CVM Virtual Public Meeting: FDA and the AAFCO Animal Feed Ingredient Definition Process

Moderator: Dr. Walter Ellenberg

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Virtual Public Meeting Zoom Recording and Transcript Link:
https://fda.zoomgov.com/rec/share/cjDmNKEnqv6mq9Oy-l3JzdgOChkSOipZAYqTNgWto6LwW4PqaBTqZMAGhOrbq4VJ.x_7HLHjNfnPax7Gn

1
00:00:07.700 --> 00:00:18.929
Walt Ellenberg, FDA CVM: Good morning, everyone. We will start our meeting in about two minutes. There is a flurry of individuals signing in at this time, and in two minutes we will go ahead and start the meeting.

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00:02:18.110 --> 00:02:19.570
Walt Ellenberg, FDA CVM: Well, good morning.

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00:02:19.580 --> 00:02:30.390
Walt Ellenberg, FDA CVM: My name is Walt Ellenberg, and we're going to kick off this CVM virtual public meeting regarding the Fda and the AAFCO animal feed ingredient definition process. But before

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00:02:30.400 --> 00:02:39.660
Walt Ellenberg, FDA CVM: or I move forward with rolling out what the agenda for today's meeting will look like. There are some logistical elements that I think are important to convey to everybody who is listening in

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00:02:39.740 --> 00:02:48.089
Walt Ellenberg, FDA CVM: First of all this meeting is being recorded, the recording will actually be available at some point after the meeting in the docket

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00:02:48.350 --> 00:03:04.839
Walt Ellenberg, FDA CVM: Closed captioning is also available, and for those of you who are. Ah! Looking at your screen. If you look at the bottom of your screen, you should see a a button that says, show caption or a closed caption. Just press that, and you'll be able to to see what the captions are throughout the meeting.

7
00:03:05.080 --> 00:03:21.710

Walt Ellenberg, FDA CVM: This is a really large meeting right now. I'm. Showing three hundred and eighty seven participants. We know that there will be a great deal more. We had approximately seven hundred and eighty registrants for this meeting, so it clearly shows there's a great deal of interest in the subject matter that we're going to talk cover today.

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00:03:21.740 --> 00:03:22.910
Walt Ellenberg, FDA CVM: Um!

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00:03:22.920 --> 00:03:46.180
Walt Ellenberg, FDA CVM: But given the fact that this is such a large meeting just be understanding, and where the technical issues may creep in from time to time. We've done everything we can to minimize that process or that issue. But we do have a Q. And a function available and operational, and we ask that if you have a technical issue with being able to view the meeting or signing in

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00:03:46.190 --> 00:03:50.980
Walt Ellenberg, FDA CVM: anything along those lines. Please type it in through the Q. And a portion.

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00:03:51.620 --> 00:04:05.009
Walt Ellenberg, FDA CVM: I will have additional comments with regards to the presentations from the public, and if, after a few minutes, But now what i'd like to do is begin by

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00:04:05.620 --> 00:04:07.840
Walt Ellenberg, FDA CVM: showing you the overview of the meeting.

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00:04:07.850 --> 00:04:37.400
Walt Ellenberg, FDA CVM: We're currently obviously opening the meeting, but after i'm finished we will ah turn it over to Ah Tracy Forfa and Timothy Schell, and we'll get a a presentation from Dave Edwards, Charlotte Conway, and Austin Therrell, and then I will wrap up the Fda portion of the presentations after they speak, and then we will have a short break. Once we return from the break, then we will actually begin the public presentation process. So at this time I would like to

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00:04:37.410 --> 00:04:40.879
Walt Ellenberg, FDA CVM: uh turn the meeting over to

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00:04:40.910 --> 00:04:49.260
Walt Ellenberg, FDA CVM: Tracy Forfa, who is the acting director for the center for veterinary Medicine and Tracy. If you will activate your camera and make sure you're unmuted.

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00:04:49.950 --> 00:04:50.980

Walt Ellenberg, FDA CVM: Thank you.

17
00:04:55.490 --> 00:05:18.179
Tracey Forfa, FDA CVM: Good morning, everyone. Thank you all so very much for joining us today as Walt indicated. The purpose of today's public meeting is to gather input from stakeholders On Fda's approach to the consultations we provide to the Association of American Feed Control officials or AAFCO during their animal feed ingredient definition process.

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00:05:18.190 --> 00:05:35.789
Tracey Forfa, FDA CVM: The registrant list for today's events demonstrates wide stakeholder interest in the topic. Registrants include consumers, animal food manufacturers, and distributors, veterinarians, academic organizations, food safety advocacy groups,

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00:05:35.800 --> 00:05:40.460
Tracey Forfa, FDA CVM: a number of Federal and State agencies and other key stakeholders

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00:05:40.640 --> 00:05:53.810
Tracey Forfa, FDA CVM: as public servants. We at Fda are committed to hearing from all our stakeholders and considering their input to ensure that we take the appropriate measures to protect human and animal health,

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00:05:53.880 --> 00:06:04.270
Tracey Forfa, FDA CVM: we appreciate our stakeholders who are presenting today, and those who submit to the public docket to share information and insight with Fda on this very, very important issue,

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00:06:04.680 --> 00:06:16.109
Tracey Forfa, FDA CVM: where we're here today to talk about one component of our work with AAFCO specifically advising AAFCO on their proposed and existing animal food ingredient definitions.

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00:06:16.120 --> 00:06:27.640
Tracey Forfa, FDA CVM: We will be opening by explaining the larger picture of how animal food is regulated by Fda and our collaboration with AAFCO and our State regulatory partners.

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00:06:28.440 --> 00:06:42.390
Tracey Forfa, FDA CVM: One of the areas that was recently that was highlighted in the recently released Reagan udall report was the need to continue to work closely in partnership with States and other trusted regulatory partners.

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00:06:42.400 --> 00:06:46.910
Tracey Forfa, FDA CVM: Fda alone cannot ensure the safety of the nation's food supply.

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00:06:47.310 --> 00:06:58.820
Tracey Forfa, FDA CVM: Indeed, while Fda and State partners have long recognized the need to work together, Congress formalized this concept in the Fda Food Safety Modernization act of two thousand and eleven Or fsma

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00:06:59.040 --> 00:07:08.220
Tracey Forfa, FDA CVM: Fsma explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve our public health goals

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00:07:08.340 --> 00:07:23.150
Tracey Forfa, FDA CVM: in Fda is explicitly authorized to rely on inspections conducted by other Federal state and local agencies to meet Fda's increased inspection mandate both domestically and in foreign facilities

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00:07:23.380 --> 00:07:43.340
Tracey Forfa, FDA CVM: Fda must develop and implement strategies to leverage and enhance the food, safety and defense capacities, of state and local agencies and additional partnerships are required to improve food-borne illness, surveillance, develop and implement a national agricultural and food defense strategy

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00:07:43.350 --> 00:07:47.560
Tracey Forfa, FDA CVM: and to establish an integrated consortium of laboratory networks

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00:07:48.080 --> 00:07:57.179
Tracey Forfa, FDA CVM: beyond fsma we continue to embed the concept of mutual alliance in Fda's business. It is simply not an option for us to go it alone.

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00:07:57.190 --> 00:08:12.470
Tracey Forfa, FDA CVM: Mutual reliance is a core component of Fda's new era of smarter food safety blueprint, and is built into the strategic and tactical plans of CVMCvm, because we truly believe in the power of working together with State programs.

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00:08:12.890 --> 00:08:38.589
Tracey Forfa, FDA CVM: Dr. Steven Solomon, who recently retired as the director of CVM and I, and many of my colleagues in the center, and throughout the agency are committed to building a fully integrated food safety system that will realize a more holistic overarching approach. I will soon be

turning the meeting over to Dr. Timothy Schell, who is the head of our office of surveillance and compliance. Where much of this work takes place,

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00:08:38.610 --> 00:08:57.040
Tracey Forfa, FDA CVM: we recognize that there are questions about our current engagement in the AAFCO ingredient definition process, and we have been considering how to improve transparency around our engagement in the process to better serve all stakeholders. This meeting is an important part of our information gathering. As we consider these questions,

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00:08:57.060 --> 00:09:11.520
Tracey Forfa, FDA CVM: Dr. Schell will walk you through some of the authorities and processes we use to review and regulate animal food. We will be sharing our perspectives on this work. But most importantly, today's meeting is our opportunity to hear from you.

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00:09:11.530 --> 00:09:23.030
Tracey Forfa, FDA CVM: We have asked you to share your ideas to improve Fda's participation in AAFCO's, animal food ingredient definition, process, improve communication, and improve transparency.

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00:09:23.770 --> 00:09:42.310
Tracey Forfa, FDA CVM: We will take all the comments received today, and those submitted to the associated public docket in the consideration. As we continue our review of Fda's role in the AAFCO animal feed ingredient definition process. We're accepting electronic and written comments to the docket until March ninth

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00:09:42.470 --> 00:09:51.159
Tracey Forfa, FDA CVM: details and how to submit. Those are on Fda's website and we'll also include information in the chat feature on where to submit your comments.

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00:09:51.370 --> 00:09:59.629
Tracey Forfa, FDA CVM: Thank you so much for sharing your input with us today to ensure we are making decisions that take all stakeholder perspectives into account.

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00:09:59.670 --> 00:10:12.510
Tracey Forfa, FDA CVM: We look forward to continued discussions with all of our stakeholders as we move forward. And now i'm going to turn it over to Dr. Schell to give you a high-level overview of our animal food. Review Work Thank you again,

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00:10:14.110 --> 00:10:20.060

Timothy Schell, FDA CVM: and thank you, Tracy, and good morning, everyone, and thank you for interest in this important topic.

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00:10:20.200 --> 00:10:24.010
Timothy Schell, FDA CVM: I'd like to start by talking about how we regulate animal food,

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00:10:24.180 --> 00:10:33.490
Timothy Schell, FDA CVM: keeping the U. S food supply safe depends on regulatory oversight and multiple levels to ensure adequate coverage of the entire product lifecycle.

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00:10:33.500 --> 00:10:36.679
Timothy Schell, FDA CVM: In the Us. We have a two-pronged system of oversight.

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00:10:36.690 --> 00:10:42.959
Timothy Schell, FDA CVM: Animal food is regulated at the Federal level by Fda, and at the State level by individual States.

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00:10:43.260 --> 00:10:57.309
Timothy Schell, FDA CVM: As Tracy mentioned in her remarks, Fda cannot oversee the entirety of the animal food supply by itself. State regulatory programs are essential partners in providing the necessary oversight of the animal food industry.

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00:10:57.800 --> 00:11:05.520
Timothy Schell, FDA CVM: State programs are incredibly valuable, not only to Fda as partners, but also to livestock producers, pet owners,

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00:11:05.530 --> 00:11:19.039
Timothy Schell, FDA CVM: and other animal caretakers. As we work together to keep animal foods safe. In addition, household consumers of meat, milk, and eggs also depend on a robust regulatory oversight of the animal food industry.

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00:11:19.640 --> 00:11:24.160
Timothy Schell, FDA CVM: State programs have been overseeing the animal food industry. For over a hundred years.

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00:11:24.320 --> 00:11:39.120
Timothy Schell, FDA CVM: States have the authority to regulate animal food, have inspection and compliance. Programs have systems in place to detect and respond to emergencies, and they develop and deliver training and outreach to their staff industry and consumers

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00:11:39.280 --> 00:11:50.910
Timothy Schell, FDA CVM: because of the long-standing expertise and capacity of these State programs Fda has been able to enhance Federal regulatory oversight by partnering with States and by using existing State programs.

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00:11:51.060 --> 00:11:58.900
Timothy Schell, FDA CVM: The majority of Fda animal food inspections have historically been conducted by State agencies under contract with the Fda.

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00:11:59.350 --> 00:12:06.979
Timothy Schell, FDA CVM: Additionally, State agencies conduct inspections under their own authority outside the scope of Fda inspection requirements.

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00:12:07.360 --> 00:12:10.129
Timothy Schell, FDA CVM: The work of these programs has been invaluable.

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00:12:10.300 --> 00:12:15.629
Timothy Schell, FDA CVM: Often States are the first to identify major safety issues in the animal food supply.

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00:12:15.790 --> 00:12:23.180
Timothy Schell, FDA CVM: Similarly, states are often able to respond quickly to public health incidents by swiftly removing products from the market.

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00:12:23.430 --> 00:12:28.729
Timothy Schell, FDA CVM: States also assist Fda with national recalls for products in interstate commerce,

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00:12:29.150 --> 00:12:36.620
Timothy Schell, FDA CVM: working in concert with our State partners has led to positive public health outcomes for the animal food supply, and those who rely on

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00:12:36.990 --> 00:12:41.349
Timothy Schell, FDA CVM: I'll add that partnering with State programs is not limited to just animal food.

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00:12:41.360 --> 00:12:45.940

Timothy Schell, FDA CVM: Fda also partners in contracts with State programs that regulate human food.

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00:12:46.430 --> 00:12:53.320
Timothy Schell, FDA CVM: Regulatory partnerships, however, require excellent communication and consistency between Federal and State agencies.

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00:12:53.510 --> 00:13:07.200
Timothy Schell, FDA CVM: AAFCO, as a volunteer member organization composed of State and Federal regulators, provides a forum for staff, from regulatory agencies to discuss differences and build consistency in animal food regulation.

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00:13:07.440 --> 00:13:18.800
Timothy Schell, FDA CVM: To be clear, AAFCO is not a regulatory body, and does not create Federal or State law Each State agency has its authority and state-run program

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00:13:18.980 --> 00:13:28.259
Timothy Schell, FDA CVM: participating State and Federal AAFCO members work together to remote effective communication and consistency across the animal food programs.

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00:13:28.800 --> 00:13:41.399
Timothy Schell, FDA CVM: Some of AAFCO's important functions include collaborating in the developing and promoting of animal feed, regulatory program standards, leading efforts to develop consistency and repeatable laboratory methods,

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00:13:41.410 --> 00:13:52.159
Timothy Schell, FDA CVM: developing model bills, building inspection and compliance programs and providing a mechanism for Fda to distribute education and outreach materials to state partners.

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00:13:52.380 --> 00:13:58.659
Timothy Schell, FDA CVM: AAFCO members contribute to AAFCO's recommendations for addressing an array of regulatory issues.

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00:13:59.200 --> 00:14:04.810
Timothy Schell, FDA CVM: Today we're going to focus on Fda's participation in the AAFCO feed ingredient definition process

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00:14:05.060 --> 00:14:07.690
Timothy Schell, FDA CVM: under the Food Drug and Cosmetic Act.

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00:14:07.700 --> 00:14:21.419
Timothy Schell, FDA CVM: Anything that's added to or becomes part of an animal. Food, directly or indirectly, must be either an approved food, animal food additive, or it must be generally recognized as safe or grass. For that use

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00:14:21.990 --> 00:14:27.400
Timothy Schell, FDA CVM: approved animal food. Additives, and ingredients that are grass are limited to specific uses.

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00:14:27.530 --> 00:14:32.670
Timothy Schell, FDA CVM: Some ingredients may be safe when used in one way, but not safe when used in other ways.

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00:14:32.840 --> 00:14:34.180
Timothy Schell, FDA CVM: For example,

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00:14:34.190 --> 00:14:41.770
Timothy Schell, FDA CVM: Xylitol is a sweetener, that is, an approved food, additive for use in certain human foods, but can be extremely toxic to dogs.

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00:14:41.900 --> 00:14:45.160
Timothy Schell, FDA CVM: Consequently it's not approved for use in dog food

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00:14:46.180 --> 00:14:52.289
Timothy Schell, FDA CVM: every year AAFCO publishes an official publication commonly referred to as the AAFCO. Okay.

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00:14:52.510 --> 00:15:05.399
Timothy Schell, FDA CVM: The publication contains a list of approved animal food additives, a list of ingredients that are considered grass for specific uses and ingredient definitions established by AAFCO through its feed ingredient definition process

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00:15:05.890 --> 00:15:23.990
Timothy Schell, FDA CVM: long before the one thousand nine hundred and fifty, eight Food Additives Amendment to the Food Drug and Cosmetic Act, which charged Fda with reviewing the safety of substances added to animal food. AAFCO was establishing a uniform set of definitions that States could apply to feed ingredients moving between the States.

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00:15:24.290 --> 00:15:29.499
Timothy Schell, FDA CVM: Many of the ingredients defined by AAFCO today date back to these early publications.

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00:15:29.640 --> 00:15:37.799
Timothy Schell, FDA CVM: The continuation of this process helps ensure that stakeholders have a single reference for definitions of ingredients used in animal food.

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00:15:38.180 --> 00:15:46.640
Timothy Schell, FDA CVM: We'd like to thank AAFCO for posting the ingredient definitions on its website for those stakeholders who are not able to access a hard copy of the official publication.

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00:15:46.710 --> 00:15:50.980
Timothy Schell, FDA CVM: Posting this material allows for wider access to this valuable information. The

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00:15:51.650 --> 00:15:58.660
Timothy Schell, FDA CVM: AAFCO has been an important resource for Federal and State regulators, as well as animal food producers. For over a hundred years.

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00:15:58.670 --> 00:16:07.680
Timothy Schell, FDA CVM: Fda and AAFCO's common goals protect and ensure the safety of our animal Food supply lies at the heart of our continued relationship.

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00:16:07.880 --> 00:16:15.629
Timothy Schell, FDA CVM: The U.S. Animal food supply is safer because of the hard work of AAFCO and State regulatory programs, and we are grateful for their work.

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00:16:16.380 --> 00:16:26.890
Timothy Schell, FDA CVM: I will now turn the meeting over to Dr. David Edwards, who will talk about Fda support for the AAFCO feed ingredient definition process which is outlined in our current. Mou

87
00:16:26.980 --> 00:16:28.419
Timothy Schell, FDA CVM: Dr. Edwards.

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00:16:32.970 --> 00:16:51.759

Dave Edwards, FDA CVM: Good morning, everybody, and i'm glad to have you at the on the meeting today, as Dr. Schell outlined. We have a working relationship with the AAFCO organization, and i'm going to cover a little bit more about what that AAFCO mou with. Fda talks about

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00:16:53.290 --> 00:16:57.290
Dave Edwards, FDA CVM: as we've seen already. Today AAFCO is an association of regulators.

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00:16:57.300 --> 00:17:17.170
Dave Edwards, FDA CVM: Non-regulatory groups are invited to participate as advisors and provide comments, but are not decision-makers as an association. AAFCO works to develop model laws, regulations, standards, and definitions and enforcement policies for animal food regulation that can be implemented by States within the us.

91
00:17:17.180 --> 00:17:18.600
Next slide, please.

92
00:17:19.089 --> 00:17:31.180
Dave Edwards, FDA CVM: At Fda we don't work under the AAFCO model laws and regulations. As Dr. Schell mentioned our authority to regulate the ingredients used in animal food comes from the Federal Food Drug and Cosmetic Act.

93
00:17:31.290 --> 00:17:32.879
Dave Edwards, FDA CVM: Next slide, please.

94
00:17:34.850 --> 00:17:40.479
Dave Edwards, FDA CVM: All ingredients in animal food must have a reasonable certainty of no harm for their intended use.

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00:17:40.840 --> 00:17:57.679
Dave Edwards, FDA CVM: When Congress amended the Federal Food Drug and Cosmetic Act in one thousand nine hundred and fifty eight to create the food, additive provisions. It acknowledged that many substances used in human and animal food had a history of safe use, and created the generally recognized as safe or grass provision.

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00:17:57.690 --> 00:18:08.969
Dave Edwards, FDA CVM: At the same time Congress required that going forward, any substance that wasn't grass would need to be reviewed for safety and approved as a food additive before entering interstate commerce,

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00:18:09.280 --> 00:18:25.369
Dave Edwards, FDA CVM: manufacturing composition, identity, and intended use all impact safety and are reviewed as part of the data package submitted to us. Within Fda we have different technical experts who contribute to Fda's review of the safety of these new ingredients.

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00:18:25.380 --> 00:18:32.970
Dave Edwards, FDA CVM: These reviewers include chemists and food scientists who look at the impact of manufacturing and analytical chemistry on safety

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00:18:32.980 --> 00:18:46.459
Dave Edwards, FDA CVM: animal nutritionists to determine if the ingredient is able to achieve its intended nutritional effect on veterinarians and toxicologists who assess how the composition and intended use affect safety for the animal eating the ingredient

100
00:18:46.470 --> 00:18:50.099
Dave Edwards, FDA CVM: and safety of the result in the human food produced by the animal.

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00:18:50.250 --> 00:18:55.899
Dave Edwards, FDA CVM: This is especially important, since many food ingredients are consumed by animals for their entire lives.

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00:18:55.930 --> 00:19:06.400
Dave Edwards, FDA CVM: Cvm. Applies the same safety standard to ingredients reviewed under AAFCO feed ingredient definition, process, as we do for food, additives and grass notified substances.

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00:19:06.410 --> 00:19:17.030
Dave Edwards, FDA CVM: Our reviewers look at information submitted in these requests to determine if the information allows a conclusion that the ingredient is safe for its intended use. Next slide, please,

104
00:19:18.480 --> 00:19:27.950
Dave Edwards, FDA CVM: as you'll likely hear. Several times today. AAFCO has held publication of ingredient definitions as one of its core tenants. Since its inception in one thousand nine hundred and nine,

105
00:19:27.990 --> 00:19:35.369
Dave Edwards, FDA CVM: the process has evolved over the years, and Fda. Scientists have been involved in these conversations and definitions for many years.

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00:19:35.490 --> 00:19:46.829

Dave Edwards, FDA CVM: Looking back through the AAFCO history, Fda scientists were involved in the ingredient definition process for many decades, including serving key roles as far back as the one thousand nine hundred and fiftys.

107
00:19:46.970 --> 00:19:57.229
Dave Edwards, FDA CVM: In recent years Fda and AAFCO have set out their respective roles in the process. In a memorandum of understanding the mou between our two entities,

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00:19:57.450 --> 00:20:04.630
Dave Edwards, FDA CVM: Fda signs mous with various entities for different purposes. These mous can be found on the Fda website.

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00:20:04.760 --> 00:20:21.180
Dave Edwards, FDA CVM: The purpose of this particular mou that we'll talk about today is to help formalize and memorialize the procedural steps for requesting that new or modified ingredient definitions be reviewed by Fda, and establish a mechanism for resolving disputes,

110
00:20:21.190 --> 00:20:25.059
Dave Edwards, FDA CVM: are removing ingredient definitions from the official publication of AAFCO,

111
00:20:25.410 --> 00:20:31.839
Dave Edwards, FDA CVM: by establishing the agreement and writing in addition to Fda and after a strong and productive working relationship,

112
00:20:31.870 --> 00:20:36.330
Dave Edwards, FDA CVM: the mou allows the responsibilities of each party to be defined.

113
00:20:36.340 --> 00:20:42.030
Dave Edwards, FDA CVM: Now let's take a closer look at what the Mou actually says, next slide, please,

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00:20:43.650 --> 00:21:01.989
Dave Edwards, FDA CVM: as you can see on this slide, the components of the mou are very procedural, and lay out the roles of AAFCO and Fda, when handling requests for new or modified ingredient definitions, requests to remove ingredients from the official publication, and how we solve the disagreements regarding those definitions

115
00:21:02.000 --> 00:21:12.550

Dave Edwards, FDA CVM: the Mou describes to which part of Fda information should be submitted when responses should be expected, and what concurrence is needed for changes to the official publication

116
00:21:14.170 --> 00:21:27.029
Dave Edwards, FDA CVM: listed on this slide are parts A. Through J. As outlined in the mou. I will briefly go through the different parts of the mou. Make sure that we're all on the same page as to what it says

117
00:21:27.610 --> 00:21:42.839
Dave Edwards, FDA CVM: In part. AAFCO maintains definitions for various feed ingredients which include the common ingredient name, description, and any appropriate limitations for use, and publishes those currently accepted feed ingredients. Definitions in the official publication

118
00:21:43.480 --> 00:21:59.010
Dave Edwards, FDA CVM: requests for new feed ingredients or requests to modify an existing feed ingredient are reviewed by AAFCO investigators and fda scientists in the center for veterinary medicine, division of animal food ingredients.

119
00:21:59.460 --> 00:22:08.800
Dave Edwards, FDA CVM: Some examples of how these ingredients have been an example of how these ingredients have been received include something that's such as an amino acid.

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00:22:09.570 --> 00:22:12.140
Dave Edwards, FDA CVM: The taurine amino acid was

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00:22:13.150 --> 00:22:31.380
Dave Edwards, FDA CVM: presented to AAFCO investigator of that looks at the Amino acid section. Data from this amino acid was then sent to Fda for review, so it involves both the AAFCO investigators as well as the Fda scientists. In the review of these types of ingredients

122
00:22:32.200 --> 00:22:45.050
Dave Edwards, FDA CVM: AAFCO will seek the advice and a letter of concurrence regarding the suitability of feet ingredients for its proposed use from Fda prior to adopting new ingredient definitions, or amending existing ones

123
00:22:45.590 --> 00:22:58.410
Dave Edwards, FDA CVM: After we'll also provide to the fda requests, both from industry, as well as requests from AAFCO for new feed ingredient definitions, or for modifications of existing definitions.

124

00:22:58.470 --> 00:23:01.589
Dave Edwards, FDA CVM: Within thirty days of the receiving this request,

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00:23:01.600 --> 00:23:03.770
Dave Edwards, FDA CVM: the Fda will respond.

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00:23:03.830 --> 00:23:11.670
Dave Edwards, FDA CVM: Provide the the official contact information for that ingredient Review.

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00:23:12.630 --> 00:23:21.169
Dave Edwards, FDA CVM: The Fda will allow the AAFCO Board to request consultations on requests for new feed ingredient definitions and modifications of existing definitions.

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00:23:21.180 --> 00:23:31.660
Dave Edwards, FDA CVM: The initial contact is laid out in the mou as well, and we will provide our decision on whether the console will be reviewed within that thirty working days.

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00:23:32.600 --> 00:23:41.670
Dave Edwards, FDA CVM: If the Fda determines that we will publish a food additive regulation under Section four hundred and nine of the Federal food, drug and cosmic

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00:23:42.090 --> 00:23:55.109
Dave Edwards, FDA CVM: that is outlined in the regulation as outlined in the regulations. AAFCO will not include that ingredient in the AAFCO official publication until the Fda completes that regulation and it approves it

131
00:23:56.770 --> 00:24:10.789
Dave Edwards, FDA CVM: Sections D Section D. Talks about how to resolve disagreements on existing feed ingredient definitions where AAFCO and Fda will work together to come up with a reasonable solution to those disagreements.

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00:24:12.020 --> 00:24:24.229
Dave Edwards, FDA CVM: So Section H. Is important, as if new science is found that substantiates the conclusion that an ingredient is no longer suitable for its stated intended use.

133
00:24:24.290 --> 00:24:32.700
Dave Edwards, FDA CVM: The Fda will work with AAFCO to be able to remove that defined ingredient from the AAFCO official publication.

134
00:24:33.590 --> 00:24:45.909
Dave Edwards, FDA CVM: The deliberative process, including the Ingredient Definition Committee, will vote on that request, making sure that proper communications and

135
00:24:46.110 --> 00:24:49.060
Dave Edwards, FDA CVM: opportunities for comment are available.

136
00:24:51.340 --> 00:25:07.850
Dave Edwards, FDA CVM: Section I talks about how AAFCO Ah, if it becomes aware of scientific evidence substantiating the conclusion that the ingredient is no longer suitable for its stated use, will work through the process in order to be able to remove that ingredient from the official publication.

137
00:25:08.160 --> 00:25:18.989
Dave Edwards, FDA CVM: And finally, Section J. Talks to how often the Mou will be reviewed, and how much time will be given to review that Mou

138
00:25:19.000 --> 00:25:25.890
Dave Edwards, FDA CVM: the mou has been signed several times, and re-upped over the years by delineating the procedures in writing.

139
00:25:25.900 --> 00:25:31.670
Dave Edwards, FDA CVM: All stakeholders can clearly understand the expectations of both AAFCO and the Fda.

140
00:25:31.760 --> 00:25:47.789
Dave Edwards, FDA CVM: As you've heard, this deliberative process gives time for input by stakeholders provides ability to those using the to provide stability to those using the definitions and retains the scientific basis for the safety of these different definitions.

141
00:25:47.920 --> 00:25:49.490
Dave Edwards, FDA CVM: Next slide, please,

142
00:25:51.440 --> 00:26:05.890
Dave Edwards, FDA CVM: while the components of the mou and its expectations are important for those that are working on new or modified ingredients. It's also important to note what's not in the in the mou. The mood does not transfer any Fda authority to AAFCO

143
00:26:05.900 --> 00:26:13.200

Dave Edwards, FDA CVM: also does not determine our relationship with AAFCO as an organization or with any of the States that are active in AAFCO

144
00:26:13.210 --> 00:26:21.719
Dave Edwards, FDA CVM: Fda, has participated in AAFCO's ingredient definition process for many decades. Even before we first entered an mou with AAFCO.

145
00:26:22.360 --> 00:26:31.100
Dave Edwards, FDA CVM: The Mou also does not affect States abilities to authorize the use of ingredients in their state under their own authorities, or to refrain from doing so

146
00:26:31.380 --> 00:26:41.920
Dave Edwards, FDA CVM: I don't think it can be restated enough. The mou does not define Fda's relationship with AAFCO or any individual regulatory bodies enforcement of the laws under which it operates.

147
00:26:41.930 --> 00:26:49.620
Dave Edwards, FDA CVM: The Mou simply delineates the responsibilities and roles of Fda and AAFCO in AAFCOa's ingredient definition process.

148
00:26:49.760 --> 00:27:01.860
Dave Edwards, FDA CVM: We've touched on the history of fda's involvement in AAFCO at large, and specifically the ingredient definition process. Several times already this morning we see great value in this relationship, and have

149
00:27:01.950 --> 00:27:19.719
Dave Edwards, FDA CVM: consistently consistency, both in the Scientific review for the safety of new ingredients, as well as seeing the importance of having a single reference list that can be leveraged both domestically and internationally, and identifies ingredients for use in animal food in the Us.

150
00:27:19.760 --> 00:27:35.279
Dave Edwards, FDA CVM: Working with AAFCO, allows us to leverage a broad set of State regulators who are familiar with particular categories of ingredients that can facilitate some of the early conversations with interested parties. When revisions to the official publication ingredient lists are proposed.

151
00:27:35.410 --> 00:27:37.020
Dave Edwards, FDA CVM: Next slide, please.

152

00:27:37.900 --> 00:27:48.639
Dave Edwards, FDA CVM: As we consider clarifying Fda's role in the AAFCO ingredient definition process, we will review the Mou, which may be modified to ensure that it continues to accurately reflect

153
00:27:48.950 --> 00:27:56.440
Dave Edwards, FDA CVM: Fda and AAFCO agreements regarding the procedures for establishing and modifying AAFCO feed ingredient definitions.

154
00:27:56.450 --> 00:28:09.429
Dave Edwards, FDA CVM: As you have heard, We have a very long history of working with AAFCO on ingredient definitions, and we intend to continue to support the harmonization of ingredient names and identities as recognized by most of the States

155
00:28:09.520 --> 00:28:28.089
Dave Edwards, FDA CVM: as Charlotte Conway will next discuss. However, we are looking for ways to make our participation in that process more transparent, and provide opportunities for public participation; and last, but certainly not least. We take very seriously our charge to protect the public health by ensuring that animal food is safe.

156
00:28:28.100 --> 00:28:36.479
Dave Edwards, FDA CVM: Reviewing ingredients through the AAFCO ingredient definition process provides a mechanism for increasing the safety of the animal food supply.

157
00:28:44.820 --> 00:28:56.489
Charlotte Conway, FDA CVM: Thanks, Dave, as he and others have already shared. Today the history of our relationship with AAFCO is very important to us, and we see the ingredient definition process as a valuable tool

158
00:28:56.500 --> 00:29:12.300
Charlotte Conway, FDA CVM: for helping to ensure that all stakeholders understand the identity of safe ingredients for use. In that being said, we understand that there are valid concerns raised by several different stakeholder groups with how we operate within the process.

159
00:29:12.430 --> 00:29:24.109
Charlotte Conway, FDA CVM: One such concern has been with the timeliness of our review, when AAFCO submits ingredients to Fda, as we got busier with increased numbers of submissions for review of new ingredients.

160
00:29:24.120 --> 00:29:38.359

Charlotte Conway, FDA CVM: We prioritized review of animal food, additive petition, and gras, notices over the submissions by AAFCO and our other work. This led to slow and unpredictable Review Times, especially for the AAFCO ingredient submission.

161
00:29:38.410 --> 00:29:51.360
Charlotte Conway, FDA CVM: In the two thousand and twenty Congressional appropriations we gained additional funds to hire twelve new reviewers. This nearly doubled our pre-market review staff, who work on all types of the pre-market submissions for animal food and

162
00:29:51.410 --> 00:29:58.670
Charlotte Conway, FDA CVM: over the last couple of years We've been training our new staff, adjusting to critical retirements and catching up on reviews.

163
00:29:58.850 --> 00:30:06.039
Charlotte Conway, FDA CVM: We have already increased the number of new submissions that we're able to review on time, and are continuing to look at ways that we can improve,

164
00:30:06.210 --> 00:30:18.770
Charlotte Conway, FDA CVM: while animal food, additive petitions and gras notices remain our top priority. We now have the staff to review ingredient definition requests from AAFCO on a more consistent and predictable time.

165
00:30:18.780 --> 00:30:27.460
Charlotte Conway, FDA CVM: We've also started to work on guidances and refinement to our internal procedures, so that all of our pre-market review pathways can continue to improve.

166
00:30:28.640 --> 00:30:47.369
Charlotte Conway, FDA CVM: We are also aware of stakeholders concerns around the perceived lack of transparency with respect to our involvement in the AAFCO feed, ingredient definition process, and many questions around public participation in the process. These concerns have come up in several forms, including meetings with CVM. Staff and leadership,

167
00:30:47.380 --> 00:30:51.210
Charlotte Conway, FDA CVM: correspondence and citizens petitions to the agency.

168
00:30:51.300 --> 00:31:05.639
Charlotte Conway, FDA CVM: Everything we've heard to date along with the information presented by stakeholders today, and in comments submitted to the docket will help us determine if and how we should work with AAFCO and modifications to the current Mou.

169
00:31:06.380 --> 00:31:20.099
Charlotte Conway, FDA CVM: It will also help us determine the types of other publications. We should develop to bolster transparency, and will help us identify opportunities for public participation regarding our role in the AAFCO ingredient definition process.

170
00:31:20.450 --> 00:31:31.289
Charlotte Conway, FDA CVM: The ideas that we have from all of our internal and external conversations over the last couple of years will serve as a jumping off point for process changes that can be implemented.

171
00:31:31.300 --> 00:31:33.690
Charlotte Conway, FDA CVM: After we consider your feedback,

172
00:31:33.710 --> 00:31:49.400
Charlotte Conway, FDA CVM: we encourage you to submit comments to the docket, responding to the questions that were posed with today's meeting announcement. As you can see from these questions, Fda is invested in improving stakeholder understanding of our role in the AAFCO ingredient definition process

173
00:31:51.870 --> 00:31:57.040
Charlotte Conway, FDA CVM: engaging with stakeholders for more transparent process.

174
00:31:57.650 --> 00:32:13.179
Charlotte Conway, FDA CVM: One such process change that we're considering is whether to publicly track all ingredient definitions that AAFCO has submitted to us for scientific review. This tracking might include a new web page on Fda's website or some other media format or location.

175
00:32:13.190 --> 00:32:32.130
Charlotte Conway, FDA CVM: We look forward to hearing from you either today or in comments submitted to the docket. But whether publicly tracking all of the ingredient definitions that AAFCO has submitted to Fda for so scientific review would be useful. And if so, where would you like to access that information? And what information needs Do we share

176
00:32:32.300 --> 00:32:48.730
Charlotte Conway, FDA CVM: in the food, additive petition and grass. Notice program. We currently have mechanisms to share. When a new submission is received, we publish in the Federal register notice of filings for animal food additives, and we maintain an animal food graph. Notice inventory on our website.

177

00:32:49.130 --> 00:33:06.889
Charlotte Conway, FDA CVM: These postings, although in different places, allow interested stakeholders to know that Fda has received its submission and is reviewing the information to date. We've not implemented a similar procedure for ingredient definitions We review for alcohol, and we look forward to hearing from you about this idea.

178
00:33:07.170 --> 00:33:24.520
Charlotte Conway, FDA CVM: We think this type of posting could facilitate awareness for all interested parties of potential, new or modified ingredient definitions. Consumers and animal food manufacturers could easily find all of the ingredients under review, and this expanded awareness could also help handle food ingredients.

179
00:33:24.530 --> 00:33:33.940
Charlotte Conway, FDA CVM: Awareness of submissions under review could help avoid redundant research and redundant submissions. If multiple companies are developing similar ingredients.

180
00:33:33.990 --> 00:33:37.740
Charlotte Conway, FDA CVM: Since the AAFCO ingredient definitions are not proprietary,

181
00:33:37.980 --> 00:33:55.489
Charlotte Conway, FDA CVM: this transparency may also facilitate fda acceptance of corroborative data and additional information that could assist Fda's understanding of the safety of a proposed ingredient, or it could help identify any relevant limitations to the use of a proposed new or modified ingredient.

182
00:33:55.510 --> 00:34:06.599
Charlotte Conway, FDA CVM: A more transparent process could also help ensure that the ingredients are identified in a way that all products that may enter the marketplace are part of the definition.

183
00:34:06.610 --> 00:34:23.649
Charlotte Conway, FDA CVM: For example, if additional information can be submitted by other firms that intend to market similar ingredients, while we're reviewing the initial submission. The definition we recommend to AAFCO may not need to be later modified to reflect a second or third company in a similar reading

184
00:34:23.659 --> 00:34:31.030
Charlotte Conway, FDA CVM: We're also considering how to better publicly convey the work completed by Fda. Before we send a recommendation to AAFCOAAFCO.

185
00:34:31.040 --> 00:34:47.630

Charlotte Conway, FDA CVM: Hopefully, after today's conversation you have a better understanding of the current state of Fda's role in the AAFCO ingredient definition process. But going forward, we want to ensure that there is more information readily about the work we do, and the information that we review

186
00:34:47.670 --> 00:34:53.539
Charlotte Conway, FDA CVM: guidance and written policies are one of the best ways for us to communicate our current thinking on a topic.

187
00:34:53.550 --> 00:35:08.479
Charlotte Conway, FDA CVM: But developing these documents takes time. So we're hoping to hear from you at this early stage the types of information that we should share to ensure that any guidances or other documents that we develop are those that would best serve our stakeholders

188
00:35:08.840 --> 00:35:09.990
Charlotte Conway, FDA CVM: in summary.

189
00:35:10.000 --> 00:35:24.650
Charlotte Conway, FDA CVM: We're here today to learn how we can better serve all stakeholders as we improve our engagement with AAFCO's ingredient definition process as part of our public Health mission to protect the safety of animal food and animal food, and

190
00:35:24.740 --> 00:35:29.820
Charlotte Conway, FDA CVM: we'll be listening today and closely reviewing the docket to look for your suggestion.

191
00:35:30.090 --> 00:35:43.349
Charlotte Conway, FDA CVM: Next, we've invited Austin Therrell AAFCO's executive director, to share more information about AAFCOAAFCO and his perspective on the relationship between AAFCO and Fda in the ingredient definition process.

192
00:35:53.100 --> 00:36:10.089
Austin Therrell: Hey? Thank you, Charlotte, and thank you everyone this morning. My name is Austin Therrell I am the executive director for the Association of American Feed Control officials, and i'm grateful this morning for the opportunity to share a little bit more about AAFCO,

193
00:36:10.100 --> 00:36:18.309
Austin Therrell: about how we work with the Fda, and a little bit more about the memorandum of understanding that we have In place

194
00:36:19.350 --> 00:36:20.669
Austin Therrell: next slide.

195
00:36:22.080 --> 00:36:31.520
Austin Therrell: I'd like to start with a brief history of AAFCO. If you're interested. The full history of AAFCO is included in the beginning of the AAFCO official publication,

196
00:36:32.050 --> 00:36:41.209
Austin Therrell: but after it was formed in the fall of one thousand nine hundred and nine, at the conclusion of a second American Feed Manufacturers Association meeting in Washington, Dc.

197
00:36:41.930 --> 00:36:53.379
Austin Therrell: That American Feed Manufacturers Association. They appointed a committee of Control officials and industry representatives to study inspection and enforcement matters and report back

198
00:36:53.880 --> 00:37:06.409
Austin Therrell: at the conclusion of that meeting Dr. E. B Vorhees of the New Jersey Agriculture Experiment Station, requested that control officials remain for a follow up meeting to continue the discussion they were having.

199
00:37:06.490 --> 00:37:10.009
Austin Therrell: That was a formation of AAFCO, as we know it today.

200
00:37:10.420 --> 00:37:11.639
Austin Therrell: Next slide

201
00:37:13.660 --> 00:37:22.680
Austin Therrell: That meeting, Dr. Vorhees, he is encouraged Regulators to prepare and provide industry with a general consensus of the regulatory community. The

202
00:37:22.860 --> 00:37:42.079
Austin Therrell: The control officials that were present at that meeting agreed that a uniform law, along with fair and equitable definition, regulations and resolution in a process to accept new feed, ingredients, and an establishment of proper labeling receivers was needed for consistency

203
00:37:42.090 --> 00:37:43.520
Austin Therrell: and uniformity

204
00:37:43.810 --> 00:37:45.049
Austin Therrell: next one

205
00:37:47.210 --> 00:37:51.609
Austin Therrell: AAFCO's purpose. Today. Hasn't changed much since that original purpose

206
00:37:52.400 --> 00:38:09.300
Austin Therrell: today. AAFCO provides a forum where controlled officials, industry, representatives, and consumers can meet in partnerships, to discuss problems, in administering and enforcing safety law, where they can meet, to identify and discuss emerging issues across the country,

207
00:38:09.320 --> 00:38:14.819
Austin Therrell: study problems, develop strategies and provide guidance and outreach

208
00:38:15.320 --> 00:38:34.530
Austin Therrell: After the volunteering membership of the organization of the State and the United States and the Federal Government, as well as government agencies in other countries like Canada and Costa Rica, that are responsible for the execution of laws and regulation pertaining to the production, labeling, distribution, use for

209
00:38:34.540 --> 00:38:37.130
Austin Therrell: of animal feed and feed ingredients.

210
00:38:37.780 --> 00:38:39.040
Austin Therrell: Next slide.

211
00:38:40.760 --> 00:38:53.140
Austin Therrell: AAFCO's mission and vision is to be a collaborative association that supports members and stakeholders and promote the safety of applied through unified system-based regulations,

212
00:38:53.150 --> 00:38:56.629
Austin Therrell: ingredient standards, and laboratory operations.

213
00:38:56.990 --> 00:39:02.019
Austin Therrell: We aim to be the trusted leader that safeguards, animal and human health.

214

00:39:02.540 --> 00:39:03.800
Next slide

215
00:39:05.980 --> 00:39:11.560
Austin Therrell: that very first meeting in one thousand nine hundred and nine. The Federal Government was present at after a meeting

216
00:39:12.250 --> 00:39:20.429
Austin Therrell: like was mentioned earlier. Fda representatives participate on many AAFCO committees providing scientific and technical advice. The

217
00:39:20.490 --> 00:39:32.099
Austin Therrell: they serve in a non-voting. advisory on the AAFCO board of directors, and they provide valuable scientific advice that many safety control officials rely on when making a decision

218
00:39:33.000 --> 00:39:34.250
Austin Therrell: next one.

219
00:39:36.520 --> 00:39:43.110
Austin Therrell: The Fda and AAFCO have had the formal memorandum of understanding in place since two thousand and seven.

220
00:39:43.230 --> 00:39:58.020
Austin Therrell: This Mou clarifies the responsibility of the Fda and AAFCO during Ingredient Definition requests process, and provides a mechanism for resolving disagreemnts that arise, and for modifying when required

221
00:39:58.730 --> 00:39:59.959
Austin Therrell: next one.

222
00:40:02.020 --> 00:40:09.959
Austin Therrell: This process of the Mou outline is one of the most transparent approval pathways that is available.

223
00:40:10.460 --> 00:40:20.049
Austin Therrell: I think the control officials, the ability to provide an input and ultimately a voice in whether or not AAFCO accepts an ingredient as official or tentative.

224

00:40:20.410 --> 00:40:25.110
Austin Therrell: Anyone that chooses to attend a meeting can listen to updates about the ingredients,

225
00:40:25.120 --> 00:40:28.420
and can also provide comment to regulators that are present.

226
00:40:28.890 --> 00:40:37.139
Austin Therrell: It creates a unique forum and process that provides more oversight and reviews than many of the ingredients We, as humans, consume

227
00:40:37.570 --> 00:40:38.890
Austin Therrell: next slide.

228
00:40:40.720 --> 00:40:42.990
Austin Therrell: The process also takes teamwork.

229
00:40:43.360 --> 00:40:50.880
Austin Therrell: AAFCO establishes after investigators that help the submitters develop a just and equitable definition.

230
00:40:51.100 --> 00:41:04.770
Austin Therrell: Those investigators also ensure the production, sale, and use of a new ingredient is safe and effective. To make sure the definition of the ingredient is not proprietary, and would not favor one producer over another,

231
00:41:04.780 --> 00:41:13.279
Austin Therrell: and they assist the submitter in making sure that all the relevant safety and utility data is present and ready for reviewed by the center for veterinary medicine.

232
00:41:14.000 --> 00:41:21.609
Austin Therrell: They ultimately serve as at liaison between the Fda and the submitter to assist Throughout the definition request

233
00:41:22.020 --> 00:41:23.250
Austin Therrell: next slide.

234
00:41:25.200 --> 00:41:29.530
Austin Therrell: This process is also mutually beneficial to many stakeholders.

235
00:41:29.750 --> 00:41:34.540
Austin Therrell: The AAFCO investigator role reduces the work that's needed from Fda. The

236
00:41:34.610 --> 00:41:46.169
Austin Therrell: much of the work. That the investigator does alleviate the needs for Cvm to set up multiple pre-submission consultation meetings which ultimately saves Fda valuable time and resources

237
00:41:46.730 --> 00:41:53.529
Austin Therrell: AAFCO investigator role provides industry with a dedicated individual to help answer questions throughout the process

238
00:42:00.570 --> 00:42:03.869
Austin Therrell: which many States Don't have the resources to do on their own.

239
00:42:05.240 --> 00:42:18.030
Austin Therrell: Like I mentioned, the AAFCO process creates the investigator role. Those people are subject matter experts that are willing to answer questions not only to regulators and industry, but also to consumers

240
00:42:18.710 --> 00:42:19.979
Austin Therrell: next slide.

241
00:42:22.140 --> 00:42:25.700
Austin Therrell: But i'd like to leave everyone with a quote today from Henry Ford.

242
00:42:25.960 --> 00:42:41.309
Austin Therrell: Everyone's moving forward together. Then success takes care of itself, and I think that that's what everyone's doing today. All parties are listening to stakeholder, feedback, and hoping to move forward and make this process even more successful than it has been.

243
00:42:41.920 --> 00:42:49.730
Austin Therrell: The AAFCO process provides another avenue for the industry to bring new products to the market quickly and more efficiently.

244
00:42:50.880 --> 00:42:57.579
Austin Therrell: It's transparent and requires Fda oversight and allows for input from a diverse group of stakeholders. The

245
00:42:58.140 --> 00:43:06.000
Austin Therrell: it relieves Fda of a lot of work in the pre submission process, saving Cvm. Valuable time and resources. The

246
00:43:06.680 --> 00:43:13.139
Austin Therrell: it promotes a uniform and consistent pathway to establish a common or usual name for new ingredients. Now

247
00:43:13.610 --> 00:43:22.290
Austin Therrell: this model has worked well for many years, and AAFCO is excited to hear input the rest of the day. That will continue to make it better

248
00:43:23.080 --> 00:43:26.889
Austin Therrell: if you have any questions. Um, Our emails on the next slide.

249
00:43:27.500 --> 00:43:29.809
Austin Therrell: I thank you for the opportunity this morning.

250
00:43:36.430 --> 00:43:37.999
Walt Ellenberg, FDA CVM: Thank you, Austin.

251
00:43:38.050 --> 00:43:45.109
Walt Ellenberg, FDA CVM: Well, at this point i'm going to shift gears a little bit and go, for how the rest of the meeting will flow.

252
00:43:45.410 --> 00:43:56.099
Walt Ellenberg, FDA CVM: Part of the meeting. Ah! Of the information i'm going to bring up is actually just for those who are watching, so you'll know where things are at any given time. The rest of it will be directed at many of the presenters.

253
00:43:59.920 --> 00:44:04.390
Walt Ellenberg, FDA CVM: So the first thing i'd like to bring up in this kind of overview, is it?

254
00:44:05.140 --> 00:44:07.209
Walt Ellenberg, FDA CVM: Today? We've separated

255

00:44:07.440 --> 00:44:22.069
Walt Ellenberg, FDA CVM: the public presentations really into two sessions, not necessarily based on individual topics, but rather just to break the day up, so that we can have time for individuals to go, either have a break or go eat lunch.

256
00:44:22.170 --> 00:44:41.280
Walt Ellenberg, FDA CVM: The agenda has been really designed, so that subsequent reviewers and you'll see this in the slides. But we designed it so that subsequent reviewers will know their position in queue, and therefore, when it becomes time for them to activate their microphone, it'll be they'll know where they are in the process,

257
00:44:41.290 --> 00:44:50.979
Walt Ellenberg, FDA CVM: and that brings me to the next point that if a presenter is unavailable at their designated time, we will move to the next speaker.

258
00:44:51.310 --> 00:45:09.449
Walt Ellenberg, FDA CVM: Having said that we don't want to omit anybody. So at the end of each session, and even at the end of the meeting we will go back through, and if we've missed anyone who had request to speak. We'll actually see if they're present, and we will allow them to give their presentation at that time

259
00:45:10.510 --> 00:45:26.519
Walt Ellenberg, FDA CVM: at the time of your presentation. Please raise your hand using the There's a queue on your zoom uh set at the bottom of the page which you'll be able to raise your hand and identify, and we will open your microphone so that you can speak.

260
00:45:26.840 --> 00:45:34.240
Walt Ellenberg, FDA CVM: Presenters will not be on camera, and the chat function is not available for this meeting.

261
00:45:34.880 --> 00:45:37.379
Walt Ellenberg, FDA CVM: If a session ends early,

262
00:45:37.730 --> 00:45:41.419
Walt Ellenberg, FDA CVM: for instance, this session may end a few minutes early.

263
00:45:41.790 --> 00:45:58.949
Walt Ellenberg, FDA CVM: If it does end early, we will take a break and resume the public presentations at the time listed on the agenda. We do this so that we make sure that we don't start

before somebody may have actually signed up. Ah! Knowing that they're going to be speaking at a particular time.

264
00:45:59.790 --> 00:46:14.889
Walt Ellenberg, FDA CVM: We also have a waiting list of speakers that we received after our deadline for speaking requests, as of today. We have three individuals who will be on this waiting list, and they will be given a chance to speak at the end of the day

265
00:46:17.070 --> 00:46:36.710
Walt Ellenberg, FDA CVM: for those who are presenting. We really need to make sure that for the transcript and the video that you state your name and affiliation at the beginning of your presentation. Be mindful of the fact that you need to speak clearly and honor your time limit. Each speaker is being given a limit of eight minutes per presentation,

266
00:46:36.720 --> 00:46:37.540
Walt Ellenberg, FDA CVM: and

267
00:46:37.800 --> 00:46:47.759
Walt Ellenberg, FDA CVM: I will not begin the timer until after each presenter has given their introductory statement and their affiliation. Once that's completed, i'll start the timer

268
00:46:47.770 --> 00:46:58.480
Walt Ellenberg, FDA CVM: at the towards the end of the presentation, or towards the end of your time period, with approximately one minute remaining, I will quietly interrupt and say one minute warning.

269
00:46:58.640 --> 00:47:03.330
Walt Ellenberg, FDA CVM: At that time you can continue. But please wrap up your presentation within that minute.

270
00:47:06.050 --> 00:47:18.979
Walt Ellenberg, FDA CVM: Please understand also that not every single presenter submitted slides for discussion. Some of the presenters are just going to give oral presentations, and that was left to their desires, to which they so chose

271
00:47:19.110 --> 00:47:29.119
Walt Ellenberg, FDA CVM: during the meeting. Keep in mind that all participants other than the speakers, their microphones will be muted, and the chat functions will be disabled;

272
00:47:29.130 --> 00:47:47.489

Walt Ellenberg, FDA CVM: and again, like I mentioned at the beginning of the meeting. The Q. And A. Feature will be used solely for the purpose of resolving technical issues. And once we're made aware of that. We will try to address them, but we will not be using the Q. And A. In any shape or form to try to answer questions that are submitted in that area

273
00:47:48.820 --> 00:48:03.450
Walt Ellenberg, FDA CVM: just as a reminder. All public presenters are responsible for submitting their own presentations, whether they've got a hard copy that they want to submit, or their slides that they may submit. But they've got to be submitted to the docket

274
00:48:03.600 --> 00:48:08.239
Walt Ellenberg, FDA CVM: them not. The Fda will not submit on your behalf,

275
00:48:08.250 --> 00:48:13.050
Walt Ellenberg, FDA CVM: and as a final reminder, the docket will remain open until March the ninth.

276
00:48:13.800 --> 00:48:17.229
Walt Ellenberg, FDA CVM: So at this time we will shift gears

277
00:48:17.660 --> 00:48:23.760
Walt Ellenberg, FDA CVM: as we've listed in the agenda. There is a break scheduled at this point in time,

278
00:48:23.800 --> 00:48:26.650
Walt Ellenberg, FDA CVM: and I know we're a little ahead of schedule,

279
00:48:26.710 --> 00:48:37.229
Walt Ellenberg, FDA CVM: but rather than try to adjust the agenda. What we will do is we will take a break, and we will come back sharply at eleven fifteen,

280
00:48:37.330 --> 00:48:43.860
Walt Ellenberg, FDA CVM: but during that time we will monitor the list of registrants to see if all of our speakers are present.

281
00:48:43.910 --> 00:49:01.270
Walt Ellenberg, FDA CVM: Ah! So that we know who to raise. Ah, the microphone. Ah, activity to once the presentations begin. So at this time I would like to. Ah start the break, and we will be back at eleven. Fifteen. Thank you. We'll see you on the other side of the break,

282
01:15:03.940 --> 01:15:06.410
and I activate my camera.

283
01:15:10.720 --> 01:15:14.699
Walt Ellenberg, FDA CVM: All right, Welcome back from the break, and we will now

284
01:15:15.030 --> 01:15:18.540
Walt Ellenberg, FDA CVM: begin the public presentation segment of the meeting.

285
01:15:23.020 --> 01:15:29.499
Walt Ellenberg, FDA CVM: So before we jump in, I'd like to point out that these presenters have asked to speak.

286
01:15:29.510 --> 01:15:47.440
Walt Ellenberg, FDA CVM: Ah! Their topics may or may not be related. Not all of them have slide presentations, and, for instance, the two individuals with asterisk next to their name, they actually have kind of a combined presentation. And so you won't hear two separate ones for them.

287
01:15:47.450 --> 01:15:49.109
Walt Ellenberg, FDA CVM: So at this time,

288
01:15:49.210 --> 01:16:08.660
Walt Ellenberg, FDA CVM: what I will do is I will recognize Muhammad Al Adult, and I was told before the end of the break that Ah, Mr. All, it all was not signed in, but we did have some telephone numbers, and so, if Mr. Al Ahdal is present.

289
01:16:08.670 --> 01:16:10.899
Walt Ellenberg, FDA CVM: Please send an email

290
01:16:10.990 --> 01:16:25.660
Walt Ellenberg, FDA CVM: or let us know that you're present, and I can give you the email address right. Now, the email address that you will use is actually the one associated with this meeting. It's Cvm. Animal feed ingredients

291
01:16:26.200 --> 01:16:28.130
Walt Ellenberg, FDA CVM: two thousand and twenty-three

292

01:16:28.840 --> 01:16:32.929
Walt Ellenberg, FDA CVM: Fda dot Hhs Gov.

293
01:16:34.070 --> 01:16:39.950
Walt Ellenberg, FDA CVM: And like I said as of now we do not see his him. We do not see that he's signed in

294
01:16:40.140 --> 01:16:43.109
Walt Ellenberg, FDA CVM: so at this point. What I will do is is

295
01:16:43.400 --> 01:17:01.510
Walt Ellenberg, FDA CVM: shift to the next speaker, which is Dana Brooks and Miss Brooks. You will be given microphone rights, and as soon as you receive those microphone rights, please speak up, and you may begin again. The timer will not start

296
01:17:02.230 --> 01:17:06.730
Walt Ellenberg, FDA CVM: until after you've given your name in your introduction about your affiliation.

297
01:17:07.530 --> 01:17:09.450
DanaBrooks: Good morning! Can you hear me.

298
01:17:09.500 --> 01:17:16.310
Walt Ellenberg, FDA CVM: Yes, I can thank you. I'm. Dana Brooks, President and Ceo of the Pet Food Institute.

299
01:17:16.330 --> 01:17:24.959
DanaBrooks: The Pet Food Institute appreciates the opportunity to provide comments regarding Fda and the AAFCO ingredient definition process,

300
01:17:24.970 --> 01:17:46.180
DanaBrooks: established in one thousand nine hundred and fifty. Eight. Pfi is the Trade Association, and the voice of us cat and dog food and treat manufacturers. Our members account for the vast majority of pet food and treats made in the United States. We are all per out to be feeding nearly one hundred and eighty million dogs and cats in Us. Households.

301
01:17:46.590 --> 01:18:05.720

DanaBrooks: Our members operate under two different sets of regulatory requirements. In one case those issued by the Fda, and separately those requirements found within each State's Commercial Feed law Enforcement of these regulations also occur, both by Federal and State officials.

302
01:18:06.050 --> 01:18:25.780
DanaBrooks: The creation of AAFCO, more than one hundred years ago, was primarily to address the needs of livestock. A farmer could go to the local feed store and know what was in the feed that they were buying, and how to use it, because AAFCO had provided ingredient definitions, rations, and other information to be included on a back or container.

303
01:18:25.840 --> 01:18:33.120
DanaBrooks: Dogs and cats were considered working animals on the farm, and their food was naturally voted into AAFCO the

304
01:18:33.130 --> 01:18:35.149
DanaBrooks: skip forward to today.

305
01:18:35.160 --> 01:18:47.589
DanaBrooks: Dogs and cats have moved from the farm to our living spaces. When a pet owner purchases pet food, they are most likely doing so in a grocery store alongside human food, not only at a farm store

306
01:18:47.600 --> 01:18:57.459
DanaBrooks: and that same food will be stored in a pantry at home right alongside Human food pets have become companion animals and members of our families.

307
01:18:57.470 --> 01:19:08.960
DanaBrooks: What worked a hundred years ago for pet food is not meeting the demands of the innovative global pet food industry of today nor our consumers and customers.

308
01:19:09.420 --> 01:19:27.280
DanaBrooks: One challenge in the process in general, an ingredient definition process specifically is that AAFCO is a voluntary organization that creates non-binding model legislation and regulations that a State can adopt in a whole in part or not at all

309
01:19:27.290 --> 01:19:30.209
DanaBrooks: into their own state's commercial feed law

310
01:19:30.220 --> 01:19:48.809

DanaBrooks: as a voluntary organization that historically focuses primarily on animal feed. It does not have the resources or specific expertise required to effectively review ingredients for pet food, at least not. In the same manner it reviews ingredients for animal feed.

311
01:19:49.000 --> 01:20:16.959
DanaBrooks: Once an ingredient definition is approved by AAFCO inconsistent interpretations across States, create a muddled regulatory landscape for pet food. A regulator in one State can disrupt commerce because of different interpretations of a definition that is included in the AAFCO official publication. For example, recently a single State had concerns about a widely used and essential ingredient.

312
01:20:16.970 --> 01:20:22.629
DanaBrooks: That State issued a stop sale on products containing that ingredient.

313
01:20:22.640 --> 01:20:39.940
DanaBrooks: This was an ingredient with nearly sixty years of safe use in dog and cat food instead of learning from other States. This State label reviewer initially attempted to use the AAFCO process to create a nationwide issue that could have harmed

314
01:20:39.950 --> 01:20:48.659
DanaBrooks: caused harm by excluding the ingredient from the market, and at a minimal would disrupt nationwide commerce of a safe food ingredient

315
01:20:48.670 --> 01:21:03.290
DanaBrooks: issues like that which highlight the inconsistencies of a voluntary system that is subject to different interpretations, create a lasting lack of trust and predictability for pet food makers in following state processes.

316
01:21:03.500 --> 01:21:10.989
DanaBrooks: Another concern with the current system is the lead of time. It takes an ingredient to go through the approval process. The

317
01:21:11.000 --> 01:21:20.289
DanaBrooks: committees are run by volunteers, which makes it difficult to get ingredients on the agenda of its very limited meeting schedule.

318
01:21:20.300 --> 01:21:31.070
DanaBrooks: I've asked industry experts to provide examples of any ingredient that had a smooth up who work a process through AAFCO. No one could provide a good example.

319
01:21:31.390 --> 01:22:00.650
DanaBrooks: The disruption to the supply chain during, Covid, and the demand for animals, fats, and proteins from other sectors has made it very clear that the pet food industry may need to look for alternative Novel ingredients continue to provide sustainable, complete and balanced and nutritious food to our pets without a structured predictable review process by experts in pet food safety and nutrition. The pet food industry will be unable to innovate, and

320
01:22:00.660 --> 01:22:19.839
DanaBrooks: on quickly to meet the rapid changes in the supply chain. Our pets also need food security. For example, there is a potential in alternative, sustainable ingredients, such as those from insects without an ingredient and approval process which fosters innovation and works efficiently

321
01:22:19.850 --> 01:22:24.880
DanaBrooks: ingredients that can bring significant benefits are delayed from reaching the market.

322
01:22:24.890 --> 01:22:50.380
DanaBrooks: The AAFCO ingredient definition process was started before there was a uniform Federal ingredient approval process with a food additive amendment of one thousand nine hundred and fifty, eight. A clear Federal process for food additive approvals was established with an explicit exemption from the approval process for substances determined to be generally recognized as safe or grass

323
01:22:50.430 --> 01:23:06.920
DanaBrooks: by States requiring pet food ingredients to go through an AAFCO ingredient definition process outside of the Federal statutory scheme a system has been created where there is an additional pre market approval process at the State level for ingredients

324
01:23:07.320 --> 01:23:36.690
DanaBrooks: at the Fda has the generally recognizes state notification or grass process. But CVM. Takes a very restrictive approach in a type of data that can be used that results in a much longer time frame for approval. However, the benefit of going through this process is a submitter has only to deal with one entity that has expertise in pet food nutrition, and there is only one interpretation of the definition. After the review is completed,

325
01:23:36.870 --> 01:23:42.490
DanaBrooks: Another significant benefit of working through AAFCO is the agency's ability to

326
01:23:42.790 --> 01:24:12.720
DanaBrooks: I mean so pardon me. Another significant benefit of working through Fda is the Agency's ability to protect confidential business information, whereas if a company were to petition a novel ingredient through the AAFCO approval process, the company would run the risk of its business plans

being hung up, while discussions of committee takes place all in front of the company's competitors. Pet food needs an ingredient review process that fosters innovation, provides assurance to the

327
01:24:12.730 --> 01:24:41.069
DanaBrooks: consumer, and uses clear and consistent timelines. In summary our recommendation will be for more uniform and predictable regulatory pathways for ingredient approvals. Despite the noble efforts of AAFCO representative a system run by State volunteers and given them and given minimum support by the Federal agency responsible for pet food. Safety is far from acceptable to meet the needs of our pets in today's environment.

328
01:24:41.120 --> 01:24:53.799
DanaBrooks: The entire AAFCO Ingredient definition process is burdensome, inefficient, and well beyond anything contemplated by the Federal drug and cosmetic act and its amendments

329
01:24:53.810 --> 01:25:03.219
DanaBrooks: again. Thank you for the opportunity for Pfi to be represented today. Pfi will be submitting additional written comments for the record. Thank you.

330
01:25:04.970 --> 01:25:06.699
Walt Ellenberg, FDA CVM: Thank you, Ms. Brooks,

331
01:25:08.630 --> 01:25:12.169
Walt Ellenberg, FDA CVM: and so now we will move to our next speaker.

332
01:25:12.240 --> 01:25:27.390
Walt Ellenberg, FDA CVM: Our next speaker is listed as Jan Campbell and I have seen that Ah, Ms. Campbell is present. So Ms. Campbell, if you will go ahead and say something so that we know you're on, and we will again.

333
01:25:27.570 --> 01:25:29.390
Jan Campbell: Good morning. Can you hear me?

334
01:25:29.400 --> 01:25:31.459
Walt Ellenberg, FDA CVM: Yes, I can.

335
01:25:31.500 --> 01:25:36.089
Jan Campbell: I'm. Jen Campbell, manager of regulatory Affairs for purina animal nutrition.

336

01:25:36.100 --> 01:25:45.240
Jan Campbell: I'll be sharing comments on behalf of myself and Dr. Kerry Schultz for purina animal nutrition, nutrablend additives

337
01:25:45.350 --> 01:26:04.930
Jan Campbell: as a feed manufacturer. The safety and utility of the ingredients we utilize and our animal food products is of utmost importance. Our products provide the nutrition necessary to support the production of meat, milk, fish, and eggs, and play a critical role in animal health and welfare as well as public health.

338
01:26:05.040 --> 01:26:18.950
Jan Campbell: The quality of our animal food products is centered on the quality of the ingredients used in the products we produce and distribute, and Fda provides the technical and scientific expertise in evaluating their safety and utility.

339
01:26:19.040 --> 01:26:31.539
Jan Campbell: AAFCO and Fda have worked cooperatively for many years, establishing the animal food, ingredient definitions, and this continued collaboration for the ingredient approval process is vital for our industry.

340
01:26:31.550 --> 01:26:42.779
Jan Campbell: However, it is essential to modernize and improve the current animal food ingredient review process as companies struggle to get ingredients approved through the review process and to market

341
01:26:42.820 --> 01:26:48.640
Jan Campbell: industry, wants to bring new innovative ingredients to market that will help improve animal nutrition in

342
01:26:48.650 --> 01:27:01.859
Jan Campbell: and advance animal health, and it is essential that stakeholders have a full understanding of Fda's engagement and AAFCO's feed ingredient definition process, including the required information for the submission.

343
01:27:01.870 --> 01:27:11.349
Jan Campbell: Fda has stated that the agency has received ingredient submissions that are incomplete and not adequate, which delays the timing of the approval.

344
01:27:11.360 --> 01:27:24.220

Jan Campbell: This is where comprehensive guidance, training, and education would benefit industry. Stakeholders in twenty twenty, one AAFCO. Granted free public access to chapter six of its official publication,

345
01:27:24.230 --> 01:27:33.070
Jan Campbell: Chapter six, is now a standalone document, and the public can access the AAFCO's Guide to so many new or modified ingredient definitions,

346
01:27:33.090 --> 01:27:43.989
Jan Campbell: while the AAFCO guide is helpful. There is still a vacuum on what information is truly needed, and the detail necessary for industry to fully understand the technical requirements,

347
01:27:44.000 --> 01:27:49.339
Jan Campbell: including the studies and data that must be included in their ingredient submission package.

348
01:27:50.100 --> 01:28:01.559
Jan Campbell: We want to acknowledge and share our appreciation for the recent collaboration efforts Fda and AAFCO have made with their comprehensive online

349
01:28:01.960 --> 01:28:20.540
Jan Campbell: and in-person trainings on the submission process which does provide more in-depth detail around the required information publishing these comprehensive training slides with free public access on the AAFCO website would help advance transparency and education for industry stakeholders.

350
01:28:20.810 --> 01:28:37.300
Jan Campbell: It would also benefit industry if Cvm would publish these slides on their website. It's encouraging that CVM. Reorganized in two thousand and twenty, two, and separated the office of surveillance and compliance into four divisions with a specific division of animal food ingredients.

351
01:28:37.310 --> 01:28:44.370
Jan Campbell: CVM has also hired additional full-time staff in the last two years however, improvements still need to be implemented.

352
01:28:45.060 --> 01:29:02.509
Jan Campbell: Regulatory requirements have increased through the years for feeding, getting approvals, and many companies must hire consultants to interpret the ingredient submission requirements, and determine the best pathway to go forward either through the actual ingredient submission process or through a food additive petition.

353
01:29:02.520 --> 01:29:16.620
Jan Campbell: CVM determines the appropriate path based on potential safety concern and those with significant safety issues require a food. Additive petition companies have submitted their ingredient definition packages through AAFCO

354
01:29:17.430 --> 01:29:24.490
Jan Campbell: only to have Cvm. Deny the submission and advise the company that a food added to petition should be submitted

355
01:29:24.530 --> 01:29:28.409
Jan Campbell: for the ingredient which increases the approval. Timeframe

356
01:29:28.420 --> 01:29:41.180
Jan Campbell: and Fda guidance like CVMs two, twenty, one recommendations for preparation and submission of animal food, additive petition that would be focused on the AAFCO ingredient submission process

357
01:29:41.190 --> 01:29:52.110
Jan Campbell: would help reduce ambiguity around the appropriate path for ingredient approvals continuation of the pre-consultation meetings with the Fda is also an important step in the process.

358
01:29:52.120 --> 01:30:11.149
Jan Campbell: Standardization of data and study requirements, between countries, especially the United States and Canada, who is an AAFCO member, would help facilitate approval of animal food ingredients, reduce the time and cost involved in different studies and facilitate marketing. The consulting role of Fda

359
01:30:11.160 --> 01:30:23.039
Jan Campbell: in the AAFCO ingredient definition, submission process per The Mou gives assurance to stakeholders and consumers that new ingredients have been reviewed for both safety and efficacy,

360
01:30:23.090 --> 01:30:37.860
Jan Campbell: the animal of food industry will continue to introduce innovative products into the marketplace. The success of such products is dependent upon the efficiency of the process, the Safety review and the clarity of ingredient names and definition.

361
01:30:37.990 --> 01:30:53.299

Jan Campbell: The process for new ingredient submissions can be very timely and costly for stakeholders, since AAFCO ingredients are not proprietary. It's important that stakeholders be able to maintain the proprietary nature of their ingredient submissions as much as possible

362
01:30:53.310 --> 01:31:10.429
Jan Campbell: for transparency general information could be shared in the AAFCO ingredients on the number of submissions and the length of the time. The submission has been in the review process. This knowledge can help stakeholders determine how they should proceed with their own submissions or entry into the market.

363
01:31:10.450 --> 01:31:17.519
Jan Campbell: The consultative role Fda plays in the AAFCO new ingredient definition submission process is vital.

364
01:31:17.610 --> 01:31:39.689
Jan Campbell: The success of that role is dependent upon providing clarity, training, and education to stakeholders on the process. It is the willingness to listen and adapt to the constantly changing industry and help to ensure the overall efficiency of the approval process. A lack of any of these can result in decelerated innovation

365
01:31:39.700 --> 01:31:47.660
Jan Campbell: or even worse stakeholders, believing the risk of introducing an unapproved product into the market, is lower than that,

366
01:31:47.670 --> 01:32:04.849
Jan Campbell: spending the time and money to obtain ingredient approval through the AAFCO ingredient definition or food additive petition process. We want to thank Fda for hosting this virtual session, and we appreciate the opportunity to share our insights. This is a clear indication

367
01:32:04.860 --> 01:32:20.030
Jan Campbell: that Fda is willing to listen and assess the needs of stakeholders within the industry. We all share a common goal to bring new, innovative, safe, and effective ingredients to our consumers. That ensures the safety of both animals and humans.

368
01:32:20.040 --> 01:32:20.920
Jan Campbell: Thank you.

369
01:32:25.370 --> 01:32:26.800
Walt Ellenberg, FDA CVM: Thank you. Ms. Campbell

370
01:32:28.340 --> 01:32:30.150
Walt Ellenberg, FDA CVM: and our next speaker

371
01:32:30.840 --> 01:32:32.059
Walt Ellenberg, FDA CVM: is

372
01:32:32.910 --> 01:32:38.089
Walt Ellenberg, FDA CVM: Dustin, and I'm going to hope I pronounce this correctly. Is dustin Crummett

373
01:32:38.170 --> 01:32:49.910
Walt Ellenberg, FDA CVM: rethink priorities, Mr. Crummett, are you? I see that he has raised his hand. Sure that you're unmuted, are you there?

374
01:32:49.920 --> 01:32:51.790
Dustin Crummett: Can you hear me? All right. Very good, uh

375
01:32:51.870 --> 01:33:05.579
Dustin Crummett: I am. Ah, Dustin Crummett, I am a lecturer in the department of politics, philosophy, and public affairs at the University of Washington, Tacoma, and here I am representing rethink priorities,

376
01:33:06.000 --> 01:33:09.240
Dustin Crummett: and I I should have slides.

377
01:33:13.310 --> 01:33:14.450
Dustin Crummett: Very good

378
01:33:14.660 --> 01:33:16.769
Dustin Crummett: uh next slide, please.

379
01:33:17.860 --> 01:33:34.240
Dustin Crummett: Rethink priorities is a nonprofit charitable. Think tank. We have been conducting research into potential benefits and challenges of novel food and feed ingredients, such as plant-based alternative proteins or insects for food and feed.

380
01:33:34.250 --> 01:33:41.609

Dustin Crummett: And This makes us interested in the feed ingredient definition. Process. Next, slide, please.

381
01:33:42.700 --> 01:34:02.630
Dustin Crummett: Um, so i'm going to cover three three main points. The first is about the Fda-AAFCO relationship. Um, Then i'll go over some general considerations to set up the second two points; the second will be about the desirability of public notice, and

382
01:34:02.640 --> 01:34:10.439
Dustin Crummett: the third will be about the desirability of more public criteria for managing risks next slide.

383
01:34:11.360 --> 01:34:24.269
Dustin Crummett: So, under the existing memorandum of understanding, Fda has entrusted part of its regulatory apparatus to AAFCO, which is a non governmental organization, with no legal mandate,

384
01:34:24.280 --> 01:34:37.190
Dustin Crummett: and we're not against AAFCO. We don't object to AAFCO's involvement, but we do believe that this raises certain concerns regarding legal compliance and public trust which need to be carefully addressed.

385
01:34:37.200 --> 01:34:51.050
Dustin Crummett: Um. And so we suggest that the revised MOUshould make clear that Fda has the final word on the approval status of any ingredient at any time, and perhaps should also increase Fda's role in other ways. Next slide

386
01:34:51.540 --> 01:34:57.369
Dustin Crummett: a particular concern to us are items G. And H. Under the existing Mou. So G

387
01:34:57.380 --> 01:35:18.220
Dustin Crummett: has it that in the event of disagreement, disagreements are referred to a review board. H. Has it that if Fda wishes to remove ingredients from the feed ingredient definition section of the AAFCO. Ah, it's supposed to approach AAFCO, and it's taken up at the next scheduled meeting of the Feed Ingredient Definitions Committee.

388
01:35:18.230 --> 01:35:34.199
Dustin Crummett: Um. We worry that this arguably reverses the ordinary burden of proof which has it that ingredients have to be demonstrated to be safe, and concerns about safety are sufficient to merit withdrawal. Um! And it also risks, hindering Fda's ability to respond rapidly to emerging safety. Data.

389
01:35:34.210 --> 01:35:46.900
Dustin Crummett: And so, under the revised Mou, we suggest that Ah Fda should reassert its rights to unilaterally remove ingredients from the approved list next slide, please.

390
01:35:47.420 --> 01:35:53.449
Dustin Crummett: So some general considerations that will set up the other two things I'm going to say

391
01:35:53.500 --> 01:36:11.750
Dustin Crummett: uh novel feed ingredients might, for instance, hold promise in making the food system more sustainable. Um. At the same time we recognize that careful regulation is needed to protect human and animal health. Um. So, for instance, in the case of insects as food and feed, which I discussed just because it's the one we've looked into. The most

392
01:36:11.760 --> 01:36:41.689
Dustin Crummett: uh things like proper choice of substrate processing requirements. LabelingRequirements are needed to address concerns around things like possible biological hazards, whether they could serve as passive vectors for uh viruses or bacteria, or you know what they're fed prions, um chemical hazards, such as the bio accumulation of toxins essentially say heavy metals. If those are the substrate um allergenic risks to either humans or animals. There's evidence of cross-reach

393
01:36:41.700 --> 01:37:01.590
Dustin Crummett: activity with shellfish, allergies with my allergies et cetera and research is also needed on the health effects of varying inclusion rates of novel ingredients, and to ensure nutritional adequacy, we know that for some ingredients low inclusion rates might be fine, but higher inclusion rates could depress growth.

394
01:37:01.600 --> 01:37:04.259
Sorry. Um, next slide, please.

395
01:37:05.450 --> 01:37:08.670
Dustin Crummett: Our judgment is that at present it is.

396
01:37:08.680 --> 01:37:32.160
Dustin Crummett: It's difficult for researchers, for consumers, for members of industry to determine how these considerations are going to be taken into account by Fda and AAFCO, and to ensure that their own concerns and interests are going to be taken into account; and we think that there are certain feasible steps that can be taken to help address this to it, which I'll go over now, next slide, please.

397
01:37:32.700 --> 01:37:54.500
Dustin Crummett: Ah, First of all, we agree that Fda should give public notice when new feed ingredients are considered for approval, and so the idea of a website, with a public list of ingredient definition for us. What would satisfy this? We also think that along with that there should be an opportunity for stakeholders in the public to submit relevant information or data.

398
01:37:54.510 --> 01:38:06.219
Dustin Crummett: We believe that this would increase transparency. It would help protect public health by gathering information that might be overlooked otherwise, whatever and would allow public actors greater input into the approval process.

399
01:38:06.320 --> 01:38:08.409
Dustin Crummett: Next slide, please.

400
01:38:09.430 --> 01:38:24.049
Dustin Crummett: Um. We also suggest that Fda might adopt some additional formal, publicly known criteria, perhaps even in the form of thanks to testing requirements, feed controls, et cetera, for managing risks Like those who mentioned above.

401
01:38:24.060 --> 01:38:37.289
Dustin Crummett: For instance, Fda might verify that applicants should provide some potentially relevant items of information which at least are not explicitly asked for in the current AAFCO guidelines. Maybe things like

402
01:38:37.300 --> 01:38:55.710
Dustin Crummett: absorption, distribution, metabolic data, excretional data, except where there is scientific justification for thinking that this is inappropriate or unnecessary, might also clarify the criteria used to ensure that information is supported by appropriate scientific evidence. So where applicable, this might mean, say,

403
01:38:55.720 --> 01:39:04.580
Dustin Crummett: some formal requirement known to the public about testing and a facility which can certify the data next slide. Please.

404
01:39:05.220 --> 01:39:06.400
Dustin Crummett: Um.

405
01:39:06.410 --> 01:39:25.719

Dustin Crummett: In the case of something like, say, bio-accumulation of toxins, fda might adopt specific controls as part of the feed ingredient in the definition process, involving, for instance, things like testing requirements for feed ingredients which could contain heavy metals or the a position of restrictions on production conditions.

406
01:39:25.730 --> 01:39:38.299
Dustin Crummett: Um, once standards like those are developed, they might be applied not only to novel ingredients, but maybe also in other contexts. Where bio-accumulation of toxins is a concern, for instance in fish production.

407
01:39:38.310 --> 01:39:53.289
Dustin Crummett: We believe that this might help protect public health, increase public trust, and also benefit industry by better clarifying regulators expectations, and providing guidance about how to maintain a product. Integrity.

408
01:39:53.300 --> 01:39:55.290
Dustin Crummett: Next slide, please.

409
01:39:55.980 --> 01:39:57.990
Dustin Crummett: Those are our references.

410
01:39:58.400 --> 01:40:00.559
Dustin Crummett: And next slide, please.

411
01:40:01.070 --> 01:40:02.260
Dustin Crummett: Ah,

412
01:40:02.350 --> 01:40:10.580
Dustin Crummett: we would like to thank you very much, and we, we look forward to hearing the other presenters. So thank you.

413
01:40:11.100 --> 01:40:12.750
Walt Ellenberg, FDA CVM: Thank you very much.

414
01:40:14.700 --> 01:40:17.460
Walt Ellenberg, FDA CVM: All right. Our next presenter

415
01:40:18.090 --> 01:40:23.949

Walt Ellenberg, FDA CVM: is Kristy Smedley for the center for regulatory services.

416
01:40:24.850 --> 01:40:26.939
Walt Ellenberg, FDA CVM: Ms. Smedley, Are you?

417
01:40:27.770 --> 01:40:32.600
Walt Ellenberg, FDA CVM: See that she's raising? Okay, Excellent, great. I'm going to for the slide

418
01:40:32.700 --> 01:40:34.489
Walt Ellenberg, FDA CVM: and you may begin.

419
01:40:34.560 --> 01:40:38.029
Kristi Smedley: Thank you. Um. I'd like my first slide, please.

420
01:40:42.620 --> 01:41:02.790
Kristi Smedley: Hi! My name is Kristi Smedley, I have been working in the animal feed ingredient um area for thirty five years. Ten years with the center for veterinary medicine, and twenty five years as a consultant um with my clients being people that are interested in bringing new feed ingredients into

421
01:41:02.800 --> 01:41:03.660
Kristi Smedley: Ah,

422
01:41:03.850 --> 01:41:07.790
Kristi Smedley: the United States! I have

423
01:41:07.800 --> 01:41:37.750
Kristi Smedley: been a part of probably eighty or more submissions, and um approvals or authorizations and um i'm thankful for this time to give my thoughts. Um, I apologize. I had emergency surgery on my mouth yesterday, so we're going to hope that I can talk and be clear. So next study next. Ah, thank you. So. Um. I thankful that Fda Tim Schell,

424
01:41:37.760 --> 01:41:50.660
Kristi Smedley: Dave Edwards, and Austin all gave a great introduction. Unfortunately, my slides have this, But there are some comments i'd like to make that just to support what they said, or to give another view.

425
01:41:50.670 --> 01:42:00.710

Kristi Smedley: This is the the fact that the Fda in the States both share. The regulatory review of feeds is very unusual. For example,

426
01:42:01.000 --> 01:42:21.650
Kristi Smedley: there is not State required registration of human food products, human food ingredients. There is no listing of ingredients for human food, and the same would go for pesticides and for quite frankly, tricycles. So we're in a different area, and we need to um embrace. That next slide

427
01:42:23.940 --> 01:42:42.929
Kristi Smedley: has been previously said that um AAFCO had this role since one thousand nine hundred and nine without uniform regulation on it. Um! There would be so um a state by State regulation, and this would be chaos for the industry and chaos for the consumers, because each State could have their own

428
01:42:42.940 --> 01:43:01.729
Kristi Smedley: decisions about what is marketable, both in the formulation of feed the ingredients definition. What is required on the label So AAFCO provides an incredibly important role of ah trying to support the uniform regulation of animal feeds in the United States

429
01:43:01.860 --> 01:43:03.410
Kristi Smedley: next slide,

430
01:43:04.810 --> 01:43:33.410
Kristi Smedley: and as we discussed Chapter six has got a listing of feed ingredients that are authorized for use in the United States. Um, I do think it's important to realize that this is not a positive list. It's not like Canada. It has a positive list. It's an it's understood that there are common foods that would not be on this AAFCO list. There's also ingredients that um were evaluated under the um independent grass conclusion status, which is a legal status, so

431
01:43:33.420 --> 01:44:03.410
Kristi Smedley: it's, although it's not um a positive list of a complete list. It's the nearest complete list we have. This list is so well regarded it is used by other Us. Federal agencies, Customs use it. Epa. Usda uses it as an understanding of safe and effective feeds, as well as our foreign governments. In fact, I've heard um when I was doing some work with IfiF. There are some governments that consider this: the gold standard of safe ingredients based on their

432
01:44:03.420 --> 01:44:08.230
Kristi Smedley: respect of the Us. Regulation of these feed ingredients. Next slide, please.

433

01:44:10.400 --> 01:44:29.279
Kristi Smedley: Most importantly ingredients. List in the AAFCO chapter six six must be safe for their intended use. Safe Feed ingredients are essential. They're essential to consumers. They're essential to the feed industry, and they're in essential for

434
01:44:29.290 --> 01:44:31.149
Kristi Smedley: supporting animal health

435
01:44:31.890 --> 01:44:40.609
Kristi Smedley: as AAFCO is an administrative arm. They need scientific support to assure that the current and new ingredients are safe.

436
01:44:40.620 --> 01:44:52.709
Kristi Smedley: Fda shares the legal responsibility for the regulation of animal feeds, and they have the required resources. They have the knowledge they have, the scientific backing to assess safety.

437
01:44:52.720 --> 01:45:03.309
Kristi Smedley: It's plainly their role to assure safety of the currently listed authorized ingredients and the safety of novel ingredients or the expanded use of existing ingredients next slide.

438
01:45:04.820 --> 01:45:22.799
Kristi Smedley: I think it's important to realize there are multiple regulatory paths. Other speakers before me. Discuss this that may be used to validate the safety of a new ingredient acceptance through any one of those paths, will result in inclusion of this substance in chapter six, so that stakeholders

439
01:45:22.810 --> 01:45:33.929
Kristi Smedley: have knowledge that this speed ingredient is safe for the described use. Next slide, please. The three paths cover a specific types of ingredients.

440
01:45:33.960 --> 01:45:52.520
Kristi Smedley: Grass is specific to substances in which there is general recognition by the scientific community that the ingredient is safe for the intended use. Food additives, food additives are specific use, have a specific use in the diet, and their safety is oftentimes based on corporate research.

441
01:45:52.610 --> 01:46:03.019
Kristi Smedley: Ingredients are materials that the safety is well understood, and the safety is transparent. Hence the route is generally simpler to negotiate, and should be quicker.

442
01:46:03.350 --> 01:46:05.070

Kristi Smedley: Next slide, please.

443
01:46:06.010 --> 01:46:24.660
Kristi Smedley: All three paths are and are needed to ensure that advances in the scientific understanding of nutrition, safety, both safety for the animal safety, for humans and safety to the environment and efficient utilization of these resources are available to support the safe and secure us feed supply.

444
01:46:24.670 --> 01:46:38.329
Kristi Smedley: Each path is tailored to a specific category of products, and the AAFCO definition process is intended for well understood feed materials that should be quickly reviewed. As I previously said. Next day next slide,

445
01:46:39.040 --> 01:46:57.189
Kristi Smedley: importantly, the mou and the informal process for AAFCO feed ingredients allow for immediate removal of an ingredient that has been found to be unsafe until and unless safety has been validated, the formal pathways require a legal process to remove the accepted feed additives, and would take much longer.

446
01:46:57.200 --> 01:47:02.209
Kristi Smedley: Hence this is another level of control, and has been previously discussed

447
01:47:02.480 --> 01:47:13.869
Kristi Smedley: by other speakers next slide. I am now going to go on to the the questions that Fda asked and and give my my understanding, based on my experience

448
01:47:14.150 --> 01:47:16.590
Kristi Smedley: one after you they called.

449
01:47:16.600 --> 01:47:17.910
Kristi Smedley: Excuse me,

450
01:47:29.440 --> 01:47:31.679
Kristi Smedley: I'm sorry. I apologize that

451
01:47:31.710 --> 01:47:41.080
Kristi Smedley: I have one of those wonderful little animals in my office today. When Fda pulled their employees from the role of investigators and section editors. This distanced

452
01:47:41.330 --> 01:47:57.740
Kristi Smedley: the Fda from the day to day business of the AAFCO regulation of ingredients. I think this also is a cause of the fact that people do not understand where Fda is and how important they are in this. In the role of feed ingredients.

453
01:47:58.210 --> 01:48:07.189
Kristi Smedley: Fda's role on the Ingredient Definition Committee, although very important, may appear to be a May appear to the public to be very minimal

454
01:48:07.200 --> 01:48:22.119
Kristi Smedley: when introducing a newly supported AAFCO ingredient. It may be helpful if Fda provided a written and oral summary of the scientific review of the ingredient, perhaps not something as difficult or lengthy as a freedom of information summary for

455
01:48:22.130 --> 01:48:34.679
Kristi Smedley: animal drugs, but something that demonstrates what Fda reviewed, so that it gives comfort and understanding to those that are not fully entrenched in this effort.

456
01:48:34.820 --> 01:48:43.499
Kristi Smedley: It seems odd to me that the Cfia employees another governmental agency on Federal agency in Canada

457
01:48:43.920 --> 01:49:03.880
Kristi Smedley: can have the role of investigator and section editors and hold AAFCO officer positions, whereas the Fda appears to Ah intend to keep an arm's length, and the reason I say this is odd, is Cfia does not embrace the list of ingredients, or provide scientific review services on feed ingredients, and I am.

458
01:49:03.890 --> 01:49:12.369
Kristi Smedley: I am pleased that they are involved. That's not my point. My point is, Fda should reconsider being as involved as Cfia is, and I do want to say.

459
01:49:12.880 --> 01:49:15.889
Walt Ellenberg, FDA CVM: You have about forty five seconds. .

460
01:49:15.900 --> 01:49:24.069
Kristi Smedley: Thank you. The recently completed ingredient definition Process Online Course was helpful. Next slide, please.

461
01:49:25.090 --> 01:49:33.359
Kristi Smedley: Um changes in the ingredient definition process. Fda's role in validating. The safety of novel ingredients is important, but it must be balanced.

462
01:49:33.370 --> 01:49:47.270
Kristi Smedley: They require exhaustive review and requirements for a single manufacturing process for a non-proprietary ingredient that is misdirected, and results in added expense, time, and in some cases blocking innovation in the United States. Next slide, please.

463
01:49:48.620 --> 01:49:50.639
Kristi Smedley: Um. I also

464
01:49:50.710 --> 01:50:10.970
Kristi Smedley: I believe that the publication of tolerances or action levels on identified hazards would be helpful. It's complicated. Um. Not having these complicates, the safety assessment products that are regulated. Um new AAFCO ingredients are regulated by other jurisdictions. We can be relying on their review, which would

465
01:50:11.080 --> 01:50:14.470
Kristi Smedley: hasten the Review next slide.

466
01:50:14.960 --> 01:50:19.730
Walt Ellenberg, FDA CVM: If you would please wrap up your presentation.ce

467
01:50:20.300 --> 01:50:22.599
Kristi Smedley: all right. If you could go to my last conclusion slide, I'd appreciate it.

468
01:50:25.350 --> 01:50:26.809
Walt Ellenberg, FDA CVM: Tell me when to stop.

469
01:50:26.950 --> 01:50:28.150
Kristi Smedley: There you go.

470
01:50:28.160 --> 01:50:53.580
Kristi Smedley: Fda's role is in ensuring that the food and food supply is safe. The individual states share the regulatory responsibilities for animal feed within their state. AAFCO's role is to promote uniformity, and the State regulation of animal feed, including the publication of the most complete list of authorized animal feed ingredients for the States to rely on. Fda needs to be

471
01:50:53.590 --> 01:51:06.790
Kristi Smedley: a resource to assure the authorized ingredients are safe, as it supports their legal mandate. Fda's review role needs to be reviewed, and change is made to assure it is efficient, predictable, and scientifically valid.

472
01:51:06.800 --> 01:51:07.820
Kristi Smedley: Thank you.

473
01:51:09.020 --> 01:51:19.859
Walt Ellenberg, FDA CVM: Thank you. And just as a reminder as we proceed to the next presentation; that is, if there is.

474
01:51:21.050 --> 01:51:33.169
Walt Ellenberg, FDA CVM: In other words, if you can't present all of your presentation during this session, please make certain to submit your slides to the docket, so that everything can be ah available to the agency for consideration.

475
01:51:33.800 --> 01:51:42.620
Walt Ellenberg, FDA CVM: All right now. I'd like to shift gears and move towards the next speaker as David Fairfield.

476
01:51:43.100 --> 01:51:46.289
Walt Ellenberg, FDA CVM: Mr. Fairfield, are you available? Are you present?

477
01:51:46.300 --> 01:51:50.389
David Fairfield - NGFA: Yes, I am.

478
01:51:50.840 --> 01:51:53.900
Walt Ellenberg, FDA CVM: all right, very good. I will mute myself and turn the floor to you.

479
01:51:54.080 --> 01:52:11.789
David Fairfield - NGFA: Thank you. My name is David Fairfield, and I'm. A senior Vice President with the National Grain and Feed Association, and NGFA member companies operate more than eight thousand facilities in the Us. That handle or process over seventy five percent of grain and animal food products that are distributed in our country.

480
01:52:11.800 --> 01:52:28.199

David Fairfield - NGFA: Our members have a significant interest in the AAFCO feed ingredient definition process, because they both use the process to grain ingredient definitions and rely on the process to source safe and effective ingredients used in the manufacture of animal feeds

481
01:52:28.210 --> 01:52:41.240
David Fairfield - NGFA: and Ngfa commends Fda for conducting today's public meeting. We believe it's beneficial to have a forum to look at how Fda is involved in AAFCO's feed ingredient process, discuss transparency issues,

482
01:52:41.250 --> 01:52:48.879
David Fairfield - NGFA: share views on Fda's continued participation as the scientific reviewers. AAFCO Ingredient definitions.

483
01:52:48.890 --> 01:53:05.279
David Fairfield - NGFA: When announcing this meeting, Fda stated it would consider stakeholder comments to evaluate the existing Fda AAFCO memorandum of understanding that clarifies responsibilities of AAFCO and an Fda during the ingredient definition process

484
01:53:05.290 --> 01:53:12.270
David Fairfield - NGFA: possibly amend its compliance. Policy Guide, entitled Common or Usual Names for animal feed Ingredients. The

485
01:53:12.280 --> 01:53:25.530
David Fairfield - NGFA: or make other adjustments to the process to better serve stakeholders in response in Ngfa encourages both Fda and AAFCO to have further dialogue with stakeholders prior to making significant changes

486
01:53:25.540 --> 01:53:37.630
David Fairfield - NGFA: to either the Mou or the Compliance Policy guide, since both play significant roles in establishing ingredient definitions in the acceptance of ingredients within jurisdictions

487
01:53:38.250 --> 01:53:49.820
David Fairfield - NGFA: before addressing the questions posed by Fda in advance of the meeting, and NGFA wants to emphasize the value of Fda and AAFCO's joint efforts in defining feed ingredients.

488
01:53:49.900 --> 01:54:07.279
David Fairfield - NGFA: The definition process utilizes Federal and State expertise to ensure the safety and utility of ingredients, thereby protecting animal health. The safety of animal based foods consumed by humans and the public. The process has worked

489
01:54:07.370 --> 01:54:25.820
David Fairfield - NGFA: and has yielded a comprehensive list of ingredients that promote a common understanding and acceptance within the industry. Fda and State regulators and consumers. The process also facilitates harmonization between State and Federal regulatory authorities. That is vital.

490
01:54:26.440 --> 01:54:39.510
David Fairfield - NGFA: We encourage Fda and AAFCO to continue to work together within the process, and this would include renewing Fda and AAFCO's Mou, that is set to expire in October of two thousand and twenty four

491
01:54:39.990 --> 01:54:50.850
David Fairfield - NGFA: more specifically, and Ngfa offers. These comments related to questions about what actions Fda could take to improve understanding of AAFCO's ingredient definition, process,

492
01:54:50.860 --> 01:55:08.020
David Fairfield - NGFA: or otherwise be helpful to stakeholders. First the quality of ingredient submissions is sometimes cited as being a reason that Fda's review process is delayed or takes longer than anticipated. Although Fda and AAFCO have made some information available about the submission process,

493
01:55:08.030 --> 01:55:30.530
David Fairfield - NGFA: We believe more readily available and detailed guidance would help improve industry's, understanding and ability to make submissions that satisfy regulatory expectations. For example, the new AAFCO-comprehensive animal feed ingredient submission course. Provides excellent information related to the process, and we encourage Fda to consider how this type of content

494
01:55:30.540 --> 01:55:41.400
David Fairfield - NGFA: can be made publicly available in a matter where cost is not a barrier to access. In addition, Fda has previously issued guidance specifically related to

495
01:55:41.820 --> 01:55:43.789
operation and submission

496
01:55:43.800 --> 01:56:07.299
David Fairfield - NGFA: of animal food. Additive petitions. We believe it would be appropriate for Fda to provide additional information on how this guidance can be used to meet requirements associated with the AAFCO ingredient definition process. Second, and Ngfa believes it would be helpful if Fda provided more information about which regulatory approval pathway is most appropriate for a given feed ingredient submission.

497
01:56:07.310 --> 01:56:17.520
David Fairfield - NGFA: The ability to term the appropriate pathway is the first step in ensuring the submission includes adequate content and can move effectively through the review

498
01:56:17.720 --> 01:56:24.530
David Fairfield - NGFA: and Ngfa believes further communication about typical timeframes associated with the process is warranted. The

499
01:56:24.540 --> 01:56:37.020
David Fairfield - NGFA: although target timelines are outlined in chapter six of AAFCO's official publication Clear direction on what triggers A reset of the timeline, and how to avoid resets would be helpful.

500
01:56:37.030 --> 01:56:54.519
David Fairfield - NGFA: We believe Fda and AAFCO be described for an efficient and predictable review process last, and Ngfa understands that a Requester needs to demonstrate that an ingredient has a reasonable certainty of no harm for it intended use.

501
01:56:54.530 --> 01:57:05.399
David Fairfield - NGFA: But we encourage Fda to carefully consider the volume of information and data required to support that determination while maintaining efficiency in the review process

502
01:57:05.410 --> 01:57:24.710
David Fairfield - NGFA: related to the question about Fda making AAFCO feed. Ingredient definition requests publicly available. We have the following perspectives to offer: First, we believe it would be valuable if Fda made publicly available generic information about current submissions along with the date of each submission.

503
01:57:24.720 --> 01:57:30.550
David Fairfield - NGFA: This ties into our previous comment about fostering a better understanding of typical review times.

504
01:57:30.950 --> 01:57:48.960
David Fairfield - NGFA: We understand the complexity associated with submissions can vary considerably, and influence the time necessary for review, but still believe high-level information about time associated with the process would be valuable. This information could be made available on the Fda website, the AAFCO website, or both

505
01:57:49.340 --> 01:57:58.419

David Fairfield - NGFA: Second and Ngfa members that utilize the process, value the current confidentiality of their identity, and the ingredient during the review.

506
01:57:58.590 --> 01:58:16.059
David Fairfield - NGFA: Since defined AAFCO ingredients are not proprietary. This confidentiality provides an incentive for Requesters to allocate resources that are necessary to make submissions, and that they have the potential to offer the ingredient prior to others, hammering the same market space

507
01:58:16.070 --> 01:58:32.529
David Fairfield - NGFA: last. Regarding stakeholder input on the safety of pending ingredient definitions, we believe that if Fda finds a submission acceptable, the definition should be made publicly available in a manner that allows stakeholders ample opportunity to offer comments

508
01:58:32.540 --> 01:58:39.509
David Fairfield - NGFA: prior to the ingredient being brought forward during meetings conducted by the AAFCO ingredient definition committee

509
01:58:40.540 --> 01:58:52.739
David Fairfield - NGFA: regarding the question about what stakeholders view a successful and Fda's continued participation as scientific reviewers for new AAFCO feed, ingredient definitions and we believes it's already expressed

510
01:58:52.750 --> 01:59:08.940
David Fairfield - NGFA: fda's role has been valuable in establishing ingredient definitions that effectively serve industry. The regulatory community and consumers, Fda's scientific expertise, combined with knowledge and experience of State feed, control officials and stakeholder input

511
01:59:08.950 --> 01:59:19.460
David Fairfield - NGFA: provide a robust forum through which safe and effective ingredients may be defined. We encourage Fda and AAFCO to continue to work together within this process.

512
01:59:19.930 --> 01:59:33.080
David Fairfield - NGFA: In closing and Ngfa again commend Fda for conducting today's meeting. We look forward to any future opportunities to provide input on the AAFCO feed ingredient definition process. Thank you.

513
01:59:33.700 --> 01:59:35.040
Walt Ellenberg, FDA CVM: Thank you.

514

01:59:35.550 --> 01:59:37.370
Walt Ellenberg, FDA CVM: And as I mentioned

515
01:59:37.450 --> 01:59:40.429
Walt Ellenberg, FDA CVM: before, we move to the lunch break,

516
01:59:40.450 --> 01:59:58.559
Walt Ellenberg, FDA CVM: i'm going to circle back, and I want to just verify that. Ah, our one speaker, who was not available, who was Muhammad Al Ahdal is not on the web, not their present on the line. We didn't see any evidence that they are, but of where he is. But I wanted to make sure

517
01:59:58.570 --> 02:00:00.569
Walt Ellenberg, FDA CVM: uh that we didn't miss that person,

518
02:00:03.260 --> 02:00:06.889
Walt Ellenberg, FDA CVM: so i'm going to pause to see if the individual

519
02:00:08.280 --> 02:00:13.639
Walt Ellenberg, FDA CVM: I'm. Gonna pause to see if he actually joins the has joined and is ready to speak.

520
02:00:24.800 --> 02:00:27.669
Walt Ellenberg, FDA CVM: Okay, it appears that he's not with us.

521
02:00:28.960 --> 02:00:32.509
Walt Ellenberg, FDA CVM: So at this time we will take our lunch, break,

522
02:00:32.790 --> 02:00:35.129
Walt Ellenberg, FDA CVM: and we will return

523
02:00:35.940 --> 02:00:48.440
Walt Ellenberg, FDA CVM: at twelve, forty, five, Pm. Eastern time, and we will begin with the next session of speakers, and i'd like to remind everybody before we take a break. Is that the transcript

524
02:00:48.450 --> 02:01:08.190
Walt Ellenberg, FDA CVM: and the recording of this meeting will be posted to the docket, and within the next few i'd say a week or two. There. There is a time lag of when we get their transcript back. So it will be there. The Transcript and and other information will not be emailed to you individually.

525
02:01:08.200 --> 02:01:16.229
Walt Ellenberg, FDA CVM: And with that I will adjourn the meeting right now for lunch break, and we will return properly at one thousand two hundred and forty five. Thank you.

526
02:02:53.420 --> 02:02:59.090
Walt Ellenberg, FDA CVM: And good afternoon, everybody. It's one thousand two hundred and forty, five, and I see that we have a

527
02:02:59.420 --> 02:03:11.899
Walt Ellenberg, FDA CVM: a fair number of people who are quickly logging on. And so what we'll do is we'll wait two more minutes as individuals log on for the afternoon session. Um! In about two minutes i'll get things underway.

528
02:04:59.160 --> 02:05:19.069
Walt Ellenberg, FDA CVM: Well, good afternoon and welcome back to the afternoon session. Um, we're going to jump right into it. And before we start with the speakers, just a reminder for those individuals who are presenting make certain that you send your presentation, or a copy of your presentation materials such as slides

529
02:05:19.080 --> 02:05:22.680
Walt Ellenberg, FDA CVM: the docket. The FDA will not submit them for you.

530
02:05:23.280 --> 02:05:27.160
Walt Ellenberg, FDA CVM: The docket will remain open until March the ninth.

531
02:05:27.470 --> 02:05:31.950
Walt Ellenberg, FDA CVM: So with that we will then move to our next speaker

532
02:05:32.470 --> 02:05:43.000
Walt Ellenberg, FDA CVM: on the list, and it's Jenna Leal. I'm going to turn off my camera and see if uh, Miss Leal was available. If you are available, you should be able to unmute

533
02:05:43.060 --> 02:05:45.380
Walt Ellenberg, FDA CVM: and um identify yourself.

534
02:05:45.790 --> 02:05:47.590
Jenna Leal: Hello! Can you hear me?

535
02:05:47.600 --> 02:05:49.990
Walt Ellenberg, FDA CVM: Yes, I can. Wonderful!

536
02:05:50.000 --> 02:05:51.189
Jenna Leal: All right.

537
02:05:52.950 --> 02:05:54.599
Walt Ellenberg, FDA CVM: Wonderful! You're gonna have. I'm

538
02:05:55.110 --> 02:05:56.389
Walt Ellenberg, FDA CVM: sorry with the clicker there,

539
02:05:56.400 --> 02:05:58.739
Walt Ellenberg, FDA CVM: mute myself, and then i'm going to turn it over to you.

540
02:05:59.080 --> 02:06:00.439
Walt Ellenberg, FDA CVM: Go ahead.

541
02:06:00.450 --> 02:06:01.490
Jenna Leal: Thank you.

542
02:06:01.910 --> 02:06:06.859
Jenna Leal: Hello. My name is Jenna Leal. I'm. The Environmental Program manager

543
02:06:06.870 --> 02:06:22.809
Jenna Leal: of the Commercial Feed Regulatory program within the California Department of food and agriculture. Our program is legislatively charged with enabling the California feed and feeding industry to ensure in every way possible a cleaner supply

544
02:06:22.890 --> 02:06:42.709
Jenna Leal: a clean and wholesome supply of meat, milk, and eggs for the benefit of the consumer. The commercial feed regulatory program has drafted robust regulations to safeguard livestock feed and assure that only feeds with a feed. Ingredient definition may be fed to livestock in California.

545
02:06:42.860 --> 02:06:54.560

Jenna Leal: Speed Ingredient definitions are just one way to guarantee feed offered to livestock is wholesome and suitable for the animal species. It is intended to be fed to

546
02:06:54.640 --> 02:07:06.480
Jenna Leal: the California Commercial Feed Regulatory program maintains an active membership within the Association of American Feed Control officials commonly referred to as AAFCO

547
02:07:06.690 --> 02:07:19.470
Jenna Leal: AAFCO allows for regulators within California to work in partnership and collaboration with feed regulators from other States and Fda at a national level.

548
02:07:19.720 --> 02:07:39.700
Jenna Leal: This collaboration is critical, and enables California to align its regulatory strategy with industry and government partners to ensure California regulations of feed meets its legislative charge of supporting a wholesome supply of meat, milk, and eggs.

549
02:07:40.750 --> 02:07:58.829
Jenna Leal: The partnership between State Agencies and Fda Center for Veterinary Medicine represented at AAFCO committee meetings allow for a collaborative, open, transparent evaluation process that takes input from a variety of industry stakeholders

550
02:07:58.840 --> 02:08:05.839
Jenna Leal: and includes State and Federal agencies as well as members of the animal feed industry.

551
02:08:05.860 --> 02:08:23.200
Jenna Leal: The AAFCO feed ingredient Definition Committee is comprised of expert State and Federal regulators, who volunteer by offering guidance and direction to feed manufacturers who are developing their safety and efficacy data

552
02:08:23.210 --> 02:08:27.289
Jenna Leal: in order to ensure a more effective package, be presented

553
02:08:27.300 --> 02:08:32.550
Jenna Leal: at AAFCO's ingredient definition Committee meetings, and Fda.

554
02:08:32.880 --> 02:08:50.830
Jenna Leal: The Ingredient Definition Committee evaluates the proposed feed ingredient definition for acceptance and publication into the official publication or op An annual document published by AAFCO.

555
02:08:50.990 --> 02:09:09.989
Jenna Leal: The Op. Is widely recognized, domestically and internationally. It is used by some State partners as their sole source of feed ingredient definitions, and is vital for many States to ensure. Livestock, feed, manufactured and distributed in their state is safe.

556
02:09:10.970 --> 02:09:21.069
Jenna Leal: The current AAFCO feed ingredient definition process ensures synergistic efforts are put forth between State and Federal partners,

557
02:09:21.080 --> 02:09:35.979
Jenna Leal: allowing each to bring their own expertise and resources to evaluate the safety and efficacy of feed ingredients. Avco does not act independent of Fda. Rather, there is a collaborative partnership

558
02:09:35.990 --> 02:09:44.830
Jenna Leal: between agencies that guarantee wholesome livestock products are available for the mutual benefit of the consumer.

559
02:09:45.190 --> 02:09:56.910
Jenna Leal: The California Commercial Feed regulatory program is committed to assisting AAFCO and Fda and offering our knowledge and expertise. Throughout this evaluation process

560
02:09:56.940 --> 02:10:14.459
Jenna Leal: we look forward to continued and even greater collaboration, participation and assistance from Fda when dealing with new and novel feed ingredients and feed additives, including those products with innovative environmental emission reduction claims.

561
02:10:15.440 --> 02:10:22.420
Jenna Leal: AAFCO recently held an ingredient submission training in conjunction with the AAFCO Midyear meeting.

562
02:10:22.430 --> 02:10:30.740
Jenna Leal: This was attended by two of my program staff members, who found this training incredibly informative and valuable,

563
02:10:30.750 --> 02:10:42.799
Jenna Leal: and we would like to see these types of trainings continue by Fda investing and focused training of AAFCO investigators and State regulatory official partners.

564
02:10:42.810 --> 02:11:00.920
Jenna Leal: It will allow us to serve as boots on the ground, in thoroughly understanding all pathways to approval, and being able to help disseminate that knowledge and guidance to the regulate, to the regulated industry and guide them to the right resources at Fda,

565
02:11:00.930 --> 02:11:03.150
Jenna Leal: many of which already exist.

566
02:11:03.450 --> 02:11:21.849
Jenna Leal: Thank you to the center for veterinary medicine for allowing us to speak today, and for being willing to not only be reminded of their strength and commitment to AAFCO and your state partners, but also being open to hearing opportunities for continuous process. Improvement. Thank you.

567
02:11:24.430 --> 02:11:25.769
Walt Ellenberg, FDA CVM: Thank you.

568
02:11:26.430 --> 02:11:40.739
Walt Ellenberg, FDA CVM: All right. Our next speaker that we have signed up is Saun Rose and i'm not sure that she's available. I've been told by the staff here that she's not signed in, so i'm gonna

569
02:11:40.750 --> 02:12:00.660
Walt Ellenberg, FDA CVM: give her the floor, and if it's silent, then we'll move to the following speaker. So i'm going to give it about thirty seconds to see if she's here, and then we'll move on, but I will. I will go back at the end of this session to see if she was able to join in. She just may be late, so i'm going to pause for thirty seconds.

570
02:12:36.360 --> 02:12:37.190
Walt Ellenberg, FDA CVM: All right.

571
02:12:37.200 --> 02:12:45.420
Walt Ellenberg, FDA CVM: Well, let's go ahead and continue on that. Our next speaker is Brittany Rowe, and I will.

572
02:12:46.050 --> 02:12:49.129
Walt Ellenberg, FDA CVM: I need to for the slides for her presentation.

573
02:12:50.730 --> 02:12:54.290

Walt Ellenberg, FDA CVM: Ms. Rowe, You're available and online. See if your hand is raised, can you?

574
02:12:54.300 --> 02:12:59.439
Brittany Rowe: Yes, I am here

575
02:12:59.960 --> 02:13:11.190
Walt Ellenberg, FDA CVM: excellent. We can hear you as well. Please move forward and begin

576
02:13:11.200 --> 02:13:19.590
Brittany Rowe: perfect. My name is Brittany Rowe. I am an Llm student and an attorney, but i'm here today as a consumer who routinely purchases cat and dog food for my companion animals. I'd like to start by thanking the Fda for holding this meeting and for the opportunity to voice my comments about the pet food, ingredient definitions process.

577
02:13:19.600 --> 02:13:27.440
Brittany Rowe: I will be focusing my comment today on the question presented about the Fda's role in AAFCO's feed ingredient definitions process.

578
02:13:27.450 --> 02:13:36.659
Brittany Rowe: The heart of the problem is the fact that the pet food ingredient process is treated as AAFCO’s process with the Fda simply playing a role in the process.

579
02:13:36.670 --> 02:13:55.899
Brittany Rowe: Congress grants broad legislative powers to administrative agencies through statutes that allow agencies to legislate their rulemaking process governed by the Administrative Procedures Act of one thousand nine hundred and forty six or the Apa. The Apa sets out specific procedures. Federal agencies must follow in the process of making amending or appealing rules.

580
02:13:56.070 --> 02:14:03.879
Brittany Rowe: Sub-delegation to a private party takes the power. Congress granted to an administrative agency, and further removes it from the government's ear.

581
02:14:03.890 --> 02:14:12.090
Brittany Rowe: Congress delegated the power to regulate food to the Fda. The Federal Food Drug and Cosmetics Act grants the fda. This authority,

582
02:14:12.100 --> 02:14:25.129

Brittany Rowe: the Fda has so delegated its regulatory power over food, ingredient definitions to AAFCO by treating it as an administrative arm, and giving away its authority to establish ingredient standards and definitions and labeling standards for pets.

583
02:14:25.140 --> 02:14:40.659
Brittany Rowe: AAFCO is a voluntary group that develops pet food, ingredient definitions, nutrient profiles and labeling requirements. It uses these developments to create model regulatory standards, and the Fda has then adopted these model standards without going through the proper administrative law channels.

584
02:14:40.670 --> 02:14:53.589
Brittany Rowe: While AAFCO says it does not regulate anything because they are not a government agency. It also names itself in its official publication as one of three agencies that work cooperatively to recognize ingredients use in the manufacturing of

585
02:14:53.790 --> 02:15:12.090
Brittany Rowe: after the largest recall in pet food history in two thousand and seven from melamine, contamination. Congress added a new provision, and the Food and drug administrative amendments act of two thousand and seven, requiring the Fda to create ingredient processing and obtaining labeling standards for pet food.

586
02:15:12.100 --> 02:15:24.760
Brittany Rowe: The Fda was directed to consult with AAFCO to establish ingredient standards and definitions, because so much groundwork had been done by AACFO, including the publishing of its ingredient definitions and an annual publication,

587
02:15:24.770 --> 02:15:38.570
Brittany Rowe: the mou between the Fda and AAFCO. A non-binding agreement allowed the two to collaborate to assign Federal legal definitions to hundreds of AAFCO-defined ingredients the lack Federal standing in two thousand and five,

588
02:15:38.580 --> 02:15:45.499
Brittany Rowe: it appeared the Fda was actively working to comply with these requirements. Despite being six years past the deadline Congressman,

589
02:15:45.510 --> 02:15:56.979
Brittany Rowe: the Fda announced its plan to streamline the process of creating new regulations to align AAFCO's ingredient listings from the official publication for the Fda's official regulatory process

590
02:15:56.990 --> 02:16:06.499

Brittany Rowe: the plan included confirming AAFCO listed food ingredients that are recognized as generally recognized as safe or approved by the agency as food additives.

591
02:16:06.510 --> 02:16:23.690
Brittany Rowe: The Fda then planned to codify these ingredients through the rule-making process, bringing animal feed definitions squarely under Federal regulatory control however, food ingredient definition, standard provision moved and to date over five hundred ingredients defined by after lack of Federal standing.

592
02:16:23.700 --> 02:16:33.690
Brittany Rowe: No determinations have been made as to whether these ingredient definitions were supported by enough data to be approved as animal food, additive or generally recognized as safe,

593
02:16:34.340 --> 02:16:40.990
Brittany Rowe: perpetuates the extra legal regulatory system by directing people or companies who are looking to start a pet food

594
02:16:41.000 --> 02:16:51.410
Brittany Rowe: business, or establish pet food business owners, not to federal or State regulatory bodies, but to their own official publication, which is AAFCO's primary source of revenue,

595
02:16:51.420 --> 02:17:03.890
Brittany Rowe: because the ingredient definitions are treated as proprietary. It costs consumers one hundred and thirty five dollars for a physical copy, or one hundred and sixty five dollars for an online. Read-only version to access these definitions.

596
02:17:03.900 --> 02:17:19.010
Brittany Rowe: The Fda holds the AAFCO definitions as proprietary information instead of as enforceable regulations by denying freedom of Information Act requests related to definitions of pet food ingredients that are part of the laws of Fda is charged with enforcing

597
02:17:19.020 --> 02:17:36.459
Brittany Rowe: for other AAFCO States. It acts as a deliberate body formulating policy, and serves as a final decision-maker when parties disagree on which way, and after the policy should be decided by this statement. Echo considers itself a regulatory body, and is fully aware of the role at place in the pet food regulatory process.

598
02:17:36.469 --> 02:18:03.989
Brittany Rowe: While there is value in continuing to collaborate with AAFCO, and I strongly urge the Fda to continue that collaboration. I also urge the Fda to take a more active role in the pet food,

regulatory process, starting with making ingredients, standards and definitions and labeling standards for pet food publicly available through a link on the Fda's website, and adhering to the requirements of the Apa by providing public notice and comment periods for new ingredients to be considered

599
02:18:04.000 --> 02:18:05.180
Brittany Rowe: for approval.

600
02:18:05.379 --> 02:18:06.590
Brittany Rowe: Thank you.

601
02:18:09.690 --> 02:18:11.120
Walt Ellenberg, FDA CVM: Thank you, Ms. Rowe.

602
02:18:13.000 --> 02:18:18.500
Walt Ellenberg, FDA CVM: So we'll now move to our next presentation by Megan Dicks.

603
02:18:18.840 --> 02:18:20.869
Walt Ellenberg, FDA CVM: Ms. Dicks are you available?

604
02:18:22.059 --> 02:18:23.489
Meghan Dicks: I am. Can you hear me?

605
02:18:23.500 --> 02:18:28.350
Walt Ellenberg, FDA CVM: Yes, I can. I will move the slide forward, and you may begin.

606
02:18:28.360 --> 02:18:29.330
Meghan Dicks: Thank you.

607
02:18:32.370 → 02:18:42.640
Meghan Dicks: Good afternoon. My name is Megan Dicks. I laid the regulatory and scientific Affairs scheme for adm's, animal nutrition, and pet solutions business in North America.

608
02:18:42.700 --> 02:18:55.590
Meghan Dicks: Adm is a global leader in human and animal nutrition, and we are committed to bringing safe and effective products to the market. We want to thank the Fda for the opportunity to participate in today's discussion.

609

02:18:55.600 --> 02:19:13.950
Meghan Dicks: Harmonization between State feed laws and harmonization between State laws and Federal regulations ensure that animal food products can be freely sold across the United States. The AAFCO process and Fda's role in the AAFCO process is critical to maintaining that harmonization.

610
02:19:14.090 --> 02:19:15.580
Meghan Dicks: Next slide, please.

611
02:19:19.889 --> 02:19:28.740
Meghan Dicks: Industry needs clear and transparent and guidance on what's required. We need more trainings and more opportunities to interact with Fda and ask questions.

612
02:19:29.309 --> 02:19:41.029
Meghan Dicks: The wide variety of ingredient types, animal species, and production purposes does make it difficult to create a one-sized fits all guidance. But that's not what we're asking for.

613
02:19:41.040 --> 02:19:50.099
Meghan Dicks: We're asking for publicly available guidance that outlines Fda's expectations and timelines in a plainly written easy to follow manner.

614
02:19:50.380 --> 02:19:59.959
Meghan Dicks: The guidance should also establish a clear balance between want to know and need to know. With regard to proving reasonable certainty of no harm,

615
02:20:00.080 --> 02:20:19.079
Meghan Dicks: We need Fda to partner with industry, to bring safe, efficacious, and innovative new ingredients for the market Ingredients that will address growing food demand, as well as the increasing societal concerns like sustainability and improved animal production practices to accomplish that

616
02:20:19.090 --> 02:20:24.550
Meghan Dicks: speed. Efficiency, transparency, and predictability is needed.

617
02:20:25.050 --> 02:20:26.479
Meghan Dicks: Next slide. Please

618
02:20:29.020 --> 02:20:37.190
Meghan Dicks: making a list of AAFCO feed. Ingredient definition requests available to the public does help with the desire for more transparency.

619
02:20:37.270 --> 02:20:46.590
Meghan Dicks: However, that transparency does need to be balanced with the proprietary nature of submissions, and that an AAFCO definition is non-proprietary

620
02:20:47.870 --> 02:20:49.319
Meghan Dicks: next slide please

621
02:20:50.660 --> 02:21:04.069
Meghan Dicks: the animal food industry. AAFCO and Fda are equally committed to bringing faith and efficacious ingredients to us Animal food producers. But none of us can play all of the instruments in the band.

622
02:21:04.350 --> 02:21:08.940
Meghan Dicks: We need to work together and utilize the expertise of the appropriate agencies.

623
02:21:09.290 --> 02:21:23.850
Meghan Dicks: Fda's involvement in the ingredient approval process builds confidence of the ingredients are safe, and the seed ingredients enact in the AAFCO official publication make it possible for companies to sell animal food ingredients in every State.

624
02:21:24.800 --> 02:21:26.149
Meghan Dicks: Next slide, please.

625
02:21:28.980 --> 02:21:41.690
Meghan Dicks: Animals with companies are working diligently to improve processes and be more efficient, so that we can produce more food for a rising global population with less of an impact on the world around us.

626
02:21:41.990 --> 02:21:49.799
Meghan Dicks: However, opportunities to address those demands can be so easily lost when the approval process takes three to five years,

627
02:21:49.860 --> 02:21:55.150
Meghan Dicks: because the longer it takes for an approval, the longer it will take to realize the benefits,

628
02:21:55.820 --> 02:22:02.250
Meghan Dicks: and when the Fda process is not timely or transparent. The animal food, industry and consumers lose

629
02:22:03.140 --> 02:22:10.930
Meghan Dicks: the animal food. Industry is agile and innovative, and we need the Fda to be agile and innovative right along with her

630
02:22:11.780 --> 02:22:13.240
Meghan Dicks: next slide. Please

631
02:22:14.860 --> 02:22:22.430
Meghan Dicks: thank you for the opportunity to share our support it. Look forward to the improvements that Fda and AAFCO will make to the ingredient approval process.

632
02:22:25.550 --> 02:22:26.789
Walt Ellenberg, FDA CVM: Thank you.

633
02:22:28.250 --> 02:22:32.939
Walt Ellenberg, FDA CVM: And now we will move to our next presentation by Greg Sunvold, Mr. Sunvold are you online, he's raised this.

634
02:22:35.840 --> 02:22:41.390
Greg Sunvold: I am. Can you hear me?

635
02:22:41.400 --> 02:22:45.009
Walt Ellenberg, FDA CVM: Well, very good. I'll advance a slide, and you may begin.

636
02:22:45.020 --> 02:22:45.980
Greg Sunvold: Thank you.

637
02:22:46.570 --> 02:22:58.450
Greg Sunvold: Hello! My name is Greg Sunvold. My Phd. Is in nutritional science, and I've been associated with pet food industry now for over thirty years, and today I'm. Representing Cool Springs International.

638
02:22:58.650 --> 02:23:12.969
Greg Sunvold: Thank you very much for the opportunity to offer what I hope will be taken as constructive comments, and I have no intentions other than to ah further build on the greatness of this industry, and further collaboration with regulatory partners.

639
02:23:13.080 --> 02:23:23.619
Greg Sunvold: I have titled this presentation, preserving the good and building for the future, because I think there are some prudent processes in place currently,

640
02:23:23.740 --> 02:23:41.409
Greg Sunvold: and I think that further leveraging these processes can address what many in this area or this industry would considered a growing avalanche of new ingredients that need to be appropriately reviewed and approved to meet the growing recognition,

641
02:23:41.470 --> 02:23:46.629
Greg Sunvold: not only meeting the nutritional needs of the pet, but also their health needs.

642
02:23:47.640 --> 02:23:58.249
Greg Sunvold: So on this slide the slide to I've mentioned there is a growing need. As I mentioned, there is a growing need to increase the number of ingredients offered in pet foods.

643
02:23:58.310 --> 02:24:10.649
Greg Sunvold: From my point of view there are a couple of reasons why the ingredients needed and pet food continues to grow. One is humanization of pet foods. In other words, I want what I eat myself to be available for my pet.

644
02:24:10.900 --> 02:24:17.609
Greg Sunvold: Secondly, the growing importance of health for these creatures, promoting their health

645
02:24:18.060 --> 02:24:24.729
Greg Sunvold: just like human food trends, include more and more healthy ingredients in our own dyes.

646
02:24:24.790 --> 02:24:32.360
Greg Sunvold: We continue to recognize these health benefits and want these same ingredients with their health benefits available for our pets.

647
02:24:33.360 --> 02:24:51.250
Greg Sunvold: And now for the perhaps difficult statement to make is my belief that many folks believe the current approval system for getting a feed ingredient identified for use in complete foods is both slow and expensive

648
02:24:52.250 --> 02:25:09.079

Greg Sunvold: rather than complaining about this, which I really appreciate the tone of the conversations so far, and and I hope is the same. Same follows with my own is that the following is a suggested approach to build and improve on existing processes;

649
02:25:09.090 --> 02:25:18.340
Greg Sunvold: that in a more efficient way of getting these new ingredients approved, both saving time as well as money in the approval process.

650
02:25:18.440 --> 02:25:21.070
Greg Sunvold: All right on slide three. Then,

651
02:25:23.330 --> 02:25:25.340
Greg Sunvold: if you could advance, please

652
02:25:26.040 --> 02:25:27.150
Greg Sunvold: thank you.

653
02:25:27.220 --> 02:25:35.990
Greg Sunvold: On the left-hand side, you see at a very very high level the current process. It involves, as many speakers have mentioned,

654
02:25:36.000 --> 02:25:55.570
Greg Sunvold: AAFCO defining the feed ingredients getting them accepted in an official publication. After Fda has provided guidance on what are acceptable claims the safety and all of that. And I think the claims, alignment and harmonization with human food claims is essential. That's a really important role that Fda plays

655
02:25:55.650 --> 02:26:00.480
Greg Sunvold: so in the proposed system those roles would stay the same.

656
02:26:00.870 --> 02:26:15.870
Greg Sunvold: The thing that I would offer here is that perhaps we could take away the requirement the strict requirement for a pet-specific grass non-object to be obtained for an ingredient to be ultimately approved.

657
02:26:16.750 --> 02:26:29.789
Greg Sunvold: Furthermore, what we would do is we put in in place an exhaustive list of pet concerning substances. Right? So there's something that people can reference and see. Is there something that is potentially

658
02:26:29.800 --> 02:26:51.039
Greg Sunvold: problematic to a pet more so, or different from that of a human being. So, for example, three of bronze onions, garlic, xylitol, and already Fda has established a somewhat of a list here, too, you can look it up on their website. Fda Gov. My, My thought here is just to further build upon that existing list.

659
02:26:51.780 --> 02:26:56.710
Greg Sunvold: Then, when a new feed ingredient is submitted to Fda,

660
02:26:57.230 --> 02:27:11.249
Greg Sunvold: that if there is a non-objection grass letter that's been established for human use on that ingredient, and when that ingredient is reviewed against this pet concerning list.

661
02:27:11.500 --> 02:27:17.039
Greg Sunvold: If there's nothing on that pet concerning list associated with that new ingredient,

662
02:27:17.060 --> 02:27:23.229
Greg Sunvold: it could go straight to approval process through AAFCO, and be done with it

663
02:27:23.370 --> 02:27:25.210
Greg Sunvold: otherwise that

664
02:27:39.320 --> 02:27:42.259
Walt Ellenberg, FDA CVM: Mr. Sunvold, we may have lost communication.

665
02:27:43.630 --> 02:27:44.910
Walt Ellenberg, FDA CVM: Are you there

666
02:28:04.500 --> 02:28:07.340
Walt Ellenberg, FDA CVM: for this? I don't know.

667
02:28:08.510 --> 02:28:14.710
Walt Ellenberg, FDA CVM: It appears that Mr. Sunvold is having a network issue on his end. Right now.

668
02:28:18.240 --> 02:28:22.909
Walt Ellenberg, FDA CVM: We will pause and try to hopefully. It'll be back on momentarily.

669
02:28:38.140 --> 02:28:39.780
Walt Ellenberg, FDA CVM: Apparently he's trying

670
02:28:41.580 --> 02:28:46.090
Walt Ellenberg, FDA CVM: until he he arrives, and we'll resume right where he left off.

671
02:29:21.380 --> 02:29:25.169
Greg Sunvold: Can you hear me?

672
02:29:25.410 --> 02:29:31.330
Greg Sunvold: I'm so. Sorry. My Internet connection inexplicably just went off. I apologize to the audience.

673
02:29:31.480 --> 02:29:39.980
Walt Ellenberg, FDA CVM: That's okay, you can, I? I I I pause the timer for you, and so you can resume right where you left off

674
02:29:40.610 --> 02:29:42.290
Greg Sunvold: all right. Well,

675
02:29:42.300 --> 02:29:52.890
Greg Sunvold: not exactly sure where I cut off here. But let me go through this. I'll make it really quick, Mr. Chairman. Um! It was under your slide, entitled A Post-solution Fair Enough. Okay.

676
02:29:52.900 --> 02:30:11.330
Greg Sunvold: And you're on number five of the both side of That graph perfect. Thank you. I won't repeat myself. Then um! So I was about to say on the number five is the Ah, for those feed ingredients that are submitted to AAFCO that have a non-objection grass for humans,

677
02:30:11.660 --> 02:30:27.890
Greg Sunvold: and those ingredients are then reviewed against the Pet. Concerning list the substances. List. If there is nothing that's been identified, then they could go straight to being approved through that normal AAFCO official publication process.

678
02:30:27.900 --> 02:30:41.889
Greg Sunvold: Otherwise, um, that ingredient would have to go through the normal process of getting a grass, not objection letter granted from Fda, and then go back to the AAFCO approval process,

679
02:30:41.900 --> 02:31:11.489
Greg Sunvold: so that I will go to my last slide, which is basically to reiterate what I just said hopefully. It's my intent that this is just a visual way to look at this. So current process. On the left is a new feed in gradient um goes to to Fda through the pet specific grass. Um review process, non-objection letter is granted. And if if that's for granted, then it can go into the AAFCO establishment of the feed in greeting definition

680
02:31:11.570 --> 02:31:24.500
Greg Sunvold: on the right. The bigger graphic towards the center If an ingredient has a human graphs non-objection to it already, if that already exists,

681
02:31:24.510 --> 02:31:39.790
Greg Sunvold: and there's nothing concerning a concerning substance as a list like theobromine, or anything else you want to think of. That's problematic to specific, to an dog or cat that could go directly to the AAFCO feeding reading definition.

682
02:31:39.800 --> 02:31:54.710
Greg Sunvold: However, if if there isn't a not a a human non-objection and grass establishment for that ingredient. Or there's something that pops up related to that ingredient on this concerning list,

683
02:31:54.720 --> 02:32:11.490
Greg Sunvold: and it does need to go through the current process of a pet-specific grass, and all the review that is needed, and so on. And if there is an odd objection given by Fda that could go through the AAFCO ingredient definition process.

684
02:32:12.020 --> 02:32:28.370
Greg Sunvold: So I apologize again for my ah technical interference here. But let me just quickly summarize for you in some all of us have the same goal right in this industry, all of you regulatory folks. We all have the same goal, and that is to ensure the best at help,

685
02:32:28.710 --> 02:32:30.820
Greg Sunvold: part of achieving that goal,

686
02:32:31.010 --> 02:32:36.249
Greg Sunvold: to protect pets from ingredients that do have detrimental effects on their health.

687
02:32:36.450 --> 02:32:49.640

Greg Sunvold: Another part of that goal I would submit to you is to assure timely allowance of new ingredients that can be used to enhance pet health and eliminate unnecessary financial burdens to those ingredients approval

688
02:32:50.600 --> 02:33:02.209
Greg Sunvold: in closing it's my hope that these ideas expressed here will be thoughtfully considered and how they may help achieve the above-stated health improvement, goal,

689
02:33:02.230 --> 02:33:07.420
Greg Sunvold: if desired, I would welcome further dialogue on these ideas. A public

690
02:33:11.540 --> 02:33:15.239
Greg Sunvold: record of this information will be available on my personal.

691
02:33:15.430 --> 02:33:16.449
Greg Sunvold: website,

692
02:33:16.530 --> 02:33:18.850
Greg Sunvold: thank you very much. Thank you for your time.

693
02:33:23.560 --> 02:33:25.320
Walt Ellenberg, FDA CVM: Now we just

694
02:33:25.370 --> 02:33:29.140
Walt Ellenberg, FDA CVM: Susan Thxton, Ms. Thixton are you on

695
02:33:42.220 --> 02:33:49.809
Susan Thixton: I i'm here, can you hear me. I am Susan Thixton of a association for truth in pet food and truth about pet food dot com.

696
02:33:51.220 --> 02:33:54.589
Susan Thixton: I represent pet food consumers.

697
02:33:54.600 --> 02:33:56.049
Susan Thixton: Our next slide.

698
02:33:56.160 --> 02:34:06.989

Walt Ellenberg, FDA CVM: Can you speak a little clearer? It's very hard to hear you. Can you get closer to your microphone?

699
02:34:07.000 --> 02:34:13.990
Susan Thixton: Okay? I'm: Sorry It's okay.

700
02:34:14.000 --> 02:34:17.149
Susan Thixton: Okay, So this any better?

701
02:34:17.160 --> 02:34:17.890
Walt Ellenberg, FDA CVM: Yes,

702
02:34:17.900 --> 02:34:18.869
Susan Thixton: okay.

703
02:34:18.880 --> 02:34:19.690
Walt Ellenberg, FDA CVM: Thank you.

704
02:34:19.700 --> 02:34:28.639
Susan Thixton: The Fda asked, What steps can they take to improve the stakeholder, understanding

705
02:34:33.530 --> 02:34:34.590
Susan Thixton: of FDA’s engagement in the AAFCO feed ingredient definition process

706
02:34:34.600 --> 02:34:38.599
Susan Thixton: and better communicate this information with the public

707
02:34:38.810 --> 02:34:40.460
Susan Thixton: next slide.

708
02:34:42.920 --> 02:34:55.289
Susan Thixton: We believe it's significant for Fda to understand that the Amerincan public is a stakeholder of feed ingredients. The phrasing of their question

709
02:34:55.300 --> 02:35:02.940
Susan Thixton: improved stakeholder understanding communicate with the public examples of problem

710
02:35:02.950 --> 02:35:04.129
Susan Thixton: No, public

711
02:35:04.140 --> 02:35:05.190
Susan Thixton: pet owners are,

712
02:35:05.200 --> 02:35:09.749
Susan Thixton: just as important of a stakeholder as industry.

713
02:35:09.980 --> 02:35:11.569
Susan Thixton: Next slide

714
02:35:26.850 --> 02:35:28.330
Susan Thixton: So rephrasing your question, what steps can FDA take to improve understanding and communication with all stakeholders, of Fda engagement in the AAFCO feed ingredient definition, next slide

715
02:35:54.760 --> 02:35:57.070
Susan Thixton: In our opinion understanding and communication of FDA's could be improved if the process becomes a public process. How can a stakeholder understand a process when much of, most of the process occurs behind a pay wall.

716
02:36:17.760 --> 02:36:19.260
Susan Thixton: How can communication improve with stakeholders when some stakeholders are limited or prevented entirely, next slide. At AAFCO discretion only select stakeholders are allowed to participate, next slide

717
02:36:20.380 --> 02:36:26.989
Susan Thixton: in March of two thousand and nineteen. The Stakeholder Organizations Association for Truth in Pet Food and Next Generation Pet Food Manufacturers Association submitted to AAFCO proposed animal origin ingredient names and definitions, these proposed ingredients were submitted to provide clarity to pet owners allowing them the opportunity to understand the identity of the ingredient in their pet's food

718
02:36:48.730 --> 02:37:01.990
Susan Thixton: and the proposed ingredients were submitted to provide manufacturers the ability to distinguish their ingredients. As example we proposed ingredient names and definitions, whole

poultry, poultry meal, poultry parts, and poultry frames to replace the existing catch all ingredient poultry

719
02:37:12.250 --> 02:37:28.070
Susan Thixton: but both stakeholder organizations were denied the opportunity to participate in the working group. We were never provided with any updates basically on request to AAFCO was completely ignored

720
02:37:28.260 --> 02:37:29.690
Susan Thixton: next slide.

721
02:37:30.930 --> 02:37:34.390
Susan Thixton: And then there is potential conflict of interest.

722
02:37:41.180 --> 02:37:49.590
Susan Thixton: It is a concern that the same attorney is representing the organization that approves their ingredients,

723
02:37:49.940 --> 02:37:53.089
Susan Thixton: and an organization that submits

724
02:37:53.100 --> 02:37:55.259
Susan Thixton: new ingredients for approval

725
02:37:55.550 --> 02:37:57.020
Susan Thixton: next slide.

726
02:37:58.030 --> 02:38:14.160
Susan Thixton: If Fda wishes to improve my understanding and communication with stakeholders. Then the Fda's engagement in the AAFCO feed ingredient definition process needs to assure a level playing field.

727
02:38:14.620 --> 02:38:16.140
Susan Thixton: Next slide

728
02:38:39.310 --> 02:38:42.949
Susan Thixton: We surveyed pet owners asking them how much they understand about how ingredients are approved. We provided a range to response options. Number one being the pet owner

knowing nothing about the approval process to number 5 meaning complete understanding. we received seven hundred and ninety six responses The majority of pet owners respond they know nothing with only two responding they completely understand.

729
02:38:50.490 --> 02:38:51.960
Susan Thixton: next slide.

730
02:38:53.140 --> 02:39:01.690
Susan Thixton: We also ask Pet Owners if they feel they are allowed to provide input on the proposed pet food ingredients overwhelming

731
02:39:01.700 --> 02:39:05.490
Susan Thixton: pet owners do not believe we have a voice in the process.

732
02:39:05.670 --> 02:39:07.270
Susan Thixton: Next slide

733
02:39:20.710 --> 02:39:31.279
Susan Thixton: Another question FDA asked was what changes do Fda's role in AAFCO feed ingredient definition process would be helpful to stakeholders and why. Besides improved transparency, we believe the feed ingredient definition process needs to includes ingredient standards, next slide. .

734
02:39:31.760 --> 02:39:36.770
Susan Thixton: As to Why, after the two thousand and seven pet food recall

735
02:39:36.780 --> 02:39:55.289
Susan Thixton: the deadliest pet food recall in history, Congress required fda to establish more regulation ingredients, standards, and definitions. Pet owners were promised this update by Congress. Unfortunately Fda did not complete this task.

736
02:39:55.440 --> 02:39:56.980
Susan Thixton: next slide

737
02:39:58.270 --> 02:40:06.289
Susan Thixton: FDA asked it made a list of ingredient requests publicly available,

738
02:40:06.300 --> 02:40:13.219

Susan Thixton: where would stakeholders prefer to find this list, and what information would we like to see?

739
02:40:28.080 --> 02:40:29.580
Susan Thixton: TWe would like to see that information on the animal food and feeds pages, for consumers, for industry page as well. The information we would like to see is the ingredient name, definition, and standard.

740
02:40:30.690 --> 02:40:38.489
Susan Thixton: We ask pet owner opinion if all of the pet food ingredients should not only be available on the Fda website but also provide opportunity for public comment. Significantly pet owners responded with yes, we wish to give you and be provided the opportunity to comment on all pending ingredients, next slide

741
02:40:54.100 --> 02:41:07.659
Susan Thixton: We ask Pet owners if all evidence to nutritional adequacy and safety should be public information, prior to ingredient approval, overwhelmingly pet owners say yes. Next slide.

742
02:41:08.610 --> 02:41:14.789
Susan Thixton: Ask for owners who should or approve, and define new pet food ingredients

743
02:41:14.800 --> 02:41:24.089
Susan Thixton: AAFCO with Fda, Fda only, or a panel of Fda AAFCO veterinarians and independent scientists.

744
02:41:24.160 --> 02:41:32.699
Susan Thixton: The largest majority of pet owners wanted to see a panel of experts to approve and define food ingredients. Thank you very much for this opportunity to provide pet food consumer stakeholder opinion.

745
02:41:41.160 --> 02:41:42.370
Walt Ellenberg, FDA CVM: Thank you.

746
02:41:43.460 --> 02:41:46.549
Walt Ellenberg, FDA CVM: And now we will move on to our next presentation.

747
02:41:47.630 --> 02:41:51.910
Walt Ellenberg, FDA CVM: Leah Wilkinson, Miss Wilkinson, are you online?

748
02:41:52.690 --> 02:41:56.560
Walt Ellenberg, FDA CVM: I have two individuals with hands that are raised.

749
02:41:57.790 --> 02:42:01.160
Walt Ellenberg, FDA CVM: I'm trying to determine who they may be

750
02:42:01.170 --> 02:42:02.590
Walt Ellenberg, FDA CVM: Ms. Wilkinson. Are you available?

751
02:42:02.600 --> 02:42:10.510
Walt Ellenberg, FDA CVM: This is Leah? Yes, Hi, Leah, if you would, I will forward it and you for the slide deck, and you can begin your presentation.

752
02:42:12.780 --> 02:42:32.179
Leah Wilkinson: Thank you very much. Uh: good afternoon. I'm. Leah Wilkinson, Vice President of Public Policy and Education for the American Feed Industry Association. Thank you for holding this public meeting on a topic that is very important to the animal food industry and for the opportunity to provide comments.

753
02:42:32.300 --> 02:42:47.910
Leah Wilkinson: The American feed Industry Association, or Afia is the world's largest organization, devoted exclusively to representing the business legislative and regulatory interests of the Us. Animal food industry and its suppliers.

754
02:42:48.290 --> 02:43:01.420
Leah Wilkinson: Afia’s members include over six hundred and fifty domestic and international companies who manufacture feed, and pet food, and those who supply the ingredients or the equipment used by our industry.

755
02:43:01.900 --> 02:43:12.030
Leah Wilkinson: The Afia was founded in one thousand nine hundred and nine, three years after the first law which gave Federal officials the authority over feeds shipped in interstate commerce.

756
02:43:12.230 --> 02:43:24.689
Leah Wilkinson: At the same time thirty States had developed their own feed laws. The industry had trouble reconciling conflicting requirements which led to difficulties conducting business across State lines,

757

02:43:24.990 --> 02:43:32.690
Leah Wilkinson: as we heard earlier. The States were also challenged with this variation, and established their own association,

758
02:43:32.700 --> 02:43:39.819
Leah Wilkinson: AAFCO, to also seek harmonization and unity across fee, legislation and regulation.

759
02:43:40.370 --> 02:43:49.650
Leah Wilkinson: That was one hundred and thirteen years ago. And still today, regulators and industry face the same problems of harmonization.

760
02:43:50.320 --> 02:43:56.859
Leah Wilkinson: Animal food regulation remains the joint responsibility of the States and Federal governments.

761
02:43:57.050 --> 02:44:09.050
Leah Wilkinson: AAFCO provides the mechanism to develop and implement uniform laws, regulations, definitions, and enforcement policies that we all strive for

762
02:44:09.120 --> 02:44:13.120
Leah Wilkinson: either to regulate or to be regulated.

763
02:44:13.510 --> 02:44:20.970
Leah Wilkinson: These discussions take place in a public and transparent manner, with all stakeholders present through AAFCO.

764
02:44:21.760 --> 02:44:34.550
Leah Wilkinson: Given the intertwined nature of the way animal food is regulated. States cannot do it alone, and the food and drug and the food and drug administration cannot regulate animal food without AAFCO in the States,

765
02:44:34.840 --> 02:44:38.320
Leah Wilkinson: each need, the other, and AAFCO is the mechanism.

766
02:44:39.690 --> 02:44:49.130
Leah Wilkinson: The AAFCO ingredient review process is one of three pathways. Industry can utilize for the safety review of animal food ingredients for an intended use.

767

02:44:49.180 --> 02:44:56.629
Leah Wilkinson: Well, there are many challenges that are hindering the ability to bring new products to the market. Those are outside of the scope of this meeting.

768
02:44:56.640 --> 02:45:05.790
Leah Wilkinson: What I want to focus on today is more around. Why, it is important for the center for veterinary medicine to be a part of the AAFCO ingredient review process.

769
02:45:06.160 --> 02:45:14.379
Leah Wilkinson: The memorandum of understanding between AAFCO and Cvm confirms the commitment necessary to make the ingredient review system work.

770
02:45:14.430 --> 02:45:22.319
Leah Wilkinson: And while you describes the expertise and responsibilities of each organization and removes confusion of how the process works,

771
02:45:22.600 --> 02:45:35.410
Leah Wilkinson: the animal food industry needs the ingredient review process to work efficiently, and the Afia remains dedicated To ensuring this working relationship between AAFCO and CVM continues:

772
02:45:35.790 --> 02:45:45.010
Leah Wilkinson: we urge AAFCO and CVM to refer this, be extending or updating the current mou in the name of feed and food safety.

773
02:45:45.380 --> 02:46:01.979
Leah Wilkinson: The partnership between AAFCO and CVM allows each organization to share resources and expertise. For example, AAFCO and most States do not have the expertise or resources to conduct the Safety review or an AAFCO ingredient definition, submission,

774
02:46:01.990 --> 02:46:12.399
Leah Wilkinson: and they rely on Cvm for the review by being involved. It affords Cvm. The knowledge to accept these definitions, which are legal ingredients per state feed loss.

775
02:46:12.700 --> 02:46:16.790
Leah Wilkinson: Some are questioning Cvm's involvement, or why it's necessary.

776
02:46:16.800 --> 02:46:32.920

Leah Wilkinson: The Afia firmly believes that the ingredient review system, while not perfect, it works. The system builds and holds confidence across the food chain that our animal food products are safe, which is the ultimate necessity for our customers.

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02:46:33.310 --> 02:46:42.899
Leah Wilkinson: As Cvm. Looks for mechanisms to improve this relationship, and in an agreement with AAFCO, we offer the following points to consider:

778
02:46:44.040 --> 02:46:57.040
Leah Wilkinson: We've seen what happens when CVM. And AAFCO Don't cooperate on AAFCO ingredients thirteen years ago, when CVM's commitment to AAFCO was questioned and stopped for a brief time it created chaos

779
02:46:57.050 --> 02:47:06.640
Leah Wilkinson: and a backlog of ingredient submissions that greatly impacted the ability to bring new animal food ingredients to the market. We do not want that repeated.

780
02:47:06.880 --> 02:47:14.709
Leah Wilkinson: Afia encourages a strong statement affirming the ongoing commitment to be completed before the current mou expires.

781
02:47:15.510 --> 02:47:27.120
Leah Wilkinson: Next, Afia members desire the three ingredient review pathways available in the United States to be speedy, efficient, and predictable.

782
02:47:27.430 --> 02:47:34.349
Leah Wilkinson: While there are different reasons for why there are three different pathways. What remains the same is that they all need to work.

783
02:47:34.440 --> 02:47:40.719
Leah Wilkinson: If one doesn't, it puts undue burden on another pathway with unintended consequences.

784
02:47:40.970 --> 02:47:49.290
Leah Wilkinson: Cvm. Needs to prioritize and review AAFCO ingredients with equal importance to food, additive petitions

785
02:47:49.300 --> 02:47:51.719
Leah Wilkinson: and grass notifications.

786
02:47:52.560 --> 02:47:58.330
Leah Wilkinson: Next regarding stakeholder understanding of Fda's engagement with AAFCO

787
02:47:58.530 --> 02:48:16.660
Leah Wilkinson: industry will always desire additional public guidance and information detailing what is required for an ingredient submission. However, we recognize the challenge to provide enough detail, but remain flexible while considering the wide variety of products and species covered,

788
02:48:17.140 --> 02:48:21.150
Leah Wilkinson: the challenge is communicating theserequirements,

789
02:48:21.560 --> 02:48:32.379
Leah Wilkinson: the recent workshop and online course from AAFCO was tremendously helpful in providing an updated view of the CVM Review process and requirements

790
02:48:32.940 --> 02:48:45.599
Leah Wilkinson: companies should take advantage of Cvm's Review of Protocols or pre-submission consultations before a submission is made and utilize the expertise of the AAFCO product Investigator

791
02:48:45.800 --> 02:48:58.779
Leah Wilkinson: and Cvm could also make the iccf guidelines on harmonized data and study requirements into guidance, for industry, like is done on the animal drug side.

792
02:48:59.310 --> 02:49:01.990
Leah Wilkinson: And lastly, regarding transparency,

793
02:49:02.000 --> 02:49:16.549
Leah Wilkinson: the Afia believes that the AAFCO process is appropriately transparent today. Given the fact that products and data are driven from proprietary submissions and data and the non-proprietary nature of the resulting ingredient definition,

794
02:49:16.690 --> 02:49:32.199
Leah Wilkinson: if cvm were to make the list public that list should state the date. The submission was received by the AAFCO and product investigator. The date received by Cvm. The category of ingredients that the product falls under

795
02:49:32.350 --> 02:49:48.369

Leah Wilkinson: it should not provide any company, name, or product information to include names and product information that will jeopardize the very short proprietary advantage a company may have by utilizing the AAFCO process, rendering it useless.

796
02:49:49.310 --> 02:50:02.480
Leah Wilkinson: The Afia understands the desire to provide public transparency in the process, and believes the current process defined within AAFCO. Of committee, discussion, review, voting board, recommendation and membership vote,

797
02:50:02.490 --> 02:50:05.630
Leah Wilkinson: all which are public for at least seven months is sufficient.

798
02:50:05.710 --> 02:50:16.749
Leah Wilkinson: The AAFCO process of establishing definitions as tentative definitions first and then moving to official after a year, also provides public notification and opportunity to comment.

799
02:50:16.760 --> 02:50:23.769
Walt Ellenberg, FDA CVM: You stand ready, we stand ready to work with CVM and AAFCO on this transparency discussion.

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02:50:23.980 --> 02:50:40.579
Leah Wilkinson: In conclusion, the Afia strongly believes that AAFCO and CVM should continue to work together to ascertain the safety of the animal food products. It makes sense from a resource perspective as necessary to maintain confidence in our regulatory system, which is highly regarded around the world.

801
02:50:40.630 --> 02:50:43.900
Leah Wilkinson: Thank you for the opportunity to provide these comments.

802
02:50:45.130 --> 02:50:46.539
Walt Ellenberg, FDA CVM: Thank you

803
02:50:46.630 --> 02:51:05.400
Walt Ellenberg, FDA CVM: all right. So at this time, before excuse me, before we move forward. I would like to. Ah, just go back and just verify that. Ah, Saun rose. Whether or not she is online or not. Ah, Miss Rose, Are you online?

804
02:51:11.480 --> 02:51:14.100
Walt Ellenberg, FDA CVM: Okay, I don't see

805
02:51:14.400 --> 02:51:18.519
Walt Ellenberg, FDA CVM: Miss Rose present. So we will now move forward.

806
02:51:24.010 --> 02:51:35.870
Walt Ellenberg, FDA CVM: And so at the beginning of the today's meeting, I mentioned that there were three people who had requested to speak, following the deadline that was posted for this meeting,

807
02:51:35.890 --> 02:51:47.889
Walt Ellenberg, FDA CVM: and the name of those three individuals are here. And so at this time We do have time in this meeting, and I would like to recognize Kannika Yavichai,

808
02:51:48.210 --> 02:51:50.300
Walt Ellenberg, FDA CVM: Ms. Yavichai. Are you present?

809
02:51:55.490 --> 02:51:57.710
Walt Ellenberg, FDA CVM: If you are, please raise your hand.

810
02:52:06.590 --> 02:52:10.279
Walt Ellenberg, FDA CVM: Okay, I don't see anybody responding to that request.

811
02:52:10.400 --> 02:52:14.360
Walt Ellenberg, FDA CVM: Then i'll move to the second name, Danny Patino

812
02:52:14.540 --> 02:52:16.360
Walt Ellenberg, FDA CVM: of trouw nutrition.

813
02:52:16.450 --> 02:52:18.559
Walt Ellenberg, FDA CVM: Mr. Patino. Are you present.

814
02:52:30.080 --> 02:52:37.249
Walt Ellenberg, FDA CVM: Okay, I don't see Mr. Patino present, so we'll move to the third speaker, Mr. Ravi Sheth.

815
02:52:37.360 --> 02:52:42.320
Walt Ellenberg, FDA CVM: Kingdom super cultures, Mr. Sheth. Are you available?

816
02:52:49.920 --> 02:52:52.460
Walt Ellenberg, FDA CVM: All right. I see no response there

817
02:52:52.480 --> 02:53:11.010
Walt Ellenberg, FDA CVM: for clarification on the record. I'd like to state that these individuals did request to speak at today's meeting. We responded and told them that they would be on the waiting list, and gave them the approximate time where they would be. Ah! Presenting. And since they're not here, we will then move forward

818
02:53:11.020 --> 02:53:16.819
Walt Ellenberg, FDA CVM: to really the closure of this meeting, and all I have right now are just some

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02:53:16.830 --> 02:53:42.160
Walt Ellenberg, FDA CVM: final thoughts with regards to the closing matters on this one, and that is, I want to remind folks that the docket will remain open to March ninth, and I strongly encourage those who spoke without slides as well as those who spoke with slides. Please submit your information to the docket that will help us. Ah, gain your insight, and better reflect what you said

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02:53:42.180 --> 02:53:50.830
Walt Ellenberg, FDA CVM: Sometimes there were some audio issues, and we want to make sure that we have a clear version of what you stated during your presentation.

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02:53:51.200 --> 02:53:57.819
Walt Ellenberg, FDA CVM: Fda is not going to present your slides on your behalf, so you have to do it.

822
02:53:58.300 --> 02:54:22.790
Walt Ellenberg, FDA CVM: The transcript and video recording of this meeting will be available on the web page for this event, but it will. Ah, they will also be submitted to the docket as well, so they there'll be several areas for you to be able to locate the information, and I would allow Ah! About two weeks or so before that information is posted. There is a lag time following the meeting. As to when we get the materials,

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02:54:22.840 --> 02:54:39.470
Walt Ellenberg, FDA CVM: and we can make sure they're ready to go for posting. With that, i'm going to just say thank you for your attendance. I appreciate all the speakers, and we appreciate all of the information that you provided, and as such I'd like to close the meeting and wish you all a very nice afternoon.

824
02:54:39.480 --> 02:54:40.970

Walt Ellenberg, FDA CVM: Thank you, and goodbye.