

FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS	Document Number: DIR-000082	Revision #: 00 Revised: 31 August 2020
Title: FMD-30B: ORA/CVM Animal Food Program Committee		Page 1 of 11

Sections in This Document

1. Purpose	1
2. Scope	1
3. Responsibility	2
4. Background	5
5. References	5
6. Procedure	6
6.1. Animal Food Program Committee Membership: Selection and Tenure.....	6
6.2. Animal Food Program Committee Meetings and Frequency.....	9
6.3. Animal Food Program Committee Communication	9
6.4. Animal Food Program Committee Reporting, Program Metrics, and Activities.....	9
6.5. Animal Food Program Committee Funding.....	9
7. Glossary/Definitions.....	10
8. Records	11
9. Supporting Documents	11
10. Document History	11
11. Change History	11
12. Attachments.....	11

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 Veterinary Medicine (CVM) Animal Food Program Committee to discuss and address Agency priorities and Center initiatives of protecting human and animal health as relates to foods for animals, food products derived from animals, and animal food additives. The Committee also identifies workplanning activities and targets, develops annual work plans (WP) and 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/CVM Animal Food Program Committee. This document covers the roles and responsibilities for

<p style="text-align: center;">FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS</p>	<p style="text-align: center;">Document Number: DIR-000082</p>	<p style="text-align: center;">Revision #: 00 Revised: 31 August 2020</p>
<p>Title: FMD-30B: ORA/CVM Animal Food Program Committee</p>		<p style="text-align: center;">Page 2 of 11</p>

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/CVM Animal Food Program Committee.
 - 2. Selects ORA representatives to support the Committee and to participate and attend meetings.
- B. CVM Executive Management
 - 1. Provides support and leadership for the ORA/CVM Animal Food Program Committee.
 - 2. Selects CVM representatives to support the Committee and to participate and attend meetings.
- C. ORA/CVM Animal Food Program Committee
 - 1. Serves as the program managers for ORA and CVM.
 - 2. Serves as the principal contact for ORA (field and headquarters (HQ)) and CVM on matters relating to food for animals, food derived from animals, animal food additives, including work planning and budget issues.
 - 3. Acts as liaison between ORA and CVM on general program matters.
 - 4. Seeks input from ORA and CVM 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.

<p style="text-align: center;">FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS</p>	<p style="text-align: center;">Document Number: DIR-000082</p>	<p style="text-align: center;">Revision #: 00 Revised: 31 August 2020</p>
<p>Title: FMD-30B: ORA/CVM Animal Food Program Committee</p>		<p style="text-align: center;">Page 3 of 11</p>

8. Regularly communicates to respective ORA and CVM 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 CVM proposals, programs, and initiatives.
3. Seek input from CVM 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 CVM to the field, consistent with ORA policy.
6. Manage program assignments and resources.
7. Execute program priorities to include related animal 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 CVM and communicates appropriately with the FDA Governance Board (GB).
10. Review new authorities granted by legislation and assist in implementation of regulations related to foods for animals, food products derived from animals, and animal food additives.
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. CVM Committee Representatives

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

<p style="text-align: center;">FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS</p>	<p style="text-align: center;">Document Number: DIR-000082</p>	<p style="text-align: center;">Revision #: 00 Revised: 31 August 2020</p>
<p>Title: FMD-30B: ORA/CVM Animal Food Program Committee</p>		<p style="text-align: center;">Page 4 of 11</p>

2. Serve as the principal contacts for CVM 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 CVM offices with operational responsibility and/or relevant experience with or impacted by the animal 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 CVM 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. Animal Food Program Committee Co-advisors
1. Provides consultation and senior level advice to the Committee.
 2. Serves as liaison with the ORA Senior Management Team and CVM Leadership Team.
 3. Provides support to the Committee Chairs execution of duties.

<p style="text-align: center;">FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS</p>	<p style="text-align: center;">Document Number: DIR-000082</p>	<p style="text-align: center;">Revision #: 00 Revised: 31 August 2020</p>
<p>Title: FMD-30B: ORA/CVM Animal Food Program Committee</p>		<p style="text-align: center;">Page 5 of 11</p>

H. Animal Food Program Committee Co-chairs

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

I. Animal Food Program Committee Vice Chair

1. Serves in the absence of the ORA Committee Co-chair 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 Advisor 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 programs. In May 2017, ORA was realigned into distinct product-based regulatory programs areas 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 the CFSAN and the 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

[FMD-30 – ORA Program Committees](#)

<p style="text-align: center;">FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS</p>	<p style="text-align: center;">Document Number: DIR-000082</p>	<p style="text-align: center;">Revision #: 00 Revised: 31 August 2020</p>
<p>Title: FMD-30B: ORA/CVM Animal Food Program Committee</p>		<p style="text-align: center;">Page 6 of 11</p>

6. Procedure

6.1. Animal Food Program Committee Membership: Selection and Tenure

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

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

<p style="text-align: center;">FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS</p>	<p style="text-align: center;">Document Number: DIR-000082</p>	<p style="text-align: center;">Revision #: 00 Revised: 31 August 2020</p>
<p>Title: FMD-30B: ORA/CVM Animal Food Program Committee</p>		<p style="text-align: center;">Page 7 of 11</p>

consultation with the ACO 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 Animal Food Program Committee Chairs to serve an indefinite term at the discretion of the Chairs.
7. Program Division Director or equivalent: One (1)
 - a. To serve as a Committee Member, selected by the Animal Food Program Committee Advisor and 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. ORS Senior Director: One (1)
 - a. To serve as a Committee Member, selected by the Committee Chairs in consultation with ORS Director to serve an indefinite term at the discretion of the Chairs.
10. 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.
11. Field Managers (below the level of Program Division Director): Two to Four (2-4)
 - a. Include at least one (1) Director, Investigations Branch (DIB) and one (1) Director, Compliance Branch (DCB).
 - b. May include any combination of Supervisory Consumer Safety Officer (SCSO) and other field managers.
 - i. To serve as Committee Member(s), selected by the Animal Food Program Committee Chairs and Advisor for an indefinite term at the discretion of the Chairs.
12. Technical Expert(s): One to Two (1-2)
 - a. This may include a Consumer Safety Officer (CSO), Compliance Officer (CO), Analyst, National or Program Expert.

<p style="text-align: center;">FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS</p>	<p style="text-align: center;">Document Number: DIR-000082</p>	<p style="text-align: center;">Revision #: 00 Revised: 31 August 2020</p>
<p>Title: FMD-30B: ORA/CVM Animal Food Program Committee</p>		<p style="text-align: center;">Page 8 of 11</p>

- b. To serve as Committee Member(s) selected by the Animal Food Program Committee Chairs and Advisor 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.
- 13. CVM Division Directors and Managers: One to Two (1-2)
 - a. To serve as Committee Member(s), selected by the Animal Food Program Committee Advisor to serve an indefinite term at the discretion of the Chairs.
- 14. CVM Technical Experts: One to Two (1-2)
 - a. To serve as Committee Member(s), nominated by the Animal 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 CVM representatives involved with or impacted by the animal food program from the following areas:
 - a. State Cooperative Programs
 - b. Federal-State Relations or Partnerships
 - c. Science (laboratory)
 - d. Imports
 - e. Foreign Offices/Program
 - f. Resources/Work Planning
 - g. Criminal Investigations
 - h. Compliance & Enforcement
 - i. Risk Management
 - j. Quality System Management
 - k. Operational Policy
 - 2. To serve as Committee Members or on Ad-Hoc Committees, selected by the Animal Food Program Committee Advisor and Chairs to serve an indefinite term at the discretion of the Chairs.

<p style="text-align: center;">FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS</p>	<p style="text-align: center;">Document Number: DIR-000082</p>	<p style="text-align: center;">Revision #: 00 Revised: 31 August 2020</p>
<p>Title: FMD-30B: ORA/CVM Animal Food Program Committee</p>		<p style="text-align: center;">Page 9 of 11</p>

6.2. Animal Food Program Committee Meetings and Frequency

- A. At a minimum, the ORA/CVM Animal 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/CFSAN Human Food Program Committee for a period during the face-to-face annual meeting.
- C. The Committee has monthly virtual calls.
- D. During the year, the ORA/CVM Animal Food Program Committee has at least one virtual call jointly with the ORA/CFSAN Human Food Program Committee.

6.3. Animal 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. Animal Food Program Committee Reporting, Program Metrics, and Activities

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

6.5. Animal Food Program Committee Funding

- A. ORA and CVM funds Committee members attendance and participation in Committee activities and meetings where appropriate.
- B. ORA and CVM support costs and resources associated with the membership outlined in this Field Management Directive (FMD).

<p style="text-align: center;">FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS</p>	<p style="text-align: center;">Document Number: DIR-000082</p>	<p style="text-align: center;">Revision #: 00 Revised: 31 August 2020</p>
<p>Title: FMD-30B: ORA/CVM Animal Food Program Committee</p>		<p style="text-align: center;">Page 10 of 11</p>

- C. For ORA funding, the ORA Committee Chairs, 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 Animal Food Program 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
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
15. OM: Office of Management
16. ORA: Office of Regulatory Affairs

FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS	Document Number: DIR-000082	Revision #: 00 Revised: 31 August 2020
Title: FMD-30B: ORA/CVM Animal Food Program Committee		Page 11 of 11

17. ORS: Office of Regulatory Science
18. SCSO: Supervisory Consumer Safety Officer
19. 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 ABOVE	CHARLES BECOAT DEPUTY DIRECTOR, OHAFO EAST PROGRAM	MICHAEL ROGERS ASSISTANT COMMISSIONER, OHAFO PROGRAM

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

11. Change History

Revision #	Change
00	NOT APPLICABLE

12. Attachments

None