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Susan Thixton <susan@truthaboutpetfood.com>

FDA MOU with AAFCO

1 message

Ask CVM <AskCVM@fda.hhs.gov> Fri, Apr 5, 2019 at 4:55 PM
To: "susan@truthaboutpetfood.com" <susan@truthaboutpetfood.com>

Dear Ms. Thixton,

CVM was asked to respond to the questions about FDA's MOU with the Association of American Feed Control Officials (AAFCO) you sent by e-mail to Sharon Alford on January 28, 2019. You asked a number of questions, some general in nature (e.g., the authority and reasons for FDA entering into MOUs; whether and how the public has input into MOUs), and other questions specific to the MOU between FDA and AAFCO (e.g., who at FDA is working with AAFCO on any new MOU; whether FDA provides any oversight function of AAFCO pursuant to the MOU). The MOU can be found on FDA's website at https://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticmous/ucm439961.htm.

You asked where FDA gets the authority to enter into MOUs and what the purposes of MOUs are if they are not legally binding. FDA's authority to enter into the MOU with AAFCO comes from section 1003(b) of FD&C Act (21 USC 393(b)), which directs FDA to protect the public health by ensuring that foods are, among other things, safe and properly labeled; and further directs FDA to do so in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products. You can find more information about FDA's use of Memoranda of Understanding at, https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/default.htm.

You also asked several questions about whether people could comment on or contest MOUs, and if so, you asked for information on how to do so. Though MOUs are not open to comment while being drafted, pursuant to 21 CFR 20.108, FDA makes these MOUs available on our website after they are finalized. If you would like to provide comment or raise concerns about existing or new CVM MOUs, you are welcome to submit information to our AskCVM@fda.hhs.gov mailbox.

Finally, you asked some specific questions about the MOU between FDA and AAFCO. You asked who is working with AAFCO on a new MOU and which party provides new language for a revised MOU. You also asked questions about whether there is anyone at FDA who provides oversight to AAFCO and whether FDA has veto power over AAFCO. You also expressed concern about FDA's absence from the January 2019 AAFCO meeting.

The MOU provides that it will be reviewed annually by the AAFCO Board and FDA and may be modified by mutual consent of both parties (See section J of the MOU). Either party can suggest changes to the MOU. Dr. David Edwards, Director of CVM's Division of Animal Feeds, is FDA's liaison with respect to the MOU. FDA does not oversee AAFCO activities under the MOU; rather, the MOU clarifies the respective roles of FDA and AAFCO in AAFCO's feed ingredient definition process. The MOU does not give FDA veto power over AAFCO decisions to establish or revoke ingredient definitions. Although FDA did not attend the January 2019 AAFCO meeting, FDA's reviews and recommendations regarding the ingredient definitions voted on during the meeting had already been completed and provided to AAFCO.

Disagreements on existing feed ingredient definitions, the establishment of new ingredient definitions, or modifications of existing definitions between the FDA and AAFCO would be handled under section G of the MOU. That being said, it is also important to understand that the MOU and the AAFCO feed ingredient definitions do not supersede federal law,

including the Federal Food, Drug, and Cosmetic Act. FDA retains the ability to take action under any applicable provision of the FD&C Act, when necessary to protect human and animal health.

Sincerely,

AskCVM