Memorandum of Understanding between the United States Food and Drug Administration and the Association of American Feed Control Officials

Background

The United States Food and Drug Administration (FDA) is the primary federal agency responsible for enforcing the Federal Food, Drug, and Cosmetic Act (the Act). Included within the FDA's responsibilities under the Act is the responsibility for regulation of animal foods/feeds. The Act provides the authority for FDA to regulate essentially all ingredients and additives used in animal feed.[1] Depending on its intended purpose or use, an ingredient or additive could be classified as a food additive, a generally recognized as safe substance, a new animal drug, or a color additive.

The Association of American Feed Control Officials (AAFCO) is a voluntary membership organization of the states in the United States (US) and Federal government agencies, as well as government agencies from other countries, responsible for the execution of laws and regulations pertaining to the production, labeling, distribution, use, or sale of animal feed and feed ingredients. The purpose of AAFCO is to provide a mechanism for developing and implementing uniform and equitable laws, regulations, standards, definitions, and enforcement policies for the manufacturing, labeling, and sale of animal feeds and ingredients. AAFCO provides "model laws" and regulations that nearly all states have adopted as the basis for their feed-control program. AAFCO membership consists of all 50 states, Puerto Rico, Costa Rica, Canada, the FDA, US Department of Agriculture, and several universities. It is governed by officers and a board of directors (known collectively as the Board) elected by the membership at the annual meeting of AAFCO. The FDA is a member of AAFCO and serves in a non-voting advisory role on the AAFCO Board.

AAFCO provides a process (herein called the AAFCO Ingredient Definition Request Process) to identify the safety, utility, and identity of ingredients used in animal feed. This process helps to ensure ingredients used in animal feed are suitable for that use and also establishes a common or usual name for the ingredients. This common or usual identity is required on feed labels by both federal law and state regulations. The AAFCO Ingredient Definition Request Process is operated by AAFCO, with the FDA providing scientific and technical assistance. The result of this collaboration has been the establishment of an effective program of benefit to feed regulatory officials, the industry, and the public.

Purpose

The purpose of this memorandum is to facilitate the FDA's collaboration with AAFCO in the AAFCO Ingredient Definition Request Process by clarifying the responsibilities of the FDA and AAFCO during the feed ingredient definition request process and providing mechanisms for resolving disputes that arise and for modifying the definitions when required.

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[1] Some articles added to animal feed fall under the purview of other federal agencies. Feed-through pesticides are regulated by the Environmental Protection Agency (EPA), and vaccines added to animal feed are the responsibility of the US Department of Agriculture (USDA).

Agreement

The FDA and AAFCO agree to the following:

A. AAFCO maintains definitions of various feed ingredients, which includes the common ingredient name, description, and any appropriate limitations for its use, and publishes the currently accepted feed ingredient definitions in the AAFCO Official Publication (OP).

B. Requests for new feed ingredients or requests to modify an existing feed ingredient definition are reviewed by AAFCO investigators chosen by the AAFCO Board and FDA scientists assigned by the agency's division director or team leader in the Division of Animal Feeds (DAF).

C. AAFCO will seek advice and a letter of concurrence regarding the suitability of the feed ingredient for its proposed use from the FDA prior to adopting new feed ingredient definitions or amending existing ones.

D. AAFCO will provide to the FDA, upon FDA's request (1) industry-generated requests and (2) requests from AAFCO for new feed ingredients and for modifications of existing definitions within 30 working days of AAFCO's receipt of the complete request. AAFCO's Board-assigned AAFCO feed investigator will make the initial contact with the FDA.

E. The FDA will allow the AAFCO Board or Board-assigned AAFCO feed investigator to request consultation from the FDA on requests for new feed ingredient definitions and modifications of existing definitions. AAFCO's initial contact will be the director of the DAF, Center for Veterinary Medicine (CVM), FDA. The FDA will provide its decision on whether it will be able to consult with AAFCO and the DAF number assigned to the request within 30 working days.

F. If the FDA determines it will publish a food additive regulation of a requested ingredient definition under section 409 of the Act and FDA's implementing regulations in 21 CFR 571.1 for a feed ingredient, AAFCO will not include that ingredient in the AAFCO OP until the FDA completes the regulation.

G. Disagreements on existing feed ingredient definitions, the establishment of new ingredient definitions, or modifications of existing definitions between the FDA and AAFCO will be referred to an arbitration board. The arbitration board will be comprised of two representatives from AAFCO appointed by the Board and two representatives from the FDA that are appointed by the director, FDA CVM Office of Surveillance and Compliance and the director, FDA CVM Division of Animal Feeds.

H. AAFCO will consider all requests from the FDA to remove an ingredient definition from the AAFCO OP upon the FDA presenting scientific evidence substantiating their conclusion the ingredient is no longer suitable for its stated intended use. The Ingredient Definitions Committee will vote on the FDA request to remove the ingredient from the Feed Ingredient Definitions section in the AAFCO OP at their next scheduled meeting. Disagreements between AAFCO and the FDA would be handled as stated in G.

I. AAFCO is allowed, on its own initiative and with FDA concurrence, to request that an AAFCO Feed Ingredient Definition be removed upon AAFCO providing scientific evidence substantiating their conclusion that the ingredient is no longer suitable for its stated use. The Ingredient Definitions Committee will vote to remove the

ingredient from the Feed Ingredient Definitions section in the AAFCO OP at their next scheduled meeting. Disagreements between AAFCO and FDA would be handled as stated in section G.

J. This Memorandum of Understanding will be reviewed annually by the AAFCO Board and the FDA and may be modified by mutual consent of both parties. Parties will provide each other with written notice 30 working days in advance regarding the modifications being sought. Any modification will be published in the Federal Register.

Liaisons

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Period of Agreement

This agreement, when accepted by both parties, will have an effective period of performance from date of signature until 10/01/2017 (and may be modified by mutual consent by both parties or may be extended or terminated as agreed upon by FDA and AAFCO). Any notice of termination will be published in the Federal Register.

Approved and Accepted for FDA:

By Dr. Bernadette Dunham

Printed Name BERNADETTE DUNHAM, D.V.M., Ph.D.

Title Director, Center for Veterinary Medicine
U.S. Food and Drug Administration

Date 3/11/2015

Approved and Accepted for AAFCO:

By R C Ten Eyck

Printed Name Richard Ten Eyck

Title AAFCO President 2015

Date 3/5/15