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| FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS | Document Number: DIR-000081 | Revision #: 00 Revised: 31 August 2020 |
| Title: FMD-30A: ORA/CFSAN Human Food Program Committee | | Page 1 of 11 |

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1. Purpose

This Directive provides for the formation and operation of the Office of Regulatory Affairs (ORA) – Office of Human and Animal Food Operations (OHAFO) and the Center for Food Safety and Applied Nutrition (CFSAN) Human Food Program Committee to discuss and address Agency priorities and Center initiatives as relates to human foods, dietary supplements, and cosmetics. The Committee also identifies workplanning activities and targets, develops annual work plans (WP), establishes strategic priorities to include inspections, compliance determinations, analytical needs, and import operations, and utilizes strategic thinking to recommend solutions to issues and challenges.

2. Scope

The scope of this document defines the role of the ORA/CFSAN Human Food Program Committee. This document covers the roles and responsibilities for

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the Committee members, as well as the process to collaborate and execute the Agency's priorities for each fiscal year (FY).

3. Responsibility

- A. ORA Executive Management
 - 1. Provides support and leadership for the ORA/CFSAN Human Food Program Committee.
 - 2. Selects ORA representatives to support the Committee and to participate and attend meetings.
- B. CFSAN Executive Management
 - 1. Provides support and leadership for the ORA/CFSAN Human Food Program Committee.
 - 2. Selects CFSAN representatives to support the Committee and to participate and attend meetings.
- C. ORA/CFSAN Human Food Program Committee
 - 1. Serves as the program managers for ORA and CFSAN.
 - 2. Serves as principal contact for ORA (field and headquarters (HQ)) and CFSAN on matters relating to human food, dietary supplements, and cosmetics, including work planning and budget issues.
 - 3. Acts as liaison between ORA and CFSAN on general program matters.
 - 4. Seeks input from ORA and CFSAN units on proposals, programs, assignments, and initiatives.
 - 5. Reviews and provides input for field assignments, compliance programs, directives and procedural changes consistent with Agency policy.
 - 6. Coordinates and participates in developing program goals, strategies, procedures, enforcement initiatives, and evaluation measures necessary to assure effective execution of the Agency's responsibilities.
 - 7. Advises appropriate offices in the monitoring of program activities, assuring that assigned resources are effectively utilized in the accomplishment of planned activities.

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8. Regularly communicates to respective ORA and CFSAN units and counterparts the status of program activities.
9. Identifies potential issues for evaluation and attention.
10. Keeps the Associate Commissioner for Regulatory Affairs (ACRA) and Center Director(s) advised of program policies and directions as appropriate.

D. ORA Committee Representatives

1. Serve as the principal contacts for ORA (field and HQ).
2. Seek input from ORA units on CFSAN proposals, programs, and initiatives.
3. Seek input from CFSAN on ORA initiatives.
4. Review and provide feedback on documents related to program impacts and priorities.
5. Review and provide input for compliance programs, directives, assignments, and procedural changes to be issued by CFSAN to the field, consistent with ORA policy.
6. Manage program assignments and resources.
7. Execute program priorities to include human food issues involving ORA field laboratories & imports operations.
8. Identify inspectional assignments, sample collections, field exams, sample analyses as needed to meet Agency priorities.
9. Develop workplans jointly with CFSAN and communicate appropriately with the FDA Governance Board (GB).
10. Review new authorities granted by legislation and assist in implementation of regulations related to human foods and cosmetics.
11. Work with external partners such as states, local and tribal officials, and territorial and foreign counterparts in the management of state, federal and local relations.
12. Maintain communications with ORA managers and field staff.
13. Identify and coordinate training needs as appropriate for field staff.

E. CFSAN Committee Representatives

1. Share information and provide insight on Commissioner and CFSAN level activities and priorities.

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2. Serve as the principal contacts for CFSAN interactions and communications with ORA.
 3. Communicate program strategic priorities and address issues raised by the Committee and during the review of documents such as the WP, compliance programs and/or assignments.
 4. Develop and share information on the WP, assignments, program summaries, and evaluations.
 5. Communicate policy, compliance, and enforcement strategies for major programs.
 6. Establish and share information on inspections, sampling data, and priorities.
 7. Address requests for resource adjustments throughout the FY.
 8. Manage communications with the GB.
 9. Share information regarding budget development and budget priorities.
 10. Facilitate approval and finalization of FY WP with the GB.
- F. Ad Hoc Committee and Invited Representatives
1. Responsible for participating in, and constructively contributing to committee activities and accomplishments throughout the year.
 2. Represent field, HQ and CFSAN offices with operational responsibility and/or relevant experience with or impacted by the human food program areas.
 3. Review and provide feedback on documents related to program operations, evaluations, and strategic priorities when appropriate.
 4. Communicate strategic objectives, action items or major program changes to ORA and CFSAN managers and staff as applicable.
 5. Participate in developing program goals, procedures, enforcement initiatives, problem solving, and evaluation measures necessary to assure effective execution of the Agency's responsibilities.
- G. Human Food Program Committee Co-advisors
1. Provide consultation and senior level advice to the Committee.
 2. Serve as liaison with the ORA Senior Management Team and CFSAN Leadership Team.
 3. Provide support to the Committee Chairs execution of duties.

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H. Human Food Program Committee Co-chairs

1. Provides overall management, operation and direction for the Committee.

I. Human Food Program Committee Vice Chair

1. Serves in the absence of the ORA Committee Co-chairs and assists the Committee Co-chairs in the management, operation and direction of the Committee.

J. Executive Secretary

1. Responsible for maintaining committee files, creating and storing minutes, tracking action items, and preparing other records to support Committee activities.
2. Responsible for distributing and routing materials to members and others; planning, scheduling and coordinating Committee meetings.
3. Conducts other administrative activities at the direction of the Committee Advisors and Chairs.

4. Background

The Associate Commissioner for Regulatory Affairs previously established a system of Field Committees (FMD 30) to assist in managing the ORA organization and its implementation of Agency program areas. In May 2017, ORA was realigned into distinct product-based regulatory programs to strengthen the workforce, improve public health response, and enable staff to work more closely with FDA scientific and technical experts on novel and complex regulatory challenges.

As part of the ORA realignment, the specialized OHAFO was established. OHAFO was designated to lead ORA's collaboration with FDA's CFSAN and the Center for Veterinary Medicine (CVM) in protecting the safety of the nation's domestically produced and imported human and animal foods, dietary supplements, food products derived from animals, cosmetics and animal food additives. In addition, OHAFO is responsible for providing advice and counsel to FDA leaders regarding human and animal food products, field operations, and emergency response activities.

5. References

- A. [FMD30 – ORA Program Committees](#)

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6. Procedure

6.1. Human Food Program Committee Membership: Selection and Tenure

Members of the ORA/CFSAN Human Food Program Committee include representatives from the ORA (field and HQ) and CFSAN offices with operational responsibilities and/or involved with or impacted by the human food program and/or have relevant experiences or expertise in the human food program areas.

- A. The ORA/CFSAN Human Food Program Committee composition consists of the following:
 1. Program Director: One (1)
 - a. To serve as Human Food Program Committee Co-advisor, selected by ORA Assistant Commissioner for Human and Animal Foods Operations (ACO) in consultation with the ACRA and CFSAN Director for an indefinite term at the discretion of the ACO.
 2. Center Senior Director: One (1)
 - a. To serve as Human Food Program Committee Co-advisor selected by the Center Director and the ORA Assistant Commissioner for Human and Animal Foods Operations (ACO) in consultation with the ACRA and CFSAN Director for an indefinite term at the discretion of the Center Director.
 3. Program Division Director: One (1)
 - a. To serve as Human Food Program Committee Co-chair selected by the ACO in consultation with the Human Food Program Committee Advisor for a 3-year term. Subsequent one (1) year extensions may be authorized at the discretion of the ACO.
 4. CFSAN Senior Director: One (1)
 - a. To serve as Human Food Program Committee Co-chair selected by the CFSAN Director in consultation with the ACO and Human Food Program Committee Advisor for a 3-year term. Subsequent one (1) year extensions may be authorized at the discretion of the CFSAN Director.
 5. Program Division Director or equivalent: One (1)

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- a. To serve as Human Food Committee Vice Chair selected by the ACO in consultation with the Human Food Program Committee Advisor for a 3-year term and mirror any extensions of the ORA Committee Co-chair. At the end of this term, the Vice Chair assumes the position of the ORA Co-chair.
6. Executive Secretary: One (1)
- a. Selected by the Committee Chairs to serve an indefinite term at the discretion of the Chairs.
7. Program Division Directors or equivalent: One to Two (1-2)
- a. To serve as a Committee Member (s), selected by the Committee Chairs to serve an indefinite term at the discretion of the Chairs.
8. Division of Import Operations (DIO) Senior Director or Import Manager: One (1)
- a. To serve as a Committee Member, selected by the Committee Chairs in consultation with the DIO Director to serve an indefinite term at the discretion of the Chairs.
9. Office of State Cooperative Programs (OSCP) Director or Branch Director: One (1)
- a. To serve as a Committee Member, selected by the Committee Chairs in consultation with the OSCP Director to serve an indefinite term at the discretion of the Chairs.
10. ORS Senior Director or Laboratory Director: One (1)
- a. To serve as a Committee Member, selected by the Committee Chairs in consultation with the ORS Director to serve an indefinite term at the discretion of the Chairs.
11. State Liaison: One (1)
- a. To serve as Committee Member, selected by the Committee Chairs and Advisors for an indefinite term at the discretion of the Chairs.
12. Field Managers (below the level of Program Division Director): Three to Five (3-5)
- a. Select at least one of each: Director, Investigations Branch (DIB), Director, Compliance Branch (DCB), Supervisory Consumer Safety Officer (SCSO).

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- b. To serve as Committee Member(s), selected by the Committee Chairs and Advisors for an indefinite term at the discretion of the Chairs.
- 13. Technical Expert(s): One to Two (1-2)
 - a. Select as needed from such positions as Consumer Safety Officer (CSO), Compliance Officer (CO), Analyst, and/or National or Program Expert
 - b. To serve as Committee Member(s) selected by the Field Food Committee Chairs and Advisors to serve an indefinite term at the discretion of the Chairs.
 - c. Other Technical Experts may be called upon as needed, on a case-by-case basis to temporarily assist with specific projects and initiatives.
- 14. CFSAN Division Directors or Managers: Two to Three (2-3)
 - a. To serve as Committee Members, selected by the Human Food Program Committee Advisor and Chairs to serve an indefinite term at the discretion of the Chairs.
- 15. CFSAN Technical Experts: Two to Three (2-3)
 - a. To serve as Committee Members, selected by the Human Food Program Committee Advisor and Chairs to serve an indefinite term at the discretion of the Chairs.
- B. Ad Hoc Committee and Invited Representatives: (As Needed)
 - 1. To include ORA or CFSAN representatives involved with or impacted by the human food program from the following areas:
 - a. Federal-State Relations or Partnerships
 - b. Science (laboratory)
 - c. Imports
 - d. Foreign Offices/Program
 - e. Resources/Work Planning
 - f. Criminal Investigations
 - g. Compliance & Enforcement
 - h. Risk Management
 - i. Quality System Management

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j. Operational Policy

2. To serve as Committee Members or on Ad-Hoc Committees, selected by the Human Food Program Committee Advisor and Chairs to serve an indefinite term at the discretion of the Chairs.

6.2. Human Food Program Committee Meetings and Frequency

- A. At a minimum, the ORA/CFSAN Human Food Program Committee meets annually face-to-face in a central location preferably during the first half of each calendar year.
- B. The Committee meets jointly with the ORA/CVM Animal Food Program Committee for a period during the face-to-face annual meeting.
- C. The Committee has monthly virtual meetings.
- D. During the year, the Committee has at least one virtual meeting jointly with the ORA/CVM Animal Food Program Committee.

6.3. Human Food Program Committee Communication

- A. The Committee Chairs and executive secretary communicate with other program committee chairs on a regular basis.
 1. To assure uniformity in policies and procedures among the various Agency program areas.
- B. The Committee Chairs standardize the way committee meeting notes are prepared and distributed.
 1. To assure content of minutes and notes are accurate and properly suitable for use, distribution, and/or action.
 2. To clearly identify issues that have not yet been adopted as official policy.

6.4. Human Food Program Committee Reporting, Program Metrics, and Activities

- A. During the Human Food Committee meetings, the Committee may identify assignments that require monitoring during the FY.
 1. The Committee determines the strategic evaluation mechanisms for food committee assignments and activities.
 2. The Committee establishes a process for memorializing decisions and meeting notes.

6.5. Human Food Program Committee Funding

- A. ORA and CFSAN funds Committee members attendance and participation in Committee activities and meetings where appropriate.

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- B. ORA and CFSAN support costs and resources associated with the membership outlined in this Field Management Directive (FMD).
- C. For ORA funding, the ORA Committee Chair, in consultation with the Committee Advisors prepares and submits a budget proposal to the ORA Office of Management (OM) at the beginning of each fiscal year (or when specified by OM).
 1. To provide funding for attendance and participation to include a face-to-face meeting of the Committee annually if possible as well as any other travel or expenses required by the Chair and/or other committee members as appropriate.
 2. To support requests for Committee special projects and/or initiatives.
 3. Upon receipt, OM reviews the budget proposal and provides the Committee with a budget that is managed by the Human Food Committee Chairs.

7. Glossary/Definitions

A. Acronyms

1. ACRA: Associate Commissioner for Regulatory Affairs
2. ACO: Assistant Commissioner for Office of Human and Animal Foods Operations
3. CFSAN: Center for Food Safety and Nutrition
4. CO: Compliance Officer
5. CSO: Consumer Safety Officer
6. CVM: Center for Veterinary Medicine
7. DCB: Director, Compliance Branch
8. DIB: Director, Investigations Branch
9. DIO: Division of Import Operations
10. FMD: Field Management Directive
11. FY: Fiscal Year
12. GB: FDA Governance Board
13. HQ: Headquarters
14. OHAFO: Office of Human and Animal Foods Operations

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- 15. OM: Office of Management
- 16. ORA: Office of Regulatory Affairs
- 17. OSCP: Office of State Cooperative Programs
- 18. ORS: Office of Regulatory Science
- 19. SCSO: Supervisory Consumer Safety Officer
- 20. WP: Work Plan

8. Records

None

9. Supporting Documents

None

10. Document History

| Revision # | Status* (D, I, R) | Date | Author Name and Title | Approving Official Name and Title |
|------------|-------------------|--------------------|--|--|
| 00 | I | SEE DATE IN HEADER | CHARLES BECOAT DEPUTY DIRECTOR, OHAFO EAST PROGRAM | MICHAEL ROGERS ASSISTANT COMMISSIONER, OHAFO PROGRAM |

* - D: Draft, I: Initial, R: Revision

11. Change History

| Revision # | Change |
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12. Attachments

None