ORA HUMAN FOODS AND COSMETICS WORK PLAN
RESOURCE SUMMARY
FY 2018

PPS NO.	PROJECT TITLE	INSPECTIONAL FTES		ANALYTICAL FTES	TOTAL OPERATIONAL FTEs
		DOMESTIC	FOREIGN	DOMESTIC	
	TOTAL	527.30	55.96	235.29	818.55
03	FOODBORNE BIOLOGICAL HAZARDS	384.97	55.96	116.84	557.77
04	PESTICIDES AND CHEMICAL CONTAMINANTS	13.97		75.90	89.87
07	MOLECULAR BIOLOGY AND NATURAL TOXINS	6.59		11.87	18.46
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	78.44		0.88	79.32
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	38.93		24.52	63.45
29	COLOR AND COSMETICS TECHNOLOGY	4.40		5.28	9.68

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Foodborne Biological Hazards- 03

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			INSPECTIONAL		ANALYTICAL		
			DOMESTIC	FOREIGN	DOMESTIC		
	TOTAL		**385.04**	**55.89**	**116.84**	**557.77**	
1	Foodborne Biological Hazards	03F810*	60.45		43.21	103.66	03-2-4
2	Domestic High Risk Inspections	03F811*	85.59			85.59	03-5
3	Domestic Non-High Risk Inspections	03F812*	62.60			62.60	03-6
4	Preventive Control Inspections	03015	22.32			22.32	03-7
5	Responsive Investigative/Laboratory Operations	03F813*	92.83		44.69	137.52	03-8-10
6	Foreign Foods Inspections	03R233		55.89		55.89	03-11
7	CFSAN Environmental Sampling Assignments	03F830*	61.25		**28.94	90.19	03-12
	* These PACS are for planning purposes only.						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC.						
	** These include 10 MICRO FTEs for Collections						

CENTER WORK PLANNER/TELEPHONE	ORA PLANNER/TELEPHONE
Mallory Kelly 240-402-2401	Shilpa Sainath 240-402-9912

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	
Foodborne Biological Hazards	Foodborne Biological Hazards - 03	
3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03F810, 03R882, 03844H, 03R878, 03R843, 03R881, 03F860, 03037, 03R816, 03803E	X ORA X CENTER	103.66 [25.12]

	6. ORGANIZATION	3rd PARTY ACCRED-ITATION ACTIVTIES (HOURS) 03R882 (1)	EXPORTER CERTIFICATION ACTIVITIES (2)	DOMESTIC INSPECTIONS IMPORTER 03844H (3)	DOMESTIC INSPECTIONS FSVP 03R878 (4)	FOOD CONTRACT INSPECTION AUDIT MGT (HOURS) 03R843 (5)	SANITARY TRANSPORTATION DOMESTIC INSPECTIONS 03R881 (6)	DOMESTIC INSPECTIONS SPROUT FIRM ASSIGNMENT 03R879 (7)	DOMESTIC SAMPLE COLLECTION PROC. AVOCADO FUTURE STATE 03F860 (7)	DOMESTIC SAMPLE COLLECTION FRESH HERBS FUTURE STATE 03F860 (7)
	TOTAL ORA	**1900**	**75**	**211**	**224**	**2850**	**150**	**90**	**500**	**634**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
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OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
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LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION			32.00	16.00	16.00		0.50	32.00	6.00	6.00
TOTAL HOURS		1900.00	2400.00	3376.00	3584.00	2850.00	75.00	2880.00	3000.00	3804.00
CONVERSION FACTOR		950.00	950.00	950.00	950.00	950.00	950.00	950.00	950.00	950.00
TOTAL OPERATIONAL FTEs		2.00	2.53	3.55	3.77	3.00	0.08	3.03	3.16	4.00

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

(1) Resources for activities include application reviews and on site evaluations of Accreditation Bodies that apply for the Third-Party Certification Program, and audits of recognized Accreditation Bodies.
(2) Exporter Listing Activities resources are to be used for EU (or other applicable countries) activties (including dairy, gelatin and seafood).
(3) Importer Inspections will be jointly done by HAF and Imports CSOs. Resources planned here are only for HAF CSOs. Division allocations may be updated in FY18; based on trained seafood HAF CSOs and past violations.
(4) FSVP Inspections will be jointly performed by HAF and Imports CSOs and the resources planned here are only for HAF CSOs. The Division allocations will be provided when the assignment is issued in FY18.
(5) Time planned for Contract Management includes resources to conduct audits. Report Foods State Contract Inspection Audit time under operation 13 (Domestic Investigation).
(6) Sanitation inspections will be add on inspections to firms already in the FSMA 201 inventory. New PAC to be created for reporting.
(7) Sprout Inspections, Processed Avocado and Fresh Herbs are carryover assignments from FY17. FY18 allocations will be updated to reflect the FY17 accomplishments.
Avocado numbers are based on historical sample collection data, and Fresh herbs based on the FY17-18 assignment.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Foodborne Biological Hazards

2. PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)
03F810, 03R882, 03844H, 03R878, 03R843, 03R881, 03F860, 03037, 03R816, 03803E

4. WORK ALLOCATION PLANNED BY
[X] ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS
103.66 [41.57]

	6. ORGANIZATION	DOMESTIC SAMPLE COLLECTION FUTURE STATE TBD ASSIGN 03F860 (8)	DOMESTIC SAMPLE COLLECTION BLUE CHEESE ASSIGNMENT MICRO 03037	DOMESTIC SAMPLE COLLECTION ALLERGEN ASSIGNMENT TBD 03803E	DOMESTIC FIELD EXAMS (9)	DOMESTIC SAMPLE ANALYSIS PROC. AVOCADO FUTURE STATE MICRO 03F860 (7)	DOMESTIC SAMPLE ANALYSIS FRESH HERBS FUTURE STATE MICRO 03F860 (7)	DOMESTIC SAMPLE ANALYSIS FUTURE STATE TBD ASSIGN 03F860 (8)	DOMESTIC SAMPLE ANALYSIS BLUE CHEESE ASSIGNMENT MICRO 03037	DOMESTIC SAMPLE ANALYSIS ALLERGEN ASSIGNMENT TBD CHEM 03803E
	TOTAL ORA	**1500**	**50**	**281**	**500**	**500**	**634**	**1500**	**50**	**281**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**	[redacted]								
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
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SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		6.00	8.00	6.00	0.90	10.73	10.73	10.73	17.07	20.00
TOTAL HOURS		9000.00	400.00	1686.00	450.00	5365.00	6803.00	16095.00	854.00	5620.00
CONVERSION FACTOR		950.00	950.00	950.00	950.00	1180.00	1180.00	1180.00	1180.00	1180.00
TOTAL OPERATIONAL FTEs		9.47	0.42	1.77	0.47	4.55	5.77	13.64	0.72	4.76

(b) (5), (b) (7)(E)

7. REMARKS

(8) CFSAN will issue Future State assignment(s) throughout the year.
(9) LACF/AF field exams are to include pH and canned seam evaluation. Field exams are to be reported under Op 53 and Label Exam/Review under Op 51 (PPS21).

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Foodborne Biological Hazards

2. PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)
03F810, 03R882, 03844H, 03R878, 03R843, 03R881, 03F860, 03037, 03R816, 03803E

4. WORK ALLOCATION PLANNED BY
X ORA
CENTER

5. OPERATIONAL FTE POSITIONS
103.66 [36.97]

	6. ORGANIZATION	APPLIED TECHNOLOGY CENTER MICRO (HOURS) 03R816	METHODS VAL/DEV MICRO (HOURS) 03R816 (10)	PRODUCE SAFETY TECHNICAL ASSISTANCE (HOURS) 03R880 (11)	NATL. EXPERT TECHNICAL ASSISTANCE (HOURS) (12)					
	TOTAL ORA	**6288**	**10176**	**13492**	**8550**					
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	(b) (5), (b) (7)(E)	[redacted]							
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SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		6288.00	10176.00	13492.00	8550.00					
CONVERSION FACTOR		1180.00	1205.00	950.00	950.00					
TOTAL OPERATIONAL FTEs		5.33	8.44	14.20	9.00					

7. REMARKS

(10) Time against Methods Validation and Development should be reported under Op Code 01.
(11) These resources are for Produce Safety Specialists to provide outreach/training, investigations and inspections to be performed in collaboration with state and regional partners.
(12) Technical Assistance may include, but is not limited to: Training, presentations, speeches, site visits, outreach, workshops, seminars or meetings with partnership groups, trade

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	5. OPERATIONAL FTE POSITIONS
Domestic High Risk Inspections	Foodborne Biological Hazards - 03	85.59

3. PROGRAM/ASSIGNMENT CODE(S): **03F811,** 03836

4. WORK ALLOCATION PLANNED BY: [X] ORA [X] CENTER

	6. ORGANIZATION	DOMESTIC INSPECTIONS FSMA HIGH RISK (1)(2)(3)	ESTIMATED STATE HR INSPECTIONS (4)	DOMESTIC INSPECTIONS EGG FARM NON-FSMA 03836 (5)
	TOTAL ORA	**2196**	**2957**	**240**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**			
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**			
DMS	Division of Milk Safety			
DRFP	Division of Retail Food Protection			
DSS	Division of Shellfish Sanitation			
IOG-HAF	International Operations - Human Foods			
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SANFL	San Francisco Lab			
SFFL	Southeast Food and Feed Lab			
WEAC	Winchester Engineering and Analytical Center			
FCC	Forensic Chemistry Center			
ESTIMATED HOURS PER OPERATION		32.00		46.00
TOTAL HOURS		70272.00		11040.00
CONVERSION FACTOR		950.00		950.00
TOTAL OPERATIONAL FTEs		73.97		11.62

(b) (5), (b) (7)(E)

7. REMARKS

NOTE: PAC 03F811 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC.
Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.

(1) If inspecting a small or other firm subject to the modernized GMP use 117 regulations and PAC 03014. If inspecting a very small firm not subject to the modernized GMP use 110 regulations.
(2) Inspections for high risk inventory are based on 'cover by' date (approximately 5455 firms) and subtracting expected State inspection numbers for FY18. The list of FSMA firms has been shared with the districts via email.
This year FSMA inspections for Medical Food, Infant Formula, and Dietary Supplements have been planned under PPS 21 and respective PACs.
FSMA Field Dashboard with the updated inventory will be available by October 2017. If the districts complete their HR inspections they may use these resources to complete NHR inspections or may continue with FY19 'cover by date' firms.
If a firm was covered during FY17, it does not need to be covered again during FY18.
There were some tweaks to the Industry Code criteria for what firms are considered HR vs. NHR since the last data run prior to FY14. Also, any firms that were associated with Class 1 recalls, outbreaks, OAI Inspections, Class 3 samples, or certain CMS actions within the last 5 years are automatically considered HR. This means there will be some firms that switch risk categories.
Firms that are new to the inventory since the last FSMA run was done, have been given an extended period of time (beyond FY18) to be covered. As we transition away from using cycles to track FSMA firms this will stop being an issue.
Shell-Egg only firms are exempt from the FSMA requirements so they don't need risk identifiers. However, identifying the SEG only firms in the inventory is very difficult. Districts may notify CFSAN of shell egg firms that are SEG only to get the FSMA risk identifiers removed.
(3) 30 FSMA HR inspections under OHAFOW are planned for National Experts.
(4) These are only estimates derived from the FSMA HR NHR inspections performed in FY17 by STATE vs FDA. Field input will be considered for the final FSMA and State allocations. Numbers may be updated after the FSMA Dashboard is published in ORADSS.
(5) Division allocations for Egg farm inspections are based on remaining inventory from FY17-18 assignment. These may be updated after the FY17 reporting is completed.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
Domestic Non-High Risk Inspections	Foodborne Biological Hazards - 03	03F812	X ORA X CENTER	62.60

	6. ORGANIZATION	DOMESTIC INSPECTIONS FSMA NON-HIGH RISK (1)(2)(3)	EXPECTED STATE NHR INSPECTIONS BASED ON FY17 ACCOM. RATIO (4)							
	TOTAL ORA	**3717**	**1101**							
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	(b) (5), (b) (7)(E)								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
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SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		16.00								
TOTAL HOURS		59472.00								
CONVERSION FACTOR		950.00								
TOTAL OPERATIONAL FTEs		62.60								

7. REMARKS

NOTE: PAC 03F812 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC.
Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.

(1) If inspecting a small or other firm subject to the modernized GMP use 117 regulations and PAC 03014. If inspecting a very small firm not subject to the modernized GMP use 110 regulations.
(2) Inspections for non-high risk inventory are based on 'cover by' date (approximately 4876 firms) and subtracting expected State inspection numbers for FY18.
This year FSMA inspections for Dietary Supplements have been planned under PPS 21 and respective PAC.
If a firm was covered during FY17, it does not need to be covered again during FY18.
There were some tweaks to the Industry Code criteria for what firms are considered HR vs. NHR since the last data run prior to FY14. Also, any firms that were associated with Class 1 recalls, outbreaks, OAI Inspections, Class 3 samples, or certain CMS actions within the last 5 years are automatically considered HR. This means there will be some firms that switch risk categories.
Firms that are new to the inventory since the last FSMA run was done, have been given an extended period of time (beyond FY18) to be covered. As we transition away from using cycles to track FSMA firms this will stop being an issue.
Shell-Egg only firms are exempt from the FSMA requirements so they don't need risk identifiers. However, identifying the SEG only firms in the inventory is very difficult. Districts may notify CFSAN of shell egg firms that are SEG only to get the FSMA risk identifiers removed.
(3) After completing the firms for FY18 FSMA NHR any remaining resources should be used to accomplish the following work in this priority order:
1. Assist other districts in the completion of their FY18 firms in order to ensure FDA FY18 FSMA goals are met: FDA & State (combined)
2. Inspect new (never been inspected) firms. Please reference CFSAN's FSMA Inventory on Field Dashboard.
3. Begin inspections for FSMA NHR FY 19-22
(4) These are only estimates derived from the FSMA HR NHR inspections performed in FY17 by STATE vs FDA. Field input will be considered for the final FSMA and State allocations.Numbers may be updated after the FSMA Dashboard is published in ORADSS.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
Preventive Control Inspections	Foodborne Biological Hazards - 03	**03015**	X ORA X CENTER	22.32

	6. **ORGANIZATION**	**DOMESTIC INSPECTIONS PREVENTIVE CONTROL 03015 (1) (2)(3)(4)**								
	TOTAL ORA	**400**								
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	(b) (5), (b) (7)(E)								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
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SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		53.00								
TOTAL HOURS		21200.00								
CONVERSION FACTOR		950.00								
TOTAL OPERATIONAL FTEs		22.32								

7. REMARKS

NOTE: Hours accomplished for 'On Job Experience' (OJE) should be reported under Op 84 and not Op11/12.

(1) Resources for Preventive Control FSMA inspections to be reported under appropriate PACs; 03015 for Comprehensive PC inspections (03S015 for State). The Division allocations will be provided when the assignment is issued in FY18.
(2) Districts will receive credit towards the FSMA HR/NHR numbers if the PC inspection is the first visit to the facility within the 'cover by date'.
(3) If environmental sampling resources are needed, please use TBD resources located in 03F830, or environmental sampling follow up resources planned under 03F813.
(4) Assignment will be issued in October 2017 for Two Tier Pilot inspections to be performed on subset of FY18 PC inventory. Resources for which are planned under PAC 03F813-Emerging Issues Inspections. New PAC will be created for the Two Tier Inspections.

FY 2018 ORA WORK PLAN — October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
Responsive Investigative/Laboratory Operations	Foodborne Biological Hazards - 03	**03F813,** 03842, 03847H, 03803, 03803A, 03R839, 03R876	X ORA X CENTER	137.52 [78.39]

	6. ORGANIZATION	DOMESTIC INSPECTIONS PRODUCE SAFETY SPECIALIST (1)	EMERGING ISSUES INSPECTIONS (HOURS) (2)	DOMESTIC INVESTI-GATIONS (HOURS) (3)	OUTBREAK EMERGENCY RESPONSE ACTIVITIES (HOURS) 03R839	DOMESTIC INSPECTIONS FOLLOW-UP (HOURS) (4)	ENVIRONMENTAL SAMPLE COLLECTION F/U WORK (HOURS) (5)	DOMESTIC SAMPLE COLLECTION SEAFOOD 03842	DOMESTIC SAMPLE COLLECTION JUICE HACCP 03847H
	TOTAL ORA	**20**	**9249**	**40000**	**5000**	**12690**	**5994**	**100**	**25**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**								
DMS	Division of Milk Safety								
DRFP	Division of Retail Food Protection								
DSS	Division of Shellfish Sanitation								
IOG-HAF	International Operations - Human Foods								
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**								
HAFE1	Division of Human and Animal Food Operations East I								
HAFE2	Division of Human and Animal Food Operations East II								
HAFE3	Division of Human and Animal Food Operations East III								
HAFE4	Division of Human and Animal Food Operations East IV								
HAFE5	Division of Human and Animal Food Operations East V								
HAFE6	Division of Human and Animal Food Operations East VI								
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**								
HAFW1	Division of Human and Animal Food Operations West I								
HAFW2	Division of Human and Animal Food Operations West II								
HAFW3	Division of Human and Animal Food Operations West III								
HAFW4	Division of Human and Animal Food Operations West IV								
HAFW5	Division of Human and Animal Food Operations West V								
HAFW6	Division of Human and Animal Food Operations West VI								
LABS	**FOOD AND FEED LABORATORIES**								
ARKL	Arkansas Lab								
DENL	Denver Lab								
KCL	Kansas City Lab								
NFFL	Northeast Food and Feed Lab								
PNL	Pacific Northwest Lab								
PSFFL	Pacific Southwest Food and Feed Lab								
SANFL	San Francisco Lab								
SFFL	Southeast Food and Feed Lab								
WEAC	Winchester Engineering and Analytical Center								
FCC	Forensic Chemistry Center								
ESTIMATED HOURS PER OPERATION		37.00						6.28	6.37
TOTAL HOURS		740.00	9249.00	40000.00	5000.00	12690.00	5994.00	628.00	159.00
CONVERSION FACTOR		950.00	950.00	950.00	950.00	950.00	950.00	950.00	950.00
TOTAL OPERATIONAL FTEs		0.78	9.74	42.11	5.26	13.36	6.31	0.66	0.17

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

NOTE: 03F813 is for planning purposes only. Resources are to be used for all outbreak, emergency activities, emerging issues, OAI follow-ups. Accomplished work must be reported against the appropriate program or assignment PAC.

Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.

(1) Produce Safety Inspections (domestic and foreign) resources are planned in the FY18 Work Plan to be used as needed for PSN activities like investigations, outbreak, and outreach activities during the fiscal year.
(2) Includes resources for Registration Verification and for Two Tier Pilot Assignment to be performed with the PC inspections. Report Two Tier inspections under PACs 03R890 TWO TIER PCHF INSPECTION PILOT – TIER 1 and 03R891 TWO TIER PCHF INSPECTION PILOT – TIER 2
(3) Includes investigational hours for all domestic investigations, and follow-up to RFR-RCR
(4) Resources to be used for any follow up domestic inspections (including environmental follow up inspections) as needed. These include resources for FSVP follow ups for importers
(5) Resources may be used for any follow up sampling for environmental sampling assignments or surveillance work.
District directed work (not CFSAN directed assignments) should be reported under PAC 03R800 Short Term assignments/ORA or Field Dir

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Responsive Investigative/Laboratory Operations

2. PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)
03F813, 03842, 03847H, 03803, 03803A, 03R839, 03R876

4. WORK ALLOCATION PLANNED BY
X ORA
CENTER

5. OPERATIONAL FTE POSITIONS
137.52 [43.96]

REGION	6. ORGANIZATION	DOMESTIC SAMPLE COLLECTION LACF/AF 03803A 535	DOMESTIC SAMPLE COLLECTION FOOD SAFETY 03803	EMERGING ISSUES SAMPLE COLLECTION (HOURS)	EMERGING ISSUES SAMPLE ANALYSIS MICRO (HOURS)	DOMESTIC SAMPLE ANALYSIS OUTBREAK EMERG MICRO (HOURS) 03R839	ENVIRONMENTAL SAMPLE ANALYSIS F/U WORK (HOURS) (5)	DOMESTIC SAMPLE ANALYSIS JUICE/HACCP MICRO 03847H	DOMESTIC SAMPLE ANALYSIS LACF/AF MICRO 03803A	DOMESTIC SAMPLE ANALYSIS FOOD SAFETY CHEM (FILTH) 03803
	TOTAL ORA	**100**	**650**	**7456**	**19915**	**12012**	**2115**	**25**	**100**	**50**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	(b) (5), (b) (7)(E) [redacted]								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
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HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
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ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		6.30	7.21					11.46	12.25	9.31
TOTAL HOURS		630.00	4687.00	7456.00	19915.00	12012.00	2115.00	287.00	1225.00	466.00
CONVERSION FACTOR		950.00	950.00	950.00	1180.00	1180.00	1180.00	1180.00	1180.00	1180.00
TOTAL OPERATIONAL FTEs		0.66	4.93	7.85	16.88	10.18	1.79	0.24	1.04	0.39

7. REMARKS

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Responsive Investigative/Laboratory Operations

2. PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)
03F813, 03842, 03847H, 03803, 03803A, 03R839, 03R876

4. WORK ALLOCATION PLANNED BY
[X] ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS
137.52 [15.17]

REGION	6. ORGANIZATION	DOMESTIC SAMPLE ANALYSIS FOOD SAFETY MICRO 03803	DOMESTIC SAMPLE ANALYSIS SEAFOOD MICRO 03842	OEI COORDINATION (HOURS) 03R876 (6)	WHOLE GENOME SEQUENCE (WGS) (HOURS)	ENUMERATION (HOURS)				
	TOTAL ORA	**600**	**100**	**950**	**5003**	**4283**				
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
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DENL	Denver Lab									
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PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		9.60	16.78							
TOTAL HOURS		5760.00	1678.00	950.00	5003.00	4283.00				
CONVERSION FACTOR		1180.00	1180.00	950.00	1180.00	1180.00				
TOTAL OPERATIONAL FTEs		4.88	1.42	1.00	4.24	3.63				

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

(6) OEI Coordination resources are planned for any CSO work related to OEI clean-up and maintenance.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Foreign Foods Inspections

2. PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)
03R233

4. WORK ALLOCATION PLANNED BY
X ORA
CENTER

5. OPERATIONAL FTE POSITIONS
55.89

	6. ORGANIZATION	FOREIGN INSPECTIONS (1)(2)	FOREIGN INSPECTIONS PREVENTIVE CONTROL 03015 (3)							
	TOTAL ORA	**1300**	**100**							
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
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OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
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PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		37.00	50.00							
TOTAL HOURS		48100.00	5000.00							
CONVERSION FACTOR		950.00	950.00							
TOTAL OPERATIONAL FTEs		50.63	5.26							

(b) (5), (b) (7) (E)

7. REMARKS

NOTE: PAC 03R233 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC.
Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.
Hours accomplished for 'On Job Experience' (OJE) should be reported under Op 84 and not Op11/12.
Resources planned under OHAFO are for the Division CSOs, and under OHAFOE are for the Cadre.

(1) Large firms that meet criteria will be inspected under modernized GMP by personnel who has reviewed the modernized GMP webinar under appropriate Preventive Control PACs. Resources for cadre are planned under OHAFOE
(2) Foreign inspection resources may be used for FSVP Follow up, VQIP and routine foreign inspections
(3) Foreign inspections will only be conducted by the PC specialists when 21 CFR 117 Subpart C (PC) applies. The inspections planned under OHAFO may be performed by OHAFO/cadre/OIP

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
CFSAN Environmental Sampling Assignments

2. PPS PROJECT NAME/NUMBER
Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)
03F830, 03F849, 03F836

4. WORK ALLOCATION PLANNED BY
X ORA X CENTER

5. OPERATIONAL FTE POSITIONS
90.19

	6. ORGANIZATION	DOMESTIC INSPECTION ENVT. SAMP. EGG RULE 03836 (1)	DOMESTIC SAMPLE COLLECTION ENVT. SAMP. EGG RULE 03836 (HOURS) (1)	DOMESTIC INSPECTION ENVT. SAMP. TBD (2)	DOMESTIC SAMPLE COLLECTION ENVT. SAMP. TBD (HOURS) (2)	DOMESTIC SAMPLE COLLECTION ENVT. SAMP. ASSIGNMENT TBD MICRO ANALYST (HOURS)	DOMESTIC SAMPLE ANALYSIS ENVT. SAMP. MICRO (HOURS)			
	TOTAL ORA	**84**	**1134**	**524**	**17449**	**11799**	**22353**			
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
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HAFW3	Division of Human and Animal Food Operations West III									
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HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
DETL	Detroit Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		46.00		68.20						
TOTAL HOURS		3864.00	1134.00	35737.00	17449.00	11799.00	22353.00			
CONVERSION FACTOR		950.00	950.00	950.00	950.00	1180.00	1180.00			
TOTAL OPERATIONAL FTEs		4.07	1.19	37.62	18.37	10.00	18.94			

(b) (5), (b) (7)(E)

7. REMARKS

NOTES: PAC 03F830 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC.
Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PAC.
The assignment inspection/sample numbers are estimates only; assignment parameters and district inventories will dictate the final number of firms to be covered.
Environmental sampling for follow-up on Outbreaks and Emergency Response activities is planned separately (See Page 03-10 on Responsive Investigative/Laboratory Operations Sheet).

(1) FY17 assignment carryover plus FY18 egg assignment are included. These numbers do not include work for States.
(2) District allocations for TBD environmental sampling assignment for Listeria monocytogenes and Salmonella will be updated when the assignment is issued.

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Pesticides and Chemical Contaminants - 04

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			INSPECTIONAL		ANALYTICAL		
			DOMESTIC	FOREIGN	DOMESTIC		
	TOTAL		**13.97**		**75.90**	**89.87**	
1	Pesticides and Chemical Contaminants	04F810 *	8.61		39.47	48.08	04-14-15
2	Total Diet Study	04839	0.70		16.73	17.43	04-16
3	Responsive Investigative/Laboratory Operations	04F813*	4.66		19.70	24.36	04-17
	* This PAC is for planning purposes only.						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC.						

CENTER WORK PLANNER/TELEPHONE	ORA PLANNER/TELEPHONE
Mallory Kelly 240-402-2401	Shilpa Sainath 240-402-9912

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Pesticides and Chemical Contaminants

2. PPS PROJECT NAME/NUMBER
Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)
04F810, 04004A/D, 04018, 04019A, 04019C, 04F838, 04R816

4. WORK ALLOCATION PLANNED BY
X ORA X CENTER

5. OPERATIONAL FTE POSITIONS
48.08 [15.91]

	6. ORGANIZATION	DOMESTIC SAMPLE COLLECTION PESTICIDE 04004A	DOMESTIC SAMPLE COLLECTION RICE CEREAL SAMPLING ASSIGNMENT	DOMESTIC SAMPLE COLLECTION CHEMO 04018	DOMESTIC SAMPLE COLLECTION TOXIC ELE 04019A	DOMESTIC SAMPLE COLLECTION RADIO-NUCLIDES 04019C (1)	DOMESTIC FIELD EXAMS	DOMESTIC SAMPLE ANALYSIS PESTICIDES 04004A	DOMESTIC SAMPLE ANALYSIS RICE CEREAL SAMPLING ASSIGNMENT	DOMESTIC SAMPLE ANALYSIS RADIO-NUCLIDES 04019C (2) (3)
	TOTAL ORA	**1200**	**150**	**100**	**440**	**67**	**19**	**1200**	**150**	**67**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	[redacted]								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**	[redacted]								
DMS	Division of Milk Safety	[redacted]								
DRFP	Division of Retail Food Protection	[redacted]								
DSS	Division of Shellfish Sanitation	[redacted]								
IOG-HAF	International Operations - Human Foods	[redacted]								
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**	[redacted]								
HAFE1	Division of Human and Animal Food Operations East I	[redacted]								
HAFE2	Division of Human and Animal Food Operations East II	[redacted]								
HAFE3	Division of Human and Animal Food Operations East III	[redacted]								
HAFE4	Division of Human and Animal Food Operations East IV	[redacted]								
HAFE5	Division of Human and Animal Food Operations East V	[redacted]								
HAFE6	Division of Human and Animal Food Operations East VI	[redacted]								
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**	[redacted]								
HAFW1	Division of Human and Animal Food Operations West I	[redacted]								
HAFW2	Division of Human and Animal Food Operations West II	[redacted]								
HAFW3	Division of Human and Animal Food Operations West III	[redacted]								
HAFW4	Division of Human and Animal Food Operations West IV	[redacted]								
HAFW5	Division of Human and Animal Food Operations West V	[redacted]								
HAFW6	Division of Human and Animal Food Operations West VI	[redacted]								
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DENL	Denver Lab	[redacted]								
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PNL	Pacific Northwest Lab	[redacted]								
PSFFL	Pacific Southwest Food and Feed Lab	[redacted]								
SANFL	San Francisco Lab	[redacted]								
SFFL	Southeast Food and Feed Lab	[redacted]								
WEAC	Winchester Engineering and Analytical Center	[redacted]								
FCC	Forensic Chemistry Center	[redacted]								
ESTIMATED HOURS PER OPERATION		3.73	4.50	7.00	4.50	5.00	0.99	5.40	12.00	5.01
TOTAL HOURS		4476.00	675.00	700.00	1980.00	335.00	19.00	6480.00	1800.00	336.00
CONVERSION FACTOR		950.00	950.00	950.00	950.00	950.00	950.00	1180.00	1180.00	1180.00
TOTAL OPERATIONAL FTEs		4.71	0.71	0.74	2.08	0.35	0.02	5.49	1.53	0.28

(b) (5), (b) (7)(E)

7. REMARKS

(1) CFSAN spreads DSCs' based on location of nuclear power plants. See compliance program for collection details.
(2) Resources include radionuclide testing of domestic seafood 'under the Toxic Element/Radionculides Complaince Program.
(3) Use resources planned under Emerging Issues, Outbreaks and Emergency Response if additional resources are needed.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Pesticides and Chemical Contaminants	Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
04F810, 04004A/D, 04018, 04019A, 04019C, 04F838, 04R816	X ORA X CENTER	48.08 [32.17]

	6. ORGANIZATION	DOMESTIC SAMPLE ANALYSIS DIOXINS 04004D (4)	DOMESTIC SAMPLE ANALYSIS CHEMO 04018	DOMESTIC SAMPLE ANALYSIS TOXIC ELEMENTS 04019A	METHODS VAL/DEV CHEM (HOURS) 04R816	APPLIED TECHNOLOGY CENTER CHEM (HOURS) 04R816	FORENSICS (HOURS) 04R838			
	TOTAL ORA	**230**	**100**	**440**	**2529**	**6372**	**14460**			
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
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KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		31.20	25.00	12.00						
TOTAL HOURS		7176.00	2500.00	5280.00	2529.00	6372.00	14460.00			
CONVERSION FACTOR		1180.00	1180.00	1180.00	1205.00	1180.00	1205.00			
TOTAL OPERATIONAL FTEs		6.08	2.12	4.47	2.10	5.40	12.00			

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

(4) This includes resources for dioxin analysis under the TDS program.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
Total Diet Study	Pesticides and Chemical Contaminants - 04	**04839**	X ORA X CENTER	17.43

	6. ORGANIZATION	DOMESTIC SAMPLE COLLECTION TOTAL DIET STUDY (TDS) (1)	DOMESTIC SAMPLE ANALYSIS CHEM (HOURS) (2)	DOMESTIC SAMPLE ANALYSIS RADIO-NUCLIDES (3)						
	TOTAL ORA	**36**	**13610**	**438**						
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		18.53		14.00						
TOTAL HOURS		667.00	13610.00	6132.00						
CONVERSION FACTOR		950.00	1180.00	1180.00						
TOTAL OPERATIONAL FTEs		0.70	11.53	5.20						

(b) (5), (b) (7)(E)

7. REMARKS

(1) Each DSC represents a Division's weekly collection of specified food items. Each market basket collection is spread over a week period and involves 3 Divisions. 36 Regional market baskets are planned annually.
(2) Represents the total number of hours to analyze the 37 (36 Regional and 1 National) market baskets. This includes mycotoxin analysis for FY18. Resources for Dioxin analysis are planned under PAC 04F810.
Collection resources for national basket are included here for KCL - 40 hours
(3) All TDS food items from two market baskets analyzed by WEAC for selected radionuclides

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Responsive Investigative/Laboratory Operations

2. PPS PROJECT NAME/NUMBER
Pesticides and Chemical Contaminants - 04

3. PROGRAM/ASSIGNMENT CODE(S)
04F813, 04R839

4. WORK ALLOCATION PLANNED BY
X ORA X CENTER

5. OPERATIONAL FTE POSITIONS
24.36

	6. ORGANIZATION	EMERGING ISSUES INSPECTIONS (HOURS)	DOMESTIC INVESTIGATIONS (HOURS)	OUTBREAK EMERGENCY RESPONSE 04R839 (HOURS)	EMERGING ISSUES SAMPLE COLLECTION (HOURS)	DOMESTIC SAMPLE COLLECTION EXPORTER ACTIVITIES (HOURS) (2)	EMERGING ISSUES SAMPLE ANALYSIS CHEM (HOURS) (3)	DOMESTIC SAMPLE ANALYSIS OUTBREAK EMERG CHEM 04R839 (HOURS)	DOMESTIC SAMPLE ANALYSIS EXPORTER ACTIVITIES CHEM (HOURS) (2)
	TOTAL ORA	**124**	**500**	**200**	**414**	**3184**	**1140**	**968**	**21128**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**								
DMS	Division of Milk Safety								
DRFP	Division of Retail Food Protection								
DSS	Division of Shellfish Sanitation								
IOG-HAF	International Operations - Human Foods								
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**								
HAFE1	Division of Human and Animal Food Operations East I								
HAFE2	Division of Human and Animal Food Operations East II								
HAFE3	Division of Human and Animal Food Operations East III								
HAFE4	Division of Human and Animal Food Operations East IV								
HAFE5	Division of Human and Animal Food Operations East V								
HAFE6	Division of Human and Animal Food Operations East VI								
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**								
HAFW1	Division of Human and Animal Food Operations West I								
HAFW2	Division of Human and Animal Food Operations West II								
HAFW3	Division of Human and Animal Food Operations West III								
HAFW4	Division of Human and Animal Food Operations West IV								
HAFW5	Division of Human and Animal Food Operations West V								
HAFW6	Division of Human and Animal Food Operations West VI								
LABS	**FOOD AND FEED LABORATORIES**								
ARKL	Arkansas Lab								
DENL	Denver Lab								
KCL	Kansas City Lab								
NFFL	Northeast Food and Feed Lab								
PNL	Pacific Northwest Lab								
PSFFL	Pacific Southwest Food and Feed Lab								
SANFL	San Francisco Lab								
SFFL	Southeast Food and Feed Lab								
WEAC	Winchester Engineering and Analytical Center								
FCC	Forensic Chemistry Center								
ESTIMATED HOURS PER OPERATION									
TOTAL HOURS		124.00	500.00	200.00	414.00	3184.00	1140.00	968.00	21128.00
CONVERSION FACTOR		950.00	950.00	950.00	950.00	950.00	1180.00	1180.00	1180.00
TOTAL OPERATIONAL FTEs		0.13	0.53	0.21	0.44	3.35	0.97	0.82	17.91

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

NOTE: 04F813 is for planning purposes only. Resources are to be used for all outbreak, emergency activities, emerging issues. Accomplished work must be reported against the appropriate PAC.
Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACs.

(1) Includes investigational hours for all domestic investigations and follow-up to RFR-RCR.
(2) Resources planned for collection and analysis of products exported by US. CFSAN will issue an assignment with targeted commodities.
(3) Emerging Issues Sample Analysis Chem resources are for unplanned/for-cause work which also includes PAC 04019S Speciation Analysis (domestic/import) and extra Chemo resources if needed for PAC 04018.

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Molecular Biology & Natural Toxins - 07

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			INSPECTIONAL		ANALYTICAL		
			DOMESTIC	FOREIGN	DOMESTIC		
	TOTAL		**6.59**		**11.87**	**18.46**	
1	Mycotoxins in Domestic and Import Foods	07001	6.32		11.81	**18.13**	07-19
2	Responsive Investigative/Laboratory Operations	07F813*	0.27		0.06	**0.33**	07-20
	* This PAC is for planning purposes only.						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC.						

CENTER WORK PLANNER/TELEPHONE	ORA PLANNER/TELEPHONE
Mallory Kelly 240-402-2401	Shilpa Sainath 240-402-9912

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Mycotoxins in Domestic and Import Foods

2. PPS PROJECT NAME/NUMBER
Molecular Biology & Natural Toxins - 07

3. PROGRAM/ASSIGNMENT CODE(S)
07001, 07R816

4. WORK ALLOCATION PLANNED BY
X ORA X CENTER

5. OPERATIONAL FTE POSITIONS
18.13

	6. ORGANIZATION	DOMESTIC SAMPLE COLL SCOPE (1)	DOMESTIC SAMPLE ANALYSIS CHEM	METHOD VAL/DEV CHEM (HOURS) 07R816	APPLIED TECHNOLOGY CENTER CHEM (HOURS) 07R816					
	TOTAL ORA	**1000**	**1000**	**823**	**4130**					
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
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HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
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NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION		6.00	9.00							
TOTAL HOURS		6000.00	9000.00	823.00	4130.00					
CONVERSION FACTOR		950.00	1180.00	1205.00	1180.00					
TOTAL OPERATIONAL FTEs		6.32	7.63	0.68	3.50					

(b) (5), (b) (7)(E)

7. REMARKS

(1) SCOPE for FY18 should be out by September 2017. The allocations will be updated based on the SCOPE.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
Responsive Investigative/Laboratory Operations	Molecular Biology & Natural Toxins - 07	07F813	X ORA ___ CENTER	0.33

	6. ORGANIZATION	EMERGING ISSUES INSPECTIONS (HOURS)	DOMESTIC INVESTIGATIONS (HOURS)	EMERGING ISSUES SAMPLE COLLECTIONS (HOURS)	EMERGING ISSUES SAMPLE ANALYSIS CHEM (HOURS)					
	TOTAL ORA	**100**	**75**	**72**	**72**					
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
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HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
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HAFW5	Division of Human and Animal Food Operations West V									
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PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
WEAC	Winchester Engineering and Analytical Center									
FCC	Forensic Chemistry Center									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		100.00	75.00	72.00	72.00					
CONVERSION FACTOR		950.00	950.00	950.00	1180.00					
TOTAL OPERATIONAL FTEs		0.11	0.08	0.08	0.06					

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

NOTE: 07F813 is for planning purposes only. Resources are to be used for all outbreak, emergency activities, emerging issues. Accomplished work must be reported against the appropriate program or assignment PAC.
Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Technical Assistance: Food and Cosmetics -18

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			INSPECTIONAL		ANALYTICAL		
			DOMESTIC	FOREIGN	DOMESTIC		
	TOTAL		**78.44**		**0.88**	**79.32**	
1	Technical Assistance - Food and Cosmetics	18F810*	11.47		0.88	**12.35**	18-22
2	Retail Food Protection - State Program	18002	27.00			**27.00**	18-23-24
3	Milk Safety Program (NCIMS)	18003	20.81			**20.81**	18-25-26
4	Molluscan Shellfish Evaluation	18004	16.00			**16.00**	18-27-28
5	Responsive Investigative/Laboratory Operations	18F813	3.16			**3.16**	18-29
	* This PAC is for planning purposes only.						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC.						
	Please see the Reporting Guidance for a listing of						
	compliance programs and corresponding PACs.						

CENTER WORK PLANNER/TELEPHONE	ORA PLANNER/TELEPHONE
Mallory Kelly 240-402-2401	Shilpa Sainath 240-402-9912

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Technical Assistance - Food and Cosmetics

2. PPS PROJECT NAME/NUMBER
Technical Assistance- Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)
18F810, 18029A/B/C/D

4. WORK ALLOCATION PLANNED BY
X ORA
CENTER

5. OPERATIONAL FTE POSITIONS
12.35

	6. ORGANIZATION	DOMESTIC INSPECTIONS NON-FSMA HIGH RISK AIRCRAFT WATERING PT (1) 18029A	DOMESTIC INSPECTIONS NON-AIRLINE WATERING POINTS	DOMESTIC INSPECTIONS CONVEYANCE IN OPERATION	DOMESTIC SAMPLE COLLECTION FOR CAUSE CHEM (2)	DOMESTIC SAMPLE COLLECTION SURVEILLANCE SCOPE MICRO (2)	DOMESTIC SAMPLE ANALYSIS CHEM	DOMESTIC SAMPLE ANALYSIS MICRO		
	TOTAL ORA	**550**	**160**	**50**	**20**	**180**	**20**	**180**		
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION		12.00	15.50	15.50	5.21	5.21	3.10	5.42		
TOTAL HOURS		6600.00	2480.00	775.00	104.00	938.00	62.00	976.00		
CONVERSION FACTOR		950.00	950.00	950.00	950.00	950.00	1180.00	1180.00		
TOTAL OPERATIONAL FTEs		6.95	2.61	0.82	0.11	0.99	0.05	0.83		

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

NOTES: PAC 18F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC.
Please see the Reporting Guidance for listing of compliance programs and corresponding reporting PACs.
Resources may be used for servicing area inspections and other related work not sepecifically resourced in the work plan.
Resources for conveyance construction activities are planned under 18F813

(1) These planned resources do not include High Risk FSMA inspections of conveyance caterers which are planned under PACs 03F811/03F812.
Inspections are planned based on ~1/3 of aircraft watering points inventory and last inspection before 09/30/2015. Divisions may be revised with feedback from the Divisions after DRAFT work plan review.
(2) Potable water samples should be collected from potable water carts or trucks if available rather than from potable water cabinets at airports with municipal supplies or from other types of cabinets or spigots if the water source is a well.
Division allocations are based on samples to be collected in SCOPE during inspections at watering points, and inspections for conveyance under construction.
If a potable water cart or truck is not available at an airline then the watering cabinet at the gate should still be sampled. Smaller airports may be getting their water from a well or a non-municipal supply and water quality may not be as high or may not be monitored as regularly as at larger airports. EPA is expecting FDA to maintain its vigilance at the aircraft watering points in support of the Aircraft Drinking Water Rule.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Retail Food Protection - State Program

2. PPS PROJECT NAME/NUMBER
Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)
18002

4. WORK ALLOCATION PLANNED BY
[ ] ORA [X] CENTER

5. OPERATIONAL FTE POSITIONS
27.00 [16.56]

	6. ORGANIZATION	NATIONAL RETAIL FOOD PROG STDs. SUPP FOR JURISDICTIONS (HOURS) (1)	STANDARD-IZATION (HOURS) (2)	RE-STANDARD-IZATION (HOURS) (3)	TEAM LEADER SCI/ NATIONAL (HOURS) (4)	NATIONAL TEAM WORK GROUP (HOURS) (5)	REGIONAL SEMINARS (HOURS) (6)	NATL. RETAIL FOOD PROG STANDARDS ENROLLMENT OF NEW JURIS (HOURS) (7)	TECHNICAL ASSISTANCE (HOURS) (8)	CONFERENCE FOR FOOD PROTECTION MEETING & COMMITTEE WORK (HOURS) (9)
	TOTAL ORA	**3888**	**1728**	**1504**	**1200**	**4160**	**1680**	**360**	**3447**	**1900**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	[redacted]								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**	[redacted]								
DMS	Division of Milk Safety	[redacted]								
DRFP	Division of Retail Food Protection	[redacted]								
DSS	Division of Shellfish Sanitation	[redacted]								
IOG-HAF	International Operations - Human Foods	[redacted]								
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**	[redacted]								
HAFE1	Division of Human and Animal Food Operations East I	[redacted]								
HAFE2	Division of Human and Animal Food Operations East II	[redacted]								
HAFE3	Division of Human and Animal Food Operations East III	[redacted]								
HAFE4	Division of Human and Animal Food Operations East IV	[redacted]								
HAFE5	Division of Human and Animal Food Operations East V	[redacted]								
HAFE6	Division of Human and Animal Food Operations East VI	[redacted]								
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**	[redacted]								
HAFW1	Division of Human and Animal Food Operations West I	[redacted]								
HAFW2	Division of Human and Animal Food Operations West II	[redacted]								
HAFW3	Division of Human and Animal Food Operations West III	[redacted]								
HAFW4	Division of Human and Animal Food Operations West IV	[redacted]								
HAFW5	Division of Human and Animal Food Operations West V	[redacted]								
HAFW6	Division of Human and Animal Food Operations West VI	[redacted]								
LABS	**FOOD AND FEED LABORATORIES**	[redacted]								
ARKL	Arkansas Lab	[redacted]								
DENL	Denver Lab	[redacted]								
KCL	Kansas City Lab	[redacted]								
NFFL	Northeast Food and Feed Lab	[redacted]								
PNL	Pacific Northwest Lab	[redacted]								
PSFFL	Pacific Southwest Food and Feed Lab	[redacted]								
SANFL	San Francisco Lab	[redacted]								
SFFL	Southeast Food and Feed Lab	[redacted]								
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		3888.00	1728.00	1504.00	1200.00	4160.00	1680.00	360.00	3447.00	1900.00
CONVERSION FACTOR		1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00
TOTAL OPERATIONAL FTEs		3.24	1.44	1.25	1.00	3.47	1.40	0.30	2.87	1.58

(b) (5), (b) (7)(E)

7. REMARKS

(1) Includes resources for meetings, consultations, conference calls, and any other direct contact with jurisdictions currently enrolled in the program standards to facilitate their continuous improvement in meeting the standards criteria.
(2) Standardization of regulatory retail food inspection/training officers in the interpretation and application of the FDA Food Code and methods of conducting inspections (ITP,CDC,HIS, State and Local).
(3) Re-standardization every three years for regulatory retail food inspection/training officers in the application of the FDA Food Code and methods in conducting risk-based inspections (ITP,STATE, and Local)
(4) Resources allocated for team leaders for retail food program planning, development, and coordination.
(5) Provides time for initiatives related to the Retail Food Program development of agency procedures, guidance documents, standards and initiatives of national importance.
(6) Includes resources for preparation work, coordination, and organization, as well as, the presentation delivered in conjunction with the Annual Regional Retail Food Seminars.
(7) Includes resources for meetings, presentations, workshops, conference calls and other direct contact with jurisdiction to facilitate their enrollment in the program standards.
(8) Includes providing assistance to external partners in interpreting and applying FDA's guidance and regulations and the effective 'use of interventions, inspection and enforcement to reduce the occurrence of foodborne illness risk factors at the retail level.
(9) Includes preliminary work on issues/position papers development and attendance at Conference for Food Protection Biennial Meeting.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Retail Food Protection - State Program	Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
18002	[ ] ORA [X] CENTER	27.00 [10.44]

	6. ORGANIZATION	FOOD DEFENSE & OTHER CFSAN DIRECTED PROJECTS (HOURS) (10)	DHRD TRAINING COURSE WORKSHOP (HOURS) (11)	REGIONAL NON-DHRD TRAINING/ COURSES WORKSHOPS (HOURS) (12)	RETAIL RISK FACTOR STUDY DATA COLLECTION (HOURS) (13)	RETAIL RISK FACTOR STUDY WORKGROUP (HOURS) (14)	SPECIALIST NAT. SPECIAL SECURITY EVENTS (HOURS) (15)	DATA ENTRY TO SHAREPOINT SITE (HOURS) (16)	NEW HIRE TRAINING (HOURS) (17)
	TOTAL ORA	**600**	**1728**	**1632**	**3840**	**920**	**350**	**600**	**2863**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**								
DMS	Division of Milk Safety								
DRFP	Division of Retail Food Protection								
DSS	Division of Shellfish Sanitation								
IOG-HAF	International Operations - Human Foods								
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**								
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HAFE3	Division of Human and Animal Food Operations East III								
HAFE4	Division of Human and Animal Food Operations East IV								
HAFE5	Division of Human and Animal Food Operations East V								
HAFE6	Division of Human and Animal Food Operations East VI								
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**								
HAFW1	Division of Human and Animal Food Operations West I								
HAFW2	Division of Human and Animal Food Operations West II								
HAFW3	Division of Human and Animal Food Operations West III								
HAFW4	Division of Human and Animal Food Operations West IV								
HAFW5	Division of Human and Animal Food Operations West V								
HAFW6	Division of Human and Animal Food Operations West VI								
LABS	**FOOD AND FEED LABORATORIES**								
ARKL	Arkansas Lab								
DENL	Denver Lab								
KCL	Kansas City Lab								
NFFL	Northeast Food and Feed Lab								
PNL	Pacific Northwest Lab								
PSFFL	Pacific Southwest Food and Feed Lab								
SANFL	San Francisco Lab								
SFFL	Southeast Food and Feed Lab								
ESTIMATED HOURS PER OPERATION									
TOTAL HOURS		600.00	1728.00	1632.00	3840.00	920.00	350.00	600.00	2863.00
CONVERSION FACTOR		1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00
TOTAL OPERATIONAL FTEs		0.50	1.44	1.36	3.20	0.77	0.29	0.50	2.39

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

(10) Resources allocated for the presentation and distribution of FDA materials related to food defense. Also, includes Specialist activities related to CFSAN priority assignments in response to National Food Safety needs.
(11) Includes support provided to DHRD in the development and delivery of DHRD training courses on topics such as the Food Code, Preparation for Standardization, Managing Retail Food Safety (HACCP), Conducting Risk-Based Inspections, Special Processes at Retail, Foodborne Illness Investigations, Plan Review, Trace-back Investigations, Regulations of Temporary Food Establishments.
(12) Includes development and delivery of regionally-coordinated training courses and workshops offered to state, tribal and local partners, excluding workshops related to program standards.
(13) Includes the collection and reporting of data from on-site assessments of roughly 400 full service and 400 fast food restaurant facilities as part of a 10 year (2013-2023) FDA study to assess the control offoodborne illness risk factors at the retail level.
(14) Includes resources of workgroup members responsible for developing the data collection tools, analyzing data and drafting a report on the occurrence of foodborne risk factors in the different retail facility types.
(15) Includes resources for food protection efforts of the Federal, State, and local governments associated with the Presidential Inauguration. Other National Security Special Events include Summits hosted by U.S. Officials and attended by World Leaders.
(16) Includes resources for maining and contributing contents to the National Retail Food Team SharePoint Site.
(17) Includes resources for recently hired Retail Food Specialists to attend trainings comprised of required courses, one-on-one field and office training with experienced specialists and superviosrs, preparation for the Specialists's initial field standardization with CFSAN, as well as Level 1 certification activities for new investigators.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
(NCIMS) Milk Safety Program

2. PPS PROJECT NAME/NUMBER
Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)
18003

4. WORK ALLOCATION PLANNED BY
[ ] ORA [X] CENTER

5. OPERATIONAL FTE POSITIONS
20.81 [17.93]

	6. ORGANIZATION	CHECK RATING PLANT (1)	CHECK RATING TRANSFER AND RECEIVING (1)	CHECK RATING BTU (1)	SINGLE SERVICE AUDITS (1)	STATE SAMPLING SURV OFF CERT (2)	STATE MILK SANITATION RATING OFF CERT (2)	STATE PROGRAM EVALUATION (3)	TECHNICAL ASSISTANCE	RMS STANDARDI-ZATION (4)
	TOTAL ORA	**161**	**33**	**288**	**76**	**57**	**51**	**17**	**51**	**17**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION		24.00	12.00	20.00	8.00	24.00	40.00	120.00	90.00	50.00
TOTAL HOURS		3864.00	396.00	5760.00	608.00	1368.00	2040.00	2040.00	4590.00	850.00
CONVERSION FACTOR		1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00
TOTAL OPERATIONAL FTEs		3.22	0.33	4.80	0.51	1.14	1.70	1.70	3.83	0.71

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

(1) Check ratings of plants, Receiving Stations and Transfer Stations (RS/TS) every 3 years; Bulk Tank Units (BTU) every 4 years; and Single-Service Container/Closure Manufacturers every 5 years.
(2) Activities include the initial and continuous certification (including Hazard Analysis Critical Control Point (HACCP) if applicable) of State Rating Officers and Sampling Surveillance Officers.
(3) State Program Evaluations conducted of 1/3 of the states (including Puerto Rico) every 3 years.
(4) Activities include the initial CFSAN Standardization and the Re-standardization (Group Field Exercise) of Regional Milk Specialists (RMSs).

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
(NCIMS) Milk Safety Program	Technical Assistance: Food and Cosmetics - 18	**18003**	[ ] ORA [X] CENTER	20.81 [2.88]

	6. ORGANIZATION	FOOD DEFENSE TECH ASSIST (5)	TRAINING GIVEN (6)	FSMA (7)	NATIONAL TEAM TECH ASSIST (8)					
	TOTAL ORA	**21**	**42**	**21**	**27**					
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	(b) (5), (b) (7)(E) [redacted]								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION		10.00	40.00	10.00	50.00					
TOTAL HOURS		210.00	1680.00	210.00	1350.00					
CONVERSION FACTOR		1200.00	1200.00	1200.00	1200.00					
TOTAL OPERATIONAL FTEs		0.18	1.40	0.18	1.13					

7. REMARKS

(5) This includes presentation and distribution of the Food Defense guidance document for Dairy Products to the State Regulatory Agencies and industry during check ratings, routine field work and State program assessments.
(6) Activities include the Regional Milk Seminar/SST Training Courses/Regional Training and Workshops.
(7) Includes time for presentation and distribution of Food Safety Modernization Act (FSMA) guidance document for dairy products to the state regulatory agencies during check ratings, routine field work, and state program assessments.
Presentations may be made at local meetings and included in training sessions for all segments of the regulatory and industry coummmunity. Coordination of FSMA field activities.
(8) Activities include the National Steering Team Meetings and Conference Calls (20 RMS's) and time for Team Leader Activities (2 RMSs with additional 150 hours each identified.)

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Molluscan Shellfish Evaluation

2. PPS PROJECT NAME/NUMBER
Technical Assistance: Food and Cosmetics - 18

3. PROGRAM/ASSIGNMENT CODE(S)
18004

4. WORK ALLOCATION PLANNED BY
[ ] ORA [X] CENTER

5. OPERATIONAL FTE POSITIONS
16.00 [13.79]

	6. ORGANIZATION	GROWING AREA EVALUATION (1)	CONTROL OF HARVEST (2)	VIBRO SPECIES MANAGEMENT (3)	TECHNICAL ASSISTANCE (HOURS) (4)	FOREIGN EVALUATION (5)	NATIONAL TEAM REPS (6)	PLANT EVALUATION (7)	STANDARD-IZATION & RE-STANDARD-IZATION (8)	NATIONAL TEAM WORKSHOP (9)
	TOTAL ORA	**165**	**16**	**22**	**3520**	**2**	**2**	**209**	**15**	**11**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
HAFW2	Division of Human and Animal Food Operations West II									
HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION		20.00	90.00	200.00		200.00	180.00	10.00	40.00	40.00
TOTAL HOURS		3300.00	1440.00	4400.00	3520.00	400.00	360.00	2090.00	600.00	440.00
CONVERSION FACTOR		1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00	1200.00
TOTAL OPERATIONAL FTEs		2.75	1.20	3.67	2.93	0.33	0.30	1.74	0.50	0.37

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

(1) Resources are allocated for planning, field evaluations, file reviews to determine state program conformity to the requirements of National Shellfish Sanitation Program (NSSP) Model Ordinance (MO).
(2) Resources are allocated for planning, field evaluations, file reviews, growing area data reviews.
(3) Activities include mangement, technical assistance and evaluation of state shellfish programs.
(4) Includes interpretations and consultation on NSSP MO requirements.
(5) Activities include planning, field evaluations, file reviews and report writing for countries with Memorandum of Understanding (MOU) or agreements with FDA.
(6) Includes resources for shellfish program planning, development and coordination.
(7) Includes resources for planning field evaluations of processing plants, file reviews, and final report writing.
(8) Standardization conducted every 5 years for all FDA and state standardization officers. Re-standardization training will be provided during evaluation and technical assistance work while working in shellfish processing plants with state and FDA Shellfish Standardization Officers(SSOs).
(9) Includes specialist initiatives related to shellfish program development of agency procedures, guidance documents, standards, initiatives of national importance.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
Molluscan Shellfish Evaluation	Technical Assistance: Food and Cosmetics - 18	18004	[ ] ORA [X] CENTER	16.00 [2.21]

	6. ORGANIZATION	TRAINING WORKSHOPS (10)	REGIONAL SEMINARS (11)	ISSC COMMITTEE CONFERENCE (12)	CENTER INITIATIVES & LABORATORY EVALUATION (13)					
	TOTAL ORA	**12**	**19**	**16**	**7**					
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	(b) (5), (b) (7)(E) [redacted]								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
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HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
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HAFW3	Division of Human and Animal Food Operations West III									
HAFW4	Division of Human and Animal Food Operations West IV									
HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
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KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION		30.00	30.00	90.00	40.00					
TOTAL HOURS		360.00	570.00	1440.00	280.00					
CONVERSION FACTOR		1200.00	1200.00	1200.00	1200.00					
TOTAL OPERATIONAL FTEs		0.30	0.48	1.20	0.23					

7. REMARKS

(10) Includes training workshops coordinated and delivered by the specialists.
(11) Includes resources for the Regional Shellfish Specialists to attend regional shellfish conferences.
(12) Resources allocated for the specialists to attend the biennial Interstate Shellfish Sanitation Conference to address program related issues and new ISSC proposals.
(13)

Program Priorities by Number Order:

#1 Vibrio Activities	#8 National Team Workshops
#2 Growing Area	#9 FMSA workgroups
#3 Control of Harvest	#10 National Team Reps
#4 Technical Assistance	#11 Training Workshops
#5 Foreign Evaluation	#12 Standardization
#6 Regional Seminars	#13 Plant Evaluation
#7 ISSC Committees	#14 Center Initiatives

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER	3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
Responsive Investigative/Laboratory Operations	Technical Assistance: Food and Cosmetics - 18	**18F813**, 18029F	X ORA / CENTER	3.16

	6. ORGANIZATION	EMERGING ISSUES ACTIVITIES (HOURS) (1)
	TOTAL ORA	**3000**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**	
DMS	Division of Milk Safety	
DRFP	Division of Retail Food Protection	
DSS	Division of Shellfish Sanitation	
IOG-HAF	International Operations - Human Foods	
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**	
HAFE1	Division of Human and Animal Food Operations East I	
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HAFE5	Division of Human and Animal Food Operations East V	
HAFE6	Division of Human and Animal Food Operations East VI	
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**	
HAFW1	Division of Human and Animal Food Operations West I	
HAFW2	Division of Human and Animal Food Operations West II	
HAFW3	Division of Human and Animal Food Operations West III	
HAFW4	Division of Human and Animal Food Operations West IV	
HAFW5	Division of Human and Animal Food Operations West V	
HAFW6	Division of Human and Animal Food Operations West VI	
LABS	**FOOD AND FEED LABORATORIES**	
ARKL	Arkansas Lab	
DENL	Denver Lab	
KCL	Kansas City Lab	
NFFL	Northeast Food and Feed Lab	
PNL	Pacific Northwest Lab	
PSFFL	Pacific Southwest Food and Feed Lab	
SANFL	San Francisco Lab	
SFFL	Southeast Food and Feed Lab	
ESTIMATED HOURS PER OPERATION		
TOTAL HOURS		3000.00
CONVERSION FACTOR		950.00
TOTAL OPERATIONAL FTEs		3.16

(b) (5), (b) (7) (E)

7. REMARKS

NOTE: 18F813 is for planning purposes only. Resources are to be used for all outbreak, emergency activities, emerging issues. Accomplished work must be reported against the appropriate program or assignment PAC.

Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.

(1) These resources are for conveyance construction activities (PAC 18029F), Chem Water Collections and any other unplanned work to be used by Districts as needed.
Planned under Domestic Inspections Op12 but to be reported under appropriate PAC and Op Codes.
The Division allocations are tentative and actual utilization will depend on the emerging needs in the Field.
Op13 should be used to report plan reviews and not Op92

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Food Composition, Standards, Labeling and Economics - 21

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			INSPECTIONAL		ANALYTICAL		
			DOMESTIC	FOREIGN	DOMESTIC		
	TOTAL		**38.93**		**24.52**	**63.45**	
1	Food Composition, Standards, Labeling and Economics	21F810*	31.59		24.09	**55.68**	21-31-33
2	Responsive Investigative/Laboratory Operations	21F813*	7.34		0.43	**7.77**	21-34
	*This PAC is for planning purposes only.						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC.						

CENTER WORK PLANNER/TELEPHONE	ORA PLANNER/TELEPHONE
Mallory Kelly 240-402-2401	Shilpa Sainath 240-402-9912

FY 2018 ORA WORK PLAN — October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Food Composition, Standards, Labeling and Economics

2. PPS PROJECT NAME/NUMBER
Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)
21F810, 21002, 21003, 21005, 21006, 21008, 21R816, 21839

4. WORK ALLOCATION PLANNED BY
X ORA X CENTER

5. OPERATIONAL FTE POSITIONS
55.68 [27.21]

	6. ORGANIZATION	DOMESTIC INSPECTIONS DIETARY SUPPLEMENT FSMA HR 21008A (1)	DOMESTIC INSPECTIONS DIETARY SUPPLEMENT FSMA NHR 21008A (1)	DOMESTIC INSPECTIONS DIETARY SUPP DMAA/DMBA ASSIGNMENT (HOURS) (2)	DOMESTIC INSPECTIONS MEDICAL FOOD FACILITY 21002 (3)	DOMESTIC INSPECTIONS INFANT FORMULA FACILITY 21006 (3)	DOMESTIC SAMPLE COLLECTION MEDICAL FOODS 21002 SCOPE	DOMESTIC SAMPLE COLLECTION ECONO 21003	DOMESTIC SAMPLE COLLECTION NLEA 21005 (4)	DOMESTIC SAMPLE COLLECTION INFANT FORMULA 21006 SCOPE
	TOTAL ORA	**332**	**58**	**320**	**16**	**21**	**32**	**400**	**340**	**27**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
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OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
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HAFW3	Division of Human and Animal Food Operations West III									
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ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
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PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		16092.04	2271.86	320.00	320.00	1208.00	192.00	3240.00	2040.00	162.00
CONVERSION FACTOR		950.00	950.00	950.00	950.00	950.00	950.00	950.00	950.00	950.00
TOTAL OPERATIONAL FTEs		16.94	2.39	0.34	0.34	1.27	0.20	3.41	2.15	0.17

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

NOTE: PAC 21F810 is for planning purposes only. Accomplished work must be reported against the appropriate program or assignment PAC.
Please see the Reporting Guidance for a listing of compliance programs and corresponding PACs.
FY18 SCOPE issued by CFSAN should be considered as final numbers. DPE will make efforts to keep work plan in sync with SCOPE numbers.

(1) These FSMA HR and NHR numbers for Dietary Supplements (DS) inspections are separated out from the FY18 FSMA HR NHR inventory which is planned under PACs 03F811 for HR and 03F812 FOR NHR. PAC 21008A is to be used for the DS inspections.
If these facilities are inspected under PC, PC PAC may also be added while reporting.
(2) This Dietary Supplement DMAA/DMBA Inspectional Assignment is carryover from FY17.
(3) Resources for medical food and infant formula facilities yearly inspections. Division allocations are tentative and updates will be made after FY18 FSMA list is updated by CFSAN.
(4) Resources include collection of documentary samples.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Food Composition, Standards, Labeling and Economics

2. PPS PROJECT NAME/NUMBER
Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)
21F810, 21002, 21003, 21005, 21006, 21008, 21R816, 21839

4. WORK ALLOCATION PLANNED BY
X ORA X CENTER

5. OPERATIONAL FTE POSITIONS
55.68 [12.86]

	6. ORGANIZATION	DOMESTIC SAMPLE COLLECTION DIETARY SUPPLEMENT 21008 (5)	DOMESTIC SAMPLE COLLECTION DIETARY SUPPLEMENT ASSIGNMENT (6)	DOMESTIC FIELD EXAMS (7)	DOMESTIC SAMPLE ANALYSIS MEDICAL FOODS MICRO 21002	DOMESTIC SAMPLE ANALYSIS MEDICAL FOODS CHEM 21002	DOMESTIC SAMPLE ANALYSIS NLEA CHEM 21005	DOMESTIC SAMPLE ANALYSIS INFANT FORMULA CHEM 21006	DOMESTIC SAMPLE ANALYSIS INFANT FORMULA MICRO 21006	DOMESTIC SAMPLE ANALYSIS DIETARY SUUPLEMENT CHEM 21008
	TOTAL ORA	**333**	**250**	**1881**	**11**	**19**	**200**	**16**	**14**	**206**
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**	[redacted]								
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
HAFE1	Division of Human and Animal Food Operations East I									
HAFE2	Division of Human and Animal Food Operations East II									
HAFE3	Division of Human and Animal Food Operations East III									
HAFE4	Division of Human and Animal Food Operations East IV									
HAFE5	Division of Human and Animal Food Operations East V									
HAFE6	Division of Human and Animal Food Operations East VI									
OHAFOW	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - WEST**									
HAFW1	Division of Human and Animal Food Operations West I									
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HAFW5	Division of Human and Animal Food Operations West V									
HAFW6	Division of Human and Animal Food Operations West VI									
LABS	**FOOD AND FEED LABORATORIES**									
ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION		5.10	5.10	0.63	25.75	66.43	14.00	130.00	21.00	16.00
TOTAL HOURS		1698.00	1275.00	1185.00	283.00	1262.00	2800.00	2080.00	294.00	3296.00
CONVERSION FACTOR		950.00	950.00	950.00	1180.00	1180.00	1180.00	1180.00	1180.00	1180.00
TOTAL OPERATIONAL FTEs		1.79	1.34	1.25	0.24	1.07	2.37	1.76	0.25	2.79

(b) (5), (b) (7)(E)

7. REMARKS

(5) Domestic Sample Collections may be collected at packers/repackers, distributors or warehouse if the requested number of samples cannot be collected during the inspection.
(6) CFSAN will issue an assignment mid year for the collection of vitamin products (assignment will carryover from FY18 to FY19)
(7) Field exams will be reported under Op 53 and Label Exams/Review should be reported under appropriate PAC and Op code 51

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Food Composition, Standards, Labeling and Economics

2. PPS PROJECT NAME/NUMBER
Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)
21F810, 21002, 21003, 21005, 21006, 21008, 21R816, 21839

4. WORK ALLOCATION PLANNED BY
X ORA
CENTER

5. OPERATIONAL FTE POSITIONS
55.68 [15.61]

REGION	6. ORGANIZATION	DOMESTIC SAMPLE ANALYSIS TOTAL DIET STUDY (TDS) CHEM 21839	DOMESTIC SAMPLE ANALYSIS DIETARY SUPPLEMENT ASSIGNMENT CHEM	DOMESTIC SAMPLE ANALYSIS ECONO 21003 (8)	METHODS VAL/DEVT CHEM (HOURS) 21R816	APPLIED TECHNOLOGY CENTER CHEM (HOURS) 21R816				
	TOTAL ORA	**1040**	**250**	**400**	**932**	**910**				
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
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ARKL	Arkansas Lab									
DENL	Denver Lab									
KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION		1.20	18.20	27.00						
TOTAL HOURS		1248.00	4550.00	10800.00	932.00	910.00				
CONVERSION FACTOR		1180.00	1180.00	1180.00	1205.00	1180.00				
TOTAL OPERATIONAL FTEs		1.06	3.86	9.15	0.77	0.77				

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

(8) CFSAN will issue an assignment or something similar to identify products for collection under the economic adulteration resources for the FY18 work plan.

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Responsive Investigative/Laboratory Operations

2. PPS PROJECT NAME/NUMBER
Food Composition, Standards, Labeling and Economics - 21

3. PROGRAM/ASSIGNMENT CODE(S)
21F813

4. WORK ALLOCATION PLANNED BY
[X] ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS
7.77

	6. ORGANIZATION	EMERGING ISSUES INSPECTIONS (HOURS)	DOMESTIC INVESTI-GATIONS (HOURS) (1)	OUTBREAK EMERGENCY RESPONSE (HOURS) 21R839	EMERGING ISSUES SAMPLE COLLECTION (HOURS)	EMERGING ISSUES SAMPLE ANALYSIS CHEM (HOURS) (2)	OUTBREAK EMERG RESP SAMPLE ANALYSIS CHEM (HOURS)			
	TOTAL ORA	**3000**	**3500**	**100**	**372**	**362**	**147**			
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
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KCL	Kansas City Lab									
NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		3000.00	3500.00	100.00	372.00	362.00	147.00			
CONVERSION FACTOR		950.00	950.00	950.00	950.00	1180.00	1180.00			
TOTAL OPERATIONAL FTEs		3.16	3.68	0.11	0.39	0.31	0.12			

(b) (5), (b) (7)(E)

7. REMARKS

NOTE: 21F813 is for planning purposes only. Resources are to be used for all outbreak, emergency activities, emerging issues. Accomplished work mustbe reported against the appropriate program or assignment PAC.

Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.

(1) Includes investigational hours for all domestic investigations and follow-up to RFR-RCR.
(2) These resources may be used for ephedrine alkaloids testing as needed.

PROJECT SUMMARY SHEET

FY 2018

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Food and Cosmetics	Colors and Cosmetics Technology - 29

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			INSPECTIONAL		ANALYTICAL		
			DOMESTIC	FOREIGN	DOMESTIC		
	TOTAL		**4.40**		**5.28**	**9.68**	
1	Cosmetics: Domestic and Imports	29001	3.46		5.11	**8.57**	29-36
2	Responsive Investigative/Laboratory Operations	29F813*	0.94		0.17	**1.11**	29-37
	*This PACis for planning purposes only.						
	Accomplished work must be reported against the						
	appropriate program or assignment PAC.						

CENTER WORK PLANNER/TELEPHONE	ORA PLANNER/TELEPHONE
Mallory Kelly 240-402-2401	Shilpa Sainath 240-402-9912

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Cosmetics: Domestic and Imports	Colors and Cosmetics Technology - 29

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
29001	X ORA ___ CENTER	8.57

	6. ORGANIZATION	DOMESTIC INSPECTIONS	DOMESTIC INSPECTIONS TARGETED (1)	DOMESTIC SAMPLE COLLECTION COSMETICS ASSIGNMENT TBD (2)	DOMESTIC SAMPLE COLLECTION (3)	DOMESTIC SAMPLE ANALYSIS COSMETICS ASSIGNMENT MICRO TBD (2)	DOMESTIC SAMPLE ANALYSIS COSMETICS ASSIGNMENT CHEM TBD (2)	DOMESTIC SAMPLE ANALYSIS MICRO (4)		
	TOTAL ORA	**75**	**25**	**75**	**200**	**75**	**75**	**200**		
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
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NFFL	Northeast Food and Feed Lab									
PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION		16.50	16.50	6.00	6.00	16.88	18.64	16.88		
TOTAL HOURS		1238.00	413.00	450.00	1200.00	1266.00	1398.00	3376.00		
CONVERSION FACTOR		950.00	950.00	950.00	950.00	1180.00	1180.00	1180.00		
TOTAL OPERATIONAL FTEs		1.30	0.43	0.47	1.26	1.07	1.18	2.86		

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

NOTES: Accomplilshed work must be reported against the appropriate program or assignment PAC.
Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.
If the Center initiates any assignments to follow up on drug claims on cosmetics, the field resources will be used from this program.

(1) Targeted firms list and assignment will be communicated through OHAFO and Division spread will be updated when assignment is issued.
(2) CFSAN will issue an assignment in FY18 to identify targeted cosmetics
(3) These resources planned in 29001 are to be used as needed.
(4) For Chem analysis resources from Emerging Issues PAC 29F813 or PAC 04F813 may be used if needed

FY 2018 ORA WORK PLAN

October 1, 2017

1. PROGRAM/ASSIGNMENT TITLE
Responsive Investigative/Laboratory Operations

2. PPS PROJECT NAME/NUMBER
Colors and Cosmetics Technology - 29

3. PROGRAM/ASSIGNMENT CODE(S)
29F813

4. WORK ALLOCATION PLANNED BY
X ORA [ ] CENTER

5. OPERATIONAL FTE POSITIONS
1.11

	6. ORGANIZATION	EMERGING ISSUES INSPECTIONS (HOURS)	DOMESTIC INVESTIGATIONS (HOURS)	OUTBREAK EMERGENCY RESPONSE (HOURS)	EMERGING ISSUES SAMPLE COLLECTION (HOURS)	EMERGING ISSUES SAMPLE ANALYSIS (CHEM) (HOURS)	DOMESTIC SAMPLE ANALYSIS OUTBREAK EMERG (CHEM) (HOURS)			
	TOTAL ORA	**124**	**550**	**100**	**109**	**109**	**100**			
ORAHQ	**OFFICE OF REGULATORY AFFAIRS**									
OHAFO	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS**									
DMS	Division of Milk Safety									
DRFP	Division of Retail Food Protection									
DSS	Division of Shellfish Sanitation									
IOG-HAF	International Operations - Human Foods									
OHAFOE	**OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS - EAST**									
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PNL	Pacific Northwest Lab									
PSFFL	Pacific Southwest Food and Feed Lab									
SANFL	San Francisco Lab									
SFFL	Southeast Food and Feed Lab									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		124	550	100	109	109	100			
CONVERSION FACTOR		950	950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs		0.13	0.58	0.11	0.11	0.09	0.08			

(b) (5), (b) (7)(E)

[redacted]

7. REMARKS

NOTE: 29F813 is for planning purposes only. Resources are to be used for all outbreak, emergency activities, emerging issues, OAI follow-ups. Accomplished work must be reported againstthe appropriate program or assignment PAC.

Please see Reporting Guidance for a listing of compliance programs and corresponding reporting PACS.