FDA Microbiology Program Review

Expert Panel Review and Recommendations

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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 one phase 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. 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. The first phase of the review was completed by Versar and culminated in a report summarizing the results of the interviews.

As part of the next phase of this review, FDA sought the aid of three experts in select fields/disciplines pertaining to microbiology testing and research on food/feed to review the report and assist with recommendations to improve the program to better meet today's microbiology challenges. This report presents the responses of the experts to the report, FDA Microbiology Program Review: Results of Microbiology Research Personnel Interviews.

1.0. INTRODUCTION

1.1. Purpose

The overall purpose of the Microbiology Program Review is to take stock of OFVM's current microbiological capacity -- how that capacity is deployed and applied across the program; the efficiency of 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 primary purpose of the second phase of the review is to obtain recommendations from the experts concerning major actions that FDA should take to improve the microbiology research/laboratory program.

1.2. Members of the Expert Review Panel

FDA requested that a panel of internationally-recognized and respected scientists and managers of large programs with relevant microbiology and laboratory experience review and analyze the report, *FDA Microbiology Program Review: Results of Microbiology Research Personnel Interviews* (dated July 31, 2014). To this end, the following panel was convened:

Sabah Bidawid, Ph.D.
Chief, Microbiology Research Division, Bureau of Microbial Hazards
Food Directorate, Health Canada

As Chief of the Microbiology Research Division since 2003, Dr. Bidawid is responsible for supervising and managing research conducted by 30 staff addressing bacterial, viral, and parasitic microbial agents related to food safety in Canada. Dr. Bidawid is also the Coordinator on a major across-Canada project entitled "Strengthening Food and Water Safety in Canada through Genomics Initiative" for which he leads 53 scientists representing six government of Canada Departments/Agencies. Dr. Bidawid's research has focused on developing rapid and sensitive molecular techniques to detect viruses in foods, conducting studies on virus survival and inactivation in foods, as well as investigating virus transfer from the finger-pads of human volunteers to foods and surfaces, and the interruption of this transfer by various means. Current research aims at developing DNA microarray chip and microfluidics technologies for the detection of Norovirus, as well as other microbial pathogens in foods. He is a member on the Expert Committee on Food Virology in the WHO/FAO and a member on the Expert Committee for EFSA (European Food Safety Authority).

J. Emilio Esteban, DVM, MBA, MPVM, Ph.D.
Executive Associate for Laboratory Services
FSIS Field Services Laboratory

As Executive Associate for Laboratory Services for the USDA FSIS Office of Public Health Sciences, Dr. Esteban oversees a nationwide network of chemists, microbiologists, and pathologists who monitor and analyze the food supply, uncover and evaluate potential foodborne hazards, and estimate risks to human health. His responsibilities include leading the development of expert scientific laboratory analysis and recommendations related to the Agency's primary mission of assuring food safety, and leading scientific programs addressing food safety from farm-to-table to support the mission. In addition, Dr. Esteban manages studies, reviews, and evaluations of scientific lab sampling data collected by the Agency and its animal and public health partners related to meat, poultry and egg products to determine potential impact on human health. He directs analyses of exposure to hazards as a science-based resource used for public health decision making, and serves as a national and international resource on foodborne hazards, and collaborates with other public health officials at the Federal, State, and local levels, and manages the ongoing coordination with FDA of the Food Emergency Response Network. He is a member of the IAFP (Executive Board).

Richard E. Isaacson, Ph.D.
Professor of Microbiology
Department of Veterinary and Biomedical Sciences
University of Minnesota

As an adjunct professor of microbiology at the University of Minnesota, Dr. Isaacson specializes in studies of pathogenic enteric bacteria. He conducts research into the molecular basis of pathogenesis of two pathogens: *Escherichia coli* and *Salmonella enterica serovar Typhimurium*. A common theme in each project is the identification of unique genes required for pathogenesis,

understanding the functions of those genes, and determining the mechanisms controlling their expression. He is currently the Chair, Division Z Animal Health Microbiology for the American Society of Microbiology and associate editor for the Journal of Zoonosis and Public Health, and has participated as a panelist in a number of external reviews of research programs conducted at USDA.

2.0. COMPILATION OF RESPONSES

The experts were provided a set of questions to consider and supporting background materials to facilitate their review. The Questions to Consider are attached (Appendix A). A compilation of their responses is presented below. Full responses from each expert are attached (Appendices B-D).

Where possible, the responses have been organized according to the list of questions that were provided, with the overall recommendations from each expert presented essentially unchanged under Question 2.1.9. Responses are presented below in the order in which they were received from the experts.

RI = Richard Isaacson
EE = Emilio Esteban
SB = Sabah Bidawid

2.1. Responses Organized by Questions to Consider

2.1.1. Interviewees felt that maintaining in-house microbiology capabilities was essential to fulfilling the mission of OFVM's Microbiology Laboratory Program and that the greatest program strength was the quality and diversity of microbiology expertise. In addition, the major program weakness identified in the report was staffing/manpower including insufficient staffing and lack of authorization to backfill and/or hire FTEs and/or convert ORISE or Staff Fellows.

RI: Activities represented in the OFVM are important for FDA and should remain in FDA. These activities are performed by dedicated research and development scientists that can rapidly address important new issues in food safety and food quality as they arise. For a unit dedicated to food safety and regulatory actions, having to "farm" this out would be inefficient, and outside research units probably would not have the expertise at the ready to perform time critical work.

EE: FDA needs to retain in-house expertise because there are unique requirements only attractive to Federal entities. Not only does FDA have world experts, it also has the state of the art facilities and recognition to be a leader in food safety and veterinary medicine. As with any other large corporation, there are moments for reassessment prompted by social, political, or economic changes. The most important resource of any Agency is its personnel. The most common source of malfunction is a loss of a common objective and specifically the role each employee plays in achieving the objectives and goals.

SB: In-house research is an important capacity within OFVM, and should be maintained. However, the research being done, some of which has been going on for years now, needs to be reviewed, evaluated and refocused to meet the new direction of prevention and regulatory implications. Nevertheless, some core investigative and inquisitive research should also be maintained and supported. New research trends and technologies, such as WGS, should be supported.

- **Does the current level and breadth of microbiology expertise within the Program appear to be appropriate to the needs of the Program?**

RI: The breadth and depth of the staffing is not really apparent from the information provided. The interviews suggest that there is breadth and excellent expertise. Most statements were based on knowledge of their own groups. It is noted that it was stated several times that there was need to have disciplinary expertise in specific areas, particularly pathogen-specific molecular pathogenesis. The reasons for this need were not stated and based on the assumed responsibilities of FDA, it is not clear why this need is required. While some level of disciplinary expertise is needed, it would seem that generalists might be really important for FDA.

- **Are there specific offices or groups that appear to be over- or under-staffed? Are there any obvious places in which redistribution of staff or expertise might benefit the program?**

RI: This is very difficult to determine as no one seems to understand the rationale and focus behind many of the research activities.

EE: One consistent comment across programs seemed to be the lack of FTEs, while at the same time there is an acknowledgement of duplication of research. It would appear that the solution is not to add FTEs, but rather combine expertise into better structured groups or clearly define objectives so that work is not duplicated.

SB: While almost all offices expressed concerns with staff shortages, OARSA was most prominent in voicing their concerns. OARSA feels that they were not given equal opportunity as was available to other offices to hire new staff, backfill vacancies, convert FTEs, or to hire permanent managers. OARSA is a research oriented office that has been doing scientific research in areas that are seeing considerable change. To this effect, scientists in ORA/ORS are filling this gap in research and are being approved and well-funded for it at the expense of OARSA. This is creating a poisonous work environment which has contributed to anger, competition, feelings of inequality, and favoritism. This is, in my view, a serious situation that can impact a smooth progress toward implementing FSMA.

- **Does it appear that the real or perceived freeze on hiring FTEs and/or converting Fellows within the Program may result in problems in the future with respect to backfilling positions or enabling the Program to meet new microbiology challenges (i.e., implementation of FSMA)?**

RI: It is claimed that many of the scientists will retire in the near future. The implementation of FSMA is going to require many new actions and even at the current level of staffing, it is likely going to be difficult to address all that is contained in FSMA. The concept of succession planning needs to be seriously considered.

2.1.2. Many interviewees felt there was a lack of coordination among all groups in the Program that was hindering effective utilization of manpower and expertise.

RI: This seems to be one of the most predominant and critical issues raised during the interviews. Without information from management side I am left with a real concern that this a dysfunctional group.

EE: The current OFVM structure appears to be the result of many years of reactive thinking rather than visionary development of a flexible structure based on long term operational and structural concepts. Such a revision would allow for the microbiological program to absorb any new challenge. For example, there is no need for having multiple Salmonella experts each working independently on water, seafood, processed foods, and produce. There is however, a need for expertise in Salmonella detection technologies that cross across pathogen and substrate, concurrent with the need to understand the particular characteristics (genotype, phenotype, virulence) of the target and the unique challenges of the different food matrices. Strategic goal 5, from the CFSAN 2011-2014 Strategic Plan aims to improve adaptability and responsiveness. Alignment of research, prioritization of research, flexibility in procurement, planning for funding variability are listed as the key expected outcomes. It appears that the current organizational structure purposely ignores this goal. Each group works independently, duplicating research, with no procurement structure, and no apparent long term business plan for investment in research.

EE: The current structure lacks order and consistency across laboratories such that the information that is generated by one group is not only shared, but applicable to the work done in other areas. While the CARTS system seemed to be an excellent attempt at approving research projects and sharing information, it is not functioning as designed. It's impossible to manage an organization without commonly shared and clear goals.

- **Does the perceived lack of coordination among groups pose real problems for the Program and if so what are they?**

RI: YES. This is a key issue that needs solutions. It is difficult to tell if there is duplication and to what degree duplication is desired by management. It is understandable that some levels of duplication are necessary but to what extent and where needs to be stated. Coordination and communications have severe effects on morale and that seems to be a continual theme heard during the interview phase of this review. Tied to this, there is little communications between the different groups and this leaves everyone with a lack of how what they are doing fits the mission of the larger OFVM.

SB: Judging by the comments of interviewees, there seems to be a lack of coordination among the different offices in the Agency. In my view, this is a serious situation that needs to be

addressed. The lack of coordination causes duplication of effort, wastes time and money, and can create real problems in the function of the program, particularly in responding to outbreak situations.

- **What steps short of re-organization might be taken in the near or long term to improve coordination?**

RI: I don't see any simple or easy fixes.

2.1.3. Issues related to communication/transparency between upper management and various offices and groups are problems that plague any large organization but were of particular concern among interviewees in groups or offices outside the College Park headquarters.

RI: This message was heard loud and clear. The message seems to be more pervasive than in other organizations and is having an effect on morale.

SB: I believe that communication is one of the most important elements/criteria that can easily be strategically addressed and improved, both for the short and long term improvement. While lack of communication is not a unique phenomenon to the OFVM, yet it can contribute to serious issues of trust, morale, productivity, stress, and effective functionality of the organization. Interviewees expressed concerns with respect to a lack or a breakdown of communication between scientific researchers, researchers and management, and within and among management itself across different offices. This is contributing to confusion, uncertainty and lack of needed guidance through this process of change.

- **Are any of the issues identified by interviewees in the report unique to the OFVM Program and if so what is their degree of seriousness and potential impact on the Program?**

RI: This is very serious but seems to go beyond the management to scientists. It is a two-way street and I'm not certain that communications to management occurs. Furthermore, and to point to the degree of dysfunction, there also does not appear to be communications between scientists within a group or between groups (especially as it relates to off site groups).

EE: As with any other Federal Agency with multiple locations nationwide, physical separation from headquarters may be a detrimental factor (for those away); however, the significance of the separation drops sharply if the goals and expectations are clearly communicated and constantly revisited. Who is the customer for ORS and for OARSA? If both Offices are under CFSAN what is their distinct product? Once again, it is clear that there are no clear and defined deliverables for each Office. The OFVM annual performance plan should clearly indicate the goals, objectives, and action items that are expected from each Office which in turn has to communicate these to Divisions and Branches and, very importantly, monitor progress towards achieving the goals. The CFSAN 2011-2014 Strategic Plan states that the focus was on "measurable outcomes useful for regulatory science". How then is it possible that the ORA labs are not a consideration in the research conducted by CFSAN and CVM? The same strategic plan

lists the examples of research outcomes. Wouldn't a logical approach be to associate these outcomes with an office responsible for delivering the product? Unless management assigns tasks, merely listing goals encourages competition between FDA researchers rather than collaboration.

- **In particular, what steps might be taken to address impact of physical separation on various groups within the Program?**

RI: A communications team is needed to develop best practices for communicating in all directions. CFSAN and CVM should consider video conferencing on a regular basis with all groups (quarterly) and should consider regular face to face meetings within groups, between groups, and to and from management. Currently it seems as though there is management and there are scientists with not good linkage. Again, this conclusion is based on what the scientists stated and does not take into consideration a management perspective.

- **Based on the report results, are changes specifically needed to improve communication through line management or can the concerns raised by interviewees be addressed via another route?**

RI: This must be addressed head on through management.

- **Are there any recommendations in general for improving communication and collaboration within the Program across the board?**

RI: Right now collaboration does not appear to be effective. This is because the OFVM is fragmented with little communications. In addition, what is the incentive to collaborate? Shouldn't management be directing where collaboration should be occurring since they are the ones who have the bigger picture and are the ones who are responding to FDA needs. Currently there is perceived distrust among groups of scientists and their management.

2.1.4. Many interviewees mentioned a culture of competition between ORS and OARSA that may be hindering microbiology research efforts.

RI: This point was repeated many times, but there was little information to clearly understand the specifics. The one example that was clearly stated was related to whole genome sequencing.

EE: OFVM is structured today with two Centers, CVM and CFSAN, both having research components. CFSAN has several groups (Office of Research, Mod 1 (OARSA); Office of Food Safety; and Office of Regulatory Science) with research activities. CVM has the Office of Applied Research and Safety Assessment, Mod 2 which also has research capability. With so many independent groups conducting research, there is inevitable resource competition and functional overlap. The current organizational structure appears to be quite inefficient with multiple administrative structures and distinct research silos. Somewhat troubling is the fact that in the almost 200 page FDA Microbiology Program Review that reflects the opinions of 94 interviewees in OFVM, there is not a single reference to the needs and work done by the ORA labs. It appears these FDA labs also conduct their own method research and development work,

while the CFSAN and CVM researchers do their own. While this subject is beyond the scope of the review, it points to a broader potential for disconnect between research and regulatory work.

SB: Some interviewees have expressed concerns with respect to increasing competition among the different offices. Most concerns were voiced by employees of OARSA who believe that other offices (e.g., ORS) are creeping into their research domain, taking away their research activities and/or duplicating them. While some competition may be healthy, excess competition within the same organization could easily lead to negative implications, such as work overlap, duplication, resentment, isolation, anger, territoriality, …etc. Ultimately, this could negatively impact the effectiveness of the organization's function.

- **Does the perceived bias within upper management appear to be based on a genuine underlying problem within the Program, and if so, what steps might be taken to address/resolve this problem?**

RI: The message from the scientists was that those involved with the WGS work were favored over all others. This was confirmed by the WGS group who stated that their way was the way of the future. To me, the biggest flaw here is that the directions of the WGS group were not apparent. Their goals and FDA's needs were not stated. While WGS is a state of the art technique and has much analytical power, its usage is really dependent upon the outcomes sought. In many instances, more traditional techniques are more than adequate. Perhaps of another concern is that the makeup of the WGS group was not stated and very little was stated about bioinformatics. Is FDA really committed to this direction and have they adequately invested in the correct personnel and disciplines to accomplish their goals? I state this, because the goals are not apparent and I interpret the outside group scientists to not even understand the goals of WGS. Does FDA even have a sense of outcomes and needed definitions of success?

SB: There seems to be some merit to OARSA concerns that ORS is competing with them. ORS's stronger and supportive management, better staffing process, better funding opportunities, clearer regulatory-driven research objectives, and better alignment with the mission, put ORS in a better position to formulate its research priorities and secures greater approval rating. Thus, the bias felt by OARSA may have contributed to creating a negative environment. Upper management should address this matter strategically and in a clear and transparent manner to reduce these concerns.

- **Does it appear that the competition between these groups may in fact be detrimental to the Program and if so in what ways?**

RI: YES.

- **Short of reorganization, what steps might be taken to encourage and improve collaboration between the two groups?**

RI: This is a major issue without an easy fix.

2.1.5. Interviewees within several groups reported problems with line management that were attributed to the lack of permanent, strong, and/or effective line management.

RI: This was a message that carried through many interviewees and between groups. It's necessary to have excellent management that truly understands microbiology, the goals of a group, and how it fits with the FDA's goals. This was stated from several groups. Some felt that there was a lack of support and this was related to expertise and the lack of permanent managers. Where WGS appears to be well supported, the other groups need a strong managerial supporter in their "corner".

- **Are there any specific groups or offices in which line management issues appear to be particularly significant and if so what might be done to address these problems?**

SB: This issue seems to vary depending on the office and the nature/level of management in place, or the lack thereof. Various aspects were identified with respect to management issues: 1) lack of permanent management, 2) personal conflict between management and staff, 3) management with expertise mismatched to the scientific function of the office they represent, 4) lack of communication and transparency, 5) conflict and/or competition, within Divisions/Offices, between same level management and/or between different levels , 6) management disengaged from the office/unit they represent, 7) weak management (doesn't fight for its unit), 8) first level management (line management) lacking authority, 9) lack of accountability, and 10) lack of clarity and guidance. While different offices had expressed different management issues of concern, greatest dissatisfaction was expressed by OARSA staff as compared to others.

- **Are there any general steps that might be taken to improve the effectiveness of line management across the board within the Program?**

RI: If excellent managers cannot be hired, it would be preferable to combine some groups to where at the least there was good management. The scientists feel as though they are off on their own with little Agency support.

2.1.6. Several organizational problems were identified within specific offices/groups including: the division structure within OARSA, the partnership between IFSH and FDA at Moffett Center; and the relationship between the NARMS program and research groups within DAFM, CVM.

- **Do these apparent problems appear to have potential to significantly impact the effectiveness of the above groups/offices? What possible changes might be made to address any of these situations?**

RI: This is probably one of the least significant problems. As communications improve, this should be an area where scientists on both sides are brought together to improve these interactions.

SB: While there seems to be a reasonable level of satisfaction with the effectiveness of the current organizational structure in the Agency, the microbiology research program seems to be dispersed in a number of different offices within OFVM. This has resulted in duplication, competition, and inequitable funding and resource practices. While many of the interviewees were satisfied with the current organizational structure, concerns were voiced particularly related to the interaction between OARSA, ORS, CVM, and the role of IFSH and its predominating role at times, as well as the interaction between CVM, DAFM and NARMS. Concerns were raised by other offices that scientists within OARSA are doing their own stuff irrespective of the regulatory role of the Agency. On the other hand, OARSA's staff is bitter over ORS's favored status and support from upper management providing ORS with the opportunity to build up a competitive microbiology research program, supported by better staffing and funding opportunities. Complaints were also raised with respect to IFSH whisking away staff from other offices to support their needs which seem to override others. I'm not sure if this represents a real problem when the scientific staff from other offices is being used to respond to/address arising needs of importance to the Agency. Some offices felt that their own microbiology program is in a much more stable and acceptable organizational structure since their function is "unique", such as the seafood program at OFS/DI, food processing technologies and proficiency testing at OFS/MC, the antimicrobial resistance program at NARMS. This level of security and uniqueness was definitely lacking in OARSA.

2.1.7. There was concern expressed across groups that the Program is not maintaining an effective balance between basic research and traditional microbiology and expansion into areas of genomics including whole genome sequencing.

RI: The question of the mix of basic and applied research is one that management must make. FDA is a service unit and to what extent is basic research needed? It is my opinion that the focus is on applied research that improves food safety and allows FDA to provide informed regulatory decisions. A certain degree of basic work is needed but it must fit within the scope of FDA's needs. Within HHS, basic research is the domain of NIH, while within USDA (mentioned because of its link to NARMS) it is within ARS. A certain degree of entitlement was perceived around this issue of basic research. Specifically that the scientists deserve to be able to do basic research and that they know better. To some extent, this also is tied to scientist development and promotion. It was stated by many that promotions required publications and that much of the microbiological research was applied and not publishable. Thus, alternative goals linked to promotion and reward are needed. Regarding WGS, the amount needed must be tied to the goals of FDA. This must be balanced with their specific needs and the recognition that staffing is limited. What is the end product of WGS? Does FDA believe that they can transition most of their research to link with WGS?

EE: The Microbiology Program Review report suggests that the vast majority of the staff is not aware of the changing OFVM needs. As researchers, we tend to focus on our work in a particular area of interest. This is great for achieving targeted results but is detrimental to the system if the lifeline of the research outlives the need for that type of research. There may always be need for basic culture-based microbiological techniques, but technology is evolving much faster than the current laboratory culture can manage. The report includes multiple references to preferential treatment given to genomics over other more traditional areas. There is no question that much of

the lab technology is moving in the direction of culture independent technologies. Rather than fight the trend, staff should embrace the opportunity. While at one time FDA set the standard for a single approved regulatory method, the focus should change to performance-based methods. This is particularly concerning in CVM where some NADA methods date back 20 or 30 years. Rather than mandating a specific technology, one should focus on the objective (i.e., to find a specific target at a specific level in a particular matrix). Such an approach would maintain FDA current, or even ahead, of analytical regulatory needs for national or international support.

SB: It is undeniable that traditional microbiology science and research have laid a strong foundation that has, and continues, to serve the scientific and stakeholder communities well over the past decades. Undeniable too is the fact that science keeps evolving, leading to newer methodologies, approaches, and perspectives. The new advances in genomics are providing us with amazing tools that will significantly enhance our capability to improve the safety of the food supply. WGS is one such technology that is revolutionizing the way we do microbiology, and may influence a shift in direction in various areas, including research, regulatory and compliance applications. It is expected that WGS and Bioinformatics will take the front seat as compared to traditional microbiology, but this should not diminish the value of some traditional microbiology that will continue to serve us well. While there may seem to be an imbalance in the support for WGS as compared to traditional approaches, nevertheless, I think that this is not an unexpected outcome when it comes to supporting new technologies. Therefore, I am with the view that greater emphasis and support should be given to these new technologies as they are evolving to support future mission needs and obligations. Having said that, however, certain aspects of traditional microbiology remain the gold standard and are indispensable and, therefore, they should not be overlooked or dismissed carelessly. Key traditional methods which are essential to regulations and compliance should be maintained and funding should be allocated to support further research to improve these methods. Method development and validation is something FDA does while others (industry and academia) do not.

- **Does it appear there is an imbalance in the current distribution between traditional microbiology and genomics-related microbiology, and if there were such an imbalance in what way might it be addressed?**

RI: Without an understanding of the goals, the exact balance is difficult to determine. Much of what FDA does not require WGS. They must consider the cost of this on completion of other goals.

- **Is the expanding focus on whole genome sequencing in keeping with the Program's mission and obligations?**

RI: This must be based on goals.

2.1.8. In terms of future challenges, the impending implementation of FSMA will have a significant impact on offices/groups within the Program.

- **Does it appear that the OFVM Program has focused sufficient effort on preparing for the implementation of FSMA?**

RI: Very little was stated about how prepared OFVM was for FSMA. Do the scientists even know what is coming? It is clear that FSMA will impact the OFVM in a very real way. A common theme from the scientists was the lack of manpower and this will be impacted to a large extent by FSMA and imminent retirements. Does management perceive that they have the expertise and quantity of scientists to make FSMA happen? What compromises will be made as currently manned?

EE: OFVM has a very broad responsibility. The current organizational structure is multilayered, both horizontally and vertically, and with overlapping responsibilities. The goals for the microbiology laboratory program should be based on a strategic plan. Each Center, Office, Division, and Branch should have a clear scope of operation with acknowledged areas for cross-collaborations. The Food Safety Modernization Act (FSMA) mandates an organization that protects food from the farm to table and incorporates strong hazard prevention controls on imported and domestic food. I perceive the scope of the microbiology laboratory program to include scientific support for prevention, monitoring, and response of food safety challenges across the entire farm to table continuum.

SB: While considerable parts of OFVM may be better prepared for FSMA implementation, there is evident disarray in OARSA.

SB: FSMA will provide a platform which will steer FDA into becoming a more cohesive, mission-oriented regulatory Agency to enhance preventive controls for food safety from farm-to-table. Overall, I believe that FDA (OFVM) is, to a large extent, prepared to take steps towards implementing FSMA, with the exception of OARSA which seems lagging behind in this process. Upper management has thought-through a comprehensive strategic plan that will assist in this process. Having said that, however, I think that the Agency can momentarily initiate some action-oriented measure to address some of the issues raised and the recommendations made. Addressing these issues early may facilitate the process of implementing FSMA with less disruption. Issues that can be addressed at present include communication and transparency, initial reorganization and staffing, and effort coordination with respect to the anticipated change on certain offices, and the impact of FSMA's implementation on the type of research to be done, staffing matters, redirection of research activities, and prioritization process.

2.1.9. Please provide a brief summation of perceived strengths, weaknesses, problems, and potential solutions associated with each office/group: OARSA, OFS/DI, OFS/MC, ORS, and CVM.

RI: Below is an outline of my main take home messages.

- Serious issue of communications
  - Communications with and from "management" is perceived as lacking
  - Communications with and between groups is perceived as lacking.
- There appears to be an air of entitlement
  - We know what we are doing
- Seem to have little guidance on what to do
- Lack of permanent leaders for some is a major issue
  - Many management leaders don't know what the group is doing and frequently are not even trained in the discipline.
- There does not appear to be a plan for succession
- Genomics and whole genome sequencing is a contentious issue
  - There does not appear to be a perceived strategy or goal
  - WGS appears to be a favored topic
- Scientists do not receive feedback both from management and possibly within and between groups.
- Scientists are not aware of what it will take for promotion
- There appears to be unhealthy levels of competition and in-fighting between groups
- Off site groups are not aware of what's going on in DC

EE: The recommendations are based on a review of multiple background documents provided by the task organizer and supplemented with information available via the FDA website. The recommendations address four areas:

- How capacity is deployed and applied across the program;
- How efficiently resources are managed;
- If microbiology research is meeting program needs; and
- Examining how OFVM's microbiology program interacts with other U.S. government and state agencies, the external scientific community, and other external stakeholders.

<u>Recommendations</u>

1. Revisit the 2012-2016 strategic priorities of the FVM program. Create a workgroup composed of leaders from the current offices and with deliberate care go through each goal and objective to align the current activities to each of the objectives. This exercise should clearly expose areas of duplication or gaps. Research currently being conducted that does not address any of the objectives, must be looked at with care to assess its worth. Not all goals may be relevant to laboratory work but the simple exercise of looking at the entire program should create some sense of common mission. In addition, this exercise could be the foundation of the next five year plan which will be completely

under a FSMA environment. Specifically, Program Goal 3 states the need to implement an integrated approach to research that links regulatory goals to research needs. Following through with the implementation of the key initiatives listed under this goal will lead to a more effective organization.

2. Increased staffing is not a solution unless all other options are first considered. Short of a very painful and lengthy reorganization, leadership at OFVM needs to implement a significantly strong communication campaign that reintroduces Center leadership through the Strategic Plan and the Annual Performance Plan. Each one of the current Divisions, Branches or Teams, need to know exactly what is to be expected as well as a timeline for delivery. Adding personnel is never the only solution; it is however, a very simple excuse for not producing results. Whether more personnel or a partial realignment is needed, would be part of a focused review based on the deliverables identified in the strategic plan.

3. All about ME should be all about US. Throughout the entire Microbiology Program Review report, we find complaints about one office getting more attention, having more resources, not having communications from "the front office", and lacking leadership. It appears, we need a moment of introspection. Rather than observing what is good at another program, we should identify what "we" can do to contribute to a common goal, thus attracting the Agency's attention which would consequentially lead to staff, funding, enhanced communication, etc. We recommend management clearly communicates the organization goals and then follows up with clear expectations for collaboration and focus that lead the organization to meet the objectives. It is clear that internal competition and dysfunction is holding back the entire system.

4. Leverage the FDA brand name. OFVM's number one asset is its staff. Collaboration with other regulatory and research organizations is essential in making sure that public health is the primary focus of the activities. CVM and CFSAN need to be informed, involved, and proactive. One cannot remain as a leader while working in a vacuum. Collaborations with other Federal Agencies, academia, and industry, such as the ones currently in place with the Centers for Excellence, must be evaluated and strengthened to enhance the value to CVM and CFSAN. How does research done in-house relate to the work being conducted at the CERSI? Could the intellectual capital at these CERSI be the answer to the perceived need for additional in-house staff? Activities conducted at the CERSI including MC and DI should supplement, not supplant or duplicate, activities conducted within the FDA Offices. There are significant benefits of working through agreements with academia such as JIFSAN, IFSH, NCNPR, WIFSS, and the Center for Excellence at the University of Arkansas. There will be an inevitable competition for resources between in-house researchers and those at the collaborative centers. The key to minimize this feeling is to be exquisitely clear on the distinction of deliverables and the advantage of conducting this research outside the Federal Centers. Some examples may be the ability to attract a constant flow of young researchers, different budget and procurement requirements, management and personnel flexibility, etc. Not all research is an eminent governmental responsibility. The environment is changing much faster than the Federal bureaucracy. We must identify and leverage those opportunities to benefit FDA.

5. Communicate, communicate, communicate. The survey suggests significant lack of focus, clarity of mission, and, most importantly, distrust in leaders. Even if this is not a widespread feeling, the fact that it was raised by a fraction of those surveyed leads us to believe that there is a need for enhanced communication. The recent appointment of a new CFSAN director provides an excellent opportunity to do a top to bottom reassessment of OFVM under FSMA. Everyone must know their role, their area of contribution, and their deliverable. There may very well be good and bad managers. Having clear goals will allow good managers to deliver and not so good managers to be identified so additional training can be offered. Not all scientists are good managers and not all managers can be scientists. Top management needs to be aware of the differences that exist between working at headquarters and away. The method, frequency, or style of communication might be different but the message must be the same.

   Through the personality or effectiveness of their leaders, some programs within offices may appear to be stronger than others. This attracts attention, resources, and staffing. Rather than trying to equilibrate the distribution of resources, we should recognize these leaders and build around their success.

6. Structure should be defined by function. The CFSAN Science and Strategic Plan for 2011-2014 clearly listed five strategic goals. It appears that absolute freedom was given to centers, offices, divisions, branches, and teams to pick and choose how to address those five goals. This has resulted in an apparent uncoordinated approach that favors competition and duplication of effort. Consolidate ORS and OARSA into a single Office with Divisions that address a functional process rather than a specific area. A simplified structure will require less managers, facilitate communication, and identify common objectives. Examples of potential divisions under a single office of research are:

   - Administrative Infrastructure
     - Provide the backbone for the technical areas.
       - Laboratory Quality Assurance (proficiency testing, method repository)
       - Personnel and procurement
       - Bioinformatics and communication (LIMS, data flow)
       - Stakeholder collaborations (intra/extramural)
   - Detection Technologies
     - Develop, validate, and implement laboratory methods for detection of the target. This Division could be organized by:
       - Type of target (microbe, parasite, virus, allergen, additive, supplement)
       - Type of substrate (produce, seafood, processed food, water)
       - Type of technology (basic micro, molecular detection, chemical)
   - Characterization Technologies
     - Learn about the target (infectivity, pathogenicity, virulence, phenotypic, and genotypic characterization).
   - Strategic Prevention and Control
     - Interventions based on the detection and characterization knowledge (by primary production to consumption stage).

- Response
  - Outbreak response and follow-up based on the knowledge and products generated by the detection, characterization, and prevention divisions.

In summary, the six recommendations above suggest a stepwise approach to address some of the inefficiencies documented in the FDA Microbiology Program Review. The process starts with revisiting the Strategic Plan, aligning the expected outcomes to individual groups, and creating a current status report. After this review, there will be obvious areas where one can find efficiencies thus identifying the need (or not) for additional staffing. The root of most of the discomfort is loss of mission objective. The current group of offices and collaborative centers has been reactive rather than proactive. Under FSMA, it is essential that FDA look forward and create a structure that is versatile. The need for basic microbiology will decrease, but will always remain at some level. We cannot continue to grow the Federal workforce. There are other mechanisms, such as the collaboration centers and other Federal Agencies that we can leverage to remain relevant and up to date without more staff. We have to recognize that the world is more fluid. Telecommunications allows for virtual associations and we must embrace the reality that the differences between headquarters and non-headquarters are not due to physical location as much as learning to communicate with different media. Those of us that don't adapt to the new telework environment, will be left behind. FDA must continue to leverage collaborations without losing its identity. The FDA name brand has a level of quality and recognition that should not be diluted by the proliferation of collaborative centers. With at least five centers for excellence, OFVM is at risk of expanding beyond its capability to manage focused growth. Again, any investment must be carefully reassessed to justify not only its short term value but also its future need. After a clear review of current projects, OFVM may want to consider realignment to eliminate duplication and improve operational performance.

<u>Limitations</u>

- The vast majority of the information comes from 94 interviewees. I could not find any statement regarding the representativeness of the comments or the population denominator for each of the offices. One has to assume that while tainted by those with negative opinions, the interviews convey a general sense of discomfort by those in OARSA, independence by those in OFS/DI, and OFS/MC, and adequacy by those in ORS and CVM.

- There is limited information available regarding the research portfolios for each of the branches and divisions. Without this factual information, it's difficult to discern between the perceived duplication of efforts and an actual overlap of activities. One has to assume that the stated negative feelings are factual, at least as stated by those interviewed.

- This is a snapshot of a very large entity with multiple moving parts. As part of a Federal Agency, OFVM will have to address a moving target at a time when FSMA is being implemented. The economic and political climate is in continuous flux. The information we have today may change in significance next year. The most significant challenge is to stay on message while the environment changes.

SB:

Strengths at FDA:

- The wealth of well recognized multi-disciplinary expertise currently supporting the Microbiology (MB) program is a definite strength. These experts have established a solid and diverse in-house research program within the confines of one organization, which would be an ominous task to emulate by industry, academia, and others.
- The in-house research program and the expertise available are in place to respond to arising situations, with fluidity of changing priorities in a timely manner, which in my view, is unmatched by others. Therefore, maintaining a well-focussed or refocused and mission-driven in-house core research program would be essential to the organization.
- The already existing strong capacity of equipment and instruments within one organization. Furthermore, the acquisition of new state-of the art technologies, such as whole genome sequencing technologies, constitute an additional strength.
- The ability to target different food commodities (produce, meat, dairy, seafood, etc.).
- The existence of centres such as the shellfish program, antibiotic resistance, proficiency testing, processing technologies, proficiency testing, WGS, methodology and validation are unique strength.
- The availability of scientific expertise to target currently known multi pathogens contaminants of food, as well as emerging ones.
- Linkages with national organisations (e.g., CDC) in joint efforts to address emerging issues of importance to public health.
- Linkages with industry, academia, and other stakeholders have contributed to strengthening the safety of the food supply.
- The breadth of national and international collaborations.
- Influence: the scientific expertise within the FDA has, over the years, established a solid respectful reputation world-wide, and in the process has conferred on the FDA a strong credibility which has influenced decision-making outcomes at various international bodies, such as CODEX.

Weaknesses at FDA:

- The <u>breadth</u> of the in-house research may need to be reviewed, streamlined and refocused towards evolving mission-needs, regulatory support, and preventive controls.
- Staffing: this is a definite weakness that has been highlighted by almost all participants in the interview process. This encompasses inability to hire new staff, inability to convert FTEs to permanent positions, inequitable hiring practices by the different offices, inability to backfill vacancies (due to retirements, departures), inability to bring in younger scientists, losing staff from one office to another…etc.
- Management issues were highlighted as key concerns with many interviewees. Some managers were perceived well while others were seen as ineffective, disengaged, and did not represent their units in an effective manner.
- Communication and Transparency: the lack of communication and transparency have been identified, by almost all offices, as <u>major</u> impediments contributing to distrust, confusion, lack of direction, unclarity of objectives, ambiguous decision making process, uneven handedness in treatment, …etc. In my view, these are serious and pressing issues that can be addressed and improved as part of a short-medium range objective.

- Geographical location/separation: FDA is a vast organization that services the entire USA. Offices in distant locations have expressed some concerns of inaccessibility to upper management, and that they are, to some extent, invisible to decision makers, which may have impacted staffing, funding, project approvals…etc. Options should be sought to give these centres better exposure and inclusion, not necessarily through relocation.
- There is an apparent disconnect, competition and resentment between different offices and groups; e.g., OARSA, CVM, ORS / ORA.
- Duplication of effort: microbiology seems to be conducted in a number of different offices, with little communication, coordination or awareness of what different groups are working on. There is a strong sense among various research groups that there is an unnecessary and wasteful duplication.
- Mandate/Role Creep and lack of coordination: this is best explained as some research groups are creeping into research domains of others, thus erasing boundaries of defined roles and responsibilities. This also results in bitterness, competition, anger, frustration, and duplication of effort.
- Inconsistency of methodologies across the Agency.
- Weakness in supporting virology and parasitology research activities.

<u>Recommendations [by topic]</u>

From the review report, it was obvious that, although there were many common sentiments expressed with respect to the Microbiology program and the current state of affairs at FDA (OFVM), employees at OARSA stood out as the most dissatisfied, with low morale, directionless and nearing a crisis mode. Nevertheless, issues of concern were raised by other units, as well. Below are my recommendations. Please note that there may be some repetition/overlap of recommendations under different headings. This is due to the blurred boundaries between some of the areas targeted for the review.

1. Review and Reorganize the Microbiology Research Program:

    a. Identify and establish a list of who's working on what, and in which office.
    b. Identify project relevance to the mandate/responsibility of the office.
    c. Clarify roles and responsibilities of each office to avoid mandate creep and duplication.
    d. Identify duplication: eliminate or merge projects of similar nature.
    e. Identify areas of research across the OFVM (OARSA, CVM, ORA) where research activities can be strengthened through collaborative efforts or a merger.
    f. Establish an SOP for collaboration within and between, different offices, emphasizing complementarity of expertise rather than competition. Establish a mechanism to ensure compliance with these collaborative rules.
    g. Establish criteria to identify unacceptable conduct hindering collaboration, and indicate potential consequences which may include, but are not limited to, reducing funding, reallocating the activity to more cooperative teams, unfavorable performance evaluation…etc. Management should be given the authority to impose such actions, and should also be held accountable for implementing needed actions.
    h. Encourage regular meetings between researchers from within Division and/or the different offices to increase interaction.

i. Establish regular inter-office rotational seminars whereby researchers present their work to other scientists in other Divisions/offices. This will allow greater awareness of what different researchers are working on in the different offices, identify potential collaborations, highlight collaborative projects and mutual benefits associated with that (which may initiate incentive for others to follow suite), and would provide a more open platform for greater integration.
j. Encourage managers to attend these seminars and to participate in any discussions that would promote collaboration.
k. Investigate possibilities to provide OARSA with some unique function (e.g., genomic responsibility) that will give them a sense of stability, as well as provide the opportunity to streamline and refocus their research efforts to better meet evolving Agency's needs as a regulatory authority.
l. Consider reorganization of research groups in the Centers, Offices, Divisions, and/or Branches to form more function-defined cohesive research groups.
m. Redefine ORA's role and responsibilities. If the focus is on inspection and surveillance, then consider removing research functions from this group and consolidate with other microbiology research groups.
n. Consider the possibility of consolidating research by unifying all research groups (OARSA, ORS, OFS/DI, OFS/MC and CVM's OR) under a single portfolio lead by a Research Director within OFVM. Within this unified structure, however, subdivide the research into specialized areas of research, grouping research along functional lines, with each area headed by a manager. Establish SOP for collaboration, coordination, and sharing of equipment. Managers should be held accountable to ensure effective cooperation and coordination across these units.
o. Consider establishing strong linkages, coordination and communication between this unified science research unit and a counterpart unit harboring policy and regulatory experts. Create a Science-Policy Linkage Committee to ensure fluid coordination and interaction between Research and policy Divisions.
p. If unifying all research groups is not possible, consider merging the activities of OARSA and CVM. Review functions of OARSA and CVM, and evaluate joining both.
q. Re-examine and redefine functions of NARMS and DAFM. It appears that they have more in common than not. If so, consider the possibility of merging both Divisions, under one management
r. Even though OARSA's research functions seem unfocussed at present, they have excellent experience and expertise in genomics. Consider creating a Genomics Unit within OARSA where experts in this area may work together. This action might help refocus part of OARSA's research direction.
s. Review of the current organization in OARSA, specifically in connection with the Division of Virulence Assessment (DVA) to determine relevance to the microbiology program. A change of name of the DVA was suggested by some staff.
t. Consider the possibility of establishing Centers of Excellence in different areas (e.g., E. coli research) within the Center. However, just creating a COE doesn't mean much if others are not aware of and link with its experts.
u. Establishment a Bioinformatics Centre within OFVM. Consider either a Central Sequencing Unit or units in different offices.

2. In-house research:

    a. Maintain in-house research, but streamline and refocus projects to align with FDA's mission and regulatory responsibilities.
    b. Strength of funding should match the strength of project alignment to mandate, as well as to new objectives of preventive measures.
    c. Establish, across the Agency, clear and consistent criteria for project ranking/ prioritization and funding formula.
    d. Stream out projects that are no longer supporting the mandate.
    e. Strengthen research in foodborne virology and parasitology. These are becoming increasingly important contaminants of food.
    f. Encourage collaborative projects across the different offices in the Agency. Provide incentive to promote collaboration, such as higher ranking score for approvals, more funding, and other potential incentives.
    g. Redistribute staff as per need and office function.
    h. Provide strong support to incorporating new technologies.

3. Staffing:

Please see points 1 and 2 for overlapping comments. If at all possible, mid and/or upper management should partake in the communication part of the recommendations made below. This will provide OARSA staff with a greater degree of comfort and trust in the process.

    a. Initiate dialogue with OARSA scientists. Assure them that the Agency values the work they do. However, explain clearly that the Agency is steering into a new direction in its research needs which will require adjustments to its research activities.
    b. Be as transparent as possible with the organization's intentions with respect to hiring/replacing staff. Point out that, in anticipation of FSMA implementation, the breadth of the research program has to be refocused, and that employees will have to adjust and/or redirect their research opportunities, to collaborate with others in other offices, or to reassign staff to other more relevant projects, as possible.
    c. Create a committee from within OARSA scientists and management to review and evaluate current research at OARSA in relation to new FSMA direction.
    d. Let the committee identify the projects and deliverables most closely aligned with the Agency's needs, both in core science and those that support regulatory needs.
    e. Refocus the non-aligned projects, if possible, or provide opportunity to have them modified to fit the purpose. Encourage collaborative projects to avoid duplication.
    f. Offer opportunities for scientist whose projects are not salvable to join forces with other researchers or move to other offices to work on more pertinent projects.
    g. Indicate that funding or staffing for irrelevant projects may not be renewed pending the project review process.
    h. Provide options for shifting type of research to meet evolving needs, as well as training that would link research expertise with policy.
    i. Hire qualified managers, convert acting qualified managers to permanent. Appoint managers who have sufficient knowledge in the subject matter of area they lead

j. Managers should hold regular meetings at the Division level to maintain continuity of communication.
k. Although budget constrains may limit hiring ability, consider backfilling important positions in research to maintain expertise, which otherwise maybe very difficult to replace in the future.
l. Establish a sound succession plan. This is very important to ensure continuity of corporate expertise.

4. Management/ leadership issues:

a. Identify dysfunctional management in offices who have expressed concerns.
b. Identify factors contributing to the ineffectiveness of current management.
c. Provide specific training where training can address and help resolve some of the issues such as those pertaining to lack of experience, unfamiliarity with the position requirement, disorganization, conflict resolution, time management, engaging employees, how to capitalize on staff expertise…etc.
d. Reassign managers to other areas where they may be a better fit.
e. Initiate dialogue between managers and staff on regular basis.
f. Improve leadership at the Division Director level and assign more project managers.
g. Improve relations between management at the agency level.
h. Select and appoint permanent, strong, and effective management where needed.
i. Examine current management layers of authority. Establish an SOP and streamline as needed to produce a more functional, cohesive and effective management.
j. Streamline obstacles contributing to difficulties in communicating issues through line management to upper management.
k. Hire qualified managers, convert or make acting qualified managers permanent. It would be wise to appoint managers who have sufficient knowledge in the subject matter of area they lead
l. Managers should hold regular meetings at the Division level to maintain continuity of effective communication.
m. Provide mandatory training to improve managers' people skills.

5. Traditional microbiology research vs new genomic-based research:

a. Establish a strong WGS and Bioinformatics program in the Agency.
b. Consider establishing a central office for Bioinformatics and WGS. However, an alternative would be to allow different OFVM-associated offices to run their own whole genome sequencing at their locations. Ensure that their WGS function does not duplicate efforts of others. Establish an SOP to define boundaries, limits, and unrestricted sharing of information or data generated across the Agency. While it might appealing to put all WGS activities in a central location, it might be advantageous to give strength in this field of work across OFVM. This will expand knowledge, expertise, and ensures no delays in performing the work. Therefore, this approach will help build up a capacity of expertise in sequencing in different offices, and will be more efficient approach for the long term. Bioinformatic analysis of sequences may be done in a central office to start with.

c. As mentioned above, consider the possibility of creating a Genomics Unit in OARSA which will house experts in that field.
d. Equip the Bioinformatics Centre with high performing computational equipment and needed software, access to open source software, as well as a high capacity for data storage.
e. Encourage IT to hire knowledgeable staff in science and bioinformatics to provide effective support to this increasingly important area of microbiology research.
f. Establish a data sharing mechanism for easy data transfer and sharing between offices.
g. Provide sufficient training to staff in these new technologies.
h. Establish a committee to re-evaluate traditional methodologies and approaches to determine which ones should be maintained and/or improved.
i. Provide sufficient funding and support to enhance some key traditional methodologies which are still the gold standard for regulation and stakeholders.
j. Re-examine and improve BAM. Review methods, identify obsolete ones, and revamp BAM, accordingly.
k. Consider strengthening the fields of virology and parasitology.
l. Evaluate the need to enhance work on specific pathogens, including Vibrio parahaemolytica, Listeria, E. coli, molds, and yeasts; genomics.
m. Encourage and establish an SOP for method consistency and harmonization across the Agency, and develop a harmonized approach for method validation.
n. Prioritize by assessing impact of projects outcomes on public health.
o. Strengthen the internal peer review process, and engage experts from different offices in this process.
p. Consider utilizing an External Peer Review process in evaluating and prioritizing projects.
q. Establish a system to monitor and track progress of projects and potential impact on the Agency's needs and obligations.

6. Communication:

a. Hold regular meetings (quarterly) between the first level management (line management, OD, DOD) and staff to discuss current issues and anticipated developments in the program.
b. Management should link well with their staff, be as transparent as possible, and establish a trusting relationship.
c. Clearly communicate work priorities as they are changing.
d. Identify needs and provide guidance on project development, prioritization, and alignment with the new direction.
e. Provide updates and rationale on potential changes to the microbiology program direction.
f. Hold bi-annual all staff meetings (by WebEx for remote areas) where upper management can update staff on any developments.
g. Hold an all staff bi-annual town hall meeting between management (mid or upper) and staff for Q&A.
h. Establish an electronic monthly newsletter from upper management to all staff highlighting current activities, success stories across the different microbiology program

units, editorials on select units to inform others of the type of work being done across the program. Also, share aspects of FSMA and the process.

i. Establish a mechanism for management (at all levels) to receive input and suggestions from staff for management's information and consideration. These could be received either through email or anonymously using suggestion boxes or other suitable means. This would allow the management to be aware of issues, and possibly ideas, that management may wish to consider or simply address in meetings or through the electronic newsletter.
j. Management (at appropriate levels) of different Units/Divisions/ Branches should hold regular meetings with each other to discuss program changes and best ways to work together and enhance coordination, with clearer vision, and putting the interest of the organization as their top priority. Consensus on actions may be translated to staff in a transparent way to reduce confusion and provide meaningful guidance.
k. Hold Divisional meeting to encourage greater dialogue amongst scientists to discuss and brain-storm new needs and priorities, strategic planning and alignment with the mission, what others in the microbiology program are doing, potential collaboration, best use of funding, …etc. Getting the scientists involved will make them feel valuable and more trusting of the process, and will reduce their "perception" of being ignored.
l. Improve communication and transparency concerning how priorities are established, including scientists and/or line management in the prioritization process
m. Expedite communication of shifts in Center's priorities, improve communication with the program offices, field laboratories, and stakeholders.
n. Establish / develop SOPs to improve communication within research groups (between line management and scientists and among scientists)
o. Clarify the prioritization and decision-making process for projects.
p. Include scientists in the research prioritization process where possible and applicable. Consider creating a committee including scientist, management, and policy representatives to evaluate, prioritize and make decisions on projects.
q. Conduct regular electronic confidential surveys of employees to assess level of satisfaction, issues of concern, work environment…etc. The results and potential solutions should be shared with the employees via electronic newsletter from management to employees.
r. Provide mandatory cross-training whereby seats are reserved for staff from each office to attend. This will bring people from different offices together (this point also applies to other areas in this document).
s. Provide educational training to update and improve scientific knowledge and to maintain expertise in the field.
t. Improve the CARTS process by 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. Consider other models such as the NIH scientific review process and NCTR review system.

7. Alignment:

    a. Address issues in OARSA where interviewees felt they were still working to achieve alignment due to becoming aware of the research prioritization system relatively late in the process and due to communication issues (interviewees: "Right now we are scrambling to try to coordinate and be in alignment with what the Center wants to do." Provide assistance as possible to help them through this process.
    b. Establish better coordination and relationship between offices/Divisions and policy offices and/or stakeholders to improve prioritization and alignment processes.
    c. Initiate effective communication (please refer to recommendations elsewhere).

8. Collaboration:

    a. Encourage management to support greater collaboration across the Agency.
    b. Address and resolve issues relating to problems with collaboration 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.
    c. Encourage and establish an SOP for more effective communication from line management and address issues of lack of interaction across groups and offices within the Centers.
    d. Identify and resolve difficulties in working with other organizations (e.g., CDC and other federal Agencies).

9. Coordination:

    a. Encourage project managers of different offices to meet regularly to ensure better coordination between their units.
    b. Develop a workable structure for coordination across the Agency.
    c. Increase awareness of coordination efforts between the Centers' microbiological research programs and any Centers of Excellence.
    d. Clarify roles, responsibilities, and areas of expertise of each office and establish an SOP to promote complementation rather than duplication of efforts.
    e. Establish an electronic list of Who's Who identifying subject matter experts within the Agency to improve awareness of available expertise across the different offices.
    f. Publicize research efforts within and outside the Centers
    g. Encourage project managers to liaison between researchers and other offices, particularly during outbreak response, and clarify roles and areas of expertise for scientists across the microbiology program.
    h. Encouraging attendance at scientific meetings and seminars.
    i. Increasing interactions with the different groups and increase direct communication between scientists working in these areas, especially with the ORA field laboratories.

10. Competition:

    a. Hold meetings with the scientists of the affected offices and clearly explain the new direction of OFVM.
    b. Engage the scientists in a frank discussion and solicit ideas and suggestions on how to adapt to this change.
    c. Address concerns raised to establish a trusting relationship.
    d. Clearly define roles and responsibilities of the offices involved, and develop an SOP or protocol to coordinate efforts.
    e. Discuss potential different options; staff redistribution, collaboration, training, redirection and refocus of projects…etc.
    f. Define boundaries of research activities to avoid duplication.
    g. Re-align and prioritize research projects based n clearly defined goals and prioritization criteria.
    h. Shift scientists to more mission-relevant work in alignment with FSMA.
    i. Establish incentives to encourage collaboration. Incentives could include higher ranking and approval of projects, better funding opportunities, better approval opportunities for potential conference travel, awards and recognition.
    j. Establish accountability process to ensure unhindered cooperation to collaborate.

11. FSMA (recommendations common with Alignment section):

    a. Address issues in OARSA where interviewees felt they were still working to achieve alignment due to becoming aware of the research prioritization system relatively late in the process and due to communication issues (interviewees: "Right now we are scrambling to try to coordinate and be in alignment with what the Center wants to do."
    b. Provide whatever assistance possible to help OARSA, and others, as they go through this process.
    c. Establish better coordination and relationship between offices/Divisions and policy offices and/or stakeholders to improve prioritization and alignment processes.
    d. Initiate effective communication (please refer to recommendations elsewhere).

12. Succession / retention planning:

    a. Increase hiring and conversion of Fellows.
    b. Backfill important positions to ensure continuity of corporate memory and availability of expertise to continue essential work. This will minimize potential gaps.
    c. Publicize/advertise opportunities within and outside the Agency.
    d. Improve the pay scale.
    e. Establish a process to improve scientific staff position levels within the organization.
    f. Review and implement a clear system for promotions across the Agency.
    g. Address issues of inequitable and mismatched levels of educational position.
    h. Improve the work environment. There seems to be a considerable level of disparity when it comes to such position levels as GS-13, GS-14, and the inequitable practice and leverage different offices have in promoting staff. There were complaints that it took

Ph.D. holders much greater effort and time to achieve same position levels which were easily obtained by less qualified individuals.

i. Address issues of Ph.D. scientists expertise not being utilized properly (one example was cited by one individual who claimed that he's/she's a Ph.D. yet washes dishes!).

13. IT:

a. Encourage IT to hire experts with scientific knowledge to better serve the needs of the microbiology program.
b. Consider the possibility of creating a Central Bioinformatics Office to handle high-powered rapid WGS data analysis.
c. Strengthen linkages with WGS centres in different groups.
d. Provide access to open source software.
e. Provide high capacity computational equipment, high capacity data storage and data analysis platforms.
f. Develop a system for rapid flow and sharing of data with and among offices, as well as to a central bioinformatics unit.

14. Award:

a. Improving the awards/promotion system,
b. Increase acknowledgement and appreciation of efforts; promoting/converting staff based on performance, as well as the impact of the project on the Agency's regulatory mission and on stakeholders.
c. Recognize the work of teams and of collaborative projects across the Agency.
d. Consider Award for technicians.
e. Award managers/supervisors only if they have contributed significantly to the team's success.

APPENDIX A. QUESTIONS TO CONSIDER

OFVM Review of Microbiology Labs Capacity, Efficiency and Management

Questions to Consider for Expert Panel Review

FDA is in the process of evaluating the scientific capacity and the management aspects of the multiple elements of the OFVM Microbiology Laboratory program, which includes microbiologists and laboratories in College Park and Laurel, MD, Dauphin Island, AL, and Chicago, IL. Versar has completed one phase of this review, which involved conducting interviews with 94 microbiologists working within the Program and generating a report summarizing the results of the interviews.

As part of the next phase of this review, FDA has requested that a panel of internationally-recognized and respected scientists and managers of large programs with relevant microbiology and laboratory experience to review and analyze the report, *FDA Microbiology Program Review: Results of Microbiology Research Personnel Interviews* (dated July 31, 2014). To this end, Versar has convened a panel of three experts in microbiology laboratory testing and research on food/feed and laboratory management both in government and academic settings. The desired outcome of this part of the review is a set of informed, practical recommendations that FDA may implement to improve the program so that it may better meet current and future microbiology challenges.

Below is a list of suggested questions intended to help focus the review efforts of the expert panel.

1. Interviewees felt that maintaining in-house microbiology capabilities was essential to fulfilling the mission of OFVM's Microbiology Laboratory Program and that the greatest program strength was the quality and diversity of microbiology expertise. In addition, the major program weakness identified in the report was staffing/manpower including insufficient staffing and lack of authorization to backfill and/or hire FTEs and/or convert ORISE or Staff Fellows.

- Does the current level and breadth of microbiology expertise within the Program appear to be appropriate to the needs of the Program?
- Does the current distribution of staff across the offices and groups included in the review appear to be fair and balanced? Are there specific offices or groups that appear to be over- or under-staffed? Are there places in which redistribution of staff or expertise would benefit the program?
- Does it appear that the real or perceived freeze on hiring FTEs and/or converting Fellows within the Program may result in problems in the future with respect to backfilling positions or enabling the Program to meet new microbiology challenges (i.e., implementation of FSMA)?

2. Many interviewees felt there was a lack of coordination among all groups in the Program that was hindering effective utilization of manpower and expertise.

- Does the perceived lack of coordination among groups pose real problems for the Program and if so what are they?

- What steps short of re-organization might be taken in the near or long term to improve coordination?
- Is re-organization necessary to improve coordination among groups within the program and if so, at what levels?

3. Issues related to communication/transparency between upper management and various offices and groups are problems that plague any large organization but were of particular concern among interviewees in groups or offices outside the College Park headquarters.

- Are any of the issues identified by interviewees in the report unique to the OFVM Program and if so what is their level of severity and potential impact on the Program?
- In particular, what steps might be taken to address impact of physical separation on various groups within the Program?
- Based on the report results, are changes specifically needed to improve communication through line management or can the concerns raised by interviewees be addressed via another route?
- Are there any recommendations in general for improving communication and collaboration within the Program across the board?

4. Many interviewees mentioned a culture of competition between ORS and OARSA that may be hindering microbiology research efforts.

- Does the perceived bias within upper management in favor of ORS over OARSA appear to be based on a genuine underlying problem within the Program, and if so, what steps might be taken to address/resolve this problem?
- Does it appear that the competition between these groups may in fact be detrimental to the Program and if so in what ways?
- Short of reorganization, what steps might be taken to encourage and improve collaboration between the two groups?

5. Interviewees within several groups reported problems with line management that were attributed to the lack of permanent, strong, and/or effective line management.

- Are there any specific groups or offices in which line management issues appear to be particularly significant and if so what might be done to address these problems?
- Are there any general steps that might be taken to improve the effectiveness of line management across the board within the Program?

6. Several organizational problems were identified within specific offices/groups including: the division structure within OARSA, the partnership between IFSH and FDA at Moffett Center; and the relationship between the NARMS program and research groups within DAFM, CVM.

- Do these apparent problems appear to be significantly impacting the effectiveness of the above groups/offices?

- Are organizational changes needed to address any of these situations and if so, what might they be?

7. There was concern expressed across groups that the Program is not maintaining an effective balance between basic research and traditional microbiology and expansion into areas of genomics including whole genome sequencing.

- Does it appear that the current distribution between traditional microbiology and genomics-related microbiology is properly balanced and if not, what changes might be made to attain the proper balance?
- Is the expanding focus on whole genome sequencing in keeping with the Program's mission and obligations, particularly in protecting the public health?

8. In terms of future challenges, the impending implementation of FSMA will have a significant impact on offices/groups within the Program.

- Does it appear that the OFVM Program has focused sufficient effort on preparing for the implementation of FSMA? If not, in what particular areas should efforts be increased?

9. Please provide a brief summation of perceived strengths, weaknesses, problems, and potential solutions associated with each office/group: OARSA, OFS/DI, OFS/MC, ORS, and CVM.

APPENDIX B. EXPERT RESPONSE: SABAH BIDAWID

OFVM Review of Microbiology Laboratories Capacity, Efficiency and Management
December 11, 2014

Responses to Questions for Expert Panel Consideration:

Sabah Bidawid, Ph.D.
Chief, Microbiology Research Division, Health Canada, Food Directorate,
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FDA is a large organization with diverse science-based disciplines. It is a world class Agency with well recognized credibility and influence. It is considered a leader in food safety, from the microbiological aspects, and has contributed significantly to the scientific community in various ways. It harbours some of the world's best scientific experts who, over the years, have demonstrated scientific leadership, innovated new science-based approaches, and have contributed to strengthening food safety for the American consumer.

As any large organization consisting of a large number of employees of multidiscipline expertise and complex platforms to address their mission, steering the ship into a different direction amidst the winds of change, as necessary as it may be, is not an easy task, yet necessary to keep up with changing needs. In changing direction, many factors have to be considered, risk-evaluated, and decisions made based on clear goals and a well-defined mission. This, of course, will impact the way the organization will function as a whole.

It is not a secret that times have changed, and adjustments have to be made accordingly to achieve the most effective performance that will have a significant impact on public health and food safety for years to come. Many other organizations are going through the same process as the FDA is. Therefore, this is not a unique situation confined to FDA and its OFVM.

Even though there was a huge amount of information (e.g., personal interviews …etc.) provided, I have approached this review from my personal experiences in microbiology, both as a research scientist and a research manager.

It is obvious that the FDA, and rightly so, is going through a transformative change from decades-long established inquisitive scientific research into a more regulatory-, risk- and prevention-based science that would focus mostly on research outcomes to support its mandated regulatory mission for better preventive controls to enhance the microbiological food safety to consumers. This translates into an almost paradigm shift in the way research is done, projects prioritized, incorporation of new methods and technologies, staffing, refocussing budget allocations, streamlining research duplication, reducing certain unnecessary or near obsolete areas while strengthening others, consolidating efforts, and charting a new long term vision for the organization.

The review report provided good insights into the strength and weaknesses in the current Microbiology Program status at FDA, and what areas I think should be addressed to improve this program.

With respects to the strength at FDA:

- The wealth of well recognized multi-disciplinary expertise currently supporting the Microbiology (MB) program is a definite strength. These experts have established a solid and diverse in-house research program within the confines of one organization, which would be an ominous task to emulate by industry, academia and others.
- The in-house research program and the expertise available are in place to respond to arising situations, with fluidity of changing priorities in a timely manner, which in my view, is unmatched by others. Therefore, maintaining a well-focussed or refocused and mission-driven in-house core research program would be essential to the organization.
- The already existing strong capacity of equipment and instruments within one organization. Furthermore, the acquisition of new state-of the art technologies, such as whole genome sequencing technologies, constitute an additional strength.
- The ability to target different food commodities (produce, meat, dairy, seafood…etc.).
- The existence of centres such as the shellfish program, antibiotic resistance, proficiency testing, processing technologies, proficiency testing, WGS, methodology and validation are unique strength.
- The availability of scientific expertise to target currently known multi pathogens contaminants of food, as well as emerging ones.
- Linkages with national organisations (e.g., CDC) in joint efforts to address emerging issues of importance to public health.
- Linkages with industry, academia, and other stakeholders have contributed to strengthening the safety of the food supply.
- The breadth of national and international collaborations.
- Influence: the scientific expertise within the FDA has, over the years, established a solid respectful reputation world-wide, and in the process has conferred on the FDA a strong credibility which has influenced decision-making outcomes at various international bodies, such as CODEX.

With respect to weaknesses at FDA:

- The breadth of the in-house research may need to be reviewed, streamlined and refocused towards evolving mission-needs, regulatory support, and preventive controls.
- Staffing: this is a definite weakness that has been highlighted by almost all participants in the interview process. This encompasses inability to hire new staff, inability to convert FTEs to permanent positions, inequitable hiring practices by the different offices, inability to backfill vacancies (due to retirements, departures), inability to bring in younger scientists, losing staff from one office to another…etc.
- Management issues were highlighted as key concerns with many interviewees. Some managers were perceived well while others were seen as ineffective, disengaged, and did not represent their units in an effective manner.
- Communication and Transparency: the lack of communication and transparency have been identified, by almost all offices, as major impediments contributing to distrust, confusion, lack of direction, unclarity of objectives, ambiguous decision making process,

uneven handedness in treatment, …etc. In my view, these are serious and pressing issues that can be addressed and improved as part of a short-medium range objective.

- Geographical location/separation: FDA is a vast organization that services the entire USA. Offices in distant locations have expressed some concerns of inaccessibility to upper management, and that they are, to some extent, invisible to decision makers, which may have impacted staffing, funding, project approvals…etc. Options should be sought to give these centres better exposure and inclusion, not necessarily through relocation.
- There is an apparent disconnect, competition and resentment between different offices and groups; e.g., OARSA, CVM, ORS / ORA.
- Duplication of effort: microbiology seems to be conducted in a number of different offices, with little communication, coordination or awareness of what different groups are working on. There is a strong sense among various research groups that there is an unnecessary and wasteful duplication.
- Mandate/Role Creep and lack of coordination: this is best explained as some research groups are creeping into research domains of others, thus erasing boundaries of defined roles and responsibilities. This also results in bitterness, competition, anger, frustration, and duplication of effort.
- Inconsistency of methodologies across the Agency.
- Weakness in supporting virology and parasitology research activities.

Comments and Recommendations:

From the review report, it was obvious that, although there were many common sentiments expressed with respect to the Microbiology program and the current state of affairs at FDA (OFVM), employees at OARSA stood out as the most dissatisfied, with low morale, directionless and nearing a crisis mode. Nevertheless, issues of concern were raised by other units, as well.

Below are my observations and recommendations. Please note that there may be some repetition/overlap of recommendations under different headings. This is due to the blurred boundaries between some of the areas targeted for the review.

1. Review and Reorganize the Microbiology Research:

While there seems to be a reasonable level of satisfaction with the effectiveness of the current organizational structure in the Agency, the microbiology research program seems to be dispersed in a number of different offices within OFVM. This has resulted in duplication, competition and inequitable funding and resource practices. While many of the interviewees were satisfied with the current organizational structure, concerns were voiced particularly related to the interaction between OARSA, ORS, CVM, and the role of IFSH and its predominating role at times, as well as the interaction between CVM, DAFM and NARMS. Concerns were raised by other offices that scientists within OARSA are doing their own stuff irrespective of the regulatory role of the Agency. On the other hand, OARSA's staff is bitter over ORS's favored status and support from upper management providing ORS with the opportunity to build up a competitive microbiology research program, supported by better staffing and funding opportunities. Complaints were also raised with respect to IFSH whisking away staff from other offices to support their needs which seem to override others. I'm not sure if this represents a real problem when the scientific staff

from other offices is being used to respond to/address arising needs of importance to the Agency. Some offices felt that their own microbiology program is in a much more stable and acceptable organizational structure since their function is "unique", such as the seafood program at OFS/DI, food processing technologies and proficiency testing at OFS/MC, the antimicrobial resistance program at NARMS. This level of security and uniqueness was definitely lacking in OARSA.

Recommendations:

- Identify and establish a list of who's working on what, and in which office.
- Identify project relevance to the mandate/responsibility of the office.
- Clarify roles and responsibilities of each office to avoid mandate creep and duplication.
- Identify duplication: eliminate or merge projects of similar nature.
- Identify areas of research across the OFVM (OARSA, CVM, ORA) where research activities can be strengthened through collaborative efforts or a merger.
- Establish a SOP for collaboration within and between, different offices, emphasizing complementarity of expertise rather than competition. Establish a mechanism to ensure compliance with these collaborative rules.
- Establish criteria to identify unacceptable conduct hindering collaboration, and indicate potential consequences which may include, but are not limited to, reducing funding, reallocating the activity to more cooperative teams, unfavorable performance evaluation…etc. Management should be given the authority to impose such actions, and should also be held accountable for implementing needed actions.
- Encourage regular meetings between researchers from within Division and/or the different offices to increase interaction.
- Establish regular inter-office rotational seminars whereby researchers present their work to other scientists in other Divisions/offices. This will allow greater awareness of what different researchers are working on in the different offices, identify potential collaborations, highlight collaborative projects and mutual benefits associated with that (which may initiate incentive for others to follow suite), and would provide a more open platform for greater integration.
- Encourage managers to attend these seminars and to participate in any discussions that would promote collaboration.
- Investigate possibilities to provide OARSA with some unique function (e.g., genomic responsibility) that will give them a sense of stability, as well as provide the opportunity to streamline and refocus their research efforts to better meet evolving Agency's needs as a regulatory authority.
- Consider reorganization of research groups in the Centers, Offices, Divisions, and/or Branches to form more function-defined cohesive research groups.
- Redefine ORA's role and responsibilities. If the focus is on inspection and surveillance, then consider removing research functions from this group and consolidate with other microbiology research groups.
- Consider the possibility of consolidating research by unifying all research groups (OARAS, ORS, OFS/DI, OFS/MC and CVM's OR) under a single portfolio lead by a Research Director within OFVM. Within this unified structure, however, subdivide the research into specialized areas of research, grouping research along functional lines, with

each area headed by a manager. Establish SOP for collaboration, coordination, and sharing of equipment. Managers should be held accountable to ensure effective cooperation and coordination across these units.

- Consider establishing strong linkages, coordination and communication between this unified science research unit and a counterpart unit harboring policy and regulatory experts. Create a Science-Policy Linkage Committee to ensure fluid coordination and interaction between Research and policy Divisions.
- If unifying all research groups is not possible, consider merging the activities of OARSA and CVM. Review functions of OARSA and CVM, and evaluate joining both.
- Re-examine and redefine functions of NARMS and DAFM. It appears that they have more in common than not. If so, consider the possibility of merging both Divisions, under one management
- Even though OARSA's research functions seem unfocussed at present, they have excellent experience and expertise in genomics. Consider creating a Genomics Unit within OARSA where experts in this area may work together. This action might help refocus part of OARSA's research direction.
- Review of the current organization in OARSA, specifically in connection with the Division of Virulence Assessment (DVA) to determine relevance to the microbiology program. A change of name of the DVA was suggested by some staff.
- Consider the possibility of establishing Centers of Excellence in different areas (e.g., E. coli research) within the Center. However, just creating a COE doesn't mean much if others are not aware of and link with its experts.
- Establishment a Bioinformatics Centre within OFVM. Consider either a Central Sequencing Unit or units in different offices.

2. In-house research:

In-house research is an important capacity within OFVM, and should be maintained. However, the research being done, some of which has been going on for years now, needs to be reviewed, evaluated and refocused to meet the new direction of prevention and regulatory implications. Nevertheless, some core investigative and inquisitive research should also be maintained and supported. New research trends and technologies, such as WGS, should be supported.

<u>Recommendations:</u>

- Maintain in-house research, but streamline and refocus projects to align with FDA's mission and regulatory responsibilities.
- Strength of funding should match the strength of project alignment to mandate, as well as to new objectives of preventive measures.
- Establish, across the Agency, clear and consistent criteria for project ranking/ prioritization and funding formula.
- Stream out projects that are no longer supporting the mandate.
- Strengthen research in foodborne virology and parasitology. These are becoming increasingly important contaminants of food.

- Encourage collaborative projects across the different offices in the Agency. Provide incentive to promote collaboration, such as higher ranking score for approvals, more funding, and other potential incentives.
- Redistribute staff as per need and office function.
- Provide strong support to incorporating new technologies.

3. Staffing:

While almost all offices expressed concerns with staff shortages, OARSA was most prominent in voicing their concerns. OARSA feels that they were not given equal opportunity as was available to other offices to hire new staff, backfill vacancies, convert FTEs, or to hire permanent managers. OARSA is a research oriented office that has been doing scientific research in areas that are seeing considerable change. To this effect, scientists in ORA/ORS are filling this gap in research and are being approved and well-funded for it at the expense of OARSA. This is creating a poisonous work environment which has contributed to anger, competition, feelings of inequality, and favoritism. This is, in my view, a serious situation that can impact a smooth progress toward implementing FSMA.

Recommendations:

Please see points 1 and 2 for overlapping comments. If at all possible, mid and/or upper management should partake in the communication part of the recommendations made below. This will provide OARSA staff with a greater degree of comfort and trust in the process.

- Initiate dialogue with OARSA scientists. Assure them that the Agency values the work they do. However, explain clearly that the Agency is steering into a new direction in its research needs which will require adjustments to its research activities.
- Be as transparent as possible with the organization's intentions with respect to hiring/replacing staff. Point out that, in anticipation of FSMA implementation, the breadth of the research program has to be refocused, and that employees will have to adjust and/or redirect their research opportunities, to collaborate with others in other offices, or to reassign staff to other more relevant projects, as possible.
- Create a committee from within OARSA scientists and management to review and evaluate current research at OARSA in relation to new FSMA direction.
- Let the committee identify the projects and deliverables most closely aligned with the Agency's needs, both in core science and those that support regulatory needs.
- Refocus the non-aligned projects, if possible, or provide opportunity to have them modified to fit the purpose. Encourage collaborative projects to avoid duplication.
- Offer opportunities for scientist whose projects are not salvable to join forces with other researchers or move to other offices to work on more pertinent projects.
- Indicate that funding or staffing for irrelevant projects may not be renewed pending the project review process.
- Provide options for shifting type of research to meet evolving needs, as well as training that would link research expertise with policy.
- Hire qualified managers, convert acting qualified managers to permanent. Appoint managers who have sufficient knowledge in the subject matter of area they lead

- Managers should hold regular meetings at the Division level to maintain continuity of communication.
- Although budget constrains may limit hiring ability, consider backfilling important positions in research to maintain expertise, which otherwise maybe very difficult to replace in the future.
- Establish a sound succession plan. This is very important to ensure continuity of corporate expertise.

4. Management/leadership issues:

This issue seems to vary depending on the office and the nature/level of management in place, or the lack thereof. Various aspects were identified with respect to management issues: 1) lack of permanent management, 2) personal conflict between management and staff, 3) management with expertise mismatched to the scientific function of the office they represent, 4) lack of communication and transparency, 5) conflict and/or competition, within Divisions/Offices, between same level management and/or between different levels , 6) management disengaged from the office/unit they represent, 7) weak management (doesn't fight for its unit), 8) first level management (line management) lacking authority, 9) lack of accountability, and 10) lack of clarity and guidance. While different offices had expressed different management issues of concern, greatest dissatisfaction was expressed by OARSA staff as compared to others.

Recommendations:

- Identify dysfunctional management in offices who have expressed concerns.
- Identify factors contributing to the ineffectiveness of current management.
- Provide specific training where training can address and help resolve some of the issues such as those pertaining to lack of experience, unfamiliarity with the position requirement, disorganization, conflict resolution, time management, engaging employees, how to capitalize on staff expertise…etc.
- Reassign managers to other areas where they may be a better fit.
- Initiate dialogue between managers and staff on regular basis.
- Improve leadership at the Division Director level and assign more project managers.
- Improve relations between management at the agency level.
- Select and appoint permanent, strong, and effective management where needed.
- Examine current management layers of authority. Establish a SOP and streamline as needed to produce a more functional, cohesive and effective management.
- Streamline obstacles contributing to difficulties in communicating issues through line management to upper management.
- Hire qualified managers, convert or make acting qualified managers permanent. It would be wise to appoint managers who have sufficient knowledge in the subject matter of area they lead
- Managers should hold regular meetings at the Division level to maintain continuity of effective communication.
- Provide mandatory training to improve managers' people skills.

5. Traditional microbiology research vs new genomic-based research:

It is undeniable that traditional microbiology science and research have laid a strong foundation that has, and continues, to serve the scientific and stakeholder communities well over the past decades. Undeniable too is the fact that science keeps evolving, leading to newer methodologies, approaches, and perspectives. The new advances in genomics are providing us with amazing tools that will significantly enhance our capability to improve the safety of the food supply. WGS is one such technology that is revolutionizing the way we do microbiology, and may influence a shift in direction in various areas, including research, regulatory and compliance applications. It is expected that WGS and Bioinformatics will take the front seat as compared to traditional microbiology, but this should not diminish the value of some traditional microbiology that will continue to serve us well. While there may seem to be an imbalance in the support for WGS as compared to traditional approaches, nevertheless, I think that this is not an unexpected outcome when it comes to supporting new technologies. Therefore, I am with the view that greater emphasis and support should be given to these new technologies as they are evolving to support future mission needs and obligations. Having said that, however, certain aspects of traditional microbiology remain the gold standard and are indispensable and, therefore, they should not be overlooked or dismissed carelessly. Key traditional methods which are essential to regulations and compliance should be maintained and funding should be allocated to support further research to improve these methods. Method development and validation is something FDA does while others (industry and academia) do not.

<u>Recommendations:</u>

- Establish a strong WGS and Bioinformatics program in the Agency.
- Consider establishing a central office for Bioinformatics and WGS. However, an alternative would be to allow different OFVM-associated offices to run their own whole genome sequencing at their locations. Ensure that their WGS function does not duplicate efforts of others. Establish a SOP to define boundaries, limits, and unrestricted sharing of information or data generated across the Agency. While it might appealing to put all WGS activities in a central location, it might be advantageous to give strength in this field of work across OFVM. This will expand knowledge, expertise, and ensures no delays in performing the work. Therefore, this approach will help build up a capacity of expertise in sequencing in different offices, and will be more efficient approach for the long term. Bioinformatic analysis of sequences may be done in a central office to start with.
- As mentioned above, consider the possibility of creating a Genomics Unit in OARSA which will house experts in that field.
- Equip the Bioinformatics Centre with high performing computational equipment and needed software, access to open source software, as well as a high capacity for data storage.
- Encourage IT to hire knowledgeable staff in science and bioinformatics to provide effective support to this increasingly important area of microbiology research.
- Establish a data sharing mechanism for easy data transfer and sharing between offices.
- Provide sufficient training to staff in these new technologies.

- Establish a committee to re-evaluate traditional methodologies and approaches to determine which ones should be maintained and/or improved.
- Provide sufficient funding and support to enhance some key traditional methodologies which are still the gold standard for regulation and stakeholders.
- Re-examine and improve BAM. Review methods, identify obsolete ones, and revamp BAM, accordingly.
- Consider strengthening the fields of virology and parasitology.
- Evaluate the need to enhance work on specific pathogens, including Vibrio parahaemolytica, Listeria, E. coli, molds, and yeasts; genomics.
- Encourage and establish a SOP for method consistency and harmonization across the Agency, and develop a harmonized approach for method validation.
- Prioritize by assessing impact of projects outcomes on public health.
- Strengthen the internal peer review process, and engage experts from different offices in this process.
- Consider utilizing an External Peer Review process in evaluating and prioritizing projects.
- Establish a system to monitor and track progress of projects and potential impact on the Agency's needs and obligations.

6. Communication:

I believe that communication is one of the most important elements/criteria that can easily be strategically addressed and improved, both for the short and long term improvement. While lack of communication is not a unique phenomenon to the OFVM, yet it can contribute to serious issues of trust, morale, productivity, stress, and effective functionality of the organization. Interviewees expressed concerns with respect to a lack or a breakdown of communication between scientific researchers, researchers and management, and within and among management itself across different offices. This is contributing to confusion, uncertainty and lack of needed guidance through this process of change.

<u>Recommendations:</u>

- Hold regular meetings (quarterly) between the first level management (line management, OD, DOD) and staff to discuss current issues and anticipated developments in the program.
- Management should link well with their staff, be as transparent as possible, and establish a trusting relationship.
- Clearly communicate work priorities as they are changing.
- Identify needs and provide guidance on project development, prioritization, and alignment with the new direction.
- Provide updates and rationale on potential changes to the microbiology program direction.
- Hold bi-annual all staff meetings (by WebEx for remote areas) where upper management can update staff on any developments.

- Hold an all staff bi-annual town hall meeting between management (mid or upper) and staff for Q&A.
- Establish an electronic monthly newsletter from upper management to all staff highlighting current activities, success stories across the different microbiology program units, editorials on select units to inform others of the type of work being done across the program. Also, share aspects of FSMA and the process.
- Establish a mechanism for management (at all levels) to receive input and suggestions from staff for management's information and consideration. These could be received either through email or anonymously using suggestion boxes or other suitable means. This would allow the management to be aware of issues, and possibly ideas, that management may wish to consider or simply address in meetings or through the electronic newsletter.
- Management (at appropriate levels) of different Units/Divisions/ Branches should hold regular meetings with each other to discuss program changes and best ways to work together and enhance coordination, with clearer vision, and putting the interest of the organization as their top priority. Consensus on actions may be translated to staff in a transparent way to reduce confusion and provide meaningful guidance.
- Hold Divisional meeting to encourage greater dialogue amongst scientists to discuss and brain-storm new needs and priorities, strategic planning and alignment with the mission, what others in the microbiology program are doing, potential collaboration, best use of funding, …etc. Getting the scientists involved will make them feel valuable and more trusting of the process, and will reduce their "perception" of being ignored.
- Improve communication and transparency concerning how priorities are established, including scientists and/or line management in the prioritization process
- Expedite communication of shifts in Center's priorities, improve communication with the program offices, field laboratories, and stakeholders.
- Establish / develop SOPs to improve communication within research groups (between line management and scientists and among scientists)
- Clarify the prioritization and decision-making process for projects.
- Include scientists in the research prioritization process where possible and applicable. Consider creating a committee including scientist, management, and policy representatives to evaluate, prioritize and make decisions on projects.
- Conduct regular electronic confidential surveys of employees to assess level of satisfaction, issues of concern, work environment…etc. The results and potential solutions should be shared with the employees via electronic newsletter from management to employees.
- Provide mandatory cross-training whereby seats are reserved for staff from each office to attend. This will bring people from different offices together (this point also applies to other areas in this document).
- Provide educational training to update and improve scientific knowledge and to maintain expertise in the field.
- Improve the CARTS process by 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. Consider other models such as the NIH scientific review process and NCTR review system.

7. Alignment:

While considerable parts of OFVM may be better prepared for FSMA implementation, there is evident disarray in OARSA.

Recommendations:

- Address issues in OARSA where interviewees felt they were still working to achieve alignment due to becoming aware of the research prioritization system relatively late in the process and due to communication issues (interviewees: "Right now we are scrambling to try to coordinate and be in alignment with what the Center wants to do." Provide assistance as possible to help them through this process.
- Establish better coordination and relationship between offices/Divisions and policy offices and/or stakeholders to improve prioritization and alignment processes.
- Initiate effective communication (please refer to recommendations elsewhere).

8. Collaboration:

Recommendations:

- Encourage management to support greater collaboration across the Agency.
- Address and resolve issues relating to problems with collaboration 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.
- Encourage and establish a SOP for more effective communication from line management and address issues of lack of interaction across groups and offices within the Centers.
- Identify and resolve difficulties in working with other organizations (e.g., CDC and other federal Agencies).

9. Coordination:

Judging by the comments of interviewees, there seems to be a lack of coordination among the different offices in the Agency. In my view, this is a serious situation that needs to be addressed. The lack of coordination causes duplication of effort, wastes time and money, and can create real problems in the function of the program, particularly in responding to outbreak situations.

Recommendations:

- Encourage project managers of different offices to meet regularly to ensure better coordination between their units.
- Develop a workable structure for coordination across the Agency.

- Increase awareness of coordination efforts between the Centers' microbiological research programs and any Centers of Excellence.
- Clarify roles, responsibilities, and areas of expertise of each office and establish a SOP to promote complementation rather than duplication of efforts.
- Establish an electronic list of Who's Who identifying subject matter experts within the Agency to improve awareness of available expertise across the different offices.
- Publicize research efforts within and outside the Centers
- Encourage project managers to liaison between researchers and other offices, particularly during outbreak response, and clarify roles and areas of expertise for scientists across the microbiology program.
- Encouraging attendance at scientific meetings and seminars.
- Increasing interactions with the different groups and increase direct communication between scientists working in these areas, especially with the ORA field laboratories.

10. Competition:

Some interviewees have expressed concerns with respect to increasing competition among the different offices. Most concerns were voiced by employees of OARSA who believe that other offices (e.g., ORS) are creeping into their research domain, taking away their research activities and/or duplicating them. While some competition may be healthy, excess competition within the same organization could easily lead to negative implications, such as work overlap, duplication, resentment, isolation, anger, territoriality, …etc. Ultimately, this could negatively impact the effectiveness of the organization's function. There seems to be some merit to OARSA concerns that ORS is competing with them. ORS's stronger and supportive management, better staffing process, better funding opportunities, clearer regulatory-driven research objectives, and better alignment with the mission, put ORS in a better position to formulate its research priorities and secures greater approval rating. Thus, the bias felt by OARSA may have contributed to creating a negative environment. Upper management should address this matter strategically and in a clear and transparent manner to reduce these concerns.

Recommendations:

- Hold meetings with the scientists of the affected offices and clearly explain the new direction of OFVM.
- Engage the scientists in a frank discussion and solicit ideas and suggestions on how to adapt to this change.
- Address concerns raised to establish a trusting relationship.
- Clearly define roles and responsibilities of the offices involved, and develop a SOP or protocol to coordinate efforts.
- Discuss potential different options; staff redistribution, collaboration, training, redirection and refocus of projects…etc.
- Define boundaries of research activities to avoid duplication.
- Re-align and prioritize research projects based on clearly defined goals and prioritization criteria.
- Shift scientists to more mission-relevant work in alignment with FSMA.

- Establish incentives to encourage collaboration. Incentives could include higher ranking and approval of projects, better funding opportunities, better approval opportunities for potential conference travel, awards and recognition.
- Establish accountability process to ensure unhindered cooperation to collaborate.

11. FSMA:

FSMA will provide a platform which will steer FDA into becoming a more cohesive, mission-oriented regulatory Agency to enhance preventive controls for food safety from farm-to-table. Overall, I believe that FDA (OFVM) is, to a large extent, prepared to take steps towards implementing FSMA, with the exception of OARSA which seems lagging behind in this process. Upper management has thought-through a comprehensive strategic plan that will assist in this process. Having said that, however, I think that the Agency can momentarily initiate some action-oriented measure to address some of the issues raised and the recommendations made. Addressing these issues early may facilitate the process of implementing FSMA with less disruption. Issues that can be addressed at present include communication and transparency, initial reorganization and staffing, and effort coordination with respect to the anticipated change on certain offices, and the impact of FSMA's implementation on the type of research to be done, staffing matters, redirection of research activities, and prioritization process.

Recommendations (common with Alignment section):

- Address issues in OARSA where interviewees felt they were still working to achieve alignment due to becoming aware of the research prioritization system relatively late in the process and due to communication issues (interviewees: "Right now we are scrambling to try to coordinate and be in alignment with what the Center wants to do."
- Provide whatever assistance possible to help OARSA, and others, as they go through this process.
- Establish better coordination and relationship between offices/Divisions and policy offices and/or stakeholders to improve prioritization and alignment processes.
- Initiate effective communication (please refer to recommendations elsewhere).

12. Succession / retention planning:

Recommendations:

- Increase hiring and conversion of Fellows.
- Backfill important positions to ensure continuity of corporate memory and availability of expertise to continue essential work. This will minimize potential gaps.
- Publicize/advertise opportunities within and outside the Agency.
- Improve the pay scale.
- Establish a process to improve scientific staff position levels within the organization.
- Review and implement a clear system for promotions across the Agency.
- Address issues of inequitable and mismatched levels of educational position.

- Improve the work environment. There seems to be a considerable level of disparity when it comes to such position levels as GS-13, GS-14, and the inequitable practice and leverage different offices have in promoting staff. There were complaints that it took Ph.D. holders much greater effort and time to achieve same position levels which were easily obtained by less qualified individuals.
- Address issues of Ph.D. scientists expertise not being utilized properly (one example was cited by one individuals who claimed that he's/she's a Ph.D. yet washes dishes!).

13. IT :

Recommendations:

- Encourage IT to hire experts with scientific knowledge to better serve the needs of the microbiology program.
- Consider the possibility of creating a Central Bioinformatics Office to handle high-powered rapid WGS data analysis.
- Strengthen linkages with WGS centres in different.
- Provide access to open source software.
- Provide high capacity computational equipment, high capacity data storage and data analysis platforms.
- Develop a system for rapid flow and sharing of data with and among offices, as well as to a central bioinformatics unit.

14. Award:

Recommendations:

- Improving the awards/promotion system,
- Increase acknowledgement and appreciation of efforts; promoting/converting staff based on performance, as well as the impact of the project on the Agency's regulatory mission and on stakeholders.
- Recognize the work of teams and of collaborative projects across the Agency.
- Consider Award for technicians.
- Award managers/supervisors only if they have contributed significantly to the team's success.

Appendix B-A

Strengths and Weaknesses *At a Glance*

Strengths:

1. Multidiscipline expertise
2. All located in same organization
3. Good blend of traditional and molecular biology
4. Well respected and trusted, nationally and internationally
5. Considerable national and international collaborations
6. Unbiased research
7. Biosafety 3 level containment unit
8. Up to date with recent advances in methodology and new technologies.
9. All resources (expertise and equipment and structure) at hand with flexible adaptability to quick change in direction when emerging issues arise.
10. Work closely with other government entities, industry, academia, and other stakeholders
11. Unique expertise in food processing and preventive control
12. Proficiency testing capacity
13. Doing specialized research that no other groups can or is willing to do
14. Rapid response to outbreaks
15. The work output supports regulation, and influences international decisions (e.g., CODEX)
16. Have huge culture collection
17. Methodology and new technology (e.g., WGS)

Weaknesses:

1. Staffing and Management issues
2. Lack of sufficient communication
3. Lack of sufficient coordination
4. Lack of collaboration
5. Perceived or real unequitable treatment among the different offices
6. Low Morale (particularly in OARSA)
7. Duplication of effort
8. Space limitation
9. Using ITT graduates is flawed
10. Weak on virology / parasitology activities
11. Award and recognition processes not working well
12. Lack of awareness of what others in other offices are doing
13. Need expertise in Bioinformatics

Appendix B-B

Short-to-Long Term Recommendations *At a Glance*

Short-Mid Term Recommendations:

1. Staffing
2. Develop parameters/criteria/SOP to rank/prioritize projects
3. Review suitability of current leadership
4. List of experts across FDA
5. Establish accountability process for managers
6. Train or replace managers who are not fit for the job
7. Apply equal treatment
8. Revise organizational structure and function
9. Improve communication
10. Organize Face-to-face meetings
11. Awards, recognition→ on merit--. Not to managers unless contributed. Allow managers to create their own awards to staff
12. Publicize microbiology research
13. Who's Who list of expertise
14. Improve awareness of what others are doing→ increase interactions with groups
15. Refocus on Mission
16. Management to encourage cooperation and coordination← with incentive
17. Instil a culture of respect among the different groups through training and seminars, meetings
18. Utilize expertise properly: I'm a PhD but wash dishes
19. Conduct online staff surveys and share results and actions
20. Establish consistency of process across OFVM→ incorporate scientists and disciplines at the start of the process
21. Maintain a core in-house science unit for emergency
22. Consider assigning one Administrative person per Division/Office to be responsible for procurements
23. Create a Project Review Board to evaluate, prioritize and approve projects.
24. Promote science that addresses prevention and metrics
25. Identify outputs and outcomes
26. Initiate all staff and town hall meetings
27. Encourage line managers to start annual Division's Appreciation Day where certificates of appreciation are awarded to select high performers among staff.
28. Develop a system for improved internal peer review
29. Create electronic newsletter from upper management sent to staff on monthly basis
30. Arrange more internal symposia and encourage staff to attend.
31. Offer on-line courses; cross-training
32. Establish sop for research collaboration between offices
33. Develop a system for methodology consistency across the Agency
34. Engage external experts for reviews

35. Encourage upper management at FVM & CFSAN, CVM and ORA to hold regular meetings
36. Address obstacles of collaboration, coordination between CFSAN, CVM and ORS
37. Tell your story to the public
38. Create committee to implement recommendations
39. Reduce culture of competition
40. Organizational problem: address 1) Division structure within OARSA 2) partnership with IFSH at Moffet Centre 3) relationship between NARMS and res group within DAFM
41. Address "perception" of inequality treatment
42. Some offices fill unique niches. Address those that don't and suggest solutions.
43. Identify gaps in research
44. Maintain and strengthen mission-critical science capabilities

Longer term:

1. Review Organizational structure.
2. Resolve Staffing and Management issues
3. Enhance WGS and Bioinformatics. Create Central office for Bioinformatics,
4. Revise BAM and incorporate new validated methods.
5. Establish Preventive Control Division
6. Joint NARMS and DAFM functions
7. Assess different research areas→ assess mission-critical ones→ allocate resources and $
8. Identify impact of research on program and PH—Metrics
9. Clarify what other offices (produce, dairy, field labs) need from us
10. One research office with one OD (so no competition between ODs) → only 2 research units in two offices
11. Realign and combine microbiology labs
12. Review staffing across offices, allocate equitably as program needs.
13. Promote collaboration utilizing incentive approach
14. Integrate new technologies
15. Implement FSMA with proper communication
16. Review all microbiology science across all offices
17. Merge microbiology program of different offices/Divisions under one unit
18. Remove research from ORA→ ORA to do only inspection and surveillance, not research
19. Allocate staff on scientific needs
20. Coordinate purchases and increase oversight of expenditure on large equipment
21. IT: Establish a centralized IT structure with high computing equipment, large storage capacity, efficient data transfer and sharing, access to relevant open source software. IT people should understand science needs. Improve video conferencing
22. Consult with Stakeholders: find what they need microbiology research to do
23. Method consistency and validation across the Agency
24. Provide training as needed
25. Enable movement of staff across the organization
26. Establish clear hierarchical accountability

27. Determine research priorities:
    a. Get priorities in consultation with regulatory office
    b. Fix CARTS to be more objective system and speed up approval process
    c. Streamline: there are 10-20 committees trying to prioritize research but PIs never get invited. Maybe CFSAN chief scientist forms a Project Review Board of senior scientists to meet and prioritize and make decisions.
    d. Establish and implement centralized planning and performance measurement process
    e. Identify critical risks that affect foods and food safety, and metrics to measure public health outcomes.
    f. Develop a clear uniform template with Executive summary for projects and rank based on clear set of criteria.
    g. Prioritize methodology for inclusion in BAM
    h. More balance between senior and junior staff
    i. Reduce competition

APPENDIX C. EXPERT RESPONSE: EMILIO ESTEBAN

OFVM Review of Microbiology Laboratories Capacity, Efficiency and Management
December 11, 2014

Responses to Questions for Expert Panel Consideration:

Emilio Esteban
FSIS Field Services Laboratory, Executive Associate for Laboratory Services, USDA

The purpose of the review is to make recommendations to improve Office of Food and Veterinary Medicine (OFVM) microbiological laboratory capacity and capability. The recommendations are based on a review of multiple background documents provided by the task organizer and supplemented with information available via the FDA website. The recommendations address four areas:

- How capacity is deployed and applied across the program;
- How efficiently resources are managed;
- If microbiology research is meeting program needs; and
- Examining how OFVM's microbiology program interacts with other U.S. government and state agencies, the external scientific community, and other external stakeholders.

OFVM has a very broad responsibility. The current organizational structure is multilayered, both horizontally and vertically, and with overlapping responsibilities. The goals for the microbiology laboratory program should be based on a strategic plan. Each Center, Office, Division, and Branch should have a clear scope of operation with acknowledged areas for cross-collaborations. The Food Safety Modernization Act (FSMA) mandates an organization that protects food from the farm to table and incorporates strong hazard prevention controls on imported and domestic food. I perceive the scope of the microbiology laboratory program to include scientific support for prevention, monitoring, and response of food safety challenges across the entire farm to table continuum.

OFVM is structured today with two Centers, CVM and CFSAN, both having research components. CFSAN has several groups (Office of Research, Mod 1 (OARSA); Office of Food Safety; and Office of Regulatory Science) with research activities. CVM has the Office of Applied Research and Safety Assessment, Mod 2 which also has research capability. With so many independent groups conducting research, there is inevitable resource competition and functional overlap. The current organizational structure appears to be quite inefficient with multiple administrative structures and distinct research silos. Somewhat troubling is the fact that in the almost 200 page FDA Microbiology Program Review that reflects the opinions of 94 interviewees in OFVM, there is not a single reference to the needs and work done by the ORA labs. It appears these FDA labs also conduct their own method research and development work, while the CFSAN and CVM researchers do their own. While this subject is beyond the scope of the review, it points to a broader potential for disconnect between research and regulatory work.

The current OFVM structure appears to be the result of many years of reactive thinking rather than visionary development of a flexible structure based on long term operational and structural concepts. Such a revision would allow for the microbiological program to absorb any new

challenge. For example, there is no need for having multiple Salmonella experts each working independently on water, seafood, processed foods, and produce. There is however, a need for expertise in Salmonella detection technologies that cross across pathogen and substrate, concurrent with the need to understand the particular characteristics (genotype, phenotype, virulence) of the target and the unique challenges of the different food matrices. Strategic goal 5, from the CFSAN 2011-2014 Strategic Plan aims to improve adaptability and responsiveness. Alignment of research, prioritization of research, flexibility in procurement, planning for funding variability are listed as the key expected outcomes. It appears that the current organizational structure purposely ignores this goal. Each group works independently, duplicating research, with no procurement structure, and no apparent long term business plan for investment in research.

One consistent comment across programs seemed to be the lack of FTEs, while at the same time there is an acknowledgement of duplication of research. It would appear that the solution is not to add FTEs, but rather combine expertise into better structured groups or clearly define objectives so that work is not duplicated.

As with any other Federal Agency with multiple locations nationwide, physical separation from headquarters may be a detrimental factor (for those away); however, the significance of the separation drops sharply if the goals and expectations are clearly communicated and constantly revisited. Who is the customer for ORS and for OARSA? If both Offices are under CFSAN what is their distinct product? Once again, it is clear that there are no clear and defined deliverables for each Office. The OFVM annual performance plan should clearly indicate the goals, objectives, and action items that are expected from each Office which in turn has to communicate these to Divisions and Branches and, very importantly, monitor progress towards achieving the goals. The CFSAN 2011-2014 Strategic Plan states that the focus was on "measurable outcomes useful for regulatory science". How then is it possible that the ORA labs are not a consideration in the research conducted by CFSAN and CVM? The same strategic plan lists the examples of research outcomes. Wouldn't a logical approach be to associate these outcomes with an office responsible for delivering the product? Unless management assigns tasks, merely listing goals encourages competition between FDA researchers rather than collaboration.

The current structure lacks order and consistency across laboratories such that the information that is generated by one group is not only shared, but applicable to the work done in other areas. While the CARTS system seemed to be an excellent attempt at approving research projects and sharing information, it is not functioning as designed. It's impossible to manage an organization without commonly shared and clear goals.

The Microbiology Program Review report suggests that the vast majority of the staff is not aware of the changing OFVM needs. As researchers, we tend to focus on our work in a particular area of interest. This is great for achieving targeted results but is detrimental to the system if the lifeline of the research outlives the need for that type of research. There may always be need for basic culture-based microbiological techniques, but technology is evolving much faster than the current laboratory culture can manage. The report includes multiple references to preferential treatment given to genomics over other more traditional areas. There is no question that much of

the lab technology is moving in the direction of culture independent technologies. Rather than fight the trend, staff should embrace the opportunity. While at one time FDA set the standard for a single approved regulatory method, the focus should change to performance-based methods. This is particularly concerning in CVM where some NADA methods date back 20 or 30 years. Rather than mandating a specific technology, one should focus on the objective (i.e. to find a specific target at a specific level in a particular matrix). Such an approach would maintain FDA current, or even ahead, of analytical regulatory needs for national or international support.

FDA needs to retain in-house expertise because there are unique requirements only attractive to Federal entities. Not only does FDA have world experts, it also has the state of the art facilities and recognition to be a leader in food safety and veterinary medicine. As with any other large corporation, there are moments for reassessment prompted by social, political or economic changes. The most important resource of any Agency is its personnel. The most common source of malfunction is a loss of a common objective and specifically the role of each employee plays in achieving the objectives and goals.

Below we present some recommendations that we feel will enhance the operation of the OFVM and two limitations that may affect the value of the recommendations.

Recommendations

1. Revisit the 2012-2016 strategic priorities of the FVM program. Create a workgroup composed of leaders from the current offices and with deliberate care go through each goal and objective to align the current activities to each of the objectives. This exercise should clearly expose areas of duplication or gaps. Research currently being conducted that does not address any of the objectives, must be looked at with care to assess its worth. Not all goals may be relevant to laboratory work but the simple exercise of looking at the entire program should create some sense of common mission. In addition, this exercise could be the foundation of the next five year plan which will be completely under a FSMA environment. Specifically, Program Goal 3 states the need to implement an integrated approach to research that links regulatory goals to research needs. Following through with the implementation of the key initiatives listed under this goal will lead to a more effective organization.

2. Increased staffing is not a solution unless all other options are first considered. Short of a very painful and lengthy reorganization, leadership at OFVM needs to implement a significantly strong communication campaign that reintroduces Center leadership through the Strategic Plan and the Annual Performance Plan. Each one of the current Divisions, Branches or Teams, need to know exactly what is to be expected as well as a timeline for delivery. Adding personnel is never the only solution; it is however, a very simple excuse for not producing results. Whether more personnel or a partial realignment is needed, would be part of a focused review based on the deliverables identified in the strategic plan.

3. All about ME should be all about US. Throughout the entire Microbiology Program Review report, we find complaints about one office getting more attention, having more resources, not having communications from “the front office”, and lacking leadership. It appears, we need a moment of introspection. Rather than observing what is good at another program, we

should identify what "we" can do to contribute to a common goal, thus attracting the Agency's attention which would consequentially lead to staff, funding, enhanced communication, etc. We recommend management clearly communicates the organization goals and then follows up with clear expectations for collaboration and focus that lead the organization to meet the objectives. It is clear that internal competition and dysfunction is holding back the entire system.

4. Leverage the FDA brand name. OFVM's number one asset is its staff. Collaboration with other regulatory and research organizations is essential in making sure that public health is the primary focus of the activities. CVM and CFSAN need to be informed, involved, and proactive. One cannot remain as a leader while working in a vacuum. Collaborations with other Federal Agencies, academia, and industry, such as the ones currently in place with the Centers for Excellence, must be evaluated and strengthened to enhance the value to CVM and CFSAN. How does research done in-house relate to the work being conducted at the CERSI? Could the intellectual capital at these CERSI be the answer to the perceived need for additional in-house staff? Activities conducted at the CERSI including MC and DI should supplement, not supplant or duplicate, activities conducted within the FDA Offices. There are significant benefits of working through agreements with academia such as JIFSAN, IFSH, NCNPR, WIFSS, and the Center for Excellence at the University of Arkansas. There will be an inevitable competition for resources between in-house researchers and those at the collaborative centers. The key to minimize this feeling is to be exquisitely clear on the distinction of deliverables and the advantage of conducting this research outside the Federal Centers. Some examples may be the ability to attract a constant flow of young researchers, different budget and procurement requirements, management and personnel flexibility, etc. Not all research is an eminent governmental responsibility. The environment is changing much faster than the Federal bureaucracy. We must identify and leverage those opportunities to benefit FDA.

5. Communicate, communicate, communicate. The survey suggests significant lack of focus, clarity of mission, and, most importantly, distrust in leaders. Even if this is not a widespread feeling, the fact that it was raised by a fraction of those surveyed leads us to believe that there is a need for enhanced communication. The recent appointment of a new CFSAN director provides an excellent opportunity to do a top to bottom reassessment of OFVM under FSMA. Everyone must know their role, their area of contribution, and their deliverable. There may very well be good and bad managers. Having clear goals will allow good managers to deliver and not so good managers to be identified so additional training can be offered. Not all scientists are good managers and not all managers can be scientists. Top management needs to be aware of the differences that exist between working at headquarters and away. The method, frequency, or style of communication might be different but the message must be the same.

> Through the personality or effectiveness of their leaders, some programs within offices may appear to be stronger than others. This attracts attention, resources, and staffing. Rather than trying to equilibrate the distribution of resources, we should recognize these leaders and build around their success.

6. Structure should be defined by function. The CFSAN Science and Strategic Plan for 2011-2014 clearly listed five strategic goals. It appears that absolute freedom was given to centers, offices, divisions, branches, and teams to pick and choose how to address those five goals. This

has resulted in an apparent uncoordinated approach that favors competition and duplication of effort. Consolidate ORS and OARSA into a single Office with Divisions that address a functional process rather than a specific area. A simplified structure will require less managers, facilitate communication, and identify common objectives. Examples of potential divisions under a single office of research are:

- Administrative Infrastructure
  - Provide the backbone for the technical areas.
    - Laboratory Quality Assurance (proficiency testing, method repository)
    - Personnel and procurement
    - Bioinformatics and communication (LIMS, data flow)
    - Stakeholder collaborations (intra/extramural)
- Detection Technologies
  - Develop, validate, and implement laboratory methods for detection of the target. This Division could be organized by:
    - Type of target (microbe, parasite, virus, allergen, additive, supplement)
    - Type of substrate (produce, seafood, processed food, water)
    - Type of technology (basic micro, molecular detection, chemical)
- Characterization Technologies
  - Learn about the target (infectivity, pathogenicity, virulence, phenotypic, and genotypic characterization).
- Strategic Prevention and Control
  - Interventions based on the detection and characterization knowledge (by primary production to consumption stage).
- Response
  - Outbreak response and follow-up based on the knowledge and products generated by the detection, characterization, and prevention divisions.

In summary, the six recommendations above suggest a stepwise approach to address some of the inefficiencies documented in the FDA Microbiology Program Review. The process starts with revisiting the Strategic Plan, aligning the expected outcomes to individual groups, and creating a current status report. After this review, there will be obvious areas where one can find efficiencies thus identifying the need (or not) for additional staffing. The root of most of the discomfort is loss of mission objective. The current group of offices and collaborative centers has been reactive rather than proactive. Under FSMA, it is essential that FDA look forward and create a structure that is versatile. The need for basic microbiology will decrease, but will always remain at some level. We cannot continue to grow the Federal workforce. There are other mechanisms, such as the collaboration centers and other Federal Agencies that we can leverage to remain relevant and up to date without more staff. We have to recognize that the world is more fluid. Telecommunications allows for virtual associations and we must embrace the reality that the differences between headquarters and non-headquarters are not due to physical location as much as learning to communicate with different media. Those of us that don't adapt to the new telework environment, will be left behind. FDA must continue to leverage collaborations without losing its identity. The FDA name brand has a level of quality and recognition that should not be diluted by the proliferation of collaborative centers. With at least five centers for excellence, OFVM is at risk of expanding beyond its capability to manage focused growth.

Again, any investment must be carefully reassessed to justify not only its short term value but also its future need. After a clear review of current projects, OFVM may want to consider realignment to eliminate duplication and improve operational performance.

Limitations

- The vast majority of the information comes from 94 interviewees. I could not find any statement regarding the representativeness of the comments or the population denominator for each of the offices. One has to assume that while tainted by those with negative opinions, the interviews convey a general sense of discomfort by those in OARSA, independence by those in OFS/DI, and OFS/MC, and adequacy by those in ORS and CVM.

- There is limited information available regarding the research portfolios for each of the branches and divisions. Without this factual information, it's difficult to discern between the perceived duplication of efforts and an actual overlap of activities. One has to assume that the stated negative feelings are factual, at least as stated by those interviewed.

- This is a snapshot of a very large entity with multiple moving parts. As part of a Federal Agency, OFVM will have to address a moving target at a time when FSMA is being implemented. The economic and political climate is in continuous flux. The information we have today may change in significance next year. The most significant challenge is to stay on message while the environment changes.

APPENDIX D. EXPERT RESPONSE: RICHARD ISAACSON

OFVM Review of Microbiology Laboratories Capacity, Efficiency and Management
December 11, 2014

Responses to Questions for Expert Panel Consideration:

Richard Isaacson, Ph.D.
Professor of Microbiology, Department of Veterinary and Biomedical Sciences,
University of Minnesota

[Organized by charge question; questions in **bold**]

1. **Interviewees felt that maintaining in-house microbiology capabilities was essential to fulfilling the mission of OFVM's Microbiology Laboratory Program and that the greatest program strength was the quality and diversity of microbiology expertise. In addition, the major program weakness identified in the report was staffing/manpower including insufficient staffing and lack of authorization to backfill and/or hire FTEs and/or convert ORISE or Staff Fellows.**

Activities represented in the OFVM are important for FDA and should remain in FDA. These activities are performed by dedicated research and development scientists that can rapidly address important new issues in food safety and food quality as they arise. For a unit dedicated to food safety and regulatory actions, having to "farm" this out would be inefficient, and outside research units probably would not have the expertise at the ready to perform time critical work.

- **Does the current level and breadth of microbiology expertise within the Program appear to be appropriate to the needs of the Program?**

  The breadth and depth of the staffing is not really apparent from the information provided. The interviews suggest that there is breadth and excellent expertise. Most statements were based on knowledge of their own groups. It is noted that it was stated several times that there was need to have disciplinary expertise in specific areas, particularly pathogen-specific molecular pathogenesis. The reasons for this need were not stated and based on the assumed responsibilities of FDA, it is not clear why this need is required. While some level of disciplinary expertise is needed, it would seem that generalists might be really important for FDA.

- **Are there specific offices or groups that appear to be over- or under-staffed? Are there any obvious places in which redistribution of staff or expertise might benefit the program?**

  This is very difficult to determine as no one seems to understand the rationale and focus behind many of the research activities.

- **Does it appear that the real or perceived freeze on hiring FTEs and/or converting Fellows within the Program may result in problems in the future with respect to**

backfilling positions or enabling the Program to meet new microbiology challenges (i.e., implementation of FSMA)?

It is claimed that many of the scientists will retire in the near future. The implementation of FSMA is going to require many new actions and even at the current level of staffing, it is likely going to be difficult to address all that is contained in FSMA. The concept of succession planning needs to be seriously considered.

2. **Many interviewees felt there was a lack of coordination among all groups in the Program that was hindering effective utilization of manpower and expertise.**

This seems to be one of the most predominant and critical issues raised during the interviews. Without information from management side, I am left with a real concern that this a dysfunctional group.

- **Does the perceived lack of coordination among groups pose real problems for the Program and if so what are they?**

  YES. This is a key issue that needs solutions. It is difficult to tell if there is duplication and to what degree duplication is desired by management. It is understandable that some levels of duplication are necessary but to what extent and where needs to be stated. Coordination and communications have severe effects on morale and that seems to be a continual theme heard during the interview phase of this review. Tied to this, there is little communications between the different groups and this leaves everyone with a lack of how what they are doing fits the mission of the larger OFVM.

- **What steps short of re-organization might be taken in the near or long term to improve coordination?**

  I don't see any simple or easy fixes.

3. Issues related to communication/transparency between upper management and various offices and groups are problems that plague any large organization but were of particular concern among interviewees in groups or offices outside the College Park headquarters.

This message was heard loud and clear. The message seems to be more pervasive than in other organizations and is having an effect on morale.

- **Are any of the issues identified by interviewees in the report unique to the OFVM Program and if so what is their degree of seriousness and potential impact on the Program?**

  This is very serious but seems to go beyond the management to scientists. It is a two-way street and I'm not certain that communications to management occurs. Furthermore, and to point to the degree of dysfunction, there also does not appear to be communications

between scientists within a group or between groups (especially as is relates to off site groups).

- **In particular, what steps might be taken to address impact of physical separation on various groups within the Program?**

  A communications team is needed to develop best practices for communicating in all directions. CFSAN and CVM should consider video conferencing on a regular basis with all groups (quarterly) and should consider regular face to face meetings within groups, between groups, and to and from management. Currently it seems as though there is management and there are scientists with not good linkage. Again, this conclusion is based on what the scientists stated and does not take into consideration a management perspective.

- **Based on the report results, are changes specifically needed to improve communication through line management or can the concerns raised by interviewees be addressed via another route?**

  This must be addressed head on through management.

- **Are there any recommendations in general for improving communication and collaboration within the Program across the board?**

  Right now collaboration does not appear to be effective. This is because the OFVM is fragmented with little communications. In addition, what is the incentive to collaborate? Shouldn't management be directing where collaboration should be occurring since they are the ones who have the bigger picture and are the ones who are responding to FDA needs. Currently there is perceived distrust among groups of scientists and their management.

4. Many interviewees mentioned a culture of competition between ORS and OARSA that may be hindering microbiology research efforts.

This point was repeated many times, but there was little information to clearly understand the specifics. The one example that was clearly stated was related to whole genome sequencing.

- **Does the perceived bias within upper management appear to be based on a genuine underlying problem within the Program, and if so, what steps might be taken to address/resolve this problem?**

  The message from the scientists was that those involved with the WGS work were favored over all others. This was confirmed by the WGS group who stated that their way was the way of the future. To me, the biggest flaw here is that the directions of the WGS group were not apparent. Their goals and FDA's needs were not stated. While WGS is a state of the art technique and has much analytical power, its usage is really dependent upon the outcomes sought. In many instances, more traditional techniques are more than

adequate. Perhaps of another concern is that the makeup of the WGS group was not stated and very little was stated about bioinformatics. Is FDA really committed to this direction and have they adequately invested in the correct personnel and disciplines to accomplish their goals? I state this, because the goals are not apparent and I interpret the outside group scientists to not even understand the goals of WGS. Does FDA even have a sense of outcomes and needed definitions of success?

- **Does it appear that the competition between these groups may in fact be detrimental to the Program and if so in what ways?**

  YES.

- **Short of reorganization, what steps might be taken to encourage and improve collaboration between the two groups?**

  This is a major issue without an easy fix.

5. Interviewees within several groups reported problems with line management that were attributed to the lack of permanent, strong, and/or effective line management.

This was a message that carried through many interviewees and between groups. It's necessary to have excellent management that truly understands microbiology, the goals of a group, and how it fits with the FDA's goals. This was stated from several groups. Some felt that there was a lack of support and this was related to expertise and the lack of permanent managers. Where WGS appears to be well supported, the other groups need a strong managerial supporter in their "corner".

- **Are there any specific groups or offices in which line management issues appear to be particularly significant and if so what might be done to address these problems?**
- **Are there any general steps that might be taken to improve the effectiveness of line management across the board within the Program**?

  If excellent managers cannot be hired, it would be preferable to combine some groups to where at the least there was good management. The scientists feel as though they are off on their own with little Agency support**.**

6. Several organizational problems were identified within specific offices/groups including: the division structure within OARSA, the partnership between IFSH and FDA at Moffett Center; and the relationship between the NARMS program and research groups within DAFM, CVM.

- **Do these apparent problems appear to have potential to significantly impact the effectiveness of the above groups/offices?**

This is probably one of the least significant problems. As communications improve, this should be an area where scientists on both sides are brought together to improve these interactions.

- **What possible changes might be made to address any of these situations?**

  [Not answered.]

7. There was concern expressed across groups that the Program is not maintaining an effective balance between basic research and traditional microbiology and expansion into areas of genomics including whole genome sequencing.

The question of the mix of basic and applied research is one that management must make. FDA is a service unit and to what extent is basic research needed? It is my opinion that the focus is on applied research that improves food safety and allows FDA to provide informed regulatory decisions. A certain degree of basic work is needed but it must fit within the scope of FDA's needs. Within HHS, basic research is the domain of NIH, while within USDA (mentioned because of its link to NARMS) it is within ARS. A certain degree of entitlement was perceived around this issue of basic research. Specifically that the scientists deserve to be able to do basic research and that they know better. To some extent, this also is tied to scientist development and promotion. It was stated by many that promotions required publications and that much of the microbiological research was applied and not publishable. Thus, alternative goals linked to promotion and reward are needed. Regarding WGS, the amount needed must be tied to the goals of FDA. This must be balanced with their specific needs and the recognition that staffing is limited. What is the end product of WGS? Does FDA believe that they can transition most of their research to link with WGS?

- **Does it appear there is an imbalance in the current distribution between traditional microbiology and genomics-related microbiology, and if there were such an imbalance in what way might it be addressed?**

- Without an understanding of the goals, the exact balance is difficult to determine. Much of what FDA does not require WGS. They must consider the cost of this on completion of other goals.

- **Is the expanding focus on whole genome sequencing in keeping with the Program's mission and obligations?**

  This must be based on goals.

8. In terms of future challenges, the impending implementation of FSMA will have a significant impact on offices/groups within the Program.

- **Does it appear that the OFVM Program has focused sufficient effort on preparing for the implementation of FSMA?**

Very little was stated about how prepared OFVM was for FSMA. Do the scientists even know what is coming? It is clear that FSMA will impact the OFVM in a very real way. A common theme from the scientists was the lack of manpower and this will be impacted to a large extent by FSMA and imminent retirements. Does management perceive that they have the expertise and quantity of scientists to make FSMA happen? What compromises will be made as currently manned?

9. Please provide a brief summation of perceived strengths, weaknesses, problems, and potential solutions associated with each office/group: OARSA, OFS/DI, OFS/MC, ORS, and CVM.

Below is an outline of my main take home messages.

1. Serious issue of communications
   a. Communications with and from "management" is perceived as lacking
   b. Communications with and between groups is perceived as lacking.
2. There appears to be an air of entitlement
   a. We know what we are doing
3. Seem to have little guidance on what to do
4. Lack of permanent leaders for some is a major issue
   a. Many management leaders don't know what the group is doing and frequently are not even trained in the discipline.
5. There does not appear to be a plan for succession
6. Genomics and whole genome sequencing is a contentious issue
   a. There does not appear to be a perceived strategy or goal
   b. WGS appears to be a favored topic
7. Scientists do not receive feedback both from management and possibly within and between groups.
8. Scientists are not aware of what it will take for promotion
9. There appears to be unhealthy levels of competition and in-fighting between groups
10. Off site groups are not aware of what's going on in DC