Whole genome sequencing
WCFS: Western Center for Food Safety

ES. EXECUTIVE SUMMARY

To assess FDA's Foods and Veterinary Medicine (FVM) Program's current microbiological capacity, the leadership of FVM is undertaking a review of its microbiology laboratory programs focusing on scientific capacity, efficiency, and the management of the program's multiple elements across the Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM).

As part of this review, FVM leadership organized in-person interviews of personnel working in microbiology research within three offices in CFSAN and one office in CVM. The microbiology "groups" represented in this report are:

- Office of Applied Research and Safety Assessment: OARSA
- Office of Food Safety, Division of Seafood Science and Technology at Dauphin Island: OFS/DI
- Office of Food Safety, Division of Food Processing Science & Technology, Moffett Center: OFS/MC
- Office of Regulatory Science: ORS
- Center for Veterinary Medicine, Office of Research (OR): CVM

For the interviews, 94 interviewees (28 from OARSA, 9 from OFS/DI, 12 from OFS/MC, 30 from ORS, and 15 from CVM) were asked a series of 26 open-ended questions in four major areas: science, organizational management, collaboration/communication, and expertise and training.

ES.1. Key Findings

1. Most of the individuals involved in microbiology research within the FVM Program are dedicated and passionate about their work, enthusiastic about the science, and truly believe in the mission. Regardless of their level of satisfaction with the current status of the Program, most interviewees had a lot to say during the interview process because they really care about what they do and want the Program to succeed.

2. Interviewees involved in microbiology research within the FVM Program believe that maintaining in-house capabilities is essential to fulfilling FDA's and the Program's mission and protecting public health, and that current scientific knowledge is required for writing regulations.

3. Across all groups, interviewees felt the greatest program strength was expertise.

- The FVM Program is home to world-renowned scientists in all offices.
- Despite a shift in the Program towards genomics methods, all groups reported expertise in both traditional and molecular microbiology, and diverse expertise within groups was cited as a strength.
- The Program possesses specialized microbiology expertise in seafood safety, food processing and technology, and antimicrobial resistance, as well as expertise in

laboratory proficiency testing and preventive controls, which may have increasing value with the implementation of FSMA.

4. Across all groups, interviewees identified staffing/manpower as a major program weakness, including insufficient staffing and lack of authorization to backfill and/or hire FTEs and/or convert ORISE or Staff Fellows.

5. There is a lack of coordination among all groups in the Program that may be hindering effective utilization of the manpower and expertise within the program.

- Under organizational management, many suggestions included unifying all or some of the groups under a single authority or unifying research expertise across groups along functional lines.
- Interviewees in different groups were often completely unaware that others in the Program were working in the same research area.
- There is no resource designated for publicizing in-house research within the Agency to identify areas of shared interest, expertise, and availability.

6. The effectiveness of current efforts in communication/transparency from upper management drops sharply for groups that are within CFSAN but outside College Park. This appears to be attributable to:

- Physical separation: Interviewees in off-site locations commented that they saw or spoke with members of upper management rarely and felt that those within ORS had much more ready access to members of upper management.
- Ineffectiveness of communicating through line management: interviewees in both OARSA and OFS/MC commented that information concerning changes in Program priorities or processes was not relayed in branch/division meetings.
- Lack of coordination among groups: addressed above.

7. There is a culture of competition between ORS and OARSA that may be hindering microbiology research efforts.

- Despite common areas of research between the two offices, interviewees felt there was little collaboration or willingness to share facilities, resulting in inefficiencies as well as duplication of research.
- The perception among OARSA interviewees that there is bias within upper management for ORS both in terms of resources and research areas which has contributed to low morale and even anger within OARSA that are counterproductive to Program efforts.
- The shift of some researchers and projects from OARSA to ORS has also contributed to the feeling of competition between the offices.

8. There appear to be issues with line management in several groups attributed to the lack of permanent, strong, and/or effective line management.

- Interviewees felt line management issues were affecting research in OARSA, collaboration between OARSA and ORS, and some research efforts within ORS.
- Although issues with line management were identified in the other groups, they were not felt to have an impact on research efforts.

9. There appear to be organizational problems in several groups that are in need of action. These include:

- Addressing the division structure within OARSA
- Addressing the partnership with IFSH at Moffett Center, and
- Addressing the relationship between the NARMS program and research groups within DAFM.

10. There is support across groups for maintaining basic research and traditional microbiology capabilities and concern that further narrowing the scope of research may negatively impact the Program's ability to protect public health.

11. In general, those who are not directly involved in whole genome sequencing, regardless of their office or group affiliation, have questions concerning the ultimate value of the program to the Agency and its implications in protecting public health.

12. There was generally little overt focus on FSMA and the challenges it will present the Program except at OFS/MC, where research in food processing and preventive controls was more directly tied to the objectives of FSMA.

13. Across the different research groups, there were major differences in perceptions of their roles within and contributions to the Program. The following is an overview of what interviewees within each group perceived their group and how the group was perceived by interviewees in other groups.

<u>OARSA</u>:

- There is a general feeling of crisis among OARSA interviewees at all levels that appears to be attributable to: lack of representation with upper management; line management issues; organizational issues at the division level; lack of authority to hire/convert staff; and the perception that they are in competition with ORS.
- Interviewees within other groups believe that scientists within OARSA are pursuing independent research without regard for Program priorities or alignment, when in fact, many OARSA interviewees indicated that their research projects had been halted and/or that they were having trouble developing projects that would be approved through the CARTS system.
- When all responses are considered, it appears that, despite being a repository of a great deal of microbiological expertise in many areas of traditional and molecular microbiology, OARSA personnel are currently being greatly under-utilized. This is at least partly due to their lack of awareness of and involvement in the research prioritization process until very recently.

OFS/DI:

- Interviewees within OFS/DI uniformly felt that their group was doing well in terms of productivity of research and interactions with their stakeholders, despite the need for additional staff and space. They attributed this success to their research being commodity driven and to their close ties with their policy group (Division of Seafood Safety).
- Interviewees within other groups generally seemed to be unaware of the research being conducted at OFS/DI except when that research crossed the boundary into matrices other than seafood.
- When all responses are considered, OFS/DI appears to fill a unique niche within the Program because of their strength in microbiology research related to seafood, the importance of seafood as a commodity internationally, and their close ties with a variety of stakeholders including industry (e.g., ISSC), ORA field laboratories, state laboratories, and international partners.

OFS/MC:

- Interviewees within OFS/MC felt strongly about their expertise in a unique spectrum of research efforts including food processing and technology, select agent research, laboratory proficiency testing, and preventive controls. Interviewees felt they had strong ties with their policy office, but were very concerned about the relationship between FDA and IIT under IFSH.
- As for OFS/DI, interviewees within other groups generally seemed to be unaware of the research being conducted at OFS/MC.
- Like OFS/DI, OFS/MC appears to fill a unique niche both as a result of its inclusion in IFSH and in its areas of research focus. Despite the problems with the consortium that were identified by interviewees, IFSH offers FDA a rare opportunity to interact with industry in a collaborative way. In addition, OFS/MC offers FDA exposure to a different group of stakeholders through their laboratory proficiency testing, and is positioned to implement FSMA-related efforts through their work on preventive controls.

ORS:

- Within ORS responses generally differed between interviewees who were involved in whole genome sequencing efforts, which appears to be receiving a great deal of funding and manpower, and those who were not. Interviewees involved in other research efforts tended to feel that there was a disproportionate focus on whole genome sequencing.
- Interviewees in OARSA felt that ORS is a favorite with upper management and might not have to go through the same processes to obtain project approval, resources, etc. Interviewees within the other groups were mainly aware of the whole genome sequencing efforts within ORS.
- When all responses are considered, ORS appears to be in a unique position due to their physical location and appears to have benefitted from this proximity. In addition, whether they are directly involved in the research being done in whole genome sequencing or not, the success of this program enables ORS interviewees to feel a greater sense of "job security" than those in most other groups within the Program.

CVM:

- As with other smaller groups, interviewees within CVM were more cohesive in their opinion of their group which was generally felt to be doing well, largely as a result of the preeminence of the NARMS program. The current area of most concern to CVM interviewees, besides staffing, appeared to be the need for a clearer organizational structure as the result of a recent reorganization.
- Interviewees in other offices were largely aware of the NARMS program, and there appeared to be positive interactions between researchers within ORS and OARSA and those in CVM.
- Because of the NARMS program, CVM appears to have the closest ties of any group with CDC and USDA, who are partners in NARMS, as well as high visibility on a global scale.

1.0 INTRODUCTION

1.1 Purpose

The purpose of the microbiology program review is to: assess how FVM's microbiological capacity is deployed and applied across the program; identify the efficiency and management practices that affect how well staff and other resources are used to oversee microbiology work; determine whether microbiology research is meeting program needs; identify if there is unnecessary duplication; and ensure that microbiological research yields mission-relevant outcomes. The review will also examine how FVM's microbiology program interacts with other U.S. government and state agencies, the external scientific community, and other external stakeholders. The outcome of the review will be recommendations to improve the Program in these areas as necessary to better meet today's microbiology challenges.

To obtain the perspective of those within the FVM Program, personnel working in microbiology research were asked a series of 26 open-ended questions:

- Science (11 questions) addressing: the need for in-house expertise in microbiology; individual program strengths and weaknesses; perceived areas for improvement at division/branch and program levels; prioritization, impact, and alignment of microbiology research; areas in which research could be reduced, maintained, or expanded; challenges facing the program regarding microbiology research; and means of improving recognition for scientific achievements.
- Organizational Management (4 questions) addressing: the effectiveness of the current organizational structure; deployment and use of staff and resources; and suggestions for improvements in information technology and other important services and capabilities.
- Collaboration/Communication (6 questions) addressing: the quality of collaboration/communication within and among microbiology research groups and between research groups and program offices; interaction between FVM microbiology programs and other Federal agencies, academia, and international bodies; suggestions for better serving program stakeholders, and identification of and suggestions for overcoming institutional or systemic barriers to coordination with partners and stakeholders.
- Expertise/Training (5 questions) targeted at: identifying needed scientific expertise and technological capability; improving recruitment, development, and retention of professional expertise; and addressing staff training and professional development needs.

The review questions are presented in Appendix A.

1.2 Interview Process

FDA identified 104 interviewees working in OARSA (32), OFS/DI (9), OFS/MC (12), ORS (34), and CVM (17) to participate in the interview process. All potential participants were contacted via email to schedule appointments for interviews, and 94 interviews were scheduled to be conducted in person in College Park and Laurel, MD, Dauphin Island, AL, and Moffett Center, IL with: 28 interviewees in OARSA, 9 interviewees in OFS/DI, 12 interviewees in

OFS/MC, 30 interviewees in ORS, and 15 interviewees in CVM. Interviewees included principal investigators, subject matter experts, support scientists and technicians, team and project leaders, and line managers, as well as others directly involved in facilitating/supporting microbiology research within the Program. In terms of experience, the durations interviewees had reportedly worked in their current positions ranged from <1 to 27 years and the number of years they had worked at FDA ranged from 1.5 to 53 years. The composition of the interviewee pool by office, division, and branch is presented in Appendix B.

Interviews were conducted by Versar, Inc. during the months of February through April 2014. During the interviews, employees' responses were written down by hand. In addition, the interviews were digitally recorded to improve accuracy of transcription. A written summary of each interview was prepared by Versar for use in writing this report, and relevant responses were extracted into the report by office/group, with no other identification, except where necessary to clarify the viewpoint of the interviewee responding (e.g., support scientist or team leader). Recordings of individual interviews and the interview summaries will be retained by Versar, and the recordings and summaries will be deleted upon delivery of the final report.

The results of the interviews were used in writing this report, as follows: (1) direct quotes and paraphrases (with no distinction made between the two) were captured and attributed by group as identified above; and (2) responses were extracted into a spreadsheet designed by Versar to capture main ideas and thoughts to produce quantitative results. In converting oral responses to written comments and statements for purposes of this report, certain liberties were taken in re-arranging sentence order and structure to clarify interviewee responses. For purposes of readability, these responses were not marked with brackets, ellipses, etc. as they would have been if direct, attributable quotes were being reproduced here. Every effort was taken to maintain the interviewee's intention during this process.

For purposes of gathering quantitative data, employee responses were categorized under headings developed by the study authors for entry into an Excel spreadsheet. For open-ended questions, where interviewees may have had several thoughts or suggestions, up to three responses were captured per interviewee, and results were generally reported herein in terms of the number of responses obtained for a given question. The purpose of the quantitative results was solely to provide a scale for evaluating the relative importance of certain responses; the numbers themselves have no intrinsic value.

Relevant observations, comments, and recommendations are presented intact or relatively intact in Appendix C with appropriate group designations, and the responses are summarized by section in Part 2 of the report: Interviewee Responses by Questions.

2.0. INTERVIEWEE RESPONSES BY QUESTIONS

This report summarizes the responses of 94 interviewees working in microbiological research in the FVA program in response to the interviewee questions. For most questions, the relevant observations, comments, opinions, and recommendations supporting the points that have been summarized below are presented in Appendix C with identifiers to indicate the office each interviewee belongs to:

- Office of Applied Research and Safety Assessment: OARSA
- Office of Food Safety, Division of Seafood Science and Technology at Dauphin Island: OFS/DI
- Office of Food Safety, Division of Food Processing Science & Technology, Moffett Center: OFS/MC
- Office of Regulatory Science: ORS
- Center for Veterinary Medicine, Office of Research (OR): CVM

In presenting quantitative results, numbers of responses are presented in this report unless otherwise noted. There is no correspondence between the numbers of responses listed in the tables below and the number of comments that appear in Appendix C.

2.1. Science Questions

2.1.1. Question 1: What do you see as the most important reasons for having in-house microbiological research programs at CFSAN and CVM?

The majority of interviewees indicated that the unique requirements of the Centers and/or that no one else in the Federal government, industry, or academia would or could do this work as the most important reasons for having in-house microbiological research programs. Additional reasons included the need to protect public health and respond in outbreaks, the need to support the mission and the program offices, the need to maintain a base of expertise in all microbiological food-related areas, FDA's role as a science-based agency, cost effectiveness, quality control, and the need for unbiased research in this effort. The distribution of the top four responses was generally consistent across Offices.

Table 1. Most Important Reasons for Having In-House Microbiological Research

Most Important Reasons for Having In-House Microbiological Research	Number of Responses[1]
Our requirements are unique/No one else can or will do	55
Public health and outbreak response	31
Support mission and program offices	22
Maintain expertise	12
Science-based agency	6
Cost	4
Quality control	3
Lack of bias	3

[1] Up to 3 responses captured/interviewee (total 136 responses).

In citing unique requirements interviewees referred to the Agency's public health and regulatory missions, the focus on pathogens in food vs. other matrices, and the need to develop practical methodology for use in the field. Interviewees felt that other Federal agencies, including CDC, NIH, and USDA could not do the same work due to their differing missions and focuses, and that academia would not do the work because much of it does not result in publishable results because of the cost of certain aspects of the work (e.g., method validation). It was felt that the private sector would not do the same breadth and/or scope of work, would not share their results, and might not be reliable due to conflict of interest. It was noted that using outside contractors, even for method development, could result in missing opportunities for alternative uses of a given method. In addressing FDA's mission to protect the public health, in addition to the need to be responsive in outbreaks and develop methods for detecting pathogens, interviewees felt it was FDA's role to fully understand the pathogens involved in outbreaks, from emergence and growth through evolution. The need for microbiological support for the Centers' mission as well as FDA regulatory policy, compliance, and enforcement efforts, including the efforts of the ORA field laboratories, was also cited. Refer to Appendix C: C.2.1.1 for interviewee observations.

2.1.2. Question 2: In your work unit, what do you see as the strengths in your program with respect to microbiological review or research?

The majority of interviewees in all offices felt that expertise was their greatest program strength. Other top responses were positive group dynamics, mission alignment, and the ability to have a positive impact on public health. Having access to the latest technology and/or resources in terms of equipment were also listed. Within OFS/DI, engagement with stakeholders was identified as a strength; strong leadership was identified as a strength by one ORS interviewee.

Table 2. Number of Responses for Program Strengths by Office[1]

Program Strengths - Office (No. of Interviewees)	OARSA (28)	OFS/DI (9)	OFS/MC (12)	ORS (30)	CVM (15)	Total (94)
Expertise	25	5	11	17	10	68
Group dynamics	12	1	2	7	5	27
Aligned with mission	3	5	2	6	3	19
Public health and outbreak response	3	1	1	5	1	11
Access to the latest technology	1	0	1	4	1	7
Resources	4	0	0	2	1	7
Engaged with stakeholders	0	2	0	0	0	2
Leadership	0	0	0	1	0	1
Total responses	**48**	**14**	**17**	**42**	**21**	**142**

[1] Up to 3 responses captured/interviewee.

Within OARSA, staff expertise, based primarily on the diversity of expertise demonstrated within the Office, and positive group dynamics were most often identified as program strengths. Interviewees also pointed out research strengths in genomics, a field in which several felt they were being out-competed by ORS. Infrastructure-type resources in terms of advanced lab capabilities including a BSL-3 lab were also cited as program strengths. Interviews at OFS/DI

cited depth of expertise and a commodity-driven approach as program strengths, but felt their alignment with the mission, attributed to close ties with their program office, and their engagement with their stakeholders were particular strengths. OFS/MC interviewees cited their unique expertise in the areas of food processing and food technology, preventive controls, laboratory proficiency testing, and select agent work as program strengths. Within ORS diverse expertise in both traditional and molecular microbiology were cited as program strengths, along with positive group dynamics. Alignment with the mission and access to the latest technology were felt to be particular strengths within this office owing to their access to the program offices, greater focus on applied research vs. basic research, and the resources devoted to genomics and especially whole genome sequencing. Diverse expertise along with positive group dynamics were also cited as major strengths within CVM, with special emphasis placed on their ability to collaborate with others both within CVM and with other offices and agencies. Refer to Appendix C: C.2.1.2 for interviewee observations.

2.1.3. Question 3: In your work unit, what do you see as the weakness in your program with respect to microbiological review or research?

The top five program weaknesses identified across all offices were staffing, leadership and/or management issues, lack of communication/transparency with upper management, insufficient resources, and insufficient communication and collaboration within and between groups. However, the Offices differed substantially in the relative emphasis placed on these issues and the reasons they were felt to be weaknesses. Sciences issues, problems of coordination between offices, low morale, and professional development and travel problems were identified as weaknesses in select Offices.

Table 3. Number of Responses for Program Weaknesses by Office[1]

Office (No. of Interviewees)	**OARSA (28)**	**OFS/DI (9)**	**OFS/MC (12)**	**ORS (30)**	**CVM (15)**	**Total (94)**
Staffing	7	3	7	9	9	35
Leadership/management	10	1	1	6	2	20
Lack of communication/transparency with upper management	10	3	1	0	0	14
Resources	2	3	2	3	2	12
Communication and collaboration	4	0	1	5	1	11
Science issues	1	0	0	4	4	9
Coordination between offices	3	0	0	5	0	8
Low morale	5	0	0	0	0	5
Professional development and travel	0	0	3	1	0	4
Other	2	0	2	3	0	7
None	0	2	1	2	1	6
Total responses	**44**	**12**	**18**	**38**	**19**	**131**

[1] Up to 3 responses captured/interviewee.

Within OARSA, leadership and/or management issues and lack of communication/transparency with upper management were most often cited as weaknesses. Leadership/management issues were attributed to the absence of a strong, permanent Office Director to represent the Office in

dealing with upper management and to problems down the line with division and branch management attributed to a lack of permanent assignments and/or to perceived weaknesses (e.g., disengagement, poor management skills, lack of professionalism) in the current line management. In discussing lack of communication/transparency with upper management, interviewees stated that they felt that upper management did not respect or support the Office and was not providing sufficient guidance concerning how the Office might adjust its research to satisfy Agency objectives. This perception was felt to be supported by the absence of action in addressing management and staffing issues in the Office. Staffing was also felt to be a significant program weakness in OARSA, with the focus primarily on the inability to convert Staff and ORISE Fellows integral to many research projects to FTEs. In terms of coordination between offices, interviewees reported that the Office received different treatment in terms of staffing and resources vs. ORS and that there was unfair competition for research areas. OARSA was the only office to identify low morale as a program weakness. Together these weaknesses contributed to a general feeling of crisis among OARSA interviewees throughout the Office.

For OFS/DI, insufficient staff was identified as a weakness and was mentioned in conjunction with a shortage of space. The lack of communication/transparency with upper management was attributed mainly to the group's remote location and resource issues. Based on responses to subsequent questions, most interviewees tended to feel pride in the high productivity of their lab despite any listed weaknesses.

Within OFS/MC, staffing was the major identified program weakness and included shortages both in PIs (especially for virology) and in support scientists and technicians. The availability of IIT graduate students to assist in research was not felt to off-set these shortages, primarily because of the amount of training that had to be invested in consideration of the 2-year duration of these masters' candidates within the Center. The lack of professional development opportunities for support scientists and technicians and the lack of travel opportunities due to budget constraints were also listed as weaknesses.

Staffing, primarily the need for additional support scientists and technicians, was also the major identified weakness in ORS; however, the need for additional manpower in general was also identified. Leadership/management issues were attributed largely to bureaucracy, although issues resulting from the increased focus on whole genome sequencing and with individual managers were also cited. Disproportionate focus on priority projects was identified as a factor in distribution of resources and some of the identified science issues. The lack of communication and collaboration within the Office as well as problems in coordinating with OARSA, including the perception that researchers within that office do not have the same level of accountability to the mission and problems obtaining access to OARSA facilities were also identified as weaknesses. Within ORS, differences in the level of seriousness attributed to program weaknesses, tended to pivot around interviewees' involvement with and/or support for the whole genome sequencing project as a major priority within the Center.

Within CVM, insufficient staff was consistently identified as the primary weakness, with various science issues ranging from specific data issues for the NARMS program to broad topics including the decline of traditional microbiology in the face of increased focus on gene

sequencing. In general, interviewees felt their office was strong, despite being short-handed. Refer to Appendix C: C.2.1.3 for interviewee observations.

2.1.4. Question 4: What can be done in the coming year that will result in improvement in your division/branch?

There was some over-lap between the categories of responses to Question 2.1.4 and Question 2.1.5, depending on whether individual interviewees perceived improvements as short-term or long-term and within Question 2.1.5 concerning whether improvements would apply to the division/branch or the entire microbiology program. For purposes of the report, responses were assigned below at the discretion of the report authors.

Addressing staffing issues was the top short-term improvement identified in all offices except OARSA, in which addressing leadership/management issues and reviewing office organization appeared to be of equal importance. Leadership/management issues were also identified by OFS/DI, ORS, and CVM interviewees, and reviewing office organization was addressed by ORS and CVM interviewees. The next three responses were clarifying Center priorities and goals and their impact on project development and approval, improving communication and transparency with upper management and the program offices, and encouraging interactions among scientists to improve research. Other areas that were mentioned included systematizing operations (including staggering timing of large projects in OFS/MC and establishing systems for accessing instrumentation and organizing data flow within ORS), and publicizing research efforts within and outside the Centers.

Table 4. Number of Responses[1] by Office to the Question "What Can be Done in the Coming Year to Improve Your Division/Branch?"

Office (No. of Interviewees)	**OARSA (28)**	**OFS/DI (9)**	**OFS/MC (12)**	**ORS (30)**	**CVM (15)**	**Total (94)**
Address staffing issues	9	4	7	11	9	40
Resolve leadership/management issues	10	3	0	1	4	18
Review organization	9	0	0	3	3	15
Clarify Center priorities/goals	6	2	1	0	3	12
Improve communication/transparency	3	0	1	4	3	10
Encourage interactions	1	1	1	3	0	6
None needed	1	0	2	1	0	4
Systematize operations	0	0	1	1	1	4
Publicize research internally	0	0	1	3	0	3
Total responses	**39**	**10**	**14**	**26**	**23**	**112**

[1] Up to 3 responses captured/interviewee.

Within OARSA, the conversion of Staff and ORISE Fellows to FTEs was considered to be one of the most important short-term improvements because of the large proportion of scientists represented by the Fellows and because of their pivotal role in ongoing research projects: "Our Branch has more nonpermanent employees than permanent employees, and only two of those permanent employees are principal investigators. The other projects are headed up by Staff

Fellows or ORISE Fellows." By contrast, other offices tended to focus more on having insufficient staff in general or in specific areas and the need for additional support scientists/technicians or administrative support.

In terms of leadership/management improvements, OARSA interviewees identified the appointment of a permanent Office Director, and OFS/DI interviewees identified the appointment of a permanent Division Director as the most important short-term improvements. The need for improvements in line management at the division and branch levels were identified in OARSA and ORS, while CVM interviewees addressed the need improvement in leadership at the division director level and the need for more project managers.

The need for a review of the current organization in OARSA was mentioned specifically in connection with the Division of Virulence Assessment, where scientists felt that both the division name and the original mission statement no longer reflected the work they were doing or their capabilities in microbiological research. In ORS the focus was on the imbalance between the two branches of the Division of Microbiology and on the need for more teams to manage the work, and in CVM the focus was on clarifying roles and responsibilities of researchers between the NARMS program and research within the Division.

Refer to Appendix C: C.2.1.4 for interviewee observations.

2.1.5. Question 5: What areas might be productive for longer term mission-related improvements in your division/branch and for the entire microbiology program?

There was some over-lap between answers to Question 2.1.4 and Question 2.1.5 and within Question 2.1.5. For purposes of the report, responses were divided at the discretion of the report authors.

Table 5. Number of Responses to the questions "What Areas Might be Productive for Longer Term Mission-Related Improvements?"

In your division/branch?	No. Responses[1]	For the entire microbiology program?	No. Responses[1]
Address staffing issues	21	Improve coordination between offices	23
Increase efforts in specific areas	16	Develop a long-term plan	10
Review organization/structure	8	Reorganize microbiology research groups	9
Improve facilities and infrastructure	7	Adjust current structure	3
Review research scope	5	Improve distribution of resources	6
Review alignment	4	Address professional development, training, and travel	10
Improve procurement process	3	Publicize research internally	2
Total responses	**64**	**Total responses**	**63**

[1] Up to two responses captured/interviewee.

Division/Branch:

In addressing longer-term mission-related improvements at the division/branch level, there was concern across all offices over succession planning and the need to hire additional and/or younger scientists to retain institutional memory because many of the current FTEs in microbiology are approaching retirement. Interviewees felt that increased efforts were needed in the long term in specific areas including: method development and validation, including increased validation of existing methods vs. development of more new methods, building leadership in developing new methods, and comparing subtyping methods; basic research in specific areas (BSL3 laboratory and alternative animal research, parasitology) and specific pathogens, including *Vibrio parahaemolytica*, *Listeria*, *E. coli*, molds, and yeasts; genomics; the NARMS program; and bioinformatics.

Suggestions related to reviewing the microbiological research organization and structure included establishment of a Division of Preventive Control and/or a Division of Process Control within CFSAN, establishment of a separate NARMS division within CVM, assigning project managers to liaison between researchers and other offices during outbreak response, and clarifying roles and areas of expertise for scientists across the microbiology program. In terms of facilities and infrastructure, interviewees mentioned the need for additional permanent space (OFS/DI), building service issues and IT restrictions (ORS), and adapting current facilities to new technologies (CVM).

The need to review the scope of research was addressed primarily within OARSA, where interviewees noted that the narrowing of the scope of research has lead to competition for projects within the Office and underutilization of expertise within the program. The need to review alignment was addressed in the context of changing requirements under FSMA and in shifting scientists to more mission-relevant work, and the need to improve the procurement process was addressed with respect to redundancy in ordering equipment, budget issues, and the current system of having principal investigators and support scientists act as credit card holders. Refer to Appendix C: C.2.1.5 for interviewee observations.

Entire FVM microbiology program:

In terms of longer-term improvements for the entire microbiology program, improving coordination between offices was of paramount concern to interviewees within OARSA, and was also mentioned by interviewees within ORS and CVM. Interviewees from all three groups felt there could be better coordination of microbiology research across all groups included in this review, as well as program and field offices, via better communication, regular meetings, resolving long-standing disputes, and increased collaboration. The need to assess duplication of efforts and redundancy within this context was also identified. The need to resolve the competition between OARSA and ORS for research areas, funding, and staff was expressed primarily by OARSA interviewees who used terminology including “favoritism,” “jealousy,” “tension,” “dislike,” “bias,” “territoriality,” “pitted against each other,” and “attacking” and “invisible” to describe the situation. Upper management was implicated in the creation of this situation, which many linked to the promotion of the Deputy Director of Science Operations from within ORS and the increasing focus of efforts and funding on whole genome sequencing.

Options to improve relations between the Offices included bringing the groups together under unbiased management, better communication and collaboration between the groups, and broadening research areas. One team leader within OARSA who has taken the initiative in improving relations between their team and counterparts in ORS stated, "I've only seen positive outcomes from our interactions. It's getting better because the scientists are taking the initiative to make it better. Management is not doing anything to facilitate it." Another researcher noted that "A lot of us do collaborate" and that "most of the issues are at the management level." An ORS interviewee commented, "Those in MOD 1, have no one here advocating their position. Those in power here have the Division Director's ear, so the Center Director gets a very one-sided picture (ORS)."

Another area in which longer-term improvements were suggested included developing a long-term vision for the program, including: broadening the scope of the mission, clarifying the process of determining what is mission relevant, retaining basic research, identifying parameters to evaluate program success, and clarifying how the microbiology program fits in the Agency as a whole. There were also suggestions for reorganizing all of microbiology research under one office with one office director or placing all of microbiology research under the direction of the Chief Science Officer/Research Director. Suggestions for redistribution of individual microbiology groups included establishing centers of excellence in different areas (e.g., *E. coli* research) within the Center, reviewing and combining microbiology laboratories to improve alignment across the Centers, and combining the microbiology research groups in ORS and OARSA. Additional areas for improvement included: suggestions for adjusting the current structure ranging from entire offices to the nature of duties for scientists and managers; general comments regarding improving the distribution of resources; and comments on professional development, training, and travel which are largely addressed elsewhere in the report. Refer to Appendix C: C.2.1.5 for interviewee observations.

2.1.6. Question 6: How are research priorities determined in your division/branch?

Many interviewees felt that research priorities were determined mainly via a research prioritization system that relies on the strategic plan, EROs, and interactions with working groups and program offices. Others felt that priorities were established primarily by upper management. Often interviewees felt a combination of the two were driving research priorities. Other responses included the CARTS system, the scientists themselves, and outbreaks or public health threats. The responses tended to vary by office, especially for those in OFS/DI and OFS/MC who appeared to be more directly connected to their stakeholders, and CVM, who appear to rely on a different prioritization system. The question of politics or bias in establishing research priorities was voiced in all offices except CVM. In general, support scientists were less likely to be aware of how priorities were determined than were PIs.

Table 6. Table 5. Number of Responses to the questions "How are Research Priorities Determined in Your Division/Branch?"

Office (No. of Interviewees)	OARSA (28)	OFS/DI (9)	OFS/MC (12)	ORS (30)	CVM (15)	Total (94)
Strategic plan, EROs, working groups, program offices	22	4	6	9	3	44
Management	12	3	7	16	6	44
CARTS	11	2	0	4	0	17
Scientists	2	3	3	3	5	16
Outbreak/threat	0	3	0	7	3	13
Politics/bias	1	1	1	1	0	4
Internal peer review	0	1	0	0	0	1
Don't know	4	2	0	6	2	14
Total responses	**52**	**19**	**17**	**46**	**19**	**153**

[1] Up to 3 responses captured/interviewee.

Within OARSA, some interviewees attributed the narrowing of the research scope within the Center to a combination of the research prioritization system, upper management decisions, and the CARTS system. It was noted that projects had been halted mid-way due to changing priorities handed down from upper management or rejected with little or no feedback as to the reason. Several noted that line managers were inactive or ineffective in the prioritization system. Within OFS/DI, prioritization was felt to come primarily from the regulatory laboratories, the program office, and the scientists, which worked well. The ERO and CARTS systems were not felt to be as useful to the process. Within OFS/MC priorities were felt to be driven by upper management in conjunction with industry partners in the IFSH consortium and other offices including ORA and CVM as well as by the research prioritization system. Interviewees indicated that there were difficulties in integrating Agency and industry priorities within the relatively new prioritization system. Within ORS, interviewees had mixed responses concerning the effectiveness of the research prioritization system, but more felt that priorities were determined by upper management. Within CVM the prioritization process appeared to be more cohesive, with more integration across offices (ONADE and OFVM), management, and scientists. Refer to Appendix C: C.2.1.6 for interviewee observations.

2.1.6.1. Question 6.a. How do you contribute to the process?

Interviewees at most levels, including those in line management, team leaders, and PIs, indicated that they contributed to the prioritization process by participating in the research prioritization process and advocated for their work or their group's work. Line managers and team leaders indicated that they consulted with PIs on projects or prioritization and helped to set priorities, while conceiving research projects was mainly the contribution of PIs. Some PIs, as well as individuals in line management felt their contributions to the process were minor, and some felt they did not contribute at all. Refer to Appendix C: C.2.1.6.a for interviewee observations.

2.1.6.2. Question 6.b. What ideas can be implemented to improve the process?

The top suggestion for improving the prioritization process was again to improve communication and transparency concerning how priorities are established. Many interviewees advocated including scientists and/or line management in the prioritization process, and specific recommendations were made concerning the need to improve the CARTS process. Other recommendations included keeping the focus on public health and food safety, improving the project review and ranking system, and allowing the state of the science to influence establishment of priorities and goals, rather than vice versa.

Table 7. Number of Responses to the Question "What Ideas Can be Implemented to Improve the Process?"

What Ideas Can be Implemented to Improve the Process?	No. Responses[1]
Improve communication/transparency	31
Include scientists/line management in the process	23
Improve CARTS process	14
Improve project review and ranking system	6
Keep the focus on public health and food safety	6
Let state of the science influence priorities and goals	2
Improve CVM system	2
None needed	6

[1] Up to 3 responses captured/interviewee; total of 90 responses.

Recommendations for improving communication and transparency included expediting communication of shifts in Center priorities, improving communication with the program offices, field laboratories, and stakeholders, improving communication within research groups (between line management and scientists and among scientists), and clarifying the prioritization and decision-making process for projects. Interviewees in all offices felt that prioritization would be improved by including scientists in the research prioritization process and in prioritization planning in general. There were many complaints about the CARTS process, but recommendations for improvement came down to improving communication of the parameters for acceptable projects, improving feedback on project rejections, expediting turn-around time for the project approval process, improving transparency of the project review process and improving the CARTS system overall. Interviewees cited specific models (NIH scientific review process and NCTR review system), as well as use of outside independent reviewers or review teams of experienced scientists as ways of improving the project review and ranking system. Recommendations for improvement to the CVM system had to do with reducing the paperwork involved and allocation of staff to meet commitments. Refer to Appendix C: C.2.1.6.b for interviewee observations.

2.1.7. Question 7: What are the ways in which you assess the impact of the research activities in your division/branch?

Although many interviewees commented that it was difficult to assess the impact of research activities, the top four responses were: how the results were received or used within FDA, publications, how the results were received/used by stakeholders and partners, and the impact of the research activities on public health. All offices were well represented by responses in each of these categories. Additional means of assessing impact that were identified were publication of methods in BAM, whether the activities lead to collaboration with others both inside and outside FDA, and trends in individual work units, e.g., "Whether your department is growing or shrinking, if upper management is listening, by approval of new hires, and by place in budget priorities."

Table 8. Number of Responses to the Question "What are the Ways in Which You Assess the Impact of the Research Activities in Your Division/Branch?"

What are the Ways in Which You Assess the Impact of the Research Activities in Your Division/Branch?	No. Responses[1]
How they are received/used within FDA	47
Publications	42
How they are received/used by our stakeholders and partners	30
Impact on public health	25
Publication in BAM	8
Whether they lead to collaborations	4
Trends in your work unit	3

[1] Up to 3 responses captured/interviewee; total of 159 responses.

When discussing impact based on how results were received/used within FDA, criteria included: recognition by upper management, feedback from the program offices and ORA field laboratories, feedback from within research groups at FDA, impact on the Agency's mission and goals, application to regulatory requirements, and application and use in the field. Interviewees noted that obtaining acknowledgement and feedback from within the Agency was difficult. Although publications were felt by many to be an important means of assessing impact, interviewees also noted that much of the work done for the Agency would not result in publications. Important stakeholders and partners identified by interviewees included state laboratories, other Federal agencies, international partners, and commercial partners. Refer to Appendix C: C.2.1.7 for interviewee observations.

2.1.8. Question 8: How is microbiological research at CFSAN and CVM aligned with the Centers' regulatory mission and priorities?

Many interviewees responded to this question in terms of how well microbiological research is aligned with the mission and priorities, in which case all responses captured were either "Well" (47 responses), "Improving" (2 responses), or Not sure (8 responses). In addition to or instead of these qualitative responses, interviewees tended to respond to the question in terms of how

alignment with the mission and priorities was achieved or maintained and/or how alignment was assessed.

Table 9. Number of Responses to the Question "How is Microbiological Research at CFSAN and CVM Aligned With the Centers' Regulatory Mission and Priorities?"

How is Microbiological Research at CFSAN and CVM Aligned With the Centers' Regulatory Mission and Priorities?	No. Responses[1]
How alignment is achieved/maintained	
Research supports the program offices/ORA field laboratories	23
Research is based on EROs	22
Project approval/rejection	16
How alignment is assessed	
Impact on public health	17
Politics/bias	2
Other	3
Don't know	1

[1] Up to 2 responses captured/interviewee; total of 84 responses.

Most interviewees who addressed the means by which alignment was being achieved/maintained seemed to feel that the process was effective. Interviewees within OFS/DI, OFS/MC, ORS, and CVM tended to feel that they were currently in alignment, whereas OARSA interviewees felt they were still working to achieve alignment due to becoming aware of the research prioritization system relatively late in the process and communication issues: "Right now we are scrambling to try to coordinate and be in alignment with what the Center wants to do." Interviewees in both OFS/DI and OFS/MC felt that they were particularly well aligned because of their unique relationships with their policy offices and/or stakeholders and their unique areas of research. Interviewees who commented on the politics or bias affecting alignment referenced, either directly or indirectly, the increasing focus within the Centers on genomics and whole genome sequencing. Refer to Appendix C: C.2.1.8 for interviewee observations.

2.1.8.1. Question 8.a. What are some examples?

Examples of alignment tended to vary widely, but generally fell into the following broad categories: whole genome sequencing research and method development, basic research and method development unrelated to whole genome sequencing, efforts related to specific outbreaks, efforts in rule-writing and guidances, surveillance-related research, and the NARMS program. Refer to Appendix C: C.2.1.8.a for interviewee observations.

2.1.8.2. Question 8.b. What suggestions do you have for improving the alignment between research and Center priorities?

Suggestions to improve communication and transparency as a means of improving the alignment between research and Center priorities by far outweighed all other suggestions, which included maintaining the Agency's research base, reorganizing microbiological research, evaluating the

impact of research, conducting branch/program reviews to assess alignment, and aligning research and priorities based on the severity of the pathogen. Improving communication and transparency comprised the majority of responses among OARSA interviewees (21 of 26 responses), OFS/MC interviewees (4 of 5 responses), and approximately half of the responses among OFS/DI, ORS, and CVM interviewees. Interviewees responding that no improvements were needed came from OARSA (1 interviewee), OFS/DI (2 interviewee), ORS (5 interviewees), and CVM (2 interviewees).

Table 10. Number of Responses to the Question "What Suggestions Do You Have for Improving the Alignment Between Research and Center Priorities?"

What Suggestions Do You Have for Improving the Alignment Between Research and Center Priorities?	No. Responses[1]
Improve communication and transparency	46
Maintain our research base	3
Reorganize microbiological research	3
Evaluate impact of research	3
Conduct branch/program reviews	2
Align by pathogen	1
None needed	10

[1] Up to 2 responses captured/interviewee; total of 68 responses.

Many of the suggestions for improving communication and transparency fell into the same categories as those addressed in Question 6 concerning improving the prioritization process, and included: improving communication between researchers, line management, and upper management; improving communication with the program offices, ORA field laboratories, and stakeholders; improving/expediting communication of Center priorities; clarifying/improving the prioritization process, and clarifying the project review and ranking process. Interviewees who recommended maintaining the research base expressed concern about losing expertise in areas where pathogens might recur. Suggestions for reorganizing microbiological research included having OFVM and Center management coordinate priorities and having a single microbiological research office. Responses concerning evaluating the impact of research had to do with accountability within FDA and with stakeholders, and responses concerning conducting branch/program reviews had to with evaluating the alignment of research projects across the Centers. Refer to Appendix C: C.2.1.8.b for interviewee observations.

2.1.9. Question 9: In what research areas should CFSAN and CVM reduce, maintain, or expand its current levels of microbiological research?

Depending on interviewees' office and area of expertise, there was a great deal of overlap in research areas to be reduced, maintained, or expanded. Efforts in specific fields or areas other than genomics, traditional/classic/basic microbiological research, genomics, and methods development and validation were recommended in all three categories. The need to reduce duplicate research was an immediate response for interviewees in most offices. Across all offices, many interviewees were reluctant to make any recommendations for reduction of efforts and many felt unable to make recommendations as to which areas should be maintained.

Table 11. Number of Responses to the Question "In What Research Areas Should CFSAN and CVM Reduce, Maintain, or Expand its Current Levels of Microbiological Research?"

In What Research Areas Should CFSAN and CVM Reduce, Maintain, or Expand its Current Levels of Microbiological Research?	Number of Responses[1]		
Office (No. of Interviewees)	**Reduce**	**Maintain**	**Expand**
Duplicate research	14		
Efforts in specific fields/areas other than genomics	7	18	28
Traditional/classic/basic microbiological research	5	12	5
Genomics	5	6	13
Methods development and validation	3	3	9
New technology in general			9
Emerging pathogens			6
Antibiotic resistance surveillance			2
None	17		
Total responses	**51**	**39**	**72**

[1] Up to 2 responses captured/interviewee.

Interviewees mentioned the need to reduce duplicate research throughout the Centers and between researchers, but several pointed out that some apparent duplication may be useful, depending on whether the research was being used to address different issues or questions. Specific areas other than genomics that were identified for reduction included research on traditional pathogens (e.g., *E. coli* and *Salmonella*), evolutionary biology, surrogate organism, food defense, and poultry and livestock management. Interviewees in OFS/DI, ORS, and CVM recommended some level of reduction in traditional/classic/basic microbiology research; whereas interviewees primarily in OARSA (and one in ORS) felt that the level of effort and funding allocated to genomics, and specifically to whole genome sequencing, should be reduced. Recommended reductions in methods development and/or validation were related to methods expected to be made obsolete by whole genome sequencing (e.g., microarray, mass spectrometry, some PCR methods, and work on PFGE) and to the number of new methods being developed without accompanying validation. Interviewees especially in CVM felt there was no room for reduction of research.

Specific areas/fields of microbiological research to be maintained other than genomics included virulence assessment, immunobiology research, virology, research on known pathogens, produce and seafood safety, and the NARMS program. Interviewees in all offices felt that it was important for FDA to maintain some level of traditional/classic/basic microbiology research to maintain breadth of expertise to support newer technologies, to respond to outbreaks, for support in compliance and enforcement actions, and to be prepared to address emerging problems. Interviewees also recommended maintaining research efforts in genomics, including whole genome sequencing, molecular methods, and meta-genomics. In terms of method development and validation, interviewees advocated maintaining certain established methods and maintaining efforts in method validation.

Increases in efforts in specific areas/fields other than genomics were recommended in: virology; food parasitology; other pathogens including traditional pathogens and newer threats, physiology of pathogenesis; pathogen evolution; microbial ecology; environmental microbiology; virulence assessment; immunobiology; preventive controls; laboratory proficiency testing; produce and seafood safety; and the NARMS program. Within genomic research, interviews recommended expanding efforts in whole genome sequencing, meta-genomics, and bioinformatics. Other research areas to be expanded included: methods development (more sensitive detection methods, rapid detection methods, and methods for emerging pathogens) and validation; new technology in general; research into emerging pathogens in food and feed; traditional/classic/ basic microbiological research to support FSMA as well as current Agency efforts; and drug use information. Refer to Appendix C: C.2.1.9 for interviewee observations.

2.1.10. Question 10: What are the most important challenges facing CFSAN/ CVM with regards to our microbiology research program?

Many of the challenges identified by interviewees corresponded with weaknesses or areas for improvement that were addressed under Questions 3-5 of this report, including issues of staffing, coordination between offices, resources, communication and transparency, and leadership and management issues. In addition interviewees felt the Centers faced challenges in integrating new technology, achieving an effective balance in research efforts, addressing outbreaks and the changing food supply, collaboration, and implementing FSMA.

Table 12. Number of Responses to the Question "What are the Most Important Challenges Facing CFSAN/ CVM with Regards to Our Microbiology Research Program?"

What are the Most Important Challenges Facing CFSAN/ CVM with Regards to Our Microbiology Research Program?	No. Responses[1]
Staffing	26
Coordination between offices	21
Resources	18
Communication and transparency	16
Integrating new technology	16
Achieving balance in research efforts	14
Outbreaks and the changing food supply	7

Leadership/management	5
Collaboration	2
Implementing FSMA	1

[1] Up to 3 responses captured/interviewee; total of 126 responses.

In terms of staffing, interviewees addressed the challenges of hiring qualified scientists and support scientists/technicians, retaining staff, succession planning to maintain institutional knowledge, achieving the proper balance of senior vs. junior staff, effective deployment of staff, and improving alignment of staff and their research with the regulatory mission. The lack of hiring/conversion in OARSA and OFS/MC was also mentioned. The challenges related to coordination between offices were much the same as those listed under Question 5 and included coordination between all microbiology offices, coordination between research and program offices, duplication of effort, competition between OARSA and ORS and coordination within offices. Resource-related challenges fell into the categories of funding, and space and time constraints. Communication and transparency both in-house and with those outside the FDA were felt to be a challenge. The majority of challenges concerning integrating new technology were related to the increase in genomic research and whole genome sequencing, but also included integrating new technologies into the ORA field laboratories. Interviewees felt there was a challenge to achieve an effective balance in research efforts both between traditional and modern microbiology research and between basic and applied research. Leadership and management challenges were much the same as those listed above under Question 5. Refer to Appendix C: C.2.1.10 for interviewee observations.

2.1.11. Question 11: How can we better recognize and reward scientific accomplishments/achievements?

While interviewees in general acknowledged that the Centers gave out many awards and often did a good job with this process, there were numerous recommendations for improvement in this area, including: improving the awards/promotion system, increasing acknowledgement and appreciation of efforts; promoting/converting staff based on performance; giving cash, travel opportunities, or time off as awards; and investing in ongoing/new research projects. This was an area addressed by scientists at all levels, and was of particular interest among support scientists/technicians who generally tended to feel that they were overlooked in the awards process.

Table 13. Number of Responses to the Question "How Can We Better Recognize and Reward Scientific Accomplishments/Achievements?"

How Can We Better Recognize and Reward Scientific Accomplishments/Achievements?	No. Responses[1]
Improve the awards/promotion system	34
Increase acknowledgement/appreciation	23
Via promotion/conversion of staff	18
Give cash awards	16
Include travel as an award/reward	11
Give time off awards	7

Invest in ongoing/new projects	6

[1] Up to 3 responses captured/interviewee; total of 115 responses.

The numerous suggestions for improving the awards/promotion system fell into the general categories listed below:

- Limit awards to significant/high impact achievements
- Fix the rotating awards cycle
- Encourage nomination of deserving staff
- Allow first-level management to give awards
- Remove/reduce emphasis on publications as a criteria
- Increase scrutiny of publications as a criteria
- Include consideration of performance of administrative duties
- Include awards for support scientists/technicians
- Include/do not include awards for managers
- Consult the co-workers of awards nominees
- Expand scientific achievement awards
- Disconnect monetary awards from merit awards
- Improve public recognition aspect for awards
- Increase transparency in the awards system
- Reduce favoritism/unfairness

In terms of increasing acknowledgement/appreciation, interviewees suggested: increasing personal acknowledgement from management (all levels) and co-workers; holding celebrations of awards/accomplishments at the division level; increasing recognition via the website and other means; and improving acknowledgement for members of the Public Health Commission Corps within the Centers. To reward scientific accomplishments/achievements via promotion/ conversion, interviewees suggested converting outstanding Fellows, increasing opportunities for advancement (via e.g., creating group leader positions, rotation of leadership, sharing responsibility); improving the promotion system; and changing the criteria for promotion of support scientists/technicians. Interviewees felt that including travel as an award would be an appropriate way to show appreciation for scientific achievement and would also help to off-set some of the current budget restrictions for travel. Although some interviewees felt that time off was an appropriate award, others questioned the value of 1 or 2 days off, especially in consideration of the accumulation of excess use-or-lose leave for senior staff members. Interviewees also suggested investing in ongoing/new projects as a means of rewarding scientific accomplishment by simply allowing them to do their research (OARSA interviewee), allocating money or support staff to a successful project, or allowing scientists to participate in projects outside their position description. Refer to Appendix C: C.2.1.11 for interviewee observations.

2.2. Organizational Management

2.2.1. Question 12: How effective is the current organization structure for management of CFSAN's and CVM's microbiological research? (Very – Fairly – Somewhat – Not Very – Ineffective – No idea)

Responses to this question tended to fall into general categories addressing organization at the center, office, and division/branch levels. Overall the majority of interviewees (62) felt that the current organization structure was somewhat to very effective, while only 21 interviewees rated the current structure as not very effective or ineffective. This distribution of responses was relatively consistent across all offices except OARSA, where 14 interviewees felt that the

structure was ineffective or not very effective and 13 interviewees felt the structure was somewhat to fairly effective.

Table 14. Number of Responses by Office to the Question "How Effective is the Current Organization Structure for Management of CFSAN's and CVM's Microbiological Research?"

Office (No. of Interviewees)	OARSA (28)	OFS/DI (9)	OFS/MC (12)	ORS (30)	CVM (15)	Total (94)
Very	0	3	1	4	3	11
Fairly	6	3	3	11	5	28
Somewhat	7	2	2	8	4	23
Not very	6	1	1	2	0	10
Ineffective	8	0	1	2	0	11
Not sure/no idea	1	0	3	2	3	9
Total responses	**28**	**9**	**11**	**29**	**15**	**92**

[1] One response captured/interviewee.

Within OARSA center-level issues were linked to the relationship between CFSAN and OFVM, the lack of interaction between the microbiology research groups, the lack of coordination between OARSA and ORS, and the lack of communication/transparency with upper management. Both office and division/branch-level issues tended to be linked to the lack of permanent, strong, and/or effective management. The need to review division structure was addressed as well. Within OFS/DI the only center-level comment targeted the lack of accountability for other research groups. Interviewees generally felt that the structure at the office level was effective, and the only issue identified at the division/branch level was the lack of permanent assignments in line management. Interviewees within OFS/MC also tended to feel that the structure at the office level was effective. This group had undergone a reorganization at the division/branch level immediately prior to the interview process; therefore, comments concerning this level seemed to be mixed. Interviewees variously commented that there were too many or not enough layers of management within the division, and that there were difficulties in communicating issues through line management to upper management. Responses concerning management at all levels varied among interviewees in ORS and often seemed to depend on the interviewee's branch. Center-level management was felt to be fairly to very effective by some interviewees, while others identified the same issues mentioned above by OARSA interviewees, except for a lack of communication/transparency with upper management. No issues were identified at the office level, but at the division/branch level, interviewees questioned the need to have two separate branches, and commented on the need for stronger line management at the division and/or branch levels. Within CVM, center-level issues were related primarily to interactions between CFSAN and CVM, and division-level issues were mostly related to the recent assignment of a new division director and to the relationship between the NARMS program and research activities and associated communication and prioritization within the Division. Refer to Appendix C: C.2.2.12 for interviewee observations.

2.2.1.2. Question 12.a. Please describe a structure you believe would be more effective.

Suggestions for improving the management structure for microbiological research fell into two major categories: reorganization of research groups in the Centers, Offices, Divisions, and/or Branches, and leadership and management issues.

In terms of reorganization of microbiological research, interviewees' suggestions ranged from reorganization of OFVM through reorganization of individual research teams and included the following:

- Let OFVM dictate the organizational structure;
- Unify research across the Centers;
- Establish a team system to coordinate research;
- Group research along functional lines;
- Merge OARSA and CVM;
- Establish a strong, independent office for OARSA;
- Merge divisions within OARSA;
- Clarify division structure at OFS/MC;
- Place Moffett Center within ORS;
- Reorganize CVM by either separating or merging the NARMS program and DAFM;
- Remove the research function from ORA; and
- Reorganize individual research teams.

Suggestions related to leadership and management issues included: improving leadership by hiring/assigning the right people for the positions; improving line management by giving managers more power, ensuring that line management is in alignment, and hiring/assigning strong managers; and reducing or increasing line management. Refer to Appendix C: C.2.2.12.a for interviewee observations.

2.2.2. Question 13. Are the staff and resources currently devoted to microbiology research effectively deployed and efficiently used across CFSAN/CVM? (Yes – No – Partly – Not sure – No idea)

In giving a qualitative response to this question, most interviewees gave the same answer for both effectively deployed and efficiently used. Overall, more OARSA and OFS/MC interviewees responded with Partly or No, while more OFS/DI, ORS, and CVM interviewees responded with Yes or Partly.

Table 15. Number of Interviewees/Response (Effectively Deployed-Efficiently Used) by Office to the Question "Are the Staff and Resources Effectively Deployed and Efficiently Used Across CFSAN/CVM?"

Office (No. of Interviewees)	OARSA (28)	OFS/DI (9)	OFS/MC (12)	ORS (30)	CVM (15)	Total (94)
Yes	3-3	3-3	1-2	6-4	7-7	20-19
Partly	11-10	3-3	3-2	10-11	3-3	30-29
No	10-12	1-1	3-3	6-6	0-0	20-22
Not sure/no idea	2-1	1-1	3-3	8-9	4-4	18-18
Total responses	**26-26**	**8-8**	**10-10**	**30-30**	**14-14**	**88-88**

In terms of allocation of resources, OARSA interviewees addressed inequities between offices (primarily between ORS and OARSA) and within OARSA between toxicology and microbiology; the inability within the Office to hire/convert staff was also mentioned here. OFS/DI interviewees mentioned the impact of the lack of permanent leadership on allocation within the division. OFS/MC interviewees brought up staffing issues (shortages and allocation within the Branches) and the use of resources by consortium partners. Within ORS, interviewees addressed allocation between offices and between projects within the Office. Comments within CVM were tied primarily to allocation of staff within the Division.

In addressing efficiency, OARSA interviewees mentioned duplication of efforts and competition within the Office, and the expenditure of Center funds outside the Center for expansion of the whole genome sequencing project and for investigations into other technologies that might be conducted in house. Staff shortages were mentioned by interviewees within OFS/DI and OFS/MC. Within ORS, interviewees attributed inefficiencies to the government funding process, lack of alignment for certain research groups, duplication of efforts between offices, and equipment issues within and between offices. Duplication of effort was also mentioned by CVM. Refer to Appendix C: C.2.2.13 for interviewee observations.

2.2.2.1. Question 13.a. How would you improve the allocation of staff and resources?

Interviewees recommended the following for improving the allocation of staff and resources:

- Address competition for research areas;
- Address competition for resources;
- Increase transparency concerning allocation and availability of resources;
- Base allocation of staff/resources on need;
- Develop a systematic approach for allocation;
- Allow some independence in research to improve efficiency;
- Realign/reorganize microbiological research programs/projects;
- Improve leadership;
- Increase oversight on purchasing;
- Hire more FTEs;
- Remove the research function from ORA; and
- Increase use of contractors.

Suggestions for addressing competition for research areas included encouraging collaboration, grouping research along functional lines, and discouraging individual ownership of areas of expertise. Suggestions for addressing competition for resources included reviewing allocation, basing allocation on scientific needs, and allowing equal opportunity for access to staff and resources. Specific recommendations for basing allocation on need included: re-allocating knowledgeable staff as needed for short- or long-term projects; allowing more flexibility in the assignment of support scientists/technicians; redistributing staff between the NARMS program and research within CVM; and cross-training support staff. Recommendations for developing a systematic approach for allocation of resources included establishing a centralized system that would indicate which groups were in need of additional resources based on workload; establishing a panel of scientists to participate in resource allocation; and applying a working group structure to the allocation of staff. Suggestions for realigning/reorganizing programs or projects fell along lines similar to those previously addressed (e.g. having a single microbiology research program), but also included the establishment of a Bioinformatics Group and conducting a total science review of microbiology projects across the offices. Refer to Appendix C: C.2.2.13.a for interviewee observations.

2.2.3. Question 14. Describe IT solutions/capabilities that could improve our microbiology research program.

The two major areas of improvement in IT identified by interviewees were resolution of firewall and security issues for scientific computing and expanding capabilities for process and storing large datasets to support Agency activities. Additional areas identified for IT improvements were implementing use of E-notebooks, improving in-house IT support, implementing better information management systems, improving the IT infrastructure, and improving meetings support. Interviewees who felt little or no improvement was needed tended to be involved in traditional microbiological research; whereas genomics research drove many of the areas where improvement was needed.

Table 16. Number Response to the Question "Describe IT Solutions/Capabilities That Could Improve Our Microbiology Research Program."

Describe IT Solutions/Capabilities That Could Improve Our Microbiology Research Program.	No. Responses[1]
Resolve firewall and security issues for scientific computing	27
Expand capabilities for processing/storing large datasets	20
E-Notebooks	13
In-house support	12
Better information management systems	6
IT infrastructure	5
Meetings support	3
None needed	19

[1] Up to 3 responses captured/interviewee; total of 105 responses.

Interviewee suggestions for IT solutions and capabilities are summarized in the table below. Refer to Appendix C: C.2.2.14 for additional observations, comments, and recommendations.

Table 17. Suggestions for IT Solutions/Capabilities.

Suggestions for IT Solutions/Capabilities.	
Resolve firewall and security issues for scientific computing	**Allow Internet access:** • For communication/collaboration with other institutions and partners • For database access: uploads and downloads • For accessing automatic updates and troubleshooting instrumentation • For accessing scientific journals and relevant websites • For delivery of presentations, grant applications, etc. • For access to webinars **Allow network access or develop a separate network for scientific computing:** • For direct transfer of files and data from instruments • For linking instruments • For transfer of data between labs and offices: no more iron keys **Develop a system that allows use of portable storage devices in house:** • E.g., allow use of memory sticks that remain within the building **Allow administrative rights to computers:** • For loading software, writing programs, validating software, and installing open source programming **Improve/increase options for working from home**
Expand capabilities for processing/storing large datasets	**Expand data processing/storing capabilities:** • To support research in genomics, whole genome sequencing, meta-genomics, microarray, bioinformatics • For importing, merging, integrating, analyzing, and interpreting data **Expand capabilities for existing systems:** • Enable Internet access • Expand capabilities for sharing data outside the Centers (e.g., with CDC) • Expand storage capacity and options. • Hire analysts **Expand capabilities/options within offices other than ORS:** • Install high performance computing (e.g., a mini-cluster) at MOD 1. • Improve access to high performance computing at other sites (CPK1 and White Oak) • Extend capabilities for bioinformatics.
E-Notebooks	• For improving tracking and analysis • To facilitate collaboration
Improve in-house IT support	• Better support and responsiveness in general • Improved trouble reporting system • Increased in-house support for scientific computing • Improved software purchase and approval process • Increased support for database and web page development • Improved support for bioinformatics by trained technicians
Better information management systems	• Laboratory Information Management Systems (LIMS) • Genomic Information Management Systems (GIMS) • Better document management resources
IT infrastructure	• Wireless capabilities • Increased band-width within and between facilities • Improved connectivity, especially for remote groups (e.g., OFS/DI)
Meetings support	**Better video conferencing capabilities** • For collaborating between offices and groups • For collaborating with other institutions and partners

Suggestions for IT Solutions/Capabilities.	
	• For attending meetings, webinars, etc.

2.2.4. Question 15. Aside from IT, please suggest other important services and capabilities we should look at to improve our microbiology programs.

Suggestions for improvement of other important services and capabilities included:

- Improving the procurement process, both by hiring administrative support and by improving the procedures;
- Improving travel services to make the application and approval process easier, especially for sponsored travel;
- Hiring additional support staff: including administrative support; scientific writers, editors, and graphic artists for publications; culture coordinators; and service contract support;
- Streamlining internal reporting procedures;
- Developing a public access website to encourage public involvement;
- Addressing certain facility and infrastructure issues within OARSA, OFS/DI, and ORS;
- Implementing a dedicated, independent QC program for laboratories; and
- Developing an information reference source identifying subject matter experts within the agency.

Refer to Appendix C: C.2.2.1.15 for additional observations and comments.

2.3. Collaboration/Communication

2.3.1. Question 16. How would you describe the quality of collaboration/communication within your group (team, branch, division, office)? (Excellent – Very good – Fair –Not very good – Poor – No idea)

As for Question 13, many interviewees gave the same qualitative response for both communication and collaboration. The majority of interviewees responding in all offices felt that collaboration/communication within their team and/or branch was very good to excellent, and that collaboration/communication at the division level was fair to excellent. The majority of interviewees responding in OFS/DI, OFS/MC, and ORS rated collaboration/communication at the office level fair to not very good, while the majority in OARSA rated it not very good to poor; responses in CVM were spread fairly evenly across very good, fair, and not very good. Responses tended to be more cohesive in the smaller groups (OFS/DI, OFS/MC, ORS, CVM), and varied more widely in the larger offices (OARSA and ORS).

Table 18. Number of Interviewees/Response (Collaboration – Communication) to the Question "How Would You Describe Collaboration/Communication Within Your Group?"

Office (No. of Interviewees)	OARSA (28)	OFS/DI (9)	OFS/MC (12)	ORS (30)	CVM (15)	Total (94)
Team						
Excellent	9-6	4-4	3-3	11-10	7-5	34-28
Very good	13-13	5-4	7-7	7-7	8-7	40-38
Fair	3-4	0-1	0-2	6-5	0-1	9-13
Not very good	1-1	0-0	0-0	3-3	0-1	4-5
Poor	0-0	0-0	0-0	2-3	0-0	2-3
Total responses	**26-24**	**9-9**	**10-12**	**29-28**	**15-14**	**89-87**
Branch						
Excellent	5-4	4-4	3-3	8-7	Not applicable	20-18
Very good	8-10	2-3	6-6	7-7	Not applicable	23-26
Fair	6-4	2-1	1-2	6-4	Not applicable	15-11
Not very good	2-2	0-0	0-0	4-4	Not applicable	6-6
Poor	2-2	0-0	0-0	2-3	Not applicable	4-5
Total responses	**23-22**	**8-8**	**10-11**	**27-25**	Not applicable	**68-66**
Division						
Excellent	4-3	3-3	2-2	3-3	4-3	16-14
Very good	4-7	3-4	5-6	3-3	8-3	23-23
Fair	5-3	1-0	1-2	3-2	1-1	11-8
Not very good	5-5	1-1	0-0	2-2	0-2	8-10
Poor	2-2	0-0	0-0	0-0	0-0	2-2
Total responses	**20-20**	**8-8**	**8-10**	**11-10**	**13-9**	**60-57**
Office						
Excellent	0-0	0-0	0-0	0-0	0-0	0-0
Very good	3-2	1-1	0-0	0-0	3-2	7-5
Fair	1-1	3-3	4-6	3-3	0-1	11-14
Not very good	8-8	1-1	0-0	2-2	2-2	13-13
Poor	6-5	1-1	0-0	2-2	0-0	9-8
Total responses	**18-16**	**6-6**	**4-6**	**7-7**	**5-5**	**40-40**

Many responses to this question also appeared to be subjective, both in terms of the rating assigned and in terms of how the interactions were perceived: e.g., an individual who was collaborating well might rate collaboration with their division as excellent, whereas another individual might rate collaboration fair based on a big-picture perception. However, many responses, especially those addressing interactions at the branch, division, and office levels tended to correspond to responses to Question 12 concerning organizational management and whether the line management was felt to be effective or ineffective. In general, problems with collaboration tended to be attributed to isolation from other groups, lack of management support, territoriality at both the management and scientist levels, lack of knowledge about areas of common interest across groups, and reluctance to engage in future collaboration based on negative experiences during prior collaborations. Problems with communication were attributed primarily to poor communication from line management and to lack of interaction across groups and offices within the Centers. Refer to Appendix C: C.2.3.16 for interviewee observations.

2.3.1.1. Question 16.a. What has worked well with respect to such collaboration/ communication?

In identifying what has worked well in terms of collaborations, interviewees mentioned the following: individual initiative; direct interactions between scientists; interactions within teams, branches, or divisions; sharing information across groups; working groups; extending contacts across offices; and management support. In terms of communication, both formal and informal meetings were mentioned. Refer to Appendix C: C.2.3.16.a for interviewee observations.

2.3.1.2. Question 16.b. What suggestions do you have to improve the collaborations/communications?

Suggestions for improving collaborations included:

- Actively encouraging collaboration within the microbiology program via direct and/or indirect management support;
- Increasing interactions between groups and scientists via formal and informal routes;
- Publicizing in-house microbiology research internally;
- Addressing competition issues between groups;
- Resolving management issues;
- Increasing the effectiveness of meetings;
- Identifying areas of expertise and interest in the program;
- Improving operations;
- Encouraging attendance at scientific meetings; and
- Offering incentives for collaborating
- Suggestions for improving communications included:
- Improving communication with: upper management; at the office/division/branch levels; and between scientists; and
- Encouraging more informal interactions between scientists.

Refer to Appendix C: C.2.3.16.b for interviewee observations.

2.3.2. Question 17. Describe current coordination efforts among CFSAN's and CVM's microbiology research groups and their programmatic counterparts in the areas of regulatory policy, compliance, enforcement, and ORA field programs.

Interviewees reported regular interactions or interactions as needed with all of the program offices and counterparts, with the most interactions reported to occur with the regulatory policy group and the ORA field programs. The fewest interactions were reported with enforcement. Proportionally, OFS/DI and CVM interviewees reported the most interaction with Regulatory Policy and ORA field programs.

Table 19. Number of Interviewees/Response to the Question "Describe Current Coordination Efforts Among Microbiology Research Groups and Their Programmatic Counterparts"

Office (No. of Interviewees)	OARSA (28)	OFS/DI (9)	OFS/MC (12)	ORS (30)	CVM (15)	Total (94)
Regulatory Policy						
Regular interactions	2	5	3	9	8	27
Interactions as needed	4	1	1	3	0	9
Interactions need improvement	7	1	0	4	1	13
None	4	0	0	3	1	8
Not sure	8	2	6	8	5	29
Total responses	**25**	**9**	**10**	**27**	**15**	**86**
Compliance						
Regular interactions	0	1	0	7	3	11
Interactions as needed	3	1	1	6	3	14
Interactions need improvement	5	1	0	4	1	11
None	4	1	0	5	1	11
Not sure	9	3	7	6	6	31
Total responses	**21**	**7**	**8**	**28**	**14**	**78**
Enforcement						
Regular interactions	0	1	0	5	0	6
Interactions as needed	2	1	0	5	2	10
Interactions need improvement	2	1	0	1	2	6
None	5	1	1	9	4	20
Not sure	10	3	7	7	6	33
Total responses	**19**	**7**	**8**	**27**	**14**	**75**
ORA Field Programs						
Regular interactions	6	7	1	8	3	25
Interactions as needed	7	0	0	9	5	21
Interactions need improvement	4	1	2	4	1	12
None	4	1	0	2	0	7
Not sure	2	0	6	5	5	18
Total responses	**23**	**9**	**9**	**28**	**14**	**83**

Coordination efforts with Regulatory Policy were reported to occur via direct interactions with the policy offices, via working groups, through the research prioritization process and CARTS, and in outbreak response activities. Interviewees noted that improvements were needed in coordination, general knowledge about the program, and communication between the scientists in the groups. Coordination efforts with Compliance were reported to occur via: work on compliance materials and programs; in outbreak response activities; in recalls and surveillance activities; and on as-needed issues and projects. Efforts with Enforcement were limited to some work on enforcement actions (interviewees in OFS/DI, ORS, and CVM), and unspecified issues and projects (OARSA and ORS). Efforts with the ORA field programs were primarily related to methods development and validation and training on methods, and also included outbreak response efforts, work on genomics and sequencing, and joint research and/or data analysis efforts. Problems were identified in achieving effective interactions, competition over research, and communication. Refer to Appendix C: C.2.3.17 for interviewee observations.

2.3.2.1. Question 17.a. What has worked well with respect to such coordination?

In identifying what has worked well, interviewees mentioned personal interactions, effective leadership in coordination efforts, defining roles, sharing new technology, regular meetings, and interactions via working groups. Refer to Appendix C: C.2.3.17.a for interviewee observations.

2.3.2.2. Question 17.b. What efforts are needed to increase and/or improve coordination efforts?

Suggestions for increasing/improving coordination efforts with these groups included:

- Improving awareness of what these groups do;
- Increasing interactions with these groups;
- Increasing direct communication between scientists working in these efforts, especially with the ORA field laboratories;
- Developing a structure for coordination;
- Increasing management encouragement and support; and
- Keeping the focus on the mission of public health.

Refer to Appendix C: C.2.3.17.b for interviewee observations.

2.3.3. Question 18. Describe current coordination efforts between intramural microbiological research programs and extramural "Centers of Excellence".

For purposes of this report, the relevant Centers of Excellence include the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) at the University of Maryland, the National Center for Natural Product Research (NCNPR) at the University of Mississippi, and the Western Center for Food Safety (WCFS) at University of California, Davis. Among interviewees, responses were mixed concerning whether the Institute for Food Safety and Health (IFSH) at the Illinois Institute of Technology/Moffett Center was a Center of Excellence or not. For purposes of this report, IFSH and Moffett Center will be included as a Center of Excellence in this section of the report.

The majority of interviewees (63) responding to this question indicated that they were unfamiliar with any coordination efforts between the Centers' microbiological research programs and any Centers of Excellence, while 26 interviewees indicated they were aware of efforts related to Centers of Excellence.

Efforts with which interviewees were familiar included interactions with JIFSAN, primarily related to teaching classes at JIFSAN, having graduate students from the program work in their laboratories, and/or serving on students advisory committees. Interactions with WCFS that were identified included coordination on *E. coli* with laboratories in OARSA, work on leafy greens production and processing with OFS/MC, and work with ORS on the 100K Genome Project. Interactions with NCNPR were described as rare.

Some interviewees questioned the value of the interactions with these Centers of Excellence. Regarding the 100K Genome Project with WCFS, interviewees noted that there was limited interaction and that limited results had been produced relative to the investment in the project.

Another interviewee commented that some of the work sent to COEs might have been done better in house.

Regarding OFS/MC, a number of questions were raised concerning the quality of the scientists participating from IIT and industry, prioritization of IFSH vs. FDA projects, the handling of grant moneys and other funding, and the disproportionately large contribution of FDA scientists to the amount of work being done by the Center. Refer to Appendix C: C.2.3.18 for interviewee observations.

2.3.3.1. Question 18.a. What has worked well with respect to such coordination?

In discussing what has worked well in coordination with COEs, interviewees mentioned good project management, having an area of interest in common, having points of contact, and collaboration at the scientist level. Refer to Appendix C: C.2.3.18.a for interviewee observations.

2.3.3.2. Question 18.b. What efforts are needed to increase and/or improve coordination efforts?

Suggestions for increasing/improving coordination efforts with these groups included:

- Increasing awareness of what these centers do;
- Drafting better contracts and memorandums of understanding (MOUs) to assure concrete deliverables and accountability; and
- Encouraging interactions.

Suggestions specific to IFSH included:

- Drafting an MOU to redefine the roles of FDA and IIT in the consortium; and
- Encouraging IIT to obtain more scientists for the program.

Refer to Appendix C: C.2.3.18.b for interviewee observations.

2.3.4. Question 19. At what levels and in what manner do the CFSAN and CVM programs interact on significant microbiological issues with: CDC, USDA, EPA, academia, other Federal agencies, and international bodies?

Most interviewees across all offices were aware of Center efforts with CDC (77 interviewees responded with examples), USDA (62), academia (66), and some international activities (47). Only 16 interviewees reported activities with EPA, and 24 commented on efforts with other Federal agencies. There did not appear to be major differences between offices in knowledge of or involvement in these kinds of efforts, despite some comments from individuals who felt there was little participation.

In addressing CDC, USDA, and EPA, interactions with CDC were reported in the areas of outbreaks response, research collaborations, and ongoing food safety/protection efforts. Both CDC and USDA were identified as partners in the NARMS program. Although many positive collaborations were reported with CDC, some interviewees commented on difficulties in working with CDC attributed to a lack of clear direction or structure for interactions, territoriality and competition issues, differences in mission, a lack of willingness to participate on the CDC's part, unresolved past differences, and specific personnel issues. Fewer interactions were reported with USDA. These tended to be primarily research collaborations and ongoing food safety/protection efforts. Fewer difficulties were reported regarding working with USDA; those identified primarily included references to differences in mission, and funding issues. Only a few specific projects were identified for EPA, with many interviewees noted that there were few areas of overlap between EPA and FDA.

Interactions with academia included general comments on the overall value of working with academia, collaborations with specific schools, and working with graduate students. Collaborations with the University of Maryland (and/or JIFSAN) were mentioned, as were collaborations with UC Davis and IIT, which may have referred to interactions with these entities as Centers of Excellence. In addition, interviewees reported collaborations with: the Universities of AL and Southern AL, DE, FL, GA, MI, MN, NH, NM, WI, Louisiana State, Mississippi State, Morgan State, NC State, Ohio State, Penn State, UC Irvine, Virginia Tech, Auburn University, Cornell University, and Emory University, Howard University, . Collaborations with international universities were also mentioned. Interviewees reported minor difficulties in working with academia attributed primarily to a lack of clear direction or structure for interactions.

In reporting efforts with other agencies, a number of interviewees in ORS and CVM reported work with NIH on whole genome sequencing, the Genome Tracker project, and the NARMS program. Work with DHS was identified primarily relating to food defense (OARSA, OFS/MC, and ORS), and work with DOD was identified relating to research on MRE food packets (OFS/MC) and investigation into laboratory set-up (ORS). Other identified agencies included the CIA, FBI, NIST, NOAA, and the White House Office of Science, Technology and Policy.

In terms of international partners, Codex and WHO were identified in most offices, but collaborations and interactions were reported both in public heath efforts and research with entities world-wide including Canada, Mexico, South America, Europe, Scandinavia, Korea, Japan, China, Australia, and New Zealand. Specific efforts were reported in bacterial pathogens, allergens, *Vibrio*, botulin research, laboratory proficiency testing, whole genome sequencing, and NARMs. Refer to Appendix C: C.2.3.19 for interviewee observations.

2.3.4.1. Question 19.a. What has worked well in developing these interactions?

In identifying what has worked well in coordination with these entities, interviewees mentioned personal interactions, identifying mutually beneficial projects, membership in organizations and working groups, willingness to collaborate, having a structure for coordination, defining roles in interactions, management support, informal interactions, maintaining honesty/openness in

interactions, appropriate recognition of contributors, and including younger scientists in the collaborations. Refer to Appendix C: C.2.3.19.a for interviewee observations.

2.3.4.2. Question 19.b. How can we improve coordination efforts with our partners?

Suggestions for improving coordination efforts with these entities included:

- Increasing management encouragement and support for these kinds of interactions;
- Addressing coordination efforts at a higher level (across agencies);
- Increasing interactions between groups and scientists;
- Developing a structure for coordination;
- Establishing regular communication;
- Encouraging attendance at scientific meetings;
- Relaxing travel restrictions to enable more interaction with international partners;
- Being respectful of partners; and
- Publicizing FDA areas of expertise and interest.

Refer to Appendix C: C.2.3.19.b for interviewee observations.

2.3.5. Question 20. What other ideas do you have for how we can better serve our stakeholders?

Ideas for better serving our stakeholders ranged from big-concept suggestions to including scientists in the decision-making process and included:

- Refocusing on our mission;
- Publicizing FDA's role and activities
- Improving communication within the Agency;
- Improving communication with our stakeholders in general;
- Improving communication with the public;
- Increasing communication and transparency with industry;
- Resolving organization and management issues;
- Expanding microbiological research scope and capabilities;
- Finishing methods;
- Implementing FSMA;
- Reducing waste;
- Increasing collaboration;
- Encouraging attendance at scientific meetings; and
- Including scientists in the decision-making process.

Refer to Appendix C: C.2.3.20 for interviewee observations.

2.3.6. Question 21. What major institutional or systemic barriers exist which contribute to a lack of coordination?

Responses to this question addressed barriers to in-house coordination as well as to coordination with partners and stakeholders, with more responses focused on in-house issues.

Table 19. Number of Responses to the Question "What Major Institutional or Systemic Barriers Exist Which Contribute to a Lack of Coordination?"

In house	No. Responses[1]	With partners and stakeholders	No. Responses[1]
Competition between groups	14	Turf/trust issues between partners	5
Lack of communication/transparency	13	Differences in the nature of the agencies involved	5
Lack of interaction between groups	9	Lack of opportunities for interaction	3
Management structure	6	Travel restrictions	2
Physical separation	6	Clashes over leadership of efforts	2
Staffing and resource issues	4	Lack of communication between partners	1
Lack of strong leadership	3	COI issues with industry	1
Lack of awareness of research being conducted in house	3	Bureaucracy	1
Lack of accountability	1		
Resistance to change	1		
Total responses	**60**	**Total responses**	**20**

[1] One response captured/interviewee.

All of the barriers that were identified regarding in-house coordination have been addressed in this report under one or more different questions. Many of the comments regarding coordination with partners and stakeholders were previously addressed under Question 19 comments regarding turf/trust issues and clashes over leadership of efforts mainly targeted CDC. Responses regarding differences in the nature of the agencies involved focused primarily on restrictions governing FDA's interactions due to its role as a regulatory agency. Refer to Appendix C: C.2.3.21 for specific observations and comments.

2.3.6.1. Question 21.a. What ideas do you have for overcoming these barriers?

Suggestions for overcoming in-house barriers included:

- Increasing communication/interactions;
- Clarifying the process of prioritization and setting goals;
- Reorganization, including suggestions both to combine and separate microbiological research groups;
- Adjusting the management structure from upper management through line management;
- Building interdisciplinary teams to address specific projects;
- Undertaking cross-cutting studies to answer questions for multiple groups; and

- Addressing personnel issues.
- Suggestions for overcoming barriers with partners and stakeholders included:
- Improving relations between management at the agency level;
- Increased management encouragement/support for these interactions;
- Increasing awareness of what each partner has to offer;
- Getting the right people involved in interactions;
- Providing training on how to interact outside the Agency;
- Streamlining overlapping research between agencies; and
- Establishing accountability.

Refer to Appendix C: C.2.3.21.a for interviewee observations.

2.4. Expertise/Training

2.4.1. Question 22. What are the gaps or imbalances in scientific expertise and technological capability that CFSAN and CVM should increase efforts in to ensure that it can address current and future regulatory demands?

In identifying gaps in scientific expertise, bioinformatics was the top response and was identified as a need in all offices. Gaps identified in specific areas or fields included expertise in food-related microbiology, environmental and cosmetic microbiology, preventive controls, statistics, virology, parasitology, gram-positive bacteria, and other pathogens including spore formers and drug-resistant and other unique pathogens, and in whole genome sequencing. Expertise in new technology was mentioned in connection with robotic/computer-controlled instrumentation and nanotechnology. Interviewees who felt that the greatest need was in expanding/maintaining current levels of expertise mentioned the areas of traditional/basic microbiology research and antibiotic resistance, addressed the need to increase depth of expertise and maintain institutional knowledge; and mentioned the need for more support scientists/technicians and to convert Staff and ORISE Fellows. One interviewee suggested conducting a gap analysis to make this determination.

Gaps or imbalances in technological capability were identified primarily in the areas of: IT, in which all suggestions had been addressed under Question 14; and new technology, in which interviewees identified the need for up-to-date instrumentation and associated data analysis and also commented on the efforts needed to stay current with advances. The need for method validation for norovirus was mentioned by an OFS/MC interviewee as an undertaking that would require substantial coordination. Interviewees who felt that no new technological capabilities were needed at this time noted the need to evaluate the value of such advances and/or noted that the Agency was fairly current: "We're flying pretty high technologically."

Table 20. Number of Responses to the Question "What are the Gaps or Imbalances in Scientific Expertise and Technological Capability that CFSAN and CVM Should Increase Efforts in to Ensure That it Can Address Current and Future Regulatory Demands?"

Expertise	No. Responses[1]	Technological Capability	No. Responses[1]
Bioinformatics	26	Better IT capabilities	12
Specific areas or fields other than genomics	11	New technology	11
Genomics (whole genome sequencing)	5	Method validation for norovirus	1
New technology	3	None	17
Expand/maintain current	27		
None needed	10		
Conduct gap analysis	1		
Total responses	**83**	**Total responses**	**41**

[1] Three response captured/interviewee for expertise; two responses captured/interviewee for technological capability.

Refer to Appendix C: C.2.4.22 for interviewee observations.

2.4.2. Question 23. How can we improve CFSAN and CVM recruitment, development, and retention of the professional expertise needed to address current and future regulatory microbiological challenges?

The top responses for improving recruitment, development, and retention of professional expertise were improving the hiring system, encouraging training and travel, and increasing opportunities for advancement, respectively. Within recruitment, interviewees also suggested: increasing hiring and conversion of Fellows; publicizing/advertising opportunities within the Agency; improving the pay scale; improving the work environment; balancing the expertise that is hired; and contracting more work within the Agency. Regarding development, in addition to training and travel, interviewees suggested: increasing opportunities for advancement; allowing staff exchanges, sabbaticals, and collaborations; and improving the work environment. Additional suggestions for improving retention included allowing conversion of Fellows; increasing recognition for work efforts; increasing pay; improving the work environment; increasing travel and attendance at meetings and training; and allowing collaborations inside and outside the Agency.

Table 21. Number of Responses to the Question "How Can We Improve CFSAN and CVM Recruitment, Development, and Retention of Professional Expertise?"

Recruitment	No. Resps.	Development	No. Resps.	Retention	No. Resps.
Improve hiring system	24	Encourage training and ed.	16	Increase advancement opps.	17
Allow hiring/conversion	12	Increase travel to meetings	13	Allow conversion	10
Publicize/advertise	9	Increase advancement opps.	12	Increase recognition	7
Improve pay scale	5	Allow staff exchanges, collabs.	6	Increase pay	3
Imp. work environment	4	Improve work environment	4	Improve work environment	6
Balance expertise	1			Increase travel to meetings	2

Recruitment	No. Resps.	Development	No. Resps.	Retention	No. Resps.
Contract more work	2			Encourage training	2
Base on need	2			Allow collaborations	2
None needed	7	None needed	5	None needed	11
Total responses	**66**	**Total responses**	**56**	**Total responses**	**60**

[1] Two response captured/interviewee for each.

For recruitment, problems with the hiring system were noted both above the center level (at USAJOBS and FDA Office of Human Resources) and within the Centers, where the following were suggested: making hiring decisions within the Centers; identifying the right candidates; and removing bias/favoritism from the hiring process. Interviewees primarily within OARSA noted that they were currently unable to hire FTEs (this was also noted within OFS/DI) and were unable to convert ORISE and Staff Fellows (also mentioned under retention). In terms of publicizing/advertising for the Centers, interviewees noted that many outside the Agency are unaware of the kind of research that is done in the Agency and recommended advertising more widely (outside USAJOBS, at scientific meetings and universities, in popular science magazines) for new hires. Changes in the pay scale with respect to other agencies and issues related to the GS scale were mentioned. Regarding improving the work environment, interviewees commented on the need to develop an appreciation for high caliber scientists and to improve the caliber of the organization as a whole. In terms of balancing expertise, it was noted that hiring tended to be based more on funding than need; interviewees recommended a risk assessment/analysis for identification of priority areas for hiring/redistribution of scientists.

Although training and education and travel and attendance at meetings were mentioned in relation to both development and retention, they featured more prominently in development, where interviewees noted the importance of encouraging/requiring training and increasing opportunities for travel, along with addressing the accompanying budget issues. Suggestions for increasing opportunities for advancement included establishing development plans and revising the criteria for advancement, including revising GS-level and publication criteria for advancement. Staff exchanges via details, sabbaticals, collaborations, and hosting visiting scientists were all recommended. In terms of improving the work environment, interviewees mentioned developing a more positive, intellectually challenging, and stable work environment.

For retention, interviewees also suggested increasing opportunities for advancement by: revising the criteria for advancement, especially for support scientists; improving the peer review process; and allowing opportunities for staff to do work they enjoy. Interviewees mentioned the need to increase recognition of efforts by allowing them to grow in their area of expertise, and demonstrating appreciation of their efforts by acknowledgement, bonuses, and/or awards. In terms of improving the work environment, issues of low morale and the narrowed research scope were mentioned among others. Refer to Appendix C: C.2.4.23 for interviewee observations.

2.4.3. Question 24. How can we better ensure that training and professional development needs are being met?

Responses concerning training needs fell into two major categories: training opportunities and facilitating training. In terms of training opportunities, 20 interviewees across all offices felt that opportunities for technical training should be increased via: providing on-site training; developing training programs between the microbiological research offices; partnering with other Centers or groups within FDA or academic partners, such as JIFSAN; or offering off-site training, especially for methods and techniques. Support scientists in particular felt that additional opportunities were needed to attend technical training because on-line training was not effective for laboratory techniques, and noted that they had few opportunities to expand their skills vs. ORISE Fellows, for whom funding for training was built into their contracts. Other suggestions for training opportunities included: details with stakeholders, such as the ORA laboratories; leadership training; and FDA training, including the Food and Drug Law class and training concerning how individual research areas fit within the bigger picture of FDA (requested by support scientists and newer employees).

In terms of facilitating training, interviewees suggested the following: asking what training was needed; tracking training opportunities and requirements by having line management be responsible, by creating a position for overseeing training, or by making sure information is made available to scientists; resolving training vs. travel budget issues (addressed by 22 interviewees), and improving application procedures.

Suggestions for meeting professional development needs again included asking what is needed. In addition, interviewees mentioned the following: attendance at scientific meetings, using FDA training resources and the CFSAN Staff College (including the Food and Drug Law class and training in writing and public speaking); participation in details; mentoring; outside collaborations; career counseling in some form, either professional or in-house; and improving the travel approval process. Refer to Appendix C: C.2.4.24 for interviewee observations.

2.4.4. Question 25. Can you suggest outside entities we can partner with for more training opportunities?

Many interviewees felt there was not a great need for the Centers to look to the outside for training. Suggestions for outside entities the Agency might partner with for training opportunities included:

- Universities and academic laboratories;
- HHS Resources, including CDER, NIH, and CDC;
- USDA;
- Other Federal agencies, including NOAA, OPM, and DOE (Joint Genome Institute);
- International counterparts in public health;
- State and local laboratories (e.g., American Public Health Laboratories); and

- Private sector entities including associations (American Society of Microbiology), non-profit organizations (International Association for Food Protection, Institute of Food Technology), laboratories (Cold Spring Harbor, Woods Hole), instrument manufacturers, and the food industry.

Refer to Appendix C: C.2.4.25 for interviewee observations.

2.4.5. Question 26. Is there anything about the microbiological program at CFSAN and CVM that we have not discussed today, if so please elaborate?

Many interviewees responded to this comment with comments and observations expanding on areas addressed in the questions above. Where relevant, these comments were presented under the appropriate question; however, in some cases, the responses were more expansive and so were left here. Others took the opportunity to share their feelings or comments about their work, the Agency, and areas of specific concern. The comments can be broken down into the following areas: work environment; value of microbiological research/science; impact of changing mission priorities; effectiveness of the organization structure; specific activities or areas of interest; and comments from individual offices. Refer to Appendix C: C.2.4.26 for interviewee observations.

APPENDIX A: REVIEW QUESTIONS

APPENDIX A: REVIEW QUESTIONS

Review of Microbiology Laboratory Capacity, Efficiency and Management

The leadership of FDA's Foods and Veterinary Medicine (FVM) Program is launching a review of its microbiology laboratory programs, focusing on scientific capacity and the management of the program's multiple elements across the Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM). This document outlines the purpose and assumptions underlying the review, some of the questions to be addressed, and how the review will be conducted.

Purpose of the Review

The purpose of the review is to take stock of FVM's current microbiological capacity -- how that capacity is deployed and applied across the program; the efficiency and management practices that affect how well staff and other resources are used to oversee microbiology work; to determine if microbiology research is meeting program needs; to identify if there is unnecessary duplication; and to ensure that microbiological research yields mission-relevant outcomes. The review will also examine how OFVM's microbiology program interacts with other U.S. government and state agencies, the external scientific community and other external stakeholders.

The outcome of the review will be recommendations to improve the program in these areas as necessary to better meet today's microbiology challenges.

Assumptions

- FVM's microbiology laboratory program faces significant challenges arising from new technologies being developed and used in food and feed, new methods of identifying and assessing microbial hazards, resource constraints, increased need for coordination across the FVM enterprise, and continued high public expectations concerning the rigor and effectiveness of FDA's research programs.

- FDA methods development and validation encompasses the recovery, detection, identification, and quantification of microbial pathogens from foods and animal feeds, as well as dietary supplements and cosmetics. The use of validated methods provides the essential laboratory science and data needs for the FDA's regulatory policy, compliance, and enforcement programs.

- To accomplish new mandates under FSMA, FDA must continue to build and sustain high quality, focused intramural and extramural scientific research programs which will continue to provide the foundation for sound regulatory policy, as well as compliance and enforcement actions.

- Achieving FVM research goals depends not only on the quality of research but also our organizational effectiveness. Only a prepared and resourceful organization can efficiently

coordinate and manage serious issues confronting our food supply in an increasingly complicated and global marketplace.

- FVM is taking the necessary steps to ensure that its science/research program continues to provide national and international scientific leadership and makes best use of current Agency resources, while at the same time assessing where additional investments need to be made based on the principles of prevention and risk-based priority setting.

Background Questions

1. On what team or unit do you work?
2. What is your role on that team or unit?
3. How long have you been in this position?
4. How long have you been at FDA?

Questions to Be Addressed

The following are questions the review will address:

Science

1. What do you see as the most important reasons for having in-house microbiological research programs at CFSAN and CVM?

2. In your work unit, what do you see as the strengths in your program with respect to microbiological review or research?

3. In your work unit, what do you see as the weakness in your program with respect to microbiological review or research?

4. What can be done in the coming year that will result in improvement in your division/branch?

5. What areas might be productive for longer term mission-related improvements in your division/branch and for the entire microbiology program?

6. How are research priorities determined in your division/branch?

6.a. How do you contribute to the process?

6.b. What ideas can be implemented to improve the process?

7. What are the ways in which you assess the impact of the research activities in your division/branch?

8. How is microbiological research at CFSAN and CVM aligned with the Center's regulatory mission and priorities?

8.a. What are some examples?

8.b. What suggestions do you have for improving the alignment between research and Center priorities?

9. In what research areas should CFSAN and CVM reduce, maintain or expand its current levels of microbiological research?

10. What are the most important challenges facing CFSAN/ CVM with regards to our microbiology research program?

11. How can we better recognize and reward scientific accomplishments/achievements?

Organizational Management

12. How effective is the current organization structure for management of CFSAN's and CVM's microbiological research? (please indicate from the choices below)

Very – Fairly – Somewhat – Not Very – Ineffective – No Idea

12.a. Please describe a structure you believe would be more effective.

13. Are the staff and resources currently devoted to microbiology research effectively deployed across CFSAN/ CVM? (Yes – No – partly – not sure – no idea) and efficiently used across CFSAN/ CVM? (Yes – No – partly – not sure – no idea)

13.a. How would you improve the allocation of staff and resources?

14. Describe IT solutions/capabilities that could improve our microbiology research program.

15. Aside from IT, please suggest other important services and capabilities should we look at to improve our microbiology programs.

Communication/Collaboration

16. How would you describe the quality of collaboration/communication within your group (team, branch, division, office)? (please indicate from the choices below)

Excellent – Very Good – Fair –Not Very Good – Poor – No Idea

16.a. What has worked well with respect to such collaboration/communication?

16.b. What suggestions do you have to improve the collaborations/communications?

17. Describe current coordination efforts among CFSAN's and CVM's microbiology research groups and their programmatic counterparts in the areas of regulatory policy, compliance, enforcement, and ORA field programs.

17.a. What has worked well with respect to such coordination?

17.b. What efforts are needed to increase and/or improve coordination efforts?

18. Describe current coordination efforts between intramural microbiological research programs and extramural "Centers of Excellence".

18.a. What has worked well with respect to such coordination?

18.b. What efforts are needed to increase and/or improve coordination efforts?

19. At what levels and in what manner does the CFSAN and CVM programs interact on significant microbiological issues with: CDC, USDA, EPA, academia, other Federal agencies, and international bodies?

19.a. What has worked well in developing these interactions?

19.b. How can we improve coordination efforts with our partners?

20. What other ideas do you have for how we can better serve our stakeholders?

21. What major institutional or systemic barriers exist which contribute to a lack of coordination?

21.a. What ideas do you have for overcoming these barriers?

Expertise/Training

22. What are the gaps or imbalances in scientific expertise and technological capability that CFSAN and CVM should increase efforts in to ensure that it can address current and future regulatory demands?

23. How can we improve CFSAN and CVM recruitment, development, and retention of the professional expertise needed to address current and future regulatory microbiological challenges?

24. How can we better ensure that training and professional development needs are being met?

25. Can you suggest outside entities we can partner with for more training opportunities?

26. Is there anything about the microbiological program at CFSAN and CVM that we have not discussed today, if so please elaborate.

APPENDIX B: COMPOSITION BY OFFICE OF INTERVIEWEES

APPENDIX B: COMPOSITION BY OFFICE OF INTERVIEWEES

Division	Branch/Team	Title	Role (if provided in interview)	Years in Position	Years with FDA
OARSA (28 interviewees)					
Virulence Assessment	Virulence Mechanisms	Research Biologist		23	23
Molecular Biology	Molecular Virology	Microbiologist	Support scientist	12	12
Virulence Assessment	Immunobiology	Biologist	Support scientist	5	25
Virulence Assessment	Virulence Mechanisms	Microbiologist	Principal investigator	14	14
Virulence Assessment	Virulence Mechanisms	Research Biologist	Research Scientist	<1	7
Virulence Assessment	Virulence Mechanisms	Supervisory Microbiologist	Line management	7	>27
Molecular Biology	Molecular Virology	Supervisory Microbiologist	Line management	3.5	11
Virulence Assessment	Virulence Mechanisms	Microbiologist		8	8
Virulence Assessment	Immunobiology	Biologist	Support scientist	13	36
Virulence Assessment	Virulence Mechanisms	Research Scientist Officer	Team leader	5	20
Molecular Biology	Molecular Genetics	Microbiologist		7	10
Molecular Biology	Molecular Genetics	Microbiologist	Principal investigator	11	11
Virulence Assessment	Virulence Mechanisms	Research Microbiologist		5	5
Molecular Biology	Molecular Genetics	Research Microbiologist	Principal investigator	10	20
Virulence Assessment	Virulence Mechanisms	Research Scientist Officer		27	27
Molecular Biology	Molecular Virology	Supervisory Microbiologist	Line management	<1	15
Molecular Biology	Molecular Genetics	Research Microbiologist		10	10
Virulence Assessment	Virulence Mechanisms	Supervisory Microbiologist	Line management	15	38
Molecular Biology	Molecular Genetics	Microbiologist	Purchasing agent	4.5	10
Molecular Biology	Molecular Genetics	Research Microbiologist		5	11
Virulence Assessment	Virulence Mechanisms	Microbiologist	Team leader	1.5	6.5
Virulence Assessment	Immunobiology	Biologist	Support scientist	13	14
Virulence Assessment	Virulence Mechanisms	Research Biologist	Principal investigator	24	24
Molecular Biology	Molecular Virology	Supervisory Microbiologist	Line management	4	25
Virulence Assessment	Virulence Mechanisms	Research Microbiologist		11	24
Virulence Assessment	Immunobiology	Research Microbiologist		6	6
Virulence Assessment	Immunobiology	Supervisory Microbiologist	Line management	5	28

Division	Branch/Team	Title	Role (if provided in interview)	Years in Position	Years with FDA
Molecular Biology	Molecular Virology	Microbiologist	Principal Investigator	2	4
OFS/DI (9 interviewees)					
Seafood Science & Technology	Chemical Hazards Science	Microbiologist	Team leader	5	9
Seafood Science & Technology	Microbiological Hazards Science	Supervisory Microbiologist	Line management	7	26
Seafood Science & Technology	Microbiological Hazards Science	Microbiologist	Principal investigator	15	20
Seafood Science & Technology	Microbiological Hazards Science	Microbiologist	Principal investigator + Policy detail	1	35
Seafood Science & Technology	Microbiological Hazards Science	Microbiologist	Support scientist	4	4
Seafood Science & Technology	Microbiological Hazards Science	Microbiologist	Principal investigator	6	15
Seafood Science & Technology	Microbiological Hazards Science	Microbiologist	Support scientist	5	5
Seafood Science & Technology	Microbiological Hazards Science	Microbiologist	Principal investigator	27	27
Seafood Science & Technology	Microbiological Hazards Science	Microbiologist	Principal investigator	2	13
OFS/MC (12 interviewees0					
Food Processing Science & Technology	Food Technology	Research Chemical Engineer	Principal investigator	22	22
Food Processing Science & Technology	Food Technology	Microbiologist	Principal investigator	20+	20+
Food Processing Science & Technology	Process Engineering	Microbiologist	Principal investigator	4	4
Food Processing Science & Technology	Process Engineering	Microbiologist	Support scientist	5	5
Food Processing Science & Technology	Laboratory Proficiency & Evaluation Team	Microbiologist	Support scientist	14	14
Food Processing Science & Technology	Process Engineering	Microbiologist	Principal investigator	25	25
Food Processing Science & Technology	Laboratory Proficiency & Evaluation Team	Microbiologist		22	22
Food Processing Science & Technology	Process Engineering	Microbiologist	Support scientist	6	6
Food Processing Science & Technology	Food Technology	Research Virologist	Principal investigator	6	17
Food Processing Science &	Process Engineering	Microbiologist	Principal investigator	23	23

Division	Branch/Team	Title	Role (if provided in interview)	Years in Position	Years with FDA
Technology					
Food Processing Science & Technology	Food Technology	Microbiologist	Principal investigator	5	23
Food Processing Science & Technology	Food Technology	Supervisory Microbiologist	Line management	8	23
ORS (30 interviewees)					
Microbiology	Molecular Subtyping	Research Microbiologist	Principal investigator	13	13
Microbiology	Molecular Subtyping	Research Microbiologist	Research area coordinator	5.5	5.5
Microbiology	Molecular Subtyping	Research Microbiologist		6	8
Microbiology		Research Microbiologist	Senior Regulatory Policy Advisor	5	53
Microbiology	Microbiological Methods Development	Research Microbiologist		5	5
Microbiology	Molecular Method & Subtyping	Supervisory Research Microbiologist	Line management	5	15
Microbiology	Microbiological Methods Development	Microbiologist	Support scientist	3.5	5
Microbiology	Microbiological Methods Development	Research Microbiologist	Subject matter expert	6	6
Microbiology	Molecular Method & Subtyping	Supervisory Research Microbiologist	Line management	1.5	1.5
Microbiology	Microbiological Methods Development	Research Microbiologist	Subject matter expert	10	20
Microbiology	Molecular Method & Subtyping	Microbiologist	Support scientist	5.5	5.5
Microbiology	Molecular Method & Subtyping	Research Microbiologist		1	6
Microbiology	Molecular Methods Development	Microbiologist	Support scientist	6	6
Microbiology	Microbiological Methods Development	Supervisory Research Microbiologist	Line management	5	24
Microbiology	Microbiological Methods Development	Microbiologist		13.5	13.5
Microbiology	Microbiological Methods Development	Research Microbiologist		5	5

Division	Branch/Team	Title	Role (if provided in interview)	Years in Position	Years with FDA
Microbiology	Molecular Method & Subtyping	Research Microbiologist	Research Area Coordinator	11	11
Microbiology	Microbiological Methods Development	Microbiologist		<1	3
Microbiology	Molecular Method & Subtyping	Microbiologist	Support scientist	6	11
Microbiology	Microbiological Methods Development	Research Microbiologist		14	14
Microbiology	Molecular Method & Subtyping	Research Microbiologist	Research Area Coordinator	4	4
Microbiology	Molecular Method & Subtyping	Research Microbiologist	Team leader	14	14
Microbiology	Molecular Methods Development	Research Microbiologist		4	5
Microbiology	Microbiological Methods Development	Research Microbiologist		8	8
Microbiology	Molecular Method & Subtyping	Research Microbiologist	Principal investigator	2.5	2.5
Microbiology	Molecular Method & Subtyping	Research Microbiologist		20	20
Microbiology	Molecular Method & Subtyping	Microbiologist	Support scientist	3	5
Microbiology	Microbiological Methods Development	Research Microbiologist		<1	5
Microbiology	Microbiological Methods Development	Research Microbiologist		NR	NR
Microbiology	Molecular Method & Subtyping	Research Microbiologist	Principal investigator	5	5
CVM (15 interviewees)					
Animal & Food Microbiology	NARMS Team	Microbiologist	Support scientist	16	24
Animal & Food Microbiology	NARMS Team	Microbiologist	Team leader	8	15
Animal & Food Microbiology		Supervisory Microbiologist	Line management	2	6.5
Animal & Food Microbiology	DAFM Team	Microbiologist	Support scientist	16	25
Animal & Food Microbiology		Microbiologist		14	40
Animal & Food Microbiology		Research Microbiologist	Principal investigator	2.5	2.5
Animal & Food Microbiology	Business Process Improvement Team	Business Process Improvement	Team leader	5	25
Animal & Food Microbiology	NARMS Team	Epidemiologist		5	5
Animal & Food Microbiology	NARMS Team	Supervisory Microbiologist	Line management	5	14
Animal & Food Microbiology	Molecular research & microbiology	Microbiologist	Support scientist	6	6

Division	Branch/Team	Title	Role (if provided in interview)	Years in Position	Years with FDA
Animal & Food Microbiology	Microbiology Team	Microbiologist	Support scientist	6	6
Animal & Food Microbiology		Research Microbiologist		3	5
Animal & Food Microbiology	NARMS Team	Microbiologist	Support scientist	3	7
Animal & Food Microbiology	NARMS Team	Microbiologist	Team leader	5.5	5.5
Animal & Food Microbiology	NARMS Team	Research Microbiologist	Principal investigator	3	16

APPENDIX C: INTERVIEWEE OBSERVATIONS

APPENDIX C: INTERVIEWEE OBSERVATIONS

In this Appendix, relevant observations, comments, and recommendations have been presented intact or relatively intact (direct quotes and paraphrasing are presented without a distinction made between the two). Interviewees involved in microbiological research are identified by their location according to the following acronyms:

- Office of Applied Research and Safety Assessment: OARSA
- Office of Food Safety, Division of Seafood Science and Technology at Dauphin Island: OFS/DI
- Office of Food Safety, Division of Food Processing Science & Technology, Moffett Center: OFS/MC
- Office of Regulatory Science: ORS
- Center for Veterinary Medicine, Office of Research (OR): CVM

Individual interviews were extracted into this appendix in random order, but are organized herein in the office order presented above. For questions where responses tended to differ by office, the responses are divided into separate sections by an off-set row for each office. For questions where responses did not appear to be affected by office, the office of the interviewee is identified in parentheses following the response.

C.2.1. Science Questions

C.2.1.1. What do you see as the most important reasons for having in-house microbiological research programs at CFSAN and CVM?

C.2.1.1. Interviewee Observations: Most Important Reasons for Having In-House Microbiological Research	
Our requirements are unique	• In terms of food safety and regulatory needs, our goals are different than a basic research group; all of our research has to be geared to answering a regulatory question. We need scientists doing research because we need to keep current—needs, methods, problems (OARSA). • General food science may look at preventing pathogens in crops, but it doesn't necessarily look at methods for detecting pathogens in food, which is a very difficult matrix to analyze. Large companies (e.g., Kraft, Hershey, Nestlé, etc.) are doing this type of research for their own reasons, but they don't release their findings to the public. From a legal perspective, it's important for FDA to be able to say this is our method—either we developed it or took somebody else's method—and validated it in-house so we can guarantee and stand behind our results (OARSA). • We are responsible for surveillance of the food industry, and we need the microbiologists to do that. Microbial pathogens are a big problem in food and without the MB expertise, we would have no way to make sense out of the information that comes in. The pathogens change constantly and if we don't have the expertise in-house, we won't be able to respond to outbreaks as these microbes mutate (OARSA). • We perform the laboratory research studies needed to develop methods. That's our special niche, and it's why we still have research here. We're supposed to lead the world in food safety issues by driving innovations (OARSA). • Since we regulate, we need to have our own experience and knowledge. You can't trust that industry will be doing everything the right and/or best way. Their focus is different than ours (OARSA). • The kind of research we do is different from the work done at outside institutions or universities that focus on basic research. We do more applied research and have to answer questions from ORA field labs. We do research to address these questions, as well as to develop methods to assist in sample analysis and detection (ORS).

C.2.1.1. Interviewee Observations: Most Important Reasons for Having In-House Microbiological Research	
	• In-house research helps us to develop methods because it allows us to study the microbes in order to inform the methods (ORS). • Research is critical to our mission--absolutely critical. We need to produce science that uniquely serves our programmatic and regulatory stakeholders. We have a center full of lawyers, of regulatory, compliance, and enforcement officials that need the backing of science to do their job. FDA has always supported its mission with a strong scientific base. That's got to continue (ORS). • Our role is to serve the ORA field laboratories, both state and federal. They need to be on the cutting edge of faster, cheaper, better. So we are doing the research to provide new genomics methods. What we do will have direct application in 3-5 years or we stop that work. We understand this connection to mission, and more money has poured into our endeavors. Next generation WGS has numerous implications for the FDA (ORS).
No one else can/will do this work	• We are charged with the conduct of research which is very unique. NIH and CDC don't do it, very few academic labs will touch it, other non-governmental agencies are not charged with it, and industry is looking for guidance from FDA, so they don't take the lead. This is the kind of research that should and must be done by someone and that someone is us (OARSA). • Who else would do the needed research for ORA and the Center? Industry does a lot of research but does not publish or share their findings with the FDA. Some of the upper management think you can pass a rule or law and the microbes will obey, but it doesn't work that way. You have to have testing and verification (OARSA). • When it comes to food safety the buck stops here in this country. Our partners, e.g., USDA, their missions and their commodities are different. We are fairly unique in what we address (OARSA). • Neither academia nor NIH attack the problems that we do. The food industry does research, but they don't release their data, and we don't want to rely on information from the food industry, because they would have a conflict of interest (OARSA). • There is not a lot of funding available for working with certain agents, e.g., Hepatitis A, which is not a high priority for the medical community because there's a vaccine. However, it does affect people, especially on a global level. If we have the resources and capacity to do research on these things that are not as high priority, we should. We have top-notch equipment and scientists (OARSA). • As government employees we have a better view and can focus our research more strictly on protecting general public health. A lot of industry research focuses on profit, which shows bias in how they carry out their research. Academia is under extreme economic pressure, making it difficult for them to be neutral. Academia can conduct good research but may be more focused on a point of view, theory, or fundamental research that's in their own interests. They may be doing good research, but finding a way to protect general public health is most important, and that's what we do here (OFS/MC). • There is a tremendous need for the work we do in proficiency testing (PT) in methods validation. I was hired to do proficiencies for milk and shellfish. In the last 5-6 years that has expanded into a huge program. Private companies cannot allocate those kinds of resources. Scientists around the world are amazed at the data quality we have. Our system needs to be implemented elsewhere within FDA. Other countries do it—U.K. and Germany, for example, and scientists there are surprised that FDA doesn't (OFS/MC). • There isn't any other way that some of the fundamental research will get done without being done in-house. Trying to contract out some of these things isn't possible. Some of the methods development work could be farmed out, but if the outside contractor only focuses on the need to develop a particular method, they're too focused and not looking at the bigger scheme. They could miss an opportunity to have a method that may do more for them than a focused method (OFS/MC). • Industry's test kits are based on just a few matrices investigated for their clients. They don't go after difficult matrices, and academia doesn't do it because it isn't cutting edge and doesn't produce papers. Similarly, no one is going to do all the genomes that we are willing to do (ORS).

C.2.1.1. Interviewee Observations: Most Important Reasons for Having In-House Microbiological Research	
	• Academia is not going to do this sort of research. They are fighting for grant money. They are only going to do sexy things. We do the research that is necessary, but no one else will do. It's sloggy, not sexy (ORS). • NARMS is the only federal program that monitors drug resistance (CVM).
Public health/response	• We need to maintain a reservoir of expertise for regulatory needs and for food-borne crises such as outbreaks (OARSA). • In outbreaks they have to understand the role of the pathogen in the disease or how to detect the pathogen. Having in-house research helps because you can immediately assign people to take care of some of the issues (OARSA). • From my CFSAN perspective, microbiological programs are integral to food safety. In order to get food more safe and to prevent food-borne outbreaks we need to understand microbial evolution, niche adaptation, and this requires basic research in the field of microbiology (OARSA). • It is critical for preventing outbreaks. FSMA is all about prevention, and if we don't have MB research, then we can't understand these pathogens. They change, they emerge, and new ones arise. Having microbiologists is critical to that part of FSMA (OARSA). • It gives scientific credibility to the Agency's food and feed safety programs. We serve our bosses, the American people, who expect us to throw everything we have at a foodborne outbreak (OARSA). • So we can deal with new issues—emerging pathogens, threats. When these come up, we need a solid research base to get an understanding of what we're dealing with so we can make decisions and protect the public (OFS/DI). • In-house microbiological programs provide a science base for everything FDA does to protect public health. As part of the investigation during an outbreak, we need to know the method to detect the pathogens, why they are there, and where they come from. This requires study on the ecology, survival, growth, and control of pathogens (OFS/MC). • The research is focused on current and important food safety issues and we are able to update our technologies quickly. We have clear and detailed guidance for method development and validation and are open to collaboration with companies or other Centers to improve and incorporate rapid methods with the culture methods. We provide support to outbreak investigations. Lastly, we have good teamwork (ORS). • We need methods so that FDA can carry out its mission to ensure safety and efficacy of drugs and foods. We need rapid methods to investigate outbreaks in a targeted fashion for regulatory purposes (CVM).
Support mission and program offices	• Our research is very much targeted to the needs of the FDA, regulatory policy, compliance and enforcement. We need to understand emerging technology and its limitations. We need to know the science firsthand to write regulations (OARSA). • We're here to provide research for the ORA field labs who don't always have time to do the basic research needed to address issues like methods development, etc. (OARSA). • To support program offices and their mission (OARSA) and to back up our regulations (CVM). • We need the research to support regulations, guidance, and policy. This is the primary function of research at CFSAN (OFS/DI). • We need in-house research for response to programmatic needs, and for development of policy. It is hard to get external research groups to be immediately responsive to the things we need. Not everything we do in support of policy is publishable; therefore, it's not as attractive to external scientists (OFS/DI). • Most of the research I do is in support of FDA priorities and the regulations. Within IFSH, our research helps to process some of the petitions/filings from industry. FDA doesn't have basic science data to do the filings. For the last 10 years we have been doing research for FDA priorities, even if it is not on their list. FDA has to have some background research and data, and that's what we are doing here (OFS/MC). • These in-house research programs allow FDA to meet specific goals and respond quickly to its data needs. FDA needs data in certain food safety areas to make decisions. We can

C.2.1.1. Interviewee Observations: Most Important Reasons for Having In-House Microbiological Research	
	turn it around quickly whereas an academic department or a contract research organization can take significant time to get up and running (OFS/MC). • We need people well versed in the science so that we can advise the policy makers (ORS). • It is important because ORA field labs do daily screening. We need to stay current on technology to develop new protocols for screening and detection and relay them to the field labs. We support the regulatory effort because some of our research helps the reviewers for new drugs or food supplements answer questions that come up in the review process concerning the protocols manufacturers are using (OARSA). • The research we do at CVM reflects the mission and priorities of the Center. We give research support to regulatory needs (CVM).
Expertise	• It's important to have in-house expertise for legal reasons. You don't want to rely on outside opinions concerning what is and isn't a pathogen when it could result in a food recall (OARSA). • Continuity and institutional knowledge: You can't just expect someone to come in and pick up research without knowing the basis or applications or impact of what they're doing. We're not swayed by the tides of thought. We're a consistent body with a vested interest (OFS/DI). • You need to have competence in certain niches and experts in fields, and you don't accomplish that by working on the flavor of the month. Even when you're contracting out some of the work, your level of expertise is there to evaluate its worth (OFS/DI). • We need to have SMEs who are involved in research. They are the ones who go to conferences and the ones who understand problems on the bench. They are a very good source of knowledge and information that we wouldn't be able to get from academia or industry because each institute has their own mission (ORS). • We need to make sure we have the science to make regulatory decisions. It wouldn't work to contract it out because you wouldn't have the **f**lexibility or the dedication you have with an in-house staff. Government employees are dedicated (CVM).
We are a science-based Agency	• As a science-based regulatory agency, science is a must for FDA/CFSAN. Maintaining our expertise will keep FDA current with the latest advances in science and actually doing this science ourselves (OARSA). • We understand the problem and know what the issues are with food testing. If the research is not done in-house, there is an education curve, and we will still have to judge the quality of the work and make sure the methods are validated in all the food products we regulate (ORS). • The most important factor is credibility. FDA is a science-based agency and the basis for FDA's regulatory calls is sound science. If our scientists lack credibility, it detracts from the FDA mission. If they are recognized, it lends credibility to FDA's regulatory decisions (ORS).
Cost	• It is probably more cost-effective to keep a full-time trained research scientist than to contract when needed (OFS/DI). • Centralization of the research effort. Instruments can be utilized by a number of groups (ORS).

C.2.1.1. Interviewee Observations: Most Important Reasons for Having In-House Microbiological Research	
Quality control	• Doing research internally gives us more control over what's being done and provides more useful results. Management has more of a say if it's done in-house. Also, if you hit a bump, you can make corrections. We adjust milestones or come up with a different method. If you farm it out, it doesn't always come back the way you want it (OFS/DI; OFS/MC). • It is better if we do our own research rather than farm it out. We care a lot more and we're part of the Agency. We're going to do what's right and for the right reasons; whereas contractors are just there for the money (OFS/DI). • We need to be an advocate for the public. We need to have the ability to test the quality of our foods, develop the best methods, and detect pathogens, and not leave this to private labs. It is also important to look at what kinds of quality control industry is doing and hold them to standards. Often industry seems to develop the standards. There needs to be a public interest (ORS).
Lack of bias	• Outside help would not be cost-effective or wise; they could be influenced by the food industry. We are unbiased. We keep the food supply safe without any ulterior motive (OFS/DI). • We are afforded more leeway because we are beholden only to the public. Our research has more integrity. If you contract the work out, you may not feel vested in the results (OFS/DI).

C.2.1.2. In your work unit, what do you see as the strengths in your program with respect to microbiological review or research?

C.2.1.2. Interviewee Observations: Program Strengths	
OARSA	
Expertise	**Diverse expertise:** • Within our division, we have scientific expertise in diverse food-related microorganisms, as well as experts in method development and validation, and novel technologies, such as microarrays or genome sequencing. • We have a multi-disciplinary group: biochemists, molecular biologists, microbiologists, immunologists. • We have a microbiologists, immunologists, even an MD. We are in the process of hiring a parasitologist to backfill a slot. We have the capability and adaptability to perform many different areas of research as needed. We can do animal work, molecular biology, protein work, and immunological testing. We don't have just one focus, but can cover a broad range of problems. • We have a good blend of microbiology and molecular biology expertise here. We come together to try and get the job done despite lack of support from some of our middle management and upper management. Our research is well respected worldwide. We now have many international collaborators and other governments are seeking our help to help drive some of the innovative programs they're setting up, such as microarray and sequencing efforts. • We have some of the best people in the world from academia and industry working in this group. Our people are cutting edge. They like supporting public health, knowing what they do makes a difference. • In my division, most of us are trained microbiologists and use our experience for food safety. The work is well distributed amongst various scientists with the abilities to detect pathogens and analyze their genetics. We are well placed with a range of expertise to work toward the mission of the Center. • While we have a variety of different expertise, the personnel in our branch are cross-trained and capable of doing many different tasks. • In our group we have a developmental toxicologist. It may seem as if he doesn't belong in our group, but he always brings good perspective, so that it's not all sequencing, sequencing, sequencing. Having a different perspective or point of view helps you identify the gaps. • It amazes me the caliber of scientists that we have, and the potential we have to fulfill all these needs, including FSMA. **Genomics:** • We are the pioneers of microbial genomics at FDA. There are other groups at FDA that are now doing microbial genomics and have started doing it in the last couple of years, whereas we were doing it 10 years ago. • In research our strengths are and have been genomics. They emanated from within this Office and Division. In addition, we have molecular biology of pathogens, genetic characterization, all the way to forensics and strain-level attributes, and we have some pre-eminence in meta-genomics and certain pathogens (*E. coli*, *Salmonella*). From before my time, through interagency agreements with DHS, we have been key in understanding strain attribution for bioterrorism etc. We were working at that level, but that has changed, and mostly because there is significant competition between other research organizations within CFSAN. Our strengths haven't changed. We're working within a confined space that is becoming more confined and pigeon-holed.
Group dynamics	• Our people have strong backgrounds in their areas, and they are dedicated to the mission. They want to do a good job, and they like working here and for the government. We all get along well. We work with toxicology folks, the molecular biology group, and we do joint projects. We have regular OARSA seminar series, we have a newsletter. Our little group here, I think is a model for how an organization should run, but the people at the top don't

C.2.1.2. Interviewee Observations: Program Strengths	
	seem to think that way. • We have a diverse group who are well trained. We are hard workers who tackle whatever projects come our way. Projects are handled thoroughly and ethically. We are a strong group of scientists who are eager and willing to do this work effectively. • We have intelligent, dedicated, well-trained, hard-working people who work weekends, long hours. • We have excellent researchers and a good, cohesive program. • For the most part, we work well together at the branch level. Everyone in our team works on multiple, different projects. Certain people may lead different projects, but there's a lot of cross-over. Sometimes we'll pull people in from the Branch, depending on the project. In addition, we've done collaborations with the other Branch within OARSA, and with ORS, CVM, state labs, and internationally. • We have a really good team that works well together without having territorial or ownership problems. You can't do research as an island anymore.
Aligned with mission	• We are focused because our group mission is to either improve current technologies, as few as they are, or develop new technologies that apply to the detection and identification of food-borne viruses. It is an exploration in scientific investigation that's based not just on an outcome (i.e., we need to detect virus A), but also on understanding the technology and the limits that may be imposed by that technology. • We adhere to EROs selected by our peers and management in our experimental design, which keeps our work in focus with the mission.
Public health and outbreak response	• The research we do is important and useful. I'm excited to be able to do research that is immediately applicable and that will serve public health by being useful to the ORA field labs.
Access to the latest technology	• The distinct advantage is that we can keep up with the latest research. It keeps us on the front line. The research here is state of the art. We have a good team.
Resources	• We have the resources and infrastructure including advanced lab technologies (e.g., scanning electron microscopes, transmission electron microscopes, confocal and fluorescence microscopes, microarrays), genome sequencing capabilities, and animal testing capabilities. • We have a Biosafety Level 3 high containment lab.
OFS/DI	
Expertise	• Depth of knowledge of the staff in their areas of investigation: They are all leaders in their respective areas of study. In several instances, they are world-known, and recognized, and respected. • We're commodity driven. We focus on seafood and that allows us to generate more expertise in our specific area. The issues tend to be cyclical so that when you've been in it for awhile, you know what's coming.
Group dynamics	• We work well together. We have no problems consulting with each other. We each know our limits and are comfortable asking others what they think. In addition, our location is ideal for what we do.
Aligned with mission	• We have a good relationship with the policy group and a good understanding of their needs. Our work as a facility is directly applicable to the Agency mission and policy. Part of what allows us to do that is where we are. No one else has the access that we do to shellfish, etc. • The connection between the program division and the research division keeps our research grounded. • Our research is engaged, applied, and really hits home as to what FDA should be doing.
Public health/response	• As a group, our main concern is contributing and doing something worthwhile--seeing that our effort makes a difference, that what we do has an effect--rather than publishing and making a name for ourselves. We are very focused.
Engaged with	• We have strong engagement with stakeholders vertically and horizontally—other people

C.2.1.2. Interviewee Observations: Program Strengths	
stakeholders	in our field, policy people, end users, regulatory analysts, other experts including those in industry. • We work closely with industry and state regulators. We've always done applied research and had a pretty clear-cut objective on the lines of research.
OFS/MC	
Expertise	**Food processing and food technology:** • The wide variety of expertise we have in the area of food processing. Our Branches are kind of loose, but interest and expertise spans all of them. For example, a few years ago we had a USDA grant looking at the ability of *E. coli* O157 to live in packaged spinach. It wasn't just a microbiologist working on this. A packaging person was helping because otherwise we'd have no knowledge of the appropriate packaging systems. In a project we're doing on milk, processing plays an important role because we're actually heat treating as they do in industry. We're using industry's systems and conditions, but we're combining it with the molecular biology side for the actual assay part. Even though we have a packaging area, processing area, and a microbiology area, they intermingle and interact. • Our unique capability is expertise in food processing and food technology that emphasizes prevention. Our location enables us to maintain contact with industry. We offer FDA a unique capability and strength. The technology and processing experts, and industry, are here. Industry will to have to pursue all the work on preventive controls required in FSMA. For FDA to understand and help, it needs expertise in food technology and food processing that is also located close to industry. • We have a unique infrastructure and expertise within FDA, and institutional knowledge that belongs to FDA. • We're good microbiologists. We try to be successful and to work on projects that CFSAN appreciates and are related to its goals. • We are doing specialized research that no other groups can do, and we have a mixed bag of scientific expertise all doing MB work, including engineers, and food scientists. **Preventive controls:** • This is the only place in the Center that researches preventive control in processing. FDA regulates packaged and processed foods, so understanding what kind of contamination can occur and how is important. In the past, with GMP regulation, we just made sure the ecology was clean. Now we're in preventive control. Processing-related research is critical because learning and understanding the process leads to ideas for control. • The Moffett Center focuses on preventative control, especially in produce. The norovirus problem is the most significant source of illness occurring from freshly prepared or ready-to-eat foods. I work directly on the problem of foodborne illnesses. My works is exciting and I enjoy the hands-on experience. **Laboratory proficiency testing:** • In methods testing, we're able to provide a variety of matrix experience and each matrix has its own analytes and pathogens. Some employees come here and in 1 year analyze several different matrices. If you go into the food industry, and they're manufacturing peanut butter or produce or coffee, all you're going to analyze is what they manufacture. **Select agent work:** • Our pathogen is a Tier 1 agent. There are extensive regulation on handling the organisms (e.g., working with the toxins and spores) and very few laboratories in the country can do it. We were the first FDA lab to be PulseNet certified, which allows us to process our samples, and we've helped other labs—inside and outside FDA—to become certified. • We're one of the few groups around the world that does this type of select agent work. There isn't much expertise about food left anywhere else.
Group dynamics	• We're like a family here. Some of us have been together for 20 years. It's hard to get things done because most of our time is spent on paperwork and following regulations. People don't recognize that. But people here bust their butts to do things right and they don't get the recognition for how much effort it takes.

C.2.1.2. Interviewee Observations: Program Strengths	
ORS	
Expertise	**Diverse expertise:** • We have good detection methods for bacteria, and bacteria is the most common pathogen in food. Our ability in genome sequencing is cutting edge, but we are also expert in doing culturing techniques. We can now determine sequences of several bacteria in a week. We are identifying genes that will be useful in identifying subtypes. This is the future of MB. In the near future genome sequencing will have a large role in outbreak detection. • We do a good job using traditional MB methods. It is valuable to have an actual live culture of the organisms. • You can get a good coordination of effort. A matrix that might be contaminated by several food-borne pathogens can be determined because we have a coordinated effort. **Genomics** • In genomics we are front runners and are driving a lot of research and generating data needed to respond to and trace sources of outbreaks. We are putting a lot of resources into generating databases that can help respond to and pinpoint sources of future foodborne outbreaks. • We have world class phylogeneticists on the team, who have been responsible for our success with genome tracking and the efforts to pinpoint the source of outbreaks. We also have leading researchers in meta-genomics.
Group dynamics	• We have people who want to work here, who want to serve the public, and think we are doing a serious undertaking that benefits the public. People are motivated because they want to help and do good. I am always amazed at the talent we have in house. • There is a hands-off management approach. Personnel are hired that are independent workers that can get the work done without constant supervision. I am rewarded for getting the work done by not having oppressive management. We are allowed to do our job. • Within our division, we all get along, share, and want to help each other. There is a collegial environment that helps drive forward the research. There is also a lot of collaboration, which has enabled us to be prolific in publishing and getting methods out. • The opportunity for collaboration is available and encouraged. The collaboration with the genomics lab is very important and integral to what I do. That collaboration has been very beneficial. • Colleagues, supervisors, and peers are all very good scientists and there is a good working environment within the Branch. • We have very good, hardworking people. We have a high performing organization, which means we communicate clearly, which isn't always easy to do. In general, we're transparent, communicating and building off each other's work. The communication and guaranteed budget [vs. academia] make it so that we don't have to compete internally, and we are more apt to cooperate with each other. • We have big thinkers, out ahead of the curve. This makes it a vibrant intellectual place to work.
Aligned with mission	• We are highly aligned with programmatic need. Our Division is divided in three major areas, each of which covers a major programmatic area, the offices of food, food safety, and compliance. We don't do basic research; almost all my people are engaged in research that is necessary for our programs in food safety to succeed now. • Almost all of the problems we investigate are very mission-related, and the effort is extremely labor intensive. There is no money in academia or industry that could cover this because it doesn't make money. • We (PFGE team) are more of a service-oriented unit. We analyze field data and interact with other Federal agencies, as well as our compliance and outbreak groups. Of everyone in our division, we are the most mission-oriented group, as we are not even really doing research: we are providing a service.
Access to technology	• We are riding the wave of the future with the latest and greatest sequencing technologies and applying them to problems that need solving. This is the first time we took next generation sequencing technologies and applied them to food born outbreaks in real time.

C.2.1.2. Interviewee Observations: Program Strengths	
	• We have resources and equipment to compete with academia. We're on the forefront using next generation WGS, which will replace PFGE. Next Generation WGS gives a lot more information and is getting faster and is getting cheaper all the time. • The genomics program. It's a major improvement over PFGE (the field that I'm an expert in). It's hard to know for sure how it will play out, but it should drastically improve policy.
Resources and Staffing	• We have had a lot of funding in the past couple of years and have gotten a lot of good equipment. • For the past few years, we have had a healthy budget and they have hired a lot of scientists, which was needed and is beneficial.
Leadership	• We have strong leadership in the program. They are willing to change and adapt.
CVM	
Expertise	**Diverse expertise:** • We have an extraordinary, well trained staff, with breadth of experience. We have an expert for each pathogen. NARMS is an interagency program with CDC and USDA, and that brings us strength. We work well together and complement each other. It's a great example of an interagency public health program. • People are very good at their job and knowledgeable. They are often at the top of their fields, and are consulted by academia and other Offices and Centers. • We have truly excellent support scientists and PIs. Not only are they extremely well-trained, they are extremely dedicated and care very much about doing an excellent job. • We have a diverse group of individuals with experience from all different areas of microbiology. • The strength of our scientists and recognized expertise. Many of our PIs are established scientists in their area of expertise. Ideally, each PI would have expertise in a distinct area.
Group dynamics	• The microbiologists at CVM have managed to create a good working environment among themselves. There is a network of people who, whether they like each other or not, are willing to work together and tackle anything that comes up. They have created a good vibe. This is not the case among other groups in the MB program. • We have a very good working rapport within our division. Everyone is fairly dedicated and realizes that the work we do is important, even though we don't see the direct results in our work. This is one of the few places I have been where the scientists take such pride in their work and are willing to put in that extra effort. • We are very collaborative. We collaborate with sister agencies and it strengthens what we do. In DAFM, in the research aspect, we work closely with ONADE and Office of Surveillance and Compliance. We also work well both Wiley and MOD 1. I'm proud of the fact that everyone likes working with us. • I work in a great division with great PIs. I have hardworking coworkers and there is a good facility and equipment.
Aligned with mission	• We are doing consequential work that is aligned with the agency, and have the flexibility to respond to outbreaks.
Access to technology	• There is commitment to implementing latest technology.
Resources	• Our culture collection is one of our strengths, we get requests for samples from both inside and outside our agency.

C.2.1.3. In your work unit, what do you see as the weakness in your program with respect to microbiological review or research?

C.2.1.3. Interviewee Observations: Program Weaknesses
OARSA

C.2.1.3. Interviewee Observations: Program Weaknesses	
Staffing	**Conversion of Fellows:** • We have Staff Fellows and ORISE Fellows whom we've brought in and trained and they are an integral part of our team and we are now having a hard time keeping them. They are unhappy, they're insecure and I am a little reluctant to make them a part of a big project with the thought that tomorrow they may be gone. The upper management is telling us that instead of being a track to a permanent position, as it has been in the past, the Staff Fellows are now in a training position not leading to a permanent position. We first heard of this change in policy in July 2013. They came in 5 years ago thinking that it would lead to a permanent position. We have one PI we have built a large project around. If she left, it would leave a big hole in the research. The uncertainty is difficult. We brought all these people in under the assumption that unless they screwed up, that they would be converted. They have achieved all the requirements for conversion, been PIs, run projects, sat on committees. I don't know what the point of all this is—if we lose all these people, our division will be wiped out. The other Office (ORS) has a much easier time converting Staff Fellows and even ORISE. All this uncertainty is very difficult way to work. These people have families. • Allow us to make permanent our Staff Fellows who are performing excellent research, and hire some of our ORISE Fellows or find another affordable contract mechanism. Otherwise, the research in my division will soon come to a screeching halt. We have some Staff Fellows doing allergen research, which is considered a high priority in the FDA strategic plan, but we've been advised that we can't convert them because FDA won't be doing allergen research in 10 years. • When we try to convert our Staff Fellows, we get pushback and are told we don't have the resources to convert these Fellows. The decision not to convert has never been made transparent enough that I was satisfied that this decision was best or justified. The response merely comes back as yes or no. This does not translate equally to other units. • When people leave there is no one to back-fill positions. Fellows work here for 5 or 6 years, don't get converted to a full-time position, and leave. So we have trained someone for 5 or 6 years, and then we start again. Before, conversion was almost automatic. If they liked you then you were converted to an FTE. There is no guarantee today. • A weakness is not having any certainty that you can at least keep some of these personnel who are on a temporary position. When you get someone who is very good, you will have invested a huge amount of time in training, and then their term is up. **Insufficient staff:** • Our biggest weakness is that ours is a very small group, despite the fact that food-borne illnesses from viruses is huge. We really don't have the number of total personnel commensurate with the food safety problem. • Five years ago, there was money coming in from the Food Protection Plan to infuse young talent into our group. The plan was for them to take over in the next decade because as many as 10 people could retire in the next 5 years. We needed that infusion of young, cutting-edge scientists. That effort has stopped now because people don't want to take any more risks. In my opinion, the worth of a scientific organization lies in its ability to attract young people. Without it, the research capabilities of that organization die. **Support scientists/technicians** • I could really use support staff and technical staff. I'm doing the same activities that I did as a postdoc. I also do the ordering for the group—this is voluntary, but it takes away from the research. Having a senior scientist be the cardholder is not an efficient use of resources.
Leadership/ management	**Office Director:** • Our OD moved from being a team leader to OD—that's a big move and he is a toxicologist, not a microbiologist. I don't know if he gets what we do. The deputy is a microbiologist and is supposed to fill that gap, but she's been out of the lab a long time. We just don't have that strong leader we need so we need to help ourselves. The DDs try, but they are not invited to a lot of the high level meetings. We don't really have a champion that will go to CD or Deputy CD and say this is what we are doing and this is why it is important. We spend time championing our own research and it takes away from our time

C.2.1.3. Interviewee Observations: Program Weaknesses	
	to actually to the research. • We haven't had a strong leader at the office level for a long time. If you are going to have an OD and Deputy, they have to be someone who believes enough in your office to be willing to fight for resources and staff. But we don't have that. We had an OD who was strong for about 10 years but, unfortunately they decided he was too mean, and forced him out. Since then we have had several directors, but none have been able to stand up to upper management, and I don't think the current one even tries. • We have had no permanent OD in several years. The current OD came in as acting about 1.5 years ago, then was changed to "term" employment, which I've never heard of. Right up the line we've had no permanent leadership. With no one permanently assigned to the OD spot, it became a free-for-all from other groups: "They're weak. They're defenseless. No one's giving them information." It was purely taking advantage. **Line management:** • Our line management is disengaged both scientifically and professionally. Our DD doesn't go to scientific meetings anymore. We need someone to support our group at that level as well. Our BC doesn't support the development of younger staff. They're both disengaged for different reasons. It's hurting the Branch and, in some ways, the whole Division. The DD is good in an advisory role, but is not helping or moving our science forward. Our BC is self-serving, and there is little confidence because of that. As a result of the micromanagement of upper management, there's no empowerment for taking the risks necessary to drive innovation. Even the seasoned scientists are backing off. • Most of our line management is acting. Right now my BC is acting. Our OD is acting and has been acting for 2 years. Even though he has been with us for 2 years he is not engaged in what we are doing. He doesn't represent our office well. We need strong office leadership. That has been lacking for almost 2 years. • It's difficult when you're off-site and don't have that voice or leader to go over there and be your spokesperson, to let people know we're a talented, intelligent group that's willing to work hard. We have some great ideas for projects, but if upper management doesn't hear about them, our projects don't get off the ground or pushed through. • There is a weakness in leadership across the board. The OD does not have any idea what we do. Our DD is not engaged, and does not provide any direction to us. And our BC is a very poor manager. He does nothing to support our branch, and favors people in his lab. Those three levels give us nowhere to go because they're not bringing the information to us. It amazes me that this is the way it is. • It would be nice to fill some management positions permanently so that we could get stronger leadership in OARSA. We have really good people, but we have an acting BC and we've had an acting OD for a long time. • Division management here is poor as far as communication and in professional manner. And the further you go up the chain, the less communication there is.
Lack of communication/ transparency with upper management	• Upper management has no respect for our employees. Our leadership ignores the needs of our office. It's hurting morale. Our employees and our Office are treated with much less respect than those located in CPK1. That applies to budget, personnel, and any other support. The CD has been to this building maybe 3 times since he was director, and the current DDSO has been out here maybe 3 or 4 times since 1991. We've had people ask if this place is closing down because of lack of support. If there's some ultimate goal, we need to know. It affects morale out here terribly. • Upper management doesn't provide us with any guidance or feedback on what's expected of us. In fact, we don't get a lot of guidance from upper management outside this building. There's an assumption that we aren't talented or dedicated, or ambitious, which is completely untrue. People have some good ideas, but they may not be the right ideas or focused exactly the way upper management wants them to be. It may just be a matter of tweaking them or letting the scientist know what they're looking for so we can design projects for their specific needs. Our talents aren't being utilized. • We don't receive support from upper management even though we have a strong research group. Sometimes we just have to follow whatever they feel is mission relevant work even

C.2.1.3. Interviewee Observations: Program Weaknesses	
	though there may be some discrepancies between what the scientists feel should be done as the research progresses and what the upper management thinks is mission relevant. In addition, what the management feels is mission relevant also keeps on changing. • We don't receive the support we need verbally or monetarily. There is a perceived negative attitude toward the work we do—it's not embraced. There is always the attitude that it is not 'mission relevant'. Projects are often rejected with just a 'no' and no explanation. But then we're told that our work matters. People just want to find out what's *really* happening. • We are not receiving a lot of direction from the Center. As team leader, I spend a lot of my time figuring out what management wants the team should do. So I have all these talented, highly motivated people who are having trouble figuring out what to work on. It is discouraging to think you know what you are doing and put time and effort into a project and then they come back and say 'no that's not what we wanted you to do'. • Recently, upper management has made an effort to change the focus of research in our division. This has put us on hold because they have not made it clear what they want and what their vision is. • There is a lack of upper management support. Management could come around the lab and put their hand on your shoulder and say 'good job' or ask about what you are doing. They need to see first-hand the work being done to see why we need more money and what we would do with it. • We don't have a place at the "high table."
Resources	• We seem to be losing resources and I don't know why. We've had a lot of projects that I thought were high priority projects that would give a lot of information back to the Center, that were cut by upper management. Even though we have all these strengths and a really good team, we are not being used to the best of our ability.
Communication/ Collaboration	• Communication could be better. There are a few scientists in my area who are very territorial. They don't like to share space, reagents, and primers with other researchers. There needs to be more cooperation. • Our team is very small. Every PI works on their own project. We kind of collaborate, but it is mainly just one person for one project, so you don't have enough scientific stimulation or discussion. • We could collaborate more with those within the Agency but also outside our office and with those outside the Agency. • We're beginning to move into separate groups or teams, and I think that may be negative. It has happened recently. We need more cooperation in our branch as to what everyone's doing rather than breaking into separate groups. Sometimes that can be beneficial, but because we have such a small group, it has not been.
Coordination between offices	• Most of the people here feel that upper management does not treat us equally or equitably. This could be partly perception because the system is not very transparent, but sometimes we are treated differently. In terms of allocation of resources: our requests are treated differently than those of CPK1. There is also a difference in conversion/hiring of FTEs. ORS has two MB branches in one division. One has 19 FTEs and 19 ORISE Fellows, vs. 8 FTEs and 3 ORISE here. • In any effective organization it is essential to have clear research boundaries for different research groups. There is a lot of grabbing research areas and taking them to the other research groups. There are no boundaries and no one seems to make them. • We get no support from the program office. They know the regulatory needs but don't share with researchers. The Office is so far removed from the lab that there is a huge disconnect.
Science issues	• We are a little limited because we're the Center for Food Safety, so everything has to be food-related. Research is a very fluid thing, so when you're doing research on a virus, it may take you places that are not directly related to food and food production, but that doesn't mean it's not valuable information. It still would benefit the health of the American public. It would be nice if we had a little more leeway.

C.2.1.3. Interviewee Observations: Program Weaknesses	
Low morale	• I am a scientist, not a manager, and I am confused. And my supervisor and their supervisor are also confused. This affects morale. • Morale can be low: A large number of personnel are in contract positions without security. They are not being converted to FTE's. We've been told by the DD that there is no hiring going on. Changes in direction of research can also cause low morale. We all understand that we have to work to satisfy the mission of the Center, but the research focus is getting narrower and narrower. We have a good team capable of publishing in the best journals, but the upper management doesn't care about that. They only want research that is strictly mission related. • The whole Office is in limbo. Our self-esteem is down; we really don't know what to do. In spite of that, we're still trying to do good work.
Other	• The Agency is trying to use its limited resources to answer questions that its stakeholders are looking for; therefore, only recently we have been asked to do more applied research. Before we had been doing a lot of basic research. Many of us became experts in our field. • We don't do basic research. We don't have the resources for that. We need to do what needs to be done rather than what we think would be fun to do. In addition, we have to get involved in projects that might be out of our area of expertise. Since we are not allowed to do whatever we want, management needs to be clearer on what they want us to do in a focused way. They are making efforts to do this, but it needs to be streamlined. • There are other responsibilities outside of research that consume time. Sometimes we have requests for outside analysis, so our work is not solely focused on research. Sometimes there are other activities outside of research and so we cannot accomplish our work like other universities or other research centers.
OFS/DI	
Staffing	**Insufficient staff:** • We are unable to replace staff. The work force is aging, but we are not bringing in new people to be mentored by the people who are departing. There is no forward thinking. This is a challenge for MB right now. We have two people here who are eligible for retirement, and I can't even get support staff positions filled. There seems to be an unbalanced commitment of replacing personnel: certain Offices are always advertising for new positions and are getting them because they are connected. • We have many good ideas and very good PIs here, but we could have more output with more staff. • We have trouble obtaining resources, mostly personnel resources. It is part of the cost/benefit of being a remote location. Our location benefits us because we're in the field where we need to be, but sometimes we get overlooked when it comes to resources. It has been much better in recent years, but it is something that we struggle with.
Leadership/ management	• In general across CFSAN, there is too much procrastination in decision making and too much caution, a non-risk taking culture. There is a 'Something happened a long time ago, so we can never try it again' attitude.
Lack of communication/ transparency with upper management	• We have problems getting access to decision makers at times. • We are fairly remote from the hub. We do well at communicating, but sometimes there a loss in the timeliness of conveying what's going down, as well as a loss of impact. Even weather differences are a big deal down here. Some of our work requires going out on a boat—affected by high winds, high seas. They might not understand why we would shut down for rain. Sometimes we have connectivity issues, even with power. Or we've lost office space for half of our scientists because our building has molded. • The Division in general may be disconnected from management. Maybe our voices aren't heard as loudly as the people who are closer.
Resources	• Space is an issue. We are practically on top of each other in lab space. • Any satellite lab has the challenges of not being on a level playing field in terms of resource allocation, etc. Sometimes that has hurt us. It depends on the strength of the

C.2.1.3. Interviewee Observations: Program Weaknesses	
	management here and what's going on up there. With a smaller lab, we don't have the ultimate infrastructure to do everything.
None	• Our research is strong.
OFS/MC	
Staffing	**PIs:** • We need more PIs with good analytical, statistical, and writing skills so we could use ORISE Fellows to help with methods validation. It's not expensive compared to waiting for AOAC or somebody else to do it. Managers think AOAC and other organizations places could do this work, but they don't deal with emerging issues. • In the 6 years working in this virology program, I'm the only FTE virologist. This contrasts with the CD asking why we have so many microbiologists. His statement certainly doesn't speak for the critical virology program here. • We have only one PI in virology, but viruses cause most food-borne illnesses. We don't understand enough about their etiology or control. Parasites are another Agency weakness in general. Those organisms are extremely difficult to control. We don't have anybody who can do that work, and I'm not sure there's much expertise in the Agency either. **Support scientists/technicians:** • There has been a definite reduction in our staff at the GS-11 or lower level, the technician level. I'm sure it's happening across FDA. When we get people, we take them—even if they're contractors. But when we can't get them in, we have to rely on the IIT graduate students, and in my opinion that program is flawed. People seem to think we're flush and can't imagine why we're out here griping when we have so many pairs of hands. Hands are one thing, but technically capable hands are another thing entirely. It takes a long time to train students who don't have the necessary skills. Plus, they're gone in 2 years and we have to start the process all over again with a new batch. This is really inefficient. We need more capable technicians—the ones we have are fantastic. Even the contractors are great after we train them. But having to rely on these students is bunk. • We have three PIs and only one lab technician. We've pulled staff from IIT, but we don't have enough technicians, which limits the number of our projects and the timeliness of gathering data and publishing research. • There are not enough support scientists working in the lab. I'm the only FDA scientist regularly working in the lab. Everyone else is a PI. We have more PIs than support people in the lab. That seems to be true throughout this building. **Insufficient staff:** • We need more people. Money has never been an issue here. We need to use the money to hire good people. • We need a statistician onsite. We could do more statistical analysis if we received training on a typical program such as SAS.
Leadership/ management	• We don't get particularly good guidance. Good management comes from the bottom up, but it has been top down since I've been here.
Lack of communication/ transparency with upper management	• Nobody in FDA knows what we do. People who work in the area know, but our managers within CFSAN don't think it's important.
Resources	• The Centers of Excellence like ours are struggling with their membership because they depend on company money, but companies don't have that kind of money anymore. They used to throw money at places like IFSH, but they don't have it now so there's a trickledown effect. People are concerned about this Center. • Our budget isn't regular. • Time and resources are a complication, but not a weakness.
Communication/ collaboration	• We are too far away from the discussion and the action. We publish papers, but we should work together better since we are in the same Center.
Professional	**Professional development:**

C.2.1.3. Interviewee Observations: Program Weaknesses	
development and travel	• We don't have a career path for personal advancement for support staff. Our training resources are very limited so we need a career path. If individuals had a career path in their area they'd be more likely to stay and advance, and be more productive instead of not improving in any area**.** Maybe we could work in one area for a while and then move on to another if the option was available. Each individual should have a goal in mind. I don't think we should rely on our managers and supervisors to pull us up, but we need to have some options, the main one being training opportunities. Not investing in the scientists is a big mistake. • There's not a lot of mentoring or passing down of technology from Ph.Ds. to support staff. • FDA doesn't reward people who do things right. I'd love to be able to reward the people in our group, but we can't. I love my work, my job, and the people I work with, but we'll lose more qualified people because of the lack of acknowledgment. **Travel:** • Budget constraints have greatly diminished our ability to travel. If we don't go out into the world, see what the issues and problems are, and talk to our colleagues there, we're essentially working in isolation. They expect us to work on CFSAN problems, but we don't know what they are because we are completely isolated and cut off. We get our information from management that doesn't appear to understand the issues themselves. • It's a problem if we can't go to meetings to see the current science and meet with the people doing the work. IAFP is a key MB meeting in the world. Many people used to go, but now they make it more trouble than it's worth. We maybe get one meeting a year.
Other	• Scheduling: Sometimes we have too many projects in the same month. We already have the big ones lined up and have to fit the smaller ones in between. • Priorities: Sometimes we run into issues on what's more important: FDA research or IFSH research? IFSH pulls IIT scientists away from us to work on something else. When they do this, it makes the priorities unclear.
ORS	
Staffing	**Support scientists/technicians:** • In spite of productivity at the FDA, I have never had any technical assistants. There is a major problem within the Division of uneven distribution of resources and staff. The focus has shifted and all resources go to a few pet projects that get millions in funding and a lot of personnel. About 70% of resources are now going into *Salmonella* and WGS. The Agency is not just about these areas – no one can tell what may pop up and cause a major outbreak in the future. There is a need to allocate proper resources to keep up expertise in all areas or FDA may be caught unprepared in the future. • I need support (technician or support scientist) to assist with the lab work. I have to constantly respond to compliance questions from other offices and ORA field labs, so my lab time is cut. Generally, all PIs need more help in addition to the temporary interns. • We do not have enough lab support personnel. I have multiple projects ongoing but only one Fellow to help. • Each PI should have a technician to help so that they may be more involved with FDA advisory committee and have more time to lend their expertise. **Insufficient staff:** • Our job is to work on the up-and-coming technology as well as transfer technology to the ORA field labs. The balance we need to achieve is how much manpower should be used for each of these activities. It would be better if we were doing more research rather than field office work. Currently, they are asking research scientists to do production, and usually they are two different kind of scientists. If they want us to take production over, we need reorganization and an increase of staff. • We have a lot of good ideas, but not enough people to carry them out. Compared to academia, who might have five people working on a grant, we only have one or two people. **Staff structure:** • All scientists here are at the same level. With everyone equal, it makes it harder to work

C.2.1.3. Interviewee Observations: Program Weaknesses	
	together: no one will take an order from an equal. We need more of a tiered structure in the lab, with the most experienced productive scientist at the top. If you want to get science done, there needs to be the ability to be strict. The current structure makes it hard to have someone in charge.
Leadership/ management	**Bureaucracy:** • There are many layers of upper management and they all have a finger in the pie. They all have different priorities and trying to resolve the priorities is a burden to the researchers. • Bureaucracy (e.g., the CARTS approval and QA/QC processes), as well as too many meetings divert time from research. We are supposed to being doing research and our whole day is spent in meetings. • Bureaucracy, bureaucracy, bureaucracy. • Organization could be improved to be able to respond more quickly to outbreaks. **Focus on WGS:** • There are a few people in places of authority calling the shots and they do not want to hear adverse opinions. Management is advocating solutions, and looking for problems, rather than identifying problems and finding solutions to resolve them. Currently, many in this program are just evaluating technology (e.g., WGS). The problem again is that those who call the shots are sold on this technology (their career and reputation rests on this), so they aren't allocating research to other technologies, which puts FDA in a dangerous position. **Line management:** • There are problems with the management of my group. The team leader is often in conflict with people in the group resulting in a toxic atmosphere.
Resources	• Resources within the Center are mismanaged. Resources are assigned based on management's definitions of priority areas vs. non-priority areas, and there are no clear guidelines as to why one area is a priority and another is not. • Mismanagement of funds and unfair distribution of resources. Resources are all going to two projects and the rest are going without. There is also a lot of favoritism. It would be nice if management would reduce the politicking and favoritism and move towards being more fair and productive. • End of the year funding make budgeting very difficult. It's hard to know how to spend money.
Communication/ collaboration	• We might coordinate or collaborate better if we had better communication with the rest of FDA (Policy, etc.). This could help develop teams within the Centers. We are a little isolated. • One of the biggest issues is a lack of communication and a lack of trust (on all levels). Within the Division, very few people discuss their projects with me, even when it is related to my subject matter. This is a failure of management. Line managers should get all those working in a specific area together to discuss projects. That is not happening. There is also distrust within the Division. • In comparison to academia, there is not much presenting of data within the Center. We do well collaborating, but unless you are collaborating with someone, you don't know what they're working on and what they're achieving. We would do better if we made better use of speaking about our work and our findings (e.g., "There is this great technique or instrument that maybe could be useful for you." • We don't interact much. We can talk one-to-one, but there are not many planned meetings where people share what they are doing. We only see what people are working on at the annual FDA science day.
Science issues	• For a lot of research done across CFSAN, there are no clear plans and no attention to where it's going or what the repercussions are. Sometimes exploratory research is needed, and the capacity for such work should be protected. However, I am finding that there is no accountability for maintaining data integrity. We are stretched so thin, we don't have the capacity for checking this. We don't have enough depth of basic functions or sufficient foundations. We have a ton of PIs and researchers and we are very top-heavy, but our

C.2.1.3. Interviewee Observations: Program Weaknesses	
	foundation (e.g., culture curation, data management, etc.) lacks depth and attention. We need better infrastructure. • The biggest weakness is that it's not moving forward with technological advances in my particular work area. • There isn't a very clear process to integrate new technologies into the field. There has been some improvement in this area over the last few years, but it needs to continue. • We are not doing research. We are supposed to be research microbiologists, but that's not what we're doing, we're doing production work. We're not doing anything new.
Coordination between offices	• We have been trying to communicate and work with MOD 1 for 5 years. They can do what they like, they are not held accountable. They do things that are counter to the plan of this Office. We communicate a tiny bit with OFS/DI, not at all with OFS/MC, a little with NCTR, a little with MOD 1--just recently we have finally been able to work with one group from there. There is a lot of autonomy at MOD 1 that goes against balance and coordination. The Center can limit basic research through limiting funding for those projects. A 10-year/$10 million software development project was just halted because it was basic research that no one was using. It didn't fit in, no one was using it, and it was a failure of management not to stop it sooner. • There is some drama and duplication of effort between us and the MB group over at MOD 1. There is a ton of duplication and not enough coordination. When we do coordinate, we get distinct roles from management, but people still go around it, resulting in overlapping efforts. • We have been trying to develop and validate a method for a pathogen for which we need to use the BSL 3 facility at MOD 1 and we have been blocked for 5 years from using the facility because they think this pathogen is too dangerous to use in their Biohazards facility. Hopefully, it is on track now. • There is a lack of collaboration with regulatory labs. There isn't much communication about what is needed and what the issues are with the methods. It's disappointing when you develop a methods and then it's not used or there is no feedback.
Professional development and travel	**Professional development:** • I'm interested in advancing in other directions, but I don't see a clear path forward. I know leadership programs exist, but I'm not familiar with those. **Travel:** • There are limitations for travel. I know of people who would have presented their work at more conferences if they weren't limited to one trip a year.
Other	• Sometimes you cannot correlate the money you spend with the money you get. 90% of the research is not publishable, so, basically, you cannot justify 90% of the research that you do. • What we do is always a response not a prevention. Maybe with meta-genomics you could do a constant screening to get an idea of a background. Everything we do is reducing the time to respond to food-borne illnesses. It would be better if there was some way we could actively approach that. • Too many researchers are focused on their career rather than the program mission. I support people building their careers, but that is secondary serving the needs of the organization. I've had to get people to change their research focus from projects that they have been working on for years and that they've gotten approval to work on, to more mission related work. There is a growing awareness of the mission of CFSAN vs. just doing science to be published. • Time diverted from science to order instruments/equipment and reconcile credit cards.
None	• Scientifically, we don't have any weakness, but, there are some things that should be fixed so that scientists can do their job.
CVM	
Staffing	**Insufficient staff:** • We need more people. We have expertise, but not depth. Usually one or two people are

C.2.1.3. Interviewee Observations: Program Weaknesses	
	knowledgeable in one aspect of the field, but if their expertise were lost we'd be hard-pressed to replace that expertise. • Right now we are down a PI. So we are one deep. We have people that are experts that focus on one area, but we don't have enough cross-training to cover all the bases. It makes if difficult when you need to do something new or different because that means somebody has to learn the field pretty quickly. • Within our division, we don't really have sufficient resources and staff. We have good PIs, with good projects but not enough staff to get it done in a timely fashion. We could use technical help as well as administrative help. The administrative staff does the ordering for us, but sometimes the requests don't get filled and then the research is stopped. I hear CFSAN gets to do their own ordering. • We have a very successful and productive group, and so have been given many projects, but we only have four PIs. We have enough support staff for the investigators, but could use more PIs. Collaborating with CFSAN would be great to ease our workload. • We need another person for the research projects. We have the equipment and dedicated supporting scientists. However, many people in our division work on NARMS, which leaves a limited number of people for research. Some who work on NARMS do other research occasionally, but NARMS is the priority. • We need expertise in bioinformatics (people to write the software to make the bioinformatics automatic) and related project management. We are becoming more data and system monitors rather than doing testing. With WGS, we are getting people trained on the tech side, but need to be able to analyze and manage the data that is being generated.
Leadership/ management	• We have consistently hired the wrong people to be in charge of the MB program. We've had some that have been dictatorial and didn't fully understand what we needed to do. Others wanted to be researchers not managers. More resources should be put into project management, personnel development, supervision, process improvement. • It would be helpful if everyone understood principles of a high performance organization--how to manage the flow of information up and down the organization, and how to manage people to get the best performance.
Resources	• Sometimes you have trouble getting what you need to do the work, encompassing logistical issues and processes (e.g., upgrading your computer so it doesn't crash on the next software update from the manufacturer).
Communication/ collaboration	• We are a small team. We have teamwork but could improve in this area. Also, our division and the review section at ONADE could have regular meetings to determine their research needs.
Science issues	• NARMS: We could improve our sampling get more isolates to make our data better. • Business Process Improvement Team: We have trouble getting people to recognize the need to change, and then getting them to change the way they do things and then sticking with it. • It seems like we are skewing very heavily in one direction. Classic MB is falling off to make room for the new molecular methods. There are still valuable questions that need to be asked from a phenotypic standpoint that the genetics may not always tell you. • Most of our research is focused on resistance mechanisms and resistance, but that may be a little narrow. If we could expand to subjects pathogenicity or virulence, that might be helpful.

C.2.1.4. What can be done in the coming year that will result in improvement in your division/branch?

C.2.1.4. Interviewee Observations: What Can be Done in the Coming Year to Improve Your division/Branch?	
OARSA	
Staffing	**Conversion of Fellows:** • Our Branch has more nonpermanent employees than permanent employees, and only two of those permanent employees are PIs. The other projects are headed up by Staff Fellows or

C.2.1.4. Interviewee Observations: What Can be Done in the Coming Year to Improve Your division/Branch?	
	ORISE Fellows. Converting the nonpermanent to permanent would boost morale and increase productivity. We hear that the Center is not doing new hires, but hiring is happening in other offices. There is an office at Wiley that is twice as big as ours and many of their FTEs were temporary employees who have been converted. We have one ORISE Fellow who has been here 5 years. Other ORISE Fellows have been converted ahead of him. There is no reason given. He's fantastic across the board. He's very knowledgeable, hardworking, does great work. He's a great team player who deserves to be permanent. • Many of our programs that have been approved by management as important have been started with an ORISE Fellow who develops the program, starts gaining expertise, starts publishing, but then is not converted when his 4 years are over, and the program is done. We spend a lot of time and resources in training Fellows and then we lose them after 4 years and are back to square 1. If the Fellow is not converted, we need to get another FTE from outside. • We have Staff Fellows, ORISE Fellows, who we have been trying to get permanent for years despite the fact that in Wiley, they are converting and hiring and expanding. MOD 2 is also converting and hiring. We don't have that sort of support and aren't given a reason why we are being targeted. If they throw us some kind of bone, it would go a long way in improving morale. A lot of us are nearing retirement. If no one is converted, there will be no continuity in the program. Maybe that's the goal, to let us die by attrition. • The BC should have more input deciding on the conversion of Staff and ORISE Fellows to permanent positions because they are in a position to assess the quality of their work. **Support scientists/Technicians:** • Addition of technical help that could be shared among the senior scientists would help a lot, along with administrative help for ordering and other administrative duties. **Better utilize support scientists:** • The existing personnel can be better utilized. I could be trained, upgraded, and could make more of a contribution.
Leadership/ management	• We need better management, and more direction. • We need a clear vision and leadership. **Appoint a permanent, strong OD**: • We have been in limbo for ~7 years. Our last OD left partly as a result of conflicts with CPK1 and we've been without a strong leader ever since. • Hire an OD that will represent us well and eliminate political impediments that would prevent a qualified OD in OARSA. • There has been significant undermining and COI on the hire committee for our new OD. Line management was consulted on the first round of hiring, but some very highly qualified candidates were rooted out before we were given a chance to choose. It was hard to believe that the people left to interview were the cream of the crop. All of the managers agreed that the woman who had been acting OD had been doing a good enough job that she could have walked into that role. I believe they had no intention of hiring her. **Address issues with line management:** • Assign a permanent BC. Now we only have an acting BC. We need someone permanent with better actual management skills. The acting BC is a good scientist but not necessarily good at management. • We need to fix the middle management problem. I don't know if removing the DD and BC is the answer, but something has to be done. • We need to fix the management issues we have. Managers aren't engaged and have their own agenda. All the way up the line, managers are not holding the managers who work under them accountable for doing anything.
Review organization	**Division of Molecular Biology** • Within our division, we could benefit from a small-scale reorganization that creates more team leads. In our current division structure, there is a DD with 25-30 people under him. All of those people fall in the same line. What we need are more branches under that person. We need more of a hierarchy, team lead, project lead, branch lead, division lead. **Division of Virulence Assessment**

C.2.1.4. Interviewee Observations: What Can be Done in the Coming Year to Improve Your division/Branch?	
	• Our Division needs a whole new mission statement. The SSA has told us they don't want virulence research any more. Well, tell us what you want, help us brainstorm. We need new direction from upper management. We need a new strategic plan for our branch and Division. Since I've been here (5 years), we've never had a division meeting, ever. It would be great to have a division meeting and go through the law and try to identify some areas that our division could try to address. We don't need a lot of meetings, but just a dialog so that people could come up with some relevant projects. • Part of the problem is our name. The Center doesn't want any more work done on virulence assessment. We need a new name and a mission statement. The name gives them a chance to write us off. We don't have a champion over there saying, "That's unfortunately their name, but they don't do that anymore." I try to have my team aligned with the Center's mission, but even for this review, they said "for the purpose of this review, we'll consider DVA part of MB." Well, everyone in my division is a microbiologist! We have this unfortunate name that came back from when virulence assessment was a priority, and we have a mission statement based on that name because that is what management wanted us to do up until this year • Our original mission was to study virulence but it led to development of new methods. We are not assessing virulence at all. Some people don't even know what it means. • We need a new name. We no longer do much virulence assessment. In the old days we would take an organism or purified protein and stick it in an animal and stand back and watch what happened. Basically we don't do that anymore. • The Immunobiology Branch doesn't do much immunobiology anymore. They used to do basic research, but now it's mostly allergens, glutens, and egg safety. We do use immunology as a tool, but don't really do immunology research. I'm not sure what the groups should be renamed. **Teams:** • The research here is too individual. W**e** need more organization and teams. We ought to be organized into working teams of 5 or 10 and better organized to use the wide range of expertise that we have. We need to be organized more like they are in industry.
Clarify priorities and goals	• Upper management needs to provide direction on what they expect and want. We need a strategic plan for the Division and the Branch. The Center's strategic plans should be conveyed to us annually, and reviewed quarterly or at least semi-annually, to ensure that our projects are on track and our work remains aligned with the Center's mission. • We have been lax in putting together a strategic plan. The group I collaborate closely with in Wiley has a strategic plan with how all their research projects fit into the Center's strategic plan. They do this on a yearly basis, so when things come up, they can pull this out to explain how they are aligned with everything. As far as I know, we don't have a well thought-out strategic plan in this Office. It would help if we had a strategic plan that was developed by everybody and that would be reviewed on a yearly basis so that we knew that we were aligned. • We need clearer goals from management. If they presented a goal divided into subprojects, we could choose areas where we have expertise, and if several scientists chose the same area, they could form a team to accomplish it. • We need meetings to determine the goals we hope to achieve as a division. We need a better understanding of what we are trying to accomplish in regards to the regulatory mission and what we can do towards that end. Without direction, people go off on their own. I'm not sure what would be best for me to work on all of the time. Sometimes I just have to pick something. • Now we have the OD, the Deputy OD, the CD, and the SSAs coming down and telling us what they want us to do. Everyone wants to have their say in what research is being done and they don't necessarily all agree. And the program offices are telling us what to do. We are being told we have to align ourselves with what the program offices want. Well, a lot of them aren't scientists or haven't been in the lab for a long time. I think it's crazy for me to go to these people on bended knee and ask them to bless my research. • We are in transition. We are shifting gears from doing applied research to doing what the Agency wants us to do. Clear direction from whoever is in charge would really help.

C.2.1.4. Interviewee Observations: What Can be Done in the Coming Year to Improve Your division/Branch?	
	• We need more assistance in our research projects as far as where CFSAN wants to go and conveying that to us. That's been lacking.
Communication/ transparency	• They need to work on information flow for all types and at all levels. There is no organized manner to disseminate the information that we need. **With upper management:** • We expect upper management and leadership at the office and division level to have better communication. We don't have any channel right now to communicate our ideas to the upper levels. **With program offices** • We have trouble getting help from the program office on choosing mission-relevant research. We send emails and get no response and then we hear that our research does not support the program office. • We need better communication between the research and regulatory side. • If the researchers would talk to the program offices before they come up with projects, that would improve the process, and that's something we've been encouraging them to do. That needs to be initiated from here.
None needed	• In our division/branch I have no complaints. The leadership has been effective. It has been real leadership--not management. They have been our "wing man" in trying to find out for us what is going on regarding our staffing issues.
OFS/DI	
Staffing	**Additional staff:** • We'd like more people, but we also need more space. We are very productive in spite of these limitations. I'm not sure other people see this. • Replacement of staff we've lost (2 positions). One scientist passed away, and still has not been replaced. **Support staff/Technicians:** • We need more support staff. We have more needs and are not getting the help we need. **Administrative support:** • We could always use more support staff. We do a lot as researchers that we shouldn't have to do (balancing books, ordering). It takes away from the things we should be doing.
Leadership/ management	**Assign permanent DD:** • With our former DD having left, there are voids that need to be filled—the faster the better for the science to move forward, although both Branches have pretty good existing management. The objectives and CARTS projects are still in place. But the DD has a lot to do with the facilities and representation and interaction up there. This is important to let everyone do their job.
Encourage interactions	• Staff needs to be swapped around to keep thinking fresh.
Clarify priorities/goals	• It would be good to have defined research priorities and objectives. This seems to be highly dependent on who is in the DD's position. Right now we don't have a permanent DD. The two acting DD's have done a good job going back and forth. But when someone permanent comes in, knowing what they expect should be well defined. • Let us know what mission-related projects might be. It's hard to determine in advance what will be a problem.
Publicize MB research internally	• You don't want to be isolated. You want to get your work out to others. We are limited in that aspect due to our location and travel restrictions.
OFS/MC	
Staffing	**Additional staff:** • Having more engineers could improve our division or branch. We have packaging chemists, standard chemists, chemists who do allergen research, etc., but for food processing technologies, we still don't have enough engineers to answer all our questions. • I am trying to study the number one food-borne disease hazard, norovirus. But one person

C.2.1.4. Interviewee Observations: What Can be Done in the Coming Year to Improve Your division/Branch?	
	here can't do this work. I face a tremendous challenge. It is difficult to train scientists in virology. The technical parts are difficult, and technical personnel are hard to get, so virology tends to be ignored. Optimally, to get my work done, I need one more support person or a Ph.D. The Center and FDA need to rethink the issue. • Nobody wants to hear about expanding government programs, but that's what we need in proficiency testing. We receive funding annually from ORA and OFD, CVM, USDA; DHS provides money in alternate years. There are so many projects. They wanted us to set up a pilot program, but it may end up being international. FDA labs don't have any way to make the filter samples required under the National Check Sample Program, so they drop their work for 1-2 months and send it to others. If they send this work to other labs, they don't get the same information we potentially could get regarding methods and how the lab has performed. In other countries, this kind of internal and international quality control, which is basically proficiency testing, is coming together. **Conversion:** • We have a tremendous amount of work to get done and most of our staff members are temporary, which affects their morale and standing. There is no job security for them. For me, it's horrible to consider that my projects depend on how many people I have to actually do the work. It varies from year to year. I'm constantly training somebody new. • Convert and/or hire more ORISE Fellows: ORISE staff is interested in becoming full time, which would be good because they've been trained on a variety of analytes and matrices. We train them for 4 years at a maximum, then they leave and we have to train the new ones knowing they will be leaving because they aren't FTEs. **Support scientists/Technicians:** • We need to hire more technicians. We can't rely on students for our lab. Background checks take so long that by the time they get in the lab, they're graduating. The PIs are concerned about the quality of the students, and some are difficult to work with because they aren't high quality. We have a sequencer and funding, but not having the people to run it is difficult. • We need to hire more qualified technician-level people to work in the labs. The IIT people are good, but they can't move up. **Administrative support:** • We spend a lot of time writing internal reports, safety plans, suitability assessment plans, etc. for the select agent group, We don't have one person dedicated to do the safety aspects and handle all the regulation requirements.
Clarify priorities/goals	• They should do some morale boosting--assuring staff they are worthwhile to the Agency and that their efforts are appreciated. There's a lot of uncertainty here. Questions are being asked: "Why do we have so many microbiologists in the Agency? Why is microbiology done in so many different places?" Our staff is dwindling. We can't replace people who leave, and there's a concern about what our purpose is here. We aren't sure if our impact is recognized. Although Center leadership comes out to the IFSH meetings, those meetings are geared toward IFSH's industry members.
Communication/ transparency	• In lieu of increasing staff and money, better communication would improve our situation here. Knowing what's in the minds of the people above us would help. Upper management sets strategic goals and we talk about current projects going on across CFSAN and what future projects could fit within these goals, but we only have access to so much information. The monthly CD meetings aren't really relevant to us. We're so far out and away from the main think tank that if we get information it's filtered by the time we get it, if we get it at all.
Encourage interactions	• Interpersonal relationships are critical to getting things done: People get things done—especially when resources are tight—when they have an opportunity to see how other people do things. Our interpersonal relationships are in decline because we're not allowed to make any. They think that if we talk to other people we'll be unhappy, but isolating people just makes things worse.
Publicize MB research internally	• Improve the importance and recognition of our work internally and have the Center use it.

C.2.1.4. Interviewee Observations: What Can be Done in the Coming Year to Improve Your division/Branch?	
Systematize operations	• It would help if we could stagger the timing of large projects: Food and milk are big projects that come within 3 or 4 weeks of each other. It would be better if they could be staggered 2-3 months apart.
ORS	
Staffing	**Insufficient staff:** • This office is short staffed, perhaps by 40% (ORS). **Support scientists/technicians:** • Hire more support personnel to help with tedious lab work. That would free up PIs to be more productive (ORS). • We don't just need funds for instruments, we also need more support personnel (e.g., lab technicians, ORISE Fellows, etc.). Some PIs have to manage research, administrative duties, field analysis, and regulatory support. There is no one to carry on lab work when one person is out or has to prioritize regulatory work. • I would like to hire more support staff for the PIs to support their work in the lab and field and administratively. **Administrative support:** • Administrative matters like ordering can take up a lot of time, especially with the current purchase tracking system, which is not functioning properly for some people and is inefficient. • We need a position to take over credit card duties. • We need to find a way to remove some of the collateral duties from the PIs and get the culture curator more help or training.
Leadership/ management	• Make the management process more transparent. Sometimes it seems as if there is a good old boys school. They don't want to be transparent about leadership and management. • Remove bureaucrats or have them be more realistic in their endeavors and clean up some of the morale issues that are holding us back. Bureaucracy is an issue at multiple levels. • We need new leadership at all levels. • Replace some of the management. Our BC hadn't had any management experience before coming on and now is asked to manage 40-50 people and does not seem comfortable with this.
Review organization	**Branches:** • We need to achieve a balance between the two branches within our division. If the Division focuses only on the serotyping, our branch would be decreasing. So a balance is very important. If both branches could collaborate, the Division would be growing. **Teams:** • Making smaller subunits (e.g., teams of 8 people with a team leader) has been discussed. Genomics could be a branch to itself. Team leaders will help take over some of the administrative duties of the BC. I don't have a problem if they want us to do more production and less research, but they need to get those units not involved in directly applicable, mission-critical research on board so they are not sucking up resources. Our unit is giving them exactly what they want and it's creating more work because we're so successful. • More team development is needed. Not actually having a team has made my life difficult when trying to deal with someone who was not fulfilling their responsibilities. Development of teams would be good for structure and collaboration. • Realign the staff to have more structured teams. For example, have two FTEs working on a program and have them supported by an ORISE Fellow or technician. More tiered teams would provide more complete teamwork.
Communication/ transparency	• There should be more bi-directional sharing of mission and research. It seems that there is just one direction of communication now, coming down from leadership. I don't think they have their finger on the pulse of science. More communication between PIs and leadership is needed. • In decision-making, we need better communication and more transparency. People tend to work in silos, with each doing their own thing.
Encourage interactions	• There is no system on how collaborations are done. • They could consider financial or resource-based incentives for collaborative projects. This

C.2.1.4. Interviewee Observations: What Can be Done in the Coming Year to Improve Your division/Branch?	
	could include hosting forums for research presentations and making it easier for scientists to come together in a forum to share their research. This would help develop research collaborations. • We need more communication with the ORA field labs to find out what they really want improved and what their method development needs are.
Systematize operations	• Implement an SOP to prioritize sequencing: There are some people that come to me directly or work their way around the SOP. That is frustrating. The priorities are constantly shifting depending who is asking for what. Having to constantly shift priorities is good but also creates a lot of stress on us in the lab. It can make us less efficient in the long run. • The queue for the use of the instruments in the genomics lab is quite long. There is no clear system for deciding who gets to use the instruments when. Friendships have an influence on who has priority. There needs to be clear policy for use. • Implementation of the GIMS would allow an interface between the management and the wet lab folks to ease data flow and sample tracking. Right now it is done with an Excel spreadsheet. It is really tedious to update manually when it could easily be done by the GIM System. • Improved data analysis and interface with IT for genomics.
Publicize MB research internally	• More sharing of findings and research in a public forum--maybe even in branch meetings, where we usually talk about money or travel. We don't spend a lot of time on what people are working on. People could give just a short summary of what they are working on or have published.
CVM	
Staffing	**Additional staff:** • We need to increase the number of PIs. I am a support scientist under the supervision of a PI. If we had more PIs our projects would be less disrupted as we move into WGS. • We need to replace one PI in a specific area of expertise. • Our program is moving toward WGS, so need to hire bioinformaticists to handle those data. • We've been unable to fill positions due to budgetary uncertainty. • We need more equipment for WGS and more FTE to carry it out. People are the most important resource. **Administrative support:** • It would be nice to have someone who did all of the contracts, all of the ordering, monitor the supplies, know what the needs are. We have managed to work out a really good process within our own group, but it takes that person away from what they really should be doing.
Leadership/ management	**DD:** • We need better leadership at the DD level. The former DD is a very good leader. The current DD needs some leadership training in order to provider stronger leadership. We are a large Division and so really need the leadership. This is a great person who lacks the training. The leadership also has changed often, and the Division lacks stability. Every time a leader changes, you lose some continuity. **Project managers:** • Hire another project manager for MB to help with day-to-day operations--a professional manager, not a scientist--to support the science and enable the work to be done more efficiently. The current person is competent, but is overwhelmed. Chemistry has a director and two team leads for 14 staff whereas MB has one director and no team leads for 24 staff. • A project manager would be good to help guide the process and keep track of projects and necessary supplies.
Review organization	**Division:** • We need clearer lines of responsibility and an organizational chart. Our Division has about 20+ people. Many supporting scientists working on the NARMS project sometimes don't have clear guidance on who they report to. There's a NARMS Director, DD, and a limited number of PIs. Those supporting scientists should also have a PI to mentor them in their daily work because most of them don't have Ph.D. training or the ability to see the real issues in the

C.2.1.4. Interviewee Observations: What Can be Done in the Coming Year to Improve Your division/Branch?	
	work. Their work on the projects is vital. One person shouldn't have to juggle too many things at once. I have one supporting scientist for five projects. Some work has to be put on hold because we can't overwhelm people. They lose focus and nothing gets accomplished. • Many people in our division work on NARMS, which leaves a limited number of people for research. Some who work on NARMS do other research occasionally, but NARMS is the priority. We need another person for the research projects. • We need a better outline and understanding of peoples' roles, and to equalize the distribution of work. The ones who have been here the longest and have the most knowledge, do the most; the ones who are coming in don't get as much work and don't have as much opportunity to expand their knowledge base and build their expertise. **Support scientists/Technicians:** • Support scientists can do more than just manual labor in the lab: they should be used for contract management, data management and long term planning. • The support scientists need clearly defined roles and any training that may be needed for new research or work.
Clarify priorities/goals	• Improve communication of research goals and objectives of the Agency and the rationale behind these decisions. We need better or clearer communication of research goals and objectives outside of basic logistics within our office or division, e.g., where the Agency or Office or Center is going in a particular area and why. • We're in the shifting/rebuilding phase. We need clear expectations and clear priorities.
Publicize MB research internally	• Despite all the technology, we are having trouble getting our information out (CVM).

C.2.1.5. What areas might be productive for longer term mission-related improvements in your division/branch and for the entire microbiology program?

The responses to this question have been divided into three tables: one for division/branch, one for responses for the entire microbiology program corresponding to Coordination between Offices, and one for the remaining responses for the entire microbiology program.

C.2.1.5-1. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements in Your Division/Branch?	
Division/Branch	
Staffing	**Succession planning:** • Right now there's a hiring freeze, and the growth we planned 5 years ago has been kicked by the wayside because we haven't been able to bring in younger scientists with cutting-edge training. We're going to end up losing by attrition. Too many of us will be leaving, and without bringing these young people on, we're going to lose the time to pass on institutional memory. We've done a good job looking for the people with the skill sets needed to take us into the next decade, but without the hiring we're stuck. We have a pretty good group of contractors and in-house scientists here that could develop into a very good bioinformatics core group. It could work with the scientists on this campus to develop projects and approaches that analyze WGS, proteomics, and meta-genomics data to drive the next innovations needed to continue our "throwing the kitchen sink at it" approach. It could be a joint CFSAN/CVM shared resource (OARSA). • We need to retain key personnel: our DD has been very open with us and he has tried to fight for personnel for us and constantly does, but a lot of it is out of his hands (OARSA; OFS/MC). • Succession planning: Many people will be retiring in the next 5-8 years, and we have nothing in place to replace them or their expertise. I have a visiting scientist whose tenure has ended and we're unable to convert her to full time or extend her because the Agency sees the need for that FTE in other areas. Right now the Agency is implementing FSMA, and research is not at the top of the priority list. FDA needs people who write regulations, policy, and guidance. But, as to this longer term need, what's going to happen when we all start retiring (OFS/MC)? • Compared to the rest of CFSAN and FDA there seems to have been a halt in hiring scientists. If this continues for 5 years, we will be in trouble. We need the constant flow of young researchers and ideas from academia. The program can be really insular (ORS). • We should be looking in long term at who we are hiring and the experience base. We have a lot of people that are retiring. The experience is not necessarily lost, but a big chunk of it is going out the door. Are we training the current people that we have in those areas and is our expertise still deep and valuable or should be refocused (CVM)? **Hiring/converting:** • There should be more transparency in the hiring process. Currently, you put two sentences in a spreadsheet concerning why you want to convert somebody and it comes back yes or no. They are making a judgment on two sentences. There is absolutely no feedback on why the decision is being made (OARSA). • More demonstrated, evident support by upper management and commitment by them to provide staffing. Our budget is fine right now. We're rich with money but poor in staff to use those resources (OFS/DI). • FDA personnel should be handling regulatory work rather than temporary contractors (ORS). • We need additional FTEs in environmental MB and cosmetics MB (ORS). • We need to know which projects will be ongoing and the new projects that will be coming on board. The support scientists need clearly defined roles and any training that may be needed for that new research or work (CVM).
Increase efforts in specific areas	**Method development/validation:** • We need to focus more testing in regulated commodities/food matrices. Many people want to spend all their energy on developing a new method, but validating the method is

C.2.1.5-1. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements in Your Division/Branch?	
Division/Branch	
	the most important. Without validation nobody can use the method. We have hundreds of new methods and people keep inventing more. Academia and industry can develop new methods, but they do not validate because it is expensive, time-consuming, labor-intensive, and not fun. The only people who do this is the government labs because they have to (ORS). • Method validation and building national and worldwide leadership in pioneering methods (ORS). • It is important to do head-to-head evaluation of subtyping methods: compare timeliness, cost, operator time (both collecting the data and making sense of the data), level of discrimination, throughput, and how the data can fit into the regulatory mission. There are a lot of candidates for useful methods, but comparison would be very valuable (ORS). • Add more validated methods to the BAM. We keep adding more foods, and the BAM cannot keep up. The food industry needs more methods because we are importing more foods and getting new outbreaks in these foods (ORS). **Basic research:** • Expand research in areas including parasitology, BSL3 laboratory research, pathogens such as *Vibrio parahaemolytica* and *Listeria*, and alternative animal research (OARSA). • Cut some resources going to *Salmonella* and give funds to other projects, e.g., molds, yeasts, *Listeria*, *E. coli*, etc. (OFS/MC). • Increase the breadth of research in emerging food-borne pathogens. Too much emphasis is placed on a single pathogen. For example, probably 20% of research is focused on *Salmonella*. We should be doing more on *Campylobacter*, *Bacillus*, and *staphylococci* (ORS). **Genomics:** • Improve the genomics team. Given the resources and staff it could make a huge impact on FDA's ability to trace back food-borne pathogens (ORS). • The whole Office/Center is moving towards WGS. We should develop more skills for the microbiologists so that more of them know how to do this. We don't want to have people who have skills that will become obsolete (CVM). • We need make sure we keep up with technology, e.g. WGS (CVM). • Implement GIMS **NARMS:** • NARMS is a nationally deployed program that has the infrastructure to collect samples to look at antibiotic resistance. It has become a platform for collecting samples for outbreak detection and attribution. This platform could be exploited to maximize public health protection. Long term, I would like to see the NARMS program become a platform for other public health priorities (CVM). **Bioinformatics and high end computing:** • We need better data analytic tools; better bioinformatics, add a database development position (CVM).We need the support of OITI (Office of Information Technology Innovation). They have initiatives for cloud-based solutions for data management that would be very useful for MB. Since the consolidation of IT in 2007, scientists have had a hard time with IT across the board. The commissioner needs to see that the new CHIO (Chief Health Information Officer) succeeds. His success will have a direct impact on MB (CVM). **Other:** • Cosmetics and dietary supplements investigations need to be expanded (ORS).
Review organization/structure	**Divisions:** • Establish a Division of Preventive Control: FDA needs to recognize preventive control is part of its job. FSMA is based on preventive control. When the rule is finalized, FDA will need knowledgeable people to implement it. This is a compliance mission. Although

C.2.1.5-1. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements in Your Division/Branch?	
Division/Branch	
	the program hasn't been established yet, we hope it will be so we can fit directly into what's really needed. The end game is to feed directly into the compliance program (e.g., setting up inspectional requirements) and improve the utility of our work (OFS/MC). • They should create a Division of Process Control to consolidate ideas about FSMA's potential research needs. Encourage more direct dialog between individual scientists and FSMA policy compliance people. Use scientists to provide technical review of policy and guidance documents before they're issued (OFS/MC). • I would like to see an actual NARMS division with its own research. It would be clearer and more productive. We do research to support NARMS, which has its own director, but are actually in DAFM and also do DAFM research. It's hard to know who to report to sometimes. The mission and goals of the two programs are different (CVM). • NARMS uses a lot of resources to do routine surveillance and this takes away from research resources (CVM). **Outbreak response:** Assign project managers for outbreak response: Currently during an outbreak, the subject expert is put on the spot to disseminate results rapidly to compliance and enforcement. A project manager who is equipped to be a liaison (i.e., can explain terminology and interpret results) between the researcher and the other offices would speed up the process and lessen confusion (ORS). **Scientists:** • Each PI needs a clear role and area of expertise. Each person should become an expert in one major area. For example, if CFSAN requests detection work, people should come to me. I'm also in charge of animal feed in microbiology so I'd expect people to come to me for that as well. Right now the staff is confused about who should be responsible for what area (CVM).
Facilities and infrastructure	• We have trailers to help out on space for the short term, but it would be nice to have permanent space (OFS/DI). • Building service issues (temperature controls) and IT restrictions must be fixed to improve quality of life. I'm frustrated with the system and the infrastructure here. How can I keep world class people here if this is what they constantly run into (ORS)? • We should be looking at the facilities that we have. Are they really set up for the kind of work we want to accomplish? We are having to bring new technologies into facilities and labs that maybe weren't designed for them (CVM).
Review research scope	• We need a wider research scope. During the time I've been here, the focus has been narrowing. Now the management is concerned that there is too much overlap, setting up competition between labs. When you keep narrowing what we can do, this is going to happen. We have been focusing on *Salmonella*, *Listeria*, *E. coli*, but there are a lot of things out there that can cause a problem. I understand that resources are tight and that it makes sense to put the resources in the areas that cause the most problem, but I don't think they are seeing the big picture. One of the big complaints we have is that we put in research projects and we are tripping over each other within our Office and with the other Office. We have a lot of talent that could do things but are stymied because it's not one of the one or two major players for the Office. It would be good for the scientists to have input into the research focus. Currently, the focus comes down from the program offices. But I don't think they have a good understanding of what can and cannot be done in the lab (OARSA). • We need a wider scope of research. They have reeled in the science to the point where we have to compete because there's not enough scope to what we need to do. Without management direction, it's hard to even function at times. Upper management has decided that we have these knowledge gaps and these strategic and research outcomes, and its very narrow. It seems that most of the items of importance are generated at CPK1 because we don't have representation over here, because people here are not engaging

C.2.1.5-1. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements in Your Division/Branch?	
Division/Branch	
	within our division. We need to figure out how to come up with a better strategy on what the science needs to look like for MB because it's really important. (OARSA). • A mix of basic and applied research is required. You can do the short-term projects in response to the crises or questions that come up, but in the meantime you need to have something else going which you are working on long term, which might be more like basic research (OARSA). • Allow little more freedom in approaches to research. E.g., we found that the *Salmonella* we were investigating was more virulent that previous strains, but were not allowed to pursue the finding because we are not virulence assessment (OARSA).
Review alignment	• Evaluate how well we are aligning our research with the missions and program goals of FDA. These keep on evolving and changing, and now with FSMA, the framework and context have changed (OARSA). • We do have some renegades in this Office who refused to align and who want to do their own thing. You used to be able to get away with that, but there is now a lot more control from the upper levels (OARSA). • Continue refocusing people into projects that are more mission related: Even though this is a painful process, doing mission-related work is important for the public health work we are doing. It is a painful process because the scientists haven't had to work like this in the past. I don't really know the history, but I think there were influential scientists who did what they wanted to do and there wasn't an organization-wide effort to describe what should be done (ORS).
Improve procurement process	• At the division level, there is a lot of redundancy in the ordering of equipment. As a result we may order more of a certain piece of equipment than we really need. There could be better coordination in the ordering (ORS). • Our procurement and purchasing system is so broken. Because of the way Congress plays games, we don't get our budget until March. So task orders, contracts and major purchasing have to be done in 30 days. That is so incredibly insulting to these professionals who are trying to do their job. We know other agencies don't have to go through this (ORS). • Right now, the PIs in our division do a lot of the ordering. It should be a collateral duty, but it can become an overwhelming responsibility. We are hiring someone who is supposed to take over Visa ordering, but it has been a long time coming and there has been a lot of hesitation at converting scientific FTE money into an administrative role (ORS). • As a credit card holder I spend 25% of my time on reconciling the account. I could more valuably use this time in the lab. This activity is of no benefit to my career. Promotions and achievements are based on science, so this task puts me behind. They have been in the process of hiring a credit card person for years, but it hasn't happened yet (ORS).

C.2.1.5-2. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements for the Entire Microbiology Program: Coordination Between Offices?	
Microbiology Program – **Coordination between Offices**	
Improve coordination between offices	**Coordination between MB research offices:** • There could more coordination between all the offices, i.e., OARSA, CPK1, CVM, regulatory, and field offices. We need more information from these offices about what they need and how we can support them rather than doing our own thing (OARSA). • Working groups should be formed that cross facility lines. We have formed an allergen working group with researchers from Wiley, OFS/MC, and OFS/DI. We have a monthly meeting to talk about the research we are doing and to keep everyone on the same page. This could be a model for other MB programs to foster more open communication (OARSA). • There should be mandatory quarterly meetings between all microbiology project leads to discuss territorial issues and who is doing what. Even though the microbiologist at MOD 1 are physically 100 feet from me, sometimes I will go 2 years without talking with them (OARSA). • Within CFSAN we do a poor job of working with sister sites (MOD 1, OFS/MC, and OFS/DI). Sometimes the barriers are geographical; sometimes there are personnel issues. There is a history of problems with MOD 1. I was told that upper management had disputes over the course of time, but it has trickled down and affects the collaboration we could be doing from a research standpoint. I was surprised when I first came here that that existed in the Center. I can see the problem with Chicago and AL, but Laurel is not that far away and we have this barrier--even to resistance over sharing facilities. We are all working for the same Center (ORS)! • They need to improve on coordination and collaboration between the different centers and leverage resources. With the development of OFVM there has been a huge improvement in communication between different centers. Before, communication between CVM and CFSAN was not good. Now it is a requirement to work with other Centers (CVM). **Coordination between MB research offices and program offices:** • There should be more collaboration between research and groups (e.g., divisions and departments) doing risk assessment and compliance so that MB is represented in the discussion (ORS). • We need better collaboration at the office level: We haven't really spoken to the compliance programs or other regulatory policy programs for the past 2 years. As researchers we don't know what they need to fill the gaps. We don't have good relationships with the ORA field labs. Sometimes as PIs we can talk directly to a PI in the field labs but sometimes that doesn't solve anything because the upper managements don't have a good relationship. They need to have a good relationship for interactions between PIs to work (ORS). **Duplication of efforts:** • We need to determine whether microbiologists in the four different locations are duplicating efforts. Some amount of duplication is necessary for science, but with the budget constraints, we need to avoid this as much as possible (OARSA). • Within CFSAN is that there is a lot of redundancy. Eliminating the redundancy is going to require a reorganization and that is a long term vision. People at CVM are doing work that is highly similar to what we are doing in MOD 1, which is highly similar to what they are working on in CPK1. This redundancy causes tension and friction among the scientists: "They are working on something they shouldn't be working on. I was working on it first. Why do they get this and we don't?" There needs to be a restructuring of the microbiological research program within CFSAN and CVM so that scientists have clear roles in what they are doing and eliminate redundancy (OARSA). • In the recent year or so, we have begun to feel that we don't really know if there are areas of focus on certain commodities or viruses that should be delineated to certain groups so there is no repetition of the investment of time. Or is that not the way it is anymore? We are finding this out piecemeal. You really begin to look over your shoulder

C.2.1.5-2. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements for the Entire Microbiology Program: Coordination Between Offices?	
Microbiology Program – **Coordination between Offices**	
	while you are doing some of this stuff. Is there an agenda or no agenda (OARSA)? **Competition between OARSA and ORS:** • Stop the competition between ORS and OARSA and make them coordinate and supplement each other (i.e., share sequencers and other equipment and analyses). Both groups need to be together under unbiased management. If they continue to compete, OARSA will lose: ORS has better funding and the ear of the management (OARSA). • There is a perception that there may be some favoritism toward one research group over another. When there was a recent viral outbreak in a certain commodity, the SME in our group was never alerted for any input until our DD intervened. It is more than an ego thing. They have invested time and money into our group and so should make use of it (OARSA). • There is a jealousy thing with Wiley. We need better communication and need to talk about projects that we have in common and how we might work together. The negative thoughts between the groups need to be eliminated. We really need to decrease the tension (OARSA). • We have 100 or more microbiologists in two buildings who are so 'close apart'. Most of the research is limited to three pathogens, how can there not be overlap? Because of human nature, there is competition and lack of trust between groups. But it has gone too far and is talked about to an excess. We need to improve relations between groups (OARSA). • There should be increased cooperation with those in the Wiley building. We are treated as a satellite space. It would be good if we could have more collaboration with them (OARSA). • Broadening the research areas would help reduce competition. If the groups could work together better, it would build a much stronger program. There is a lot of overlap, partly because much of the research done at CPK1 started over here. When the current DD of MB at ORS left MOD 1, he took researchers and projects with him. We continued the same lines of research here, but it is the cause of a lot of the competition and dislike between buildings (OARSA). • They need to do a better job of fostering collaborative work between and within the Office and outside the Office to prevent the notion of competition (OARSA). • There should be more coordination with the Wiley Bldg. Our people need to be treated equally with those in other offices in regards to promotion, conversion opportunities. What is needed is a lack of bias in terms of personnel, budget, and approval of projects. We submit projects for approval and then they go into a black hole and we don't hear anything for months. When we ask, they say, "Oh, that's not mission relevant." They use the term mission relevant when they don't want to give straight answers (OARSA). • There is a lot of tension between our branch and division and upper management outside our office. The relationship is more competitive than collaborative. There are territoriality issues. We are all working for the same agency, but it doesn't feel like that (OARSA). • I think our Office has an "us-versus-them" mentality. I refuse to get involved in that. My team has had a lot of good interactions/collaborations with ORS. I think that is the only way it is going to work. I'm finding that "you have to join 'em" is the only way. They have the resources, and the ear of management. I've only seen positive outcomes from our interactions. It's getting better because the scientists are taking the initiative to make it better. Management is not doing anything to facilitate it. We are taking heat for getting the groups together from BCs, DDs and some Team Leaders. We have to get rid of that (OARSA). • It seems like they may have purposely pitted us against each other. For example, parasitology has always been part of our division. Now CPK1 has hired parasitologists. There was no coordination with that. The *Listeria* experts were always located over here, now they are in CPK1. Maybe I'm not high enough up in the hierarchy to know what is

C.2.1.5-2. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements for the Entire Microbiology Program: Coordination Between Offices?	
Microbiology Program – **Coordination between Offices**	
	going on, but it feels like every time we come up with an idea, it is coopted by CPK1. They probably feel the same way (OARSA). • We need to have more inter-Office collaborations (a lot of us do collaborate). There's a lot of "us vs. them," and there are a lot of issues. Most of the issues are at the management level. At the scientist level, we could all work together very well. The problem is getting through the barriers set by some of our management. If we could minimize competition or the threat of competition, that would help. Using technology integration across offices and having leaders with visions that complement one another would help. There are people here who could provide that kind of leadership. They just don't have the authority to do it. There are great ideas around here. The whole CPK1 vs. MOD 1 thing needs to go away (OARSA). • The other Division says "CPK1 is always attacking us." Well, at least they get attacked. We're invisible (OARSA). • There is a lack of communication between groups (MOD 1 and ORS) and from upper management. Right now, researchers are behaving as if they are all individual biotech companies trying to put each other out of business. All of us should be focused on the primary mission – protecting the consumer. Those in MOD 1, have no one here advocating their position. Those in power here have the DDSO's ear, so the CD gets a very one-sided picture (ORS).

C.2.1.5-3. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements for the Entire Microbiology Program – Remaining Responses?	
Microbiology Program – **Remaining Responses**	
Develop a long-term vision	**Broaden scope of mission:** • CFSAN's mission is too narrow. Our scope used to be wider, but it seems they're channeling us down a narrower path. A wider scope would better utilize everyone's talent, and FDA would benefit as well. There's competition to find which methods are the best and to narrow them down to the single best method. That's not necessarily in the FDA's best interests. We should use a variety of different technologies. One technology may better answer a particular question, but as a regulatory agency, when FDA goes to court, more pieces of evidence from a variety of different resources is more beneficial than saying only one true method counts. There needs to be a shift in the way they approach the type of research being done. We have a depth of resources, including the infrastructure, equipment, and the knowledge that the FDA has already invested time and money into acquiring. It needs to be used to its fullest potential instead of being bottle-necked into a narrow scope (OARSA). • The current direction is too narrowly focused on a few priorities. The entire program needs to be reassessed, to look at critical areas in public health and be more proactive in allocating staff and resources to look into some other areas (ORS) **Clarify what is mission relevant:** • Develop a long-term vision of the program. The people in the trenches don't have much say about what is mission-relevant, what is hot and what is not. The process of identifying what is mission-relevant in a long-term way has never been clear to us. We have a program that people think is very important, and then one day they say, "We are not interested anymore: just drop everything." What do you do with the people who are affected? Having a clear idea of the program will be very useful, as will having some kind of participation from the people who will actually be doing the work (OARSA). **Retain an element of basic research:** • There seems to be a lot of reach-down by the Foods Program into CFSAN business, and we aren't given autonomy in our research. The head of that programs is a lawyer (as is our CD), and he has a very narrow idea of why we need research and what we should be doing. That's a lawyer telling scientists what they should be doing. Scientists should be given the ability to rely on their training and their best judgment to identify aspects of research. We are getting constrained and the constraints we are being put under are unrealistic. How is this project going to result in regulatory guidance? You can't look at it that way, you have to be more holistic. In some ways you do have to have that element of fundamental basic work that isn't tied to getting the letter of the law redefined. Science doesn't work that way. If you destroy that fundamental presence and expertise in the Agency, and this can be done in a matter of years, it will destroy something that will take 10 years to build back up. (OARSA). **Identify parameters to evaluate program success:** • One thing I wish they would address is what parameters are used evaluate the success of a program. One thing that is used is publications and their impact and how you quantify that. This can be misleading because you could have an outstanding article in Science but it doesn't impact our program at all because it will never be implemented. A lot of the journals we publish in would be considered minor journals because they are niches. Even if we publish in Water Research, the results will be taken up by industry because that's what they read. They should be asking how the results have been implemented instead of worrying about how many publications and in what journal (OFS/DI). **Clarify how the MB program fits in the Agency as a whole:** • We need to better understand how the program fits into the Agency as a whole. What do the product-specific offices like produce, dairy, cosmetics, field labs and dietary supplements need from us (ORS)?
Reorganize MB research	**One research office:** • Consider putting all MB research under one office so that one OD doesn't compete with

C.2.1.5-3. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements for the Entire Microbiology Program – Remaining Responses?	
Microbiology Program – **Remaining Responses**	
	another OD. The real problem is not having equitable distribution of resources. This is not FSMA-related. It is related to their way of treating us as "them" vs. "us." It is partly because physically we are not there. It has also been aggravated by personalities, and by having two research units located in two different offices. In competing for funding, it comes down to which OD is more resourceful. We currently have a temporary OD who doesn't seem to have very much of a say compared to permanent ODs. In addition, people who are closer to the seat of power get more resources, more things done (OARSA). MB needs to be in one group, but it's a scary proposition, because how well it would work would depend on who is in charge (OARSA). • MB should be one group. It would be a very difficult job to accomplish, but it would make the most sense (OARSA). • Remove the DDSO from the scientific management of CFSAN and place all of microbiology (OARSA, ORS, OFS/DI, OFS/MC, and CVM's OR) under the direction of the CSO/RD at OFVM. That would give the Office of Foods the capability to apply innovative science to outbreak investigations and tie that focus into the core group already established under the Office of Foods. All of the research would be under one person, instead of multiple people. It would also separate the policymaking and regulatory side from the science side and allow scientists to focus and concentrate on important FSMA and laboratory issues (OARSA). • The MB programs need to be merged. It will be very difficult, but is needed to increase efficiency (CVM). **Redistribute:** • We need to get people to sit down and buy into partitioning research in a productive way. One possibility is to set up some centers of excellence in different areas, which we've tried to do. Say, let us have the center of excellence for *E. coli*. Why hire an *E. coli* expert if we already have one? Let us consolidate and put some people here on *E. coli* and send some of ours there on genomics. The division can't be "genomics," because when you have an underpinning by saying "We do genomics," it can be applied to anything. It has to be specific program-relevant areas—maybe give them genomics, us meta-genomics? As soon as an idea is pitched it seems they are hiring someone in that area. The discussion has to be at DD level but with upper management buy-in because of conflict of interest (ORS). • Realign and combine MB labs: Some of our divisions are well aligned with the mission of the Center, but there are a lot of microbiologists who are underutilized and misaligned. They should review all research programs and realign and get them tidied up and directed toward mission-relevant problems. The program office goes to the groups who they know are going to answer the questions they want answered and they are going to keep going to the same groups. You have a whole other body of microbiologists in the Center who are not aligned properly who not moving forward to help the programmatic needs. And make no mistake, my people know their colleagues up the road are not aligned and are doing basic research or whatever they want to do. It hurts my people's morale because they are held accountable (ORS). • At CVM, we are in the unique position of working both with Wiley and MOD 1 and we see that we are doing the same thing for groups in both places and that there is duplication of research. It would be more productive to combine those groups and bring those doing the same things together. There isn't a difference in some of the MB we do--we just do MB in feed vs. food. Even NCTR does some of the same research. It would be more productive and would save cost as well as end duplication of effort and equipment. We could all even be housed together. We really doing the same work (CVM). • We should be working more closely with CFSAN microbiologists. They have tremendous resources there. MOD 1 should be combined with the Wiley building and maybe some of their scientists should join us, because there is much duplication. Just collaborating between offices probably wouldn't work because it would be hard to

C.2.1.5-3. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements for the Entire Microbiology Program – Remaining Responses?	
Microbiology Program – **Remaining Responses**	
	determine who should take the lead on any particular project (CVM). **Hierarchy in the labs:** • The program needs to have real scientists to lead and they should be supported with staff. There should be a reorganization by ability to a more tiered structure (ORS). **Comment:** • It is difficult to envision a reorganization that would be effective in helping microbiologists at the bench level (CVM).
Adjust current structure	• Some of these offices are completely broken: OARSA is broken, the external offices are off mission, not communicating, no leadership to move it in that direction. If some of these offices were doing more mission-critical work, supporting our work, we would have less to do (ORS). • It's a tricky thing to balance the age structure and the staff. In general, most of the hiring is done at the lowest level, mostly young PhD's, who don't have the experience to manage. We need to hire more at the intermediate level. The DD moving up to DDSO also has created a management gap (ORS). • Method development seems to be diffuse across the Agency and there is some duplication of effort. There are working groups to get these labs together as well as bringing in the ORA field labs to improve coordination of effort. This is good and needs to be expanded. A project manager for the working group would be useful to act as a facilitator to work with the various strong personalities that science provides. Trust among peers is needlessly damaged in some of these interactions (ORS). • Delegate the science projects, CARTS approvals, and other research matters to competent scientists who have knowledge about various research areas and projects (OARSA). • PIs should be able to concentrate on research: Currently we have researchers being pulled into administrative duties and managers doing research. While you can't separate these two functions completely, the crossover should be minimized. That way researchers can concentrate on what they're good at and their passions. You need managers that understand research, but they shouldn't be doing it (ORS).
Improve distribution of resources	• Productivity, efficiency, duplication of efforts: everything relates to how we distribute our resources--how effectively the allocation matches with the needs. Things in CPK1 are very different. They are hiring and having people converted. There is a fixed amount of dollars, so if one area gains, another loses (OARSA). • The most important improvement would be realignment of resources and the work force. Allocate more resources to other projects. When a method is developed or approved, management should allocate funds for method validation. When we don't get these funds, it is very ineffective. We can publish it, but it can't go into BAM and isn't recognized as an official method (ORS). • It seems that the Center does not fully exploit the expertise of the people with the most experience and longest tenure. Their contributions have been marginalized (ORS). • The Center needs to realign, refocus, reengage, and allocate resources and responsibilities so that they can tap these personnel and be more productive (ORS).
Professional development, training, and travel	**Professional development:** • Originally when we were hired it was stressed that your promotions were based on publication. But the short-term projects that the Agency wants you to do, answering some of the stakeholders questions, will usually never result in a publication. So what do people do about their promotion potential (OARSA)? • They should develop a program to teach scientists how to have impact: Utilize the Senior Biomedical Research Service to be role models and to mentor younger scientists to help develop their leadership, originality and independence (i.e., the qualifications to advance to GS-13 and above). Assign young scientists from various labs to work together on a short-term project and assign those that aren't usually leaders, leadership roles.

C.2.1.5-3. Interviewee Observations: What Areas Might be Productive for Longer Term Mission-Related Improvements for the Entire Microbiology Program – Remaining Responses?	
Microbiology Program – **Remaining Responses**	
	Maybe have 10% of young scientists' time devoted to doing this project and if they are productive, grow their independence (OFS/DI). • Support staff need to be better recognized and a career path developed (ORS). • The promotion structure is left up to the individual, so even though I have high visibility throughout the Agency, I don't have the time to fulfill requirements needed for promotion when they are not part of my regular duties. There isn't time for me or my manager to sit down and have a conversation about long term development (ORS). • Developing leaders at the lower science levels would be useful, e.g., at the branch level vs. at the office level (ORS). • They should help division members with professional development – goals and motivations (ORS). • Supervisors could use some management training. The new DD seems to be a good leader whose vision needs to filter down to the managers, some of whom need to learn how to build trust, how to treat people equally, to make transparent decisions and to motivate an employee (CVM). **Training:** • Continued training and education (ORS). • We need some training for some of the new areas that we are going into. There are restrictions on travel so we are having a hard time with the training. This is specific training, not just going to meetings and conferences (CVM). **Travel and meetings:** • Make it easier to attend meetings and present our research instead of denying this sort of thing. I don't understand why we're still under "mission critical" when we have a budget. It is really difficult. There have been problems with people being denied travel at the last minute, passports arriving late, etc. Sometimes it depends on who the inviter is (OFS/DI). • Travel to allow interactions outside our immediate community and to allow interactions with our partners (ORS). • Resolve funding issues: I was invited to participate in an international meeting and workshops, but attendance is limited to one (CVM). • Right now travel is so restricted we're not getting to go anywhere. It is hard to keep up with what's new and happening in the scientific world. You can keep up with some of it through journals, but it is hard to find the time to do that. If you go to a major conference, you get immersed in it for several days. You can pick up the new technologies and methods quickly (CVM).
Publicize efforts [One response: Not included in body of report]	• If PIs had websites to interface with the public, it would allow for citizen science. Members of the public could ask relevant questions and PIs could respond. Congress is also not up to date with how much we have learned in recent years – the information is not getting to them. Such information sharing could be facilitated by an increased web presence (ORS).

C.2.1.6. How are research priorities determined in your division/branch?

C.2.1.6. Interviewee Observations: How are Research Priorities Determined?	
OARSA	
Strategic plan, EROs, working groups, program offices	• This is done in the context of the EROs in conjunction with the DD, their subordinates, and the individual investigator, so it's a strategic planning process. Usually we write projects to the EROs. Having those in place, we are really constrained because your project won't be approved unless it addresses one of those. We have some leeway in the milestone development so that we can address the ERO and still get some of the aspects that the investigator would like to see developed. • We have working groups that we all participate in. The problem is that there are non-scientists and former lab scientists who propose things that can't be done or don't make any sense. Scientists should have more input into the strategic plan, and nonscientists shouldn't be making the decision on what projects go forward. • The BC and DD attend working group meetings. They find out what needs to be done to take care of certain problems and bring those back and ask us. We then write a CARTS proposal. This is also in transition. I hope that is the way it is going to go. • There is a lot of work going on to improve the CARTS process. I applaud the SSA for his efforts. I realize it's a work in progress.
Management	**Upper management:** • They are not determined in our division, they are determined mainly by the Center. The working groups have some input that determine the EROs and knowledge gaps. All our research projects have to be guided/pre-approved by the Center management before we put them into the CARTS system. Sometimes this process can take a long time because of the availability of those involved. We harbor the dark suspicion that ORS doesn't have to do this. We don't know though. • All of our projects are approved by management, but sometimes halfway through a project, management will call over and say "Oh we're not interested in that anymore." We have cases where the project has been approved up to the top and then 2 years later we're told that we shouldn't be working on that anymore. We get no feedback or explanations. That hurts peoples' careers, and shows a real lack of respect. • For some of us, research projects have been suggested to us. Some have been independent, but in my case, more have been suggested to me. I think this is based on what upper management feels is of interest to the Center. Once we've received an assignment, we've been able to make suggestions about our research and have freedom in determining in which direction it should go. • The process is not clear. I think our BC receives priorities from the upper management and then we brainstorm about current and future projects to achieve these priorities. It is my understanding that what is and is not a priority comes from upper management. Sometimes we propose projects that we think fit the mission and we are just told "no" without any feedback on why it is not mission relevant. **Line management:** • I think that my BC works with PIs to determine the best way to present a project. The PI comes up with the idea, then the BC tries to hone it in such a way that it will make it through the approval process. Then it would go to the DD who would rank it and send it to the OD.
CARTS	• We are restricted to doing applied research by the Center by the use of the CARTS program. The way it works now is that we think they need something, we spend time preparing a CARTS project, and then it gets rejected. It isn't clear who is reviewing our proposals and rejecting them. We don't know if it is one person or multiple people. • Each PI writes a CARTS project that gets approved by middle or upper management and then we just work on that. Not every CARTS project is supposed to work, but people are going for the low-lying fruit just to survive the current situation. We're basically in a rut. The whole Center is in a rut. • Until a project is approved, it is in limbo. If a project is not approved, there is no feedback. They just say no. The lack of feedback is a pervasive criticism. • It is not easy to collaborate with CPK1. CARTS should be a way we could know what

C.2.1.6. Interviewee Observations: How are Research Priorities Determined?	
	they are working on and what would be good areas for collaboration, but it is so hard to get approval for a CARTS project.
Scientists	• Because we are a small group and also because virology is a very focused area of microbiological research, a few years we were charged to define ourselves in a better way. We have kept that, refined our decision, and kept our research goals and mission intact. They have been approved by my leadership and the Office and the Center.
Politics/bias	• There is a complex interplay of individual initiative, CARTS approval, and heavy-duty lobbying at ERO meetings. There are also layers of push and undermining within management and sales pitches at the upper administrative levels of CFSAN/OFVM/FDA management.
Don't know	• Before, we would discuss our research ideas with our BC, then write them up and he would discuss with the DDs and then it would go to the office level. Now there is no mechanism. After my last project was finished, I talked to my BC, and he had no ideas. • We don't necessarily know. The projects we select to work on and submit for CARTS projects are the ones we came up with at a team level and not at a division or branch level. Part of that goes back to not receiving guidance from upper management. Our team leader is very active and willing to go to CPK1 and talk to people at the higher levels (e.g., SSA) to find out exactly what the Center is looking for and then come back and meet with us to discuss some ideas, techniques, or technologies we have access to, what we can do, what kind of projects we can come up with that fit the mission, etc. It's done at a lower level instead of at the division or branch level where it should be done. Some scientists here feel lost and on their own. One scientist's project was cut because the Center wasn't interested in his type of research anymore. He'd been working on it for 7 years. He doesn't quite know what to do now and has received very little guidance or feedback. • The way it's supposed to work is that we have a strategic plan and we would use that. Right now, the information coming from my BC is almost nonexistent. So a lot of people are floundering and they are not sure what their priorities are. There isn't really good direction. • There's not a specific process. I am fortunate to have a resourceful enough team that we have interactions with a lot of different people and plan our own projects, but not everyone in our branch has that. There are a lot of people who are suffering right now because nobody's telling them what to do, and they're trying to figure out their purpose in life.
OFS/DI	
Strategic plan, EROs, working groups, program offices	• We get our priorities from the regulatory labs and program office. They tell us what they need, what's out there, what changes they're expecting to make. They hear it from their stakeholders. • By the program office. We have frequent communication (~10 calls/week). We are up to speed with the things they deal with, e.g., regulatory issues, and we try to gear the research to answer their questions. • At the Center level, the ERO system is not very good because there is no accountability. • I know the Center has the EROs and the work plan, and we contributed to that when it was first developed. But I haven't seen a direct connection there. From what I've seen they're not very reflective of what really needs to be done in the Agency. Some are very, very specific, and some are very broad, and they don't seem to have a commonality of intent. • I don't know if we need a process like the EROs, but we do pretty well on our own. Other groups need more oversight and direction.
CARTS	• A method may be more politically determined than by merit. Once work is started on a method, rarely do people step back and determine that this isn't the right course. The project is completed as written because management is held accountable by deliverables. They are trapped by CARTS and milestones. • It is a useless burdensome system. No one uses it. If management has a question about our research, they don't look at CARTS, they come and ask us directly. And there is some finagling concerning which projects are OK based on preferences of certain managers. They're looking for a way to hold people accountable, but it doesn't really show what the impact is going to be. There's no open dialog, and the people making the decisions may not

C.2.1.6. Interviewee Observations: How are Research Priorities Determined?	
	know the whole story--they just have superfluous knowledge. • In terms of the whole Center, EROs and CARTS may not be bad, but there doesn't seem to be the oversight in thinking over what are the real priorities for the Agency. A lot of the EROs were developed by the researchers who may not have been in touch with the problems the Agency is addressing.
Outbreak or threat	• Priorities are driven by the industry and outbreaks and a common need for better methods.
Scientists	• As a project lead, I may talk to someone at a meeting who has a question for the shellfish people. I talk to the folks in the policy group, and if they agree that we need some data to help fulfill a policy stance, I'll go to my BC and discuss, and he says yea or nay. I don't think there's a formal process for prioritizing the ideas. It's more first come, first serve on whatever ideas that people come up with that are valid, legitimate, and really need to be addressed. • We try to cover our research niches with respect to how they're impacted and try to come up with research ideas that might answer those data gaps. One of the benefits of being in a small branch is that we do have a little more leeway to have that dialog with our BCs and then the DD, and by that time, it's fairly solid. Even when we had no top management push to be involved in the process, we've always seemed to come out on point when we do our 5-year research review and they look at our deliverables vs. their problems. Upper management sometimes wants a big push, but in the trenches we evaluate a success in little steps, not a big change.
Politics/bias	• By inbred discussions by line management that rarely have all the people in the room. Part of the problem is that scientists who are promoted to middle management have their own pet projects and this can skew priorities. In addition, priorities get translated and mistranslated up and down the line. This results in the bench scientists not always getting the big vision of the person wanting the project done. People with the big ideas should stay involved in the process and empower the scientists to personalize the project, and assessment of projects should be independent of line management—maybe by the Senior Biomedical Research Service. There is a competitive culture rather than a collaborative one. Not that competition is bad, but people with power don't play fair. Those with a less forceful personality will just back down and do what they're told and not be engaged in the process.
Internal peer review	• Every several years we have a scientific peer review of ongoing research projects. We also have EROs both for the Center and for FDA in general. That is done in conjunction with what our policy group thinks they need.
Don't know	• I'm not sure whether the PIs fight for their cause or whether the most prevalent pathogen takes precedence.
OFS/MC	
Management	**Upper management and industry partners:** • The process is flawed. FDA should consider implementing an outside, independent review of how our projects align with agency priorities. Industry used to have more input. About 20+ years ago, they'd present research ideas and be involved in the ranking. In the past 10 years, that has been replaced with finding out what industry's problems are and devising research around them**.** Upper management undergoes established processes to determine which ones are the most relevant, practical, fundable, and can be completed within a certain timeline; there's not a lot of "Absolutely not, we're not going to do this." That cut is made at a lower level where we don't quite know what's going on. Some upper-level things go up to our OD, or even to external or side reviewers, who are still within the overall group. **Upper management and other offices:** • Our priorities are FDA regulations on milk, shellfish, vitamins, etc. ORA and CVM send us money and we agree to do their projects too. Sometimes ORA, CVM, etc., take precedence. Everything's a priority, except right now the priority is not to take any more projects even though we're asked. Management asks if we have the people to do this and when I say, "No," they tell me not to do it. But when I do that, my colleagues in other parts of FDA go to upper management and ask why we aren't doing it. **Line management:**

C.2.1.6. Interviewee Observations: How are Research Priorities Determined?	
	• They're decided by the BC. When I have differences with the BC, I go to the DD, who is the second line supervisor who always tells me I have to go through my BC. The power stops with the BC. I can't go anywhere.
Strategic plan, EROs, working groups, program offices	• CFSAN's EROs are changing how priorities are determined. In the past, if someone needed help with safety issues, an industry researcher would develop a proposal for a project to address those issues. The proposal would be sent to industry members and FDA. The members would review it and give it points, and the project granted the highest number was ranked higher. Now there are many things in the EROs that FDA scientists should work on but that may not be in industry's interests. The IFSH platform addresses industry needs, so who's going to do that ERO? Our division is confused. Management never made it clear what our goal is: Promote IFSH or FDA? When I joined FDA we only had FDA projects. Because the resources are now in the IFSH platform, there's no place for the EROs unless a management initiative moves them together. Everyone here feels the same frustration. We are FDA, we are paid by FDA, but we are working for IFSH. The managers' jobs are to promote this place so they don't want us to fear, but it's a big problem. • Priorities are determined using EROs, a strategic plan, and working groups. Our group functions well and involves very qualified people. Management picks what's important now. We come up with research ideas and the boss tells us if they're worth it. Having more information related to current safety concerns and policies would make it easier for us to come up with research ideas that better serve the Agency. That's a communication issue, but obviously their job isn't to tell us everything. • CFSAN's new working groups are mostly attended by BCs and not scientists. At some point the researcher needs to hear firsthand exactly what the data needs are. In a Webinar presentation, the CSO/RD said anybody who wanted to attend a working group should just indicate their interest. Why didn't those BCs tell anyone? All of the projects we do here are relevant. Many of them at MOD 1 aren't. Who do you blame? The scientist? No, you blame the people who didn't tell them what was important or invite them to the meetings. MOD 1 people don't go because they don't know. We are close to industry so we know the issues. • Our working group, which includes our team, researchers at CPK1, chemists, other microbiologists involved in research projects, etc., meets quarterly to brainstorm projects and ideas that align with FDA's mission. We bounce our ideas off the SSA, who tells us if the project(s) meet FDA's goals. We then meet as an FDA Working Group and prioritize the research projects. Once they're prioritized, we vote on them and decide whether to move forward. As part of IFSH, we meet with industry members to discuss their interests and determine the types of research they want us to perform. We come up with research projects that would help answer industry questions but are still part of FDA's main focus. We make sure FDA is happy first, industry members second. Some people are concerned that one minute we're supposed to forget what FDA wants and do what industry wants, and then we're supposed to do what FDA wants. It changes, but it's all the same to me. • We used to meet with our collaborating partners in industry, and they'd vote to prioritize the proposed projects. Now it's the working groups that CFSAN has set up. I attend three of them, but only a few of our scientists are involved so when proposals are ranked, the staff often doesn't understand how it's done.
Scientists	• Because we work in a consortium, priorities should be determined by the industry people because our Center includes academia, industry, and FDA. However, most of the time we (PIs) go with the priorities we think we should do and then the industry people vote as to whether this is worthwhile to them or not. The research we propose should be helpful not only to industry but also to FDA regulations. Very rarely industry falls in the research priorities.
Politics/bias	• Whoever has the best lobbying group: If I can lobby different groups in CFSAN to push for me, or if I lobby certain industry members to indicate a particular issue is critical to them than those priorities are approved more.
ORS	
Management	**Upper management:**

C.2.1.6. Interviewee Observations: How are Research Priorities Determined?	
	• Sometimes it seems to trickle down from upper management. It may be triggered by an outbreak, which becomes the focus of all our attention. But that doesn't mean we shouldn't be working on other things as well. • They are determined by the managers and this is the major problem. There is no input from scientists or junior scientists in establishing priorities. • There is a science advisory team that sets the high priority work. They decide how to allocate resources and staff for new projects. • These priorities are mostly set by upper management in response to what is going on in food safety (contamination and recalls). This has been pretty reasonable. We also have some lower priority research that is still relevant, and individual PIs do have some freedom in these types of projects, which involve more discussion between PI and supervisors related to priority setting. • It starts at the upper management level, where they are aware of what is happening and what would be important to pursue. They do a lot of good proactive stuff to address issues before they arise. They trickle out information as they deem necessary. They seem pretty good at staying ahead of things. • The priorities come from the CD's office in a top-down fashion. After priorities are handed down, we discuss the best way to move forward and carry out projects in an efficient manner, as well as timing, hurdles, and teams. • In consultation with our DD and the DDSO, we look at CFSAN priorities and OFVM and the strategic plan and try to link what we are doing with what has been announced as a priority. Ultimately this gets filtered into a CARTS project. **Line management:** • Directly from our Center's line management. Usually in response to acute needs.
Strategic plan, EROs, working groups, program offices	• EROs and CARTS are good in concept, but are not particularly well implemented. Things keep changing. It's the right thing to do but, it's a fairly new process. We have run into some problems where people who were reviewing our proposals were trying to settle some personal scores with us, and impeding the process for nonscientific reasons. They need to get rid of the game playing and politics. • We need to see where our project fits in the CSR Strategic Plan. If it doesn't fit, they will not fund it. • CFSAN program offices in foods/dairy/seafood have working groups that determine priorities that they would like to see science address. We rely on those heavily. • It's a way of knowing who is doing what, but are people finding me because of CARTS? I suspect not. For me, it's a bureaucratic burden, but I see how it's used to keep the other folks in line, keep people from doing basic research. It's more a managerial tool. • I don't think the ERO/CARTS system is working. We have bizarre meetings to rank ERO's and report on how they are doing. They are a total waste of time and a bureaucratic mess. I don't know how to make it better, but don't know how it could be working for anybody.
Scientists	• It is a cooperative effort between investigators and upper management. Individuals come up with the research, but the primary aims are probably dictated from on high with input from scientists on committees. The Deputy Commissioner comes up with very broad objectives. It is left to the individual to decide how to meet these objectives. It then becomes a matter of propaganda to convince the management that it needs to be done.
Outbreak or threat	• Ultimately, the priorities are set by the dangerousness of the pathogen and the severity and frequency of the outbreaks, and whether or not we have a method for it yet. • It is probably determined by the organism, the scope and scale of outbreaks. The food matrix can also determine the priority. I'm told what I do is important, but don't know if that's just lip-service to get me motivated.
Politics/bias	• Resources are unevenly allocated to a few pet projects.
Don't know	• We [support scientists] need to understand the process of setting priorities better. • It is a mystery to me. There is no formal process at our level. CFSAN and ORA meet and

C.2.1.6. Interviewee Observations: How are Research Priorities Determined?	
	decide what foods they'll be testing this year, but we aren't involved in that decision and the decision is never even really communicated to us. • I am not clear on how they determine priorities. Sometimes, they assign projects and it isn't explained why it's a priority, but, in my case, there is usually some discussion.
CVM	
Management	• The research priorities are determined more on the office and center level. It will come down as low as the DD or PI. • Priorities are determined at the managerial level. The managers of the four divisions meet with the OD and the Deputy OD, and they decide on the priorities. Our manager gets input from the PIs on what projects would be good to propose. • We have planning sessions for methods projects where you can have advance planning. The Center has an annual cycle. This forces us to sit down and ask ourselves what our research priorities are. We have a mechanism for scoring proposals, but haven't used it for the past year. We are back to reacting to emergencies and more of a hodgepodge approach for determining priorities. • There is an informal step in which the PIs discuss what they want to do with people in the rest of CVM and ONADE. They talk to their peers and the DD about it. Then we have an informal discussion with the higher management to see if they agree that it fits the mission. If they agree then we start down the formal pathway. The PIs develop a research plan followed by a research protocol which have to be approved formally. The management section has regular meetings where we discuss the new projects, then we prioritize them based on funds, resources, and what we think is the most important. If we have direct information from ONADE and the rest of CVM that they really need something then that gets bumped up to top priority. • Investment in new program areas happens by consensus, where everyone acknowledges that we need this new program.
Strategic plan, EROs, working groups, program offices	• In a formal way, in consultation with the program offices: They are our first customers. We have a distinct mission from CFSAN. We meet regularly with ONADE and OSC. We make sure that we are answering the questions they need to fulfill their mission. We have very little latitude to do what we think is important. • The Center has a Strategic Plan, and our priorities are also clearly spelled out in CVM's mission. Whenever we come up with research ideas, we run them through our DD and upper management and they make the decision to move forward or not. The priority is to support CVM's regulatory mission.
Scientists	• The PIs usually have a set of research needs. They discuss them, and rank them, and then evaluate them in terms of the Center and OF priorities from most to least important. • Each PI has the primary responsibility to determine priorities. Our roles are clearly identified. We have regular meetings among the PIs to determine priorities because there are limited resources.
Outbreak or threat	• NARMS is our main focus and drives our deadlines. I am not directly involved with NARMS, but when deadlines come up for NARMS, I will contribute. Sometimes NARMS priorities are a dilemma for us because our research is a priority too.

C.2.1.6.a. How do you contribute to the process?

C.2.1.6.a. Interviewee Observations: How do You Contribute to the Process?	
EROs, CARTS, working groups	**Line management:** • The process starts with me. I try to make it clear that the EROs, OFVM should be referenced and we should aligned ourselves with CFSAN priorities (ORS). • We meet directly with the regulatory program office monthly, and I ask "What are the most important questions you need the microbiologists to answer?" We are directly plugged in to the regulatory side and their needs. We try to integrate emerging problems as well as areas we need to maintain a base in (ORS).

C.2.1.6.a. Interviewee Observations: How do You Contribute to the Process?	
	Team leaders: • As an unofficial team leader, I pitch research ideas and I serve on an ERO panel that decides which projects are prioritized (OARSA). • I am in a bunch working groups and have gotten members of my team on these working groups, so that we have some idea of what these priorities are. I don't get a lot of help from my BC, DD, or OD. I have a good working relationship with our SSA and his Deputy and ask them. Also, because we work closely with ORS, and they are definitely in the loop, I ask them. I ask their DD and get guidance from him. But I don't think that's the way it's supposed to work (OARSA). **PIs:** • Via individual initiative, CARTS applications, and at ERO meetings (OARSA). • If I am asked to write something we usually sit down. It is a collaborative effort, not an individual effort. There is always just one person responsible for the CARTS, the reporting person (OARSA). • Everyone uses their own expertise to achieve an ERO (OARSA). • We write up a CARTS project and then send it over to upper management who then forward it to other offices that might have an interest in that project. Then they say yes or no without an objective review. There is no feedback on why it was rejected. There is no discussion. The process takes 6 months, all the time you are left wondering if it will get approved or not. It is no way to run things when you have people judging the merit of the proposals who haven't worked in the lab or have been away for a long time. We are much more in touch with what research people are doing and needs to be done by talking to people at meetings and in the food industry, but our input is not sufficient. Any bottom-up ideas are rejected (OARSA). • You need to justify your science for the project you are proposing. Sometimes I fail and they ask me to move to another project (that I may think is worse), so I move on (ORS). • I sit on two working groups. At each meeting we tie projects to EROs and prioritize the research programs (ORS).

C.2.1.6.a. Interviewee Observations: How do You Contribute to the Process?	
Consult on projects/prioritization	**Line management:** • I participate in the prioritization process with CFSAN upper management by trying to bring work to the fore that our office does (OARSA). • I'm also on the SRSC (Science and Research Strategic Committee), an OFVM sponsored committee comprised of CFSAN, CVM, ORA, and NCTR. They do their own prioritization (OARSA). • I participate in the peer review process, via presentations, help people prepare their ongoing projects for review, participate in ERO quarterly updates, and help identify what I think are voids that need to be addressed and determine if there are consistent themes with the policy group (OFS/DI). • The process starts with me. I try to make it clear that the EROs and OFVM should be referenced and that we should align ourselves with CFSAN priorities. People need to look more closely at the CFSAN priorities and recognize that these are what upper management are trying to achieve and that management is not just trying to quash what the scientists want to do (ORS). • Keep projects mission related and realistic. I have a good idea of mission relatedness and what the Agency and industry need. I have a good idea of what projects are possible and the time span required to accomplish them (ORS). **Team leader:** • I hold meetings to discuss priorities, and give presentations reviewing past research and future planning (CVM).
Advocate for my work or my group's work	**Line managers:** • I act as an intermediary between the scientists and the Center. I have to sign off on the projects, but I don't have any real authority (OARSA). • We directly meet with the regulatory program office monthly and I ask, "What are the most important questions you need the microbiologists to answer?" So we are directly plugged in to the regulatory side and their needs. We try to integrate emerging problems as well as the areas we need to maintain a base in (ORS). **Team leaders:** • By listening to the researcher and also listening to management to see what they want and trying to mix it together (OARSA). **PIs:** • We are free to go and talk to upper management and give them ideas (OARSA). • I lobby them when I can, but I'm getting old, cranky, and tired and sometimes it just seems so useless (OFS/MC). • In my own work, priorities are set based on what is working. I set my own targets on the methods that I am developing. Priorities are set on a time and need basis (ORS). • I work with two organisms and know them well. I go to meetings and advocate, talk to senior management, try to push it forward. But I'm not sure how much influence that has (ORS). • We develop protocols for new methods, which are then sent through the review and approval process. QA protocols are also developed and, sometimes, preliminary tests are performed before proposing a method for a new project (ORS). • I participate in the prioritization meeting at the scientist level or where they talk about the knowledge gap level. I also talk with the BC and DD about where I feel my research needs to go or where I feel there is a gap that needs to be filled (ORS). • I'm the SME in resistance, so I have input on the science in consultation with the Division of Human and Food Safety (CVM).
Conceive research projects	**PIs:** • I come up with the projects (OARSA). • We write project proposals and submit them to the Working Group. On the IFSH side, we develop project proposals, and submit them to a technical advisory committee, which votes on them in IFSH's science forum and decides if these projects are good, bad, or indifferent, and if they're high priority (OFS/MC).

C.2.1.6.a. Interviewee Observations: How do You Contribute to the Process?	
	• I come up with research ideas. Sometimes the program office contacts us directly. Most of those projects move forward because a customer has requested it. Our new OD wants most projects to have an endorsement/request from someone and for us not to move forward just because we want to do it (CVM).
Help set priorities	**Line management:** • I am involved with management as we discuss proposed projects, their importance, and timelines. I am first line of the approval. After that I am trying to provide the resources. That sometimes means juggling people's jobs around, assignments they need to work on, making sure the resources are there in terms of equipment, supplies, money (CVM).
Minor role	**Line management:** • Middle management is not involved in the process. Our OD, and deputy OD are not involved in the decision-making process. What do we need them for? BCs not involved in the decision making process. What do we need middle management for (OARSA)? • Sometimes we do suggest things which are then passed on to two or three decision-makers at the SSA and to the CD and his deputies. Decisions are not even made at the office level (OARSA). **PIs:** • I am not really involved in priority setting. My work is more low priority, so there are not as many people working on it. It is still needed work, so I am part of the mission (ORS). • We aren't given the opportunity (ORS). • I help set priorities within our genomics program via bi-weekly meetings to discuss where the work is heading (ORS). • I had a stake in what I did when I was actually doing research on new technology. But now that I've been relegated to this old technology, I have no input (ORS). • I make sure that the systems we are using in the labs are functional and operational, that we have what we need to be functional and operational, and there are times I tell the director, "No, we are not going to do that" because it's not feasible or thee are not enough people or there will be insufficient gain from doing it (CVM).
Don't know	**Team leader:** • So far not at all (ORS). **PIs:** • There are 10-20 committees trying to prioritize research, but I've never been invited to any of those and did not know that they existed. I would love to contribute to the process of prioritization, but I don't know how they choose the committees, who are in them, how you get into them (OARSA). • I don't really. This is the first time I've been asked to speak my mind. Maybe I've contributed in some informal comments (ORS). • As a support scientist, I am not heavily involved with that process aside from when a study is proposed they will ask if we have the time and ability to participate (CVM).

C.2.1.6.b. What ideas can be implemented to improve the process?

C.2.1.6.b. Interviewee Observations: What Ideas Can be Implemented to Improve The Process?	
Improve communication/ transparency	**Expedite communication of shifts in Center priorities:** • If the interest of the Center shifts, then we should be made aware of that sooner rather than later. We may start on a project and not know the Center has shifted their interest. We're continuing on the project because we think it's a wonderful project, but if that interest shifts, it should be communicated to us, and that's not done. I think that part of it is that our Office management may not know, but some of our BCs and DDs sit in on those decisions, and somehow it is still not communicated to us (OARSA). • We could use more inside information. We don't get as much information from FDA as we get from other people. I have friends in other countries who I call for information when something comes up (e.g., a botulism case or a botulism scare). If people like the SSA, who's involved in everything, would just come out and talk to us for a couple of days, we'd learn so much (OFS/MC). • It would be helpful to learn where the ship is headed through better communication. We could contribute more if we knew where the science was headed and what goals we have to meet in the coming years (ORS). **Improve communication with program offices, ORA field labs, and stakeholders:** • With more communication with other offices and divisions and with the ORA field labs, we would have a more concrete idea of research we should work toward (OARSA). • Once we get the direction of what the working group wants to have done, then we can come up with the ideas. Most of us have been here for a long time, so we have gone through all the different transitions, and we can come up with good ideas (OARSA). • I've seen a vast improvement in the last couple of months, and that's only because of greater transparency. We're beginning to communicate with some of the key players. We didn't even realize that was supposed to happen. Right now, we're talking to our SSAs. We're talking through ideas and passing drafts back and forth before we actually put projects into CARTS (OARSA). • During IFSH annual and mid-year meetings there doesn't appear to be much communication on what industry would like, what they're interested in, or what problems or concerns they have. Looking to the future, I don't know what they want. Maybe they don't know who to talk to at these meetings. It's a communication problem from IFSH's standpoint and probably mine too. I should make myself more available to industry members. We have good relationships with certain companies, but developing new networking relationships is lacking (OFS/MC). • This year they're starting to have microbiology platform meetings to discuss possible research ideas and which projects can be selected as special projects to receive year-end extra money. In the past, the process has been very secretive. When managers make the selection, as PIs we'd like to be informed of what their selection criteria were. They need to provide us with explanations for their decisions (OFS/MC). • Since OFS/MC is supposed to be collaborative research, industry should come with research priorities that would benefit both themselves and FDA, but essentially they are not doing it. We are doing most of the work, and recently industry's input is very minimum on the research (OFS/MC). **Improve communication within research groups:** • My management needs to more engaged. The working groups mostly have DDs and BCs on them, then they come back and relay the information back to their teams. But we don't have that kind of support, we have to be on those working groups ourselves. They have brought the SSA over to give broad strokes of what is expected, but that isn't really a help to develop projects. We're kind of on our own, so we have people who are floundering because they have had their projects cut and have no direction. I am on these working groups for my team. So everyone wants to be on my team. So there are people who are not on my team who have no idea what is going on because the information doesn't flow. It's sad (OARSA). • We have research meetings and discussions among ourselves. That is where a lot of the improving the process comes. Finding out what other people are doing, finding out what

C.2.1.6.b. Interviewee Observations: What Ideas Can be Implemented to Improve The Process?	
	our stakeholders need, the public needs, and going from there, but keeping within our research mission (OARSA). • There needs to be an open, comfortable atmosphere that fosters an open dialog so that there is input from all sides (CVM). **Clarify the prioritization/decision process:** • Make the process more transparent and provide the knowledge base involved in the decision (OARSA). • Our people are working on projects related to the strategic research plan, and our projects have been approved, yet, when I request for someone to be made permanent, I'm told that their research isn't mission relevant. If our stuff isn't mission relevant, why is it right here in the mission statement? It would be good to get feedback rather than one-word decisions. (OARSA). • There are different rules for different research offices. There are overarching programmatic areas (e.g., genomics) that are pushed at a higher level, done in a non-transparent way, and those decisions are not public. They are disguised and under cover. There are things we've worked on for several years here that are undermined because they don't fit the grand scheme of where we are going, but no one's ever laid that out (OARSA). • It would help if we knew how this was done (OFS/DI).
Include scientists/line management	**Include line management:** • They should trust their managers. If they trust me as a scientist, my opinion, my years of expertise, and that I've been hired into, they should trust that I will keep the best interests at heart and interact through the proper channels. Telling us what to do makes us bean counters, paper pushers. We work within the system, but they could give us the general issues that need to be addressed and let us develop the research. I think that's how other places work. It seems to be a tug of war between those who are for science and those who don't want science. This is one level of distrust (OARSA). • We need to communicate more with the BC or DD to share our ideas on method improvement; they are often too busy (ORS). **Include scientists:** • The people here understand what they are doing and know how to do it well. Upper management needs to trust them to do their jobs and not come in and say 'do it this way' with no reason. If we had explanations, we would have something to work with. Otherwise, we just keep trying to come up with ideas until we hit on a winner. That's not the most efficient use of our time (OARSA). • CFSAN's chief scientist should form a panel of 20 senior scientist that would meet four times a year to collectively make scientific decisions. The meeting should be recorded so that an accurate record of what people think is known. Bold decisions could be made because it would be a collective decision and no particular person would bear all the responsibility for any one decision (OARSA). • It is hard to sit down in a working group with management and figure things out. Working groups with the PIs do better. Everyone may agree that 40 EROs are of value, but the final decision comes down to one person. There is no rebuttal (OARSA). • There should be more interaction between policy people and bench scientists (OARSA). • There should be more proactiveness up the chain of command. It's important to have more involvement and feedback from the scientists when they develop the strategic plan (OARSA). • Researchers and SMEs should have more independence on setting priorities. There should be more back and forth between researchers and management both in setting and changing priorities. The scientists don't have a voice. Maybe the Senior Scientist Research Service could act as an advocate for the scientists. This would give the scientists a conduit back up to the senior management without having to go through line management. The scientists need to have ownership of their work (OFS/DI). • Start with a little more bottom up management instead of the current dictatorial style: They should let people who know about these things look at the problems, instead of our leader who is a lawyer and not a scientist, or other members of upper management--people

C.2.1.6.b. Interviewee Observations: What Ideas Can be Implemented to Improve The Process?	
	who think by virtue of their position, even if they're scientists, that they should know everything. They should defer to people who know more. But that would be seen as a sign of weakness (OFS/MC). • The working groups are a good mechanism, but they should allow different membership in the groups to improve understanding of the process. Bringing the policy people and research scientists together increases awareness of what the policy needs are and what data are needed. They should consider rotating committee membership so more people understand how the process works (OFS/MC). • PIs should always be consulted regarding research projects in their area of expertise (ORS). • Allot time for the managers to get input from staff. There's always a crisis. I really only sit down with my manager during PMAP sessions (ORS). • Implement an open system. Use the expertise of the junior scientists in setting priorities. They currently have no input on this, but it is important because all funds are allocated on the basis of priorities. Research outside high priority areas is left without funding and may prove to be important in the future so should not be abandoned (ORS). • They should ask the scientists who are in the lab. But in the end, we just do the research we are asked to. Occasionally we set our own priorities. I know there are some people who do whatever they want. If I could set my own priorities, I could get anything done (ORS). • People should be encouraged to contribute ideas (ORS). • It's good that they have started to incorporate scientists' views into decision making, but the upper management still have too many fingers in the pie (ORS). • It would be nice to get input from support staff. It is the support staff who are actually doing the work. We have an idea of which projects should be continued based on data we're collecting. I think all levels would have valuable input into the process (CVM).
Improve CARTS process	**Improve communication of parameters for acceptable projects:** • There should be some advisement to BCs and DDs on the sort of projects that are desired. We have smart people, they can adapt (OARSA). • So far I haven't had good luck getting a CARTS project approved. There's a dead zone when you put the projects in. My BC doesn't really understand what I'm doing, so this time around he kept crossing out things. So I finally just put it in the way he wanted it, and it's probably going to get rejected. I can't get it through if I try to put it in the right way. I don't know what's going to happen (OARSA). • In the course having a project approved, I found out what our mission is (we did not know this): we are permitted to do research that is essential to allowing CFSAN to enforce our regulations, providing scientific support for new regulations that we intend to write, provide scientific support for guidance to industry that we intend to write. But there is lack of communication: We have no idea what anyone intends to write (OFS/DI). • In CARTS, you only have a brief paragraph to make your case for your project. We rely on our BCs who meet regularly with senior management to plead our case, but we don't always know what happens at those meetings. CARTS hasn't always been viewed as "selling" your project. Now they are being scrutinized more. And I think there could be more discussion back and forth with the researcher about what they see as priorities (ORS). **Improve feedback on project rejections:** • To be fair, we have been told we can talk to the CARTS people, and get a better idea whether something will be accepted or not. That part is becoming better (OARSA). **Expediting turn-around time:** • CARTS was never meant to be used the way it is now. If it were really used for vetting projects, that might be an improvement. One of my current projects has been sitting there for 6 months. By the time they get around to approving it, it may be half over. What kind of vetting process is that? If you're going to vet projects, you have to do it beforehand. The whole thing is too cumbersome and slow. For one project, by the time we got the data, they'd already decided what they were going to do with their regulations. They look for data to back up their bad decisions. The data should come first (OFS/MC). **Improve transparency of project review process:**

C.2.1.6.b. Interviewee Observations: What Ideas Can be Implemented to Improve The Process?	
	• There is often only one scientific reader. We don't really know who's in charge. Per my understanding, there is one scientific person, and one above or below, rather than three people. There is zero transparency on this. My last project took 9 months for approval (OARSA). • In the CARTS system, there are approval layers, but even for projects in the system, you may be called in and told your project is discontinued, and the only reason is the CD doesn't like it (OARSA). • I submitted a CARTS project, and started working on it, but heard nothing for 3.5 months. It was rejected because it "wouldn't work" and had never been proven to work in the past, but it turned out that the reviewers did not understand what we were trying to do, and in fact, it was already working beautifully. When we explained it in more detail, we were approved to proceed with the project (OFS/DI). **Improve system overall:** • It is very cumbersome. It has a terrible interface and is an outdated software package. There should be a team to help PIs get their information in there. The concept is good, but CARTS has not been successful (ORS). • It can take months to submit a new CARTS project and get it approved. Maybe if there was a way to get the CARTS process expedited, it would encourage collaboration (OARSA). • Upper management needs to harmonize their priorities and should give working group recommendations more weight. Our Center's leadership needs to be more aligned with the regulatory programs, I understand that when the Center needs something done in a crisis that it will come directly from the CD or the DDSO. But for dictating longer term needs, it would be nice to have more harmonization between our program leads and contacts and Center management. We go through a long prioritization process where my scientists are asked to spend their time sitting on these boards, for program priorities, and by the time their suggestions are filtered through the leadership, some of the suggestions aren't even there (ORS).
Improve project review and ranking process	• CFSAN needs a scientific review process that is modeled after the NIH scientific review process. There should be a panel of 15 experienced CFSAN scientists with 15 years of experience under their belt each that all sit together in a room and weigh the various research projects. This is how it is done at NIH and in every scientific review process I have ever seen or heard of. One of the problems within CFSAN is that CARTS projects can be conceived of by people like me, and approved by their line management through the OD, and that CARTS project can then go to CPK1 and be rejected by one person. That is not a scientific review process that works. It is highly dysfunctional (OARSA). • It would be fairer if there were some sort of process that involved our policy and program people so that they would have an input on what they view as a priority. • FDA should consider implementing an outside, independent review of how our projects align with agency priorities (OFS/MC). • They should implement a review system such as the one NCTR uses. Every year NCTR brings together people from FDA, OARSA, and other groups that don't have much to do with toxicology. NCTR explains its priorities and asks these groups how they think these projects fit into those priorities and to rank them. This type of review could be valuable to understanding the value of our work in terms of the bigger picture and not just what we're doing in our little group (OFS/MC)**.** • We are working on SOPs for research plan and protocol submission to make the formal part of the prioritization process easier and faster, and more flexible (CVM).
Keep the focus on public health and food safety	• We need to come up with ideas that help food safety and we need to address the needs of the ORA field labs. We need to have a way to find out what the food scientists and industry needs as well (OARSA). • They need to determine what the areas of public health importance are, identify the holes, and allocate resources and research projects to properly address those holes (ORS). • Projects should always be related back to food (ORS).

C.2.1.6.b. Interviewee Observations: What Ideas Can be Implemented to Improve The Process?	
	• It is important not to forget the lower priority pathogens, which could cause issues in the future, especially when considering imports (ORS). • We need to make ourselves more visible to the public and stakeholders (CVM). • PIs need to be aware of the Food and Drug Act and how their research needs to fulfill the act (CVM).
Let state of the science influence priorities and goals	• There is a problem in the ranking system. Some of the projects, e.g., development of a culture method for a food-borne virus, cannot be achieved in 2 or 3 years or even 5years, but the management probably doesn't understand that. Scientists in academia having been working on this for decades, but we have a 2-day program and 1-year completion target date and have it ranked as Number One. You cannot achieve this (OARSA). • Make sure technology is being used for research ends and not driving the research. There seems to be a real focus on 'my method' and I want my method to be up on the list as opposed to 'how do we use molecular epidemiology'. The technology is driving the whole conversation rather than the use driving the conversation. That's reflected in the EROs, which are constantly changing (ORS). • It would also be helpful if there could be some way to ensure that upper management is reading our research papers. If there was some sort of review committee that would go through the papers with upper management. It would give them a better understanding of what's already been done and where we can improve. It seems that more in academia read our papers than those within our own Agency. They need to be informed of what we are capable of doing and what we are finding (ORS). • OFVM is trying to figure out a model whereby they set strategic goals from the top, and then we are trying to work from the bottom up by figuring out what we can do to meet these goals. Sometimes, the goals and the research pipeline are not aligned. Sometimes there is no way to get at the strategic goals with current scientific knowledge and methods. Getting the alignment between strategic goals and the research pipeline is very difficult (CVM).
Improve CVM system	• We have so much paperwork. Right now there are two processes: the paper format and the electronic format, which are a complete duplication. A project has to have a 1-page initial plan with all the basic information, which goes for initial approval. Then we have the research protocol, which takes a lot of time getting through the system. I'd recommend one simple format. Upper management only needs basic information in terms of the research. The protocol details can be left to the individual research group. The detailed protocol may not go all the way up. It could stay within the group. We definitely don't need two processes, just one with basic protocol (CVM). • Management needs to look at the available staff, where commitments have been made, as well as the workload, to see if a shift is necessary or if something needs to be postponed (CVM).
None needed	• Currently what we do works well. Often our priorities are outbreak driven and result from calls from the CDC to help trace back contamination. We coordinate well with them and have weekly conference calls with USDA and CDC. We also discuss research priorities during the conference calls (CVM).

C.2.1.7. What are the ways in which you assess the impact of the research activities in your division/branch?

C.2.1.7. Interviewee Observations: In What Ways do You Assess the Impact of Research Activities?	
How they are received or used within FDA	**Recognition by upper management:** • How we are recognized within the Agency is very important. Does upper management have enough time to really sift through the scientific stuff to get a feel for who is doing what? If they need people underneath them to do the sifting, then they should get them. In order to get recognition you have to have people who understand what is important (OARSA). • How high up it is recognized within our management system. For example, my work is recognized up to the level of the Deputy Commissioner of OFVM. He feels what I am working on is important, especially with FSMA (ORS). • If accolades are being received from the Center level, the Commissioner, or the Office of Foods and Veterinary Medicine (CVM). **Feedback from the program offices and ORA field laboratories:** • Hopefully, our research helps the regulatory people make decisions, but we don't get any feedback in this regard (OARSA). • By giving our customers (i.e., the program office) what they want. Either they ask for research, and we answer the question or we attempt to anticipate what they're going to ask and try to develop research products to address a future need, which is more difficult (OFS/DI). • Feedback from our stakeholders in ORA who apply the methods we develop and for whom we supply technical support in investigations (OFS/DI). • There's no process for taking into account the real impact of some of our work. I don't think it's accurate to assess impact based on publications. There are a lot of things that we do to support the policy group that aren't reflected in publications. These are more impactful in terms of the program, but we don't necessarily have a mechanism for recognizing that (OFS/DI). • Providing enough good science to base policy on it is probably the best way to assess impact. To me, it's that interpersonal relationship with the policy makers—they ask a question, we answer them, they say thank you. That's impact. The research is an important part of it because surveillance often gives an incomplete answer (CVM). • I have tried to characterize our research portfolio by who our customers are, and to characterize the outcomes and benefits, the deliverables and what is done with this information. But I have to guess because I don't have time to interview all the customers, and barely have enough time to keep track of all the projects. E.g., someone asks for a method, research is done, 6 months later it's delivered. We may or may not get feedback on whether it does what they want it to or the OD may say, "Oh they aren't interested in that anymore, didn't anyone tell you?" There is no follow up on either end (CVM). **Feedback from within research groups:** • On my team we don't have a product to publish. Everyone agrees that the service we provide is critical, but it is hard to measure. This also affects the promotion peer review process, which has a section that depends on number of publications. If we see a method deployed, that is good. We just assess it by getting through the week without customer complaints. I think we need more feedback (ORS). **Impact on mission and goals:** • Assessing the impact of our research activities also includes considering if it has a direct impact on the Agency's mission and goals (OFS/MC). • It's by whether or not programmatic goals were met this year. How did what you discovered fit in? How was it used? How did it meet a need of the program office? I have to filter everything through those criteria because that's why we're here (ORS). • I sometimes see the results of laboratory research affecting compliance and enforcement. One of my goals this year is to compile results of outbreak—did we find the source or not? For compliance, did it result in a policy change (ORS)? **Application to regulatory requirements:** • Our impact is assessed by concrete deliverables: What are you doing that is tied to

C.2.1.7. Interviewee Observations: In What Ways do You Assess the Impact of Research Activities?	
	regulatory goals: methods development, science-based guidance on prevalence, distribution, and safety? That's being done to focus in on us and what we're doing, but there is another program, an empire that's being built, that has no concrete deliverables. It has no accountability (OARSA). • Does any of our data form the basis for guidance or regulations that the Agency issues (OFS/MC)? • Research can be assessed based on whether it's being implemented into a regulation, white paper, guidance, the BAM, etc. (OFS/MC). • Based on subject matter opinions delivered for regulatory action (SME reports; ORS). • Based on if there has been any regulatory action from the research outcomes (CVM). • Did we satisfactorily address regulatory questions we were asked to answer? Did our customers get what they needed (publications, presentations, etc.; CVM)? • Based on use of NARMS data for ONADE decisions (CVM). **Application/use in the field:** • To see that what has started here in gene sequencing is starting to spread. This past year there were 12 sequencers put out into the field and we have been interfacing with them a lot and generating a lot of data (ORS). **Other metrics:** • If we could just measure value added, value created and customer utilization, rather than number of publications, number of projects, number of employees, and number of isolates analyzed, that would get people focused on producing research of value (CVM).
Publications	• Publications, but quality publications. One really good publication is as good as three mediocre publications (OARSA, OFS/MC). • Our methods are acceptable to academia and the scientific community as demonstrated by publishing, presenting at meetings, and feedback (OARSA). • One measure is the number of papers published, but how this helps the FDA is another question (OARSA). • Go to the literature and check the number of citations your recent publications have received (OFS/MC). • Publications are very important as well as media reports. Recently we found out that blurbs in the media or on the website result in people contacting us about the research we are doing. This is important feedback: that there is public awareness of our research (ORS). • To see your published work is highly cited by outside scientists, as well as receiving positive feedback from colleagues (ORS). • It's all driven by publications, which, in my opinion, is not a great way to do it. We need more interaction with ORA field science labs (ORS). • Seeing that my work in a small way is contributing to large goals. As a support scientist, it is hard for me to see impact because I am down in the trenches. Occasionally my name is put on some publications and I see publications before they get published (ORS). • A lot of things we do get published in journals. But historically what we have used is the final reports that we write for studies for ONADE and whatever publications come out of those. Some of what we do can never be published (CVM). • If you start looking on the impact on regulatory decisions, many times we have no idea. Measuring impact is really difficult. None of our methods are pushed out to the field labs to use because we don't have those types of field labs. We don't know if people use them or not unless they get referenced. That is one reason we publish (CVM).

C.2.1.7. Interviewee Observations: In What Ways do You Assess the Impact of Research Activities?	
How they are received by our stakeholders and partners	• Publications, presentations at meetings, work with EU and Health Canada, invitations to outside meetings, participation in advisory groups (e.g., AOAC) for different methods. Any of our accomplishments are self-generated. We don't get support or input from management (OARSA). • Feedback from our stakeholders including commercial partners, such as the ISSC. They often ask us for technical support and give us positive and negative feedback--and state public health officials—we hear back from them as to what they need us to help them do (OFS/DI). • Assess how the work has influenced the field by how many people are using your research products, citing your papers and using them for food safety programs. Assess number of patents and whether they pay royalties (OFS/DI). • If we make a proposal to ISSC and we can get both state regulators and industry to entertain those changes, then we're doing something right. (Or sometimes if they totally hate it, we're doing something right too). I can sleep well knowing the best science has been put forward (OFS/DI). • We have a harder time assessing things that are truer research and don't necessarily fit into a regulatory vein. FDA calls for some research that never gets published. It's not necessarily fit for publication and/or it's not substantial enough to warrant a publication, but the data are useful. Unless we see that being used in some manner, we don't have a way to assess it. We have to go on faith. Sometimes we present data through posters or oral presentations at conferences or meetings, and through our interactions with people we may get an idea of whether the work is good or meaningful, but impact is something else. E.g., in our work with the sprout industry, we doing a lot of work helping industry do things properly to ensure food safety. But how do you assess the impact of that? The only way is if the sprouts industry is still alive and well (OFS/MC). • Based on international acceptance, industry and academic interest, acceptance by other agencies, such as USDA and international agencies with a similar mission, and ultimately on whether the research answers regulatory needs (ORS). • Recently, we have been able to solve cases and take legal action based on tracking the source of pathogens. This effort has included a lot of collaboration, and we have added a lot of information to the global database. The Global Microbial Identifier system is starting to work. We are seeing outbreaks being solved in real time. Having others begin to mimic our work is indicative that we are on to something useful (ORS). • We are involved in next generation WGS and getting that information out to the state labs. We've created networks to do this. We work with NCBI to get the information into data bases. The purpose of this program of distributed sequencers feeding into the database at NCBI is to increase the number of sequences catalogued so we can say we have more sequences this year than last year. But beyond that, I don't know what the impact is. Will there be fewer food-borne illnesses? Will there be shorter time to detection and identification? Will it enable more laboratories to be involved? Currently it is mostly about the numbers (ORS). • Media interviews about NARMS. NARMS is cited often by universities, in publications, and by industry. NARMS data are used for drug reviews within the FDA, and Congress has been very supportive of the NARMS program (CVM).
Impact on public health	• Implementation of the methods we develop in FDA regulatory labs helps protect public health (OARSA). • Publications are important, but to meet the needs of the Center and FDA we need to show that our work is actually helping people (OARSA). • Improving food safety is more important than publication (OARSA). • Over the years we have developed some methods which were based on what we were doing for virulence assessment (e.g., research on *Cronobacter*). People outside are using the method and confirming this pathogen (OARSA). • My measuring stick is to see how our innovations are being utilized by other food safety community groups, as well as considering how people from the outside think we're doing (OARSA).

C.2.1.7. Interviewee Observations: In What Ways do You Assess the Impact of Research Activities?	
	• By providing training and transferring the technology and then having that technology used to improve food safety (OFS/DI). • Based on the impact on our population: Are we doing research, developing methods that are helping our state counterparts ensure that the food people are eating is as safe as possible? Based on outbreaks that we see in domestic products. If I see fewer norovirus outbreaks and more education going out to the population, I see that as a success of what we are doing. Also, if I see more states knowing about it and being able to detect these pathogens and signing up for the courses and implementing them, that's a sign of the impact that we're having (OFS/DI). • By whether we can effect changes or support existing monolog ordinance language that we feel is in the best interest of public health (OFS/DI). • We have a formal statement of work so there's no formal process of evaluating the impact. Management needs to understand the impact is a food safety issue. For example, proficiency testing is the main part of the FERN and Vet-LRN programs. The other impact is milk and shellfish. Not doing methods validation would be like abdicating our responsibility. These are regulatory obligations and FDA would have to explain to stakeholders why they were stopped (OFS/MC). • We measure it by the number of food outbreaks, but that's also abstract because food outbreaks are not directly related to methods development. Also, you don't see the impact of your work in a year or two or three (ORS). • By assessing whether the research is directly answering public health questions or addressing public health issues. This is a regulatory agency not a research agency. If the success of research is based on publications, there is no balance (ORS). • My research directly impacts our ability to detect outbreaks and prevention and control of outbreaks. I see my research having a direct impact on public health (ORS). • Our work is assessed by how well reports and the research related to the reports are received by the public and public health interest groups, and by how effective that research is in getting certain drugs withdrawn or uses mitigated--how well we affect policy and change (CVM). • The assessment would be whether or not they approve a given drug based on a study that I have conducted (CVM). • In one study we showed that antibiotics in water fed to chickens increased the *Campylobacter* resistance in chickens, and the manufacturer pulled the drug as a result (CVM).
Publication in BAM	• There seems to be a lot of research and papers, but not that many new methods that actually make it into the manual. An analysis should be done on how much research actually leads to new methods (ORS). • Ask whether the method you're developing or improving is being used by our field labs or does it end up in the BAM (OFS/MC)?
Whether they lead to collaborations	• How we are recognized by our partners. Do we have the scientific respect of people outside the Agency? Enough so that they will call us either because they know us personally or have met us at a meeting. Do they want to collaborate with us (OARSA)? • Collaborations with other divisions and Centers, AOAC, and EU (OARSA). • Diversity of collaborations: We need to build that up by responding when asked for assistance. Sometimes the FDA asks shortsightedly, what is the FDA going to get out of this? What it's going to get is a friend and sometimes this has spectacular unintended payouts. Be a partner. Form coalitions such as CODEX (OFS/DI). • How work is received by outside collaborators and even the larger scientific community, e.g., how it is received as a peer-reviewed publication and at scientific meetings when we speak to others in the field and see what their reactions are (ORS). • The collaborations we are building with CDC, NCBI (NIH) and the federal and state labs (ORS).
Trends in work group/unit	• Whether your department is growing or shrinking, if upper management is listening, by approval of new hires, and by place in budget priorities. Until the last 2-3 years, 90% of the

C.2.1.7. Interviewee Observations: In What Ways do You Assess the Impact of Research Activities?	
	time people have received what they needed to get the job done (OARSA). • Whether I have been given priority to continue working on that project (ORS).
Other metrics	• I look at the novelty and the contribution to microbiology that the research is affording. There is no scale or scoring system. I am passionate about science and get excited about things that I see as good and novel and ground breaking (OARSA).

C.2.1.8. How is microbiological research at CFSAN and CVM aligned with the Center's regulatory mission and priorities?

C.2.1.8. Interviewee Observations: How is Microbiological Research Aligned with the Center's Regulatory Mission and Priorities	
How alignment is achieved/maintained	
Research supports the program offices and ORA field laboratories	• During the past 3 or 4 years, CFSAN has formed working groups made up of researchers and program office members. In this way the program offices can let the researchers know what information they need. We need to work with the program offices to bring about research projects to the work groups so that we're aligned with the Center's mission (OARSA). • Before we did a lot of basic research that probably had nothing to do with the ORA labs. They didn't know what we were doing and many of us didn't know what the ORA did. Now it is quite common for scientists from our division to work with scientists from ORA. If you develop a method, eventually it has to be validated by the ORA scientists. There is much more collaboration now (OARSA). • Our research is well aligned but CFSAN could be doing more to fulfill its regulatory mission and its obligation to public health. In fact we are really being constricted to what we are allowed to focus on. The ongoing research is highly aligned to CFSAN's mission but is only a fraction of what could be done (OARSA). • Right now the regulatory side and the science side aren't talking to each other very well. Attempts have been made to improve communication. The working groups were supposed to help, but there's no continuity. The people sitting on them aren't sharing information with the staff so information stops there, and we can't all go to every working group or sit on every one (OARSA). • FDA has a problem with integrating its science into its regulatory people because you need senior, experienced people, but they aren't really scientists anymore at that point. The regulators don't speak science and the scientists don't really speak regulatory. It's much easier at NIH where the mission is very clear. The mission here is mixed (OARSA). • The regulatory side program offices lack scientific depth. They're good regulatory writers, but they don't have the scientific knowledge base that the science side of the shop has, so it's hard to bring it all together (OARSA). • Our projects are aligned based on our collaboration and relationship with the policy office and regulatory labs. I think we are improving in this (OFS/DI). • For the shellfish program and seafood in general, we are well aligned because we're in the same office as our policy counterparts. We work and interact with them a lot. Some of the other groups in CFSAN, do not have this. Based on some of the research outputs (via posters, presentations) that some of the other groups do, they don't seem to have an application to our regulatory mission or Agency goals (OFS/DI). • The working groups are improving the alignment. Policy people and research scientists meet regularly to identify the data needs and discuss if a research project can be developed in that area. In the past, sometimes we only had a clue about the kind of data the Agency needed (OFS/MC).
	• We are heavily aligned because we have interactions every day with outbreak response and compliance (ORS). • My research is geared to regulatory policy to help develop guidelines (ORS). • We do work to support methods being used for regulation. We have a direct impact. We have contracts with companies doing surveys for bacteria in fresh produce. We require them to follow our methodologies. We will forward on the information that we see (e.g., report to

C.2.1.8. Interviewee Observations: How is Microbiological Research Aligned with the Center's Regulatory Mission and Priorities	
	compliance so they can take action; ORS). • Method development aids in regulatory investigations. Sample analysis is important in outbreak investigations. We also channel research results to different branches--compliance, regulatory, others—who use our results to make decisions (ORS). • NARMS data are used by ONADE for their decision making. Data we produce are used by the policy-making arm of FDA (CVM). • They use our research to determine whether existing drugs are approved for new uses or how they are used, whether new drugs are approved based on resistance, and when they are withdrawn (CVM).
Research is based on EROs	• Since we figured out that the working group, EROs, and knowledge gaps existed, those on my team have designed projects around those items. In our next working group meeting, we will address new knowledge gaps that hopefully will foster new projects that we can bring back here and share with other people too. Then we can write a CARTS project and go through the process (OARSA). • ERO's show that we are aligned. They address specific knowledge gaps and the Center's needs. The EROs are a good thing that have been developed, and they are accessible to all of us (OARSA). • They've given us the EROs and the knowledge gaps. We've been told to write our CARTS projects toward those knowledge gaps, which get bucketed into the ERO groups (OARSA). • We're starting to do EROs and prioritize what's needed and what's important. Many scientists are involved in the monthly meetings so they're aware of the priorities, which always feed into the regulatory issues. The Moffett Center is unique. We do a lot with co-preventive control, which nobody else is looking into. Even with virology, right now we're looking at advanced technology, high pressure processing, and how it affects the survival of the virus. This is of value to industry as well because they want to do the minimum processing, but they also have to inactivate the pathogen sufficiently. All of this is preventive control. It's unique in CSFAN and will be important under FSMA (OFS/MC). • Based on the working groups and EROs, I assume they're steering us in the direction they want us to go (OFS/MC). • Upper management is concerned with the EROs and asking if we have current or proposed projects that fit into them, and whether the projects have at least some relevance to FSMA. Many FSMA regulations don't have an exact ERO. It's more of a broad-based design, but upper management looks to see if there's a fit with FSMA and/or the existing EROS. The EROs fit well and do a good job of making sure we're on track with the Center's regulatory mission and priorities as our main criteria (OFS/MC).
Project approval/rejection	• A lot of CARTS projects that we've presented have been rejected with the explanation that they are not aligned any longer with the Center's mission. Right now, we are scrambling to try to coordinate and be in alignment with what the Center wants to do. I've been working on coming up with projects that will fit with the EROs. We are all looking at that (OARSA). • Five to seven years ago people did whatever they wanted, but now we have a short leash. Now we are very aligned. The management did not hesitate to whack some projects that weren't going anywhere. Someone is always going to be unhappy, but it's a trade-off. In academia you might not be able to do a project because you couldn't get money to fund it. In our case, they tell us: "Don't do it (ORS)." • There is no excuse for work not to be relevant to the mission. If projects that are not relevant to FDA's mission are entered into CARTS, they should be cut before they reach final review. That means those who are responsible for reviewing and approving proposed research need to have a clear view of the mission (ORS). • Our management has been slowly trimming projects that are not in alignment (ORS). • This is all we do. We submit our research proposal to our DD, and during the review process, if it isn't aligned it doesn't go anywhere. We need to determine the research needs of the Center. The regulatory needs (ONADE) get the priority (CVM). • All projects must align with the Center's mission and priorities before they can be approved

C.2.1.8. Interviewee Observations: How is Microbiological Research Aligned with the Center's Regulatory Mission and Priorities	
	(CVM).
How alignment is assessed	
Impact on public health	• Our research is geared towards food safety. But we have a problem with priorities. Upper management determines what the threats are, but they have a lot of us down here telling them different things (OARSA). • The Center's regulatory mission and priorities fundamentally require only a low level input of microbiological knowledge relative to legal knowledge and legal interpretations. CFSAN has a secondary or even tertiary participation role in outbreaks, after primary physicians, state health departments, and the CDC, although there is a secondary FDA field lab (CORE) and Central Research participation in outbreak trace-back. We tend to follow CDC after people are sick (OARSA). • We're working on several projects that are validating current methods to detect toxins and developing new methods of detecting toxins rapidly in a food matrix, which are aligned with FDA's mission to prevent foodborne outbreaks by detecting toxins faster (OFS/MC). • Congress and public health needs make it so (OFS/DI). • One of the largest challenges we face is addressing *Vibrio* and viruses in shellfish and food in general. Even though we're not supposed to be doing other types of research here, our findings apply to other food matrices and protect public health (OFS/DI). • We are in line with respect to MB hazards. E.g., norovirus is one of those pathogens that makes the papers, and we try to keep everybody out of the papers. We're aligned with the mission of mitigating that transfer within shellfish. And where there is a problem, we help develop the tools and support the epidemiology, along with CDC, to characterize the outbreaks so we can learn from them (OFS/DI). • Our work has a direct impact on the regulatory issue and public safety. We're not doing anything that's wasteful to the general public's safety (OFS/MC). • We aim research to be applied to problems. This is the most meaningful way to do research. We work on bacteria of interest to food safety. We come up with workable, inclusive methods that can be used world-wide. We belong to ISO and other international committees to help standardize methods to be used (ORS). • It is pretty directly aligned with the mission to protect the food supply, for example, being able to pinpoint pathogen sources and shut down that source until it's safe (ORS). • Research priorities shifted in response to FSMA. We have shifted more to prevention, for example doing ecological surveys so that we can be more proactive (ORS). • We are modernizing the subtyping branch of food-borne illness tracking with the Genome Tracker (ORS). • The NARMS program closely fulfills the mission to improve food safety. We closely work with CDC and USDA to track resistant bacteria (CVM).
Politics/bias	• Regarding the mission and priorities, there seem to be the priorities that the big boys are behind and then there are the EROs, which provide them cover to do what they want. It's big science research and small science research. Big science is helping larger programmatic areas, and is an easier job to do because you're not held to tight standards or accountability. It's always selling the science of tomorrow. For small science it's "What have you done for me today (OARSA)?" • Politics drives the science. The biggest example right now is that everyone is on the genomics wagon, wanting to sequence everything. But they are forgetting they still need basic tools and research to verify the existence of a particular organism in a given media (ORS).
Other	• During the last couple of years priorities have been moving targets. You hear, "We need methods to work on X", then 3 months later, "No we don't need these methods. Now we need something else." Science is long-term; you can't change projects every 3 months (OARSA). • Proficiency testing and methods validation are two of the most important things FDA could do, in any field—not just in food (OFS/MC). • Our research is well aligned because we are so connected to industry (OFS/MC).

C.2.1.8. Interviewee Observations: How is Microbiological Research Aligned with the Center's Regulatory Mission and Priorities	
Don't know	• I don't know about the regulatory mission and priorities. I'm sure I could find it, but they don't sit down and talk to new employees about this. Now there is an FDA 101 course. When I was hired I didn't even know where to find the various divisions. There is a mission statement, but not an overall objective. You have to learn about this by asking questions (OFS/DI).

C.2.1.8.a. What are some example?

C.2.1.8.a. Interviewee Observations: What are some examples?	
WGS	• My group is the training center for WGS. We are sequencing as well (OARSA). • The WGS program has had a good start, but it has lost its way because it's now narrowly focused on getting as much sequence out of a sequencer as possible and using that sequence to develop the PFGE mode, but without any biological significance of what that sequence means, we're not helping ourselves. The bioinformatic analysis of those sequences will give us the information we need. We have to begin to develop approaches that can use all of the data—not just sequencing data, but also microarray data, etc.—to solve the nature of foodborne outbreaks (OARSA). • Some field cultures are sent directly to me from field labs for detecting and for sequencing, and a lot of my lab work is related to questions from field labs. Whole Genome Sequencing also helps to trace outbreaks (ORS). • We are developing and evaluating tools for detecting subtypes and using them to identify outbreaks. We are getting the technology out to the states, because they are doing most of the testing of the food supply and clinical testing (ORS). • We evaluate tools developed by the private sector. We collaborate with 5 or 6 companies providing feedback on how they would help the FDA mission. Important role of our group (ORS). • Our role as PulseNet gatekeeper (ORS) • We've initiated Genome Tracker which is WGS for the tracking of outbreaks It is for the building of a database to help us do trace-back using WGS (ORS). • Working with the states and WHO to be a resource to share sequences. This is in collaboration with Illumina, a technology developer. We are determining how sequencing is best used through this network (ORS). • Developing WGS to replace PFGE in identifying strains. WGS will give much more precise and detailed information that will give the policy makers more confidence in their decisions (CVM).
Efforts related to specific outbreaks	• 2006 Spinach *E. coli* O157:H7 outbreak, 2009 peanut butter *Salmonella* outbreaks (OARSA). • Other initiatives such as "Team Tomato" which is using preharvest preventive control via environment surveillance (ORS). • Peanut butter outbreak in 2010: They had a witness, but we had genomic evidence as well. Salami outbreak in Rhode Island: We worked with CDC, USDA, State labs to identify the scope of the problem. For other old case studies we ran samples to prove the method (ORS). • Use of next generation WGS: We bought our first instruments in 2009 and investigated their use for the next 3 years. 2012 bought desk top sequencers. In 2013 we started pilot test in the field labs to link past outbreaks to food and pathogens. In September 2013, CDC asked us to use the sequencers to investigate a real-time *Listeria* outbreak. In March 2014 we provided genomic data for the first regulatory action. As far as we know, this is the first use of genomic data in a federal compliance action (ORS).

C.2.1.8.a. Interviewee Observations: What are some examples?	
Basic research and methods development	• Select agent research (BSL3 facility): research how to detect the four select agents in FDA-regulated foods. There are many methods for *Salmonella*, but not many for anthrax. FDA needs to be ready when we are asked to screen thousands of samples (OARSA). • We are collaborating with Nutrition Group on how obesity can affect immune response to food-borne contaminants. It turns out that obesity is a risk factor in developing hemolytic uremic syndrome following *E. coli* infection. We developed an obese mouse model over 6 months and the nutrition group had a fatty liver model. Projects were approved, put into CARTS, etc. Then about 6 months later, both projects were terminated without explanation (OARSA). • Egg safety and allergen research (OARSA). • Development of real-time assays to be used in the field labs (OARSA). • Developing technology for microbial strain identification for food-borne outbreak investigations, and developing methods to grow virus in culture. Right now it is impossible to do so (OARSA). • Detection methods for bacteria and parasites which cause diseases and are found in food (OARSA). • Extraction and detection techniques for viruses that can be translated to other laboratories (OARSA). • Identification methods for identifying strain and source via molecular subtyping (OARSA). • Meta-genomics: using non-culture methods for rapid detect of pathogens (OARSA). • We work to improve methods for detection, isolation, as well as to quickly characterize and respond to foodborne outbreaks and minimize public health impacts. It is a big effort, especially given the high degree of foods coming into the U.S. via import (ORS). • We're developing methods to identify the pathogen and the source better, faster, and cheaper so that the source can be shut down more quickly and fewer people will get sick (ORS).
Rule writing and guidances	• Hazard analysis on shellfish contaminants, melamine (OARSA) • Guideline for pistachio processing (OFS/MC)
Surveillance	• Studies in nutritional supplements (OARSA). • Research scientists at FDA confirmed that vitamin ingredient(s) that the manufacturer reported to occur naturally were in fact not naturally occurring. FDA was the only one to do this (ORS).
NARMS	• The CVM NARMS project is an excellent program, but it has only been in the last 5-6 years that it has grown to the point where people are coming to realize we have this tool that can be used to see if things are happening in real time. The use of NARMS and the PulseNet system has worked out well, but it's only recently been used to help drive the search for foodborne pathogens. Combining what NARMS does with the microarray programs at CVM and OARSA into one tool would be helpful (OARSA).

C.2.1.8.b. What suggestions do you have for improving the alignment between research and Center priorities?

C.2.1.8.b. Interviewee Observations: What suggestions do you have for improving the alignment between research and Center priorities?	
Improve communication and transparency	**Improve communication between researchers/line management/upper management:** • Better communication between upper levels of management and mid management (OARSA). • Better communication along all lines. Support from upper management within the Center. Better communication with the regulatory side (OARSA). • There should be more communication, more open dialog, and transparency. I think they are doing this. They are willing to listen to scientists and react. E.g., when someone in industry came to us to tell us they had found a contaminant in fish that they had not seen before, we sent an e-mail to the SSA and they reacted by putting the Office of Seafood on alert (ORS). • There is no vehicle for letting others know what is being worked on, such as a database to let others know that a particular method is being or has been developed (ORS). • Those making decisions in upper management should speak more to the PIs to get a more realistic view of time and effort needed to carry out experiments and projects effectively (ORS). • There is still little communication at the science level. I wouldn't know what's going on at CVM or MOD 1 unless I looked it up (ORS). • Liaisons between researchers and center leadership might be useful (ORS). • We need experienced scientists to interact with the decisions makers at CFSAN. This would lead to more practical priorities (ORS). **Improve communication with program offices, ORA field labs, and stakeholders:** • The scientists should have some input. A lot of this is driven by program offices, but I don't think they always have a good idea of what can and cannot be done in the lab. Until recently, the working groups were always the same people, populated mostly by those at ORS, because those at OARSA didn't even know that these things were going on. I found out about them when I was asked to sit in on one. And then I found out there were all these working groups and all this information on the website. They were very open to having us join the working groups. If we had known that these existed, we could have been involved a long time ago and been more aligned all along. We didn't even know any of this was going on (OARSA). • Better communication between scientists and the program office, less nitpicking and micromanaging (OARSA). • Better communication with the regulatory side (OARSA). • Better communication between the program offices and the researchers and to make the program offices aware of what the different research units can do (OARSA). • We have been told that we should call program office to see what they need from us because they don't know what we do. On the other hand, we don't know what they do. I don't know if they are interested in the things we are working on (OARSA). • Researchers need to get out into the field more, to ORA and state labs and come back and think about where they can provide value (OFS/DI). • Participation in National Food Borne Surveys with partners: Would provide a baseline of where we are and a report card of how we're doing (OFS/DI). • The working groups don't seem to be a good way to bring in the researchers' opinions. In my experience, the working groups want to know how our research projects fit into the EROs, and if they don't, we're told they won't be a priority. One of our researchers was able to get her projects on the effect of processing on virological hazards placed by convincing the working group that she had a good point. That's one good example of how the researchers can influence the projects, but they're few and far between. More often than not, they're setting these EROs and seeing how the projects fit into them (OFS/MC)
Improve communication and	• Direct conversation between policy people and researchers can help develop relevant research projects. BCs don't represent scientists or policy people. They are managers. BCs

C.2.1.8.b. Interviewee Observations: What suggestions do you have for improving the alignment between research and Center priorities?	
transparency	have been talking to each other for years, and somehow they need to make sure the information is transmitted to the scientists or just bring their people so they can be included in the discussion (OFS/MC). • Enhance communication between the field labs and us. We get feedback from time to time, but it often comes too late. We also need enhanced communication within CFSAN--between us and the policy and compliance people (ORS). • Working groups facilitated by a manager would improve alignment (ORS). • A major issue is lack of communication between different groups, e.g., between ORA (oversees field labs) and the Center (oversees compliance). ORA likely has better insight into method deficiencies and issues in commodity testing, but the Center develops the compliance programs. They need to get scientists more involved in these issues (ORS). • We need to have regular meetings with ONADE (CVM). • We need to do more talking with the main people at CVM. We are physically separated, and they forget we are out here. It is hard to know what they need if we don't talk to each other. Within DAFM we have a good relationship with the human food safety group, but outside of that group not so much. They have started an antimicrobial resistance seminar series which should help a lot because we will get to talk to more people (CVM). • We could put more emphasis on the animal microbiology in order to serve the Center better. The research is heavily weighted to the food research (CVM). • We work well with ONADE and help each other out. But it is not always a smooth communication process. We are not always aware of how our research is being used, and they are not always aware of all the research we are doing. Better communication on both parts would help in the drug approval process at CVM (CVM). **Improve/expedite communication of Center priorities:** • Center priorities should be clear to the scientists, and not ever-changing. We can be flexible, but we cannot change our projects every 3 months (OARSA). • I hope they keep the priorities consistent. A lot of times we are working in a "black box". We don't know what they want. The story that comes from them keeps changing. One day they say this is important and then the next day they say they don't have money, so why are you doing that? It's confusing (OARSA). • We need direction from the Center: what the Center priorities are, and what they need us to do. It should be transmitted through the DDs and BCs, so we, as bench scientists can get together to take care of the problem (OARSA). • We need to know right away when the focus changes. It is hard to know what their interest will be. It's hard to predict far out. But still, within the last 6 months we've been told to go to the EROs or join the working groups. These are new things that we didn't know about (OARSA). • Communication from the Center about what is needed and feedback on whether the research is helpful would help improve alignment (OARSA). • They should have a new hire program for people to learn about the Center's regulatory mission and priorities. In ORA, new hires have certificates and courses they have to take on this (OFS/DI). • It's confusing to know what the priorities are. You'll be working on a project because it answers a certain priority, but then FDA changes the priority, and you're stuck with a project they don't really want to continue. I don't know how to change or fix it (OFS/MC). • FSMA came out 2-3 years ago, and we hear they're almost done with the training curriculum, but we haven't a clue what that's going to be. I helped work on the hazard guide, but I'm not really privy to how the whole thing fits together. Many of us would love to see what this curriculum's going to look like when it comes out for training (OFS/MC). **Clarify/improve the prioritization process:** • A clearer strategic plan and EROs might help (OARSA). • Clearer EROs (OARSA). • There could be better transparency in how this process works. Often scientists will discuss among themselves and with some level of management about what a research

C.2.1.8.b. Interviewee Observations: What suggestions do you have for improving the alignment between research and Center priorities?	
	priority should be, and send the priorities up to senior management with input from our line management. Then it comes back reshuffled in priority order. It is their right to do so, but we'd like to know why (OARSA). • There needs to be more information on what the Center feels is critical, and clearer understanding of what is top priority, as well as a broader spectrum criteria of what is going to be supported by the Center and more feedback when projects are rejected (OARSA). • We need better communication on what the priorities are. The working groups come up with EROs, and other information that is posted on the website, but they'll admit the website is months behind. We need a mechanism to have more of a real-time knowledge of what is going on. If our line management were more involved in these activities it would help (OARSA). • When a project moves forward, it needs a check box identifying which priority it's addressing and that information should be clearly stated in the project plan (CVM). **Clarify project review and ranking process:** • There needs to be clearer communication on what projects would fulfill the Center's priorities and why projects are denied (OARSA). • Communication would help us understand and compare priorities. CARTS projects originally did not go beyond a certain level. We had no idea they were going further up until we started getting rejections. That just started happening this year (OFS/DI). • Researchers need to be brought into the decision-making process earlier so they're on the front end rather than the receiving end of the projects. Sometimes researchers have a better idea of what's going on than upper management. We could have more input into what might be a research outcome or goal that would be beneficial, at least to the strategic plan (OFS/MC).
Maintain our research base	• Upper management just wants us to develop the methods; however, without knowledge about which strains are harmful and which genes are making them virulent, we can't develop those methods. You can't find this in a literature search. We need research to understand the system and microorganism better, and then we can develop detection methods. If they limit research, the knowledge needed to develop methods will be exhausted in a couple of years, and then what's next (OARSA)? • When someone tries to get the virus out of food they don't know if it is alive or dead. It may seem like a simple issue, but it is not. At some point we have made it part of our research mission to try to develop methods to identify the difference between alive and dead viruses. I will give the Center credit because they have actually allowed us to incorporate that kind of research into our technology development. So improvement could be, if other things like this come up in the research organizations and they seem a little bit long-term or time heavy, the Center should be willing to go out on a limb and promote some of these things (OARSA). • Sometimes Center priorities may not be what we need to continue on. If you stop researching something that may not be a big problem now, and lose your expertise in the field, you may miss out. Even though at the moment something may be a huge priority for Center management, science doesn't work that way. We gain expertise in our fields by amassing it over the years. There seem to be cycles, and the things we stop hitting on come back to bite us. You have to have expertise that remains intimately involved in the line of research, so that when things do happen, you're ready. Parasitology is a good example of expertise that we have backed away from that is probably lacking in the Center because it's not normally a huge problem. Now we have toxoplasmosis, *Cryptosporidium*, etc. So, now when something pops up, it would be nice to have an in-house expert who could give an Agency perspective of whether it's really a risk or not (OFS/DI).
Reorganize microbiological research	• Administratively, CFSAN is under the OFVM. They, too, have their own senior science board that is trying to get their priorities integrated into our laboratory. Why don't we get the OFVM leadership, the Center's scientific leadership and the program leaders who do regulatory work to say, "Here is one thing we can all agree on?" We don't just need alignment between CPK1 and MOD 1, priorities need to be aligned at the upper levels as

C.2.1.8.b. Interviewee Observations: What suggestions do you have for improving the alignment between research and Center priorities?	
	well (ORS). • It makes no sense that MB is distributed across four offices. Chemistry is together, toxicology is together. The only reason that MB is not all together is because of a man who was here 10 years ago. All the people in this building fought hard to stay in a separate office because they didn't want to work for him. Now that he's gone, we need to coalesce into one MB unit to make sure we don't duplicate or compete for resources. We should be working together, divvying up priorities and getting the work done (ORS). • There is a lot of tension between ORA researchers and the Centers, CVM and CFSAN. There is a lot of overlap. The Centers should provide the research and ORA should concentrate on providing high quality, well organized, coordinated laboratory services for the field. ORA should focus on providing service to inspection and doing surveys, collecting and testing samples. Or if research is to be done in field labs, have that research arm part of CFSAN and bring it under CFSAN research priorities (ORS).
Evaluate impact	• Only when you have transparency and accountability, can you have true alignment. There's no question of the power of genomics. The problem is folks running off the path to how organisms evolved, timeline in course of eons, etc. That's not relevant to what we're doing. It's interesting, and I'd like to do it, but I'm not allowed to. They are showing a couple of successful examples of trace-back. If they develop a database and fill it from here to Timbuktu, that database will be more confounding then it will be helpful (OARSA). • I would like to see evaluations performed the impact of your research. What did the Agency get out of your research? And not just more information or I wrote a publication. Where did you make a difference in how FDA regulates a commodity or sets up a threshold or develops a guideline? Show me how your stakeholders (state, public health) used your results. I think some in upper management see this. But I think many research scientists see the publication as the endpoint, rather than how FDA will use the research (OFS/DI).
Conduct branch/program reviews	• They should conduct a review similar to this one, but break it out in smaller pieces: do branch-wise review, and review each program and its impact, etc., then present all of the results to the Center (ORS). • There should be a total science review of MB projects across the Offices. I don't know of any other group, aside from OFS/MC, which is part of our office, that has routine scientific peer reviews where the researcher gives a 15- to 20-minute presentation and people ask questions (e.g., where is this really going, why are you doing this, and does FDA really need it?). I would recommend a similar process but bring in a committee including people from outside your Office—from CVM, from OFVM—and let the chips fall where they may. The committee could be comprised of BCs from all research divisions—people who are supervisors but also still technically savvy. Each member could write an independent evaluation or maybe each member could give a grade and they would tally them at the end. This might help address the issue of some EROs being on the list simply because there are more people on the committees for them (OFS/DI).
Align by pathogen	• We need to look at occurrence and severity of food-borne pathogens and adjust resources to align with need (OFS/DI).
None needed	• With the establishment of liaison position between our group and headquarters, we are communicating better with industry and the regulatory and policy aspects of CFSAN. We are doing exactly what they need to do (OFS/DI). • ORS is in a great alignment. I cannot speak for CVM. It would be nice if OARSA would provide them with more help. I feel that ORS carries the brunt of the mission-related work (ORS). • Right now the projects are aligned through ERO's and our working groups, which management attends. This has turned out to be a really good idea. We have a better idea of what management wants (ORS). • We do a good job. It's a cooperative effort between management and researchers (ORS).

C.2.1.9. In what research areas should CFSAN and CVM reduce, maintain, or expand its current levels of microbiological research?

The responses to this question have been divided into three tables: one for reduce, one for maintain, and one for expand.

C.2.1.9-1. Interviewee Observations: Areas in Which CFSAN and CVM Should Reduce Current Levels Of Microbiological Research?	
Reduce	
Duplicate research	**Throughout the Center:** • We should look at what CVM does so that we don't duplicate research efforts. Sometimes methods developed for food can be applied for feeds. We don't need two groups developing methods for food and another group at CVM developing methods for feed, because they are interchangeable (OARSA). • There is too much duplicate research: Some of this doesn't have a concrete connection to what's going on, and some of it has already been done. Doing some of this highly academic, research-based work causes issues and is not directly relevant to the mission of keeping our food supply safe. They may be working on finding better probes and primers when we already have a really precise set (if it's 99% accurate, why do we want 99.2%?). For some pathogens they're still working on methods that have already been shown to be less effective. There is constant research on *Salmonella*. It's there, it's done. Every industry out there has the detection method (OFS/DI). • Duplication in detection strategies and method development. Management knows this and is working towards fixing it (ORS). • Eliminate duplication seen in examples like the collaboration study on *Salmonella* detection in animal feeds with culture and molecular methods (ORS). • Currently we have a lot of methods floating around. We need to consolidate people working on methods so there are not multiple groups working on the same thing (ORS). **Between researchers:** • Some scientists see something that another scientist is doing and see that it is working and that the scientist is getting a lot of good press. So those scientists will copy what that scientist is doing, and no one stops them from doing that. That is very frustrating (OARSA). **Some apparent duplication may be useful:** • There is a bit of redundancy when several groups are researching the same thing. This might be useful if some people are working on the method and some people are working on the microbe (ORS). • It seems like we have a lot of groups striving to look at the same thing but this may be more of a byproduct of using the same technologies to answer different questions based on which Center or Office we are in. I am not sure whether or not that should be centralized, whether we should take a method-driven approach, or whether it is good to keep it distributed among the Centers because we are all so different (CVM).
Efforts in specific areas/fields other than genomics7	**Traditional pathogens:** • *Salmonella* research (ORS; OFS/DI). • We should refocus efforts from traditional pathogens to new and emerging pathogens. We don't have to keep doing the same experiments with *E. coli* or *Salmonella*. We have all these others (*Cryptosporidium*, toxoplasmosis, *Campylobacter*, viruses). We can't keep doing the same thing and expecting a different outcome. Those areas have been beaten to death. Let's focus on areas that are still causing illnesses. How can we establish new mitigation strategies? Be more proactive? Think prevention (OFS/DI). • Since we are always looking at food-borne pathogens, we should minimize areas where statistical datasets show we are unlikely to encounter issues (ORS). **Evolutionary biology:** • Evolutionary biology research is not related to public health. There is only a narrow area in which it is justified (ORS). **Surrogate organisms:**

C.2.1.9-1. Interviewee Observations: Areas in Which CFSAN and CVM Should Reduce Current Levels Of Microbiological Research?	
Reduce	
	• People ask us to do a lot of surrogate work. Every organism is different, strain-dependent, and I don't know if a magical surrogate exists (OFS/MC). **Food defense:** • I don't think FDA should be involved with this work as heavily. If it's not naturally occurring in food, I don't know if we should be focusing on it (ORS). **Poultry and livestock management:** • CFSAN should be focused less on poultry and livestock management (ORS).
Genomic research	**WGS:** • Some aspects of genomics should be reduced, especially the focus on WGS. It is being put forward as the answer to everything: "We will have a one-assay system for everything we need." You will always have a need for solid state assays, but some people think these will be obsolete. The problem is we haven't gotten there yet with sequencing. It's not been useful. The amount of money we've put into it hasn't generated any real-world value. It's an information source that you use. Who will do the development of assays and how will you use the development to employ that information? That's where we need to focus, but every time any effort is made, they'll say, "We're not going to do that kind of development because we're just going to sequence everything (OARSA)." • Everyone is being diverted to this project. Everyone is thinking, "If I don't do this, I'll be a pariah. I'll be left behind." For the money being spent, how much is really being learned? Other areas are suffering as a result. Not that it should be stopped, but don't let it be the only thing we do (OARSA). • CFSAN has sequestered funds from programs throughout the Center and are throwing that money at the sequencing effort. They've stopped the progress of other programs for the sake of sequencing. That's wrong (OARSA).
Traditional/basic microbiology research	• Certain areas of MB (e.g., OARSA) are wasting our resources in basic research with no real applications down the road, including fundamental investigations such as research applied to culturing wild-type Hepatitis A, and general investigation into what certain bacterial genes do. Some of these seem to be protected. They have a virology program that hasn't had much impact because they have big ideas with no application. We have two people working in this area here and we work circles around them in terms of impact (OFS/DI). • They should reduce research areas at OARSA that have been surpassed by more modern technologies: OARSA is not moving on from certain technologies that have been "leap-frogged" by more modern techniques like WGS. They are still focusing a lot of money, time, and energy on developing technologies that are obsolete. This leads to a lot of wasted resources that could be used in other areas (ORS). • They need to remove all that research that is 20 years out from being applied or is not applicable or has failed. That money should be moved into the pieces that are working (ORS). • More basic types of science study because our efforts should be focused on higher rather than basic science (CVM).
Method development and validation	• Genomics needs to be expanded at the expense of something. As sequencing gets cheaper, everything will be sequenced. Detection will be done using PCR methods and then it will be sequenced, either as a pure sample or as a mixed sample by WGS. Everything else in between is a bridge technology that costs the same as WGS. We should get rid of all that research and all associated equipment: the optical mappers, the microarrays. It's old technology that never got adapted into the field laboratories. Mass spectrometry will go the same way. I will get hostile disagreement with this view. Someone who has spent the last 10 years developing a microarray doesn't want it to go away. But they haven't been able to show that it is cheaper or faster (ORS). • There are already too many new methods that have not been validated (ORS). • Some methods are persisting in the Agency way too long, e.g., some PCR methods have

C.2.1.9-1. Interviewee Observations: Areas in Which CFSAN and CVM Should Reduce Current Levels Of Microbiological Research?	
Reduce	
	never been aligned, so our field labs have multiple platforms (ORS). • Work on PFGE: It's not research anymore, especially here at the Center. The field lab could do the production work which would free up resources to do research (ORS).
None	• We do not have any fat in the system, so we cannot lose any personnel. If we lose our ORISE Fellows, a whole program may need to be dropped. In academia there is overlapping of expertise because new post-docs are trained by those who are leaving. We don't have this transition planning in our system. We are having difficulties even in covering attrition (OARSA). • Nothing should be reduced, especially in consideration of FSMA (ORS). • None. If there is an area that I think should be reduced, I move researchers over to other things (ORS). • None. CVM cannot be reduced (CVM).

C.2.1.9-2. Interviewee Observations: Areas in Which CFSAN and CVM Should Maintain Current Levels Of Microbiological Research?	
Maintain	
Efforts in specific areas/fields other than genomics	**In general:** • We have good research programs that exist that are being cut for personal and political agendas that are not based on scientific merit. These programs are dying the death of a thousand stabs. Either support these programs or eliminate them once and for all (OARSA). **Virulence assessment:** • The Center has told us that virulence assessment is no longer important; however, they should reconsider research in virulence assessment because pathogens are constantly evolving. They're showing up in new and different environments (e.g., *Listeria* on cantaloupe). It is important to figure out how or why these pathogens are changing, and why they're showing up in other environments. It could help us to create better methods for detection and monitoring, or even help us determine where we might expect to see them next. Virulence assessment is part of that process (OARSA). **Immunobiology:** • Continue research in all the current areas of the Immunobiology Branch: pathogen, allergens, immunological impact (OARSA). **Virology:** • There didn't used to be any way of detecting or determining a virus. Even now, you can't grow it; it's just there. A lot of work still needs to be done. The former CD said, "Anyone who comes up with research ideas in virology, we'll pay them certain money." That was a good idea. It's very hard work, and now we just have one person doing it here (OFS/MC). **Known pathogens:** • We need to maintain proficiency along all the lines of what's in the FDA "Bad Bug" book--all the potential pathogens in food that could be related to humans. They should all have a permanent place in the Agency (not an ORISE, not a temporary hire, not a contractor, not an academician who does not have the Agency's perspective; OFS/DI). • Select agent program: Our program is important because such a limited number of people are involved in the area. When issues come up, there aren't many places to go anymore. The universities are pretty much dried up other than Madison, UC Davis. Even the big companies (e.g., Campbell's) have dried up, which is a shame from the science perspective (OFS/MC). **Produce and seafood safety:** • All the produce safety and seafood safety programs should be maintained (ORS). **NARMS:** • Maintain efforts on the NARMS program (CVM). • Maintain AST as a main focus in our monitoring system. We have discussed whether we should replace that with WGS, but I don't think that would be a good thing (CVM).

C.2.1.9-2. Interviewee Observations: Areas in Which CFSAN and CVM Should Maintain Current Levels Of Microbiological Research?	
Maintain	
Traditional/ conventional/basic microbiological research	• Other governments have taken this same approach of shifting their focus to applied research because basic research is too expensive and they think other countries will do it. But all advancement comes from basic research. Without this foundation, the program will collapse. We need all those methods in the field, but we need a base for that (OARSA). • Everything we have is important in its own way and should be maintained. Sometimes you do need the petri dish to help you with molecular biology (OARSA). • The Center needs to maintain its microbiological research (i.e., maintain the biology in microbiology) and balance its over-commitment to sequencing. 100,000 genomes? Nice piece of PR and nice award, but is it practical? And at what cost? The Center has gone way over its sequencing perspective and is losing sight of the biology of microbiology (OARSA). • There is currently a huge push to sequence everything. We are not allowed to use the term "host response" in any of our proposals because that should be done at NIH: we work on food not the host. How do you do a safety assessment and test for virulence if you don't look at host response? If you are not assessing virulence, what good does sequencing do? Currently, one of the big pushes is to identify biomarkers. What is a biomarker if it is not a host response? When you look at risk assessment, half of it is the offending agent and the other half is host response (OARSA). • The management should encourage some basic, mission-related research that will be useful in the longer term. It would enable us to be prepared for emerging problems. Basic research doesn't have to be the main focus, but it shouldn't be allowed to die out entirely (OARSA). • Conventional MB should remain a focus along with molecular biology. Molecular MB plays an important role in faster detection because MB research takes a while, and there are very few ways to speed it up. Getting rid of the traditional MB altogether might actually create more problems for FDA. From a legal perspective, if you're going to implicate a company as being responsible for an outbreak situation, you have to be able to show that this is the colony we isolated from your location vs. what came out of the food. It's important to develop more MB methods because many molecular methods are based on the MB that you already have. And you can't get your molecular methods to work until you have a minimal level of detection (OARSA). • We should keep a little bit of exploratory capacity, some of the basic science. There is a baseline that should be maintained. The backbone of basic science keeps us steady, and then the applied science alternates between the hot topics of the moment. We do a good job of maintaining our level of expertise in our area. All of these pathogens kind of ebb and flow. There's a balance that should come from Center management of maintaining expertise but allowing focus in the hot topic areas as they arise (OFS/DI). • It's critical to maintain a general, overall good background so you can move people quickly to where the research is required. I see more people going into the molecular end of microbiology. I can't say that's necessarily good. I know very few good microbial physiologists in our area, which is too bad. They dropped that entirely in lieu of molecular biology and we have several molecular biologists now (OFS/MC). • Keep performing basic microbiological techniques in our lab. Our cultures are all historical cultures. It's important to keep those because we can still learn things from them (OFS/MC). • It is dangerous to focus on a few projects. They need to take a look at the big picture of what problem areas may come up in public health and be proactive, allocating resources to look into some of these areas. The current attitude is that the technology they are focusing on will solve all problems, but without microbiologists to isolate organisms, you can't apply this technology (ORS). • Basic microbiological research is going by the wayside outside, but our Agency really needs to maintain this and ensure we are staying on top of it. Outside, there is talk of moving to culture-independent processes and kits. However, if we don't have a culture here, we don't have anything to run through a genomics program. A lot of our litigation depends on having that culture. However, we also have to learn how to integrate culture-independent

C.2.1.9-2. Interviewee Observations: Areas in Which CFSAN and CVM Should Maintain Current Levels Of Microbiological Research?	
Maintain	
	methods and diagnostics and what they mean in case we have to switch over in the future (ORS). • We need to assess the value of classical microbiology techniques and methods and retain that expertise that is valuable. Maybe we should not abandon everything in favor of the newest technology because that newest technology in 5 years is not going to be the newest technology (CVM).
Genomic research	• Instead of just sequencing, they should be doing a genomic/molecular build-out of the research program in field science and convert to molecular-based analysis. Of course, if they felt that any of that would be fruitful, it would be jumped on right away (OARSA). • Meta-genomics, particularly in produce (OARSA). • WGS is the hot new topic. The Center is trying to expand the program by putting more money and funding into it. It doesn't need to be expanded at this point. Before it's expanded, they need to vet it fully and validate it to make sure it's actually capable of doing all the things they say it does or think it can do. There's a huge bottleneck with analysis and pipelining the data. Before FDA expands it and literally sells it to the world, the Agency needs to make sure it works in-house and has a good and reliable plan and mechanism (OARSA). • This project will help us to cut through the trace-back process in an outbreak. E.g., an organism is isolated from pepper in New Mexico, we would run through database, and discover that it appeared 2 years ago in Ohio, so could trace it back to its origin much faster (ORS). • CFSAN currently leads the world in using modern technology (i.e., WGS) for source tracking outbreaks. This leadership should be maintained. Friday [February 28, 2014] was the first time WGS was used to trace back to the contamination source in a legal action by the Office of Compliance against a company. Our leadership in outbreak source tracking is the most important contribution the laboratory has made in the last 30 years (ORS).
Method development and validation	• Microarray should also be maintained, even though it's falling from favor. We need more than one method for identification (OARSA). • Make sure the methods developed are needed and validated. Too much work is being done on the detection part of the method. We have plenty of detection platforms for detecting pathogens and other adulterants in food. But we don't have the up-front part, the sample prep part. Everybody wants to work on detection because it's fun—where the microbiology happens—but the upfront stuff (e.g., how do you handle the peanut butter?) is important (OFS/MC).

C.2.1.9-3. Interviewee Observations: Areas in Which CFSAN and CVM Should Expand Current Levels Of Microbiological Research?	
Expand	
Efforts in specific areas/fields other than genomics	**Virology:** • There should be modest expansion with a caveat: Simply putting different virologists in different locations doesn't necessarily get the job done. Maybe we should be focusing more in produce in one area and more in shellfish in another area. If you start putting more people in these other areas without first getting everyone in line, then you are just multiplying the problem (OARSA). • There is only one person doing the virus cell culture aspect here. There are some people at OFS/MC, but we don't talk very much. Improving the culturing of viruses is one of the Number One priorities. They're not hiring anybody, and contractors won't necessarily get their contracts renewed (OARSA). • Norovirus research (OARSA). • Our capabilities and capacities are limited especially outside of DI (OFS/DI). • We're so busy here. We focus on the produce, and OFS/DI focuses on shellfish and its

C.2.1.9-3. Interviewee Observations: Areas in Which CFSAN and CVM Should Expand Current Levels Of Microbiological Research?	
Expand	
	survey methodology. MOD 1 tends to do more fundamental research. I would love to collaborate, but we don't have the time to even deal with the day-to-day student problem. (OFS/MC). **Food parasitology:** • Parasitology is a good example of expertise that we have backed away from that is probably lacking in the Center level because it's not normally a huge problem (OFS/DI; OARSA). **Other pathogens research:** • Egg safety and *Salmonella* research (OARSA) • Biology of the chicken cecum and its relationship with *Salmonella* (CVM). • *Listeria* (OFS/DI). • Marine biotoxins and bacterial pathogens in seafood (OFS/DI). • *Rickettsia*, *Cyclospora* (ORS). • Physiology of pathogenesis (OARSA). • Pathogen evolution: A time will come when the pathogens will change and we will not be able to detect them. As new pathogens evolve, we need to know how to detect them. When the *E. coli* O104 outbreak occurred, it was a completely new serotype for us. Luckily, we had some people working on it and some tests could be developed to detect it. We are going so molecular, that we are losing expertise in the more traditional MB culture and detection. Moving into completely molecular methods is a big mistake (OARSA). • Microbial ecology (OFS/DI). • Environmental MB (ORS) **Virulence assessment**: • They don't want virulence any more. You can call it signature identification--whatever you want. The things we know the most about are the things that the bacteria have that make people sick. These are the things that are used to identify and track them—to separate them from one another. They are virulence factors. We're not studying what they do to make you sick, we're using them as tags to track and trace and figure out what's in the lettuce. If you want melons in December, you'd better be paying attention to this stuff (OARSA). **Immunobiology:** • Allergen research (OARSA). **Preventive controls:** • Before, industry people would come here to ensure their process or product could be promoted by coming to FDA. It was like a stamp. Scientists spent time evaluating industry procedure, their products, and process. But now we're talking about preventive control. When our inspectors go to a bakery process, for example, they have to ensure the wheat flour coming in has no contamination and figure out what kind of questions they should ask as part of the inspection. But how do we know if they're meeting FSMA standards? Somebody needs to come up with questions first and then the scientist can tell them what they need to do. This processing research is a future need for investigation of FSMA compliance (OFS/MC). • Expanding the preventive control aspect, as we did with Team Tomato. Environmental surveillance needs to be expanded (ORS). • New prevention and control techniques developed by industry should be evaluated by the FDA, perhaps by MOD 1 (ORS). • Research into prevention of outbreaks, e.g., ecology surveys (ORS). **Laboratory proficiency testing:** • Proficiency testing needs to be expanded because this area has been neglected (OFS/MC). **Produce and seafood safety:** • CFSAN should focus more on the critical areas of produce safety, seafood safety and

C.2.1.9-3. Interviewee Observations: Areas in Which CFSAN and CVM Should Expand Current Levels Of Microbiological Research?	
Expand	
	outbreak response. Of the ten most dangerous foods, eight are produce (ORS). **NARMS and antibiotics resistance:** • There should be a major push by the NARMS group, CDC, and FDA to mandate that if a researcher uses PFGE in a study that gets published in a journal, than that journal has to have a relationship with the PulseNet group. A line needs to be drawn in the sand--one that states from here on out everybody who writes about the use of PFGE in a study has to go through NARMS or CDC to vet their studies using the procedures in PulseNet. That would open up relationship-type studies and increase people's confidence in the data set (OARSA). • Antibiotics resistance, which is the biggest threat to public health. Collecting the data about antibiotics is more important than addressing issues in food processing. Antibiotic resistance, our farming practices, processing, etc., are microbiological challenges. There is no robust program to control the use of antibiotics. We are overusing them and that has an impact on public health (OFS/MC). • NARMS needs to be expanded: There are two people working on this for the whole Agency, one at CFSAN and another at CVM. They are so heavily involved in just getting the data in that they're not really sharing it with the rest of the scientists. It should be opened up to everybody. The more transparent we are about it, the easier it will be for others to utilize it. (OARSA). • NARMS should be expanded into all states (CVM). • Evaluation of probiotics in animal use (CVM). • Antibiotic resistance prevalence and mechanism (CVM).
Genomic research	**WGS:** • They're spending money all over the place, but if you find something that works right now the technology is already behind. There needs to be some sort of standardization. On the one hand, people say there are too many pieces of equipment all over, but even if they were in the same place, there still wouldn't be enough capacity to suit everybody's needs. They need to look at how to manage that big chunk (OFS/MC). • Genomics has been expanded, but we still need more personnel since it requires such a major effort (ORS). • We do need to expand the computational side. We've been good at collecting data but not so good at analyzing it (ORS). • We need to increase support in data analysis and especially in the reporting structure. The data are there, but the ability to disseminate the information is lacking, especially as the program grows (ORS). • The genomics programs need to grow. We have been committed to do this, but not sure that we have the resources to follow through. The foundations have not been properly laid. We need better infrastructure for these programs. A LIMS is coming in this year, but it is a little late (ORS). • We should repurpose staff from failing projects into genomics (ORS). • More sequencers and more field labs would be awesome to take some of the work load off of us here. We would become less of a core facility and shift back to more research which I would love. Before we were sequencing samples in-house but now we are sequencing a lot of regulatory samples that come in from the field (ORS). • We will be expanding here, but we need improved communication, coordination and collaboration between the Centers. It's going to be a beast (CVM). Our research program is expanding to develop a good in-house system to do WGS of entire organisms. WGS might replace PFGE, but we should not stop doing AST (CVM). **Meta-genomics:** • We need to expand our abilities to analyze and make sense of large amounts of genomic data. We need to be able to do meta-genomic sequences (the analysis of mixed genetic material). As hospitals and CDC move toward cultureless identification, we are not going

C.2.1.9-3. Interviewee Observations: Areas in Which CFSAN and CVM Should Expand Current Levels Of Microbiological Research?	
Expand	
	to be looking at single isolates, we are going to be looking at multiple organisms in mixed samples (OARSA). • Human gut microbiome research. For applied research: how will it be applied, how can we define it, how can we have robust methods to look at it, challenge with variants, toxicants, and show that it is truly a component interacting with human research. This will require some basic research (OARSA). • We have talked with people at CFSAN about doing some sequencing, meta-genomic studies. We are going into these areas and one of our major problems is storage and fast access. We have talked about making this a Muirkirk Complex computing center. Maybe that would bump it up to a higher level for FDA to consider for funding and building it (CVM). • We need to anticipate meta-genomics for decision making. Historically, there has always been an isolate. We need to research to be able to interpret data from others and to provide tools of our own (CVM). **Bioinformatics:** • We're sequencing everything and not getting benefit because we're not getting relevant information. We're pulling people away from projects that might have more impact in order to sequence when we don't have the ability to analyze the information we're getting (OFS/DI). • We should expand bioinformatics support. We have one person to QA all the data that is coming off the machine. People in the lab can generate so much data it is hard to keep up with all the projects. Each project has a different set of tasks. It could be automated but it is a lot of work to automate it. Bioinformatics is so broad. It includes implementing the GIMS, doing QA, or getting the sequencers on the network (ORS).
Methods development and/or validation	**Methods development:** • More sensitive detection methods for high level detection of low levels of bacterial and viral presences in foods (OARSA). • We need to be more proactive and prepared for new hazards that might occur. Method development would be important, predominantly on the molecular level (e.g., microarray, sequencing, etc.; OARSA). • We should start with the last ten most deadly outbreaks and look to see if we have a method for all of those. (e.g., for *Brucella* there is currently no method). It would probably be informative as well to go back to the FDA or state labs who processed those outbreaks and find out how their method worked. Getting feedback on what methods are working or not working would be useful (ORS). • We are pretty good in detection, but methodology should be expanded a little to become more sophisticated and portable, making it easier for final users. We are a little behind in that (ORS). • Development of rapid detection methods for pathogen detection, as well as collaborative studies (ORS; CVM). • Getting rapid detection methods used in the field labs. We have a lot of really good rapid molecular methods for tracking foodborne pathogens (e.g., qPCR, ELISA, and MS-based stuff) that people here have validated and worked really hard to get up to speed for use in the field. What is it going to take to get the field labs to integrate these modern tool into the day-to-day regulatory testing schemes? FDA's field programs are the thing that is the most out of alignment with reality. This will take our senior leadership talking with their senior leadership. How can we expect industry to use modern methods if the FDA field labs won't (ORS)? **Method validation:** • Methods validation need to be expanded because these areas have been neglected (OFS/MC). • We have hundreds of new methods and people keep inventing more. Academia and

C.2.1.9-3. Interviewee Observations: Areas in Which CFSAN and CVM Should Expand Current Levels Of Microbiological Research?	
Expand	
	industry can develop new methods, but they do not validate because it is expensive, time-consuming, labor-intensive, and not fun. The only people who do this is the government labs because they have to (ORS).
New technology in general	• Emerging technologies. CPK1 does a lot of this, and we should be doing more here. There could be a collaboration between the two Offices on this. It's very important, especially with FSMA. We're going to need to know what kind of *Salmonella* is involved in an outbreak. We are obligated to pay attention to that kind of information. It's our responsibility. If you use some old-school philosophy, you're going to get nailed (OARSA). • There will always be a case for being reactive, but you have to add in this new proactive research attitude, which will necessitate expanding FDA's types and areas of research. Some things will always fall through the cracks. Outbreaks will always occur. There will always be new technology or an error in processing that hasn't been identified before. No one ever thought there would be a *Listeria* outbreak in cantaloupe. These things will continue to happen. They've done a pretty good job of expanding. Some of their efforts into the nanotechnology have been smart. They've also done a decent job expanding into different types of molecular technology, but I'm not sure the amount of money they're putting in is warranted. Maybe they could shift some of that money to more fundamental research because the technology changes so rapidly. By the time they figure out a technology is really good, it's archaic already (OFS/MC). • We shouldn't be afraid to look into new technologies as they come up, but should keep high deference for the old ones that work. We should look into areas where we could develop methodologies that could be put into industry so that they could do some of this control themselves on a preventive level. We've worked with industries who've set up their own lab so they can do their own testing in-house vs. blindly having to listen to what we say (OFS/DI). • We're focused on the pathogens we know which do appear again and again, but it would be valuable to talk to upper management about some other microorganisms that might be emerging that we should be aware of so when something happens, we would be prepared with methods (ORS). • We need to expand resources for new technologies: we are now relying on CFSAN technologies. For example, sequencing technologies and IT infrastructure (CVM).
Emerging pathogens	• We need to have labs that are willing to tackle the tough pathogens, especially those that might occur in foreign food sources, like avian flu virus, TB (especially multi-drug resistant strains). Labs that are currently duplicating efforts could be put on these areas (ORS). • Currently we look at pathogens that make people sick, we should also look at pathogens that make animals sick (CVM).
Traditional/classis/ basic microbiological research	• Some of the basic research into pathogen associations and environments. Why are microorganisms associated more with new commodities you've never seen before and what is the basis for that? Otherwise, we're always reactionary to outbreaks rather than proactive in terms of prevention. Prevention is a key aspect of FSMA, but it is prevention in a defined, narrow perspective. We should be given some freedom to do this (OARSA). • MB research and FDA regulation are both driven by Koch's Postulate. We have to find the live organism and therefore we need MB research. With new developments in molecular biology, we need to close the circle and remove food/drugs containing these organisms from the market (OARSA). • Currently we are not putting enough resources into the microbiological aspects of research. There is too much focus on DNA and genome sequencing, rather than a balanced allocation of resources between people doing the MB stuff (find the live organism) and people doing DNA stuff. We should channel more resources into classical MB research (e.g., why bacteria grows in some foods and not others). The community is

C.2.1.9-3. Interviewee Observations: Areas in Which CFSAN and CVM Should Expand Current Levels Of Microbiological Research?	
Expand	
	divided as to the value of WGS (OARSA). • Research within CFSAN is currently being cut. We are taking positions and money away from research. It needs to be going the other way because the type of research that is critical for CFSAN is only done by CFSAN. If you cut it, it will hurt CFSAN (OARSA). • We need to increase basic research because resources are used up by NARMS and outbreak response. I have worked with MOD 1 and Wiley building, and it's obvious that MOD 1 is looking for things to do, whereas we feel like we have too much to do (CVM).
Antibiotic resistance surveillance	• We are struggling to get drug use information. We approve the drugs, but once approved we don't have a good way of tracking how they are used and when, as that affects surveillance on our end in looking at resistance. We are not always able to correlate how a drug is used and when resistance develops. A better way to monitor that part of the process would help our mission (CVM). • Add companion animal drug resistance surveillance. Currently just food animals are surveyed. Pets are getting antibiotics all the time and people get bugs from their pets all the time (CVM).

C.2.1.10. What are the most important challenges facing CFSAN/ CVM with regards to our microbiology research program?

C.2.1.10. Interviewee Observations: Most Important Challenges	
Staffing	**Hiring qualified scientists:** • Hiring employees based on merit, not some politically motivated decision. Some folks are consistently passed over for those who have less experience and expertise (OARSA). • Getting funding and talent. Without money you can't hire the talented folks (OFS/DI). • Getting more microbiologists to address outbreaks: we need more research to come up with preventive controls (OFS/MC). • In terms of emergency response, I don't know if FDA has the resources to handle a major outbreak, particularly a new one (OFS/MC). • We can't control the budget issues, but we can manage better by hiring those with the skill set and experience needed, rather than basing hiring decisions on favoritism or politics (ORS). • We need more depth. We are spread so thin, they often assign only one person to something, leading to issues with bottlenecks when that person is out. HR is a huge stumbling block for us, both with hiring and firing. We can't get rid of people, even during their probation period. It's really hard to hire people. It is also very difficult to select qualified people from the lists they give us. We can deal with contractors instead, but when the budget is impacted, they are the first to be affected, which makes them unstable. It is also scary how much contractors are supporting some of our programs. If we don't get money for them in the next year, there goes the program (ORS). **Hiring support scientists/technicians:** • There is a shortage of support staff in the labs to help take care of laboratory equipment and to communicate with manufacturers about repairs, etc. (ORS). • Getting the funding needed to get more support personnel (ORS). • When I was at CVM, there was more support staff than here and they were more confident and less downtrodden. When I came here, there were more PIs all needing support and the support staff feels overburdened (ORS). • We need more support staff. We have four ORISE Fellows, but we need to convert them because otherwise they'll leave with everything we've taught them. We need to a process to convert them, or just skip the ORISE program and hire FTE's. We have more projects than we have people. The support staff are overextended. We have maybe four PIs and 30 projects (CVM). **Retention:**

C.2.1.10. Interviewee Observations: Most Important Challenges	
	• It is becoming harder to retain people, especially younger people who have been here 4-12 years, and are well-trained. Because of resources the Agency is not able to offer them full-time positions and they get frustrated and leave (OARSA). • Keeping good personnel: We've always struggled with having people with industry experience. So many people come to us straight out of school without any perspective on industry. Some people are unhappy here, but so much of it has to do with working every day with people you enjoy being with (OFS/MC). **Succession planning:** • Maintaining institutional memory and expertise and hiring new staff that has the expertise we need. *Clostridium botulinum* is a particular strength of our organization here. It's hard to work with, it produces the most lethal toxins known, and the select agent regulation makes it difficult. All the industry people who used to work on bot have gotten out of it because they don't want to deal with the paperwork. Our bot group will be retiring soon. What's going to happen to our institutional knowledge in that group? (OFS/MC). • What's going to happen when all of us who were hired at the same time, 60 percent within the same year, retire (OFS/MC)? **Balance senior vs. junior staff:** • We have a difficult situation in our balance of senior vs. junior employees. In academia, every year you have a fresh batch of kids. In the FDA you have a large group of older senior people and a new wave of younger people, and there seems to be a random hire/no-hire approach. We need more balance and interplay. The classic definition of a good research unit is a senior Ph.D. and a technician or junior associate. Now in CVM, you'll have a senior PI and maybe 10 junior people. In our lab right now there are 2 technicians and 12 Ph.Ds. (OARSA). • A research group is only as good as its ability to bring in young people. That's the only way we're going to get innovation (OARSA). **Effective deployment:** • We need to make better use of the available resources (money and staff). We don't have the luxury of staying in our own groups and ignoring others (OARSA). • The overall CFSAN resources aren't distributed according to the level of risk. Upper management needs to look at the global distribution of the staff and resources. If they're saying we have too many microbiologists, I think the opposite is true (OFS/MC). • **Improving alignment:** • It is a challenge to get people to change projects to be more aligned without causing so much anxiety (OARSA). • Getting researchers connected to programs and commodities (OFS/DI). • Reducing research that is unfocused not directly mission related--research that is being done just because people have been doing it for a long time and no one wants to tell them to stop doing it. They don't fit into to the program. I've found this in my own group and I'm trying to make changes and it's difficult for me and for the people making the changes. People need to work towards the organizational goals. It's not a university. The DDSO has been good in that sense and he's told people that this has got to stop and people are really upset with him, he's made some enemies (ORS). **Lack of hiring within offices:** • We can't hire anymore. Sometimes they will backfill, but they will not expand our FTEs (OARSA). • There is too much uncertainty. Many folks do not know if they will keep their temporary status, or should be busy looking for a new job. We get told it shouldn't be a problem, but every 2 years have to go through the uncertainty again (OARSA). • They want to get projects done, but they don't want to hire people to get the work done. We have tons of equipment, lots of money, but nobody really to get the work done. If we expanded the number of technicians we have, we could take on more projects and generate more data and research (OFS/MC).
Coordination between offices	**Coordination between MB research offices:**

C.2.1.10. Interviewee Observations: Most Important Challenges	
	• There are several MB groups. One is close to upper management and therefore has better access to resources. This may be incidental, but management should be more careful to distribute resources more equally and to be clear as to who is getting what and why (OARSA). • CVM and OFVM priorities are sometimes in conflict. If CVM's business is to see that animal drugs are used and OFVM's preference is that animal drugs are not used, what are we to do (CVM)? **Coordination between MB research offices and program offices:** • Merging the regulatory need and research so there is a comfortable relationship. A pipeline needs to be established to enable casual interactions. The fact that we are physically separated from ONADE hinders interaction (CVM). **Duplication of effort:** • There is redundancy between offices. How do you take on a project that has been going on for several years and has a couple of million dollars invested in it and then support a redundant project that has been going on 200 feet away that is basically reinventing the wheel. One way of eliminating the redundancy problem is a reorganization. As long as we are physically separated from each other and managerially separated from each other there will always be a tug-of-war (OARSA). • Program consolidation between the four MB groups. It has been improved a little, but there are still overlapping projects wasting resources (ORS). • Ensuring that there isn't duplication of effort within our program, including MOD 1, OFS/MC, and OFS/DI. It's a waste of effort and resources (ORS). • The question of duplication of effort needs to be addressed because things may not be as clear-cut as they appear. It may look like three or four groups are doing the same thing but in reality they are not (CVM). **Competition between OARSA and ORS:** • Getting OARSA and ORS to work together: There is a lot of bad blood and I can't even tell you why (OARSA). • There is territoriality around resources and projects (OARSA). • Right now our MB group here is in competition with the MB group in CPK1, because funds are being sequestered from our program to support efforts for their program. That has to stop. We need someone to oversee this who is not partial to one technology over the other, or one group over another. This person should have the budget and the authority to make things happen (OARSA). • Lack of trust between ORS and OARSA is a real impediment. If we could bring everyone under one roof, if we were closer together, there would be more understanding of each other's projects (OARSA). • There have been some rough battles not properly facilitated, so there is a lack of trust that is hurting us (ORS). **Coordination within offices:** • Two branches may do the same thing, and instead of working together they'll compete with one another. This makes it very hard to have a successful research program, but we do have a successful program here in spite of that. I think it's because of the tenacity that people have here. For this site you need to be willing to work with the public and have that collaborative effort (OFS/DI).
Resources	**Funds:** • Congressional funding is a problem: We do a good job and we get less funding. We do a crappy job and have more outbreaks and we get more funding (OFS/DI). • The challenges are always funding. Can we provide the level and consistency of funding to maintain our expertise? If you have good personnel but no funding, they will lose their expertise. Where we have lacked is in the travel budgets and the ability to go to scientific meetings, and the way meetings are seen (OFS/DI). • FDA regulates the whole country. To do so, certain things have to be done onsite and that's expensive. I used to travel, but I don't anymore because of budgets (OFS/MC).

C.2.1.10. Interviewee Observations: Most Important Challenges	
	• There are constant continuing resolutions and budgetary effects. It doesn't help morale when we are wondering whether or not we will have resources. We haven't gone without, but the uncertainty isn't good for morale (ORS). • We may not be able to keep up with technological advances due to decreased dollars. This is felt in the research budget and travel allocations (ORS). • IT has been really well integrated over the past few years, but I worry about their budget. If they can't provide the same services moving forward, most of us will be impacted (ORS). • Because the genomics program is very expensive, the program is very dependent on budget issues (ORS). • At CVM, we need funding to support new technologies and training (CVM). • Funding is a challenge. We don't get the same sort of funding as CFSAN, but when we go to food conferences, we are producing a lot of data and papers with what we get (CVM). **Space:** • Space is our main issue (OFS/DI). • We don't have enough space to accommodate all project scientists in the Wiley building (ORS). **Time:** • Even if we could appropriate a certain amount of time toward research, we always want more (OFS/MC). • We tend to do more "non-research" than we should, e.g., working groups, and not enough time at the bench (ORS).
Communication/ transparency	**In-house:** • Communication is currently top down, but it needs to be both ways (OARSA). • There needs to be more direct communication between bench research and those writing rules and guidance. Without communication, you may think what you do is the most important (OARSA). • More transparency and feedback are needed in research decisions (OARSA). • Establishment of priorities by the Center and transmitting these to the researchers. They need to communicate what they would like proposals written on (OARSA). • The work we do needs recognition. Sometimes this doesn't happen. We need to get the word out. People know what we do here, but they should also know what we do and have accomplished in CFSAN (OFS/MC). **Outside FDA:** • The major problem is the public view of what we do. When you mention that you work for the FDA, people back off. There is this perception that government workers are lazy and overpaid. It's hard to get people to want to work with you in the face of this. Even industry and the states don't want the Feds to come in. They don't want to release their information (OFS/DI). • People have a bad impression of our agency. Most people don't even know we do research (OFS/DI). • FDA should be more visible and let people know more about the good things we do here (OFS/MC).
Integrating new technology	**Genomic research and WGS:** • The large amounts of data produced by genomic analysis require more IT infrastructure to analyze and handle the data. We need to keep up with the technology (OARSA). • One of the challenges is to do the genomic research, which is becoming more and more important, with limited resources and poor organization of facility use (ORS). • For WGS, large amounts of data need to be transferred between the Center, ORA and state field labs. Then results and analyses have to be transferred to CORE and regulatory policy and enforcement offices. There is no structure for these transfers. Who has to listen to whom? And how do they communicate? There needs to be a more formal pipeline structure similar to the current structure for the validation of new methods (ORS). • The genomics data we are generating has so much other research use. We are publishing to NCBI and making it available. But there are so many questions to be asked and answers to

C.2.1.10. Interviewee Observations: Most Important Challenges	
	be found. We are using it for one purpose but there is so much potential (ORS). • We have diverse data coming from satellite images, WGS, CDC outbreak data, etc. that is all fragmented. We need data management systems that can allow people to share data, keep data private, analyze data, and triage actions. Our analyses are too limited to what we generate to the exclusion of what others are generating. At the National Weather Service they do a very good job of this by taking all sorts of data and are constantly updating their models in order to make their predictions. We don't have the agility to respond to things. Our upper management is too bogged down doing things like approving travel to think of the big things (OFS/DI). • Culture-independent diagnostics: The day is going to come, that, when you get ill, not only will the bug be determined by WGS, but the food you ate as well. Meta-genomics will give us this. It's going to be extraordinary (CVM). • WGS is something they want done right now, but if we rush through it, it's not going to work long term. We are not going to gain any value from it over time (CVM). • Bioinformatics: There are huge amounts of data and data storage is needed. We are using CFSAN right now but sharing will be limited. We need to have our own infrastructure (CVM). • There are changes occurring now with how we generate data and how we will be doing it in the near future. We're going to be moving into WGS. Right now PFGE is the gold standard, but at some point it will probably be phased out (CVM). • Setting up WGS in our Center. This is requiring a lot of changes (CVM). **Integrating into the ORA field laboratories:** • Our most important challenge is integration of CFSAN/CVM's methodology into the field labs. They have to start using the tools that their own agency gives them to succeed more quickly and more accurately, including qPCR and WGS. I have to give the leadership credit for holding ORA accountable for integrating modern testing methods and being transparent in their plans (ORS). **General comments:** • The biggest challenge is wise use of new technology (OFS/DI). • There are new ways coming out of how specimens are looked at. The old practices are changing and will eventually become obsolete. How do we keep abreast/ahead of the new technology? We need to know how to use it and how to regulate it (CVM).
Achieving balance in research efforts	**Balance between traditional vs. modern MB:** • Balancing microbiological research with efforts in gene sequencing (OARSA). • We need to have a place that is more broadly accepting of a broad base of science. They will end up with 60 or 70 scientists here who can only do one thing, and they will realize what a pickle they are in (OARSA). • There seems to be this competition to shock the field with the newest and greatest technologies out there. FDA seems comfortable with throwing the older technologies out the window and relying mostly on this new technology. Some technology is outdated and needs to be set aside, but there should be a variety (OARSA). • Transitioning people from old technology to new technology is the most difficult. Getting them [MOD 1, Moffett Center, NCTR] restructured and keeping them happy and productive is going to be very difficult. They will feel like their freedom is being taken away, so they will feel like it is a negative thing rather than a positive thing for the Agency to be productive in its mission (ORS). **Balance between basic vs. applied research:** • I'm not sure whether upper management really values research if this is the first area they cut when they have a budget problem. If they believe basic research is dispensable, it will hurt CFSAN in the long run (OARSA). • In upper management's mind and heart, is research as really important as is often said? It should be and must be, because what we do here is not done elsewhere. If it is important, then it should include not just application of assays already developed, it has to include research and development into that assay, and understanding the technologies (OARSA).

C.2.1.10. Interviewee Observations: Most Important Challenges	
	• The challenge we are facing in terms of research is: is it a real priority for FDA? When we were hired we were always told that FDA is a science-based agency, but in reality they are more focused on regulatory efforts in CFSAN. When the budget is cut, we have no hiring, no renewed positions, but in CPK1 on the regulatory side they are hiring like crazy (OARSA). • While most of the methods we develop and the technologies we use have to be transitioned into the field labs, there's a component of what we do that is for research purposes only. Sometimes people say a particular technology is not useful because it can't be used in a field lab; however, it could still be useful in other ways (OARSA). • One of the big challenges is proving our value as researchers. Some of the Center management that preceded the current management didn't like research at all. Before the last reorganization our branch names included "Research" and we had to change to "Science" because they didn't want the word research anywhere in the Center (OFS/DI). • There's a clear undercurrent of feeling that CFSAN and FDA in general should not be involved in research. If that's not draining on morale, what is? Not to mention the other challenge that so many of our people are just temporary. In my opinion, any researcher can do regulatory work, but regulatory writers can't be researchers. Is integration the answer? Being isolated out here makes a big difference (OFS/MC).
Outbreaks and the changing food supply	• Outbreaks are our biggest challenges: determining how to address them and how we could prevent them; finding ways to do things faster in response to an outbreak. Other challenges are finding ways industry can prevent outbreaks and to keep the food supply safe and educating the public on food safety (OARSA). • Keeping up with changes in the way food is being produce, globalization of food production; and the impact of climate change on pathogen occurrence (OFS/DI). • Anticipating needs: When you don't have outbreaks, people assume everything's OK. Then you start cutting back, and they re-emerge (OFS/DI). • Education of the public on food safety (OFS/MC). • The increase in imported foods (ORS) • The microbiological challenges associated with increased use of antibiotics in farming practices, processing, etc. (OFS/MC).
Leadership/ management	**Leadership:** • We need strong leadership that can convey the big vision and excite people about where they fit into the master plan to address the underlying worry about future instability (ORS). • We need good management to build good teamwork and help with professional development and motivating people. This is a challenge right now (ORS). • In general across CFSAN, there is too much procrastination in decision making and too much caution--a non-risk taking culture, i.e., "Something happened a long time ago, so we can never try it again" attitude (OFS/DI). **Line management:** • There is a really poor attitude, mainly among management, starting at the division level and going up. It is starting to affect morale. It gets in the way of collaborating and gets in the way of the common goal. During the first half hour of meetings they talk about how upper management is out to get us. Some of this may be valid, but is not something we should have to deal with if we can't do anything about it (OARSA). • Poor alignment between managers and personnel causes poor morale, especially when scientists feel their expertise is not being utilized or that their program is being neglected (ORS). **Project management**: • There is a need for project management and improved participation in tracking of projects. We need a fast track process as well as a conventional process to get things done (CVM).

C.2.1.10. Interviewee Observations: Most Important Challenges	
Collaboration	• Need mechanism to get people to collaborate more and know what others are working on. We don't always know what the person down the hall is working on, much less in another building 20 minutes away or in another state. No one really has the time to look at CARTS. They'll do it initially when deciding to do a project (ORS). • When you're trying to get work done, particularly with limited resources, it's your interactions with other people that get things done. It's bad when you don't have or build those relationships, but management seems to discourage that (OFS/MC).
Implementing FSMA	• Not knowing how to utilize talents for implementing FSMA: It's common for managers to decide on the message and people on the bottom to get frustrated because nobody understands them. The perception right now is that they feel like they have too many microbiologists for what's going on; however, they haven't really evaluated or assessed the full needs of FSMA for microbiology, one of which is process-related research that microbiologists could provide. It would be more practical for the scientists to be involved in the review and discussion before the guidance is written. Scientists are needed, not only to gather data, but also to help review any of the technical or scientific basis of the document. Hopefully, with this new FSMA rule, somebody will see this (OFS/MC).

C.2.1.11. How can we better recognize and reward scientific accomplishments/achievements?

C.2.1.11. Interviewee Observations: How Can We Better Recognize and Reward Scientific Accomplishments/Achievements?	
Improve awards/ promotion system	**Limit awards to significant/high impact achievements:** • It would be interesting if we gave slightly fewer awards because giving too many may dilute recognition for those really significant and important accomplishments. If we are still going to reward at the current level then some other level or step should be made to point out those very few individuals or achievements that are really significant, high impact. There should be transparency and dialog with at least some of the senior scientists concerning what should be defined as really significant (OARSA). • Maybe an award needs to be more relevant: based on a set type of guideline or competency one would be expected to have. They give awards away like a raffle prizes. To me an award should be: you did your job, did it well, went above and beyond, and there was something extraordinary about what was done (OFS/DI). • There's a difference between everyone doing their job and someone excelling at it. I'm not sure that doing your job justifies a bonus. It downplays an exceptional employee whose work is well above expectations because everyone has to have a piece of the pie (OFS/MC).
Improve awards/ promotion system	**Fix the rotating awards cycle:** • It is nice to be recognized by receiving a CFSAN award or even an FDA-level award, but it takes away the sense of achievement and accomplishment when awards are given to people just because they haven't gotten an award in 3 years and it's their turn (OARSA). • Most people here need to go above and beyond their general job description daily, to work around and with people. We are required to stay up to date and to be innovators. We have to be extraordinary to survive in this environment. In PMAPS you can have 1% exceptional. We know that it's going to around: if you don't get it this year, you are going to get it next year. Why can't more than one person be exceptional (OFS/DI)? • The PMAP system tends to operate in a way that gives people turns to be the best, which is ridiculous. It seems unconnected to actual success or performance and makes it difficult to know how to succeed within this system. You will get better performance if you give people something to shoot for, rather than just having people wait their turn (ORS). • The annual review process is based on a quota-like system, where they can only hand out a couple "outstanding" designations each year and tend to spread it around, rather than award it to those who deserve it. You can have a successful year and earn an award, and still not get an "outstanding" rating during annual review (ORS). • FDA gives lots of awards. They eventually rotate through everyone. There are so many categories now, if you don't get one, you have to ask yourself what's the problem (CVM). **Encourage nomination of deserving staff:** • To get an award, you have to be nominated. Not everyone has a supervisor that does that type of thing (OARSA). • They should encourage managers to actually nominate people. We receive e-mails about nominating people, but it's one of those mass e-mails that everyone just deletes (OARSA). • Certain groups are recognized more often--maybe because their management recommends them for recognition more often. It would be nice if this were more "evenly applied." Maybe a simpler process or a process that would level the playing field a bit would be better, so that even the busiest managers could nominate someone (ORS). • Make the employee feel the nomination process is open. If needed, encourage people to nominate themselves or colleague(s) for achievement awards. Once the office leadership make their decision, they should update employees regarding who is/are nominated from the office (CVM). **Allow first-level management to give awards:** • Our Center needs to give the first level of management the authority and funds to

C.2.1.11. Interviewee Observations: How Can We Better Recognize and Reward Scientific Accomplishments/Achievements?	
	reward people directly with annual leave or cash. I should be able to give spot awards to outstanding people to say thank you (ORS). **Remove/reduce emphasis on publication as a criteria for an award/promotion:** • The focus for the PIs is publications, but that is not necessarily the best for our field of work. Our mission is public safety. If the focus is on the number of papers, then not all of them are on the mission and public safety (OARSA). • By promoting people when they do good work instead of tying up promotions with publications. It is really hard to publish these days, especially because we are shifting to these short-termed projects which are not going to be published. (OARSA). • It does decrease the incentive to collaborate when you're not going to be first author on a paper. You have to evaluate the benefit when deciding to collaborate (ORS). • We need to recognize work that is fulfills the mission, whether it is published or not. We are different from academia in that not all our work that is important for public health leads to publications (CVM). • For support scientists, our biggest accomplishment is getting our work published. The more we get published, the more our division will know what we are doing. I have no control over publication. I generate data and give the PI the data for the paper. At that point, many times, it just sits there and doesn't go anywhere (CVM). **Increase scrutiny of publications as a criteria for an award/promotion:** • There should be very tight attribution of what work has been done toward a concrete deliverable and who has done it. Some manuscripts have a string of names all the way up to the Deputy CD. You should only get your name on a manuscript if you've contributed to it (OARSA). • People with their names on the papers should be able to honestly say what they contributed. Managers should not be tagging their names onto papers, nor should divisions be putting everyone's name on every paper (OFS/DI). **Include consideration of performance of administrative duties if they are part of a scientist's job:** • I spend a lot of time with credit card purchasing. It is necessary to keep things running, but the problem is that all the work and time I put in to it cannot go into my employee evaluation to be considered for bonuses or promotion because this administrative work does not fit my job description. It bothers that me that we cannot be recognized for doing a good job on this because it is something that we shouldn't be doing (OARSA). **Include awards for support scientists/technicians:** • The process can be improved at the lower levels. At least in our division, they are not recognized enough (ORS). I**nclude/do not include awards for managers:** • Awards should also be given to managers (OFS/DI). • If I go down the list, I notice who got left off rather than who's included. Too many awards are given out, especially in management (OFS/MC). • Maybe at the mid-management level, people feel unrecognized, especially when their group is not doing high priority stuff like sequencing. WGS sucks a lot of the recognition and then others feel short shifted (ORS). **Consult the co-workers of awards nominees:** • Your co-workers should have a say in whether you get that award (OFS/DI). **Expand scientific achievement awards:** • Scientific achievement awards should be expanded. We should have more than three or four categories, and Staff Fellows should be eligible (ORS). **Disconnect monetary awards from merit awards:** • They need to re-visit how they do it and maybe disconnect some of the awards from monetary awards because the monetary awards are driven more by unions. The award should be tied to a merit or an achievement. If you have two people who both deserve the award, divide the cash pool between them (OFS/DI). **Improve the public recognition aspect for awards:**

C.2.1.11. Interviewee Observations: How Can We Better Recognize and Reward Scientific Accomplishments/Achievements?	
	• They certainly could do a better job in public recognition, even in the interdepartmental awards. They could make them a little more ceremonial (OFS/DI). • More public recognition of achievements is needed (ORS). • There could also be some more in-house recognition in front of group at the office level. It doesn't have to be monetary. It is not that they don't do it, but should do it a little more (ORS). **Increase transparency in the awards system:** • It is not clear sometimes why certain prizes are given. In the PMAP system, we are not sure how we rank among others. More transparency would be beneficial (ORS). • Awards criteria should be credible, transparent, and accountable (CVM). **Reduce favoritism/unfairness:** • The reward process is not fair. There is favoritism. Some people are able to work on whatever they like and have projects that lead to quick papers and therefore promotions. Currently promotions are based on publication. If everyone is not given the same opportunity to publish, this is not a fair criteria. There is a big difference in the rapidity of publication in traditional microbiology compared to molecular techniques. It might take me 15 years to have the same output as a molecular microbiologist has in 2-3 years (ORS). • We need more fairness when it comes to PMAPs (and promotion committees). Too often we have upper management who are not fair and there is too much favoritism. On these committees that determine, assessment, awards, and promotions, no one is responsible for insuring the ethical conduct of the committee. If they want to insure employee dedication, the employees need to be treated fairly (ORS). • Right now, the process is not fair. People who get certain designations (e.g., "excellent") may not really deserve it. Meanwhile others get FDA or outside awards and that can go unrecognized. Recently, someone received a very high FDA award and none of the management showed up at the ceremony (ORS).
Increase acknowledgement/ appreciation	**Personal acknowledgement from management and co-workers:** • Just hearing from the management (including at the branch level) that you are doing a good job and contributing to CFSAN's mission can work wonders. We don't hear enough of this from CPK1 (OARSA). • I'm OK with just being told I'm doing a good job. That still happens, but some days are harder than others (OARSA). • If upper management would recognize the lowly researcher sometimes (after their efforts have been implemented), that would be nice (OFS/DI). • Just being appreciated. All it takes is someone saying I know you worked hard and we're grateful for your hard work. Having a good relationship with my manager also helps: knowing that if I need something I can go to him and if he needs to go to bat for me he will because he knows I'm working hard (ORS). • It is nice to let people know that what they are doing is good--even a simple thank you. Even in my performance review I've never heard it here. It's not that they don't appreciate it, but that it isn't verbalized (ORS). • By daily interaction and thanking people for what they do: If you know someone is stepping outside what their normal duties it would be valuable to say "Thanks, I really appreciate it." FDA is good about the annual awarding thing, which some years it is fair and some years it is not fair, depending on who is in charge. But the daily interaction with your colleagues is really important (CVM). • I prefer personal acknowledgement rather than broadcasting. When I get an e-mail saying thank you from one person to me it means everything (OARSA). **Hold celebrations at the division level:** • There needs to be a celebration aspect to achieving goals. We're so busy that when we do achieve a goal, we're half-way through six other half-done things and it doesn't feel as if there is time to celebrate. We need activities that foster team building. Our

C.2.1.11. Interviewee Observations: How Can We Better Recognize and Reward Scientific Accomplishments/Achievements?	
	DD tries, but the pizza money has to come out of his own pocket (ORS). • Part of the problem of moving people out of basic research is that they will feel unappreciated. We need to make them understand where they need to go and appreciate them when they go there (ORS). • Maybe instead of a big ceremony, recognize achievement at a division meeting. People are working extraordinarily hard and because of that we don't always thank each other like we should (CVM). • Within DAFM we have a lot of parties. It sounds dopey but it brings people together and we celebrate successes. We have little gifts that we give to say thank you for doing such a good job. We also try to make sure people know that a new paper has been published but are bad at communicating that to the rest of CVM. We are not really great at telling each other how wonderful we are (CVM). **Increase recognition via the website and other means:** • If we had a web team that could keep up with the latest publications, and research activities, it would help us get recognized internally and externally. In putting together a website for the WGS group, it has been so enlightening to read peoples' bios, see the papers they've published—I had no idea (ORS)! • We should use internal means such as web sites, marketing, newsletter, etc. to recognize people's achievements or research findings (CVM).
Increase acknowledgement/ Appreciation (continued)	**Acknowledgement for members of the Commission Corps:** • Within CFSAN, we get blown away compared to other agencies when it comes to highlighting the Corps officers. Some of it's the Good Old Boy network up there. It's not on a par with IHS (Indian Health Service) or CDC. Their officers achieve a far better track record when it comes to awards and achievements. The Center should be better taking care of all its officers whether they're in DC or satellite labs. We serve FDA and the Public Health Services. We have to be deployable and do a whole bunch of other things in addition to what we do for the Agency. The way the awards program works is that the officer is initiating his own awards, and that's terrible: those who aren't doing anything else but self promotion get the most ribbons. And now the Commission Corps has gone to ribbons as a measure for promotion. I have solicited colleagues to recommend me. It is a time-consuming process, but ultimately, your management should promulgate the award (OFS/DI). **Acknowledgement in the scientific community:** • We're given awards for novel work. That's a nice recognition. If colleagues in the field recognize our work, that's a good accomplishment (OARSA).
Promotion/ Conversion	**Convert Fellow:** • Let us make these great employees permanent. The Center management will tell us that they aren't hiring elsewhere in CFSAN. Don't they think we talk to people in other buildings (OARSA)? • There is a disconnect when a scientist has been told they are doing great work, but they are not converted (OARSA). • Conversion is so important, especially for the scientists who really prove themselves. People high up in this Center are very much against converting scientists. They say they don't want to make the financial investment, but sometimes when you have really talented scientists, you need to invest in them (OARSA). • The biggest thing would be to retain this work force and hire people. Someone over here needs to get some FTEs for this office and these divisions. It makes me sick to think of some of the people we might lose. And it's a waste of money in terms of all the time put into training and getting them acclimated (OARSA). • We do have award ceremonies several time a year and we get certificates and that's helpful, but what we really need is to make the Staff Fellows permanent (OARSA). **Increase opportunities for advancement:**

C.2.1.11. Interviewee Observations: How Can We Better Recognize and Reward Scientific Accomplishments/Achievements?	
	• More opportunities for advancement, maybe a group leader position. I haven't seen the opportunities to advance within science while here. People shouldn't be allow to stagnate. There should be more opportunities for advancement. Maybe there could be more of a leadership rotation policy, where someone is lab chief for 5-10 years and then they step down to give someone else a leadership opportunity. Or maybe there could be some shared responsibility. We need an innovative way to develop people as a reward (OARSA). **Improve promotion system:** • The system is corrupted. The decisions are made more by politics and alliances than merit. There should be some consequences for being unproductive. It's so corrosive to the young investigators to have GS-14's around who haven't published this century (OFS/DI). • The peer-review system for promotion is not very good. It relies heavily on numbers of publications, but doesn't take into account other types of activities that are important. At a certain level, we go for cyclical 5-year reviews. On paper you can be promoted based on these. In reality everybody stays the same. If you want a promotion, you have to put in a promotion package. This process minimizes achievements: those who are doing extremely well get lumped in with those doing just OK. It doesn't really allow a mechanism for people to stand out (OFS/DI).
Promotion/ Conversion (continued)	• With fair and efficient promotions. Some people are promoted quickly without working hard due to good personal relationships. It also takes too long between passing peer review and the promotion going into effect. There is poor communication between HR and the peer review process (ORS). **Change criteria for promotion of support scientists/technicians:** • Support scientists are huge contributors to what we do. We should acknowledge their work, and not just in terms of awards/accolades. They should be provided with better investments so they can feel that the work they put out is rewarded and they can move up/on and create successful careers for themselves and not just in this one niche (CVM). • There is a ceiling for support staff. For us to advance to GS-13, we have to leave the lab. I understand that ORA and CFSAN are promoting support staff to GS-13s (CVM).
Give cash awards	• They should have a cash award program for research projects. Plaques are nice, but they don't pay the bills. The same is true of ribbons for the Public Health Commission (OFS/DI).
Make travel a reward	• Allow people to travel and attend more meetings. Awards don't mean much to the scientists here (OARSA). • You could consider travel to meetings an award, especially if you've achieved notoriety in your area and are an invited speaker at a symposium. That is a reward to a scientist (OFS/DI). • Scientists are not motivated by money in FDA. They are rewarded by travel--to Canada, Europe to present their research. If you cut this, you kill their ambition (ORS). • It would be helpful to lift restrictions on travel to scientific meetings since it is beneficial for those in the larger scientific community to recognize our work (ORS). • Scientists are told they get to go to one meeting per year. What about those who are very productive and who may be invited to several meetings per year? It is an honor for the Agency to showcase your scientists at such events. Instead of rewarding those who are truly productive, everyone is treated the same (ORS). • FDA already gives tons of awards. A good way to reward accomplishments would be to allow travel to more than one meeting a year (ORS). • They could dump their whole incentive program if they would allow people to travel and do the things that professional scientists do (OFS/MC). • It's a reward for people to attend conferences, but that's being taken away now. The amount of justification you have to go through to attend a conference is absurd

C.2.1.11. Interviewee Observations: How Can We Better Recognize and Reward Scientific Accomplishments/Achievements?	
	(OFS/MC). • In addition to monetary or time-off awards, they could also reward people by allowing them to present somewhere (ORS). • In our field, many times the work is its own reward. People in this field are self-motivated. Management should recognize that and allow us our "trips" and morale boosters. What really motivates me is the ability to do my job well and go and talk to the people I know (OFS/MC).
Give time off awards	• Hours off don't work. A month could be put to good use, but 15 hours isn't much (OFS/MC). • I've worked here for 23 years and for at least the last 20 years I've had use or lose time that I've lost. If you give someone a time-off reward and they're losing time-off already, it's irrelevant (OFS/MC).
Invest in ongoing/new projects	• Just let us do the research. This is more the first step before recognition (OARSA). • Most people would say that instead of receiving a piece of paper, they would like to get more funding for their research. If you really think that the work is good, give more seed money or an ORISE Fellow. You could still make an announcement that Joe Schmoe got $10,000 for his research, but we don't need the hors d'oeuvres (OARSA). • Give more independence, more resources, and more access to decision makers (OFS/DI). • Allow scientists to participate in research projects outside their position description: At CVM we have a very open management and open form of communication but to a certain degree if you are in a specific role it is very difficult for you to branch beyond that. It may hinder people from wanting to contribute outside of their given position description (CVM).
The Center does a good job	• We do a good job recognizing and rewarding scientific accomplishments and achievements. I don't know anyone who's not being promoted or recognized for their accomplishments and achievements. We send out notices announcing papers published. That's a congratulations. Somebody gets promoted, we all say congratulations (OFS/MC). • CFSAN does a good job in recognition and promotion. There are a lot of awards (ORS). • Generally, CVM and FDA do a good job with awards. When I first started, they used to give token gift cards. Besides saying thank you, that was a nice way to show appreciation. You can never say thank you enough (CVM).

C.2.2. Organizational Management

C.2.2.12. How effective is the current organization structure for management of CFSAN's and CVM's microbiological research?

C.2.2.12. Interviewee Observations: How effective is the current organization structure for management of CFSAN's and CVM's microbiological research?	
OARSA	
Fairly	**Office and division/branch levels:** • The basic structure works well for the individual sections but, there needs to be more overall organization and coordination of sections. • Middle management doesn't have much power, influence or knowledge of what the Center wants. • The main problem is that not a lot of permanent positions are filled. A lot of management positions are "acting" so they can come and go at any time. • Our organization is dysfunctional, but work is still getting done. There was talk of merging our two MB Divisions over here, but it was badly handled. Instead of approaching it with a proposal and asking for feedback and talking about it, they just came

C.2.2.12. Interviewee Observations: How effective is the current organization structure for management of CFSAN's and CVM's microbiological research?	
	over and said this is what we are going to do. It didn't go well. In our division, leadership is a problem, partly because it is not a permanent position.
Somewhat	**Center level:** • When upper management tells us what research to do, the scientists are rarely consulted in the decision-making process. We would like to know why this is important and how it has come about. We are talking about human resources--scientists who spend many of their years learning and developing in an area. • We could really use more frequent meetings with upper management. The physical distance is a hindrance. They probably meet more often with the people in the Wiley building because that's where they are. **Office level:** • It works for some, not for others. The Office should be allowed to manage itself. We have people who have been here for a number of years—give us a chance to assess things on our own. We have a good working relationship here.
Not very	**Center level:** • It is not very effective because we have four different microbiology groups in different locations. Each one is doing different things. We hardly ever come together. We are 10 miles from CPK1 and don't know what goes on down there. We meet them at our annual scientific meetings and sometimes we find out we are doing the same thing. When I joined there was only one division of microbiology, so you knew exactly what everybody was doing and there was no duplication. • We have a two-office paradigm that doesn't work unless you have well-defined missions. **Office level and division/branch levels:** • We are directly managed by the Center, and middle management is ineffective and has no authority. • The BCs, deputy OD and OD don't make any decisions. It used to be that the mid-level management would get a budget and make decisions on priorities within our group. It's all decided at the top levels now. • We have instability of management in our office. It gets to morale. • The physical separation from CPK1 makes things more difficult. And there seem to be personal "vendettas." It seems as if some of the managers over there just don't like us. Because of that, a lot of the managers here resent the management over there. It's a childish back-and-forth thing, but at the same time, peoples' jobs and livelihood are affected. There are politics in everything, but it would be nice if there were less in science. • It seems we are in a transition period because upper management is trying to change as a result of FSMA. That adds to the feeling that we are not very well organized. • I am in a branch that is not actually doing what the branch title indicates. So that shows that it probably might be time for some reorganization.
Ineffective	**Center level:** • Having CFSAN in OFVM is problematic. No one is sure how they are supposed to work together. OFVM is supposed to be driving the research, but we don't see it. Both OFVM and CFSAN are headed by lawyers, so it's hard to explain the science to them. It would be good if we had more science in the mix, or if someone could figure out this structure. We are told that OFVM is the highest priority, but we can only fulfill CFSAN EROs. How can this be? • I'm glad we now have a single OFVM; however, I see issues in it being another layer of bureaucracy. Furthermore, there are groups of scientists at the OFVM that really should be given more authority, rather than just advisory roles. • I have been in the group for 4 years but I do not know the "behind the door" policies and decisions. I don't know what the different functions are for ORS and OARSA. There are a lot of programs they are doing and we are doing. I feel it is the lack of leadership at

C.2.2.12. Interviewee Observations: How effective is the current organization structure for management of CFSAN's and CVM's microbiological research?	
	the upper management level. • Upper management fails us by not being clear and by not treating us as valuable people doing necessary work. They have let us know that they are not sure whether they need us or our programs and that they haven't decided what to do. If people are confused and feel lost and not valued, they can't be productive. **Office level:** • We have some very good managers, but also have some very bad managers. The problem lies with its instability. Many of these positions are acting. My boss is acting. His boss's boss is acting. Everyone is in this feeling of limbo. • It is not working. There is no cohesiveness and no direction. We seem to be on our own. We can work well on our own in our niche, but this is no longer accepted by upper management. **Division/branch level:** • This past year we sat down as a branch without leaders, and found that we were in agreement that our BC and our DD are ineffective. We decided to start asking questions at the branch meeting to get the information we needed. We did that. It kind of worked. We decided we should have branch meetings every week so we could present science one week and have administrative discussions the next. It never happened. Then we decided that people who attended working groups or meetings should discuss what they learned, but that isn't part of the agenda. We all try to do what we can to bring things up that others might find important because we know it's not going to be brought up any other way.
OFS/DI	
Very	**Office level:** • We like it here. We don't want to go to another office. Our OD likes us and stands up for us. We don't want to be part of a larger group. We don't want to get lost in the shuffle where we would probably suffer research- and funding-wise.
Fairly	**Center level:** • The establishment of EROs to help coordinate what MB is being performed and what is identified as being priorities for the Center have helped; however, there are still challenges because certain groups are still doing just what they want to do and there is no accountability for some and no consequences. **Office level:** • We are our own division, and we feed into OFS. We are one of the few science branches that feed directly to the regulatory office for compliance. We get a lot more feedback from their needs, and it helps us direct our research. Even before upper management hears about it, we are hearing it from the Compliance people (shellfish specialists). We have ORA people in each region, and they are the first in line to see potential issues that the regulations are causing or not addressing. Our OD and Deputy OD have always been very supportive of this program. I think this is because we've been on point in delivering things that keep them off the Hill. • Our current structure is good. We were reorganized in the last couple of years. We have close ties with our policy office and that's the way it should be for everyone doing research-related work. **Division/branch level:** • We have staffing issues now because our DD left and it takes a long time to fill that position; however, I don't think we've missed a beat as far as the research program and our products go.
Not very	**Division/branch level:** • If the organization structure were more organized and concrete, it might affect some of the challenges. We have so many acting people in charge. I don't know why they're not making these people permanent. Why don't they appreciate how this affects us? That we're losing faith in the people up there? And yet, I'm not sure it affects us at all. We're

C.2.2.12. Interviewee Observations: How effective is the current organization structure for management of CFSAN's and CVM's microbiological research?	
	fairly productive in spite of what goes on.
OFS/MC	
Fairly	**Office level:** • We are lined up nicely. We were realigned 7 or 8 years ago because of our remote location. Our DD is local, and our OD is in CPK1. We have good communication and emails with the Center. We watch meetings on video, which they try to schedule once a month to provide information on CFSAN's goals. • The structure for our division and Dauphin Island is pretty good because our policy people and research organizations are in the same office.
Somewhat	**Division/branch level:** • The most recent reorganization within our division makes sense. • We have to follow the chain of command, and communication always stops between the managers. I had an issue with an ORISE staff member who I wanted to have replaced. After communication through my first line supervisor to upper management, he was assigned to another PI and I ended up with no one. How can that word make its way back up the chain of command so top management understands the consequences of its decisions?
Not very	**Division/branch level:** • There's been a huge push to have "less" managers now. However, in my lab, my boss isn't running the show, I am. But I'm not the boss: I have no input into anyone's review, and to get the job done I have to beg, borrow, and please people because I have no authority. They're not eliminating management, they're just making it harder.
Ineffective	**Division/branch level:** • Why are there three BCs and a DD for the number of people we have here? I don't want to eliminate the BCs, but it seems inefficient. One person could lead this whole crew of people. • There is a problem in how people become BCs and supervisors. In my mind, the best people who are wonderful scientists become managers, BCs, etc., and that's not where their strengths lie. With all of their science knowledge, they actually can become a problem in getting things done. They're fantastic scientists, but marginal managers. This seems to be consistent throughout FDA—people who are fantastic scientists are rewarded by becoming something they aren't.
ORS	
Very	**Center level:** CFSAN is fairly streamlined. The new DDSO is straightforward in what he wants you to do. You don't have to use your ESP. No changes are needed. **Office level:** • We are very good at accomplishing our mission, and we are able to publish. • Our structure is straightforward. We report to our supervisor, who reports to our DD, who reports to our OD.
Fairly	**Center level:** • There have been some recent personnel changes in the management area that have made it better--areas that needed a stronger person who wouldn't just go with the status quo. There has been some redundancy. That can't be addressed in a division, but can be at the center level and this is why they are putting the people in key positions. • Within the Federal system, it is very difficult to make the structure more effective. It would be very difficult to improve. • Up to DD, it's fairly effective. Above that, I am not sure. The chasm between our division and the microbiologists at OARSA creates a major waste of resources. The scientists can't be integrated right now: the individuals do not work well together, and line management has not effectively encouraged coordination. Within our genomics program, each group is allowed to keep separate sets of data. We have been trying to

C.2.2.12. Interviewee Observations: How effective is the current organization structure for management of CFSAN's and CVM's microbiological research?	
	build a structure more FDA-centric, but those at OARSA won't participate, so we can't see their data. There would have to be a major culture shift to fix these issues. **Division/branch level:** • There has been a desire to keep the identities of the two microbiology branches in ORS separate. They used to have distinct roles (traditional micro methods and molecular methods). There is so much cross-talk presently between the two that I am not sure it's the best way to organize it. • Within our division, we are in the process of reorganizing into teams. It's good, and will be better. There are good relationships within the line management. Currently we are considering a reorganization, moving people around and I don't worry about it being a problem, because we have a good supportive relationship and not an adversarial one.
Somewhat	**Federal agency level:** • The offices are not integrated well. We need to pull the people in who are on the outside, and align them using the funds and/or moving everyone to the same place. Being closer matters. We have lots of conflict with CDC because we are in different places and have different streams of money. They're more clinical and we're more food and environmental. I'd like to see CDC move up to DC and have FDA control their budget. Or vice versa. But of course this is a secretary level move and no one wants to do this. **Center level:** • There seems to be tension between OFVM and CFSAN. There are some overlaps in what they do, and they don't always have the same priorities. This tension needs to be resolved and responsibilities delineated so there isn't so much overlap. • The groups (ORS, MOD 1, OFS/MC, and OFS/DI) are too spread out. There is no coordination between MOD 1 and here, and there is competition among internal parties that we should not have. There is no central point for coordinated effort. Some projects are duplicated at different sites. They may be 2 or 3 years along before someone realizes there is duplication. • We have too many microbiological offices within CFSAN and this may lead to some redundancies. • At the division or office level down, it's pretty good, but above that it gets in the way of the lower levels. The different levels of management seem to interfere with one another. • Upper management is too large. At the lower levels it's okay, but there are many upper levels. It's like the FDA is an umbrella and the researchers are the stem. **Division/branch level:** • They've made an effort, with the RACs to have more flow. We've been pretty effective with our main directives. • It's much better than several years ago, when it was not very well organized. Everyone used to want to go directly to the DD and skip over the BC. This can still be an issue if the BC is not decisive. • For our program, there isn't a problem with the structure, because we are have been successful. Part of this is because we've been allowed more flexibility and a quicker response by going around the strict line management in both directions. • The problem is that we have a BC who is managing 40-50 people. They are instituting RACs, but many are not qualified to be managing anyone. Many professionals have expressed to me their frustrations with current line management. There's some flexing of power: some are too controlling and micromanaging, others are too busy to sit down and have a conversation.
Not very	**Center level:** • You have four separate MB units in four separate places and scientists are scientists and then they end up competing. A lot of that could be mitigated if we could unify the clans. • The research priorities are being micromanaged from high up, e.g., by Center Deputy Directors. These managers should have other priorities to respond to, rather than micromanaging at the researcher's level.

C.2.2.12. Interviewee Observations: How effective is the current organization structure for management of CFSAN's and CVM's microbiological research?	
	Division/branch level: • Line management at the division and branch levels is not strong enough to express their opinions or perhaps do not want to. Those that express adverse opinions are ostracized. When the time comes to hire line management, they hire those who are obedient.
Ineffective	• There is a lack of professionalism and objectivity. • The priority here seems to be loyalty and favors, which is not effective.
Not sure/no idea	• There is a need for leadership to promote a big vision that would help overcome pettiness and fear and elicit excitement to become a high functioning organization. I'm willing to work a very hard 40 hours, but it's difficult when you feel like 80% of the work is done by 20% of the workforce. That's a problem with government. The Centers could do a better job of managing the staff resources they have. It might require removing or re-motivating some of the staff. • Things are well managed in my Branch, but I don't have any idea about the big picture. Leadership should make an effort to let us know how what we are doing relates to CFSAN, how it fits in. This would give us a sense of accomplishment.
CVM	
Very	**Division level:** • We have a very tight structure. There is no hobby research, no "I wonder what would happen if." It's all got to be aligned. • Our division is very self-motivated. We are all team players. We know what needs to be done and we do it. We don't need a lot of management. It is a well-run group, so if management were not effective it might not matter. Our first-level supervisor is very available and a good manager. Her boss is new, so I don't know how what his impact will be.
Fairly	**Center level:** • Within CVM/OR it is fairly effective, but I am not sure how effective it is with the rest of CVM. Communications from the Center executive board filter down to us but we don't necessarily know what was discussed. We are communicating more with CFSAN, but there is not a lot of cross-talk at the higher levels between CFSAN and CVM. **Office level:** • We have a new OD. So far what I have seen is good, I'd like to say very good, but he hasn't been here long enough to get that assessment. **Division level:** • The organization path is unclear since most of what we do is NARMS related, but NARMS is separate from DAFM. Our new DD will take some time to become a good leader. We've all been in this Division so long, that we know what our role is. We don't have time to sit around and wait for the manager to tell us what to do, we just do it. There is a problem with communication sometimes. NARMS is the priority of this Division, but the NARMS Team Director is not our supervisor. So when there is a problem, we don't always know who to go to. This causes some confusion and problems in communication and can lead to bad feelings, but is doesn't slow down the work. • If I have been working for one PI and they leave, I might end up working for several different people. I can't decide who I work with myself. At that point, I expect management to take action to put me with someone I enjoy working with and in an area where I have expertise. Sometimes, I have had to approach the PI I would like to work with myself. I don't think that's right.
Somewhat	**Division level:** • It is getting better. There is better communication on current projects and priorities. In the past we've had a lot of projects, but were not always sure what the priorities were. They are doing a better job of communicating the priorities to the people doing the work so they know what to put first.
Not sure/no idea	**Center level:**

C.2.2.12. Interviewee Observations: How effective is the current organization structure for management of CFSAN's and CVM's microbiological research?	
	• The process or structure to me is unclear, at least between CFSAN and CVM. I have a pretty good idea on how it works within my office and Division but beyond that it seems hard to judge.

C.2.2.12.a. Please describe a structure you believe would be more effective.

C.2.2.12.a. Interviewee Observations: Please Describe a Structure You Believe Would be More Effective.	
Reorganize research groups in the Centers, Offices, Divisions, and/or Branches	
Let OFVM dictate organizational structure	• OFVM should be the governing body that dictates the organizational structure within CFSAN and CVM. In reality people in OFVM are being told what is going to happen in CFSAN and CVM. That flow of information is going the wrong way (OARSA).
Unify microbiology research across Centers	• We have to consolidate, bring microbiology all back together again under one person who would trickle down the needs to experts underneath. When I joined FDA, the Office consisted of two groups: the Division of Microbiology and the Division of Chemistry. Now it all seems to be commodity-driven, and the scientists aren't talking to the program people. Ca. 2000s, when the powder infant formula events began to occur, our management brought all the scientists together and told us to try and find something that worked. A few years later, we had a method. It's still not the greatest method, but that's how it works. I see the same thing going on with *Salmonella*, but the competition going on with ORS, OARSA, etc., is now starting to dilute efforts to find a solution. All of this is essentially diluting our capabilities to serve the American people. These turf battles have to stop, no matter how good intentions are—all of that just stops the effort (OARSA). • Put all research under one office. Then one OD would be responsible for all research and it would result in a more equitable distribution of funds (OARSA). • We need something above the Centers to make them work together. It would nice if we could get people with more incentive to play nicely together, but I don't think any structure could do that (OARSA). • There should be a single MB unit at the Office level, not at the center level. There should be a unified Office of Microbiology like there is for Chemistry, Toxicology and Seafood (ORS).
Establish a team system for micro-biological research	• Establish a centralized team system to coordinate microbiological research. E.g., for food safety, create a Food Safety Team. There could be a Food Defense Team, a Regulatory Microbiology Research Team, etc. Currently it is a hodge-podge (ORS).
Group MB research along functional lines	• MB research should be grouped along functional lines. There is lots of overlap in areas of expertise between here and CPK1 so it is a real option (OARSA). • If they have to operate with all the microbiology groups at different locations and since the Agency is trying to focus on answering questions the stakeholders have, maybe they should assign microbiologists at our facility to do certain types of projects. It should be clear-cut so that there is no duplication. That way you also utilize microbiologists in different places (OARSA). • Within the larger research groups (bacteriologists, virologists, and parasitologists) there may be one or two issues that could be a focus of a central group with collaboration from other bacteriologists, virologists, and parasitologists. For one or two efforts scientific management might say "we need Group A to work on this and then make it known to the other groups (OARSA). • It would be better if each group were given a specialized function. Then there would be a boundary between groups so you would know which group is working on what. Then when you had questions you could go to another group or collaborate (OARSA). • It would be better to reassess who is doing what and group similar work together. The current structure is based on older research. There is a lot of cross-branch and cross-division collaboration, but it is more difficult when you go from one division to the other because people are obliged to work with people in their own division first (OARSA). • Match scientists to commodities, learn about their matrix. Develop teams to test for

C.2.2.12.a. Interviewee Observations: Please Describe a Structure You Believe Would be More Effective.	
	multiple pathogens in a single matrix (OFS/DI). • In other program areas there is some willy-nilly research going on. These researchers need to be connected to a program or a commodity situation in which the research products, just based on study design, have a usable outcome (OFS/DI). • There should be realignment to a commodity-based structure: Similar to OFS/DI, there could be a group devoted to fresh produce safety, one to dairy, etc. The analytical methods people could be included because they are more oriented toward organisms. The large *Salmonella*, *Listeria*, and *E. coli* groups could be included, which would help integrate the scientists better. It's more common now for people to think commodity-driven organizations might be successful (OFS/MC). • There should be reorganization within the Agency so that those who work in method development are part of the same unit as those in the field who use the method to achieve continual feedback between the developer and the applier. Communication between the Center and field is horrible. There are cultural and bureaucratic differences between the two organizations. The geographic separation and the culture of collaboration is also a problem. This separation commits you to failure. If you want the Agency to fail, keep doing things this way. The model that works is when the developers and the end users are in the same place (CVM).
Merge OARSA and CVM	• Why not make this the Foods Program Research Complex? OARSA needs to separate from CFSAN. We are already physically separated. We have an interesting Foods Program component. We currently serve two masters. We could have one research component that reports directly to the OFVM. It would be a very simple re-alignment. We're physically separated, we already have CVM in the same building. That way we wouldn't have to deal with those at Wiley, and we'd have the ability to address Foods Program issues. This would take care of the boundary issue, the competition angle, and the mission. Our mission would be to address Foods Program needs. It would bring some clarity to the issue, and we'd be reporting to the CSO/RD, who we all know very well. The structure is already in place. The CSO/RD, could be our research director. It would give resources to the CSO/RD, who is already trying to influence research (OARSA). • MOD 1 and MOD 2 are right next to each other. What power we would have if we were one research office or group. With a little bit of expansion in virology we could cover those adventitious agents that might be in feeds or serum which is part of their purview and not biologics which is the other Center. There is no impediment for us to work together. If we were one, we would strengthen tremendously. (OARSA). The idea has been floated that if we and CVM could be a semi-independent complex, that might be nice. We could still have collaborations with CPK1. It seems that it would be better if we were removed from that situation because of some of these so-called personal issues with folks over here. Even if they are on the managerial level, there is a trickle-down effect (OARSA).
Establish OARSA as a strong, independent offices	• There are two research offices in the Center: one here and one in CPK1. And they are no longer independent in that our OD reports to the DDSO, and is therefore, reliant on his decisions. In a quality organization, there needs to be a balance of power or a checks and balances process. I see no checks and balances. Two strong ODs would balance each other (OARSA). • At the office level, we do not have strong leadership. If there is confusion at the Center level, you need clarity at the Office level. You need to know that your OD is taking your ideas to upper management, but that is not happening (OARSA). • The office should have more power when it comes to personnel and research priorities (OARSA). • Allow the Office to manage itself. Get rid of micro-management and any favoritism that is shown with regard to project approval (OARSA). • We need a strong, permanent OD. We've had an acting OD for a long time. They brought in candidates to fill the position, and we listened to all their talks and thought that we would have some input into the selection of a director. In the end, they brought in someone else entirely as an acting director. No one had a say in the hire (OARSA).

C.2.2.12.a. Interviewee Observations: Please Describe a Structure You Believe Would be More Effective.	
Merge divisions within OARSA	• Merge microbiologists in MOD 1. Each division has some uniqueness, but if you drew a Venn diagram, you'd see how much overlap there is. It is not necessarily duplication, but there is overlap in the nature of the research (OARSA). • The Division of Molecular Biology and the Division of Virulence Assessment need to be merged. Right now they are two independent bodies that are mimicking each other and not communicating with each other. There is a tug-of-war going on there in terms of resources (OARSA).
Clarify division structure at OFS/MC	• Clarify the distinction between platforms and branches: Projects are in platforms, but people are in branches. You can be in a different branch and still be in the microbiology platform depending on your project. But I have a project that's half MB and half chemistry. Where does it go? Sometimes we don't know who should attend a platform meeting. The answer is anybody can go if their project is in that platform. But I don't understand the point of having platforms because we have branches (OFS/MC).
Place Moffett Center within ORS instead of OFS	• There was talk about whether our division should be merged with ORS or stay as part of OFS. Everybody in our branch says we should stay in OFS because we do process-related research and prevention control. But if ORS's mission changes and it has more communication and input directly from the policy people then maybe we need a structure change. Managers think there are too many of us because they think scientists can only do one thing, but if you let those 10 scientists go find a solution, they will come up with 10 different areas and that complaint would disappear (OFS/MC).
Reorganize CVM	**Separate NARMS and DAFM:** • NARMS and DAFM need to be separated. The reporting structure doesn't work well with the present structure (CVM). • There are two parts to our division: research and NARMS. There should be more separation between the two. We don't have enough PIs to do the research and we have a lot of research. If we had more PIs distributed to research, it would be properly done, and the results would be written up. Sometimes we get confused about whether the NARMS director gets to decide everything or whether the DD should take charge. If a NARMS priority comes up, it is understood that we will help with that (CVM). **Merge NARMS and DAFM:** • NARMS and DAFM should come together as one division. Right now, a majority of people work on NARMS, but we're in DAFM. Most DAFM research is NARMS research anyway. The supporting scientists working on NARMS also work on DAFM. Technically, they have two bosses. We should have one DD. Under that person there should be four or five PIs with supporting scientists under them. A mentoring, more linear relationship would be more efficient. Also, the NARMS research PIs are responsible for several bugs. Each PI should be responsible for a single bug, so the supporting scientist who works on that bug would naturally come under the supervision of those PIs (CVM).
Remove research function from ORA	• Research and surveillance should be split. ORA should not be doing research, and they should get their house in order (ORS).

C.2.2.12.a. Interviewee Observations: Please Describe a Structure You Believe Would be More Effective.	
Reorganize individual research teams	• FDA should look at USDA's research system and how EPA prioritizes its needs. The USDA system co-pairs its scientists so that whatever their expertise, they always have another PI to work on the research and discuss issues that develop. EPA is working with funding distribution for risk hazard distribution issues using risk assessment to evaluate priorities. FDA needs to look into what the hazards are and decide how much it wants to resolve them. If this is the critical risk than shouldn't we put in a little more instead of just saying, "Well, technically, people are difficult to get." That type of thinking tends to ignore the problem (OFS/MC). • Don't occupy PIs research time with administrative and collateral duties. Each PI should have at least one lab support personnel with a scientific background (ORS). • Currently, our research teams are a series of investigators with their support staff. For an investigator to support his grade, he needs to do a variety of activities. He may be given a support scientist who also has to do a variety of activities. You can't scale this model up beyond 3 or 4 investigators. To scale up to a large organization, we need to add a layer of specialized support to aid all of the investigators and support staff that would include informatics, analytics, project management, contract management, and human resource person specializing in microbiologists (CVM).
Address leadership and management issues	
Improve leadership	• Bring people in from the outside for positions at the higher level, and even the lower level, to generate new ideas or approaches. The leadership here continues to be recycled or moved around or pushed up the system, and not necessarily because they're the best leaders. If someone isn't effective as a leader, they shouldn't be pushed up the system. It doesn't mean you can't be useful in another role. But if you get a lot of negative feedback from the people beneath you, something needs to change. The people above you may love you, but if the people beneath you don't like the way you run things, you're not going to have a very effective group (OARSA). • We need stronger leadership. Sometimes I feel we are being patronized. We often hear leadership say, "You're hardworking and have been doing more with less for a long time, blah, blah…." What I want is to hear them telling it like it is: "This needs improvement. That has to be better. We're behind the ball here, and no more excuses and how can we fix this?" We need leadership who really tackles problems and has an open discourse (ORS). • Choose managers based on merit and relevant skills (ORS). • Better people will give better management (ORS). • An improvement would be that as soon as they identified a bad boss they would remove him/her right away (ORS).
Improve line management	• There is not enough cooperation between middle management (BC, DD) and upper management. Either the middle management needs more power in their decision making or upper management needs to be clearer in how it wants middle management to make decisions. Middle management needs to have a better idea of what sort of projects will be rejected if proposed through the CARTS program: I can make a proposal that my DD agrees to, but when it is put into CARTS, it's rejected. This shows me that there isn't clear communication between upper and mid management (OARSA). • The current management structure is not working properly. We are not operating to the fullest extent we could be. I am a proponent for small-scale reviews at the Branch, Office, and Division levels to solve some problems (ORS). • Line management has to get into alignment first. The individuals are a problem, but if their line management is not in alignment, the change is never going to flow through (ORS). • We have seen many suitable candidates for these positions, but micromanagers upstairs felt some of their personalities were too strong, they were excluded. They didn't even make it to the interview process. With this type of environment, how can we bring in the expertise that is capable of re-shaping the group (ORS)? • We had an acting BC who was well liked and was so competent, that we all wrote

C.2.2.12.a. Interviewee Observations: Please Describe a Structure You Believe Would be More Effective.	
	letters of recommendation for him to be BC. But the person who they finally selected hadn't had managerial experience. I have heard that the only reason that he was selected was that they wanted more of a "yes man" in the position (ORS). • The BC should demonstrate more decisiveness and authority (ORS). • When a scientist moves into management, they should concentrate on managing and give up research (ORS).
Reduce line management levels	• The middle management could be more efficient—we don't need the branch level management (OARSA). • Consider fewer layers of management for smaller groups. It makes sense for bigger groups (OFS/DI).
Increase line management levels	• They should call PIs managers or actually acknowledge that they have people reporting to them instead of pretending everyone's at the same level. When you're treating a bachelor's degree person with virtually no experience exactly the same as your 20-year veteran with a Ph.D., it's not real and everybody knows it (OFS/MC). • We probably need a project team leader. That may help things move faster and be more organized (ORS). • We may need one more secretary or Deputy DD. Our DD seems to be too busy. Many colleagues would like to speak with him, but he is swamped with his many responsibilities (ORS).
Other	
Increase communication and transparency in management	• The Center needs to create transparency in the administration and management aspects of OARSA so that we do not have to assume situations (sometimes rumors). They need to increase transparency in the areas of hiring, budgets, etc. (OARSA). • There should be more open communications, rather than back-door decisions or discussions (ORS).
Increase support structure for working groups	• Increase cross-office support for working groups like the one we have for meta-genomics (ORS). • We need people skilled in facilitation to run working groups (ORS).
No change needed	• I haven't seen a lot of benefits in any reorganization I've been through in 20 years. Whenever they do reorganizations, someone's going to have to lose their job. The name on the door doesn't matter as long as there are professionals in the job to get it done (OFS/DI). • I worry about increasing the structure and the number of managers; I like it the way it is. Maybe in the current arrangement our manager gets the short end of the stick, but it's to our benefit (ORS). • CVM may be unique within FDA because we are not top-down management. Our communication and decision-making involves people from all levels. So there is a lot more communication from side-to-side and up-and-down. I don't think there could be a better structure for CVM. It is a very open, easy to work in environment and so people don't feel intimidated. When we have our all-hands meetings we are not a gripe group. People ask questions and give opinions. CVM is one of the best places I have ever worked for listening to people and getting their opinions (CVM).
No idea	• I have a paper boss, but I work for me. I respond to the Center's needs, but basically I work for me. I work for myself and the good of mankind. That allows you to sidestep all the irritants in the Agency (ORS).

C.2.2.13. Are the staff and resources currently devoted to microbiology research effectively deployed and efficiently used across CFSAN/ CVM?

C.2.2.13. Interviewee Observations: Are the Staff and Resources Currently Devoted to Microbiology Research Effectively Deployed a and Efficiently Used	
Effectively deployed	
OARSA	
Partly	**Between offices and within the Office:** • Some research offices are supported more than others. One research office will get millions of dollars of research funding while another is getting a couple hundred thousand. It is not only funding but people as well: FTEs, contractors, post docs. • Within CFSAN, Wiley building is given preferential treatment, and within OARSA, toxicology is given preferential treatment. • In the MB program, it seems as if sequencing is receiving resources at the expense of everything else. It should be well funded, but it may be getting out of balance.
No	**Lack of hiring/conversion:** • We have an aging scientist population. Half of our division is in or close to retirement. The other half is temporary (staff or ORISE Fellows). In the past there was a staff transition from Fellow to FTE. But recently management has decided not to convert Staff Fellows. This has a major impact on the morale of the younger scientist, and they are the ones doing the majority of the research. So we are losing those people, and in a couple years we will be losing our senior scientists. There needs to be a solution for this. • We need more transparency in hiring and resource allocation so we can see what's going in other groups and equalize the allocation. Many of our Staff Fellows aren't permanent positions. We'd like to hire them, but we keep getting push-back (there's a hiring freeze, no FTE hiring, resources are unavailable, etc.). We also have some talented ORISE who would like to get into the Staff Fellow positions, which is even more out of the question than converting the Staff Fellows. Yet, we get regular emails about positions opening elsewhere in the Center and FDA. We have a very talented group of scientists in this building, and we keep being told resources aren't available, but we're seeing job openings for brand new people from the outside, or they're taking Staff Fellows and ORISE and converting them. Why are other offices in the Center able to do these conversions while we're being specifically told it's not possible? **Between OARSA and ORS:** • Definitely more resources go to Wiley than us. I know that they are bigger, but they are allowed to hire, so it is sort of a self-perpetuating cycle. They are getting bigger and bigger at our expense. • The distribution between offices is not equal. Part of the reason is that they're bigger, but why do they get more hires? I think it has to with us being unaligned. But it should be transparent and explained why the resources are distributed as they are, and why one group is so much bigger. They have the money, they have the people. At the end of the year, they had a lot of money to spend and we did not. They opened up iProcurement for them, but not us. It looks so lopsided. We can barely go on trips or training, yet every time I turn around, people from ORS are going to training or meetings or hosting meetings, or giving big contracts. We just don't get that kind of support. • Between ORS (huge) and OARSA (not), there is a lot of overlap because they've narrowed down the scope of what we're supposed to think is important. If you want people to concentrate on such a narrow scope, then there has to be more cross-over between these offices. And we need to keep the resources in the Center. They have a program in which they are giving money out to companies to address research areas that are really important but nobody here knows how to fix them. I'm sure there are people here who could be addressing these problems, but instead of keeping the money in house, they're outsourcing all of it. I didn't know about this. Shouldn't it have been brought to their own people first? This applies to both Offices. • Resources, both personnel and equipment, are heavily weighted towards the other research group, and it has gotten worse. There is clear bias. They are throwing money at

C.2.2.13. Interviewee Observations: Are the Staff and Resources Currently Devoted to Microbiology Research Effectively Deployed a and Efficiently Used	
	the genomic beast. There are now 13-16 sequencing platforms over there (two worth over a million $). If they keep them all up and running all the time, it would bankrupt the Office. We operate with 2 here. And they are supposed to share, but that's never happened. They say that we don't have training on it and there are issues of publication rights on the data. And they pull priority rank. They wanted to get a year ahead of everyone, and once they had them up and running, they started giving out to the field labs. For everything before the NG sequencing thing came out, we were the go-to people for genomics. **Between offices and within the Office:** • We think that all the resources go to Wiley. They get millions and we are always pinching pennies. Out here, it seems like the resources are going to toxicology.
OFS/DI	
No	**Within the Division:** • Because of all the "acting" positions and the lack of stability, some people are not ready to "build that house" if they will have to turn it over. Also, there's the general lack of knowledge that some of us have about what is going on. When you can't even find your hierarchy and don't even know who to send your mission-critical form to, that's a problem.
OFS/MC	
Partly	**Within the Division/Branch:** • I have a colleague who needs help, but because of the hiring freeze, she can't get it. I also need help, but I'm not that picky. We have 160 students here. They knock on my door all the time so I use them. As a result, I use up my money very quickly, but I'm not complaining. • Staff resources (e.g., post-docs, ORISE) aren't shared equally among the Branch. I couldn't get just one post-doc, even with the extramural funding. • The resources should not be used for IIT, but they have been. We can't change or control that; it's a fact.
Not sure/no idea	**Within the Center:** • We're off-site and don't have a lot of knowledge about how things work. Many people seem to be working on *Salmonella* projects, but perhaps that's because it's an organism in all kinds of foods.
ORS	
Yes	• Although some people will always complain, changes in deployment due to fluctuations in funding are built into our process and adaptability.
Partly	**Between offices:** • Our resources are adequate to our needs within our division, but for sharing with others, there are barriers to get though, even for sharing facilities. **Within the Division/Branch:** • The priority areas defined by management receive all the resources. The priorities should be reviewed every year so that other areas are not left behind. • The staff is very talented, but is unmotivated because of the other issues like communication. It is not a very functional group.
No	**Within the Division/Branch:** • Sometimes equipment is purchased with some grandiose plan and it ends up collecting dust. • All resources are going to one project, but all projects need resources to succeed.
CVM	
Yes	• We are very cognitive of not wasting resources.
Partly	**Within the Division:** • We are still working on this: DAFM looks like chaos from the outside but we pretty much let our support scientists schedule their own time and other duties. They know their

C.2.2.13. Interviewee Observations: Are the Staff and Resources Currently Devoted to Microbiology Research Effectively Deployed a and Efficiently Used	
	primary responsibilities. Almost everybody in DAFM has some responsibility to NARMS. The people have their primary responsibilities and then if they have time to work on other things they help each other. We do have a weekly meeting to discuss who's doing what that week. • We don't have enough technical staff working on research. I only have one staff member working on research. It's not efficient for PIs to spend all their lab time working on research. We need to work on ideas, etc. We need the people to do both surveillance and research. NARMS is the priority; research doesn't have to get done within the same strict timelines.
Not sure	**Within the Division:** • You have certain individuals who are heavily relied upon or over-assigned and others that are under-utilized due to issues with communication of priorities.
Efficiently used	
OARSA	
Partly	**Within the Office:** • There is duplication of effort and competition. We may have capability in one area, but we can't get the samples we need. Also people working alone and information is not shared. People are doing the same thing and they are competing with each other within the same center.
No	**In government:** • Typical government: You can't spend at the beginning of the fiscal year, and need to spend at the end. So you can't get what you need in a timely manner, and you buy things you don't need at the end of the year. This is a huge waste. **Within the Center:** • A lot of Center-budgeted money is being spent on projects outside of the Center. • As part of the WGS project, the Center pays to put ORISE personnel in the state labs to help them conduct sequencing work. Instead of bringing the work in-house, they're paying an outside company to put people into an outside entity. They're also paying to set up sequencing programs in foreign countries. FDA is spending a lot of Center money to expand this program and is paying for personnel, resources, training, supplies, etc. outside of the Center for something it hasn't fully vetted in-house yet. • There's a project called in which FDA is going outside the Agency and telling different groups (e.g., universities, technology companies) that it's looking for technologies that may be able to answer specific questions. From what I understand, this project was started internally a couple of years ago when they brought together a group of people and asked this question. At the time nobody could answer it, so they started down this path. We have some people, technologies, and resources now that could potentially answer parts of that question as well as other questions that might be brought up. But we can't apply for that funding because of the way the project was written. Instead, the money will be spent on outside companies.
OFS/DI	
Partly	**Within the Division:** • We can't replace our staff who are leaving, but we have done pretty well with ORISE Fellows and they've been extended, and we get help from grad students and summer help that benefits us a lot.
OFS/MC	
Partly	**Within the Division:** • Our funding is probably used to its maximum, but whether it's efficient is another thing because there's a point of limited returns. When money is so tight and constrained, people are doing a lot of work but it's not focused. When projects are underfunded, they slow or stop completely. It's not just in research. I'm sure the same thing is happening all across the Center. People are overworked. They're spread thin and doing multiple things, which

C.2.2.13. Interviewee Observations: Are the Staff and Resources Currently Devoted to Microbiology Research Effectively Deployed a and Efficiently Used	
	makes their work inefficient. You get people juggling things. If FDA wants to take their EROs and say, we think we can adequately support this project and have that layout with one PI, a couple of lower level staff, if you can get a couple of grad students to wash dishes for you, because that's about what they're capable of, and have this project done in 2 years, great. Right now we're treading water, we're not making progress, as quickly or as efficiently as we could if we were fully funded with the manpower we need.
ORS	
Partly	**In government:** • The small amount of inefficiency is largely the result of Congress. We don't always know how much money we will get, and then we get the money and we have 3 days to spend it. That is not controlled by CFSAN. It results in people buying things they don't really need. But this is how the government works. **Within the Center:** • We have large groups in CFSAN who are not aligned properly. We are giving these groups millions of dollars, and they are not spending it effectively on problems that matter to the Center. Seventy to eighty percent are used effectively and efficiently. The rest go to "black holes." **Between offices:** • Here at ORS, we are handling the brunt of the work relating to center priorities, while other offices are given more leeway and are not necessarily doing mission-relevant work. • It's not an efficient use of resources if they are not doing mission-relevant work. • There are four offices that may have groups working on similar things and maybe having disagreements. There was a problem with *Vibrio* research being worked on here and at OFS/DI, there was *botulinum* here and at OFS/MC, there are subtyping methods here and at OARSA. There has been talk about there being a single office of MB, but I don't think this will penetrate the problem at the bench level. EROs and CARTS need to be better managed. CARTS could be used to limit people working on exactly the same project; although different aspects could be undertaken by different labs. That layer of management put in place to oversee research in four different places is going to work. • Yes for Wiley, MC and DI. Not sure for MOD 1. • We need to eliminate duplication of effort. **Within the Division/Branch:** • The laboratory people are very territorial and protective of work and instruments. This can lead to a waste of resources and complaints. • There is redundancy in instrument ordering or ordering unused equipment. • I don't feel as if my time and talents are being effectively used. This is also true for others in my division.
No	**Between centers and offices:** • There is redundancy, and there is a history of people not really wanting to talk to each other or wanting to collaborate across Centers. You don't see a lot of publications involving people from across the Centers/offices. • There is duplication of effort and equipment. Resources shouldn't be spent on old bridge technology that is more expensive and gives less information than WGS.
CVM	
Yes	• We are pretty flexible, so we readily reallocate when it's necessary. • We get a lot of work done in a short amount of time. We have fantastic people. They just see a problem and they do it.
Not sure	**Between CVM and OARSA:** • Whether it is because of jurisdictional boundaries or just the lack of communication, it seems like there is duplication of effort between the two Centers across ORS and OARSA. More often than not it is said, "Well we did not know such and such group was actually working on this or they had the resources to actually work on this." It would help to know

C.2.2.13. Interviewee Observations: Are the Staff and Resources Currently Devoted to Microbiology Research Effectively Deployed a and Efficiently Used	
	what studies are going on even within the Center and then across the Centers, and knowing what resources and work groups that exist in the Centers.

C.2.2.13.a. How would you improve the allocation of staff and resources?

C.2.2.13.a. Interviewee Observations: How would you improve the allocation of staff and resources?	
Address competition for research areas	**Encourage collaboration:** • But people should be respectful too. If someone wants to investigate the same subject as someone who has spent a lot of time on it, they should talk about it and maybe even collaborate**.** That's the better model (OFS/DI). • I would start looking at redundancies and getting to the root of why people were unwilling to collaborate (ORS). • We need to have better communication and collaboration among groups working in similar areas so that researchers know what others are doing. We should use CARTs to minimize overlap. E.g., there is collaboration between the meta-genomics group here and bioinformatics people in MOD 1 who have similar interests. They meet regularly to coordinate what they are working on and how their goals meet EROs. They are working together, not under the same management or in the same place, but they are aware of what the other is doing. They can identify the strengths of people working in this area. A similar collaboration with OARSA is underway in WGS, with OARSA assisting in getting methods to ORA labs and providing training and QA in the field (ORS). • When I initiated this project of head-to-head evaluation of subtyping methods, I included two OARSA groups. I learned more about what they are doing and they learned more about what we are doing. We will jointly issue a report on our evaluation of subtyping methods (ORS). • We can work with OARSA—there are some people there with a big chip on their shoulder. They're upset because one group gets more resources than another. But they don't necessarily ask for the resources. We ask for resources. Some people in those groups are working on stuff they have been working on for a long, long time and they've been told to change their direction and that's difficult to do (ORS). **Group research along functional lines:** • If we had people who worked on the same issues working together rather than trying to divide resources between offices for the same thing, that would be a little better. They should divide the resources based on function rather than Office, and try to align people with the same function and have them work together (OARSA). **Discourage individual ownership of an area of expertise:** • Some individuals have ownership of certain subject areas and they don't want to let other people in on that turf and they don't do much with it. People are afraid that they've been working on something their whole career and made some small advances, and that someone else will surpass them. You don't "own" anything in the government. This behavior shouldn't be tolerated by management (OFS/DI).
Address competition for resources	**Review allocation of resources:** • The current allocation should be reviewed by upper management in terms of mission relevance and in consideration of short- and long-term goals (OARSA). **Base allocation on scientific needs:** • I would try to make allocation based on scientific needs (gaps in information or methods needed by ORA). Currently a lot of scientific decisions are made by nonscientists. I'm not sure the correct decisions are being made (OARSA). **Allow equal opportunity:** • Give everyone an equal opportunity for FTE's and resources (OARSA). • We need more equal opportunity and a redistribution of the funds (ORS).
Increase transparency	**Increase transparency in allocation:** • There needs to be transparent allocation of staff and resources. ORS is a bigger operation, but the bias does not fit the staff. Access to resources is as much the equipment as it is the data. There is secretiveness surrounding equipment purchases. And we've never had access to any of the sequencing data. They have the data and the database. They can publish, manipulate, and we're out here in the cold. They need to eliminate roadblocks as much as possible. Share access to the data which are supposed to be public and there for all, not for them to publish first and have preeminence and we get nothing (OARSA).

C.2.2.13.a. Interviewee Observations: How would you improve the allocation of staff and resources?	
	Increase transparency concerning availability: • Better communication about what resources are available might improve upon this, it might allow for more efficient use of equipment (ORS).
Base allocation on need	**Staff:** • Staff needs to be where the priorities are. For example, if it's a short- or long-term project, staff that's most familiar with that process could be put on those projects to help them run smoothly. At the same time, give other people opportunities to learn something new (CVM). • It seems like there are a lot of technicians connected to projects that are moving along pretty quietly. The structure of who works for who is too rigid. A looser structure for technicians, where they could expect to move around to various projects, might be useful in filling resource gaps and preventing stagnation (ORS). • NARMS needs to determine how many essential people they need. Nonessential people could be aligned to the research side (CVM). • It would be helpful if we were told more clearly which staff would be working on which project, and if the work were assigned according to the staff's capability and interest (CVM). • Cross-training support staff would be valuable so that each microbiologist isn't just good at one thing and could be available if needed to help in other areas. Cross-training would be preferable to training them in one area at a time (CVM). **Resources:** • Resource allocations should be based on scientific needs: the areas that need to be studied in greater depth to be able to make regulatory decisions should get more money. It should be dependent on whether the research is fulfilling the mission (OARSA).
Develop a systematic approach for allocation	• They could create a centralized system that would indicate which group had work and the capacity, and then upper management could look and justify who gets what resources (OARSA). • A panel of senior scientists (or possibly including more junior scientists) should be formed to have more participation in the allocation of resources (OARSA). • We could improve deployment of staff. The structure is very loose here. Working group structure would be helpful (OARSA).
Allow some independence in research	• Researchers could be more effective if allowed a little more leniency in their research. A little more research in an area, even though not necessarily directly applicable, could yield big results (OARSA). • Let the scientists have a little more say in what they do with part of their time (OFS/DI).
Realign/reorganize MB research programs/projects	**Programs:** • Realign the programs that are not meeting the Center's needs (ORS). • ORS and OARSA need to be in better alignment so the ORS workload is not so high (ORS). • Consider a single MB program. It might remove redundancies, but redundancies are not all bad. Sometimes it's good to have more than one group working on a difficult problem (ORS). • Establish a Bioinformatics Group because computational science—the blending of computers and biology—represents the future (OARSA). • We need a more transparent bioinformatics program that transcends Offices. We are trying to get that going but one Division in ORS has all the resources and that's where the knowledge remains. We have to go to them to ask for things. There is not a core. This should have a technical work group of its own. This is needed by multiple groups so why is it consolidated in one office (OFS/DI)? **Projects:** • There should be a total science review of MB projects across the Offices (OFS/DI).
Improve leadership	• Hire leaders with vision (OFS/MC). • They need to make a decision and get someone in these acting positions. They should take the best person we have now, rather than waiting for someone better to come so that we have some stability and accountability. Permanent leaders would be vested and would be better at

C.2.2.13.a. Interviewee Observations: How would you improve the allocation of staff and resources?	
	getting the people below them to be vested. It pains our acting director to not know what is going on. After that is done, they need to be open and information needs to be easily accessible (OFS/DI).
Increase oversight on purchasing	• It would be beneficial to have coordination in the purchase of instruments. This might require a manager to oversee the purchase of equipment and that probably wouldn't be very popular. The space committee is crucial. They make sure that if an instrument is purchased, there is a place to put it (ORS). • Equipment purchases should be reviewed more so 'old junk' is not purchased (ORS).
Hire more FTEs	**PIs:** • I just asked for more FTEs. We've got more work than we can possibly do. Two of our PIs are gravely over-worked. We shift workloads and we shift people as we need to, but I don't think we need any more FTEs as worker bees. We need more help at the top. There are too many projects that need to be done now (CVM). **Support scientists/technicians:** • Hiring would be preferable to the use of graduate students and Fellows that we have now (OFS/MC). • I wouldn't hire so many people with a Ph.D. I'd hire more with masters' or bachelor's degrees to work in the lab. We need research scientists, associate scientists who are like a post-doc, but who don't leave every 2 years (OFS/MC). **Other support:** • We desperately need admin people, a dedicated travel person, and personnel in computation. We only have one secretary for the whole Division. Getting some of the paperwork off the scientists' desks would be a huge help (ORS).
Increase use of contractors	• Contractors, such as ORISE Fellows tend to be young, motivated. I love to interact and work with them (ORS).

C.2.2.14. Describe IT solutions/capabilities that could improve our microbiology research program.

C.2.2.14. Interviewee Observations: IT Solutions/Capabilities.	
Resolve firewall and security issues for scientific computing	**Allow Internet access:** • Security is important, but it's really hard to access some very important databases. It blocks a lot of the research I would like to do (OARSA). • They have closed us down so much, that we can't do our job. People have to take data home to do the analyses because they can't do it here because of the firewalls. Iron keys, secure hard drives. IT is so afraid that something might happen and that they might have to do their job and get rid of a virus that they make it almost impossible for us to communicate. It's hard even to get a presentation out of the building. I couldn't get my scores for a grant out the door to the DHS because the viral wall shut me down. We have some IT people in the CFSAN group who are really trying, but it's the group above them that make it impossible for us. In this day in age, computer communication and analysis is critical (OARSA). • Access to the outside world is a major problem because there are so many restrictions. After struggling with IT problems for 10-12 years, I solved them myself. I used the IT servers as a collaborative project. I used their share files and they transferred the data. It's ridiculous and a waste of my time (OFS/MC). • There should be a balance between being cautious while avoiding slowing down our work. For example, we were trying to access and read a food safety webpage that was blocked by IT. We have also had issues reading some journals due to something about the webpage that hosts them that they were concerned about (ORS). • We have groups set up with international partners, but we have no tool to host a website for sharing documents with them for security reasons. We can't allow them into any services, like SharePoint, that we have here. We have no way to communicate with people that are a 5- or 6-hour time difference from us, especially when trying to set up a meeting. It would be nice to use Doodle to schedule more efficiently (ORS). • We've tried to establish a website where the state labs would have access to the most current protocols for methods. We thought it would be easy and quick to do through Yahoo or Google Teams. But no, this was an FDA website, so we had to go through a whole contracting process with JIFSAN. They set up a website using a commercial product. Then, IT said that it wasn't acceptable for an FDA website and that eventually we won't be able to do that. We are moving forward with it, but I don't understand what the vulnerability would be, and IT aren't very good at explaining it. I understand you don't want to open up confidential FDA information, but I don't see how a website hosted by another organization would make that information vulnerable (ORS). • Some instruments need to be connected to the Internet to be updated or for beta monitoring but cannot be because of the firewall. We need high speed Internet access and less hassle installing software. We cannot use Google Science because of security issues. Last week we just got approved to have our own web site which should resolve a lot of problems (ORS). • Protecting information makes things difficult. When we need to update our machines, the companies have to send someone out to do it manually since we can't use the automatic web update. This wastes some time and money (ORS). • We need tools to collaborate within FDA and with non-FDA researchers. IT supposedly can help people at different locations collaborate but I'm skeptical that this is true. Even to collaborate with Wiley or White Oak can be difficult. If you don't see people on a regular basis, you forget to include them, you make incorrect assumptions, and you can't read between the lines in e-mails (CVM). • The science computers should be separated from the rest of FDA computers (ORS).

C.2.2.14. Interviewee Observations: IT Solutions/Capabilities.	
	• In the genomics program everything is information-based, and we don't have an efficient way to transfer data. It all has to be walked about and sent on drives. It seems ridiculous in today's age (ORS).
Resolve firewall and security issues for scientific computing (continued)	• In our lab, for security reasons the computer is not in-network. We always need to bring a memory stick to save our data. Sometimes that is inconvenient (ORS). • The computers for policy and regulation should be separated from those used for research. Then what is on our computers would be low risk. It's the public's information anyway. It would greatly increase our efficiency if high security was not necessary (ORS). • We need a program that would make a system networkable. Even though the government does not want to spend the money to do that, it would improve our processes (CVM). • We have computers that run our instruments and we can't put them on the network. That means we can't transfer files. They don't want us to use flash drives or hard drives to move data from one machine to another. If we can't put it on the network and we can't save the file as a PDF, then we have to print it. We have no other choice. Then we take the printed piece of paper and scan it (CVM). **Develop a system that allows use of portable storage devices in house:** • I understand that we're a regulatory agency, but the fact that we can't use thumb drives any more makes everything so difficult. Let us at least use them from one room to the next. Iron keys are one solution but we can't get them because we don't have the money. They've been ordered for 6 months and no one has received them (OARSA). • Iron keys are a problem. It is very difficult and time consuming to deal with, say, working on a power point project at home (OARSA). **Allow administrative rights to computers:** • For genomics, we need the ability to write our own programs, validate others' software, and install open source programming from academia. The IT rules just don't account for that. It's sometimes impossible run the analyses I need to run. We run up against that framework that just doesn't fit for a computational biologist. We need a new category of computers for scientists. We need admin access to the computers to do our work, but this access is only given to contractors and that seems backwards (ORS). **Improve/increase options for working from home:** • Sometimes I would like to work from home but don't want an FDA laptop, so had to buy my own PIV card reader, and I have no support on it (OARSA). **General comments:** • The IT at FDA is slow to adopt new technology and is paranoid (OARSA). • We spend never-ending money in the IT world. IT is such a challenge because it changes so fast. Since all of our instruments now rely on computer technology, we need to do a better job with IT. Yet, sometimes we're our own worst enemies because the security issues we have make it harder to get things accomplished (OARSA). • Apparently, other offices or centers within FDA are able to get past many of the local barriers and firewalls, etc., that we can't. IT tells us it's not possible, we can't do it for legal reasons, or it's proprietary to FDA, etc., but other organizations don't have these problems. Even other Centers in FDA are able to get around these things. If other people are doing it, why is it not possible for us (OARSA)? • We have a really obsolete security group here that has undermined researchers that need to use bioinformatics methods. They don't have the skill-set to manage IT security with the advances that we need. We need in-house super computers and need to be able to install new programs. We need sequencing machines that interface with international databases (ORS). • Things have been improving over the years. They have put in better ways to move data around. Our IT contact has been awesome to work with, but he needs more help and support (ORS). • The IT here has improved tremendously over the last several years. We have a "go to" person to call when something isn't working. That has been a huge help (CVM).

C.2.2.14. Interviewee Observations: IT Solutions/Capabilities.	
Expand capabilities for processing/storing large datasets	**Expand data processing/storing capabilities:** • Research is going towards whole genomes, huge data sets, and bioinformatics. Even secure storage of these data is a big problem (OARSA). • We are now collecting huge amounts of data, and they are useless if we can't make sense of them. The two problem areas are storage of the data and analytical tools (including analysts), and CFSAN is probably lagging behind in both, especially vs. academia and industry. Software alone won't solve the problem. We need people who know how to use it. It is difficult to hire these people, and we don't do a good job of keeping them (OARSA). • We need ways to import data efficiently and to merge it with similar data sets from other sources and integrate it with other measurements that would enable you to analyze or model the data and make better interpretations. We started an outside contract through OARSA to analyze data 4 years ago. We had capabilities to bring in data from remote locations and correlate it to illnesses and other data. We had partners in Washington as well as other organizations on board, and they were populating it with data. Last September, management pulled the plug on the project because they did not like the contractors. But we thought they were doing a great job. I should have at least been part of the conversation to end the project (OFS/DI). **Expand capabilities for existing systems:** • Management says we need one system for all of FDA and it should be in-house. But we need the capability to share information with outside agencies (NOAA, CDC). Food safety is not just about CFSAN and FDA. It's about CDC and the states. We need to go to Congress together and ask for modernization and don't give us the low bid/low budget system that we always get like CARTS. Management should empower us to design a system. It doesn't have to be the same system that you keep track of leave in; it needs to be a scientific system that you can integrate WGS data with weather observations and food safety illnesses. The NWS has these sort of capabilities. ORA and CFSAN can't even share data. Give us something until we can come up with something better (OFS/DI). • Computer data analysis is required to analyze the vast amounts of data we are generating. In trying to do this, we are in conflict with the IT security guys because there is no separation between our computing and the rest of the FDA. Our research is being stymied in a critical area. We need high performance computing that is off the grid. If we don't get this we can't be on the forefront genomics research. The communication to IT infrastructure has improved greatly over the last year, but it's still basically broken. We are still regularly told "no." We have just started having regular meetings with the FDA IT people including the new CIO (Chief Information Officer) and these are good to get our needs across (ORS). • The genomics people generate a lot of data, but they can't analyze it quickly or well or even utilize much of it because of not being able connect to the Internet. It would be huge for them. It is a firewall issue, but I know that other Centers have been able to do it (ORS). **Expand capabilities within offices other than ORS:** • For doing microarray, those in our office need high performing computers. Sometimes they have issues because we are not at CPK1 so a lot of things go really slow. It is a disadvantage not being at headquarters (OARSA). • We need support for UNIX computing: the best bioinformatics is on MAC- or UNIX-based machines. When we approach IT about using these platforms, they say, well you can buy them but when something goes wrong, we won't help you. That shouldn't be (OARSA). • We don't have access to the high performance computer at CPK1, and the one at White Oak has a history of being unreliable and crashing. MOD 1 really could use one because we are generating a lot of data. We have just been approved to use iron keys to transfer data, but the number of iron keys is limited, and time on the existing computer is limited and difficult to coordinate (OARSA).

C.2.2.14. Interviewee Observations: IT Solutions/Capabilities.	
	• MOD 1 doesn't have access to a big computing center for handling huge amounts of data. We have access through White Oak, but the system keeps crashing with large data sets. At CPK1, they have one that we haven't been able to get access to, and they won't let us have our own here (OARSA). • A high performance computing cluster is being bought, paid for, and put in to support the sequencing. That will have access for us. We'd like to have a mini-cluster here so that if we wanted to have pre-eminence in meta-genomics here, we'd have some computing capacity in-house (OARSA). • We are very happy with high performance computing from CDRH/OSEL when it works. We need the computing power of Blue Meadow for our data to be analyzed within days: 2016 cores, providing 21 TFlops, 6 TB RAM; 40TB GPFS storage; distributed memory model between nodes; shared memory model inside nodes (OARSA). • For larger files from MISeq (Illumina), even though the initial file sizes are only 25 GB, we need Infiniband, 120 GB RAM, and 25-30 processors for the data to be analyzed within 2-3 days. The output files and temporary files that are generated are large (≥100 GB (OARSA). • We'd like to the capabilities to do some bioinformatics here rather than send it out to CFSAN (OFS/DI). • Storage capacity for the enormous amounts of data that we get from sequencing, and bioinformatics support: both people and computing power (CVM).
E-Notebooks	• We should have had electronic lab notebooks years ago. We still don't have them and they haven't even started testing possibly using them (OARSA) • E-notebooks would facilitate collaboration. Why are we not using these and saving our time (OARSA)? • We need easy access to both the analyzed and raw data. Everything should be trackable. I don't understand why we're still writing in these lined lab notebooks. The system needs to be brought up to date, even if it's done incrementally. We need to become more current with the technology and in recording data. We can't keep doing this with notebooks. We can't keep operating under the premise that if it's called into court and it isn't written down in the notebook, it didn't happen—that's crazy (OFS/MC). **Comments:** • In general, IT at FDA is horrible. Especially on the regulatory side. I hear they are testing using iPads, but they are having them emulate Windows. So they've taken something that functions well and make it dysfunctional (ORS).
In-house support	**Better support and responsiveness in general:** • My colleagues and myself get no support from CFSAN's IT group. Over the past 5 years, I have been refused numerous IT requests (e.g., computer system put up on the FDA network, laptop to do Linux, WebEx for teleconferencing). They are supposed to be here to support us; yet they dictate to us what we can and cannot do (OARSA). • IT personnel need to serve the science. The Director of CFSAN Computing fights every day for scientists so we can do more. Our scientists don't have the IT freedom to research things that are of high priority to our Center. Until the IT get into alignment with the goals of our center, we've got a problem. Many of the IT guys have lost sight of the fact that they are supposed to be here to support the science (ORS). • My local IT support is very good, but the FDA IT is difficult to deal with. I think that IT at the FDA level is overwhelmed (ORS). • We need IT people that understand the scientists' needs: people who will work with us, that will work on finding solutions rather than just spewing back a rule that they've heard. We try to find workarounds, but it's very inefficient. All the computational scientists I know want to comply and follow the rules. But it seems as if the IT people think that the FDA is there for them. It's really hard to collaborate, even with other government agencies. Sharing data is almost impossible. We're sending data on thumb drives! It's almost easier to share data with outside entities than it is to share it within HHS (ORS). **Improved trouble reporting system:**

C.2.2.14. Interviewee Observations: IT Solutions/Capabilities.	
	• The IT ticket process isn't very efficient (ORS). **Increased in-house support for scientific computing:** • We don't have the help we need. A contractor comes out weekly for our scientific computing needs, and regular desktop support comes from downtown. It would be better if we had someone in-house to deal with IT issues. We have to wait for IT to call us back to fix a password problem, gain access to our card-readers, etc., and there's always a communication problem. Why does scientific computing have to be separate from our normal desktop computer? There should be a way to have one person integrated into this system who knows both sides (OFS/MC). • The IT person for our office computers is only here a couple of days a week and doesn't know much. Maybe he should be offered more training classes (OFS/MC). **Improved software purchase and approval process:** • The software approval and purchase process is very slow. One system has taken us over 2 years to procure and it still isn't implemented. There are things that I cannot do with my own research because I now have to have a person do this for me because we don't have the software that can do it (ORS). **Increased support for database and web page development:** • Get away from contract services for database or web page development. It's a disaster. 94% of IT contracts are not complete by the end of the contract. I find it an embarrassment to the government. This should be insourced instead of being wed to contractors who produce largely ineffective and overpriced results (CVM). **Improved support for bioinformatics by trained technicians:** • Bioinformatic computational resources should be supported by IT people who are trained bioinformaticists and understand what bioinformatics and computational biology is (OARSA).
Better information management systems	• A lot of offices and other labs have LIMS that can automate MB work and make it easier to use. It's a better way to organize the results in a more timely fashion (CVM). • We need more LIMS system-type solutions, like the one coming to the genomics program. Management has already committed to offer it to CVM and MOD 1 (their genomics program) if it works well here (ORS). • GIMS: We are commuting things that could easily be automated. We are checking with each other and asking what is my next priority. Asking about the status of samples. Are they done yet? Did these samples fail? Why did they fail? These are all things that can and should be automated (ORS). • They need some sort of computerized information system for us to access our lab notebooks and sample data. We need some real-time, computerized, monitoring laboratory equipment. Everything is manual now (ORS). • We should develop an overall laboratory information management system to track resources and capabilities for the purposes of capturing information electronically as well as for tracking resources and capabilities. They are moving towards this via the CARTS system and the SharePoint systems, but we should have one over-arching system that anyone could query and say "I need to know if anybody is working on this organism or this method or if these groups exist (CVM)." • We could really use a LIMS system or at least use electronic lab notebooks like ORA does. We are still writing everything down by hand. Everything we use has a bar code. You can just scan that information. It would definitely improve day-to-day operations. A LIMS system would also be crucial for WGS. We need to get an automated system established before we get too far into WGS (CVM). • We need better document management resources. There are document management systems available to FDA offices, but scientists do not seem to be aware of them (ORS).
IT infrastructure	• They rewired this place to have wireless capability and rapid information data transfer. Some people use the facility at White Oak to do their large computing processing, and there are bottle-necks in information transfer because of speed differences between us and them (OARSA).

C.2.2.14. Interviewee Observations: IT Solutions/Capabilities.	
	• That is being worked on right now through a collaborative effort. We have good band width between the two buildings. How useful will it all be? There is a huge IT contract. It's being put in and leveraged because ORS have so much data (OARSA). • We have connectivity issues—not enough raw power to do what we need to do (i.e., open our e-mail and not have it take 10 minutes to get a file). We need the correct wiring, correct speed, and raw power that we need. We do now have an IT liaison here, and that helps a lot. (OFS/DI). • The Chief Information Officer is already trying to address the need for improved infrastructure to support WGS infrastructure (CVM). • There is not enough bandwidth to the building to move big files around. Ten times the capacity is needed (CVM).
Meetings support	• We need functional video conferencing. It is especially important because we are remote. It would be great if we could share a map, for example, with someone we are working with. Due to poor connectivity, we have trouble keeping Adobe Connect up (OFS/DI). • We have Pictel, Adobe Connect, and WebEx technologies for meetings, but they often fail. The technology doesn't work. They need to look at improving ways for people to interact across groups. For example, there was a large meeting about the Field Food Committee Meetings. I hooked into Adobe Connect to see the slides, but the sound was unintelligible (OFS/MC). • Collaboration tools to collaborate within FDA and with non-FDA researchers. IT supposedly can help people at different locations collaborate but I'm skeptical that this is true. Even to collaborate with Wiley or White Oak can be difficult. If you don't see people on a regular basis, you forget to include them, you make incorrect assumptions, and you can't read between the lines in e-mails (CVM).

C.2.2.15. Aside from IT, please suggest other important services and capabilities should we look at to improve our microbiology programs.

C.2.2.15. Interviewee Observations: Other Important Services and Capabilities	
Improve procurement process	**Provide administrative support for procurement:** • It would be much more cost effective for the Center to have lower level GS-level people taking care of all the ordering issues (OARSA). • When I started, we had a purchasing agent onsite. When she left, her FTE went with her and then they started using credit cards. There's no way any researcher here should be doing purchasing. Things get so routine with administrative duties that you take for granted there's no other way to do things and you don't even realize how inefficient it is (OFS/MC). • Within the Division, a lot of things that could be done at an administrative level are done by scientists (e.g., scientists hold credit cards for purchasing). It would be valuable to have someone dedicated to taking care of these activities (ORS). • We need more administrative support staff for researchers to take care of purchases, travel, and surplussing equipment. The process of surplussing equipment is broken. It's taken 9 months to get some equipment out of here. We are finally hiring someone to do VISA, but it took 2-3 years to hire (ORS). **Improve procurement procedures:** • Make purchasing easier. Scientist spend a lot of time reconciling the Visa cards and tracking down bits of paper—allow this to be done electronically. For UFMS (large purchases), the paperwork is very time consuming and it is not always clear what the purchasing office wants (OARSA). • It takes so long to receive an order under the Large Order Procurement System. I placed a request back in November, and in March, they are just sending me emails asking about the order. It's just been assigned to a contract officer, so it is just starting to be worked on. It is especially difficult for people who have immediate needs (OARSA). • Credit card limits needs to be increased to $5000 because $3000 doesn't cover much. The paperwork for procurement over $3000 is onerous and takes a long time. Do a credit check on credit card holders if necessary to increase the limit for monthly expenditures (OARSA). • The limits on daily and one-time transactions can put us in a very difficult position sometimes. If we need to exceed the limit, the process then can take weeks and months to get the materials, delaying the research (OARSA). • Make iProcurement an easier process, and stop requiring researchers and support staff to jump through hoops when it is not necessary. This only wastes time and hurts morale. When we try to order things, often times we are told we can't do this or that, or our decisions are questioned. We know what we are ordering is appropriate for our uses and can document it. Sometimes we may have been using a particular product and have to keep using it for our study to be valid. The process has improved, but it could be better. iProcurement makes sense for large purchases such as equipment, standing contracts, radioisotopes, etc., but for the items you need routinely or quickly, iProcurement doesn't work (OARSA). • Appoint a person on-site that has access to credit card checks. It is not common, but there are times we need to pay by check. This is not really an option, as it is difficult to convince the current individual to write the check we need for payment (OARSA). • We would do our microbiology program a service by having all project leads meet quarterly to discuss common issues. E.g., cost savings could be obtained for group orders for software licenses as opposed to requesting licenses individually (OARSA). • Procurement is complicated and ineffective, even for small purchases such as a refrigerator. Sometimes procurement doesn't understand biotech. For example they don't understand that some supplies can only come from the manufacturer of the equipment you own (CVM). • We could save a lot of money if we could use some of the competitive companies rather than just Fisher Scientific (CVM).
Improve travel services	• There are too many rules regarding travel. It would be great if we could just give people the money, have them make the arrangements, and then have them give a travel report when they get back. We would probably save a trillion dollars. It's discouraging and morale

C.2.2.15. Interviewee Observations: Other Important Services and Capabilities	
	crushing when people have work to present and they can't go to the Microbiology meeting (OARSA). • The support staff in the travel office are supposed to be there to help us fulfill the Agency's mission, but they're not advocates for us. It hurts us professionally, and it hurts us as an Agency (OFS/DI). • Improve the process for sponsored travel. They should not be putting up roadblocks. If we give them enough advance notice, that should be enough. We don't even ask any more, especially for international travel (OFS/DI). • Recently, FDA has started to scrutinize sponsored travel (after the GSA scandal), and there is an additional layer whereby an office at White Oak has to approve the sponsor before you can put in a travel request. Now it is very bureaucratic, and we have people who are not knowledgeable in the scientific world making decisions about who is and who is not an approved sponsor. This can lead to undue denials of travel for prestigious meetings, with no easy manner to appeal such decisions (ORS).
Hire support staff	**Administrative support:** • Better administrative support. There is a lot of work that is pushed onto the scientists that they shouldn't have to do. We have two secretaries who were hired to do some of these things, but it has all gotten pushed onto the scientists. The scientists even have to order office supplies and keep the supply cabinet stocked (OARSA). • We need a capable and stable administrative staff--those who are not just using the position as a springboard for a better government posting. We don't have anyone to take care of things we are not allowed to take care of such as travel arrangements (ORS). **Scientific writers, editors, graphic artists for publications:** • A co-worker discovered that CPK1 had a contractor on staff who reviewed manuscripts (since discontinued). We didn't even know this person existed; the information was never relayed to us. Writing manuscripts and publishing is very important and many scientists struggle with getting it done in a timely manner. Many times if you have a scientific mindset you aren't a good writer, so having somebody with those skills would be useful (OARSA). • We need graphic artists and science writers to edit papers, both critical for publications (ORS). • We need to maintain the following support personnel: scientific writer (on contract), press office, and graphics office staff. They've done a great job helping us make a bigger impact in our papers and posters and also freed up time to do research (ORS). • The science writer has been very helpful, but she has gone down to part time and it has created a backlog. It would be very useful to have a full-time writer or a second part-time writer (ORS). **Culture coordinators:** • If we can't justify another full FTE for the culture coordinator position, we may need to contract that out as a service. It needs to be overhauled Agency-wide. We need to preserve all these culture collections and they should also be accessible (ORS). • Our culture collection is large and has grown extensively over the years. We need a dedicated person to take care of this service. Securing the culture is also important because we receive cultures from off site, and when we publish a paper someone may request our isolates. This is a critical area for microbiological research. CFSAN has one person just for that purpose and we need one here (CVM). **Service contract support:** • It would be good to have service contracts for instruments again (OARSA). • The regulation of service contracts is already difficult and should not be further regulated. Already it wastes time that could be used in the lab. Increased regulation also means that time has to be spent in training to understand the new regulations (ORS). • Monitoring contracts takes up a lot of microbiologists' time, this needs to be done by someone else (CVM).
Streamline internal reporting procedures	• Streamline the reporting process. We have so many different types of reports—CARTS, reports to Congress, etc. There's talk of condensing them into a single report for a project.

C.2.2.15. Interviewee Observations: Other Important Services and Capabilities	
	For CARTS, the reports are staggered, depending on when the project began. The PIs like the idea of doing them all quarterly, so for half a day or one day you work on reports. Having a Project Manager to extract the information from that one report to fulfill all the required reporting requests would be helpful (CVM). • Minimize or consolidate the report process: There are several reports for the CARTS system and EROs, and within the Center there is a report. Is there a way to get all three into one report and then share the information? There is no coordination, and all three reports come at different times (CVM). • We have to write too many redundant progress reports. Every 6 months we have to write them for CARTS, EROs, and FDA fast-tracking for each project (usually 3 or 4 projects). This takes way too much time away from research (CVM). • Electronic submissions are needlessly complicated. Different filing procedures are required for everything that is submitted electronically: manuscripts, purchase orders, travel. This could be simplified (CVM). • Right now, everything we do is on paper, e.g., manuscript clearance paperwork. We are not making use of digital signatures to save time. Even timesheets are done manually. It could be a lot faster if everything wasn't manual (ORS).
Public access website	• We could have a website where we choose one question from the public and write a response paper to respond. This could drive interesting research and public involvement (ORS).
Facilities/ infrastructure	• We are at the end of the electrical line, and when the wind blows, the power goes out. We should be able to work in a building where this doesn't happen. If your computer shuts down, it's one thing, if you're running a PCR and the results are skewed, it's another (OARSA). • We could use a better connection between DI and the rest of the world. We need an optic line or a T1 or something to maintain communication (OFS/DI). • My office is always too hot and the labs are too cold. If you go two doors down it is the exact opposite. It is difficult to work in this environment (ORS). • We could use electronic monitoring of water baths, freezers, incubators, etc. It was tried a few years ago with an outside contractor and it was a failure. We need something more modern that actually works. We have started putting some temperature monitors in, but the program needs to be accelerated (ORS).
QC program	• We need a dedicated QC program. The current program is unfriendly to MB research--it is more of a policing system. We should start with the laboratories by establishing an independent QC system that can establish standards rather than just implement regulations (ORS).
Source of information on SMEs	• We have lots of expertise across the Agency but we don't have a resource to find out who is the SME for each organism. If I need access to a virologist with a certain training, I don't know where to go. I can ask around but I might or might not get the answer. Lists in the government are hard to keep up to date, but an up-to-date web interface would be great (ORS).

C.2.3. Collaboration/Communication

C.2.3.16. How would you describe the quality of collaboration/communication within your group (team, branch, division, office)?

The responses to this question have been divided into two tables: one for collaboration and one for communication.

C.2.3.16-1. Interviewee Observations: Quality of Collaboration Within Your Group?	
Collaboration	
OARSA	
Team	• Excellent: For the resources we have, we do a really good job with what we feel we can do without stepping on anyone's toes because there's no one making sure you're not stepping on anyone's toes.
Branch	• Fair: Within my branch (and division), I can name half the people who are wonderful to interact with and collaborate with and to bounce scientific ideas off of. The other half are hermits who not only don't engage with their colleagues but are disrespectful and uncaring of what their colleagues are working on.
Division	• Excellent: I collaborate with quite a few people in the Division, and it generally works very well. My collaborators have been very helpful. I am banking on their expertise to accomplish my research. • Not very good: There is division within our unit. There is lack of communication and collaboration. At the Division management level, there is no encouragement for collaboration. It's not suggested.
Office	• Very good: We can ask for help from the other divisions (e.g., how to use a fluorescence microscope). These are not official collaborations, but in day-to-day operations, it has been pretty good. • Very good: We have one non-MB group, and they bring all three divisions in our Office together. We all get a piece of that specific project, and that's worked really well. There used to be a lot of camaraderie. We used to be a team, and that has kind of changed now. • Not very good: We feel like we get penalized when we work outside our building, so we pretty much stay away from it. Interaction on an individual level works, but we avoid doing it through official channels. • Poor: It's a problem in some ways because of lack of permanent leadership. In addition, there are problems between the divisions with the constriction of research. Scientists in the other MB division are now trying to do some of the same projects that we are doing with a different flavor. We have helped them set up some research in different areas in a collaborative, useful way. Now, because we're so constricted, they're saying they're the experts in one of those areas. That will be used against us. They'll say we don't have our own act figured out. I can't fend off issues with boundaries and territories with an empire-building organization and still help direct what other groups are doing because they think that what we do looks good.
Center	• Very good: Within our branch, we've done collaborations with the other branch within OARSA and with ORS. We've done collaborations in the past with CVM. We have an ongoing collaboration that is pretty large with both OARSA branches, ORA, CVM, ORS, and state labs. • Not very good: In collaborations with ORS, we have one person in my group who works really well with them. The rest of us have had bad experiences. • Poor: Upper management at CPK1 never comes here. We are an isolated group. But it does go both ways. We could make more of an effort to change things too.
OFS/DI	
Team	• Excellent: Our teams are excellent because we're small--same for the Branch and the Division. We work together as a team extremely well. We collaborate across lines when there is a need. • Fair: Fair and getting better as we've learned more about each other. It is difficult to

C.2.3.16-1. Interviewee Observations: Quality of Collaboration Within Your Group?	
	work in new people and personalities. However, despite poor communication in the past, we are incredibly collaborative. We are all adults and need to get the job done, and everyone has the ability to do it. So the team effort has always been there despite initial underlying distrust.
Division	• Not very good: In the Division things have been getting better because of more trust. The DD before was a nice guy but not very forthcoming with information. When he left people were more willing to share information and try to collaborate/communicate and ask for help. We are getting better and are expecting to be held accountable. This has a lot to do with our leadership. You can have good scientists who aren't good managers. It is hard to manage without expertise, but they need to train these experts to manage—give them those leadership skills. It is best to promote from within for these small groups, but they need to have them do these leadership programs beforehand.
Center	• Not very good: Within CFSAN as a whole, it's not a collaborative culture because scientists tend to be introverts by nature, and managers can be reluctant to collaborate because they want control of the interactions. What they don't understand is that by collaborating they can have a large slice of a much bigger pie. The folks at OFS/DI have seen the benefits of collaboration.
OFS/MC	
Branch	• Very good among the staff here. If I need help I can get it or my supervisor can get it for me, so there's no problem with cooperation here.
Division	• Excellent: Collaboration and communication are excellent because we are small and off site. Everybody is willing to help someone they don't normally work with. We were created to be collaborative. That doesn't seem to be the case in some other offices and divisions, where there's an unwillingness to share, to stay away from each other's territory. • Very good: Based on the types of projects we have, there is a lot of cross reactivity among a variety of people in many different disciplines. Some collaboration occurs sporadically outside the level (e.g., collaboration on validation of a method for HIV detection in green onions with OFS/DI and others). Some people go to CPK1 to collaborate, but that's not everybody within FDA.
Center	• Fair: A group recently asked us for a strain, but we're holding off because we're planning to do some research on it and don't want to have the sequencing equipment scooped. It's a problem across offices. People don't want to give up their information. I'd love to collaborate. I wouldn't mind sharing our data with CPK1, but sometimes egos get in the way. There's a lot of resentment for Wiley having so much of the sequencing stuff going on there. They say we'll do something for you, but you have to give us some of your data, and people don't want to do that.
ORS	
Team	• Poor: The key here is a lack of trust, and there is a lot of internal competition. Instead of collaborating and fostering the FDA mission, there is a lot of competition. There is likely collaboration going on within the select few pet projects – otherwise, not much. • Poor: I collaborated when I first got here, but collaboration was never a good experience for me.
Branch	• Excellent: We work well together, collaborate, and publish together. However, beyond our organism or focus, there is not much communication. • Very good: Collaborations are encouraged, and the ones with the genomics have been very beneficial. If you're not collaborating, it's because you don't want to. • Fair: There are some personality issues – some work together better than others. • Fair: Collaboration is tenuous. Everyone is amicable, but I'm not sure that they ever talk to each other about what they are doing. I don't know what most other people are doing, unless I am working closely with others on a project. I have a very minimal understanding of what other people are doing since it's assigned at a management level and I don't need to know. It works – I don't think me not knowing affects our ability to

C.2.3.16-1. Interviewee Observations: Quality of Collaboration Within Your Group?	
	pursue and execute mission-related objectives. So long as management assigns good objectives to the right people, this shouldn't be an issue. • Fair: Those involved with big projects may say good or fair; however, if you are not working on a highlighted project, supervisory permission is needed for collaboration, so it is not very good. • Not very good: I work in two groups, one of which is very cooperative with good collaborations and the other is very competitive. There are people there who try to shine at the expense of others.
Division	• Excellent: Our Division is divided into two groups. They do two different things, yet are not isolated. In the matrix management model employed, if expertise is needed by one group they can use a scientist from the other. We have an open and fluid leadership structure. It happens organically and it works. • Excellent: Management doesn't put up with people not wanting to work together and will put the right people together. The result is the two branches have been blurred, but that may not be a bad thing. • Fair. It's partly because we are going through these technology changes (i.e., shift towards genomics). People get along well until we get up to the office level, then conflicts and past histories get in the way. • Fair: The DD allows for some strong personalities to dominate and influence the direction. As the leader, he needs to not allow this to happen.
Center	• Not very good: OFS/DI has a *Vibrio* genomic program. We paid for a lot of the instruments for it, but they don't want to communicate or integrate. I don't really know what they're doing and our own *Vibrio* person doesn't know what they're doing. They don't want to communicate, they want to do their own thing. It's the same for OFS/MC: They have a botulism expert using our contract to buy sequencers more cheaply, I don't know what they're sequencing, what they are doing with those sequences, nor does our botulism expert. We let them use our contract for sequencers and reagents, and provided them with SOPs for methods and development. I'm sure we will be helping them with the data processing. We have done analyses for them and then it goes into a black hole. We don't hear back from them and there are no papers written.
CVM	
Team	• Excellent: NARMS is broken into four teams, and we work well together. You have to work with the epidemiology and the IT group to get things accomplished.
Division	• Very good: When we are faced with an ONADE request of high priority, we are all very good at jumping in and getting the work done on time. We're very good at this. • Very good: In our group, if one study becomes overwhelming, people in other groups will volunteer to assist. We are short-handed, and that can be stressful because our work gets behind. To improve that you just need more people. • Fair: I'd like to see more collaboration within the Division. Each PI should take responsibility for one NARMS bug. Right now, only one PI has been assigned to NARMS research, but we could all work together. Ninety percent of our research is NARMS anyway.
Center	• Very good: We are the neutral party with the different CFSAN groups, and we work well with them all. We collaborate a lot because we share our culture collection within the FDA. • Very good: We work well with both MOD 1 and Wiley even though they don't work well together. My experience is that the collaborations with Wiley have been more productive. • Not very good: We have a lot of experts here. We should be the Center for whatever our expertise is. We can expand the levels of research based on what we do best and what we're known for. If there's something we're doing that's outside our range of expertise, we should collaborate with the experts that are out there in other Centers. I feel we are all trying to grab the ring first.

C.2.3.16-2. Interviewee Observations: Quality of Communication Within Your Group?	
Communication	
OARSA	
Team	• Excellent: We have excellent collaboration and communication within our group. There is an open door mind-set. We communicate with emails and phone calls. There is a very welcoming atmosphere for new ideas and constructive criticism.
Branch	• Very good within the Branch and Division because we have weekly lab meetings where we are required to sit down and face each other and talk about what we are doing. • Fair: People get help with projects. We're doing really well considering the lack of leadership. • Poor: We get very little information. We've had interventions where we have demanded that our BC give us information. We've done this on more than one occasion. We faked a seminar one day just to get him in a room to ask him questions. • Poor: Communication at the branch/division level is terrible. They are unprofessional. If they don't like someone, they don't talk to them. This leads to problems with upper management because it gets personal. It would be helpful if the managers treated everyone fairly, kept professional, and didn't gossip about others.
Division	• Excellent. The DD is transparent as much as he can be. I realize there are things we are just not privy to. He may make decisions I may or may not like, but I trust him. • Very good for team, branch, and division. We have a good dynamic. People are generally happy. I've had good 360s. I'd say the feedback you get from folks in my group would be good/fairly good. • Fair: Sometimes the BC and I don't like to pass on bad news that perhaps we should. We do have Branch meetings regularly. • Fair: It would be good to have meetings within the Division, so that we know what the other labs are doing. • Not very good: We just have a big problem with communication here. The managers don't tell us a lot of stuff that we need to know. They are not supporting us in ways we feel we should be supported. In some cases this is the result of weak personalities or hands-off management style. In some cases managers don't want to be managers--they have their own agenda. Some are disengaged because they don't want to work here anymore. • Not very good: Our team has a collaboration with the other half of our division, and I think we're the only people. And we've never had a division meeting.
Office	• Fair: At the office level, I have a little reticence about the quality of communication that I would ascribe to personnel there. I feel that our OD is being left out of the loop with the other offices. They can only communicate what they know. I feel they do tell us what they know, but there are things that we hear from other investigators in other offices that we would think our own ODs would know and they don't. • Not very good: I've never seen our branch and division have such low morale. The previous OD was a pretty good scientist and a good advocate, but he was a bully. We don't have the same advocacy today in our current situation. We seem to be in limbo and no one seems to want to be responsible without having the authority. • Not very good: Our Office has three divisions. Between divisions we don't have much communication. Sometime I feel decisions are not made transparent down to our level. For example, last year we had money left that actually belonged to the other division. I was asked to come up with a proposal or purchase order for this money. But this year when I wanted to use it I was told this money doesn't belong to us. They just put my requisition in to hold the money because the other division was not ready to come up with a requisition. • Poor: We have two different divisions that don't talk to each other and are mimicking one another. • Poor: Our OD tells us nothing unless we go and ask him. He had me give the presentation on how to write up a CARTS project after I took my team over to talk to the SSA and the CARTS people and we learned how to do it. So then he had me give the presentation to the

C.2.3.16-2. Interviewee Observations: Quality of Communication Within Your Group?	
	rest of OARSA. That's his job. We get no information from the top.
Center	• Fair: Overall things have improved. We don't have to use onionskin and carbon paper to fill out forms, we've embraced technology to help things run more smoothly. But communication between Offices needs to improve so that we are not coming at the same problem from different directions and then missing in the middle.
OFS/DI	
Team	• Excellent: A lot of what the PIs do is over my head, but they take the time to explain it to me. They communicate very effectively and make me a real part of the team. They inspire me to work harder.
Branch	• Fair: Until recently some of us didn't know what the other people did.
Division	• Excellent: Because we're small, we know what everyone is doing. There are monthly research meetings, and, more importantly, cross attendance at the meetings. And we talk to each other about research, budgets, etc.
Office	• Fair: In our interactions with the other seafood safety division, I wish there were a little more feedback on their side. We have a little interaction with OFS/MC but not much because we work on different things. • Fair: Within OFS, there is very good communication between us and the Division of Seafood Safety (our policy group), but we have almost none with OFS/MC and other groups.
Center	• Poor: We have had interactions with ORS and OARSA, but this seems to be one-way: we help them out, but there is no reciprocation. • Poor: We have virtually no communication but we probably should with ORS and OARSA. There are researchers in those groups who work on the same organisms as we do (but are not the organism experts). We should be working together to maximize outputs.
OFS/MC	
Team	• Fair: Communication is pretty good among the lab personnel, but it's not as good between lab personnel and the Project Manager and Team Leader. We have a weekly meeting, but sometimes at a critical point I can't find that person. If there were more informal communication, it might be easier for this to occur.
Office	• Fair: We do some minimal collaboration with headquarters on an individual basis. • Fair: We don't know the DC people very well because we're isolated here. We really need the face-to-face time. Technology can be used to maintain the relationship but not entirely. • Fair: In group settings, it would be nice to have managers at least pass on what's going on in the bigger picture between divisions.
Center	• Fair: Collaboration and communication within our group is good, but it isn't so great with CPK1. We don't find out about some of their work until it's published. What if I was planning to do that or already working on it? The working group list doesn't include all projects. Even with CARTS, it's difficult. You can spend hours weeding through it until you find the project you are looking for—and that's if it's even listed. It's hard to find out what's currently being performed on a research basis. • Not very good: I'm sure somebody in CVM is working on a method to detect residues in milk and eggs, which makes sense. But I don't know of anyone on the CFSAN side is doing anything similar. There have to be corollaries between the groups, but we generally think of CVM as pet food and animal drugs. We don't interact and have no communication so how do we know what they're doing, unless it's written on a piece of paper? It's pretty bad. • Not very good: We need more communication between us and CVM so maybe CVM could get an idea of the kind of processing we do here in milk and dairy products and other research aspects.
ORS	
Team	• Excellent: In our small group, it's very good and, in our larger group, pretty good. We have good immediate leaders, who are very good at disseminating information and details. And scientific presentations at branch meetings and reports from RACs have been useful. It

C.2.3.16-2. Interviewee Observations: Quality of Communication Within Your Group?	
	is nice to hear what others are doing. • Not very good. I try to avoid communication at all costs. I'm glad to have a job and all, but this is just a bureaucracy. You get emails but there is little two-way communication.
Branch	• Excellent: The communication with my direct supervisor is great, but communications are very limited beyond that. There are no lab meetings where people present their work, so I don't know what other people are working on. • Very good: I try to facilitate communication by putting together groups with similar interests to talk to each other. I have people present their research on a regular basis. We have lots of meetings to get everyone the same page. • Fair: Beyond our organism or focus, there is not much communication. • Fair: Right now there's a lack of communication. I've gotten used to doing my own work and only checking in when necessary. The micromanagement freaks me out. • Not very good: The communication from the branch level and division level to the staff is lacking. There is also a problem in communication from top management to the division level.
Division	• Excellent: Our Division is divided into two groups. They do two different things, yet are not isolated. In the matrix management model employed, if expertise is needed by one group they can use a scientist from the other. We have an open and fluid leadership structure. It happens organically and it works. • Very good: We have some people that won't work with others, but no one that won't work with anybody. So it's not bad, that we need a work psychologist at our meetings. We worked across branches to get things done.
CVM	
Team	• Excellent: We have biweekly meetings where my supervisor tracks who is working on what project and determines who needs help. She welcomes all suggestions on how to make things better in the Division, on how our work could be better. • Excellent: When multiple people are involved in a project we have monthly meetings to discuss our data, what we can do, whether we can meet our deadlines, etc.. • Very good: It could improve between support staff and PIs in terms of communicating priorities, allocating work so no one person is overloaded. It is better between the support staff. • Very good: It really comes down to the people, we have very open, generous, committed people who are mission oriented and have a public health consciousness about them. • Fair: With communication, not everyone is on board with transparency. The downside of transparency is that if some of the details haven't been fleshed out completely that can cause some unnecessary complications. Knowing the right time to give what information, but being open about it, is important.
Division	• Not very good: Sometimes the communication breaks down within the Division. Sometimes the teams within the Division receive conflicting information. • Excellent: We have meetings once a week. By talking about problems, solutions come out. We have increased the frequency because we are busier and it keeps things running smoothly. • Fair: At the Division level, communication is fair. Office level, fair. At the Division level, we should have monthly PI meetings. It hasn't been a priority. We're asked to go to weekly Division meetings, but that isn't a good use of people's time. The PIs should have weekly group meetings and supporting scientists should meet bi-weekly.
Office	• Very good: In the WGS project, we are doing well with collaboration and communication. Epidemiologists, PIs, and support staff are doing a good job of keeping each other aware of what we're doing and the progress of the work. • Very good: Communication has improved recently within the Office. The new OD has an interest to improve communication and is making a good effort. • Not very good: Information comes down, but doesn't go both ways. If we have a problem and we would like our supervisor to communicate issues with the OD, I don't think that

C.2.3.16-2. Interviewee Observations: Quality of Communication Within Your Group?	
	happens. We also don't get all the information coming down the chain. Our new OD sends a lot of emails, but they have very little content. They are always asking for feedback, but there hasn't been a positive response when I've provided it. • Not very good: A priority project for one investigator or one office may be communicated on the Office management level but it does not always come down to the support scientist who is actually doing the work. If it does it can be either vague or maybe the correct emphasis isn't put on it. Also, sometimes you get conflicting priorities depending on who you ask.
Center	• Our CD is a really good example of a communicator. I've sent her emails, she's replied, we've had one-on-one conversations, and she's been very responsive. I just wish her example would trickle down to the office and division level. • Communication needs to be improved among CFSAN, ORS, and MOD 1. The Centers don't communicate well. We all essentially receive the same requests for research, and different offices within CFSAN ask us to do the same thing, so we need to communicate and coordinate our efforts better.

C.2.3.16.a. What has worked well with respect to such collaboration/communication?

C.2.3.16.a. Interviewee Observations: What has worked well with respect to such collaboration/communication?	
Collaboration	
Individual initiative	• We have one person in our division who collaborates outside (academia, internationally). That has been a good collaboration, but he is one of the few (OARSA).
Direct interactions between scientists	• Collaboration in the labs, at the non-managerial level (OARSA). • Walking and talking: most people have an open-office policy (ORS). • Getting people together to discuss projects. Sometimes managers can get in the way of this (ORS). • I do collaborate with a couple of people. It worked, but it is generated by one-to-one interaction (ORS). • A culture of allowing scientists to collaborate independently with one another (ORS). • I have good collaboration with the field labs and with MOD 1, all done via my personal interactions (ORS).
Interactions within teams, branches, or divisions	• Within our group, we are able to reach or exceed our goals for all the research projects we do with a collaborative effort. Different people have different expertise and that works pretty well for getting the solution to a certain problem (OARSA). • Most of the projects within our division are now collaborative. People work together by collaborating on specific projects. By pooling their expertise they can maximize their productivity. The days of single person projects are gone (OARSA).
Sharing information across groups	• Poster sessions, meetings, seminars: We have center-wide and FDA-wide research days were people present the work they are doing. These are valuable for us to show the capabilities we have to other offices (ORS).
Working groups	• We've started a meta-genomics working group and it has crossed offices and is very exciting (ORS).
Extending contacts across offices	• We collaborate with OFS/MC—we share resources and data. This often arises from personal interactions. Recently there has been more emphasis on doing collaboration, and people are extending themselves more than we did before with other branches of CFSAN, academia, and even industry on a limited basis (OARSA). • We have great collaboration with CFSAN CPK1 bot group. The only duplication in our bot group may be genomic sequencing, but it may only be in methodology. Having our own sequencer means we don't have to wait in line. We've been lucky to visit MOD 1 to meet the people, and OFS/DI people have come here. We all got together to do some work in the BSL3 laboratory (OFS/MC). • Often times in government you have people in transition. If you can keep someone in one spot so those collaborators have someone to contact every year, you can usually respond to requests more quickly (CVM).
Management support	• In 2010 we started the SRSC from OFVM, and that has started to increase collaboration between the two Centers and ORA. It's not great because there is still resistance, and people are still very possessive and don't want to share with other people, but this has been a step towards the better (OARSA). • Dialogs and discussions among individuals are encouraged. I never felt that I had to go to my BC or Team Leader and say I would like to talk to so and so about this. The policy is if you need to talk about something you don't have to ask my permission. "If something cool comes up just keep me in the loop and send me a note (OARSA)." • Sometimes when you collaborate with someone, their expertise may not match what you need to do, but usually it does work out. You may need to go to their boss to make it work, but usually that is a last resort (ORS). • Management getting the right people together to work on a given project (ORS).
What hasn't worked	• My experience has been really good at all levels until this last year. The turning point was when several projects were discontinued in our division. Now we don't know what our next

C.2.3.16.a. Interviewee Observations: What has worked well with respect to such collaboration/communication?	
	project will be, so collaboration can't come until later (OARSA). • Upper management has poisoned some collaborations by trying to put the Center at the forefront. We worked with an international collaborator to develop a test for a pathogen. The collaborator had a collection of strains that we arranged to be used. The Center published a nice paper based on that collection but failed to include the collaborator's name on the paper because management wanted it to be a CFSAN-only publication. But that wasn't our agreement with the collaborator, and it poisoned the relationship with this man (OFS/DI). • I spent time collaborating with someone at MOD 1 years ago and he recently came back and asked if we would like to collaborate again. I asked him if the paper from the previous collaboration had ever been written up. When he said it hadn't, I didn't want to waste my time collaborating this time around. It's not that I'm not willing to collaborate, I just want to have an effective collaboration (CVM).
Communication:	
Formal and informal meetings	• Branch meetings: Branch meetings are better now. We got together without our BC and had some discussions that things are not good here. So we started pushing him at meetings, asking him more questions and forcing a format that involved more answering questions and explaining things to us (OARSA). • Getting people in the same room and talking works wonders. Even people who are reluctant to be there will find themselves interacting and engaging with their colleagues. What also needs to be done is to take disciplinary actions on those scientists who are disrespectful and unwilling to communicate and engage their colleagues in a productive way (OARSA). • We have a journal club in our branch to discuss our projects, data and new ideas. We normally hold them once a month. Publications and abstracts are reviewed by the whole group for input. I've always been asked for my input before the final draft. It gives the feeling of transparency—we know what is going on in the Branch (OARSA).

C.2.3.16.b. What suggestions do you have to improve the collaborations/communications?

The responses to this question have been divided into two tables: one for collaboration and one for communication.

C.2.3.16.b-1. Interviewee Observations: What suggestions do you have to improve the collaborations?	
Collaboration	
Actively encourage collaboration	• Management needs to encourage a creative environment and scientist-to-scientist connectivity. We need to have greater connectivity with each other and external partners. A "virtual hallway" is needed to bring offices together where they can have unscripted conversations that lead to brainstorming of ideas. Currently, informal contact is discouraged or forbidden unless it is preapproved by management**.** The point where commitments are made is when management should begin its role (OFS/DI). • A culture of collaboration needs to be promoted and rewarded. Collectively doing things we can do better for less. Communication would improve when collaborations improve. Why we are here and what our goals are need to be foremost in our thinking, not who gets the glory (OARSA). • We've tried to do some collaborative work with some people at CPK1. Some of it has been successful. We are working individually on that without any help at all. We're doing it on our own (OARSA). • Give researchers a little more freedom to seek collaborations (OARSA). • We need to improve inter-Office communication based on area of research. This goes back to management oversight. As projects are being prioritized and approved, when they see someone in OARSA and ORS is working on *Vibrio*, management would say "You should work with or talk with so-and-so about that (OFS/DI)." • Collaboration with CVM or an outside university on WGS would be helpful. If we

C.2.3.16.b-1. Interviewee Observations: What suggestions do you have to improve the collaborations?	
	collaborated with other groups the output would be higher and faster. If the upper management could organize to make it work it would be easier for us (ORS). • Our last OD held high performance organization training which was helpful. This needs to be done regularly because it wears off. It gets people thinking about how they can work together. And, some people in my branch need training on how to communicate with others. They're a little rough around the edges. It inhibits my ability to have certain people work together (ORS). • Let the scientists decide on collaboration for different areas or objectives. Don't assign collaborations (ORS).
Increase interactions between groups and scientists	• Better interactions with other branches and divisions will improve the work outcome. Being physically in the same place would greatly improve collaboration and communication (OARSA). • Have informal meetings at least two to three times per year. The last one was 5-7 years ago. There used to be team-building exercises, but that isn't done anymore. Bringing people together physically and mentally to solve a problem would be useful (OFS/MC). • Every research institution has retreats. Retreats are where creative ideas come from, but government has no retreats, and there are also no sabbaticals, so scientists can't re-tool. A sabbatical would be a good opportunity to expand knowledge and even change your field (ORS). • I would love to have the budget to enhance formal team-building skills in my division (ORS). • You have to bring people together more often for us to become familiar with each other. Why is there not more internal cafeteria space where you can come together? We do have the outside cafeteria, but it isn't very conducive. Scientists are introverted by nature, so often they are eating alone at their desks. It takes an extra effort to build those real relationships because there is no common space (ORS). • To improve collaboration with the other groups in common areas of technical expertise, we need to get people connected so they're working together and not doing redundant work or wasting time learning something new that they shouldn't have to learn. We need to get them to interact truly interactively (OFS/DI). • When a study or a priority project comes up there should be more input and involvement across all levels--not just from the investigators' side or from the executive level, but all the way down to the support level. If people on the bench don't know why we are doing what we're doing, or the critical nature of the assignment, or the timeline, it is hard to prioritize our own work to support it. When we are involved in this discussion, we can evaluate whether or not if we can commit to a particular project or study and whether all the logistics have been considered because these are the problems that people doing the work are going to run into (CVM). • Instead of just looking at CARTS, reach out and have an actual conversation. PIs or those involved in deciding what research is going to happen could reach out, sit down, and have a meeting to discuss the research to see if maybe one of the Centers could take a different angle or help in some type of way (CVM). • We need to improve teamwork and working on relations with ONADE (CVM).
Publicize MB research internally	• Office-level monthly meetings where research is presented to let everyone know what is going on (OARSA). • There should be a total science review of MB projects across the Offices to make it clear and transparent what everyone is doing (OFS/DI). • Better and more communication of what research is being done in the Centers is essential. Collaboration happens once in a lifetime, when it should be happening all the time. Management tells us to look in CARTS because theoretically it contains that information, but it doesn't work effectively. We need a regular write up of our projects: something detailed, but simpler than CARTS. E.g., periodic updates of one or two paragraphs, a one-pager that says this was our objective or our reasoning, here's our reason for doing this. Or the public disclosure in CARTS could be expanded: "Here's the problem, here's what we're doing to

C.2.3.16.b-1. Interviewee Observations: What suggestions do you have to improve the collaborations?	
	look at it, here are some of the relevant findings, and here's how it impacts public health." It could be disseminated sideways. I'm sure some CVM projects have similar corollaries, but we have no idea what they are. At OFS/MC, we have to write a technical report every year. A shorter, edited narrative version minus much of the technical data would make sense (OFS/MC). • A monthly lab meeting where people talk about their research would not only be informative but would give scientists an opportunity to practice talks that will be given at meetings (ORS). • More sharing of results, projects, even a description of what you're doing. If you ask someone, they are open to talking with you, but there is not a process in place. You have to seek it out (ORS). • More communication may help through lab or group meetings. Currently, group meetings focus on the budget or other administrative functions rather than what's going on (ORS). • We have started regular monthly meetings with OARSA to discuss what is going on with our work that is similar and it has helped in enabling to personnel to sit in a room and honest with one another and to be able to clear the air and have an open discussion. There were problems in the past with rumors and bitterness. There are personality conflicts that you have to work through (ORS). • Expanding SharePoint: the program offices use it a lot and are familiar with it, but the research office doesn't use SharePoint very much. They are switching over from a different system that used to be called E-Rooms. It might be helpful to get the research offices a little more involved with SharePoint, at least within FDA collaboration. Then maybe we could cut down on a meeting and just upload documents (ORS). • Have more frequent group meeting led by a team leader to discuss research progress and issues (ORS). • We should have more PI meetings. Maybe the NARMS Team Director should rejoin the Division. He is needed in the Division since 90% of the Division's work is for NARMS. At least he and the DD should meet more often (CVM).
Address competition between groups	• There needs to be a fundamental change in attitude instead of the "us vs. them" that we have now (OARSA). • This narrowing of the scope of research has made collaboration and communication more difficult. People are getting territorial and that doesn't make for good communication or open-minded collaborations. Also, we had an instance in which one group didn't properly (or publicly) credit another group's research contributions at a professional meeting, even though they'd contributed a good portion of the research on which the analysis was based (OARSA). • There need to be boundaries for research (OARSA). • Our working environment is currently more competitive than collaborative, but it shouldn't be (OARSA). • Collaborations have to make everyone winners. You can't be only thinking of yourself when establishing a collaboration (OFS/DI). • We need to foster the idea that we one big team and we are all working to promote public health. I think we've lost that and now we are competing with each other for resources and to publish first. The competition has to stop. This has to come from the top leadership. I've been in ORA, CFSAN and now CVM so I've seen this in action. We lose a lot time fighting amongst ourselves (CVM). • If our expertise is in resistance, and CFSAN's is in WGS, then we should collaborate with each other in the areas where we are not expert. It should be that way throughout the whole FDA system. If CFSAN is doing sequencing, then they should have all the sequencing equipment, rather than us having a couple and other groups having a couple, and all doing the same thing, and all putting their money into the same equipment. The groups should all be specialized. CFSAN just purchased some PFGE equipment and I'm wondering why. If they're running a study and need some data, why not ask us and we can collaborate. And just recently some of them came over wanting training. Why should we take time out to train them when we could so easily do it ourselves. It's not cost effective (CVM).

C.2.3.16.b-1. Interviewee Observations: What suggestions do you have to improve the collaborations?	
Resolve management issues	• We know that we are capable of collaborating. All we need is working research programs (OARSA). • They need to find a permanent DD and making sure the fit is right for a satellite lab. It's a field lab with a different mentality and different research than laboratory research. We tend to be more soup-to-nuts (OFS/DI). • The only way they will be able to improve what is broken is to replace some of the people currently in management (ORS). • Team structure in our division will promote collaborations and communication because when people are used to working in teams and working out team dynamics, it will build interpersonal communication skills. This will build collaboration and innovation (ORS). • Maybe the NARMS Team Director should rejoin the Division. He is needed in the Division since 90% of the Division's work is for NARMS. Maybe it would work if he and the DD met more often (CVM).
Increase effectiveness of meetings	• We need to have more effective meetings – they should end with a conclusion and next steps. It might be helpful to write up action items that everyone can agree on after the meeting (ORS). • It is difficult to get decisions, time lines, and actions documented. Minutes of meetings need to be taken and actions need to be followed up on. The addition of a planned project manager should help with this (CVM).
Identify areas of expertise and interest in the program	• My manager knows my strengths, but how far up does that go? I may be labeled with my organism, but am I labeled with everything I can do? There is no way to track all the things we are good at or interested in--e.g., survey with check boxes (ORS). • There should be a better assessment of the areas of expertise and interest of our PIs and supporting scientists, which should then be aligned with our program. Management should look at the PIs to see who has what expertise and then invite people to participate on projects. At the division level, management should have a greater understanding of our interests, expertise, etc. For example, we have a new person with WGS expertise. Ideally, she'd lead all the new initiatives in that area. She should be given the lead over perhaps a more senior PI who's interested in this new area but doesn't have the expertise. When a new project comes in, whoever grabs it first is not the most efficient use of our resources and expertise (CVM).
Improve operations	• Collaborations with the genomics group could be improved by better organization of instrument access (ORS).
Encourage attendance at scientific meetings	• Part of doing research involves communicating with other scientists by going to meetings. Often meeting requests are turned down because of perceived COI issues. Even if there are no ties to industry but the meeting is funded by the drug industry, it may be rejected (OARSA). • We all probably need to go out and speak to people who are working on the same sort of research projects that we are. We need to try to meet them at scientific meetings, general meeting, etc. We need to do more of this on our own (OARSA).
Offer Incentives	• There are problems of ownership on new research ideas. It is difficult to get people to want to share. That isn't a government issue, it is the nature of research. Because it is an intellectual commodity and they can keep hidden, people seem to be more territorial. Maybe we should consider something like changing the awards program to make it worthwhile to share data and work on a team rather than have the prize themselves (OFS/DI). • Maybe including some incentive for collaborating, e.g., going to a meeting if you tackle a cross-over project (ORS).

C.2.3.16.b-2. Interviewee Observations: What suggestions do you have to improve the communications?	
Communication	
Improve communication	**With upper management:** • Upper management hinders communication by making certain questions off limits. When the CD came out for a meeting with us last month, we were told not to ask certain questions.

C.2.3.16.b-2. Interviewee Observations: What suggestions do you have to improve the communications?	
	We don't live in the kind of society where certain questions are off limits (OARSA). **At the office/division/branch level:** • At the management/branch/division level, they are not as clear as they could be if there is a misunderstanding. Sometimes they make it worse. They need to be constructive, clear, and concise, as well as being non-accusatory (ORS). • The communication needs to be improved at the Divisions and Office level to remove barriers to enable PIs from those Divisions and Offices to communicate and collaborate with each other (ORS). • To address the issue of communication, our DD started semi-regular monthly meetings for about 6 months before dropping them. We only have them on special occasions now. It would be great if he got back into doing more regular meetings. I'm sure there are situations where he can't be transparent or reveal things coming down the pipeline, or things that are of a more sensitive nature, but it would be nice to have cursory updates of things going on that might be relevant to us. We've seen him disseminate information to two or three BCs, depending on the organizational structure at the time, but they aren't always as expedient in getting information down to the lower-level people. Why can't we all get the same information from the DD and not rely on second-, third-, or fourth-hand information? Let the BCs deal with their branch and not have information trickling down about what's going on at the Division level (OFS/MC). • One-to-one meetings (10-15 minutes) once every two months would be a good way to communicate (ORS). • We are in the process of reorganizing into teams, but currently we have RACs to handle day-to-day operations. All contractors are under either a RAC or myself. Some RACs hold routine meetings, others do not. So some groups are more cohesive then others (ORS). • Sometimes when there are big changes coming, the changes get ahead of the communication. So sometimes it's excellent, other times can be poor, but is generally very good (CVM). **At the scientist level:** • Some people in my Branch need training on how to communicate with others. They're a little rough around the edges. It inhibits my ability to have certain people work together (ORS). • There should be more PI meetings (CVM).
Encourage more informal interactions	• I'd like to see more informal social interaction from people who can support one another. Every year we get government ethics material telling us how we should be acting (gifts, etc.), but an informal meeting offsite with a third-party to teach work ethics would be more effective. People put in the extra time for pure social events (e.g., Christmas party), but when it comes to doing their job, the feeling is not the same. This has to come from the top (OFS/MC).

C.2.3.17. Describe current coordination efforts among CFSAN's and CVM's microbiology research groups and their programmatic counterparts in the areas of regulatory policy, compliance, enforcement, and ORA field programs.

C.2.3.17. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts.	
Regulatory policy	
Direct interactions with the policy office	• We're starting to get some of that work, mostly through the efforts of our Deputy OD reaching out and contacting the program components. It's as much to do with her efforts as with the ERO business. The SSA has told us we won't get any CARTS approved unless there is a component in these offices that wants that research (OARSA). • We work with the policy group to try to tailor our research toward policy decisions. They do a good job of letting us know of any improvements that should be made. We have a good working relationship (OFS/DI). • We deal with regulatory policy questions weekly (OFS/DI).

C.2.3.17. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts.	
	• We do collaborations on risk assessments. Our bosses think that what we do should have that impact, so there are four questions we ask of any project (OFS/DI). • We're SMEs. We don't want to do the policy here, we're just trying to inform the policy. I think our benefit is in having the knowledge of the hazard in the shellfish and transferring it into real-time decision-making in a policy decision. This is why we're better off in OFS—we sit closer to the fire (OFS/DI). • We work regularly with them, but I'm not sure about interactions among these groups. It seems like most of the coordination is happening between the Division of Microbiology and not much is coming from the other research groups (ORS). • We have direct link to our regulatory program people. We talk to them regularly. We keep in mind their needs. It is very good, but it could be more formal (ORS). • Within the Center, between us and regulatory, compliance, and enforcement people, we have a good level of communication. We were recently invited to start attending some of their meetings. It can be improved, but it is getting better (ORS). • I talk regularly to the produce safety staff to find out what their needs are and to see how my work might assist or fill in those gaps. My DD knows and encourages these meetings, but I don't know of any other formal process (ORS). • Interaction tends to be by relationship rather than systematic. If they know someone is good at something, they may send him to a particular area. Someone else may want to do this, but they can't because they don't know the right person. It would be better if it were more systematic (ORS). • We interact with them, at least as it related to the field lab, since they are the ones who decide what foods and pathogens are to be tested each year. This requires collaboration between ORA and ORS, as well as some at CFSAN (ORS). • At times, we do surveys that serve as a basis for regulatory policy discussions (ORS). • ONADE uses our NARMS data as well as animal feed data for regulatory policy (CVM). • We work well with Compliance and Regulatory Policy but not as well with ORA and CFSAN (CVM). • We provide data for drug review for risk assessment for antibiotic resistance (CVM). • Our Feed Additive Working Group looks at CFSAN's documents related to food additives to revise our guidance document. We search for what we can adopt from CFSAN and seek out expertise in CFSAN from people who've worked in a similar area (CVM).
Working groups	• There are some working groups for different subjects, e.g., molecular genetics, which have people from here, CPK1, and CVM. We establish priorities for helping the regulatory people (OARSA). • The working groups are led by the program offices, which focus on the regulation and compliance, and we're told to write our CARTS projects to the EROs and the knowledge gaps developed by the program office (OARSA). • The working groups are the mechanism for interacting with Regulatory Policy. Coordination between our research and the regulatory policy people happens in those groups (e.g., policy people on fresh produce safety are interacting with the produce safety research people; OFS/MC). • For the past 2 years, we have talked to the OFS Fresh Produce Working Group, so I know what their gaps are, what research they are looking for. They also speak to us about what we are working on and techniques we have available (ORS). • There has been a huge improvement after the formation of OFVM led by the CSO/RD. He pushes working with others. We now have different research working groups for each area at CFSAN, CVM, and ORA (CVM).
ERO-based prioritization process and CARTS	• Efforts occur at the ERO level; otherwise, I do my regulatory work, and we follow policy, but since fundamental policy is mostly legal, it is not lead by science. Science has more of a passive role (OARSA). • There is some communication through the CARTS process (OARSA).
Outbreak response	• We consult on outbreak investigations (OFS/MC).

C.2.3.17. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts.	
	• The NARMS program interacts with everyone on the list. In PFGE whenever we generate patterns, we upload them to CDC's PulseNet database for tracking outbreaks (CVM).
Need improvement	• There is very little coordination with any of these programs. In the last 6 months, people have gone out and tried to improve on this and find out the program needs. This is where we are now. This is a new development for most of us, as far as trying to coordinate our research with their programs (OARSA). • We go to meetings at OFAS, so know a little about Regulatory Policy from them, but sometimes we learn about outbreaks from CNN rather than the Center. This interaction should definitely be improved. We could go to them and present what we do and vice versa (OARSA). • There are coordination efforts? I would say there haven't been a whole lot of coordination efforts (OARSA). • Our research projects go to the regulatory offices for review, but they don't have expertise in those areas in terms of research. They may agree that we need this type of research, but they cannot evaluate whether this is a good approach. When their response comes back, you can't understand what they mean or whether they understand what you are trying to do. The review process should be a way to communicate (OARSA). • It's not a very effective coordination. Scientists need direct connections to their counterparts to better match resources to needs. We need to form strong connections through collaborations, outside CARTS (OFS/DI). • Regulatory policy has a plan and a working group, but whether that translates to compliance and enforcement is not clear (OFS/MC). • I don't see research affecting policy nor regulatory people asking questions of researchers (ORS). • We need a way to communicate easily with these groups (ORS). • Coordination of CFSAN and CVM research with regulatory policy people is horrid. There is also a lack of coordination with Compliance and Enforcement (CVM).
None	• The research my division I am involved in is not under a regulatory initiative. We don't interact (OARSA).
Not sure	• I cannot make any intelligent statement regarding this. The way FDA works with research and these program people was never explained to me. I am just picking up little bits of what else goes on outside of the lab (OARSA). • Regulatory policy is still evolving with FERN and FSMA. Laboratory proficiency testing and methods validation play an important role, but I don't know who's going to do it: FDA, industry, or us (OFS/MC). • I am not aware of any coordination. We have a new science director, who has talked to us, but that's it. There is no coordination or team building between groups. Team building exercises (not meetings) could go a long way in helping our poor communication (ORS).
Compliance	
Work on compliance materials and programs	• We help review compliance policy guides and programs (OFS/DI). • We are involved with compliance with the Pasteurized Milk Ordinance (PMO) on pasteurized milk cartons and with the interstate shellfish program (OFS/MC). • We work them in development of compliance guidelines. We have to sell our detection methods to them and ensure they get utilized by the field (ORS). • We have communication with them, e.g., reviewing analytical worksheets for them (ORS).
Outbreak response	• We just worked with compliance using next generation WGS to effect a legal action (ORS). • We meet quarterly with CORE and the Office of Compliance for interpretation of genomic results. These meetings have just been instituted and should provide better communication and coordination between our groups (ORS).

C.2.3.17. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts.	
	• In the past few weeks, sequencing has been used in court in the *Listeria* cheese outbreak to shut down the company. CORE has come to realize how much genomic sequencing has done for them. There is a lot of traffic between Compliance and us (ORS). • We talk weekly to the compliance policy people and CORE. I'm trying to help them on top of my regular work (ORS).
Recalls and surveillance	• We work closely with the Office of Surveillance and Compliance. We analyze data to determine if an animal feed should be recalled. We also do post monitoring for them (CVM). • Our coordination with Compliance consists of whatever they want us to do. Usually for MB that consists of pulse field gel electrophoresis (PFGE) or maybe some serotyping for *Salmonella*. We can do PFGE for multiple organisms. We have our own database of animal origin *Salmonella*, *E. coli*, etc. (CVM).
On unspecified issues/projects	• Not much except on specific issues (OARSA). • The Risk Assessment Office is supporting one or two of our projects (OARSA).
Developing interactions	• We have added working with Compliance and Enforcement to our staff PMAPS so that these groups know how genome sequencing can be used and to find out what they need the best way to provide it to them (ORS).
Indirectly	• We are involved with Compliance and Enforcement indirectly through ORA (OARSA).
None	• In the past I used to get involved with Compliance because we were in one location. If they had a question in Compliance about reviewing certain cases then they would walk down to my lab and grab me, and I would look at the case files. Now that we are 10 miles away no one is going to come here. So we don't get involved with Compliance. I don't think any of us are listed as SMEs anymore. They prefer to have someone right there (OARSA). • The shellfish program is a cooperative program. Our partners (the states) are responsible for their own compliance and enforcement, so those are not applicable to our part of the partnership (OFS/DI). • We have no interaction with Compliance here. They make all these guidelines and policies, and we are supposed to be able to follow them (ORS).
Enforcement	
Work on enforcement actions	• We deal with enforcement actions: consult in deciding whether to go forward or not on cases received from the field (OFS/DI). • We provide data interpretation and analysis for the Office of Criminal Investigation when we are asked (ORS). • They use our data to determine policy on judicial use of antimicrobials (CVM).
On unspecified issues/projects	• Not much except on specific issues (OARSA). • If they have a need, they let us know. Their needs are high priority (ORS).
Developing interactions	• We don't have regular communication with them. I've been giving talks to senior scientists in all the offices about the genomics program and what our capabilities are (ORS).
Need improvement	• There's room to tighten up how research affects enforcement. There haven't been any formalized seminars or communication of how our work affects enforcement (ORS).
ORA Field Programs	
Method development and validation	• We have worked with ORA for method validation and multi-lab validation, so we are part of the effort. We also develop new methods and introduce the methods to them if they have the resources and money to go with this technology. Sometimes you reach out, and sometimes they come to you, and if you have the capability you may agree to work on something together (OARSA). • Some of the technology that we are developing is being implemented in ORA field labs. We were asked to develop this technology for the ORA field labs, but one of the senior scientists at CFSAN is trying to stop that because it does not jive with his personal political agenda (OARSA).

C.2.3.17. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts.	
	• We work with the field labs on PEG array methods. PEG is inexpensive and quick to run. It is great for the labs (OARSA). • We collaborate with them when it comes to validating methods. We always try to get ORA involved when we get to the point of validating a method because they're the ones who'll be implementing it. We ask for feedback on what does and doesn't work (OARSA). • Even though we're supposed to be developing methods for the field labs, we have very little actual contact with the field labs (OARSA). • Through efforts to extend science into the field programs, e.g., by implementation of new technologies like microarray (OARSA). • We produce products that are being used or incorporated into ORA programs: virology testing of foods and *Vibrio* testing in seafood. I think we're doing exactly what we are supposed to be doing (OFS/DI). • Within their regional laboratories, we try hard to develop methods that will be accepted and implemented. We've had good success working with them (OFS/DI). • We share some of the validation work to save time (ORS). • We collaborate a lot validating methods and sanctioning methods used in the lab. These collaborations have worked well. We work with the field office to make sure the right methods are being used in the field lab for the particular matrix (ORS). • Our research efforts exist to support ORA labs (ORS). • We have a lot of interaction with this group. They are supposed to test and provide feedback on methods so we can work towards optimizing detection methods (ORS). • If they need help with validation of methods, we will participate to the extent it is possible (CVM).
Methods training	• We've done classes and trainings together. We've brought ORA people in to train them on some of the methods. ORA hosts an informational class on what they do and what kind of methods they're looking for so that our scientists can gear their research toward ORA's research needs (OARSA). • We are working on a project involving training them. But there could be so much more. In the working group meetings, there was a sense that there could be a lot more coordination that could foster a lot more good work (OARSA). • Anything we develop is targeted to get our regulatory people trained and out there with the tools that they need. It must be able to be done in a timely manner, comprehensible. Not every MB research area does that. I think this mentality was reinforced by the CD. It has been in place since I've been working here (OFS/DI). • We have a training program that helps transmit the information we get at the laboratory level to ORA laboratories (OFS/DI). • We are designing training programs on oysters for ORA so that they can help the states more effectively and uniformly. We're planning demonstrations for the industry to show them that they can ice the oysters and they won't die and they'll have fewer pathogens in them (OFS/DI). • We do training courses with ORA labs three times a year on method transfer. We develop the methods and train them in their use. We do the same type of training for FERN labs (OFS/DI). • We work with them to teach methods (ORS).
Outbreak response	• For outbreak investigations, if we can get the sample, we work together (OARSA). • We have a good working relationship with them. We are registered as a Food Emergency Response Program. We are the lead lab or FERN at FDA and all the ORA field labs are part of FERN, so we work together well and often. We are heading up the WGS training program for the field labs (OARSA). • We work closely on some cases. We get samples for analysis. E.g., we helped them determine that their tests were accurate in testing for *Salmonella* in turtles. We provide technical support. We also have looked at isolates from food animals and companion animals and compared them to the ones found in humans (CVM).

C.2.3.17. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts.	
Work on genomics and sequencing	• We're collaborating with the ORA field labs on a sequencing project (OARSA). • We work with ORA labs during outbreaks and sometimes get strains or food samples from outbreaks. We received *Listeria* infected cheese from that the field labs got from grocery stores. We are sequencing those strains to validate sequencing as a detection method for ORA field labs (OARSA). • We have weekly meetings with the people involved in genomics in the field labs. We are helping them integrate the field labs and then establishing one pipeline so they can talk to us and another so they can share information with the state labs. Regarding other technologies, the Center meets with the field labs only annually. I think this should be more often (ORS). • We're part of sequencing networks with the labs. Most support comes from OARSA, but we've helped them as well. I'd like to evaluate primary candidates for typing methods for incurred samples, but we haven't initiated anything in that direction (ORS). • I interact with them in the WGS network. They just appointed a project manager to oversee the program, so that will help a lot (ORS).
Research and analysis	• We work closely with these programs, have routine conversations, and publish together (ORS). • I interact with eight field labs who send us data and we send them feedback (ORS). • Our group monitors and analyzes the gels that come out of the field labs (ORS). • We review worksheets from field labs and assist them with issues they encounter (ORS). • We are collaborating with them on *Salmonella* resistance. They are collecting the AST (Antibiotic Susceptibility Test) data. They send us the data and we analyze it. We also analyze PFGE data from feed samples run by the field labs (CVM). • They have done some testing for us for the NARMS program. We haven't done a lot of research with them, but they have done some research with us that has resulted in publications (CVM). • We have a good connection with the person who works on that in the CVM Office. When I first came here, there was a complete disconnect between us and the program office in terms of the feeder programs. Now my CVM program counterparts and I meet monthly to discuss what's going on, any research they need us to do, etc. We look at CFSAN's detection methods, sampling plan, etc., to make sure we coordinate our efforts, especially in *Salmonella* because it's a major organism for feed (CVM). • We are involved in field assignments that the program office makes. There is an animal feed program were the field lab sends us bacteria isolates from animal feed and we characterize the isolates. We have a support role in that program (CVM).
Work with shellfish specialists	• We work really well and frequently with shellfish specialists who work with the states. These are FDA employees under ORA who are liaisons with each individual state. We don't work with the ORA field laboratories very often. The states are responsible for their own testing because of the nature of the cooperative program, so it's not applicable (OFS/DI).
Indirectly	• We're directly involved with FERN and Vet-LRN (OFS/MC).
Need improvement	• Field program personnel may want to institute some sort of testing in the field, so they will try to find the experts at CFSAN in the lab and will call you and ask you what you think. They have these ideas, but in all the cases so far, nothing has come of it, either because there are delays or they don't have clearance from upper management to move forward (OARSA). • Sometimes people complain about working with them because they ask so many questions, that they are trying to set up road blocks. Well, they need to do it in a very specific way because they are the regulatory arm and you need to understand how they work. I think there are problems sometimes because people here think that ORA is at our beck and call and they're not. It's a collaboration. It's not as if CFSAN can tell ORA what to do (OARSA). • There is some kind of a turf war between ORA and CFSAN in research. ORA shouldn't do research, but they do it. They did not want to put their research on the CART system

C.2.3.17. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts.	
	because they wanted to hide it. They keep hiring Ph.Ds. because they bring prestige to the program, but Ph.Ds. get bored if they are just analyzing samples (ORS). • It is difficult to get rapid detection methods into field labs (ORS). • Communication is bad right now. Because we are analyzing field data, I can contact field scientists directly, but that's unusual, and field management doesn't like that. They want us to go up our management chain to their management and back down to scientists, which is like a bad game of telephone. Our field labs act like independent entities, and there is no coordination or consistency. There are awesome people in the field labs, but they are run poorly (ORS). • The upper management has started talking to each other, and we are starting to implement the genomic sequencing network into the field labs so they can do screening using high throughput sequencing. It's up to the supervisory level to talk and make it a priority for the field lab. It's not as if they have nothing to do and are just waiting for us to give them work. Also they are stuck in their routine. We have more flexibility in what to do. It's a slow start, but I see it growing (ORS). • They are in the hands of district and regional lab directors, most of whom don't know how to constructively engage with the Centers. They don't have the power, the influence, or the time to tell the Centers "What you are doing isn't helping, here is what I need (CVM)."

C.2.3.17.a. What has worked well with respect to such coordination?

C.2.3.17.a. Interviewee Observations: What has worked well with respect to such coordination?	
Personal interactions	• Actually going to the field lab and seeing what they are doing has helped to determine how to assist them (OARSA). • What works best is if we just call somebody at ORA that we have met through programs or a seminar series and we just talk (OARSA). • When I submitted my CARTS project, ORA wanted to know if it was something that they would have any use for. When I presented it to ORA, they were excited by the project and that is how my project got approved. I have gotten assistance from Compliance and others on how to go about validating the method. So the coordination has worked well for me (OARSA). • What has worked well is the interactions between the research scientists and the microbiologist and the ORA field-level personnel (OARSA). • Personal interactions with collaborators: hashing out the details and logistics of methodology before issuing compliance assignments. There is no reason that this cannot be more broadly applied (ORS). • We are a small group and are able to just call people or speak with them directly (ORS). • To work with the field labs before, you had to go through the Division of Field Services, so if you contacted someone who was either overworked or crazy, you never dealt with the field labs. Now, we can contact the field labs directly (ORS). • Establishing personal contacts. I know the person at CFSAN who does *Salmonella* so I call and ask him questions if necessary (CVM).
Effective leadership	• MOD 1 and OFS/DI attempted to bring everyone together in virology to work on projects. There was good representation, but it was a mess. When the leader coordinating things left the project, it fell apart. Instead of sharing, everyone did it their way (ORS). • It works great where there is an individual who "gets it." The leadership of ONADE understand what is needed to develop an idea that can be converted into an achievable research project. However, the directors of the surveillance and compliance groups don't know how to analyze their own needs, how to translate their data gaps into doable projects, don't understand what we can and cannot do, and can't assess their own time lines (CVM). • In the methods validation program, aligning ourselves with the field programs has helped

C.2.3.17.a. Interviewee Observations: What has worked well with respect to such coordination?	
	in jointly developing and validating methods. On the research side of headquarters (i.e., CFSAN and CVM) there's a pyramid of field labs. On the top of the pyramid are those labs testing futuristic capabilities that will eventually be rolled out as innovations down to the base of the pyramid, which are the trenches where the public health labs are sampling the foods that are making people sick. All of that has to be coordinated, ideally by a single person at the top who's responsible for bringing that innovation down to the base. But it's not just top down; let's bring it back up too (OARSA).
Define roles in interactions	• If you define what each part does, and everyone agrees. Sometimes the issue is as simple as the first name that appears on a paper (ORS). • There are clear and established rules in the organizational structure, and our interactions work well (ORS). • Formalizing the prioritization process with the regulatory and compliance offices has worked very well in coordinating our research to their needs (CVM).
Sharing new technology	• We have only had positive interactions with the field labs. We have two labs here that are ORA labs here in MOD 1 so that we can see whether the methods we develop will work for them in the field. Our sequencers actually belong to ORA because we are their technical advisors and trainers (OARSA). • Using WGS in compliance actions and enforcement has been extraordinary. We know that WGS would be the future, but we didn't expect that it would happen so quickly (ORS). • Most of our regulatory samples are coming from the field labs. We are getting a tremendous amount more data than if we were operating alone. Instead of having to request strains from the field labs, the field labs can sequence them themselves and feed the data into our pipeline (ORS).
Regular meetings	• The weekly calls and reports with ORA field labs is working well (ORS). • Meeting with ONADE. We also meet with ORA once a year to ask what we can do for them. We have a good working relationship with a lot of groups (CVM).
Working groups	• The working groups seem to be a step in the right direction, but the information isn't going beyond the group members and back to the rank and file. There's some hope for transparency because everything's up on the web site. But I'm a bench scientist. I can't spend my time in meetings or I won't get any work done (OARSA). • Working groups between the different centers have worked well (CVM).

C.2.3.17.b. What efforts are needed to increase and/or improve coordination efforts?

C.2.3.17.b. Interviewee Observations: What efforts are needed to increase and/or improve coordination efforts?	
Improving awareness of what these groups do	• A semi-annual meeting with some of the people from these groups talking directly to the scientists would be very valuable. It could be done in the form of a webinar since everyone is in different locations. In addition, working group meetings also could be shared via webinar (OARSA). • They could design interactive sessions between these different groups and researchers so we could find out what they are doing. We really don't understand that aspect of FDA. Some of what is going on in the other program offices has become obvious to me because of these phone calls that I get, but not because it was explained to me how FDA works ever (OARSA). • We should provide more information about what these areas do (OARSA). • There should be more informational classes like ORA provides on what they do and what kind of methods they're looking for (OARSA). • People here have to understand what ORA's limitations and working conditions are. Their work environment is different from ours. We work at our own pace, but they have surveillance activities and product coming in to be tested. We have to understand that that is their first priority and that methods we develop have to be something they can do in the field. We have to understand what their work flow is like. Anything they do can be challenged in court, so everything has to follow an SOP (OARSA). • ORS and OARSA don't seem to be very much in touch, even with the field programs. I think ORS does a good job of making sure their method development efforts are things the field labs really need and could use. But OARSA seems to be a little more out of touch with that, and I don't think either one is really in touch with the regulatory needs (OFS/DI). • There needs to be more trust fostered and more communication so everyone can be on the same page before methodologies are issued. This is lacking between the Center and ORA, and has led to issues in the past with the review and rejection of compliance violation cases that used non-sanctioned methodologies. The program office isn't talking to Compliance, who isn't talking to the scientists, who aren't talking to the field labs. It could be much improved through communication (ORS). • Bring the groups together to talk. Have more meetings to discuss each person's research. They are looking into "Speedline Conferences" in which each person speaks 10 minutes about their research. FDA has not brought all of their scientists together for years (since 2006, convention center in DC; ORS). • Before, CFSAN would develop compliance programs and would issue them to ORA for comment and correction before final programs were issued. Now, there is a breakdown of communication with ORA and the field labs, and compliance assignments are sent out before the details are worked out (ORS). • We need to find a way to communicate the science to them. We don't even know how to talk to each other. We speak in completely different jargon. It would be good to have someone to facilitate the communication. We have a Commissioner's Fellow posted to fill that role this summer, so that will help (ORS). • There needs to be more coordination and collaboration with Compliance to see what they need. This might happen if we conducted small branch reviews similar to this one (ORS). • We need to be more involved in these activities and understand their work flow and what they are doing. Sometimes compliance officers come to a training session to discuss their work and this is helpful to our understanding (ORS). • Improve direct communication between Centers and regulatory side (CVM).
Increase interactions with these groups	• Research people should get at least 1 week to 1 month rotation into field labs every 3-5 years. Scientists in our group who have done field lab rotations have gained appreciation for the importance of the field labs (OARSA). • Provide more opportunity to interact, maybe via short-term (3-month) details in

C.2.3.17.b. Interviewee Observations: What efforts are needed to increase and/or improve coordination efforts?	
	compliance or policy-making or field program (OARSA). • In the working groups, when you put program offices and researchers together, we can determine what research is needed for the different areas. We need to be involved in as many programmatic office issues as possible that are going on at the Center. There is no prohibition against being involved. Also, we need to keep our researchers informed about things we hear at management council meetings, e-mails we receive concerning outbreak responses that we forward on, etc. It gives the researchers a better idea of what they should be doing and how their research actually helps. Even little things like this are useful (OARSA). • Someone from each of these program offices should be part of each working group. This should be the function of the working groups, but I'm just navigating this now. This may exist, and I don't know about it (OARSA). • We have a terrible business model with ORA. We need a more interaction/cooperation**.** We have ORA using crappy methods every day to test the pathogen/commodity pairs where we think the biggest problems are. CSFAN, as the developers of the methods, have no respect for their capabilities because we don't know them. Very few of them get on our publications. We need to run our methods side-by-side with theirs. If ours are better, they'll accept it (OFS/DI). • We need to interact and communicate with the ORA field labs and find solutions that fit their business models. If we develop a PCR method and they don't have the equipment, what good does that do? Become friends with your collaborators. Give them a reason to communicate with you. It doesn't have to be all business (OFS/DI). • We have to meet with them more. We need to really understand their processes and needs so that we can support those needs and can help integrate the new technology into their processes. The formality of the meetings helps the communication (ORS). • There is a lot of disagreement within ORA about how the labs are to be run and what analyses should be run. There needs to be more consistency between labs in ORA (ORS). • Increase opportunities for communication. Maybe management should set up a visit to ORA field labs for an understanding of how they do analysis and what they need. We could also have meetings where scientists can share their research (ORS). • I've interacted with people at the ORA field labs and brought back things that have really improved our research. The BCs and PIs should go to the field labs and OFS/MC and interact with the investigators there. If you have a great idea, but it's not workable in the field lab, there is no point in pursuing that line of investigation. E.g., I developed a method for tomatoes using a knife. They didn't like using a knife, so they wouldn't do it by that method. I could have saved so much of my time by just talking to them first. Spending $2K to send someone to the field lab for a couple of days could save a couple of years and $100K developing a method that will never be used in the field. In addition, visiting the field labs has resulted in two methods being published in the BAM (ORS). • Bring people get together (e.g., have the feed additive group meet with the food additive group to discuss how they come up with regulations) so we present a consistent voice when publishing guidance. Outside, there's only one FDA (CVM).
Increase direct communication between scientists working in these efforts	• ORA senior scientists need to be more vocal about what they need. We are asked to develop tools for an office where many of the people don't even know what they do (OARSA). • Allow direct communication with other groups rather than having to go through channels (OFS/DI). • It would be helpful to receive more feedback from field programs and as quickly as possible. I am not sure how ORA communicates issues to us or how they can improve. In the past, we took a trip to the field labs and the technicians there had many comments for us on the methods. These comments are not reaching us regularly. It would be great if they could communicate their research efforts with us. We complement each other and combining results could lead to more efficient methods (ORS). • It is frowned upon for ORA to call us with issues or questions on methods. The ORA

C.2.3.17.b. Interviewee Observations: What efforts are needed to increase and/or improve coordination efforts?	
	scientists have to go up the chain through managers before we get the question, if it comes to us at all. Some scientists are allowed to call or email us directly (CA and NY), so this direct communication would be helpful elsewhere (ORS). • Direct communication with field lab scientists would be more effective and efficient. Ease communication between our lab scientists and the ORA field labs. It is difficult to directly communicate with the field analysts; we are supposed to talk to their supervisors (ORS). • Walking around and talking with people. It helps if you have personnel that are open to that. The answer is not more meetings. All that does is create discontent (ORS). • It seems like there are extraneous middle-men. Management should be in-the-know, but not in a position to block communication (ORS). • We need more communication with the field to get feedback on methods we develop. They know the best methods for field application. Here in the Center, we don't have much idea what is going on in the field. They also have their own Ph.Ds. developing their own methods. We find it frustrating that they never use our methods. Scientists need direct connections to their counterparts to better match resources to needs (ORS).
Develop a structure for coordination	• This is not a strong point of CFSAN research. It is not institutionalized, and I am not sure why not. It is often driven by interpersonal relationships among people who are willing to work together. There is no conscious effort to teach our staff what is done in these different areas. There are many people here who don't know what Compliance does, and, if you don't know anything, it is difficult to think of how you might work with them or contribute to their activities (OARSA). • Establish research boundaries. The Center should be referring people to the appropriate groups, instead of someone saying, "Oh we'll do that for you." (OARSA). • People who have CARTS projects can join working groups. I suppose limiting the number of people interacting with these groups is good, but if people don't have CARTS projects, and they still have an interest in these groups, they should somehow be able to interact with these groups. Right now it is very limited. For some of us who do not have CARTS projects, there is no interaction (OARSA). • We should have a MB SWAT team for outbreaks to work with ORA. Everything that ORA does for gathering evidence for court cases is burdened by mountains of paperwork. We need a CFSAN investigative team, perhaps in mobile labs, that can use rapid methods, make decisions on risk, triage the case, and then turn it over to ORA to use the slower methods needed for compiling the legal case. We need to become better detectives—you have your investigators and law enforcement, but team them with specialists. ORA people tend to be generalists. The SWAT team could be made up of specialists for a given pathogen. The investigative team would need to have complementary skills and could run multiple approaches to determine whose method works the best (OFS/DI). • There is no central coordination of the field labs, so we have to contact each individual lab separately (ORS). • There needs to be higher coordination within the field labs. We work through the ORA genomics lead and he works with the different labs. We need a coordinated way to request isolates and a coordinated way to receive the isolates. Where the reports go are also becoming formalized. These are good recent developments (ORS). • Not sure of how the infrastructure is set up for the future. We are doing a lot of the ordering for the field labs. It would be good if they could set up something where they can have their own support so they can order what they need instead of asking us to order something and having it shipped there (ORS). • There needs to be a facilitator to bridge the gap between researchers and the other programs, and a bridge to help the field offices communicate with the Center and vice versa (CVM).
Increase management encouragement/	• Management needs to acknowledge that there is science and research involved, and to

C.2.3.17.b. Interviewee Observations: What efforts are needed to increase and/or improve coordination efforts?	
support	allow us to communicate with each other in as free a fashion as possible within the guidelines (OARSA). • Our leadership needs to meet and talk with the program offices and high-level field program offices so we can better align our research efforts. Following through with them is important too (OARSA). • To maintain coordination, it needs to be recognized and applauded. When our office management comes down here, they seem to be impressed. It's always a positive vibe that we are hitting our mark and keeping everyone in the loop that needs to be in. As a scientist I like that because I get a pulse of what is the next big issue. When designing research to answer a question that just may be developing, it's important to have those ties in because that's where you hear about it (OFS/DI). • For WGS, we need to be coordinating our efforts now. It will involve CVM, CFSAN and the Field Labs. This has to happen at the management level (CVM).
Refocus on our mission	• There needs to be reinforcement of what our purpose is as MB research groups; to realize that the end-game is to be able to put forth methodologies and tools that can be used to keep our seafood and food supply safe. This means we need to adapt it to the regulatory officers who are out there doing it. Researchers need to be reminded of this (OFS/DI).

C.2.3.18. Describe current coordination efforts between intramural microbiological research programs and extramural "Centers of Excellence".

The responses to this question have been divided into two tables: one for COEs other than IFSH/Moffett Center, and one for IFSH/Moffett Center.

C.2.3.18-1. Interviewee Observations: Describe Current Coordination Efforts Between Intramural Microbiological Research Programs and Extramural "Centers of Excellence".	
Interactions with COEs in general	• Some of our people are on the board or project advisory group for COEs (OARSA). • I know of JIFSAN and UCLA. As long as there is good project management, these seem to work really well. It helps to bring recognition to our scientists here when they are involved (OARSA). • I know of COEs but I do not know many people working with them on a research basis. They do have research projects that are supported by FDA, but I'm not sure whether it's not encouraged for them to work with researchers in our division (ORS).
JIFSAN	• Of the four, two are involved with CFSAN directly—JIFSAN and IFSH. Both are more hybrid programs. They take part in ERO development, strategic planning (OARSA). • We have some collaborations with the JIFSAN students (OARSA). • JIFSAN academic labs are associated with the WGS project (OARSA). • There may be some interaction with JIFSAN because they also work with allergens, but it's probably sporadic at best (OFS/MC). • Our division has a long-standing relationship with JIFSAN. This has been very productive. Our staff have sat on the students' committees. JIFSAN has been great with helping us with a website we are trying to develop, even though IT have been sticks in the mud (ORS). • We have a lot of interaction with JIFSAN, e.g., we are invited to teach courses by JIFSAN. We also receive students from them during the summer (ORS). • We work a lot with the UMD and JIFSAN program. We have strong ties with food science program at UMD. Plant science students are doing meta-genomic work here (ORS). • JIFSAN offers training courses and has invited us to give presentations and to serve as lab instructors. JIFSAN has also sent employees and students to work on FDA projects (ORS). • We have a good relationship with JIFSAN. We get graduate students working here (CVM). • I'm on the team that is helping JIFSAN with a training program for scientists from other countries. The program trains them how to isolate *Salmonella* and *Campylobacter* and do molecular techniques for identifying these bacteria. We work really well together (CVM).
Western Center for Food Safety (WCFS)	• There is some field coordination between labs here and at WCFS on *E. coli* (OARSA). • We work with the WCFS, which is at the front end (the farm side) of leafy greens production and processing. Our expertise is in the middle, once it gets off the field and into the processing plant. Their research might affect farm productions, GAPs, etc. This obviously influences our work because we're downstream form them. If they have process controls they can devise and implement for the farm, and to get crops to the processing facility, than maybe it would be easier for us to facilitate mitigation or processing steps on our end (OFS/MC). • UC Davis is working on genomics, in the 100K Genome Project. These collaborations are handled by our management (ORS).
National Center for Natural Product Research (NCNPR)	• Interactions with NCNPR and IFSH are rare (ORS).
Other entities identified as COEs by	• We have some interaction with NCTR. It is hard to keep them in the loop and connected but not allow them to highjack projects or to involve us without a prior

C.2.3.18-1. Interviewee Observations: Describe Current Coordination Efforts Between Intramural Microbiological Research Programs and Extramural "Centers of Excellence".	
interviewees	agreement (ORS). • We have contact with the Florida Center of Excellence [for Regenerative Health Biotechnology?]. With the genome tracker, we worked with the field lab in the network, but we identified five state labs as well. The University of Florida COE was next to one of the state labs and could help with the sequencing and the bioinformatics (ORS).
Value of interactions	• I have had experience with JIFSAN students. That program is good for the students, but doesn't work out too well for the PIs since the students have erratic schedules during the semester. I've had better experiences in the past with students from HACU's summer program. It was managed through the Center, so there was less favoritism in applying for and being approved to have a student helper (ORS). • Our efforts on the 100K Genome Project with WCFS are working, but we really haven't gotten what we needed, partly because the contract was not well written (ORS). • Work with WCFS on the 100K Genome Project: It's a good idea, but we don't have much interaction. The government has given them a big chunk of money, but in reality, we don't interact (ORS). • We have been working on the 100K Genome Project with WCFS. This has been slow to produce results and has been very frustrating to the DD and the DDSO. There have been communication problems, and it has taken longer to get the lab set up to produce large amounts of data. There needs to be some accountability. They are ready to give up on it, but we have a lot invested in it, so we can't walk away (ORS). • Our laboratories have not integrated as well as we could with COEs. We give many of these COEs millions of dollars every year, and I think that the program office is getting some things that they need, but there are many things that I'm stunned that they send out to these labs instead of their own, which could have done them better. I don't know whether all of those funds are being focused properly on our needs (ORS).
Don't know	• I didn't even know of COEs until this question (OARSA). • We have no interaction with any of these. We don't know why they've been established, what their area of expertise is, what are their products. Why are they needed? Why are they not solely FDA research? I know that funds are ear-marked for them (OFS/DI). • There is a lot of collaborative research here. Almost all of us have collaborators somewhere, but not necessarily with COEs. This is because we have our primary research capabilities under control (OFS/DI). • Centers of Excellence is an FDA motto, but it doesn't draw the attention of many people (OFS/MC).

C.2.3.18-2. Interviewee Observations: Describe Current Coordination Efforts Between Intramural Microbiological Research Programs and Extramural "Centers of Excellence": IFSH	
IFSH	{All responses from OFS/MC] • IFSH is one of the Centers of Excellence so the coordination is pretty good because we're onsite. • We're doing a mixed project right now. IFSH has a big role to play in my area, but I don't know if IFSH or CFSAN management understands it. What can be done in this area? It's impractical to think FDA can do it alone.
IFSH (continued)	The relationship here has started to improve, but until IFSH bring in better people who are actually worth the money, it's not going to get much better. Occasionally, one or two good people are brought in, but management is still bad. The Director is a good strong scientist, but not a very good manager. He should have good people working under him. He inherited what was there, and it wouldn't be his style to change it. I'm interested to see what will happen in the next several years because some of the IIT people were switched over to tenure track positions with the university. I'll be curious to see how and if their staff manages to get tenure. It also could be a political issue. But when you see the lack of publications that some of them have, you have to shake your head and ask how

C.2.3.18-2. Interviewee Observations: Describe Current Coordination Efforts Between Intramural Microbiological Research Programs and Extramural "Centers of Excellence": IFSH	
	can this be (OFS/MC)? • The problem, is that we aren't here to work for industry. When I joined FDA we only had FDA projects. Because the resources are now in the IFSH platform, there's no place for EROs unless a management initiative moves them together. Everyone here feels the same frustration. We are FDA, we are paid by FDA, but we are working for IFSH. Why? • The IFSH staff has always been limited. They aren't necessarily researchers you'd collaborate with on your own if you really had a choice, but we don't have a choice. Some of it is symbiotic in that we're not allowed to do certain things. For example, we can't initiate a grant. Grants and money have to come from the COE, so some people here (not me) have written grants for them. They get no credit for that. The COE gets credit for the grants and the money. FDA has many strong scientists, and a lot of good people who work really hard. The COE doesn't: Just look at the number of publications and who's writing them. • FDA puts a lot of money into the COE and gets nothing back. On the industry side, there are mostly managers and not real scientists. Even with more pressure from FDA, it doesn't seem as if that will change. We are doing essentially 100% of the work for this center. • There is inequity in FDA's relationship with IFSH. Within IFSH we have to work together with IIT for grant money. When former colleagues invited me to collaborate on a USDA grant, an FDA manager here stopped me. He said if I competed for the funds, IIT would lose out. Eventually I agreed. Instead, my resume was included in a proposal with two other PIs from IIT. The result was good: >$900,000 came in. But IIT claimed all the money as its own. They said that I was a collaborator, but they were going to decide how to spend the money. In the proposal, I asked for a post-doc to work on this tough project. IIT proposed and obtained two post-docs, which were funded, but they used them for other things. This is the third year of the grant. The worst part of this is right now there's only one PI. The IIT person doesn't do any research. He travels domestically and internationally to conferences. This is totally wrong, and it happened under the current Director of IFSH. I was shocked. Under the previous Director of IIT I had another grant. He handled it very fairly. FDA was on one side, IIT on the other, and we laid out the plan. • Sometimes we run into issues on what's more important: FDA research or IFSH research? IFSH pulls IIT scientists away from us to work on something else. When they do this, it makes the priorities unclear. • I shouldn't be involved in three projects at the same time. Fortunately, I'm not running them all by myself. We're able to tag team with some of the people from IFSH because it's collaborative research. What's wrong with this "collaborative research" is that not much of the collaborative money for the Center gets is funneled over to us. Is it really collaborative if we don't see the money? The fact that we're physically in this building makes it collaborative. • Many scientists here have no direct contact with anyone outside. We rely on our bosses, but they're not experts in all these areas. They need to understand our value and advocate for us to be involved in compliance and policy. In 20 years, there's never been a clear scope of what we do and what our role is in this part of IFSH. It depends on the year or the time. When this place was formed, the industry was changing rapidly, and FDA was having a hard time keeping up with industry development and safety issues. Industry and FDA had to work together to develop a process that considered everything. That was good, but in practice, the IIT people were underlying the whole thing. • We work with IIT. It has been good, although we give IIT money and the PIs spend it on things they shouldn't. For instance, one of our technicians left and we gave IIT money to hire a replacement. It took them forever. They said there wasn't enough money.

C.2.3.18.a. What has worked well with respect to such coordination?

C.2.3.18.a. Interviewee Observations: What has worked well with respect to such coordination?	
Good project management	• As long as there is good project management, these seem to work really well. It helps to bring recognition to our scientists here when they are involved (OARSA). • As long as FDA keeps them on a short leash with a specific focus on solving a problem and continuous feedback. This allows more money to the COEs (ORS).
Having an area of interest in common	• Interactions are limited by what you work on and the COE's area of specialization (OARSA). • Their missions are directly related to FDA interests (ORS).
Having points of contact	• Having point persons who interact. We are publishing two papers with WCFS. These will be the first two concrete deliverables with them despite their work with ORS in WGS (ORS).
Collaboration at the scientist level	• Collaboration at the scientist-to-scientist level has worked (ORS).

C.2.3.18.b. What efforts are needed to increase and/or improve coordination efforts?

C.2.3.18.b. Interviewee Observations: Efforts Needed to Increase and/or Improve Coordination Efforts.	
Increase awareness of what these centers do	• There's no coordination or flow of information between the Centers and the rank and file scientists, which has essentially blocked any collaboration (OARSA). • COEs have not been at the forefront of CFSAN activities. We know they exist and have a vague idea of their different areas. More information on what they do and can provide would be helpful to researchers (OARSA). • I would like to see an overview of the objectives of these COEs. They should have peer reviews on those programs to evaluate their impacts and benefits. The level of scrutiny on intramural research is completely different than for these COEs. I don't know if what they're doing is important. And how do we know if we can leverage off what they're doing (OFS/DI)? • They may not have a direct effect, or we wouldn't necessarily collaborate, but knowing what they're doing, trying to do, and how that could influence what we're trying to do would be beneficial (OFS/MC). • There should be more meetings and sharing data/information (ORS). • One goal of the Speedline Conference is to bring FDA, other Centers, and other COEs together to see what they are doing (ORS). • I would like to be better informed about when and how to get involved in the JIFSAN program (ORS). • If they sought collaborations or gave presentations, it would encourage interaction (ORS). • We need to be made aware of the Centers of Excellence (CVM).
Better contracts	• We need to make sure there are concrete deliverables instead of just meetings without people involved. A lot of communication is not transparent and you don't find out until afterwards that it happened (OARSA). • There needs to more support from the Agency when writing contracts and MOUs, so that you get what you pay for in a timely manner. In my experience, managers are given this writing job without support, and the contract or MOU ends up with too many loopholes. It would be great to have the support of a legal team that would help the contract be tight. Maybe even a negotiator would be helpful (ORS).
Encourage interactions	• If the leadership dictates collaboration, the scientists don't know what this place has to offer, or how they are going to work with them. I'm not sure we're getting all we can out of our COEs, but when you let the scientists go out and find centers that they can work with, we see big things happen. This is especially true for produce safety and farm MB. Being here in CPK1, we don't have access to a lot of farms (ORS).
For IFSH	• We need an MOU between IIT and FDA. I've heard many people say IIT takes the FDA scientists' data and solicits research projects. And the funding comes in. But only

C.2.3.18.b. Interviewee Observations: Efforts Needed to Increase and/or Improve Coordination Efforts.	
	the FDA scientists are doing the work. The memorandum has to be direct and state that IIT will act as consultants. They don't need an FDA collaborator. They can do the consulting and be the mediator with the industry and FDA. IIT can function as a school, the IIT Department of Food Science and Nutrition. Academia should be part of the memorandum. We shouldn't be restricted to working with IIT because they don't work well with us. Current policy at the Moffett Center is we have to go through IIT. If we worked with other universities that would force IIT to become more competitive and strengthen its capabilities. My main question is: Can we get extramural funding with universities other than just IIT? (OFS/MC). • We don't have enough staff to handle all the IFSH students. IFSH now requires many more students to sustain its business model. It needs more scientists to direct the students. Allowing them to get more scientists on staff would improve coordination immensely (OFS/MC). • We collaborate with IIT in writing grants: FDA can apply for USDA grants but only through IIT. We need an IFSH counterpart to be the PI, but they don't have enough experts. Having that expert increases our chances for funding. I can't be a PI, only a collaborator. Hopefully, this will change (OFS/MC).

C.2.3.19. At what levels and in what manner do the CFSAN and CVM programs interact on significant microbiological issues with: CDC, USDA, EPA, academia, other federal agencies, and international bodies?

The responses to this question have been divided into six tables: one each for CDC, USDA, EPA, Academia, other federal agencies, and international bodies.

C.2.3.19-1. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: CDC.	
CDC	
OARSA	
Reported interactions	**Outbreaks and collaborations:** • We work pretty closely in different areas, and in outbreak situations, and we have a CDC liaison to facilitate our work with them. We are currently working on a joint manuscript with CDC and published last year as part of an institutional interaction. • A lot of conference calls take place during and after outbreaks. Sometimes during or after the outbreak is completed, CDC will send us isolates so we can continue to research the clinical isolates vs. some of the isolates that our ORA labs isolate through the food. It's important to compare them so we can confirm that what is being found in patients is also what is being found in the food or the environment. **Collaborations:** • We (virology) interact with CDC very well. We have a collaboration and also work through an exempted IRB (Institutional Review Board), as well as on-paper and hand-shake agreements about dealing with norovirus samples. They trust us enough and we trust them. They have helped us to establish some connections and collaborations with some other labs outside. • With CDC we have always had good interactions from our perspectives: virology program, and norovirus and *E. coli* program. We've had interagency agreements. It has worked well. • Our group collaborates with CDC for fecal samples for norovirus outbreaks. Our collaborator on this at CDC is great! • We worked with them on allergic response to GMO products. • We've worked with CDC, USDA, Academia, Codex, FAO/WHO, U.S. Japan Natural Resources Council. Some of them are mainly scientific, collaborations. We've worked through the CDC liaison to FDA, and she's helped us. We've worked with USDA and CDC on other bacteria/microorganisms. We are doing pretty well as far as collaborations are concerned.

C.2.3.19-1. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: CDC.	
	• My team and myself have a good working relationship with the CDC; however, some of my colleagues within CFSAN have had collaborations with the CDC that have gone down in flames. There is quite a bit of tension and animosity between them now. • The microarray people have gone to CDC and talked to them about the microarray and they're collaborating.
Areas for improvement	**Outbreaks and collaborations:** • Efforts are well coordinated at the basic, functioning level of what we are supposed to be doing--responses to outbreaks. But we should be able to work together better at a higher level too. CDC is also doing a lot of research and it is never quite clear how far we are supposed to go in collaborations with CDC. **Collaborations:** • Interactions tend to be ego-by-ego driven. We do have an ongoing effort right now with CDC on microarray, but upper management does not want us to do it. • CDC is a problem. It is very difficult to work with them. If they see something that we're doing that they like, they take it and get a better budget for it. We have tried, we are trying now with a *Listeria* WGS project, but it's not working. It's like relatives that don't get along. • I've reached out to CDC throughout my career. I've been rebuffed by them and scolded by my superiors so I don't try anymore.
Should increase interactions	• We don't collaborate with the hepatitis people and I don't know why. It would be great to work with them because we have a common goal.
OFS/DI	
Reported interactions	**Collaborations and mutual food safety/protection efforts:** • We have a really good relationship both in research and in epidemiology reporting. We can call the lead epidemiologist for *Vibrio* issues and ask her to look at the stats for us to tease out information we need for changes we are trying to make in the cooperative program. We have a high level of interaction. • We publish with them a lot—with their bioterrorism group, epidemiology group. We have 3 or 4 projects currently running. I bet we have more publications with CDC than the rest of FDA combined.
Areas for improvement	**Outbreaks:** • If there's an outbreak, then we will work with CDC. For the most part we try not to—or they try not to. But we will if we have to. **Collaborations:** • We work very well with certain groups where there are areas of overlap in research. Institutionally CDC has a different mindset. They are often not very forthcoming. They think they're the only ones: "You have to come to us to get the information." • Working with them has always been a chafing issue. Even with liaisons, they just have a different mission, and they are guarded in their little fiefdoms too. We work hard to work with them, and they probably say the same. • We try to work with them. I don't think they feel they need to work with anybody. I am certified to use one of their databases, but there are so many issues with using it. They may tout that as collaboration, but it is not because it is so guarded. It's as if they're trying to apply some of their rules for the states to other Federal agencies. • There is a very toxic relationship between CFSAN and CDC that resulted from CFSAN having taken advantage in a collaboration in the past. This needs to be fixed. We have initiated most of the collaborations, but now they are reaching out to us.
OFS/MC	
Reported interactions	**Mutual food safety/protection efforts:** • We have monthly conference calls with CDC via the IBRCC. IBRCC holds an international meeting where everybody in the world who works on *Clostridium botulinum* gets together annually. CDC and FDA have hosted it, but the meetings are usually in

C.2.3.19-1. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: CDC.	
	September, when we don't have money. • Our interactions are usually informational. We're not actively engaged in cross-cutting research. **Preventive controls:** • We put together a working group with people from USDA, CDC, academia, and industry to examine how fresh cut produce producers can validate their preventive controls. We still need someone from EPA. Forming small working groups is how we do it here. We also have a Low Moisture Food Task Force that has partners from other agencies, academia, and industry. It is investigator initiated with backing from management. **Proficiency testing:** • ICLN coordinates the lab networks for FDA, CDC, and EPA. Every year or every other year, we do one proficiency testing for CDC as part of the fund.
Areas for improvement	**Collaborations:** • Right now CDC is difficult to go through. FDA should have someone reside in CDC as a liaison to make it easier for us to obtain samples.
ORS	
Reported interactions	**Outbreaks and collaborations:** • The subtyping Branch helps identify pathogens in current outbreaks. We discuss validations of methods for ISO. We get isolates from CDC to try to understand what virulence factors cause illness in *E. coli* O157:H7. • We work with them very closely, especially in response to an outbreak. We respond to their epidemiological reports, PulseNet reports. **Collaborations:** • We share a lot of the same strains. In the beginning CDC was testing our system by sending us blinded samples--testing the robustness of using sequencing for tracking food-borne illnesses. Recently CDC has started picking up their own sequencers and doing sequencing support for themselves. • We collaborate on PFGE and sequencing work, including weekly conference calls. • We have a monthly call that came about recently. This has helped with collaboration. We are breaking down some of the barriers that have existed. • We're supporting the real-time *Listeria* project with environmental and food. We've built the network with NCBI to automate the upload of sequences to the SRA (Sequence Read Archive). A data analysis pipeline tool has been developed to for the data and then all the data is shared with the CDC. **Mutual food safety/protection efforts:** • We have monthly calls with CDC to discuss various topics like genomics efforts, *Listeria* program, and culture-independent work. We do try to have a lot of communication with them on ongoing efforts at CFSAN. • We work with the CDC through the LRN.
Areas for improvement	**Outbreaks:** • CDC can be difficult to work with. There are valiant efforts on both sides to improve relations. FDA has extended many olive branches to increase collaborations. The *Listeria* real-time sequencing is an example of recent successful collaboration. There are issues still being debated, but cooperation between us and CDC is good for public health and should be expanded. • During an outbreak there is a lot of interaction. They have to interact on TV even if they don't like each other. Interaction at the manager level is the key to an outbreak. Maybe we should be combined into one agency. State agencies and CDC should be mandated to report outbreaks to the FDA as soon as possible. • It is a bit complicated with CDC. During outbreak investigations, we each collect samples and do analysis before combining results. These interactions are not research collaborations/projects. There are some issues between us, e.g., CDC tried to cut FDA

C.2.3.19-1. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: CDC.	
	authors out of a joint outbreak investigation manuscript. Sometimes, CDC is not great about sharing full information about samples. The communication with CDC has improved somewhat. • It's always a pain. We work with them on outbreaks but they have different philosophy. They are very reluctant to change. We are spearheading a lot of things and are changing very fast, but they are dragging us down. • The problem is ORA. In an outbreak, ORA interacts with CDC, then may call in CFSAN. So there is no direct interaction between CFSAN and CDC. **Collaborations:** • I have very good collaborations with the CDC colleagues, which is not the case at the management level, where a level of mistrust was created by microbiological managers who cut CDC out of the loop on a collaborative effort and published without them. • Generally, there is a lot of competition and dissension in working with CDC, but the WGS group meet on a monthly basis with the CDC liaison who just started in the last year. She takes our issues to heart. • We were told that if we publish a paper with any kind of clinical strain of *Salmonella* or *E. coli*, we have to give our manuscript to the CDC for review and comment before it's published. I don't think they're passing everything by us. • They are very good at manipulating the press to get their budget. They don't want to share the credit for next generation WGS and it shows pigheadedness all the way to the top. • Things are very tenuous with CDC. They seem to go out of their way to jam up what they can. It might be pretty mutual. We do not all seem to be on the same team. • There is one person blocking interactions between CFSAN and CDC. He is an obstacle for every single collaboration. Otherwise, we have good interactions. For the 100K Genome Project, they have the largest collection of bacteria, but they don't actually want to collaborate. Every time you ask them for something, they tell you they don't have money, but their budget is much higher than FDA's. • We get microbial strains from the CDC, but this is through a personal contact. In general the relationship with CDC is strained. **Mutual food safety/protection efforts:** • I work with the CDC almost daily, but they're a tough nut to crack. They look at the world a little differently than the FDA I look at our relationship with them as the FBI must feel with the ATF.
CVM	
Reported interactions	• NARMS does a lot with CDC because they are one of the major arms of NARMS. There are research coordination groups within the CDC, USDA, and FDA that focus on specific aspects of NARMS research. • There is some coordination for the NARMS program. We test similar bacteria, use the same methods. We try to make sure we are in line with them. In working together on WGS we do research to try to tie the human MB end of resistance to the animal. • Under NARMS, we have been working with CDC and USDA for the last 12 years on a weekly, sometimes daily basis. We have molecular, epidemiology, and pathogen-specific lab working groups with CDC. • For antimicrobial resistance, there are regular conference calls, work groups, and individual emails happening at the scientist level with both CDC and USDA.
Areas for improvement	• At the policy level, CDC and FDA have territorial clashes.

C.2.3.19-2. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: USDA.	
USDA	
OARSA	
Reported interactions	**Outbreaks:** • Some our scientists collaborate with USDA and work with them through FERN. **Collaborations:** • Understanding virulence associated with Shiga Toxin-Producing *E. coli* (STEC) and NARMS. It is something they and we hold as a priority program. • We work with them on egg safety. They share reagents with us. They have developed chicken arrays to analyze genetic expression of immune responses. We've shared chicken antibodies with them and they use our flow cytometer. • We've had some interaction, but it takes time. We did have some with USDA Beltsville and went to the ARS lab in Philadelphia to try to find areas of collaboration.
Areas for improvement	• Interactions are difficult because you are attempting to collaborate with someone who is technically your competitor. You need to build up trust for interactions like this. • We try to work with them. They are kind of broke, so they're always looking for money.
OFS/DI	
Reported interactions	**Collaborations:** • We work with them on projects. They are developing methods for norovirus in seafood and we are collaborating in using some of that technology in our research projects. **Methods training:** • We have invited them to be instructors on real-time PCR methods. We've trained about 500 people. We've brought real-time PCR to state labs, FERN labs and international labs. That collaboration thing really works. • They are part of FERN, so we have some methods that we have validated and submitted to FERN for approval.
Should increase interactions	**Collaborations**: • We should look into more collaboration on aquaculture. We should become more proactive with that because food resources will go that way (shellfish, shrimp, fish; OFS/DI).
OFS/MC	
Reported interactions	**Proficiency testing:** • We have a Proficiency Testing program with USDA and a signed statement of work every year. • We don't do collaborative research, but we interact with USDA probably more than anybody else because we have so many things in common. If we know of research that's going on within USDA, we may inquire as to the nature of it, what they're doing, how they're doing it, etc. We certainly could collaborate.
Areas for improvement	• Many of the grants we apply for are USDA-funded grants, but dealing with USDA is one thing; having grants funded through USDA is another.
Should increase interactions	**Collaborations:** • I don't have a direct contact with USDA. My interaction with them is through IFSH. I'd love to work with them, but we're always blocked by the funding and IIT's role.
ORS	
Reported interactions	**Mutual food safety/protection efforts:** • We work with FSIS (Food Safety and Inspection Service), as they have a similar mission and regulatory constraints. They also have a more similar culture than those from CDC. • They are involved with some of the monthly CDC calls. For example, *Listeria* involves FDA, USDA, and CDC because we all have a problem with *Listeria*. **Collaborations:** • We are working with USDA on the persistence of *Salmonella* on the farm. Doing diversity testing of what kind of *Salmonella* exists on the farm and how it persists in the gut. • There is a lot of collaboration with USDA. They have access to the field and we often

C.2.3.19-2. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: USDA.	
	have more resources and higher levels of technology. We can use their excellent questions and fields and apply our high-level methods. • We have collaborations with them on *Salmonella* and *E. coli* in meat and animals, and some small research.
Areas for improvement	**Collaborations:** • They are slower to share isolates and the meta-data. They tend to protect the meat industry. They are a good partner, but they don't have much money and are cautious. • We have team-level collaborations. They are another bureaucratic agency, but they are better than CDC.
Poor interactions – need improvement	**Mutual food safety/protection efforts:** USDA should focus on farm-level safety. Their role in food safety should be clearly limited. It makes it unclear for the state and industry what standards to follow.
CVM	
Good interactions – no issues noted	**NARMS:** • We work very closely through NARMS. We provide organisms, testing for specific things. We talk to them. Other than personal contact there is a meeting once per year with USDA where they are talking about their Agricultural Research Service research plans for the next year. **Collaborations:** • We've done some collaboration in QC of methods with both CDC and USDA, and also do some collaborative research and papers. In the past we have assisted both CDC and USDA when there is an outbreak.

C.2.3.19-3. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: EPA.	
EPA	
Reported interactions	• We don't have many projects or coordination, but do talk with them (OARSA). • We share information concerning microbial indicators in wastewater (OFS/DI). • Good interactions on food defense (ORS). • They care mostly about water, and this is not a high priority for FDA (ORS). • We have had them review our preventive control strategies on the farm for biological control agents (ORS). • A colleague has been doing studies on the microbiome of a tomato field--studying the use of a probiotic to treat *Salmonella* in tomato fields. We have to go through EPA to put things back on the field (ORS). • We've been consultants for EPA because antibiotics are used for fruit trees (CVM).
Should increase interactions	• We've done some symposia and papers with them. I would like to see us do more with them (OFS/DI). • They do only a little bit that is in alignment with our work. In the next couple of years I think you will see us collaborating more because they are getting into the virus game. The data that we collect on sewage treatment plants and shellfish areas are very valuable to them (OFS/DI). • Our interaction is literally zero. They go to ISSC. There is no interaction (OFS/DI).

C.2.3.19-4. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: Academia.[1]	
Academia	
OARSA	
Reported interactions	**Collaborations in general:** • A number of our investigators came from academia and they have retained their ties.

C.2.3.19-4. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: Academia.[1]	
	There is an exchange of information and dialog between investigators. We are also on some research as consultants under a federally funded norovirus research grant using the technologies we are developing here. They recognize the fact that we have the technology that they don't want to invest in because it is a huge investment up front. **Collaborations with specific schools:** • We have a CRADA (Cooperative Research and Development Agreement) with NC State on *Salmonella* in eggs. • CFSAN has some good academic collaborations: University of MD, University of MN, University of WI, and UC Irvine. • We have very strong collaborations with Virginia Tech and NC State, but we have to find ways to help fund the work we need them to do and that can be difficult. • Work with University of DE, Emory University. • We've done some work with international universities: Dublin, Pasteur Institute. **Work with graduate students:** • We end up helping students frequently. • We also regularly have JIFSAN students and students from Howard University, who come in and either do internships or work on their theses).
Should increase	**Collaborations with specific schools:** • Morgan State is just down the road and might be a good option for us (OARSA).
OFS/DI	
Reported interactions	**Collaborations in general:** • Collaboration with academia is essential (vs. having academia as your sole source of information in government). Collaboration gives us additional ability to work in a certain area by tying into their expertise. • We field questions from academic groups to help them set up testing methods to produce data that we and the state regulators would be comfortable). **Collaborations with specific schools/entities:** • We collaborate with DISL (Dauphin Island Sea Lab), a consortium. It has been great for us. We have more ideas than hands to accommodate. It is a great advantage when you can get a student in working on some of this). • We have collaborations with University of FL on *Vibrio*. The virus and *Vibrio* people work with the University of NM. We also collaboration with the University of NH. • We work with quite a few institutions: University of AL at Birmingham, Auburn University, University of NH, Cornell, and Mississippi State. • I've co-written grants with Auburn (shellfish specialist) and Mississippi State University (food scientist). I am working with someone from Louisiana State University. **Work with graduate students:** • We get graduate students from many schools along the Eastern Seaboard. • I am a co-advisor for a grad student at the University of Hamburg. Also a co-advisor for a student from the University of Southern AL.
OFS/MC	
Reported interactions	**Collaborations with specific schools:** • We interact with the University of Maryland, IIT, and UC Davis. We also have over 100 IIT students from outside the country, which is a big plus for us because they're involved in many of our projects. • We do some work with the University of WI.
ORS	
Reported interactions	**Collaborations in general:** • We've had a lot of collaborations with those in academia because of the genomics program that have been win/wins. **Collaborations with specific schools:** • One of our scientists has a collaboration with NC State for tomato safety. She was able to

C.2.3.19-4. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: Academia.[1]	
	leverage NC State so that we were able to learn all about the prevalence, sources and risk of *Salmonella* in tomato production in NC. It was a great investment). • Collaborations with Penn State, NC State, University of MD, Ohio State). • We have contracts with Universities of GA, WI, and MI.
Areas for improvement	**Collaborations in general:** • We have tried to collaborate more in working with USDA grants, but felt it was frowned upon to work in the grant obtaining process. It was discouraging--they didn't want us to participate in any grant proposals with academia. • As a regulatory agency, it can be difficult to work with academia. Maybe if we were clearer regarding what information we can share and what we can't share, it would help collaboration. **Collaborations with specific schools:** • Sometimes we contract out scientific research that can be better handled in an academic setting, especially basic research.
CVM	
Reported interactions	**Collaborations in general:** • We have lots of collaboration with academia because those working on resistant microbes or on food safety are always asking to collaborate. We are often a co-investigator or consultant. • We are currently doing pilot work with academics through the USDA in the NARMS program. We consult academics for feedback on how our programs are functioning. • Interactions are usually at the individual PI level, but there isn't much going on now. • As a support scientist, I have had to work on some collaborative studies with academic partners in more of a service type role. That is something that is beneficial, not only for the Center but the government on the whole because it does help broaden our exposure to academia and non-federal agencies. It is a definite avenue of collaboration that isn't always utilized and could be. CVM does have a very good reputation for the type of research that it does and the type of work that we put out. **Collaborations with specific schools:** • We do some work with UC Davis and Ohio State on antibiotic resistance, and some WGS with UC Davis.

[1] Any responses concerning JIFSAN and IIT that were felt to be more relevant to Question 18 are presented there.

C.2.3.19-5. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: Other Federal Agencies.	
Other Federal Agencies	
Reported interactions	**CIA:** • Reported by (OARSA). **DHS:** • Food defense and involvement in select agents work (OARSA; OFS/MC) • We've had some collaboration with DHS to get research help (ORS). **DOD:** • On MRE food packets (OFS/MC). • We go to them to see how they set up their labs because they have more money and access to instruments that are not broadly available. We collect and share data with them as well (ORS). • Reported by (CVM). **FBI:** • Reported by (ORS). **NIH:** • In virology (OARSA). • NIH/NCBI: For the Genome Tracker, they host the data (ORS). • NLM (NCBI in particular) has helped us with managing big data MB with genome sequencing. No other agency is equipped to handle and curate terabytes and petabytes of information. It's just working out great (ORS). • NIH/NCBI has been a key partner in our work: developing the software, curating the data, bearing the expense of bioinformatics support. They have been a great partner, and they like what we're doing because it's a clear public health delivery. They are going to use the same network that we have developed together for food pathogens for tracking medical emergency response, hospital acquired infection, etc. Everyone has benefited from this interaction: FDA, NIH, and CDC. CDC is actually sharing data with NCBI—this is a new thing, they never share data. This is going to change public health (ORS). • We just started working with NCBI to support the NARMS program. It is a little early to evaluate how it will be (CVM). • Indirectly through NLM on the bioinformatics (CVM). **NIST:** • For reference materials (ORS). **NOAA:** • During the oil spill and for ecological forecasting models for *Vibrio* (OFS/DI). • Collaborative project looking at oysters on the West Coast (ORS). **White House Office of Science, Technology and Policy**: • They are developing broad interagency collaborations to get integrations and efficiencies. They are instituting a Microforensic Review Board that we are going to be part of (ORS). **State Agencies/Entities:** • We work with the state agencies in Maine, Rhode Island, and other New England States). We work very well, typically on outbreak emergencies but we also have collaborative agreements in areas of interest (OFS/DI). • State Health Departments: They do the WGS for the Genome Tracker, and the data are uploaded to NCBI. There is a lot of coordination with that (ORS). • FERN (All offices)

C.2.3.19-6. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: International partners.	
International	
OARSA	
Reported interactions	• We interact with public health agencies of other countries, including Canada, UK, Ireland, and others. • We had collaborations with Codex, FAO/WHO, the U.S.-Japan Natural Resources Council. • We have a collaboration with Health Canada on allergens. • We are trying to validate a method which is used by the European Union (EU) for isolating *Cronobacter* from different food matrices. We receive samples from Europe and follow the EU's protocol for isolating this pathogen, then report what we found. Then we evaluate the method. That has worked really well. • The immunobiology group interacts with the EU group that sets standards of allergens in food. We test and evaluate each other's methods. • We also work with Mexico, Canada, EFSA (European Food Safety Authority), Japan • People in our branch have done a lot of in-depth work with collaborators in Ireland, Germany, and Korea. At any given time, our branch has two or three interns from the University of Korea who are associated with Korea's version of FDA. • One of our investigators has a few connections with European counterparts (Spain, Italy, and Denmark), the health agencies. It is basically about techniques and procedures. It is occasional and it is good).
OFS/DI	
Reported interactions	• In connection with our research in *Vibrio*, we work with WHO/FAO (risk assessments, training workshops), CODEX, the Japanese NIH, European CDC, European Lab for Pathogens, Peru, Chile, the Danish Veterinary Institute, the Italian Reference Lab, the Spanish University of Santiago de Compostela, and Asian groups. Vibrio a bit unique because it's in the sea water, but we should be doing this worldwide with *Listeria*, *Campylobacter*, *Salmonella*, Norovirus, hepatitis. • Our lab works with a lot of international government agencies: Italy, England, Ireland, and Chile. Chile sought us out to help with an outbreak, and they were very grateful. But our management doesn't seem to recognize that we are really respected elsewhere. • We work with the Canadian government and EU on risk assessment. We have to because of the nature of the food supply. • We do a lot of training with international labs on methods, especially in developing countries to bring up trade standards. We've worked with South Korea and are getting ready to work with Mexico. • I have worked with individual researchers in New Zealand, Chile, Australia, Brazil, Canada, Spain, UK, Italy, and China. • We've done work with Codex and WHO, and are now working on shellfish equivalencies for trade issues. We are working with the EU a lot on shellfish equivalencies: we have a water quality standard, they have a meat standard.
OFS/MC	
Reported interactions	• Since the "bot" community is so small we work with labs in U.K., Italy, Kuwait, etc. • I have colleagues at Health Canada and at CSI in Australia. Truthfully, when there's an outbreak here, I contact colleagues in Canada because they'll tell me more than I can find out internally. • This year we're going to do one proficiency testing project through the ICLN on malathion. It's chemistry primarily in water and milk. It may be useful for CFSAN management because of the leak in West Virginia. They want to see the surge capacity of labs and the methods. • In proficiency testing we work with BBL (Germany) which has a very sophisticated proficiency and methods validation program, ISO, and other international programs such as AOAC.

C.2.3.19-6. Interviewee Observations: Current Coordination Efforts Among CFSAN/CVM Microbiology Research Groups and Their Programmatic Counterparts: International partners.	
	• Interactions with Canadian and Puerto Rican labs for laboratory evaluation and proficiency testing, as well as a move to get some European and Mexican labs involved.
Should increase interactions	• We should develop coordinating relationships with Latin American labs: Most of our fresh food is imported from Latin America. FDA managers need help there because of the political dynamics in the area. FDA's Office of International Programs asked us to develop a training program for Latin America and India and to help set up the main part of their local proficiency testing programs, so hopefully the quality of imports from those countries will improve. I was told to look into this, but at my level I cannot do that without the support of upper management. The demand is there, and FDA has unique expertise and ability to do this.
ORS	
Reported interactions	• We work with WHO through their GFN program and with ISO through the MB Development Branch, doing mostly traditional MB. Our division sponsors a U.S. technical advisory group (TAG) that focuses on molecular typing to interact with ISO. • We were instrumental in creating the GMI, a loosely knit organization of us, Denmark, UK, and Germany. We sponsored four meetings in the U.S. to explore how genome data can be used to control food-borne disease. This allows us to understand the global players and for them to know what we are thinking. It helps to develop global standards. • The GMI effort includes a large international consortium (China, Mexico, European countries). There are annual face-to-face meetings, but it can be difficult for us to send people overseas for these meetings due to limited travel budgets. We are a major shareholder and stakeholder as this effort goes forward and we can't get the people we need because they limit our travel budget. • We do a lot of international collaborations, GMI meetings. One biostatistician from the Food Environment Research Agency (FERA) of the UK provided bioinformatics support for us. • We have a twice-yearly meeting with the following to facilitate collaboration and communication: GMI, Irish Center Food Safety, Danish Center Food Safety, FERA (London), Italian collaborators, Argentina Food Safety, Canadian Food Safety, Mexico Food Safety. • AOAC. • ISO: We are looking for international standards for different food matrices for staph and bacillus. • We are training Mexican scientists in use of PFGE.
CVM	
Reported interactions	• WHO is taking the NARMS program global, so we sit on steering committees to assist in that process, and we are a collaborating center for the World Organization of Animal Health (OIE). • WHO, OIE, Codex, Denmark's Food Institute. We have brought large groups from China and Japan to learn specific procedures. • Under NARMS we work with WHO. We're their confirmation lab. We test samples for them before they send them out to other labs. CIPAR is our Canadian partner, and DANMAP is the Danish antibiotic resistance group. • Our NARMS program has worked with WHO (World Health Organization), GFN, etc., to work on antibiotic resistance issues, proficiency testing, and fleshing out protocols. • We have worked with Canada: NARMS on CIPARS (Canadian Integrated Program for Antimicrobial Resistance Surveillance). The NARMS team has worked with WHO to try to set up similar programs in smaller countries. We are also involved in European Surveillance Programs on microbial resistance in a collaborative to see what they're doing and where we can cross paths. We try to use similar methods.

C.2.3.19.a. What has worked well in developing these interactions?

C.2.3.19.a. Interviewee Observations: What has worked well in developing these interactions?	
Personal interactions	• Meeting people at scientific meetings (OARSA). • There is an idea of trying to create a unilateral voice to interact with them to control internal dissent within CFSAN. We need to open that back up again. We've never gone through channels because we have our own personal relationships. With a unilateral voice there is control, and it leads to cutting other people out of the interaction (OARSA). • We recently discovered that a *Vibrio* strain had jumped from the Pacific NW to the Atlantic and caused the largest outbreaks that had ever been reported on the east and west coasts of the Atlantic. The discovery was made with FDA, CDC, EUCDC and the European Reference Laboratory for Shellfish Pathogens working together. The discovery came about because we were talking about other things and started comparing notes. This lead to the investigation that lead to the discovery that lead to publication in the New England Journal of Medicine. This influenced food safety programs. The connectivity comes back (OFS/DI). • Most of this comes from personal contacts; although having a liaison at CDC has been useful (ORS). • Personal efforts, reaching out, establishing collaborations (ORS). • The people we collaborate with are very good. We have had productive results like joint publications, which gives FDA good exposure (ORS). • Somebody has got to make the call (ORS). • Peer-to-peer contact/collaboration: When we first started, we ran a genomics meeting every 6 months for 3 years at NIH. We got together 150 people interested in MB WGS. It was a lot of work, but it resulted in many lasting interactions. Setting up the first meetings was expensive, but it was well worth it and will have a lasting impact now that the meetings have been adopted (ORS). • Personal contact. We've invited these people to come talk about their programs. There are frequent conference calls with the CDC group and USDA because we're all part of NARMS. We have face-to-face meetings at least annually (CVM).
Mutual benefits	• Combining resources to address a common problem (OARSA). • It works best when both parties benefit. E.g., in our work with the University of Korea, the Korean students are a good source of labor, and we provide them with training, technology, and equipment (OARSA). • Finding a problem that you were working on and it's the same problem that someone else is working on and combining resources (OARSA). • What works well in interactions is need. The most successful relationships are because we've maintained a certain level of expertise or have availability of resource (e.g., proximity to fish, samples, etc.). It facilitates interactions when you're bringing something to the table (OFS/DI). • With academia, USDA, CDC, there have been genomic collaborations that have been win/wins. Genomics makes us very popular (ORS). • Because we have shared responsibilities in food safety, we naturally work well with USDA and CDC (CVM).
Membership in organizations and working groups	• Being a member of FERN and LRN groups has been helpful in meeting scientists and developing relationships. We have **t**rained people from some of the ORA labs, USDA and state labs here in BSL3 practices, etc. (OARSA). • Attending meetings and sharing information: such events are good for data sharing, communication, and training (ORS). • Being able to go to their meetings. It is much harder to interact with these people without actually going to their meetings. They come here some of the time. We can actually work things out when meeting face to face. Sometimes you just have to go there (ORS). • We formulated some working groups among the different agencies involved with NARMS to address some issues and that worked really, really well. We sat down and got through everything piece by piece, figured out why things deviate the way that they do

C.2.3.19.a. Interviewee Observations: What has worked well in developing these interactions?	
	and looked for ways to reduce those deviations (CVM). • We have regular meetings for NARMS. We all contribute a lot of data that is important to other agencies and industry. It works well because we have this major important collaboration and are partners in it. I think that we are the only surveillance program looking at antibiotic resistance issues. We provide data on retail meats, USDA on animals, and CDC on humans (CVM).
Willingness to collaborate	• NARMS has been helpful in terms of exposure. It seems like we have a broad experience base with the people we have and maintain connections with organizations they have worked with in the past or that they were part of. We have a good group of networkers. The willingness to collaborate is there (CVM). • You have to have a decent enough reputation that they'll consider working with you (OFS/DI).
Having a structure for coordination	• We do a good job at the personal level, but there is not a formal structure to help encourage these interactions. Having a formal structure could help others get involved who are not already involved (OFS/DI). • It has been very helpful to have a process to recognize collaborations within FDA. We've worked with the Technology Transfer Officer to create Research Collaboration Agreements (RCA's) and CRADA's with academics and with private companies. We have material transfer agreements to be able to provide different strains or vice versa. Our state networks were formed through RCA's so that we and the states knew what we were getting into (ORS).
Defining roles in interactions	• In NARMS study, FDA does retail meat portion, CDC does human isolates. USDA does the farm animal isolates. We do the same type of experiment. We correlate our data. If they are similar, we combine the two. We combine results. For the last 2 years USDA has been sending everything to us, so our workload has increased (CVM).
Management support	• It's up to the leadership on both sides to have an understanding of the collaboration (ORS). • Our management made the contacts for us to be SMEs for ISO (ORS).
Informal requests	• It works well when they just ask for something informally and we do it. For example, there is a whole bunch of *Salmonella*s that CDC needs sequenced. They do not have the capability to do the sequencing. We can do but we're overloaded and don't have the time to do it. So we asked CFSAN if they could do the sequencing. They were enthusiastic about it and wanted to do it because they are under-utilizing one of their sequencing groups. So they are going to do the sequencing for us for CDC (CVM).
Honesty/openness	• The key is being honest and open with people and the group as a whole. There has to be a certain openness to change and reform and ideas. If they are closed-minded it doesn't work. That's not something we can fix here at CFSAN unless we are the ones with the problem. But from my perspective we are not the ones with the problem (ORS).
Appropriate recognition	• Giving everyone credit for the work they do (OARSA).
Including younger scientists	• Having younger people (those who haven't been here as long) meet and keeping those with ego issues out of it. There have been some issues between some of the PIs who have been here a while (ORS).

C.2.3.19.b. How can we improve coordination efforts with our partners?

C.2.3.19.b. Interviewee Observations: How Can We Improve Coordination Efforts with our Partners?	
Increase management encouragement/ support	• There should be more encouragement. Sometimes people do not see collaboration as a good thing. Sometimes there are turf battles between CDC and FDA. Sometimes what looks good on a personal level may not be approved by upper management (OARSA). • Putting department heads into a room and saying here's what we are working on and here is what we can work together on. As an example, last year our deputy OD took it upon herself to reach out to the USDA. She took a group of us in a car up to PA to sit

C.2.3.19.b. Interviewee Observations: How Can We Improve Coordination Efforts with our Partners?	
	down with the USDA and talk about what we do. It was a wonderful interaction (OARSA). • One of our PIs has a lot of collaboration with academia and internationally, but most of us do not. This should be more encouraged from the top (OARSA). • Encouraging people to not be afraid to reach out. There are two mentalities. One is: Don't over-step your bounds, don't make waves. You work for the Federal government. The other one is: Why not make the effort? It is a good thing to put more minds to a problem (OARSA). • It would take an edict from above stating that we really want to do collaborative research outside of the Center and/or the Division. But it would have to be an initiative with dedicated funding, a dedicated or defined mechanism on how to do it, and support. There would be great value in collaborating with these groups. If someone is a step ahead of us with a method, we don't have to duplicate it. If we could retrofit it or adapt it, modify it, do something to get a good start on what we're trying to find, than that should happen. We shouldn't be reinventing the wheel (OFS/MC). • When we do see a success story, when we have a good coordination where we have real leverage for our Center, it would be good for our leadership to foster and support that coordination to see that it grows and lasts. That would include matching resources that would compel a partner to stay on board with you (ORS). • FDA is a front-runner in a lot of these efforts and some of the other agencies are not open to these discussions on change or transparency. I don't know how we can fix it on our end if they are not open. We need to find ways to remove inhibitory people (ORS). • If we had liaisons between researchers and management, they could help coordinate efforts with the outside groups (ORS).
Address coordination at a higher level	• There is much overlap especially within the government. There should be a Federal Food Safety meeting to bring managers together so they can talk and coordinate (ORS). • We need to know what MB subtyping research is being done by other federal agencies, including FBI, CDC, and USDA. We need a process for comparing and communicating with those groups (ORS). • They should set up an outside collaboration website. Our industry, state and international partners all need to be able to share data. We are piloting the first one for the Genome Tracker network (ORS).
Increase interactions between groups and scientists	• It would be good to have webinars with CDC, FDA, and USDA on common concerns such as food-borne disease, diarrheal diseases, etc. and float ideas, brainstorm (OARSA). • We used to have annual meetings with FERN, but we haven't had one for the past 3 years. Getting together in-person is important when you collaborate frequently. Once a year isn't too much to ask (OARSA). • The problem we often face is the hierarchy of the institutions. Scientists should be able to talk to scientists, but there appears to be a muzzling of who gets to talk to whom (OFS/DI). • We should interact more with scientists in other countries. For example, Germany, BBL, and U.K. want more than collaboration. I can't make those connections at my level (OFS/MC). • More PI-level meetings would be helpful (ORS). • The technical peer-to-peer interactions are beneficial. There can be fighting at the upper levels, but there should be an environment where the scientists can speak freely with each other (CVM). • We could have more opportunities to meet in person such as a collaborative meeting or workshop (ORS). • Researcher-to-researcher interactions get a lot done for public health. There needs to be support or training on how to deal with people who are glued to their specific agenda. This is a stumbling block we need to overcome when dealing with especially the upper levels of CDC (ORS). • We need to increase opportunities to meet and communicate, e.g., meetings or symposia

C.2.3.19.b. Interviewee Observations: How Can We Improve Coordination Efforts with our Partners?	
	or inviting each other to give presentations (ORS). • I think having mutual projects is the best way to improve coordination. Being part of FERN and LRN has enabled bench scientists to know each other, so requests for samples (e.g., cilantro) can be made directly. Without the previous interactions, we would not have known who to ask for these samples. Sometimes when requests are made to the top, the request never makes it down to those that can fill it (OARSA).
Develop a structure for coordination	• In our international efforts, we are trying to do better in coordinating how we present the data in a more universal/uniform format so that they are more easily compared across countries, and an easier understanding the results (OARSA). • If I have a question about whether I should do something that CDC wants me to do, then depending on who I ask, I am going to get a different answer. They could clarify to us what the overall policy is on coordinating and doing things together in our collaborations with CDC (OARSA). • For us in a cooperative program, it's easy. Our stakeholders are the states and the ISSC. We have biannual meetings with them. Through our policy group and shellfish specialists, we're very engaged with them. We are working to improve that within the two divisions. We are working to develop a process by which states can request assistance from us. In the past this has been informal (call, e-mail). We're working on a mechanism to centralize requests so they can be evaluated for response. If it works, it could be applied to something broader (OFS/DI). • SharePoint to ShareDocuments is good internally, but there are a lot of barriers to sharing with external collaborators. To move the research faster, it is necessary to work with national and international partners. There's no FTP site where genomic data can be shared because of security issues. We can't use Google or Yahoo, and SharePoint is only for government. We got a website two months ago, but it's too early to know if this is going to work (ORS). • We do have a single lab manual for CVM, USDA, CDC, so we all have to do things the same way. That has worked well (CVM). • Give the NARMS director signatory authority. The NARMS director doesn't have signatory authority, so collaborations involving NARMS and other agencies always requires negotiations to get funding if they are to occur (CVM).
Establish regular communication	• Having routine conversations and being more transparent with other partners, as we are with CDC, would help (ORS). • It would be helpful to have routine meetings and agenda to keep things organized and moving forward (ORS). • We could have improved communication—SharePoint has just been instituted in FDA, CDC, and USDA for the NARMS program and that should help with sharing ideas (CVM). • Talk to them more. If there is one thing that the Scientific Steering Review Committee for the OF has done is that it has forced us to talk to each other more because we have to go to the meetings (CVM).
Encourage attendance at scientific meetings	• When you go to scientific meetings, you can see what everyone is working on, learn about significant microbiological issues, and have discussions. It is important to foster collaboration and see what's going on in the field (ORS). • Through going to meetings, such as the American Society of Microbiological Research, and seeing what other people are working on and meeting the individuals doing the research (OARSA). • Go to meetings and do collaborative work. Sometimes we have to do it off the books because it wouldn't be approved as mission relevant (OARSA). • We need more focus on international organizations and meetings. It is important to go to the technical talks and talk to international trading partners. It is important to share research efforts and have a transparent exchange of scientific information (ORS).
Relax travel restrictions	• They should remove restrictions on travel. The roadblocks are unbelievable. Chile invited me and was willing to pay but there were too many roadblocks. This would

C.2.3.19.b. Interviewee Observations: How Can We Improve Coordination Efforts with our Partners?	
	benefit from some common sense. A government was willing to pay $5000 for me to travel, but I could not go because they owed FDA $100 from some time ago (OFS/DI). • Remove travel barrier. The more we're out there, the better we relationship we can have, especially internationally (OFS/DI). • Increase travel budget. There's never any travel budget for us to attend the largest annual IBRCC meeting. It's usually held in October, which is also bad timing for us. But attending that meeting would provide us a great opportunity to talk with CDC and USDA. Pretty much everything we do is talked about there, but we rarely get to go. I went once because it was in September and there was leftover money. Now we don't have any money to do anything. There's only critical travel and that's not considered critical travel for any of us (OFS/MC). • Improved travel to meet people face to face to get to know valuable contacts so that relationship is there during outbreaks that require an emergency response (ORS). • Being allowed to travel to meetings with our partners is huge. You can't have collaborations and communication without occasionally meeting in person. It would be great to have help planning those meetings, because that falls on the scientists as well (ORS).
Be respectful of partners	• The partnerships that the Division has and that we have in our branch are quite good. But more than once I have heard that investigators disparage one of these organizations in a not-so-nonpublic forum. It struck me as unprofessional and counterproductive. As a Center you have to be on the same page (OARSA). • CDC would love to take over the NARMS program. As much as I love working with them, I hate working with them. Because we are a regulatory agency and they are not, we look at data differently. I wish we could give CDC a class on FDA regulation so they would have a better understanding of how we look at information and how we conduct research (CVM).
Publicize areas of expertise/interest	• Advertise our capacity and research output, both internationally and nationally (CVM).
Resist micro-management	• Sometimes the best thing management can do is stay out of the way. They have to govern the interactions and it has to be transparent up front, but I don't know if they can actually improve the coordination efforts (OFS/DI).

C.2.3.20. What other ideas do you have for how we can better serve our stakeholders?

C.2.3.20. Interviewee Observations: What Ideas do You Have for How We Can Better Serve Our Stakeholders?	
Refocus on our mission	• Everything that we do should be useful for the public. The world is our stakeholder (OARSA). • We need to be clearer about the missions in FDA. Instead of "to improve food safety and public health" bring the mission down to manageable bits. It is these that don't percolate to individual researchers (OARSA). • Ask of each of the research initiatives: What is this doing for public health? What is this doing for food safety? Is this a good deal for the American people? What is it doing in the near term? This applies to equipment purchases too. We make every penny count. There are always things that don't work out, but for all practical purposes, the only thing we can do is keep our eye on these ideas (OARSA). • We need to keep in mind that we work for the Federal government and the public, and their health and well being is our primary goal. While I think it's important to have some leeway in research, we are not an academic institution. We need to keep the big picture in mind (OARSA). • It needs to be integral to our functionality/job that our stakeholders are what's important. The government mentality is that we will always get paid. Maybe that should change, so that if you're not serving your stakeholders we don't need you. There needs to be a real tangibility of service to our stakeholders. It is happening with teachers unions:

C.2.3.20. Interviewee Observations: What Ideas do You Have for How We Can Better Serve Our Stakeholders?	
	states have voted out tenure, and they ask students about their teachers. Government should start working that way. In government, we take the cut in pay and recognition to serve people, and we need to be aware of it (OFS/DI). • One thing that could really help is to drill into every researcher's head that we are not a research organization. We are a regulatory agency with a well-focused mission to protect the consumer. Doing research is a luxury, but it has to be applied research (ORS). • We need to always remember our mission is to positively affect Public Health. We need to ask, "How is this affecting public health?" Sometimes people need to loosen up a little, forget that they don't want to deal with somebody and remember the big picture is to protect public health (ORS). • Do honest work. Downplay politics. Make sure scientists here know the subject, FDA's mission, and other microbiologically-relevant subjects through training, especially for new hires (ORS). • We have to be willing to take more risks to live up to the expectations of consumers. We too often end up serving ourselves or corporate interests (CVM).
Publicize FDA's role and activities	• I think the public has a lack of understanding about what we really do. FDA takes a lot of hits for things that really aren't our fault (OARSA). • We need to do a better job reporting on our successes. It's often hard to communicate why our work is important. It's a tough sell because research is long term. It's not always immediate technology transfer, but when we do that technology transfer, when we get those data in to support new guidance or regulations, we have to do a better job of selling it. Now we have these public disclosure statements and CARTS, but I don't think many people get a good sense of how we're working based on them (OFS/MC). • We need to be more vocal and proactive in outbreak situations (OFS/DI). • We could communicate more with the public (e.g., via podcasts, like CDC does) to let them know what we're doing. We could interview researchers and let them speak about what they're doing and why it is helping. Our stakeholders would probably be surprised about all the stuff is happening in the building. Even within the Agency, I don't know much about what is being done. I heard about FDA work on gluten on Good Morning America (ORS). • We need an improved place for the public to see our efforts and science so that they know what we are doing. We have a very safe food system, but the public needs to better understand the science that is keeping their food safe. Education efforts would be good (ORS). • We need a better web presence. No one knows what we are doing – not even those within the Division or agency. We need a place for public interaction. All research should be in public access journals only – not in paid journals. Public science writers may be able to help make our work more approachable. Our CARTS program is meant to achieve some of this, but it hasn't been fully successful (ORS). • We do a lot of work that is not easily communicated to the public. We need to figure out how to do this so the public knows what is going on and the efforts that are going into the work that we are doing, and how that work has helped to improve public health (CVM). • We should have community outreach to explain what FDA is doing related to food protection. We should inform the public on what our strengths and limitations are (ORS). • Provide information using terminology the public can understand and advertise it better (CVM). • We should try to better market the type of work that we are doing. It was a surprise to me when I initially applied here. I had no idea that FDA had a research arm in any capacity. When it comes to research, everyone thinks of NIH and CDC, but nobody thinks of FDA because we are a regulatory agency. Doing more to try to expose that and champion that would be beneficial. It seems like within the Government it is known, but once you step outside the Government, unless you work with us, nobody knows we exist (CVM).

C.2.3.20. Interviewee Observations: What Ideas do You Have for How We Can Better Serve Our Stakeholders?	
Improve communication within the Agency	• We have been serving our stakeholders well, and we can do better through improved communications with different parts of CFSAN (OARSA). • Having regular and effective communication as to what is important and what is expected (e.g., is publication valued more than other activities (OARSA)? • Ask the policy groups what they want and be willing to listen. Some researchers don't want to hear from the policy people. Some don't want to be told what to do (especially older folks) and don't think they should have to listen to policy (OFS/DI). • One of our biggest problems is our communication between main CVM and OR. It just doesn't happen very well. The things we tried on our end did not work (CVM).
Improve communication with our stakeholders in general	• Find out what they want. When the stakeholders have questions, we have the expertise to answer almost everything they want to know. It is a matter of somebody conveying the questions to us and then leaving us to come up with a solution (OARSA). • We need to have a better understanding of what our stakeholders want us to do (OARSA). • We need to find out what our stakeholders actually need and then get feedback on how we are doing and whether we are helping (OARSA). • It would be a good exercise for everyone to consider who their stakeholders are. Management may need to make us more aware. You can't serve them until they are identified, and I don't think most researchers have identified them. Our group operates in a customer-service oriented mindset, which I think should be encouraged throughout (ORS). • We should ask our partners and stakeholders what we can do for them and if we're meeting their needs. I don't think we've ever reached out to partners and asked. Maybe a survey asking 'what can we do for you (CVM)?' • We should meet with them regularly and solicit their input on research ideas and needs. Provide timely feedback and follow up if it's appropriate (CVM).
Improve communication with the public	• We could have more public education in food safety areas, how to prevent and how to avoid (OARSA). • If our scientists could explain things in plain English rather than scientific terms, we could let our stakeholders know what our results are and how our research can help us help them (OARSA). • If we could make our science understandable on an 11th-grade level, that would be great. If we could have well-rounded teams that included a personable scientist instead of all policy people, that might help. It might not be easy to get a scientist to be a liaison, but I know they're out there (OFS/DI). • If we can educate American people to wash their hands and cook their food properly, we'd have less *Salmonella* outbreaks. And if the food were properly handled, there would be fewer CVM projects (OFS/MC).
Increase communication and transparency with industry	• Working together builds mutual trust. In my experience, industry likes to work with the FDA. The submissions made by Monsanto and DuPont are voluntary submissions. They don't need to go through the FDA, but they feel that it is good policy to have FDA review of their products. In general, FDA has a positive impact. FDA doesn't tend to go in and say "Do it my way." It tends to be a more cooperative regulator (OARSA). • We need more interaction at the industry level: we need to go to those meetings. What we do here sometimes limits our view of our impact. Going to meetings broadens it quite a bit (OFS/DI). • Companies want to expand into middle processed foods. What are the challenges in this area? We need a link, a go-between between researchers and industry members (OFS/MC). • Industry wants consistency and transparency in regulation. If they are being regulated, they want to know the reason. FDA does surveys, but does not publish the results of these surveys. Then they make regulatory decisions like "we're going to sample this from now on" based on a survey that has not been publicly vetted. USDA on the other hand, has a

C.2.3.20. Interviewee Observations: What Ideas do You Have for How We Can Better Serve Our Stakeholders?	
	very public process. They publish a plan, they receive public comments, then update the plan based on comments, do the work then publish the results. Then they determine a performance objective, i.e., the number of organisms allowed. I don't see this public process happening at the FDA (ORS).
Resolve organization and management issues	• We have to stop fighting amongst ourselves (OARSA). • We need to organize the microbiology program internally so that our appearance is more professional to the outside. People at CDC, USDA, and academia look at CFSAN as this dysfunctional family. We need to get our act together internally to make our appearance more professional and more apparent to our stakeholders (OARSA). • We would function more efficiently if we were better organized and had better management (OARSA). • We need to start utilizing all of our talents to solve problems. Because of all of our issues, stakeholders aren't being served. We're failing (OARSA). • Realign the management structure to increase research productivity (ORS). • MB needs to be consolidated into a single effort. It could be better managed, better triaged, and better parted out so that everyone is working on something important (ORS).
Expand research scope and capabilities	• We need to expand our research scope to be prepared for new pathogens (OARSA). • We need to get a handle on imported food (OARSA). • For proficiency testing, more matrices would be better because outbreaks happen in other matrices. We could include some dry matrices, some semi-solid (condiments and spices), and some liquid matrices so analysts in the field could get a better handle on how to do different kinds of food (OFS/MC). • We could better serve the public by focusing on emerging technologies. We have a super clean food supply compared to other countries, so we're doing a pretty good job, but with the right funding and leadership, it could even be better (ORS).
Finish methods	• Anything that we can do that can do finish a method would be beneficial to the public and to industry. If we can reward finishing and validating a method rather than just publishing, I think that we will better serve the stakeholders, including the public and the FDA labs as well (ORS).
Implement FSMA	• It would be great if they could speed up FSMA and streamline it enough so they could get a metric of how it's affecting public health. It's going to take such a long time to get industry up to speed, that the whole idea of this preventive maintenance could end up falling by the wayside. They may return to being more reactionary because it will seem to be more efficient and a better use of their funds. They should be putting FSMA out there, telling industry this is what FSMA is, this is the regulation, and this is what you will do. Make it explicit and industry will see an effect. Until that happens, they'll stay mired in the question/answer periods and keep modifying FSMA. It's going to take so long to get settled and enacted properly that it won't have a measurable effect and people will lose sight of the objective (OFS/MC).
Reduce waste	• We store kits that are ready to be shipped to ORA labs in the event of an outbreak. The trouble is, is that the kits have expiration dates. We usually end up having to discard them. It's a huge waste. I don't know what the best way around this is, maybe an agreement with the supplier to have the kits available until needed (OARSA).
Increase collaboration	• The public wants quicker, better detection methods. The world is becoming a smaller place, as the food supply is global or is being cultured differently. All these things need to be evaluated, but we lack the manpower. We need to maximize our efforts by collaborating, sharing equipment and by limiting the inefficiencies. Things could be run more smoothly—we spend time arguing our case when we could be doing our work. Sometimes there is way too much red tape. Too much time is spent dealing with bureaucracy and not enough doing the science (OARSA). • There should be more collaboration on important projects (ORS).
Encourage attendance	• Open up the ability to go to scientific meetings so we can share our information and

C.2.3.20. Interviewee Observations: What Ideas do You Have for How We Can Better Serve Our Stakeholders?	
at scientific meetings	learn from others. We can't help our people grow if we can't take them out and introduce them to our colleagues (OFS/MC).
Include scientists in decisions	• Let scientists make more of the scientific decisions (OARSA).

C.2.3.21. What major institutional or systemic barriers exist which contribute to a lack of coordination?

The responses to this question have been divided into two tables: one for in-house issues and one for issues with other partners and stakeholders.

C.2.3.21-1. Interviewee Observations: What Major Institutional or Systemic Barriers Exist Which Contribute to a Lack of Coordination: In House?	
In house	
Competition between groups at various levels	• There is tension between OFVM and CFSAN scientific advisor group. They have overlapping objectives and they don't see eye to eye. There is competition for resources and political games, making people more critical of other peoples' work to try to get more resources for themselves (ORS). • There are politics, turf battles, and competiveness among groups that really should be collaborating (OARSA). • There is favoritism from the leadership that leads to unfair treatment. If favoritism didn't exist, there would be a better work environment. Everyone should be held accountable for their actions and have equal opportunities to improve and be promoted (ORS). • There is a lack of trust. The current environment here is reminiscent of individual biotech firms competing against each other instead of working together for the common good. There is uneven resource allocation, all going into a few pet projects (ORS). • It is almost like a competition with this group and the group at CPK1. That hinders progress because everybody is keeping things from the others. It also results in duplication (OARSA). • There is competition between CPK1 and OARSA. They have more money and people, and they have hired lots of people, and we have not been able to hire or convert anyone (OARSA). • There is also a very big problem with certain managers here and at ORS not being able to work together. I don't know how you fix that. A lot of people here have chips on their shoulder because of the number of projects that were canceled (OARSA). • The tension between CPK1 and MOD 1 makes things difficult. We feel like we're in the middle. It is human nature to try to not damage people's feelings. Very awkward sometimes (CVM).
Lack of communication/ transparency	**From upper management:** • There is undermining at the highest levels. Decisions are being made with select people in a room, not even giving us the common courtesy of communicating that decision. Don't start moving ahead in a non-transparent way and undermine other efforts. You owe people to tell them (OARSA). • The Center is afraid of what the scientists have to say. We want to tell them that there are problems, but they don't want to know about it. E.g., there are pathogens in certain foods, but it's going to cause a headache, so they don't want to hear about it. I think they want things status quo too much at this point (OARSA). • We are often told one thing and then another happens (OARSA). **From line management:** • We rely too much on line management. They don't intentionally ignore the scientists; it's just their way. Hopefully, managers give their scientists the right information, but that doesn't usually happen. Information is never shared completely (OFS/MC). **Between scientists:** • There is a barrier between Wiley and OARSA and, to a smaller degree, those at OFS/DI and OFS/MC. There is also a barrier between CFSAN and the field labs. You have to get all microbiologists on the same page (ORS). • This is an attitude issue. Communication is not discouraged, although it may have been in the past. Now it's a matter of people needing or wanting to communicate. Someone has to reach out. This can't be forced from upper management because researchers will resist (OFS/DI). • A big barrier is that people don't open up. Everybody is afraid of saying too much or

C.2.3.21-1. Interviewee Observations: What Major Institutional or Systemic Barriers Exist Which Contribute to a Lack of Coordination: In House?	
	not saying enough (OFS/MC).
Lack of interaction between groups	• There are cultural issues as well between research offices and program offices. They are like two different worlds (OARSA). • A lot of the barriers are human behavior, e.g. low morale (ORS).
Management structure	• Within CFSAN MB has grown in the last 5 years. Each division has ~30 people, and this is unmanageable. If you can't manage them, then how will they be productive? The divisions should be broken into smaller teams or branches with senior people in charge to manage them (ORS). • Barriers exist because of imbalance in the terms of hiring and projects. Upper management makes all the scientific decisions and then give no feedback (OARSA). • While upper management might say we have panels of people that make decisions, I would argue that ultimately one person is making the decisions (OARSA). • Compartmentalization of what each center and office within each center does has resulted in a lack of understanding our jurisdictional boundaries. From the perspective of the support scientist level, it is not always clear what we can and cannot look into. What are our jurisdictional boundaries? What are the limitations because of the Center's mission and the offices' mission (CVM)? • Bureaucratic hierarchy is an institutional barrier. It gives the false sense that communication follows the chain of command. People in upper management think they can direct the research of people whose budget they don't control or time they don't direct. Everyone in the bureaucratic chain has to be on board for this model to be effective (CVM).
Physical separation	• When we were in one building, we bumped into each other every day. That helped us to know people, who to go to when we needed something. Now we are scattered. I even find it difficult to know who is sitting where in CPK1 (OARSA). • We're in different locations. Overcoming that has to be based on IT technologies or the ability to attend conferences together. I know how we coordinate with our regulatory policy people, but I have no idea how we do compliance, enforcement, or ORA programs. We should meet with those people and try to coordinate with them (OFS/MC). • Disparate locations of centers has led to a degree of isolation, particularly without a web format for easy access to information on who is working on what. CARTS is designed to be the epicenter of research, and maybe it will be, but we haven't been trained to use it in the way that would facilitate such sharing. There is still this isolation based on where you are located and a lack of a functional central pool for research (ORS). • MB is spread among four different offices in the Center. That barrier needs to be overcome (ORS). • Researchers are in different locations. Managers interact, but researchers don't see each other. There are physical barriers because of different locations. They wouldn't need to change much to enable scientist interaction (ORS).
Staffing and resource issues	• For our Office, lack of manpower. ORS has so many people, that they have specialists for even small tasks. I'm doing 4 different things where they have one person for each thing. We need more manpower, but we can't get it if we don't have anyone going over there saying we're doing great and wonderful things and we need manpower (OARSA). • Mismanagement of funds and the lack of resources for certain research areas (ORS). • People spreading themselves too thin. We get a lack of coordination by running and running and changing, but not going anywhere (ORS).
Lack of strong leadership	• OARSA needs strong leadership at every layer. A strong BC will help us develop projects and will present our projects to the upper level. Right now we don't have that. Now we are just a group of scientists who are confused, along with some layers of management who are confused (OARSA).
Lack of awareness of research being	• We haven't developed a robust information-sharing system within the Center (ORS). • Not knowing what CFSAN does in terms of research makes it hard not to duplicate

C.2.3.21-1. Interviewee Observations: What Major Institutional or Systemic Barriers Exist Which Contribute to a Lack of Coordination: In House?	
conducted in house	efforts. CARTS doesn't always work in this process. We do have our OFVM Foods Conference, but it's only once a year and not everyone goes. I know that some groups are doing the same work and have duplicate equipment because I work with them. It boggles my mind. There is so much animosity between the groups (CVM). • Not knowing who's taking the lead on food research efforts (CVM).
Lack of accountability	• Everybody is trying to CYA. Everyone is afraid of the blame game and no one wants to take responsibility for anything. Everybody is treading lightly on certain topics (ORS).
Resistance to change	• People are doing what they've always done and are resistant to change and redirect their research (ORS).

C.2.3.21-2. Interviewee Observations: What Major Institutional or Systemic Barriers Exist Which Contribute to a Lack of Coordination: With Partners and Stakeholders?	
With partners and stakeholders	
Turf/trust issues between partners	• As a result of some people having had bad experiences, trust is a problem between different institutions (OARSA). • Sometimes I feel that we and CDC are not from the same country (ORS). • Things are difficult with one group of people within CDC who are very territorial and want all things to go through their channels. They are very protective of their data, which should be made public and shared. Managers here are working on this but are not having much success. We are all part of the GMI program, which seeks to make information public as soon as sequencing is complete to give everyone access to data to help respond to outbreaks world-wide, but CDC wants to control the flow of information (ORS). • There is a competitiveness between agencies. This is a human trait that becomes an institutional barrier, especially between CDC and FDA (ORS).
Differences in the nature of the agencies involved	• There are barriers because we are a regulatory agency and there is some information that we cannot share. Researchers have to walk fine line in their collaborations (ORS). • We have to follow all these laws and regulations to the letter so that they can hold up in court. This lends itself to a lot of bureaucratic barriers. Everything takes so much longer to be processed and reviewed before it goes out. We should try to create a better system that keeps to the letter of the law but is more efficient in communicating information gets communicated across offices and agencies (CVM). • The agencies have different cultures (CVM).
Lack of opportunities for interaction	• It is a matter of chance who you get to interact with. Increased opportunities to interact would be helpful, such as more conferences (ORS).
Travel restrictions	• CFSAN's policy for sponsored travel requires that the sponsor pay 95% of travel costs and categorically denies any less. Everything is considered a conference. They make exceptions for everything but not for everybody. Pulling travel plans and inhibiting travel has poisoned our reputation worldwide. In one case Chile wanted us to come speak and they were going to pay everything, but Chile owned another part of FDA a couple $100 from 10 years ago, so they weren't an approved sponsor. Or Australia wanted us to come chair sessions, run some workshops and be keynote speaker, but it was denied because it wasn't mission critical (OFS/DI). • Reductions in travel to meetings such as AOAC, ASM, IAFP. These are big meetings, people need to go to them. They need to see what other people are doing. I have a rule that in order to go to a meeting, you have to be presenting or attending a particular training session that is really necessary. I'm not suggesting just sending people, but where it will be very useful (ORS).
Clashes over leadership of efforts	• It's where there no clear leadership—between the offices and between the agencies, e.g. FDA and CDC. They shouldn't be allowed to do this, but the department-level administration doesn't pay attention (ORS). • Every agency wants to be the leader in the area. If you never change, (e.g., the CDC)

C.2.3.21-2. Interviewee Observations: What Major Institutional or Systemic Barriers Exist Which Contribute to a Lack of Coordination: With Partners and Stakeholders?	
	we can't coordinate (ORS).
Lack of communication between partners	• IFSH's Technical Advisory Committee ranks our projects according to their platform and we have conference calls to answer industry members' questions or comments. Someone may speak out and question why we're going down one avenue as opposed to another while other callers remain silent. Sometimes nobody is even on the call (OFS/MC).
COI with industry	• COI can prohibit a lot of interaction with industry. It could be good to see the industry point of view, but we always have to consider COI. It could pose a barrier, to some extent, between industry and FDA, and perhaps this carries over to academia in some aspects (ORS).
Bureaucracy	• There is too much paperwork for collaborations to get an agreement. The collaboration with NC State took months of aggravation to set up. After a while, you break down and start asking if it is worth it (OARSA).

C.2.3.21.a. What ideas do you have for overcoming these barriers?

The responses to this question have been divided into two tables: one for suggestions for in-house improvements and one for suggestions for improvements with partners and stakeholders.

C.2.3.21.a-1. Interviewee Observations: Ideas for Overcoming Barriers Which Contribute to Lack of Coordination: In House	
In house	
Increase communication/ Interactions	• There should be better communication between the Offices and the Center. We need to have a better idea of what OARSA means to the Center, of the work we are doing here. Do they want us to go in a new direction? Do they want us to maintain with a slight variation? We would like direct answers to the questions we have, which are: When will we see hires, if ever? Will there be more equable distribution of funds and resources (OARSA)? • There should be more opportunities like online conferences and phone conferences. Just because we are separated shouldn't hinder communication nowadays (OARSA). • We need to keep an open communication with CPK1 and insist that they hear what we have to say. The transparency must come from upper management (OARSA). • MOD 1 and those in the Wiley building need to communicate more. If they can't get together physically, they can use electronic means to meet (e.g., video conferencing; OARSA). • We need to have an open dialog and work towards being one Center rather than two groups (OARSA). • Two weeks ago there was a rumor that there was going to be a whole reorganization, and we go to the branch meeting and there was no mention until I asked about it. They tried not to answer me. Our BC doesn't tell us anything. The CD came and said there would be no re-org. Now we are all "Just forget it. Just carry on. Who knows what's coming down the pike?" I don't believe the CD, but that's what he said (OARSA). • They have to have better communication. Team building would be a great way for everyone to get to know each other and start interacting (ORS). • Maybe having a broader understanding of each others' needs would lessen the competitive atmosphere (ORS). • We have to convince people to get involved across programs and not hide in their organizational boxes (CVM). • We need to talk more openly. Our focus here is antibiotic resistance. CVM should take the lead on most of those types of research. We shouldn't do many food research projects. CFSAN should, but if the issue is bacteria, such as *Salmonella*, there should be no territory and we should all coordinate and collaborate (CVM).

C.2.3.21.a-1. Interviewee Observations: Ideas for Overcoming Barriers Which Contribute to Lack of Coordination: In House	
Clarify prioritization and goals	• Decisions in scientific programs cannot be made by single individuals, and the fate of a project cannot be decided by a single individual. We need to get input from eight different people on both sides of the table. And input from the stakeholders. We need to hear from the people that we serve and have them tell us what is working and not working and what they want and what they don't want (OARSA). • We need efficient use of the personnel we have, clear designation of what their roles are, and the resources to carry out these roles (ORS). • Clearer communication of what the Agency's, Center's, and Offices' missions are, clearer communication of the research prioritization process and project selection process, and clarification of what our roles are with respect to the Center and Agency. We have a lot of great ideas but often don't know whether or not we can work on them or how we can apply them to the Agency's or Center's mission (CVM). • Leadership needs promote the necessity of doing mission related work and be clear and consistent about it. To get people to change their research focus is difficult. When a CARTS project is rejected, people's first response is to get angry and try to figure out how to "game" the system. But in one case I know of, the researcher worked with the reviewer to find a way to salvage the project so that it was more mission focused. We need to be willing to concede that we don't have the last answer. The same thing goes for the people over at OARSA. Some have seen the writing on the wall and have been willing to work within the system. Others are very upset and want to rebel. I don't know how to solve the dissention, maybe some people just need to move on (ORS).
Reorganization	• FDA is so huge and diverse in objectives. Maybe it is not feasible to keep FDA as one. The desire to have a "face of FDA" gets in its own way. Maybe separate parts with separate functions works best. The same is true of the different parts of the government. They're not recognizing they're a system with separate goals and functions that work together as a whole. When you're trying to work with the CDC, there are so many people in FDA who do exactly what the CDC does, so why work with CDC (OFS/DI)? • There should be reorganization into a single office (ORS). • It would be better just to have one big MB group broken up into teams (CVM). • Wiley and MOD 1 have two different identities, but if they could work out their differences, or be one unit, that would be the best way (CVM).
Adjust management structure	• They could have upper management serve in terms so they do not occupy one position and play favorites forever (OARSA). • The OD should not be reporting to the former Deputy Director of another office, who has all his contacts and biases firmly established. In the past, the two research offices have always reported to different Deputy Directors. That change occurred about 2 years ago. There is an inherent conflict of interest in the current arrangement (OARSA). • The offices should have more autonomy in research (OARSA). • As far as the managers go, there should be a better way of evaluating their effectiveness. The 360 evaluation is one process, but it is not completely effective because managers can choose the personnel who will do the evaluation. The evaluation of managers should be broader and more transparent (ORS)
Build interdisciplinary teams	• For example, Battelle created multidisciplinary teams, temporary group structures, to tackle and complete specific projects that were disbanded on completion. Something similar could work in FDA. When putting together teams at the program offices, they need to include bench scientists. This is the only way to break these barriers. On completion, individuals from the teams could transfer their knowledge to their co-workers (OARSA).
Undertake cross-cutting studies	• We should be doing more crosscutting studies that span all three divisions within our Office--not just the microbiology side, but there may be an animal study component that we can incorporate into the microbiology side and maybe there is a residue component in all three. Questions from all three groups could be answered with one study if it was conducted that way (CVM).

C.2.3.21.a-1. Interviewee Observations: Ideas for Overcoming Barriers Which Contribute to Lack of Coordination: In House	
Address personnel issues	• Dealing with specific people when there is a problem could help. Nobody ever wants to bring it up. Everyone is avoiding confrontations (ORS).

C.2.3.21.a-2. Interviewee Observations: Ideas for Overcoming Barriers Which Contribute to Lack of Coordination: With Partners and Stakeholders	
With partners and stakeholders	
Improve relations between management at the agency level	• Make the upper level management in the agencies meet more often. It is management who wants to protect the turf. The scientists are very happy to interact with each other (ORS). • It would take a change in leadership at the CDC (ORS).
Increase management encouragement/ Support	• Sometimes there is a perception that scientists, either individually or as a group, are discouraged nonverbally or prohibited through other actions on directly interacting with other institutions or within our institutions with other people. The perception should not exist (OARSA).
Increase awareness of what each partner has to offer	• Make the IFSH meetings more open, collaborative, and accessible for developing working relationships. The first day of the meeting is very administrative. Somebody introduces our different groups and capabilities, but there's no interaction between the companies or groups. Perhaps membership could speak to different groups instead. They could tell us their problems and we could begin collaborating. Companies bring us equipment they want us to use for a project. That's fine—we see their technology, but they don't see our capabilities. They should know what our capabilities are and the kinds of research we do. These meetings lack any discussion of science (OFS/MC). • Barriers between agencies can be overcome by having a better understanding of the other agencies through training and/or visits (CVM).
Get the right people involved	• We need more knowledgeable people involved to make good informed decisions. Right now a lot of these decisions are made out of fear of the unknown (ORS).
Provide training on how to interact	• There are clear lines when dealing with sensitive data, and you have to know what those lines are. I've had good training from team members but there needs to be a more formal training in these guidelines. Especially in outbreak situations, there are a lot of people who want to do the 'right' thing in sharing information but who don't understand the laws and restrictions we have to follow. There needs to be a resource, especially during outbreaks where there is high visibility and decisions have to be made quickly, that someone could turn to determine what is may be divulged (ORS).
Streamline overlapping research	• There is need to streamline overlapping research between agencies. It would result in less duplication and would cost less. Having so many agencies involved is confusing for industry (ORS). • Establish a single food safety agency (CVM).
Establish accountability	• If we are going to attempt these interactions, we need to state an objective and meet that objective, rather than just saying we tried (OFS/DI).

C.2.4. Expertise/Training

C.2.4.22. What are the gaps or imbalances in scientific expertise and technological capability that CFSAN and CVM should increase efforts in to ensure that it can address current and future regulatory demands?

The responses to this question have been divided into two tables: one for scientific expertise and one for technological capability.

C.2.4.22-1. Interviewee Observations: Gaps or Imbalances in Scientific Expertise.	
Scientific Expertise	
Bioinformatics	• We could strengthen the program by having bioinformaticists who are knowledgeable in the fields relevant to where the data are being generated. So they should be microbiologists or bacteriologists, not just a statistical background (OARSA). • Older generation scientists do not have this expertise. Mid-career scientists have some experience from projects. We do have some staff and ORISE Fellows with formal training in these skills, but we are not sure if they will be able to continue; they are not permanent. We need to retain these people (OARSA). • When I wanted to hire a bioinformaticist, I was told that we are going to centralize it all at OAO and then you can get all the help you need. Well, it's not happening. We are currently using an outside contractor to analyze our data. We need these people equally in all the places that are generating WGS data (OARSA). • Bioinformatics are needed for most MB going forward. With WGS, we have a need for some bioinformatics. We have a high performance computer to handle the bioinformatic analysis and we have a couple of bioinformaticists coming down here from CPK1 to train us, but FDA could benefit from hiring bioinformaticists rather than having microbiologists trying to become bioinformaticists (OFS/DI). • We need bioinformaticists because CPK1 is bogged down with just one. But we don't need two independent Centers doing the same work. My dream would be to have personnel who can do the sequencing, analyzing the data and then communicating and collaborating with the scientists in CPK1 and sharing all that data. We should at least have someone here who can analyze and review the data because, while we have a sequencer, we need the bioinformaticist to analyze it. CPK1 have offered their services, but it's difficult to communicate when we aren't in the same location, and they're overwhelmed too (OFS/MC). • There should be an entire division or branch dedicated to do bioinformatics support. It is hard because it is so broad. It is easy to get a life science background but it is hard to find someone with a computer background who is also able to apply those skills to life science (ORS). • The biggest need for us right now is bioinformatics support. We have one person that is learning and training and trying to do everything to get us somewhat up to speed. We do not have the number of people or the training for the people to do the work that we are already doing. I don't know how this will be resolved (CVM). • Looking at the molecular revolution, it seems like our technology is ahead of our understanding. We are able to generate vast amounts of data but the statistical analysis and interpretation of it is still unknown. We are lagging in terms of looking at WGS on the bioinformatics side of it. Having the trained bioinformaticists or even training our own people in terms of the data analysis quality and integrity assessment to know (CVM).
Specific field/area	**Food-related MB:** • More expertise in food MB. We are lopsided in favor of DNA-based research (OARSA). • We need someone with more experience in food processing to complement our decomposition project which is tied with the compliance people in DC (OFS/DI). • More expertise in different matrices (e.g., cantaloupe, tomatoes, cheese) would be very beneficial, rather than focusing on microbes only (ORS). • We need good field and food microbiologists that are willing to go out to the farms and

C.2.4.22-1. Interviewee Observations: Gaps or Imbalances in Scientific Expertise.	
	start attacking the problems where they start (ORS) • **Environmental and cosmetic MB:** • They should hire environmental MB and cosmetic MB FTE's (ORS). **Preventive controls:** • Expand efforts in preventive controls (OFS/MC). • Preventive controls and interventions for pathogens. That's where FSMA is. That's the new way industry will have to operate and we need to have expertise on hand to handle those decisions (OFS/MC). **Statistics** • Recommended by interviewees in OARSA, OFS/MC, ORS, and CVM **Virology:** • Increased staff in virology (OARSA) • Virology (OFS/MC). **Parasitology:** • They need to hire more parasitologists (OARSA; OFS/MC). **Gram-positive bacteria:** • Someone to work on gram positive organisms (CVM). **Other pathogens:** • Spore formers (OFS/MC) • We need to get a handle on things like drug resistant TB, Avian Flu and other unique pathogens before there is an outbreak (ORS).
Genomics	• The 100K genome project is on life support now. We have invested so much money in it. It is difficult because it is a long-term project with no short-term victories. Ten years from now, we will say it is so great that we did this (ORS). • Since WGS is the way of the future, we could use additional training for the support staff because most are traditional microbiologists. This is coming fast and we need to be proactive. We are already collecting lots of data, but I have no idea how it can be used by enforcement and in the courts (CVM). • We need more expertise in WGS. One person is training everyone. That is too much.
New technology	• Robotic instrumentation • We need to move more to computer controlled systems. It has moved beyond the knowledge of our in-house expertise (ORS). • Nanotechnology expertise (CVM).
No major gaps	• From the bottom up, everyone has the responsibility to stay current, so there isn't a systemic problem with expertise. You can't institutionalize this (OARSA). • Mostly it is possible to learn new expertise. Learning new things should be encouraged. We can develop any expertise we need with the personnel we have, as long as there is funding available. Sequencing used to be a big deal, now anyone can do it (OARSA).
Gap analysis	• We currently have a diverse set of scientists and support scientists, but we don't know what the future regulatory demands will be. Our OD wants to do a gap analysis on expertise and skills (CVM).
Expand/maintain current	**Traditional microbiology/basic research:** • The way hiring is going over there, they are forsaking anyone without a component in genomics aspects. Without this, a candidate is not considered hire worthy. We are losing basic, fundamental MB expertise: fundamental molecular biology, fundamental protein chemistry, and biochemistry-based expertise in favor of sequencing, bioinformatics, and phylogenetics. Those are the big three that are being over-emphasized and we're losing the basic MB and biology components that should be maintained (OARSA). • We have the expertise but sometimes we need to do background research first, and it is very difficult to get some of our management to recognize that you need to do some basic research before you can do the applied research. We are slowly getting there with the SSA, but it can only be about 5% of our time or something (OARSA).

C.2.4.22-1. Interviewee Observations: Gaps or Imbalances in Scientific Expertise.	
	• Every time there is a new technology, FDA tends to hire people, rather than train and nurture the people they have (OARSA). • FDA needs to support a broader focus. The more evidence you have to take to court, the more support you'll have for your case (OARSA). • There is too much emphasis on sequencing. They are missing any other capacity, such as general molecular biological techniques. We will get to the point where we don't have people who are able to do this (OARSA). • When upper management or outside entities ask certain questions, we can't always answer because we haven't had the time or resources to look into them. We really need to expand the current research programs. We need time and resources and people to examine these questions (ORS). • Classical microbiologists that can improve the BAM (ORS). **Antibiotic resistance:** • Hire a PI in antibiotic resistance (CVM). **Increase depth; maintain institutional knowledge:** • Some areas only have one expert. We should have at least two people in each area to cover the other or to plan ahead for when one of the experts retires (ORS). • About a decade ago, we lost a lot of institutional knowledge – some areas of expertise that were lost were never replaced (e.g., virologist, parasitologist). These are things we have to farm out. Maybe that is appropriate, or maybe CFSAN should centralize these areas of expertise within (ORS). **Support scientists/technicians:** • Six years ago I could hire 2-3 students, now each PI can only hire one. One solution would be to use more JIFSAN interns from CPK1. It's a very cost-effective program so should have more funding. It would make it so much easier to accomplish the goals that the Center wants us to accomplish (OARSA). • We need more support scientists. If we hire people, we have to hire a Ph.D. I don't have someone to wash dishes for me, I still have to do it. How effective is it to use a Ph.D. with 25 years of experience to spend the day washing dishes (OFS/MC)? • We need more help at the technician level, the hands in the lab. We are a bit too top heavy. The Ph.D. scientists are involved in prioritization meetings and other meetings, which makes it difficult to advance your science if 7 of your 8 hours is spent at a meeting (ORS). We need more support staff to help with lab equipment, paperwork, lab work, ordering, etc. (ORS). **Conversion of Fellows:** • We have the personnel if we can keep the scientists we now have—convert, hire Staff Fellows, and find the means to keep some of our ORISE. We've had to let some go already. Maybe some affordable contract program to keep them on. I don't see a need for large increases in personnel, if we can keep those that we have (OARSA). • Conversion of Staff Fellows would fill the gaps (OARSA). • There is an imbalance because we rely on ORISE staff and not being able to hire FTEs. Our expertise goes up and then down when they leave, and we're back to square one, but the regulatory demand remains the same (OFS/MC). • ORISE and Staff Fellows need to be made permanent. We have good people out here. I don't know how they expect us to meet future demands if there are no permanent employees and the ones that are permanent are about to retire. (OARSA).

C.2.4.22-2. Interviewee Observations: Gaps or Imbalances in Technological Capability.	
Technological Capability	
Better IT	• We have pretty good networking, hardware, and computers, but the restrictions on computers make it less useful as it could be (OARSA). • Technology to support bioinformatics (ORS). • High speed computing (ORS).

C.2.4.22-2. Interviewee Observations: Gaps or Imbalances in Technological Capability.	
	• Integrated LIMS and GIMS. LIMS is not working well here, it's partly because it needs a structured environment, and research can be unstructured. Where research and regular production come together is where it fails. We bought a system, and we are hiring the people to write the software to integrate it (ORS). • IT people trained to set up infrastructure for scientists (ORS). • Need Internet2 to come through and better connections over to NCBI (ORS).
New technology	**Instrumentation:** • It would be good to have a program to try instruments in our setting before having to purchase them. The deficiencies of an instrument are not usually presented by the salesman (OARSA). • In virology, a lot of technology available these days is not sensitive enough to do food surveillance (OARSA). • We should empower our stakeholders to do their own analyses so that we can advance our field and handle emerging problems. We have the best equipment we've ever had, but the products coming out of them are not there. E.g., we develop a method using mass spec, but the field labs don't have mass spec, so they have to send the samples to us (OFS/DI). • Some labs do need new instruments, while others get costly new instruments very frequently (ORS). • Our model of working with private industry is working well. It keeps us cutting edge. Working with the private sector in instruments that we might use or that the food industry might use keeps our technology current and on the leading edge. We are then is a position to recommend (or not) instruments to the food industry (OFS/MC). • Sequencers and WGS related equipment (CVM). **Data analysis:** • I know how to run the instrument but there may be only one or two people who really work with the data who understand whether or not it is good and what value we can get from the data. Because there are no data standards for analysis and interpretation, the data may be seen differently depending on which analyst you ask. We are generating a lot of data but we don't have the capability to fully utilize it or see where it can be applied. That is a byproduct of technology changing so rapidly in the last 3-5 years. There are also issues concerning harmonization of new data with older methods and older data sets that we have (CVM). **Efforts to stay current with advances:** • More collaboration with academia on basic research to stay current with technological advances (ORS). • We need a process to evaluate new technology that is a little more formalized. Perhaps a work group involved in assessing new technology, so everyone is on the same page and knows what is being evaluated and where we are going and who is doing what in the evaluation process (ORS).
Method validation	• We have a lot of norovirus methodology that now needs to be validated for regulation. We need a committee to look into this and not some person who has the time and wants to be involved. It would require substantial coordination and good people to do it (OFS/MC).
None	• Sometimes the newest thing is just the newest thing. As researchers we want to jump on the most technologically advanced piece of equipment out there. But now we all have it, and it turns out not to be of value and goes to the warehouse and sits there. This is another example of not having that link to our stakeholders and our mission and purpose. We have funding and accessibility to get this new thing but it is not in any way feasible for our stakeholders to have that. Now we have this great way to molecularly detect and sequence the genome of something that's virulent and nobody else can do this. That's a gap in the process (OFS/DI). • I'm not sure there are gaps. We lag behind a bit because we don't have the funds. But in the food world, we don't need to be that innovative. We do need to use new technologies, but not necessarily right away when they're the newest thing (OFS/DI). • We have a lot of funding and most advanced equipment. We are able to evaluate a lot of

C.2.4.22-2. Interviewee Observations: Gaps or Imbalances in Technological Capability.	
	new technology and management is very supportive of this effort. Our technological capability is pretty good (ORS). • We have the newest toys here already (ORS). • We're flying pretty high technologically (ORS).

C.2.4.23. How can we improve CFSAN and CVM recruitment, development, and retention of the professional expertise needed to address current and future regulatory microbiological challenges?

The responses to this question have been divided into three tables: one for recruitment, one for development, and one for retention.

C.2.4.23-1. Interviewee Observations: How Can We Improve CFSAN and CVM Recruitment?	
Recruitment	
Improve hiring system above and within the Centers	**Improve the system at the Federal and Agency Level:** • **USAJOBS:** • This is a challenge through USAJOBS. People may meet the certifications but they are not quite what we need. This makes it hard to recruit people who we know are good (ORS). • **FDA Office of Human Resources:** • Make personnel actions easier, not harder and don't come out with a new regulation, rule or set of paperwork requirements every year. There are roadblocks within HR (OARSA). • The hiring system is broken. Personnel is broken: how jobs are created, how position descriptions are made. It appears that these people do not have the knowledge required to make decisions on hiring technical staff, and we are losing out on opportunities to hire very talented people because the system is so rigid. I had a position here for a GS-7 dishwasher, and I had Ph.D.'s applying and they made the search! Meanwhile, people who would have been happy with that grade were being bumped out. This forces us to hire people via ORISE contract or Staff Fellows. The list we receive from FDA's personnel office is often cut off because the people there are inexperienced. The people who are actually advertising the job should have some scientific expertise. You can't have someone with a non-scientific background identifying who should go on the list for suitable applicants (OFS/DI). • Hiring is discussed at the management level and never with the scientists (OFS/MC). • We need to improve the way selections of people who are qualified is done. We can find good people, but when they go through the process they don't come up as good candidates. The people who are screening have no idea what we do. They're just looking for words. That's not a good system (CVM). **Improve the system within Centers:** • **Make hiring decisions within the Centers:** • We need to be able to make more hiring decisions locally. I believe the CD has been working on this. The right people don't get through the HR process. We ask for a list of applicants from HR for a position and we get 6 out of the 100's that have applied. If you throw the first six back in the pot because no one is suitable, you might lose your hiring opportunity by the time you get your next six. I've been on search committees inside and outside the government, and this is by far the worst experience trying to hire here (ORS). **Identify the right candidates:** • You have to find people who fit this job—who like what they're doing because of what they're doing. Although this may not be the best and the brightest, there are those who might feel restrained at FDA (OFS/DI). • It is not clear how we can refer experts from the outside or forward resumes of candidates that meet Center needs (ORS). • It's so hard to get good candidates through HR in Atlanta. It would be better to have

C.2.4.23-1. Interviewee Observations: How Can We Improve CFSAN and CVM Recruitment?	
	search committee and bring people in for seminars. We could attract the best from the new crop of graduates rather than just who knows someone (ORS). • They need an HR specializing in MB recruitment. We have an active collaboration with leading academic labs and hire people coming out of those labs. This works well for CVM because we are small. (CVM). • **Remove bias/favoritism:** • Recruitment is pretty biased. For most job postings, they already know who they want to place, which is a bad practice (ORS). • Hire based on merit rather than favoritism (ORS). • We may be biased towards picking up people from the University of MD just because of proximity. I don't think we are doing enough to reach out to other high caliber bioinformatics programs in other schools (ORS).
Allow hiring/conversion	• By allowing new hires or extending Staff and ORISE Fellows: They told us we could not hire, but that's not true at CPK1. The Fellows are great researchers and a real asset to the Division (OARSA). • I can't even retain the people I'd like to retain because we're not being given the slots. Our CD has said he's not in favor of expanding research, and the Deputy CD has told us that positions that open up due to retirement aren't ours any more. What kind of position does that put us in (OARSA)? • We need to stop treating Staff Fellows so poorly. We will no longer go the Staff Fellow route. Even though hiring someone as an FTE is riskier because you don't get a chance to try them out before they are a permanent hire, this is the route we need to take because of lack of conversion. It used to be normal route, but we were told that that was not the route to take by the CD (OARSA). • If they don't hire some of these Fellows that are trained it is going to leave a gap. They are younger people and so they have knowledge of much more recent developments than the old-timers like me. If we don't retain them, it will just leave larger gaps in terms of scientific expertise and technological capability (OARSA). • In government there is no retirement age limit. So if people don't retire then others cannot get in. So Fellows and contractors just get discouraged. No matter how good you are you are not guaranteed to get a position. When the term is over you have to leave and then the research suffers (OARSA). • Hire more people and hire more selectively (OARSA). We need to be able to hire people to retain them (OARSA). • I don't see that they are doing a lot of recruiting. There are no new FTEs. We have a lot of temporary researchers that are in staff scientist positions. We have been warned that these people won't necessarily get converted to permanent positions (OARSA). • Let us hire: we are lacking 6 FTEs. Some positions have been approved but because of the system, it's very difficult to hire good people. The system is broken in OPM. It's easier to hire Staff Fellows and then convert (OFS/DI).
Publicize/advertise	• Most people know FDA exists but not what we do. Improving communication of what we do and how we do it so more people are aware of it, it would foster more interest. I think most people don't realize just how much science gets done here. To recruit the scientists we need, they need to be aware that it exists and that we do the research (CVM). • We should increase collaborations with academics. You need to use your network to find a good fit for positions. You're not going to find it through USA jobs. We should match people up with productive people so they want to come back (OFS/DI). • Maintain collaborations with students and schools so we can see what is up-and-coming (OFS/DI). • We need to communicate about the different programs we have and how to differentiate. When I was an undergrad I didn't even think about working for FDA. To me FDA was drugs and tobacco. I didn't know we had a food safety program with microbiological support. And now we have Next Generation WGS. I sort of doubt how many people know about that (ORS).

C.2.4.23-1. Interviewee Observations: How Can We Improve CFSAN and CVM Recruitment?	
	• Let us advertise more freely. We need to advertise beyond USJOBS in places like *Science* and *Nature* so we can recruit really good people (ORS). • They need to lay out how good professional career development can be in this agency (ORS). • Scientific meetings are a good places for recruitment. ASM, IAFP are good places (ORS). • We need more of a presence at scientific meetings. A CVM booth at meetings or at universities might be helpful (CVM).
Improve pay scale	• Post docs out of academia would make $50,000 working at the NIH, let's pay them $80,000 to come here (OARSA). • We need to be able to provide more attractive package, perhaps a development track. Maybe we need to redistribute resources so that we can pay more (OARSA). • We can improve recruitment by not compartmentalizing to meet the GS scale. It's ridiculous that someone can come out with a Masters and 5 years of experience and can't be a GS-12 because they don't have supervisory experience (OFS/DI).
Improve work environment	• We need to develop the mentality that obtaining and retaining high caliber people is important to CFSAN in the long run (OARSA). • We need to continue to develop an institution of excellence, having proper structure, known responsibilities and dedicated support staff will attract those who want to work for an excellent institution (ORS). • OFVM has started an annual scientific program that brings together people from the field side, the regulatory side, and the science side. It's still in its infancy and needs more monetary support and additional people to be involved. The only way to solve the problems before us is to get a critical mass of people around to talk in forums such as at the National Science Day, which is sponsored by the Office. There's potential if the program gets more funding and collaboration and coordination efforts get underway. Last year was its third year and I've never seen Centers of Excellence people there. It's a perfect opportunity to bring these people in (OARSA).
Balance expertise	• Right now recruitment is funding-based, rather than according to what you need (OARSA). • Managers should conduct a risk assessment for recruitment and match microbiologists to risk areas and priorities so that they don't put too many in one area. If they think we have too many microbiologists, they need to redistribute them (OFS/MC). • With the micromanagement, tunnel vision, and morale issues, we need to have a place that is more broadly accepting of a broad base of science. They will end up with 60 or 70 scientists here who can only do one thing, and they will realize what a pickle they are in. It is key to have a fundamentally broad base of expertise (OARSA). • Before hiring new staff, analyze current staff's capabilities and align them with projects that match their skill sets (CVM).
Contract more work	• We currently use contractors, e.g., ORISE**,** JIFSAN, Goldbelt (expensive though), and the Commissioner's Fellowship works well (ORS).
None needed	• We do very well in this. We bring scientists over as ORISE Fellows, and only the good people are hired (ORS). • We have such a good team with low turnover, I think we're doing a good job. The reason people have turned down jobs with us is because it's an expensive area and people don't want to move to DC. CVM is a nice a place work (CVM).

C.2.4.23-2. Interviewee Observations: How Can We Improve CFSAN and CVM Development?	
Development	
Encourage training and education	• CPK1 has the Staff College. They provide a lot of trainings and courses. But because we are not in CPK1, sometimes it is difficult to go to CPK1. You have to interrupt everything you are doing here. It is not convenient (OARSA).

C.2.4.23-2. Interviewee Observations: How Can We Improve CFSAN and CVM Development?	
	• Any kind of training—technical, writing, communication, etc. (OFS/MC). • Require staff to undergo training or hold a position on a committee for a professional society in order to get promoted. That would ensure their involvement. People would do it if they thought they'd get more money (OFS/MC). • Give us the budget to help with team building and other training exercises (ORS). • Implement a rating system for various training courses so that employees can make good decisions on worthwhile training (ORS). • I did a training last year at a conference to do bioinformatics. It really extended my perspective to understand what they do and how difficult it is (ORS). • People should take leadership and training classes. I was not a fan of leadership classes until I got my current position and now I think they really help (ORS). • Everybody should have the opportunity to learn a new technology such as WGS and work on a project involving it (CVM). • For people who already have an investment in our Centers, allowing them to go get trained (e.g., get an M.S. or training etc.) to improve their skill sets is important (CVM).
Increase travel and attendance at meetings	• Allow travel. It has been restricted due to budget cuts. They should come up with as many training opportunities as possible (OARSA). • Revise procedures for meeting or training attendance. Someone at FDA has come up with this idea that only 20 people are allowed to go to certain meetings. Who came up with that number and why? There should be some latitude for areas in which you are research heavy and should present (OARSA). • Attending meetings and conferences keeps researchers current in methods and knowledge in their areas. It is also a good opportunity to develop collaborations outside the Agency. Sometimes you get your best ideas when you are outside your normal, everyday box (OARSA). • Here we are very dependent on the ability to get out to some of these scientific meetings. When you have a cap on travel, you could be bringing in money and still not be able to use that money for travel because you have a cap. Artificial caps hurt the scientists more than anything else. There are all these constraints, partly because technical meetings are looked at as junket trips. Someone should call them on this. Not all meetings are scientific meetings, some are compliance and regulatory, like ISSC. At a scientific meeting like ASM or IAFP, not only are you having an opportunity to present the research to the community and the consumers of it, but also, your collaborators and future collaborators are there. It's strengthening your network to be able to maintain that level of expertise. This hasn't been defended strongly enough by our Center management (OFS/DI). • You can't apply the same travel solutions to technicians and PIs. This creates an issue with professional development. If PIs cannot go to meetings to foster collaborations and interactions, they will lose contact with colleagues. Make it so those that really need travel to fulfill the Agency mission have the opportunity to do that. Many people consider travel a luxury. We need it to foster international collaborations (ORS). • We have been lucky to be able to send FTE and ORISE to national meetings. More senior management go to work group meeting such as, GMI meetings, CDC, state and local health departments. Travel is essential for a research organization (ORS).
Increase opportunities for advancement	**Establish development plans:** • It would be if there were a development track. It would be nice if we discussed this at our PMAP meetings. Instead we talked about my CARTS project. That's not what my PMAP is for. Leadership is the key to a lot of these things (OARSA). • Depending on your track, your growth potential may be capped. There may be growth opportunities available, but your ability to take advantage of those may be limited once you get to the top of your GS scale. There are no real mechanisms for career transition, and it seems to be difficult to transition to that next step. For people in the journeyman classification there is no real career ladder. I can move laterally but I cannot advance my career to that next level unless I completely change position descriptions or classifications

C.2.4.23-2. Interviewee Observations: How Can We Improve CFSAN and CVM Development?	
	(CVM). • Develop IDP (individual development plans) for our employees. During these conversations with employees, it would be important for the DDs or the Office leadership to address the current and future state of microbiology. Before they consider new employees, they should develop the current staff and give them opportunities to train and take courses. That would help retain them by giving them opportunities to grow. After developing the current staff, if there are any needs gaps, recruitment should occur. I believe in promoting from within and giving current staff new opportunities and then looking outside if necessary (CVM). • Conduct skills analysis of staff: Everyone should be offered the opportunity to learn and develop his or her own career. Some research scientists are always asked to do *Salmonella* because they know the technique, but they may want to move on to something else. If we have a skills analysis we can make adjustments. Deciding who works on what shouldn't be an arbitrary decision from upper management (CVM). **Revise criteria for advancement:** • **GS-level criteria** • There needs to be a better way of being able to increase your position (pay or level). The worst is the management component of GS-12 and up. If someone comes here and continues to improve and continues to contribute without being a manager, there is no route. The mentality that you need to be a supervisor to have a value or a worth needs to change, especially in research. Once someone goes into a supervisory role, you've lost a researcher. I don't think you should want to lose your researchers (OFS/DI). • There are executive assistant positions in Washington that are GS-13s. We have some here. This level does not correspond to the same level of expertise of someone who has worked for years on a degree or is working on methodology that is saving the food supply. That shouldn't happen. It's demoralizing. Administration seems to have an easier route to advancement (OFS/DI). • Another challenge is the disparity of grades of scientists vs. non-scientist staffers. Non-scientists are getting GS-13s and -14s in DC just by asking their bosses to submit approval. Meanwhile, scientists are going through this laborious peer review process. It's not right. We have an administrative person here who is a GS-13. She is one of the least educated people on the staff, yet she's a GS-13! And yet people with Ph.Ds. are GS-12s or -13s (OFS/DI). • The standard for promoting scientists in FDA is much higher than for non-scientists. For scientists to be GS-14 you have to bring the moon (ORS). • We need a development plan for our support scientists. We need GS-13 level research coordinator to get people to work together, to mentor younger scientists and help them have a development plan. This person could also pitch in in the lab in a crisis. HR says this position doesn't exist, that it would have to be a GS-12 (CVM). • For a lot of the work that a few of us in NARMS do, we exceed the GS-12 level. If you compare it to some of the other GS-13 positions throughout the government, we are doing far more and are far more specialized. There is no room for growth here (CVM). • We need more IDPs (Individual Development Plans) for the support staff to help them overcome the glass ceilings. For those willing to do the extra work required, there should be a plan, if followed, would result in a promotion. At the moment, we are told if we want a GS-13, we have to leave the lab (CVM). • **Publication criteria:** • Remove the requirement that someone be a first author or PI for promotion. They should look at everybody who contributed to a publication. This will also decrease turf wars/increase collaboration (ORS). **Establish a mechanism for correcting position titles:** • We need a mechanism for correcting position titles. I no long am a research MB even though that is what my title is (ORS).
Allow staff exchanges,	• Encourage going on details and exchanges within the Center (OARSA). • Encourage sabbaticals in academia/industry (OARSA).

C.2.4.23-2. Interviewee Observations: How Can We Improve CFSAN and CVM Development?	
sabbaticals, and collaborations	• Allow the opportunity for sabbaticals between us and field labs. Part of improving communication with our other partners would be getting out there to see how they actually do things. We are all bench researchers and we can do that. For some of them it would be a great opportunity to get back to the research that led them to where they are in the first place and contribute to the development of an assay that they will see in the end (OARSA). • Invite scientists from the outside (academia/industry) into FDA laboratories (OARSA). • Allow younger people within their PMAP enough time in their annual duties to do something different (e.g., go help someone else). This doesn't have to be formal details. This is the most valuable type of training (OFS/DI). • Sabbaticals, even between agencies, would be great (ORS). • Increase opportunities for collaboration (ORS).
Improve the work environment	• We are doing a better job here in terms of lab support: allocations have gone up, and we are able to buy chemicals and equipment. Providing an encouraging, nurturing environment would be useful. We need to do more reinforcement (OARSA). • We need to make it a better place to work. It needs to be more intellectually challenging, and we need to make people agents of change (OFS/DI). • It is demoralizing to have to continually fight to do your job. To have to fight for resources, access to facilities, etc. can cause people to leave or move onto the program offices (ORS).
No problem	• Development is an individual choice. The FDA has a lot of opportunity for training, it's down to the individual to take advantage of it (ORS).

C.2.4.23-3. Interviewee Observations: How Can We Improve CFSAN and CVM Retention?	
Retention	
Increase opportunities for advancement	**Revise criteria for advancement:** • It's hard to keep people at my level (support scientist) because the ceiling is only so high and without a Ph.D. we can only get promoted so far. I've seen people at my level go from being a microbiologist to being in admin because you can be promoted if you're admin. I don't know how to fix it. Once I've reached the top step in my grade, there's nowhere else for me to go (OFS/MC). • Being able to advance or go on detail without repercussions would be very helpful. Being able to further your career without repercussions is necessary (ORS). • The scientific review process for promotions is not balanced. The criteria are vague and include the number of publications. The candidate has no opportunity to argue the outcome of the promotion decision (ORS). • We need a better HR interface that more clearly delineates requirements needed for advancement especially for the support staff. This would allow better planning for development (ORS). • Creating a career ladder for researchers should be emphasized and streamlined (CVM). • Depending on your track, your growth potential may be capped. There may be growth opportunities available, but your ability to take advantage of those may be limited once you get to the top of your GS scale. There are no real mechanisms for career transition, and it seems to be difficult to transition to that next step. For people in the journeyman classification there is no real career ladder. I can move laterally but I cannot advance my career to that next level unless I completely change position descriptions or classifications (CVM). • Support scientists can't get promoted here to a GS level that requires a Ph.D. At CFSAN and other Centers, even if they don't have Ph.Ds. they can get to a higher level depending on experience (CVM). **Improve peer review process:** • A fair and impartial peer review process so our scientists are getting promoted when they deserve it and not five years later. Or not denied promotion because there was some

C.2.4.23-3. Interviewee Observations: How Can We Improve CFSAN and CVM Retention?	
	sort of bean counting exercise that they couldn't pass (ORS). • Most PhD lab positions should start at GS13 and/or the promotion from GS12 to -13 promotion should be able to be done administratively: I can offer a PhD postdoc a GS12 in the lab, but someone with a B.S. can get a GS12 in the program office. It would be great to start people as a GS13 with the understanding that they might be there for a while. Peer review should not be needed for a GS13 for microbiologists. The chemists can do it administratively (ORS). • The whole peer review process needs to be reexamined. To get a peer review takes a tremendous a lot of time for everyone involved. The peer review panel is a whole scam in itself because it's all subjective. Some reviewers have prejudices about the journals people are published in or won't approve if someone doesn't have a Ph.D. There is nothing in the guidelines that says a Ph.D. is required, it's all about independence, originality and accomplishments. The peer review panels should be ad hoc like they used to be. They shouldn't have the same people sitting there all the time (ORS). • The requirements and eligibility for the promotion via the peer review process are not clear. The process also seems to be biased—some seem to be promoted on very little whereas others are overlooked. The path is not clear. This area needs more oversight. In addition, researchers have many responsibilities outside of lab work, but promotions are based solely on our research (ORS). **Allowing opportunities for staff to do work they enjoy:** • If you want to retain people, you need to allow people to utilize their strengths, rather than forcing them into positions or laboratories where they don't fit (ORS). • We are seeing people leave here to go to other areas. Either they're losing interest here or not getting rewarded as expected. This can be addressed by matching people with the work that they will enjoy (CVM). • If people aren't happy with what they're working on and looking for other opportunities—but they aren't available—they won't stay. Accommodate them as much as possible. It's not fair to people if they have to fill an unmet need when their interests lie elsewhere (CVM).
Allow conversion	• We should not be treating Staff Fellows as disposable, but this is the current theme coming from the CD's office. There is no interest in retention (OARSA). • We have a problem. We bring young people in as Staff Fellows and we train them. There should be a contract vehicle in which we keep them. They're here for a certain amount of time, then they're let go or they're not renewed. The people have trained and are knowledgeable of our techniques, etc., and we're not allowed to keep them. That is a big problem in my division. These are young, bright minds. This is not how it was in the past (OARSA). • It's hard to see such talented people with great ideas and great contacts come and join our research family and then not be retained. Why would we want to lose such a valuable resource (OARSA)? • Offering full time positions to people who are of great utility is important (ORS).
Increase recognition of efforts	• People who come to government do not expect to be reimbursed as they would be industry, but they do expect recognition and the ability to grow in their field of expertise. There are people here who are on a par with any professor in academia because they have been supported and FDA has invested in them (OARSA). • People need to know they are appreciated. It doesn't have to be a big cash prize, there just needs to be some understanding of your achievements (OARSA). • Bonuses, awards for scientific achievement. Ease of doing your research (OARSA). • Don't stop projects that have been approved mid-way (OARSA). • Rewards: monetary and acknowledgement of achievements (via trips, funding OFS/DI). • Reward the young people for their work. Push awards on them. Give them cash bonuses. IFSH lets them attend meetings so they feel like they're an integral part of what we're doing. We try to get them to one meeting a year. We try to mentor them, but we're

C.2.4.23-3. Interviewee Observations: How Can We Improve CFSAN and CVM Retention?	
	all so busy. Explaining why a project is important gives them a sense of ownership. That's how to grow people (OFS/MC). • Treat good scientists with respect and fairness and stop playing favorites (ORS).
Increase pay	• Helping us pay off student loans would be excellent (OFS/DI) • There are salary balance issues. A lab technician shouldn't be making more than their PI. I am not sure how to manage scientific grade issues, but there should be some consistency. There are inconsistencies in pay between those coming in with Ph.Ds. and those who came right out of college, but have been here a longer time. There needs to be some balance (ORS).
Improve work environment	• The morale is low, so it's going to hard to keep young people when they are so limited in what they can do, when the funding is low. People that have been here a long time like me are talking about retirement because morale is not good. It's hard to work in a situation where you don't really know what you are supposed to be doing. Most people feel very underappreciated. We feel expendable (OARSA). • Relax some of the rigidity within OFVM. E.g., CARTS is fine but now our projects are overseen and many are rejected. Sometimes it's as if they want you to know the answer before you start. This is not advancing anything (OFS/DI). • Allow flex-place (ORS). • The organization needs to exhibit ethical human behavior and evaluate and promote employees in a right and proper manner (ORS). • There is more and more bureaucracy required by those in the lab, e.g., committees and justifications are required for everything. It is becoming a heavier and heavier load and this takes time out of our essential lab duties (ORS).
Increase travel and attendance at meetings	• For a lot of the meetings that we send abstracts to and get accepted, we find out at the last minute that we can't go. Some of these associations may actually ban you from going to that meeting for a few years. I know we have mission-critical travel and the budget has decreased, but they really need to allow scientists to travel and go to meetings to maintain their credibility and recognition (OARSA). • We have really good scientists who need to go to professional meetings to build and grow. Stop slashing the travel budget (ORS).
Encourage training	• There is a staff college, computer training, or the Division buys local training passes, but that's office, computer-literate things. When it comes to lab, high-tech, etc., I don't think we have a budget, which requires travel, hotel, and conference costs (OFS/MC).
Allow collaboration	• CVM and CFSAN should have more collaborative work. Upper management should give equal chances to those people who may not know many people to get collaborative work, rather than letting lab people stay in the lab and not get much credit for their efforts. Colleagues have advised me not to work too hard or people will take advantage, which has led to conflict (ORS). • Supervisors should promote outside collaborations for existing employees (ORS).
No problem	• Retention is pretty good. But, I wonder whether we have the appropriate people in the appropriate spots. There should be less hesitation with moving people around to find a better fit (ORS). • We have the opposite problem: People stay too long. The cyclic review of scientists is a waste of time and money. There are people who are clearly no longer pulling their weight at these high levels, and they just say "Aw, you're fine." The program has no teeth (OFS/DI). • People aren't leaving here voluntarily. People are being asked to go because their money is disappearing, the money is drying up (OARSA).

C.2.4.24. How can we better ensure that training and professional development needs are being met?

The responses to this question have been divided into two tables: one for training and one for professional development.

C.2.4.24-1. Interviewee Observations: How Can We Ensure that Training Needs are Being Met?	
Training opportunities	
Technical training	**On-site:** • We don't have a lot of on-site training for scientific research. They've had training for some of the regulatory things, but it would be helpful to have someone to come in for a week's training in some technological area. I've never known that to happen (OARSA). **Between MB offices:** • If there are no training courses available we should invent our own training courses. Let scientist design them. That's what we did with the Real Time PCR course. There should be a process for the scientists have input into course development (OFS/DI). • Other FDA scientists could come here to learn about processing and our people could go to CPK1 to learn molecular techniques (OFS/MC). • Offer training courses on microbiology and molecular techniques. Using sequencing as an example, we could have a class on how groups provide their sequences to us or how to perform sequencing to our standards. Consider providing something similar to what the LRN does. The LRN is an immediate reporting of an organism in a food product if there is an outbreak. LRN offers training on how to perform an ELISA assay test, or how to do real-time PCR. We used to send our people there to be trained on how to do the assays and when they came back, our laboratory had the capability to perform them. It would beneficial to have that type of training for projects as well (OFS/MC). **With other FDA entities:** • We could partner with CFSAN or other groups in FDA, maybe the cancer people or the Crohn's Disease people in CDER to bring in specialized training in some types of bioinformatics or meta-genomics (CVM). **With academic partners:** • CFSAN adapted the USDA model of interacting with an academic institute (JIFSAN, etc.) and we need more of that throughout the Agency. There are field labs sitting right next to campuses of universities, and many of the field lab scientists are teaching at those universities. There just doesn't seem to be much partnering going on at the agency level (OARSA). • We've been asked to do a lot of training, but we really don't have time to carry out this role. So continued support of the JIFSAN training program is important to relieve our burden (ORS). **Off-site:** • It would be nice to take outside courses to learn e.g., microarray. A contractor was able to take a course in this. I am doing that, but I am unwilling to spend $3K out of pocket to take that course. I think this money would be better spent for some people than going to an annual meeting (OARSA). • They should set money aside or have some sort of mechanism for being reimbursed for taking classes on techniques we use in the laboratory. We would have to outsource this kind of training to people who really know what they're doing (OARSA). • Identify labs to work with or collaborate with (OFS/DI). • Improve training for scientific expertise. Research scientists don't have the opportunity to maintain their edge, especially since they're no longer allowed to attend conferences. Instituting a program of mini-sabbaticals could improve scientific expertise. People could go someplace for 1-3 months to learn new skills. If these opportunities were available and scientists were rewarded for taking them, it might help them maintain their edge better (OFS/MC). • Educational opportunities such as visiting large food processors would be very beneficial (e.g., for cheese processing; ORS).

C.2.4.24-1. Interviewee Observations: How Can We Ensure that Training Needs are Being Met?	
	• We'd really like to get some training in WGS (one course at Johns Hopkins), but we were not able to because of funding (CVM). **For support scientists/technicians:** • Supervisors should allow for lab people to go to one training each year. We keep asking for training, but that's all we can do—ask. We could provide three suggestions and then be given permission to attend one this year and possibly the others in years to come (OFS/MC). • Scientific training (e.g., techniques, equipment, and new findings) would improve every aspect of the work we do. It's difficult to find technical training that ends up costing $2,000 if you include the travel and training. There is the staff college, but it's not technical or scientific. And it's not just taking online classes; sometimes hands-on training is necessary. Going for credit takes time, your supervisor's support, and management's approval. Some PIs aren't too happy about us taking off. They prefer their work to be done right away. If you're an ORISE that's a different story than if you're regular FDA staff. ORISE seem to have more training funds than we do (OFS/MC). • Online training doesn't do much when you're a lab worker. It's hard to gain technical skills online. I've done a lot of training since I started, but these last 2 years everything has been cut back. I've stopped looking for trainings because I know I can't attend (OFS/MC). **Other suggestions:** • Give everyone the opportunity to learn new skills. Maybe make some training mandatory for new scientists. Make funds available for those to learn updated skills in their areas of expertise, as well as for everyone who needs to receive training in a given area to get that training, rather than just a select few (ORS). • Provide more training and workshop opportunities for researchers to improve their expertise and increase their job-related knowledge. Examples include training in risk assessment, HACCP, GMP, etc. It would be helpful to have more knowledge of the related food safety topics – not just limited to microbiology. Many researchers have no practical experience in industry, so it would be helpful to have visits with industry to learn how they collect samples, perform microbiological tests, etc. (ORS). • There needs to be proper transfer of methods to the field. Training of field employees should occur more often (ORS).
Details	• Some of the training should be to learn what the stakeholders do: Go to the ORA labs, go on inspections. Span the process of your pathogen. Visit other laboratories within CFSAN, maybe your competitors, so that you might collaborate (OFS/DI). • We used to allow new scientists to go spend two weeks at a field lab to see their process and analysis. Now, many scientists have never gotten this exposure, nor been to court to testify. It would be productive for our scientists to shadow an inspector to see how samples are collected. I am guessing up to ¾ of scientists here don't know about sample integrity or chain of custody, which are part of FDA (ORS).
Leadership training	• Everyone should have access to these leadership programs because you can lead from within. You shouldn't have to be a GS-12 or want to be a manager to develop some leadership skills (OFS/DI).
FDA Training	• I went to the week-long Food and Drug Law class about 15 years ago, and I'd desperately like to have a refresher. There are so many people here who want it, why can't we have someone come in to do it? It's not that we're writing regulations or making policy, but it never hurts to understand why you're doing things and what the legal impact of something is. We can't get this training. They said that could cost more than sending three people to one of the bigger classes in CPK1. So what's more efficient? Sending two to three people every year to that training and spending that money to constantly getting refreshed versus bringing someone out here to have everyone receive the training at once? Why isn't someone pushing hard for that? I'm sure the general answer is money. Everyone feels discouraged and just doesn't want to try anymore because the answer is no (OFS/MC).

C.2.4.24-1. Interviewee Observations: How Can We Ensure that Training Needs are Being Met?	
	• Since everyone comes with basic training in MB, not a lot is necessary. What would be useful is more training on how what we do fits into the bigger picture (ORS).
Staff college	• Staff College is supposed to be doing training, but I have no idea what they are doing now. We used to arrange a lot of training and Staff College was always there to assist. The last time I asked I was told they don't do that anymore. Everyone needs to be certified to be a Contracting Officer Representative (COR). The training process is very confusing and requires many classes. You'd think that Staff College would step in and help us with that, but they don't. Most people don't fill out the Staff College's forms that ask what classes people want anymore because nothing comes of it. It would be good to have a staff college that helped us through this non-scientific training. I need help finding my way through that quagmire for all the required training (OARSA).
Other	• We used to have access to Rosetta Stone, but funding for that was discontinued. Multi-lingual personnel are beneficial if FDA plans to expand globally and encourage collaboration with international companies, etc. (OARSA). • We need to be careful about over-training. Some people may take lots of training without ever applying it to their job. It's important to provide the opportunity for training to do their job better, but opportunities need to be scrutinized (OFS/DI).
No additional efforts are needed	• The Staff College seems to cover the bases for training in areas such as Group Dynamics, etc. (OARSA). • I think they do a pretty good job of online courses. There are programs that help people pay off student loans—I think that program still exists (OARSA). • We have a lot of opportunities for training in management, non-scientific areas, how to get along with your boss. Specific trainings exist in academia and elsewhere, and they are always available (ORS). • They are actually doing a pretty good job here. Budgets are always the problem and so are restrictions or hindrances to doing what you want. Nobody can get everything they want all the time, but in this Office they do try and get us out there (OARSA). • It is up to the individual to partner with their supervisor to make sure these needs are being met (CVM). • We need to make sure money is spent wisely. We could improve the efficiency of how training money is spent (ORS).
Facilitating training	
Ask what is needed	• This a conversation that needs to happen between a supervisor and their reports and between them make individual development plans. The center is moving to make this process better (CVM).
Track training opportunities	**Have line management oversee training opportunities, needs, and requirements:** • Managers could try to keep track of training and development to see what is being done and make sure people are aware of opportunities (OARSA). • Hold line management accountable (ORS) • Managers need to let staff know what value they are expected to receive from training. We need to ensure that the people I send to meetings make the effort to forge new contacts and attend seminars. Managers need to let people know that there are these expectations (ORS). **Create a position for overseeing training opportunities, needs, and requirements:** • It would be good to have a position dedicated to training and making sure needs are being met. The managers are so busy, that it is not apparent that anyone cares about staff development. We need someone to talk to researchers to ask about training and how it would impact their research and their personal development (ORS). • More stability and knowledge about what would be available across several years so that you could plan for a certification or degree (ORS). **Provide scientists with information concerning training opportunities, needs, and requirements:** • Training should be up to the individual, but should be supported by the Agency. At the

C.2.4.24-1. Interviewee Observations: How Can We Ensure that Training Needs are Being Met?	
	level we are as scientists within the Federal government you should be aware of what training opportunities are available to you. If I am not getting the right training I am not blaming my supervisor. I am blaming myself (OARSA). • We need a written list of expected training for staff. There are many unwritten rules and policies regarding training, and I need to get these out in a concrete form. The training that we are asked to do is done in piecemeal fashion over the course of the year. I know that people need to be recertified in certain things every year, so I need a list of training that needs to be done in the coming year, so that people can anticipate that this needs to be done (ORS). • There should be more transparency about how much is available for an FTE. Then you would know if it was worth requesting an expensive, very good course as opposed to an okay, but cheaper course (ORS). • Provide a schedule of what training is available for the upcoming year: Show us a plan of what you are going to have available over the next year. Don't spring it on us a week ahead of time and say you need to be at this training on Friday (CVM). • There should be a core set of curricula based on your position classification so that you know the trainings FDA and CVM and the Office require, and can assess the value and utility of the trainings offered. A lot of trainings that may be routinely offered may not necessarily apply outside of some of the more soft skills, courses like communication and conflict management. A lot of what applies to reviewers doing drug evaluation may not apply to minor use or minor species or research, so it is hard to know (CVM). • The Center is putting together a committee that will ask the Division what training is needed and then will arrange training in those areas. CVM does a good job with training, but this will make it better (CVM). • At the office level, we have a newly formed training and education committee. We've surveyed employees at the Center level to see what they need to do their job. At the office level, it would be helpful to create a training and education template for the diverse group of employees we have. That training would include mandatory training from the FDA agency level or the Center level. Within the Office, address what is needed to do your specific job. Come up with a framework that addresses mandatory things, such as being a Federal employee; things you need to do your current job; and then other things that come highly recommended and would interest you that were not necessarily technical/scientific (CVM).
Resolve training vs. travel budget issue	• We have a set limit for travel. They provide funding for training, then they combine travel and training. If we reach our limit for travel, we can't go to training. They need to separate out travel from training and allow people to go to training if they need to (OARSA). • We are provided funds for training, but we need to keep the ability to send people to scientific meetings as well. We should use some training funds to send people to meetings, then we can send people to workshops at those meetings (OARSA). • Support travel and training efforts. Make sure we have the funds available to do that. This generally has been OK (OARSA). • We are at a disadvantage down here because training falls under travel. Some training is mandated, so we have to get better at web training to take full advantage of that. We may complain about how bad it is that we don't get all the stuff, but this is the price to pay for having what we have (OFS/DI). • I wanted to go to the University of North Carolina to work on critical state-of-the-art techniques in virology for 1 week. I was told I couldn't go because the training is related to travel. Scientists can't go to meetings unless they can justify it. By going to meetings we can take advantage of the work being done by others, work with other scientists, and share our own research. Limiting us in this area really limits the science. The ORISE staff has a large amount of training money. Travel is limited for FDA employees, but the same rules don't apply to ORISE staff (OFS/MC). • They should have a bigger travel budget that includes training costs. We have a big training budget, but you usually have to travel with the training. The training budget goes

C.2.4.24-1. Interviewee Observations: How Can We Ensure that Training Needs are Being Met?	
	unspent because we can't go anywhere (OFS/MC). • We can request the training we need, and the managers have been supportive. Because of the budget, we are limited to one training or one conference. PIs should be able to do more than one conference or training a year (CVM).
Improve application procedures	• We have funds for training, but filling out the paperwork takes too much time (OARSA). • Getting training and travel is so difficult now, some people don't even bother. If your travel is not on the preapproved list, it can take months to get your travel approved. So if some great training shows up, you can't do it because chances are you will not get it on the approved list in time (OARSA). • For training, the travel requirements are burdensome. You have to establish that it is "critical travel." And the same forms are required for local travel, even training in Baltimore. There is no benefit in going local (ORS).

C.2.4.24-2. Interviewee Observations: How Can We Ensure that Professional Development Needs are Being Met?	
Professional development	
Ask what is needed	• No one has ever asked me what I want to do, where I want to go, what I'd like to become. There was never a clear development plan. There's nothing to tell me what I need to do to get to the next level. I'm a goal-oriented person. I'd like to know what I need to do to get to the next step. It's tough without a clear path or goals. What's my incentive? I don't think there's really any interest in this, and it's difficult to find information. Even IDPs are difficult to locate on the website (OFS/DI). • You can give them a list of what's available, but give them a chance to say "I'd like to develop in this area" (OFS/DI).
Attendance at scientific meetings	• The FDA should pay for membership in professional societies to save the government money. The two largest meetings people here attend are AFM and the IAFP. Both are membership bodies. It costs $50 to become an AFM member. If you want to attend the meeting and you're a non-member, it costs $675. If you pay your membership fee, it's $475. But the government refuses to pay membership fees. FDA is telling its scientists that they have to pay $50 out of their own pocket to save the government $200. The government should pay the $50 and save itself $150. The government ends up paying an extra $200 per person because they won't pay the membership fees, and it happens at both meetings (OARSA). • Everyone has a training allowance each year. You are allowed to go to one or two meetings a year if you present your research. They are doing a pretty good job. A lot of the better professional organizations are international and would require international travel. In some cases it might be good to let people do that (OARSA). • There are two major meetings that MB go to: ASM and IFAP. If we were able to go to more than one that would be helpful (International Food Protection; OARSA). • The limiting of our budget to attend meetings is stifling our ability to interact with our peers. We are at a disadvantage here because everywhere we go is considered travel. When I go to a meeting in DC, it takes money out of our travel and research budget. That's not fair to us. We are often asked to participate in international conferences as representatives of our agency, and our travel team puts up roadblocks. It really hurts our careers. I was recently invited to attend a workshop in Italy. The travel office kept asking the same questions over and over again until I was uninvited. This has happened to others too (OFS/DI). • We get railed on a lot about wanting to go to these scientific meetings, which are really relevant to us because they allow us to interact with researchers from government, industry, and academia. We see what's going on, what new technologies are out there, new ways people are doing things, etc. We have so little travel funding. We have to pick one meeting and that is the one most critiqued and restricted. If we can't disseminate our information and get information from that particular meeting and if we only get our

C.2.4.24-2. Interviewee Observations: How Can We Ensure that Professional Development Needs are Being Met?	
	research out for publications, it's not really that helpful (OFS/MC). • If you want the PIs to develop a productive and effective career, they need to be given the opportunities to interact, rather than work in a vacuum. They have to go to meetings, and not be limited to one meeting per year (ORS). • If you want to become an international expert, you need to go to and present at international meetings, which is not widely supported (it's case by case). We need more exposure in the outside scientific communities, e.g., giving presentations about our work and how things are impacting food supply. We get so focused on what is going on here, we forget to promote. We have an FDA meeting every summer for this purpose for internal sharing, but maybe this should also include outside people (ORS).
FDA training resources for professional development	• The Staff College works hard to bring in training modules. It could be a conduit for others. More interactions with ORA university would be of value (OARSA). • Scientists need to understand more about the regulatory mission of the FDA, perhaps take the Law course offered by the FDA so that they have a better understanding of the mission of the FDA. This should probably be required (OARSA). • Communication tools, such as writing and public speaking, would be beneficial (OFS/MC). • The CFSAN Staff College has a number of courses that are very helpful, like the FDA Law course, which is top notch. We can take anything we want, but this won't help towards networking with others in the field (ORS). • Technical writing classes or writing coach especially for foreign born staff (ORS).
Leadership development	• There should be opportunities for leadership development for those who want it (OARSA). • Make sure the supervisors are well trained on how to develop their people (CVM). • Some staff would benefit from management training. E.g., UMUC leadership training. This encourages people to build their management skills. Also they have sent people to Shepherdstown, WV management course. This training is good for those that we would like to make team leaders in our reorganization (ORS).
Details	• I need leadership skills to advance, but I'm not going to get that here. I think I would have to go on detail to get that experience (ORS).
Mentoring	• There is also no real mentoring going on here. When we hire someone new, they may or may not have someone else showing them simple things new hires may need to know – even in the laboratory (ORS).
Outside collaborations	• Be more supportive of outside collaborations (OARSA).
Career counseling	• HR resources: Access to professional counseling (ORS). • People need to know their place and responsibilities, this would make things more efficient. We should have more information concerning what responsibilities the position entails, where it might go, where it caps off. Also, we should have people understand that they are important and that they are being developed while working here, and allot time to discuss development with your manager (ORS). • There is a tug of war between individual advancement and group productivity. We need to foster productive [in a mission related way] people. We need to grow their positions. We have a hard time knowing how to do this (CVM).
Improve travel approval process	• The approval/disapproval process for travel has been painful at times. We have had personnel in our own group who found out the day of travel that they could not go. If you are going to say no, just say no. We're going to fume either way but better to fume three weeks before. It is just insulting (OARSA). • We need funds for foreign travel because international recognition is required for promotion and unless we travel internationally, it is impossible to achieve. Management can travel internationally, but not the researchers (OARSA).
No problem	• I think you have individual responsibility for your professional development. We are tight on money here, but we can get it if we can justify it (OARSA).

C.2.4.24-2. Interviewee Observations: How Can We Ensure that Professional Development Needs are Being Met?	
	• That is conducted here. We bring contractors in for workshops, etc. (ORS). • Our travel services are not great, but I think scientists are traveling too much given the communication capabilities we have now. I don't think scientists need to go to two meetings a year. The reason people push so hard to go to conferences is that when they're peer-reviewed they get credit for that presentation. If you're going to make that a metric, then of course they're going to want to travel. Make it less of a metric (OFS/DI).

C.2.4.25. Can you suggest outside entities we can partner with for more training opportunities?

C.2.4.25. Interviewee Observations: Outside Training Entities	
Universities	• University of MD: Scientific coursework and Center for Creative Leadership • University of Maryland Baltimore Campus, BC, Institute for Genome Sciences courses: We have been sending people for some of the things that we need for molecular biology (sequencing, bioinformatics; CVM) • Johns Hopkins for genomics • George Washington University • Business schools for leadership training **Comments:** • FDA could offer tuition breaks to help defray cost for public and community colleges. IIT, which has higher fees, offers tuition breaks to its employees but not to FDA employees (OFS/MC). • We could seek professional development and training certificates from places such as Johns Hopkins or Harvard--not necessarily 1-year courses, but maybe 1-3 months (OFS/MC). • We could bring in universities to put on specific technique workshops (e.g., sequencing workshops, PCR workshop). Training requirements could be coupled with local universities to perform that training (OFS/MC). • There are so many good universities here in Chicago, such as the University of Illinois at Chicago and the University of Chicago. There are also so many good online universities now (e.g., Purdue). It seems like it's just not something they've even thought about. Maybe they have, but decided not to pursue it (OFS/MC). • Consultant universities, virtual universities, or even bringing someone in to do onsite, specific, scientific-based training (OFS/MC). • Participation in workshops by academia, e.g. Kansas State and U of Wisconsin at River Falls. It's an effective way of ensuring understanding of methods (ORS).
HHS Resources	• CDER • NIH for bioinformatics • CDC
USDA	• USDA university
Other Federal agencies	• NOAA • OPM • DOE: Joint Genome Institute
International counterparts	• We should be partnering with our counterparts in other countries. The Office of International Programs is working on that. It started with the Beyond Our Borders program, and now we have FDA people in other countries. Most of that collaboration is on policy and regulatory issues and isn't necessarily scientific. There's a possibility of broadening into the scientific arena through analyst exchange programs. NIH runs the U.S.-Japan Cholera Conference and Related Diarrheal Diseases annual meeting and that model could be established with other entities. There are groups around the world like the ICDDR (The International Centre for Diarrhoeal Disease Research) in Bangladesh that CDC sends its epidemiologist to put on a training program. That's a Center of Excellence type of program. Other groups have these capabilities and we need to find ways to partner with them (OARSA).
State and local laboratories	• APHL (Association of Public Health Laboratories) • Public health labs at the state level. **Comments:** • Academic and state laboratories: Those are two great partners because they would love to partner with FDA. They see us as a resource-heavier organization, and we have manpower. We could leverage there and get some ideas, share our ideas, and get the job done. Likewise, we could train from them because they do things in a way that we don't and vice versa (OARSA).

C.2.4.25. Interviewee Observations: Outside Training Entities	
	• Association of Public Health Laboratories do training and it would be good to reach out and define training programs with them (ORS). • They could send people on details to labs in Canada or Europe or to laboratories in the U.S (CVM).
Private sector	• ASM • IAFP • IFT (Institute of Food Technology) • Instrument manufacturers • Cold Spring Harbor Laboratory • Woods Hole has a week-long crash course in bioinformatics • Training from instrument manufacturers • Six Sigma training • Food industry, food processors **Comments:** • It would be interesting to see industry's point of view, and interacting with them could improve relations between FDA and industry. I would be interested to see their method, system, process for ensuring no contamination, etc. (ORS). • When we evaluate a new technology, the company will come to train us (ORS). • We tend not to get involved with the private sector since we are a regulatory agency. They have some world-class scientists, however. There must be some type of conduit that would allow us to take advantage of their expertise without stepping on the regulatory aspects of the relationship. The fact that nothing is being shared is a limiting factor (ORS). • Illumina offers in-house training. It is one of the manufacturers of one of the machines we run. We are capable in labs in reading protocol and clearly adapt it. But sometimes going in-house and training there and getting all the tips and tricks you can't put on paper (ORS).

C.2.4.26. Is there anything else that you would like to say about the microbiological program at CFSAN and CVM that we have not discussed today?

This section includes direct responses to this question as well as comments and observations that were felt to be relevant to the overall review but could not be inserted effectively into the remainder of the report. Where relevant, remaining responses to this question were inserted under the appropriate questions above.

C.2.4.26. Interviewee Observations: Is There Anything Else You Would Like to Say?	
Work environment	
Positive work environment CFSAN	• I'm happy here. The people in this building are great (OARSA). • Working at FDA is the most rewarding job I've ever had. I feel so at home and not necessarily because it's a government job. I've told my supervisor I really love my job. It feels positive working on the good side for people. You can't underrate that, but the general public doesn't really see it. After the furlough, people in my neighborhood were so against Federal employees for not doing anything. It's a difficult situation to be in. To me, at least somebody is really thinking about our fruits and vegetables and why some of these outbreaks happen. If they can't appreciate it, sorry. Next time they get sick in a restaurant, don't blame FDA (OFS/MC). • I'm happy. I love the people I work with. They are family and it will be hard to leave them. We're lucky to have highly qualified people in our group (OFS/MC). • Working here is like a calling. It might start as a job, but if you're here long enough you buy into the idea that there's a bigger purpose in life. The people who leave FDA go to USDA or EPA, or they'll circle around and come back to FDA. They're certainly not doing it for the pay. We can make double in industry. Stability is part of it, but there's this idea that you're really making a difference and not just helping a company make more money. Whether you see it or not or have a way to measure the impact is another story.

C.2.4.26. Interviewee Observations: Is There Anything Else You Would Like to Say?	
	Sometimes it happens, sometimes it doesn't (OFS/MC). • The microbiological program at CFSAN is working really well. The proof is the number of papers we have published in good journals, demonstrating we are doing good science that can be translated into good regulatory science. This also helps field labs with methods and enforcement litigation support (ORS). • 99% of the people here do a great job, but there is 1% who we have to watch. Their effect is big, even though they are only 1% (ORS). • I really like my coworkers. I feel appreciated and that I can work unimpeded. I am very happy here. I like the collaboration. Politics exist, but they don't affect me (ORS). • I never expected coming to a government program to find so many willing and hard-working people to make the program better. To have open communication and a friendly work environment where I can feel comfortable is really appreciated (ORS).
Positive work environment CVM	• The people that I know and talk with and people we collaborate with at CFSAN are very nice but apparently the whole culture is very different. CVM is much more like working in an academic group. You get the feeling that you are valued, your opinion matters, and the people that you work with are important to you and you are important to them. It is like being at the best of the universities. People were free to volunteer to help each other when necessary. You have some role in determining your own life and work load. It is more like that here. CVM has done a really good job at making people feel that they are valuable and wanted where they are (CVM). • I'm proud of the organization. They do good work. It's important to keep animals, food, and us healthy (CVM).
Value of microbiological research/science	
Value of in-house microbiological research/science within the Centers	• Upper management has to recognize that science is important if they truly believe so. I don't see a lot of that except when it is expedient to do so. How often have I heard at a meeting, "Oh, FDA does research?" Are you kidding me? After all these years, I should never hear that phrase. It is not just us going to meetings, which we should and must do, but it is also about leadership pushing this in the right places so people know the quality and type of research we do. When they do that, the researchers will come because they know we exist and they will want to be part of that organization. And people will want to stay (OARSA). • A mixed message about science has developed at CFSAN/OFVM. In 2013, in a series of all-hands type meetings and in more limited research discussions, three senior executives in CFSAN/OFVM seriously questioned the overall value of scientific publications and undermined the contribution and value of research publication. Management asked: "Who reads these publications?" Before this, in 2013 at ERO meetings, there was a great deal of discussion about establishing "Work Class Science" at FDA. So there was this odd back-flip undermining publications, which are the bread and butter of science. In light of this, it is not clear that management can offer much except to reward the participation in science in regulatory decisions and address the inconsistency in management's relationship with science (OARSA). • The science needs to happen before rules and regulations are written. Instead, sometimes the science is being driven by the laws and regulations—they're trying to pinhole the science to fit the specific laws and regulations they're writing. For example, upper management wanted to write a regulation that reduced *Salmonella* by 5 logs. The scientists said they didn't even have a method yet for determining how much there is to begin with so how could they determine if it had been reduced by 5 logs? The response was, "I'm going to go ahead and write the regulation and you figure it out." You can't write a regulation before you have the methods in place to uphold the regulation. There should be goals in mind, but the actual regulations should be driven by the currently available science. If you pigeon-hole the science, and your scope is too narrow, you are underutilizing your talent, knowledge, resources, and the imagination of your scientists. A better structure would be to have it driven by the science and then translated into legal terms. Our CD is a lawyer who has science advisors. It would be better if the CD were a

C.2.4.26. Interviewee Observations: Is There Anything Else You Would Like to Say?	
	scientist who had legal advisors (OARSA). • An in-house research program costs money and doesn't pay immediate dividends except in an emergency. An in-house staff is capable of dropping what it is doing and working on the Agency's immediate needs. About 10-15 years ago, the nation had annual sprout outbreaks. We thought we had some good, rapid validated methods that would help the sprout industry keep its product safe. We dropped what we were doing and went to work on validating rapid methods that the sprout industry could use for testing. We also provided guidance on what kind of sample to take, when to take it—all the questions involving pathogen growth. We did growth studies in an industrial sprouter we put in the pilot plant. Much of this information was obtained through our interaction with industry. Our work ended up in an FDA guidance in the *Federal Register*. FDA could have contracted the work out, but we understood the situation better because of our interaction with the industry (OFS/MC). • In one of his CD Meetings, the CD asked why we have to do microbiological analysis in four different areas. I guess microbiology is the same to him. But, to me, managers hire people and if changes are needed then you make sure those people are put to work on something useful instead of saying we have too many of you. We don't have that problem here because we're really needed. There could be duplication, but those scientists can be shifted to do processing-related research. Upper management focuses on FSMA too, but it's still not embedded in their thinking. We understand it here because that's what we do. We talk to industry more than they do. The Office of Outreach needs to provide consistent, constant communication on FSMA, but information is always provided by people who don't really know research (OFS/MC).
Impact of changing mission priorities	
Impact of changing mission priorities	**Public health:** • Upper management seems to be moving towards more emphasis on current threats and ignoring potential threats. This make a lot of us here very nervous. This is only time I will say that I agree with this whole thing about being run by a lawyer and not a scientist. They don't understand how much time research takes. So there are some thing that are coming close or have already crossed our borders but are not really making people ill yet. It seems like the consensus in upper management is that if nobody has gotten sick then we are not going to work on it (OARSA). **Staffing:** • If you have a given number of researchers with a certain area of expertise and then priorities suddenly change, what do you do with those personnel, and how do you obtain the new expertise if we are not getting any new FTEs or staff or ORISE Fellows. How do you address this change in mission? One way is retraining. This is a reasonable idea, but it is a very difficult job to do this in science. It takes time to change, and during that time, the priority may change again. This is where the vision comes in: If you are able to see what is coming down the pike, you can start preparing for it (OARSA). • Change is not easy. I believe upper management has good intentions, but their expectations are not realistic. The way they are approaching these changes is top-down, and I don't think it is going to work. It is just causing people to be unproductive, and this place has always been really productive. My friends are concerned about their jobs, whether their projects will be approved, why their projects are not being approved (OARSA). • There is a balancing act between focusing on the regulatory mission and doing some exploratory research. I have seen management at OARSA defend projects that aren't in alignment and staunchly defend the people. But, the research is not moving in the right direction and those projects are allowed to go on. You can't just pull the rug out from under these projects. You have to have a plan for integrating those people elsewhere. There is already a lot of fear among researches that if their project gets pulled they are doomed. There are good researchers over there and a lot of money going into it. It's slow, but changes are being made (ORS). **Facilities:**

C.2.4.26. Interviewee Observations: Is There Anything Else You Would Like to Say?	
	• This building was designed as an animal facility and we were put out here because at one time we did microbial immunology *in vivo*. Our facility is underutilized. They have told us to submit animal projects, but none have been approved. So why should we submit them? I'm afraid to say that the facility is underutilized because they'll use it as an excuse to shut it down. There should still be the ability to do *in vivo* studies. It makes you want to cry. Sometimes I go home at night and cry (OARSA). • Use of the BSL3 facility has died down during the last few years. We have spent millions of dollars building it but the focus has shifted. If something happens we are not ready. Everything needs to be replaced. When the management changed, they thought it wasn't a good idea. It has to be an ongoing project. You cannot work on it sporadically (OARSA). **Long-term planning:** • The Agency tends to be reactionary and has many outside influences that result in rapidly shifting priorities. As an agency, we are subject to a lot of external pressures, so tend to be reactionary and not proactive. It trickles down to individuals, who don't see a long-term plan and then go off and work on whatever they feel like. Priorities can change so rapidly. We suffer from this large environment. At the highest levels of the Agency tends to be pulled around by politicians, consumer groups, industry, international partners and Congress (CVM).
Effectiveness of organization structure	
Effectiveness of the current organization structure	• The only way to fix the dysfunction at CFSAN is to reorganize. I have been against a reorganization because I like where I am. But it is dysfunctional and that dysfunctionality is starting to affect me personally: my project, my happiness, and my success. I think when I am lying down at bed at night, how do we fix this? It can only be fixed through a reorganization (OARSA). • Breaking up MB into what we have now was the dumbest thing that ever happened. If they hadn't broken us up, we wouldn't be having these problems. We've had people here that are really good, but they go to CPK1 because they know they'll have better support and resources over there. Or they'll entice people to go over there. The rumor mill here is ridiculous. There was a rumor that there was going to be a big reorganization and we didn't get any work done for 3 weeks. When we don't have the real information, we get rumors (OARSA). • They are looking to bring in a permanent OD and many qualified people will apply. The last time we went through this process we still didn't get a permanent OD. The process that was done was kind of secretive. Maybe it needs to be that way; however, it would be to the benefit of the Office to have someone who is a scientist that everyone here respects have some input into the triaging process. There was a sense, with some evidence to support it, that some highly qualified people were knocked out of the process the last go-round. Ultimately one or two people have to make the decision but at least try to get everybody in who's the best of what they can be for that position (OARSA). • A few weeks ago, the OD and Deputy OD decided to reorganize my division out of existence. What they were proposing didn't make any sense. Part of my group was to go into toxicology and part in Molecular Biology. This was just announced at a meeting of the Office with no prior discussion with me. Ultimately upper management intervened and told us there would be no reorganization. I still don't know what this was all about and not sure what I did to stop it, but it has left me upset with the office management (OARSA). • In order to change the microbiology program, we would need a major overhaul. The players in place right now are all in the same camp. Additionally, management has been vindictive to the point of insulting. This is a sick culture when you have managers who place personal feelings ahead of the Agency mission. To me, the foremost job of a manager is to protect your people from any B.S. that flows down from above so that they can do their job, and we do not have that here. I do love my job and the science I am doing and am thankful to the FDA for the opportunity to develop myself and research, but I have never seen the poisonous or vindictive culture that we have now. In the old days,

C.2.4.26. Interviewee Observations: Is There Anything Else You Would Like to Say?	
	people were more collaborative and cordial (ORS). • Hopefully there is not a preordained re-organization plan, and this survey isn't going to used to justify what's already been decided. Will another layer of management bring any value? Are there other ways to ensure that the groups work more productively together? We don't want overlapping or competing projects nor projects that don't directly support the mission (ORS).
Coordination between CFSAN and CVM	• We aren't coordinating our efforts. There are scientists duplicating or who have duplicated projects at CVM. We really should be talking to one another, coordinating efforts, and jointly running those programs. But CVM is separate from us even though we're in the same Office. It's not really being overseen from above. It's everyone's problem, but no one wants to put the dollars to it (OARSA). • We could be merged with ORS, but not CVM. CVM's research is very distinct from ours. Our research culture is different, so I don't see that we could be merged easily. We are more exploratory, theirs is more documentary, even though we have some common interests (OARSA). • I hope we can work more closely with CFSAN. It would be good because we have the same public health mission. It should be more than collaboration, perhaps a reorganization to more effectively use resources. It would be a big challenge, but would be good for all the scientists in the end (CVM).
Coordination with Regulatory Policy	• This is the first year we've really had talks with the regulatory side. It makes you feel better to see what you're working toward (OARSA). • Our sister division within OFS deals with the policy aspects of seafood safety and we deal with the research aspects. We're very program-connected here. We have a good model to follow. The scientists stay connected as closely as possible with the program needs and therefore our research almost always produces something that they need, rather than having to try to fit research outcomes into some program (OFS/DI). • Originally I didn't expect to be in such a huge regulatory role where sequencing samples are used in regulatory actions. I have attended a couple of trainings on how to maintain a lab notebook and what it is like to be a witness in a court case. I am doing everything I can to document what I do, but we don't have an official in-lab protocol that is enforced to make sure we are capable of being held to regulatory standards. I am holding it to my own personal standards. Some things are overkill, like chain-of-custody. We have to sign-off on every sample. I have never been called in to be a witness. I am preparing the best I can, but I am not sure what is needed (ORS).
Coordination between groups	• Our virology program is unique to OARSA. The only other place is OFS/DI. They deal with seafood. Last year there was a Hep-A outbreak in berries. Our people were working with it looking for methods applicable to berries. Next thing we knew, OFS/DI was working on a protocol and testing it. Upper management sent the assignment to OFS/DI, and I called them on that. I don't know what's being done here, but it's not very good. We were actively cut out of that. But we wouldn't do that (OARSA). • The WGS CORE facility is fantastic from a scientific perspective, but I'm not sure how that relates to the whole FDA Mission—I'm not sure how it will help us solve anything or prevent illness/outbreaks. Also, if they are going to develop a CORE center for FDA, if I need something sequenced, I should be able to send it up there, and have them do the analysis and give me that information. But they have a rule that if you send anything up there, they then have partial ownership of your data, and they request that you release 25% of it to the public as soon as it's done. They shouldn't be involved in our research this way (OFS/DI).
Interactions among scientists	• We used to have group meetings on Tuesday afternoons where everybody either was required to present their research or a journal article. It gave the students practice, but it also let us know who was working on what. I knew what was happening in certain laboratories. Our meetings are more administrative. We don't talk about each person's project. That's part of the atmosphere of being a scientist. We have seminars, but nobody attends them. Attendance should be required and outside people could be invited.

C.2.4.26. Interviewee Observations: Is There Anything Else You Would Like to Say?	
	Relationships between scientists are undervalued here. I want to hire more people in my group who know what I'm talking about and are interested in our projects (OFS/MC). • They should have more seminars to help the group remain current with the literature. There isn't enough time to go through all the literature individually and seminars that review the relevant literature would help increase group knowledge (ORS).
Specific activities/areas of interest	
Promotion process	• The promotion peer review process is flawed. They now have a permanent committee. It should be *ad hoc*. There seems to be a lot of personal bias, and decisions do not align well with PMAP evaluation results (ORS). • There should be a single standard within the organization for promotion: Within ORS, if you want to be a BC or DD, it's a long tortuous process with presentations and other things; in MOD 1 they do it administratively without the long drawn out process. The move from GS-12 to -13 requires peer review for MBs but not for chemists. Someone with a B.S. can only get a GS-7 in the lab, but can get a GS-12 in OFS. They claim scientists have more freedom and windows, but that really doesn't explain it. I'd give up the windows to be able to offer more than a GS-7 (ORS).
Training	• Training is one of the metrics of our PMAPs. It can be anything from an online writing course to a technical course. So someone who takes an online writing class gets the same amount of merit toward their PMAP as someone who takes a technical course. The technical instrumentation class is a week-long class that cost $1,000 in registration fees, plus another $1,000 in per diem and hotel. The online writing class is basically $50 online and takes a few hours. Which one are they more likely to fund? Which one is most beneficial? You'll get much more knowledge from the technical instrumentation course, but they won't fund that one because it takes money (OFS/MC). • I'd like to see the Centers develop a cross-training program that would benefit both places (CVM).
Method validation	• Our validation process is horrendous. It's a long slog through committees. By the time something gets validated, it's obsolete. Methods that were being used in 1978 and that take a week are still being used. The throughput is practically nothing and you have to make decisions on very little information from a small number of sample. PCR methods can be knocked out in a day if you have access to the strains. We've finally broken through with CDC by giving them some of our strains and putting out publications together (OFS/DI). • When a method is developed or approved, management should allocate funds for method validation. When we don't get these funds, it is very ineffective. We can publish it, but it can't go into BAM and isn't recognized as an official method (ORS).
Culture curating	• Culture is essential to the microbiology program. If we assign the culture we requested from ATCC (American Type Culture Collection) a CVM number, and then CFSAN requests the same thing and gives it a CFSAN number, and then MOD 1 gives it their number, that's a disservice to the scientific community. Different numbers should not be required, especially now with WGS. People's sequence can be duplicated multiple times. We already have an initiative to align the method development efforts to be more streamlined rather than duplicated. We have one person here designated for culture. If each program office had one it would be so much easier to share the database (CVM).
Use of contractors	• Don't rely on contractors, who will give you data, but who have no insight as to why they are doing what they're doing. We spend a pile of money on contractors, but if we used this money to support our own programs, we'd be getting institutional knowledge as well as just getting data. We should set up a technical team that does this kind of work: hire 10 people to work on a new project in a given year (OFS/DI).
Additional comments from individual offices	
Additional comments from OARSA	• The work we do is important for food safety and nutrition in immunological impact. It's current and of great importance the Agency's mission. I know that my boss tries to go through the proper channels and fights very hard for our people. In many instances she is

C.2.4.26. Interviewee Observations: Is There Anything Else You Would Like to Say?	
	given the run around. She is led to believe that this is the way it is across the board, but we see hiring occurring in other areas. She works very hard to support our researchers and go through the channels to get the staff converted. • We feel like we get lost in the shuffle sometimes. We were the first group out here. Now we feel a little forgotten. We had an OD who was tough as nails—maybe that's what you need in order to not be forgotten. We feel like we're in a state of flux right now. We're really not sure what we're supposed to be doing, where we're going or what the future holds. We just want some straight answers. Are things going to stay the way they are? Are we going to be reorganized? Is our name going to be changed again? • In a collaboration with CVM we are doing an egg study where we orally infect chickens with *Salmonella* and look at transmission to the egg and fecal shedding. CVM asked if they could collaborate looking at a *Salmonella* vaccine. We wanted to work with them, and we're supposed to work with them. I wrote up a proposal for CVM to use our model. Three months later, I was told that maybe my Branch should be eliminated because we are not supposed to be doing vaccine development. They just saw vaccine and targeted this Branch for elimination without reading the proposal. We were not developing the vaccine, CVM was, but we almost got eliminated because of it. • It would be good if OARSA could get a better flow of information in the areas of purchasing, personnel, and travel from the Wiley Building. I don't know how to do this. All our contacts are at Wiley, it's not as if we run into them in the hallways or anything. Sometimes they ignore our calls and emails. They don't seem to respond to us. We had someone whose position was expiring next week and couldn't get an answer about whether it was going to be extended. It's difficult because I have people crying in my office because they don't know if they have a job or not. I don't know what to tell them. • There has been a lot of gossip, high school mentality, a lot of hearsay because we don't hear anything directly from upper management. You should hear what they're saying about why this review is being done. I try to stay above it all, but that's hard for a lot of people. It really is bringing morale down. • The uncertainty of what is going to happen to the Staff Fellows has led to very low morale generally. In the 13 years I have been here, I have never felt so discouraged. Upper management comes and tells you that you are doing a good job, but then makes no effort to allow you to continue to do a good job.
Additional comments from OFS/MC	• We're very resource crunched. People are frustrated. We need time and research for people, not supplies or funding, etc. How do we communicate with the people who make the decisions? How do we skip through those boxes on the org chart without offending anybody or stepping on anyone's toes? How do we get our voice heard without going through our manager who might boil it down to something else? How do we differentiate somebody who thinks they're right from someone who talks the same talk but doesn't align with the priorities? • I'd like for upper management to really understand the level of support and application our research really has. We're not just doing research for the sake of doing research. People recognize our contributions and seek out our assistance. We are not just doing research for publication: there is someone waiting for our results when we're done. • Our laboratory proficiency testing program is more comprehensive and integrated than commercial programs. It provides data that include how data performs over time. We could use properly designed proficiency testing as a method for Level 1 or Level 2 validation. What we're doing is more important than what the commercial labs are doing. But our program is not a substitute for commercial vendors. Our goals and mandate are different, or could be different. Specifically, we could look into the analyzer tests, a PCR test for specific programs such as allergens. Commercial vendors usually send one or two samples and we usually send about eight, which gives us repeatability data and reproducibility data which could be a rapid way of semi-validating a method. • Each year, for the past three years, I've discussed the IIT situation with my supervisor. I tell her that IFSH IIT took all of the grant money and won't let me know where it's being used. I've been fighting for years, but I'm not getting anything. Who's responsible

C.2.4.26. Interviewee Observations: Is There Anything Else You Would Like to Say?	
	for a situation such as mine? The FDA manager should be responsible for handling this.
Additional comments from ORS	• Many scientists in ORS are drowning in work and need the workload lightened. We need more help, whether that comes from better alignment from some of the other offices or from hiring more people. • I do notice that our small team has a different view of the Agency than a lot of other researchers, who often forget they work for a regulatory agency, rather than a university. We may need more awareness – who they are doing research for and where materials are coming from. For example, I see a lot of people throwing around information that they shouldn't be at meetings (e.g., data that are part of an ongoing regulatory issue). The research they are doing is phenomenal, but it would be beneficial to enhance their organizational awareness. • I do notice that our small team has a different view of the Agency than a lot of other researchers, who often forget they work for a regulatory agency, rather than a university. We may need more awareness – who they are doing research for and where materials are coming from. For example, I see a lot of people throwing around information that they shouldn't be at meetings (e.g., data that are part of an ongoing regulatory issue). The research they are doing is phenomenal, but it would be beneficial to enhance their organizational awareness. • Personnel don't feel like they are listened to or asked for their feedback.
Comments regarding this report	• Is anything going to happen as a result of this? I could be wrong but we have had other things in the past. They have this higher performing organization thing that they have been doing ever since I was here. Meetings with this particular guy and how can we improve, blah, blah, blah. I can't say that I have seen anything come out of it (OARSA). • Why aren't the ORISE and Staff Fellows being interviewed? They are the people that are actually writing up the research proposals in the groups I work in (OARSA). • I would like to salute the management for undertaking this survey and report. The history of the barriers that have been created within CFSAN should be exposed and reconciled (CVM). • I'd like to thank Mike Landa for starting this review. It is a good start (OFS/DI).