Cover Page

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Tuesday, May 13, 2008

I N D E X

Keynote: "---" indicates inaudible in transcript.
Keynote: "(*)" indicates phonetic spelling in the transcript.

M O R N I N G S E S S I O N

(8:25 a.m.)

Introduction

By Dr. Dan McChesney

DR. McCHESNEY: Good morning. We would like to go ahead and get started here.

(Pause)

DR. McCHESNEY: I am Dan McChesney and I am the Director of the Office of Surveillance and Compliance at the Center of Veterinary Medicine and I would like to welcome you all to this public meeting on pet food today especially on the provisions of FDAAA. We have a pretty broad group of folks here from industry, consumers and government and we are very much looking forward to your input.

What I would like to do today is introduce our first speaker Dr. David Acheson who is the Associate Commissioner for Foods. The point I would like to make, I guess over the past year I have gotten to know David fairly well. And the one thing that I would really like to say here is that when he first came into the job shortly after the melamine situation broke -- it was not because of melamine but it was because of a variety of other issues that were going on on the human food side of the house. We have had salmonella in spinach and just a whole variety of other issues out there, but the one thing that I would really like to emphasize is that when David came into his new job, and

the Commissioner obviously put him in that job, it really raised the status of animal feed and pet food to that being equal with food.

In the past we have always sort of been the stepchild where our Center for Food Safety and Applied Nutrition did a lot of things, had a fair amount of money, went at it their own way and pet food and animal feed was always an after thought.

When David came in and he was really heavily involved in the melamine situation, there was a realization that he brought to it, really a unifier, he said “Yes there is a food issue out there but he also realized that there was a feed issue.” And now we have equal footing.

So CVM is always at the table on all food issues, we are always there. We have been in China and kind of been around the world and done the tour on food. We are part of every Tuesday and Thursday morning calls on food protection. We are heavily involved and I think that is solely due to David and his vision that there need to be one food safety system and I applaud him for that and with that, I think that I will introduce him.

One other thing that I will say is that David is a physician, infectious disease person. He practiced in England but he spent a lot of time at the University of

Maryland and Tufts doing public health. He was at CFSAN in a public health role not as an infectious disease role, David.

Welcome

by Dr. David Acheson

DR. ACHESON: Good morning and thanks Dan and please do not hold the fact that I am a physician against me. I would like to extend a warm welcome to you all as well to today's meeting.

To Dan's point, what I wanted to do is just take a few moments so not to get in the way of good discussion today, but really just too sort of take a few seconds and talk about what we are doing at FDA in terms of protecting the food supply. And as Dan has said, this is not all about human foods, it is about foods period, foods for humans and foods for animals.

In my role what we are endeavoring to do is to integrate food issues across the whole agency and that was essentially why we developed the Food Protection Plan that was published last November. I am sure, hopefully, most of you are familiar with that. If you are not, there is a lot of information available on the FDA website about it but let me just sort of say a bit about that and how what you are doing today plays into that.

The Food Protection Plan is really a big shift from

FDA being predominantly reactive to the FDA being proactive that is what we want to do. We want to build in preventive controls up front and that is what this plan is heavily focused on. But the plan just is not all about prevention, it has got three elements, it has prevention, it has got intervention, and it has got response. The prevention piece lets us build safety in up front whether it is domestic food/feed or imported food/feed. To do that, we need to understand where the risks are. We need to work with industry, work with other stakeholders in terms of the role of industry, corporate responsibility to ensure that they are producing a safe product. Again, whether it is a domestic or an imported product.

Around that we need to be understanding what are the mitigation steps, what are the things that need to be done to prevent the problems in the first place building the safety in up front.

The second major element on intervention is more the FDA role and the regulators' role of how do you focus the inspections and the sampling based again on risk. We are all very familiar with limited resources and with the volumes of food and feed coming into the United States. We cannot inspect it all so it needs to be focused on risk that intervention piece is focused on the risk and if we do that

right, targeted inspections, targeted sampling, we will be very fine that those preventive controls are working and reducing the likelihood that product would actually make it to a consumer whether it be human or animal and make them sick.

Inevitably things will slip through the cracks, it is going to happen so the third important element here is response and ensuring that we have a rapid, robust response system and that includes getting a better handle on traceability, tracing back, and tracing forward. It includes responding quickly to signals and what I mean by that is when something begins to go wrong in the agency, we are able to get a handle on those early signals of a problem whether it is an adverse event, a consumer complaint, a positive sample so that we can build that picture rapidly and respond quickly.

Finally, the part of response is when something does go wrong is insuring that we communicate adequately down to those who need to know and that is across the board and certainly we have had problems and difficulties around that of getting that word out as quickly as we would like.

I think probably on the animal side that may work better than on the human side. We have certainly had struggles on the human side of getting word out to small

retail stores when there have been problems with foods. So to build this, what we are looking at is this prevention, intervention, response structure. It needs to be risk-based and that is critical. It is focusing on food safety as well as food defense so that is unintentional as well as deliberate and the fact that last year we went through the melamine situation certainly has highlighted our vulnerabilities to somebody deliberately doing something to the food supply.

I do not put that in the same bucket as bio terrorism. I do not believe that was done with the intent of actually causing harm but it was clearly deliberate and we need to pay attention to that. It needs to look at the production life cycle, so going from growing or production right through to the consumer, looking at that whole piece. And importantly a big shift for us is FDA beyond our borders. And traditionally what we have done is focused on inspecting at the port of entry again based on where we think the risk is, but we are now putting more and more emphasis on trying to understand what is going on in foreign manufacturers.

Working with industry to get a better handle on that and to develop, hopefully, voluntary certification programs which will allow that kind of information to be verified and to be used to help us determine “may proceed”

rates at the port of entry because there have to be appropriate transparency in this, appropriate controls and of course appropriate incentives for people to use it.

Overall as we do that, we are looking to try and build this integrated system. It is not going to happen overnight. It is not going to be quick. It is going to be dependent on the resources that we get and we certainly got some new money in 2008 and hopefully we will get some new money in 2009 to move these things forward.

As Dan alluded to a big part of this FDA beyond our borders are the things we have been doing in China and pet food and pet treats is a focus of that. The initial work is actually being focused on some human food, agriculture and certain kinds of ingredients but those ingredients can wind up in pet food because it is wheat gluten, it is rice protein and it is corn gluten. So they can certainly get into the human food supply as well as the food supply for animals.

So I think the discussion today on the Food and Drug Administration Amendments Act is going to be critical in helping form that process. I have given you the big picture, but at the end of the day we want to make sure that the pet foods, which is the focus of today's discussion, are safe and that all of the parameters are built in, the prevention, intervention and the response around pet foods. That they

are properly labeled and the consumers know what is going on and that we are building that transparency into the system as we move forward and obviously again the process today is part of that transparency is getting that public discussion going.

So with that I will end, I thank you for allowing me to make a couple of comments. I wish you well and again extend a warm welcome to what I am sure will be a very interesting dialogue and helpful for all, so I appreciate it and thank you. Eric let me hand it over to you.

Comments

by Dr. Eric Dubbin

DR. DUBBIN: Thank you Drs. McChesney and Acheson, I am Eric Dubbin and I would like to welcome you all here today as well. This meeting is being held to ask for your input on these very important initiatives as Dr. Acheson explained.

I will sort of explain the anatomy of today. We will start with discussion from the panelists as it says on your agenda. They will give a brief overview of each section of the Act and then we will turn over the microphone to our registered speakers. Some speakers will be removed from your agenda and I will just announce that as we go down the agenda.

Today we have a total of five speakers registered,

but I believe there are seven or eight on your agenda. Each speaker will have 15 minutes to give their presentation. The panelists may ask clarifying questions but they will not be responding to any of the speakers' comments. Any comments that you wish for the FDA to consider as we formally draft regulations or as we develop systems, please submit to the FDA Dockets Management Branch and that information is available at the bottom of the agenda.

On a personal note I am a veterinarian and I share my house with many pets and recognize that all of us in this room feel pretty strongly and elsewhere, but all of us feel pretty strongly and passionately about this subject matter and just so you are aware that this hits home to a lot of us.

Dr. Acheson mentioned that we are concerned about pets and we are doing the best we can do to make sure that we do not have another one of these massive recalls. I urge that our comments be positive and construction and that we behave and speak with civility. I will be keeping time. Every speaker will have 15 minutes and I will sort of stand up and give you the two minute warning and then after those two minutes I will come up and introduce the next speaker.

If you have a Power Point presentation, please make sure that a copy of that gets to the transcriber in the back corner there by the round mirror. Also, if you are speaking

and your name is not on the agenda, please spell your name for her as that helps her make sure the spelling is correct. So many thanks and I will now turn the presentation over to our panelists.

FDAAA Section Overview

Section 1002(a)

Ingredient Standards and Definitions

by Dr. Mika Alewynse

DR. ALEWYNSE: Good morning, I am Mika Alewynse. I see a lot of familiar faces out there. As some of you may know I am the leader of the nutrition and labeling team in the Division of Animal Feeds and today I and the other panel members are going to give a brief overview of the Food and Drug Administration Amendments Act of 2007. Basically most of us either abbreviate FDAAA or FDAAA.

(Slide)

We are going to talk primarily about Section 1002(a) initially of FDAAA. This section, basically as it says up at the top, is to ensure the safety of pet food. Subsection(a) talks about processing and ingredients standards and basically states that, “Not later than two years after the date of the enactment of this Act, the

Secretary of Health and Human Services in consultation with the Association of American Feed Control Officials and other relevant stakeholder groups including veterinary medical associations, animal health organizations and pet food manufacturers, shall by regulation establish three separate pieces."

I am briefly going to talk about ingredient standards. Mr. Kim Young will address processing standards and Dr. William Burkholder will talk about pet food labeling.

(Slide)

Subsection(a)(1) basically addresses pet food ingredients and standards. If you looked at the Federal Register Notice announcing this meeting, you will see that there were five questions that addressed pet food ingredients and standards. These are the types of issues that we would really appreciate receiving comments about.

The questions were, what kind of ingredient definitions would provide adequate information to ensure the safe and suitable use of the ingredients in pet foods?

Should ingredient standards also be developed for other animal food in addition to pet food? Congress directed that this section address pet food. The agency is asking if these standards should also be expanded to include other animal foods.

Should formal ingredient standards be a part of ingredient definitions? If so, what information could be considered to establish a standard. This is another comment where we are soliciting comments from the public and interested parties.

Should such standards be developed for ingredients intended for other animal feed in addition to pet food? Here again we are asking if standards established for pet food should be expanded to all animal feed.

That concludes my portion of the presentation.

Mr. Kim Young will address Processing Standards for Pet Food.

Section 1002(a)(1)

Processing Standards for Pet Food

by Mr. Kim Young

MR. YOUNG: My name is Kim Young and I am with the Division of Compliance and I am the Deputy Director there.

(Slide)

For the Processing Standards for Pet Food and as Mika said there are three questions regarding the processing standards. First question, would standards based on a risk-based, preventive and comprehensive feed control measures approach, such as the approach described as an element of FDA's Animal Feed Safety System Initiative, adequately

address the processing standards requirement of section 1002(a) of FDAAA? More information on the AFSS is going to be given tomorrow during a meeting here in the same hotel.

(Slide)

The second question for the Processing Standards for Pet Food was, if so, what aspects of procurement, processing and distribution should be included in such an approach?

The third question was, should such standards be developed and applied to all animal feeds rather than be limited to pet food?

Next Dr. Bill Burkholder will talk on the 1002(a)(3).

Section 1002(a)(3)

Standards for Labeling - - Nutritional & Ingredient Information

by Dr. Bill Burkholder

DR. BURKHOLDER: Good morning, I am Dr. William Burkholder. I am a member of the Division of Animal Feeds in the Center of Veterinary Medicine. The public notice for this meeting asked eight questions regarding the updated standards for labeling of pet food to include nutritional and ingredient information.

(Slide)

The first question that we asked was, how could the

nutritional information such as the guaranteed analysis, the nutritional adequacy statements/life stage claims that are already present on pet food labels be improved?

The second question was, how could the ingredient information already present on the pet food labels be improved; that is the ingredient list.

(Slide)

The third question was, how could the current feeding instructions or recommendations section on pet food labels be improved? Fourth was, should feeding recommendations be required on the labels of all types of pet food?

(Slide)

The fifth question was, should a nutrition facts box, similar to the format that appears on human food labels, replace the current Guaranteed Analysis that currently appears on pet food labels? And then we went on to ask, if so, how could this nutrition facts box be made to clearly distinguish it from food labeling fact boxes?

(Slide)

The sixth question was, what other information should be required on pet food labels that is not generally present on pet food products sold in the United States now?

And finally we asked for input on existing state

laws, regulations, guidelines, or other models that FDA should consider when drafting the proposed pet food labeling regulations?

These questions were to prompt your input, get you focused on certain areas of the pet food labels but are not meant to be all inclusive, i.e., there could be other aspects that you would comment on that we should look at and so we welcome your input. Dr. Neal Bataller will take the next section.

Section 1002(b)

Early Warning Surveillance Systems And Notifications During Pet Food Recalls

by Dr. Neal Bataller

DR. BATALLER: Good morning, I am Neal Bataller. I am a veterinarian and I am the Director of Compliance at the FDA Center for Veterinary Medicine and I am tasked to deal with the Amendments Act Section 1002(b).

(Slide)

This one is entitled, Early Warning Surveillance Systems and Notifications During Pet Food Recalls. I am going to read just a little slower here so we can get the key words here too.

"Not later than one year after the date of the

enactment of this Act, the Secretary shall establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. There is a lot in that. And, in establishing such systems, the Secretary shall, and there are a few elements here, number one, consider using surveillance and monitoring mechanisms similar to, or in coordination with, those used to monitor human or animal health, such as the Food Borne Diseases Active Surveillance Network also called FoodNet the CDC is part of that but also USDA and the FDA and the same thing with PulseNet. The three agencies are involved with that and all Human Departments of Health, local and state are involved in these efforts also.

The second one, an example again, is the Food Emergency Response Network of the Food and Drug Administration and the Department of Agriculture and again there are a number of other organizations involved with that. The FDA is actively involved with that and that is something that was utilized quite heavily and quite successfully during the melamine situation.

The other example is the National Animal Health Laboratory Network of the USDA basically. This typically deals with diagnostic labs related to large animal diseases. Again these are all models that we can work in a manner

similar to or in coordination with.

(Slide)

Number two, in establishing such a system, we will consult with relevant professional associations and private sector veterinary hospitals. Number three, in establishing such a system we will work with the National Companion Animal Surveillance Program which is a program that involves the vet school at Purdue along with a private veterinary hospital.

The Health Alert Network which is primarily a CDC effort and other agencies are involved with that or other notification networks as appropriate to inform veterinarians and the relevant stakeholders during any recall of pet food; and last in establishing such a system we will use such information and conduct such other activities as the Secretary deems appropriate. Kim are you --

Section 1003 & 1005

Ensuring Efficient and Effective Communications During A Recall

FDAA Title X - Section 105 Reportable Food Registry

by Mr. Kim Young

MR. YOUNG: In the Federal Register we had questions to do with the pet food for other areas that is in FDAAA Section 1003 which has to do with recall and Section 1005 which has to do with Food Registry even though we do not have any questions in the Federal Register we will be taking

any comments that you may have on those two sections.

(Slide)

For 1003 ensuring efficient and effective communications during a recall. What that section has that the Secretary shall during an ongoing recall of human or pet food regulated by the Secretary:

One, work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall.

(Slide)

Two, use existing networks of communication, including electronic form of information dissemination, to enhance the quality and speed of communication with the public.

(Slide)

Three, post information regarding recalled human and pet foods on the Internet Website of the Food and Drug Administration in a single location, which shall include a searchable database of recalled human foods and a searchable database of recalled pet foods, that is easily accessed and understood by the public.

(Slide)

Section 1005 has to do with reportable food registry and the Congressional identified purpose of the

registry is to provide a reliable measurement or mechanism for tracking adulteration in food. In the Section 1005 the Congress put in an amendment for the Food, Drug and Cosmetic Act which is going to be Section 417. What I have done here is given an oversight of Section 417.

One, Reportable Food Registry. Establish a Reportable Food Registry no later than one year after the enactment of the FDAAA and one year is going to be September 27, 2008, to which instances of reportable food may be submitted via an electronic portal and a unique number issued to the person submitting the report on receipt.

What is reportable food? That means an article of food other than infant formula for which there is a reasonable probability that the use of or exposure to, will cause serious adverse health consequences or death to humans or animals?

(Slide)

Three, responsible parties include, anyone that submits the registration under section 415(a), 415(a) was under the Bioterrorism Act -- which would be the owner, operator or agent in charge of domestic or foreign facility if engaged in manufacturing, processing, packing or holding of food for consumption in the U.S. For a food facility that is require to register under section 415(a), at which such

article of food is manufactured, processed, packed, or held and this includes both domestic and international firms. So if you have a registration number under Bioterrorism Act -- if you have a problem you shall put information into the registry.

(Slide)

Voluntary submissions may also be made by, Federal, State, and Local Public Health Officials.

(Slide)

What are the roles and responsibilities of the FDA with the Food Registry? FDA list, establish a reportable food registry to receive submissions through an electronic portal. Promptly review and assess information submitted to the Reportable Food Registry. Issue or cause to be issued an alert or notification with respect to a reportable food as deemed necessary.

(Slide)

Additional roles, share information and coordinate efforts with the Department of Agriculture. If Health and Human Services Secretary believes food is intentionally adulterated, must notify the Department of Homeland Security immediately. Share information and coordinate efforts with states and local public health officials. Also, the FDA must issue guidance, no later than nine months after the date of

enactment which is going to be June 27, 2008, to industry about how to submit reports to the electronic Reportable Food Registry.

(Slide)

What are the responsibilities for the responsible parties?

They must report as soon as practical but no later than 24 hours after a responsible party determines that an article of food is a reportable food.

They must submit a report through the electric portal system. They must investigate the cause of the adulteration if the cause of the adulteration if the article of food may have originated with the responsible party.

(Slide)

They must submit information to support required data elements. They may be required to report back to the FDA, investigate cause of adulteration and/or provide notification to sources and recipients of the article of food. They must maintain records related to each report submitted and any notifications made to the FDA for two years.

(Slide)

There are 11 data elements identified and they include, the registration Number which is the Food Facility

Registration Number the number that you receive during Bioterrorism Act requirement.

Date in which article of food was determined to be reportable.

Description of the food, including quantity and amount.

Extent and nature of the adulteration.

Results of the investigation.

(Slide)

Disposition of the article of food.

Product information.

Contact information.

Contact information linked in the supply chain.

Unique number which is needed if amending previous submission.

Other data that may be required.

(Slide)

You do not need to report to the Food Registry if the adulteration originated with the responsible party; and the responsible party detected the adulteration prior to any transfer to another person of such article of food; and the responsible party corrected such adulteration or destroyed or caused the destruction of such article of food.

(Slide)

Failure to submit to the Food Registry. Additions have been added to the Prohibited Act of the Food Drug and Cosmetic Acts. It is going to be known as “MM” Failure to Submit Report or Provide Notification as required under 417(d). And what is going to be known as NN Falsification of a Report or Notification and Refusal to Permit Access to or Coping of Any Related Records. This will again be under the Prohibited Acts.

That is the summation of what is going to be known as Section 417 at this point. Eric

Comments

MR. DUBBIN: Thank you Kim, Mika, Neal and Bill. We are a little ahead of schedule and also have some issues with some speakers who have not shown up yet. So in order to maintain the flow of the meeting I would like to first ask if at this point in the program if there any people who would like to make a public comment based on what they have heard. You are welcome to do that now.

(No response)

DR. DUBBIN: I am singing the Jeopardy theme in my head, boom, boom. Okay, you will have the opportunity throughout the day to make public comments for inclusion in the record. Unbeknown to John Branam who is not scheduled to go until later is here and we have an opportunity now.

Mr. Branam are you - could you raise --

DR. DUBBIN: Oh there you are. Would you be available to speak now?

DR. BRANAM: Sure

DR. DUBBIN: Great and with that I introduce from the American Veterinary Medical Association, Dr. John Branam for his comments.

Comments

by Dr. John (Ed) Branam

DR. BRANAM: Good morning and as mentioned my name is really Ed Branam, John is a family name. If you say John in my household, the dinner table gets full pretty quick. Both myself Dr. Chuck Lemy who are veterinarians that serve on the Council for Biologic and Therapeutic Agents which is one of the councils of the American Veterinary Medical Association are here this morning to present what we think are recommendations that are important to this aspect of the veterinary community and to pets.

As representatives of the AVMA which is the world's largest veterinary association we speak for approximately 85 percent of the veterinarians in our nation.

The mission of the AVMA is to advance the science and the art of veterinary medicine and as veterinarians our utmost concern is the nation's public health as well as the

health of animals particularly those that we are entrusted to care for on a daily basis.

First of all I would like to thank the FDA for the opportunity for us to provide comments on labeling and safety standards for foods as they prepare and move forward with implementing the mandates that we have viewed to this point relative to the FDA Amendments Act of 2007.

The AVMA applauds the FDA for its continued leadership to protect the public and health through ensuring safe drugs and foods for both people and for pets.

And certainly the FDA is to be commended on its engagement with stakeholders and the general public on issues such as this that are important to the health and welfare of the pets and animals of our nation.

While our country's foods certainly are among the most safe in the world, the AVMA feels very strongly that we must do more. We feel that we can never forget the ingredient contamination that led to last year's pet food recall and the tragic loss of a very large number of beloved pets to our nation's population as well as the challenges that we faced in identifying and communicating in a timely and appropriate manner to those that were both affected by those pet foods as well as the veterinary medical professionals who were trying to treat them.

During this time frame AVMA worked very diligently to serve as a resource to both our profession and the public, attempting to provide them with timely information and ongoing communication relative to this event. However, as I will speak to in a minute, we very much look forward to participating in the formation of a much more formalized and a much more multidisciplinary program led by the FDA that will help prevent such tragic losses in the future. And if indeed they do occur which as we heard earlier this morning, the potential always exists. I think that the quote was, "We cannot test everything that comes into our country." That we are collectively in a position to where we can both recognize and identify the issues in a very expedient manner and collectively disseminate any information to all stakeholders involved and take appropriate actions to mitigate the extent of any future tragedies.

We come today with three specific recommendations. One is the modification of labels of pet food with health claims; two is the addition calorie statements on pet food labels and three as I just spoke to is the development of a formalized multidisciplinary emergency preparedness program led by the FDA that we heard other speakers talk about at least in concept this morning.

Relative to pet food health claims, this is

something that has over the last few years become of significant concern to veterinarians both relative to the scope and breath of the variety of pet foods that exist in our country today and the breath of delivery mechanism that exists to these products to the public.

We have everything from a private label to major corporate branded products. We have everything from raw and frozen and canned and semi-moist and dry, on and on that are available in the marketplace through a number of different retail outlets, super stores, feed stores, pet stores, veterinarians, et cetera.

There is also an ever increasing trend that we see as veterinarians to include various and assundry* claims to pet foods and these health claims indicate that the food does more than just meet the nutritional requirements of a healthy pet.

For example the food may be marketed to senior dogs with degenerative arthritic disease and that claim and that product may state that it in some way improves, promotes, slows down joint disease and promotes or improves joint health.

From our standpoint and I think from the standpoint of the FDA personnel that we have talked to, we are both in agreement that those are indeed health clams and far

outstretch the realm of comments relative to providing nutritional requirements necessary to maintain health in an animal. Many of these foods are only available through veterinarians in an effort ensure some form of professional supervision of the foods with these perceived potent therapeutic claims.

The AVMA recognizes that by Federal mandate FDA regulates pet foods and pet food claims but also recognizes that the FDA utilizes a significant degree enforcement discretion in their oversight of pet foods and of pet food claims and therefore in many instances delegating the validation of pet food claims to the veterinary community specifically clinical practicing veterinarians and/or specialty veterinarians or veterinarians involved in nutritional science and research.

The AVMA is extremely concerned that veterinarians do not have the evidence required to appropriately verify that such pet foods do what they are purported to do before recommending or prescribing them to their patients as well as communicating and answering questions to pet owners and other individuals involved in the pet industry regarding those reported claims.

Obviously pet retail employees have neither the training nor do they have the data to make an informed

recommendation to their customers. I think that all of you as well as I am certainly well aware that regardless of the training or the data available these recommendations are made on a daily basis. The first question that people ask is, "What do you recommend that I feed my pet?"

The AVMA recognizes the FDA's critical need to prioritize its regulatory activities but it feels that it is imperative that specific actions are taken to promote communication and transparency to the public regarding pet food with health claims.

Specifically we are recommending that pet food labels be modified to promote accurate information and label awareness for the pet owning public. I think that if you took a poll the vast majority of veterinarians and certainly the vast majority of the pet owning public and those in the pet retail industry, talking to pet owning public, would indicate that they think that those claims that are on many of the pet food products have been vigorously tested and go through many if not all of the same regulatory evaluation and certification processes that do FDA approved drugs specifically for human and veterinary use and as we know that is simply not the case.

We talked about transparency this morning and the AVMA thinks that it is imperative that as we look at issues

related to pet foods that transparency in health claims related to pets is some something that is addressed as part of this overall program we are looking at here today.

Therefore in the interest of pet safety the AVMA recommends that the FDA require all pet food products with implied or explicit health or drug claims to include a prominent statement on the label indicating that such claims have not been evaluated and/or have not been certified by the FDA. Requiring such disclaimers on pet foods bearing health claims will enhance transparency and accurate information to individual veterinarians and consumers that there is a greater understanding of the relative absence of not necessarily oversight, but in -- of regulation but enforcement relative to these claims.

The AVMA is also concerned about obesity which is an epidemic sweeping across the nation. Obesity is being observed in an alarming rate in pets. There are estimates of anywhere from 25 to 44 percent of dogs are clinically obese in our society today. There is other evidence of the increase risk of disease and premature death in cats relative to excessive body weight. So this has become a major safety factor that we see every day in clinical veterinary medicine.

The AVMA is committed to helping promote healthful lives for pets and as many of you are probably aware of we

have engaged in a weight control and awareness program, national program to reach the pet owning public to try to communicate many of these important points to them.

However, pet owners do not always know how much to feed and they may not realize the high number of calories associated with some of the pet foods they are giving to their pets. To control obesity we need to raise this awareness with pet owners.

This is why AVMA recommends that calorie information be required on all dog and cat foods in particular such calorie statement should be expressed both as kilocalories of metabolizable energy per kilogram of food and as kilocalories metabolizable energy per familiar household measure, such as a can or a cup. The former measurement allows direct comparison between products while the lateral expresses calories relative to familiar household items.

Lastly the AVMA would request that the FDA require that such labels expressly and clearly differentiate where the calorie content information was determined either by chemical analysis and calculations or by animal feeding. One cannot tell how digestible the food is from chemical analysis and calculation method, but the feeding method does yield these digestibility numbers.

Therefore, the best means to compare the foods is

to have a clear understanding of which method was used to calculate calories for each food. We feel that these types of labeling would assist both pet owners as well as the veterinary community to communicate simply and clearly how much of a particular food product is necessary to meet their energy and nutritional requirements and also how much to feed.

Sadly we have seen that obesity related disease robs our beloved pets of longevity and quality of life, therefore, the AVMA recommends that common sense caloric information be included on pet food packaging so that animal owners can readily and easily feed their pets appropriate portions of their food.

Our final point is in regards to the nation's pet food recall of 2007 which clearly was a pet food safety crisis. The AVMA asserts that this exemplifies the need for federal agency coordination and utilization of the National Incident Management System.

The NIMS is a nationwide comprehensive approach to incident management that is applicable across the jurisdictions and functional disciplines. The NIMS can only work well if it is comprehensive and if all federal agencies utilize it.

We recognized the FDA's commitment to continue to

strengthen its emergency preparedness measures. We applaud this and we recommend specifically that the FDA utilize NIMS in order to fully coordinate its emergency preparedness activities.

Comprehensive federal development and implementation of NIMS based strategies with the assistance of stakeholder expertise would address the needs for coordinating emergency response and for the effective communication to support the resolution of food and safety feed events. As the global marketplace becomes more interconnected, federal agencies and its partners must continue to enhance the coordination of the preparedness and response activities. This is paramount for the United States supply to remain among the safest in the world. The AVMA appreciates the opportunity to provide its recommendations for these pertinent animal health and safety issues. We look forward to continued dialogue with the FDA and other stakeholders as it further strengthens our nation's food standard. Thank you very much.

DR. DUBBIN: Actually we do have time if there are questions or public comments either way there is time for that opportunity.

(No response)

DR. BRANAM: Coffee, we need more coffee.

DR. DUBBIN: We have a request on the floor all of those in favor. Thank you Dr. Branam and I am sorry about your first name there. By the way, the 15-minute rule, I am going to cut you some slack on that as we are not quite as pressed for time as we originally thought based on the fewer number of speakers that are actually signed up to speak.

Our next speaker who is here is Mr. Ricky Schroeder if he is available. He is with the Association of American Feed Control Officials also known as AAFCO.

Comments

by Mr. Ricky Schroeder

MR. SCHROEDER: Hello, my name is Ricky Schroeder and I am president of the Association of American Feed Control Officials. I have a few short comments that I would like to make.

AAFCO's membership includes regulatory representatives from 50 states, the Canadian Food Inspection Agency, the U.S. Food and Drug Administration, USDA, Puerto Rico and Costa Rico. AAFCO has developed a model Bill and Regulation for states to adopt to promote uniformity and ensure the safety and quality of animal feeds including pet foods.

Currently AAFCO has the most comprehensive list of ingredient definitions that is recognized around the world.

The ingredient definitions are for all animals. The AAFCO Ingredient Definition Process is recognized by the FDA through a Memorandum of Understanding published in the Federal Register.

AAFCO submitted a written response to the docket dated February 20, 2008 that reflects the view point of its members. I would like to add that the FDA has refrained from these comments to avoid any conflict of interest.

I really want to point out that the state regulatory programs already have laws and regulations in place that are based upon the AAFCO model and provide a level of assurance for feed safety.

We recognize the FDA has embarked upon the scientific risk-based animal feed safety system initiative to identify and close gaps in the current regulatory environment and AAFCO would like to state that it supports these efforts by FDA. Thank you for the opportunity to allow AAFCO to submit comments regarding Title X of the FDAAA Act. Thank you.

DR. DUBBIN: Thank you Mr. Schroeder. I did ask about the coffee and it turns out that we do not really supply coffee at these kinds of meetings and we are checking into where coffee is available for those who are in need.

Now I would like to say that we have other speakers

who have not arrived yet, so I would again like to offer an opportunity for anyone to make a comment, public comment, that this would be a good time to do that. If someone has comment, they can step up to the microphone. Please, would you step up to the microphone and just to remind you to state your name and spell it for our transcriber that would be very helpful.

MR. GISHOLT: My name is Paal Gisholt and I have a question for Dr. Branam. As it relates to pet obesity and since there is a relook at labeling here, I had two questions. One question is, does the FDA take a position on whether looking at body conditioning scores might be appropriate as part of the educational program for individuals and might there be a role to play putting guidance related to body conditioning scores as opposed to recommended cups per day feeding? So that is one question.

The other question is just as a consumer, I have always found that animals that I fed that the recommended daily feeding amounts were rather large compared to what it took to sustain a healthy weight in my pet and I wonder if it might be time to either relook at the recommended total amount caloric intake? Maybe the dogs that we are keeping in homes today do not get adequate exercise and if people are feeding by the directions a lot of people are going to have

fat dogs and is there an opportunity to look at that and either encourage consumers to work with their pets to maintain an appropriate body conditioning as opposed to feeding X-number of cups per day? Please.

DR. DUBBIN: Dr. Branam would you like to respond?

DR. BRANAM: I am here today as a pet owner with an overweight animal. Body condition scoring is certainly one of the prime clinical approaches that we use both clinically from our own standpoint and as a communication tool and monitory tool for our clients for their pets, you are absolutely correct.

There are a couple types of scoring programs; one is from 1 to 5 and another is from 1 to 9. I usually use the from 1 to 5 because I am from Michigan and once I get past one hand it gets more difficult to count, plus it seems to confuse the heck out of clients so keep it simple stupid, right. So I think that any type of very simple body scoring system is appropriate and helps.

The challenge is that we have a plethora of pet foods some which are purported to be lite, spelled in three or four different ways, low calorie, et cetera to help promote weight loss that range enormously in there is caloric content per measurement. And so it makes it difficult to make feeding recommendations. It also makes it difficult I

think for clients to appreciate the volume of food to feed their animals.

We have two major challenges in veterinary medicine when talking about obesity and number one is in our world all events both happy and sad whether you go to a bar mitzvah or you go to a funeral what is the one thing in common? We eat. We go to a wedding or go to a business function and if we do not have coffee we are unhappy.

So we obviously anthropomorphize that into our pets and with our busy schedules and the fact that animals are at home many times all day by themselves they do not get enough exercise and they certainly do not lead a life that would be "standard" in the wild. We sort of make up for that hopefully one walk around the block a day but certainly some type oral communication with our pets as in food.

The other problem is that the vast majority of pet owners gives some type of supplemental treat to their pets and we do not very often have a very good understanding of the calorie content of that as well.

So that becomes a second major factor that needs to be calculated into the labeling of pet foods. It is not just completely balanced pet foods but also things like supplements and treats. So is the body condition scoring of benefit, yes. I think it is and probably at this point the

“Gold” standard of how most veterinarians evaluate their patients, how they monitor them, how they communicate to their clients and also I think it is the best method for pet owners to evaluate their own pets and in an objective and honest way be able to determine how they are doing.

Relative to feeding practices and recommended feeding amounts and pet food, I think that we all certainly appreciate that if you follow some of the feeding recommendations on pet food you would be spending a lot of time buying pet food because it would go pretty quick.

You know the point is though in the defense of pet food manufacturers, pet food labeling, et cetera, the caloric requirements for individual animals are as different as they are for you and me. We all know the person who eats four meals a day and a large dessert at the end of each one and is skinny and then there are others that can walk by a donut shop and gain 15 pounds.

To a great degree that analogy holds true for animals too, you know. What is the reproductive status? What is their activity level? What is their breed? You know we certainly know that certain breeds are at far greater risk of developing obesity than other breeds are. You do not see many fat Whippets, but see a whole lot of fat Labs. Lifestyle and other things probably play a role in that as

well but there is certainly genetics built in there somewhere.

So if you are going to make broad statements about how much food to feed, you have to be cautious in that but at the same time I think that if you can communicate how many calories and not how much you should feed, but how many calories are in a given unit of measure that the pet owning public can relate to, a cup, a can. Then it can assist the veterinarian and other health care professionals in giving recommendations of how many calories you should feed per day and then be able to convert that to a measurement that the clients can more validly relate to. If they give a treat, or if they give some other kind of supplemental food, know how much additional they are giving by doing that because we usually do not count those snacks, do we? I mean that we are the same way, right. We eat three meals a day and everything else does not count, well it is the same thing for pets.

Then you use the body condition scoring as a monitor to determine for that specific animal if your calculations as far as caloric intake on a daily basis is appropriate or not. Because again, it is going to vary.

We need some kind of standardized and some kind of simple to understand method for pet owners to understand and for us to communicate to them about total amounts of food

that are fed in the varying forms and types that an animal receives on a daily basis. Otherwise, you are just going to guess and feel the ribs every day and so that is my recommendation on that. Thank you.

DR. DUBBIN: Thank you Dr. Branam. Apropos to that but you left out one common household measure. When I was taught nutrition by Dr. Bataller and Dr. Burkholder at Virginia Tech, the common household measure for feeding horses was a coffee can and you left that out so let me just put that in the mix. Thank you. Thank your Neal and Bill for that background and training.

DR. DUBBIN: Is there any other public comment or question for the panel or for any of the speakers at this time?

(No response)

DR. DUBBIN: If not, what I would like to suggest is that we take a break now until 10 o'clock. There is one speaker who should be here by then and then we can have some more speakers to make their statements. So we will break for a half hour.

(Whereupon a break was taken)

DR. DUBBIN: As you find your way back to your seats, I just want to give you a couple of reminders that on the table out front is the Federal Register Notice and the

agenda which does have the contact information for you all if you do want to submit comments to the docket so that is certainly an option.

Also want to let you know that we have one speaker this afternoon or rather coming up here in the later morning session and we will have time for public comments. So if you think that you may have some public comments, organize your thoughts now if you would and be ready for that. We will not be having an afternoon session as we will be done this morning just so you know that.

So if you planned on making comments this afternoon the time to make them will be before we break this morning at the end. So with that said as you all find your seats, our next speaker is Mr. Mike Floyd from Defend Our Pets.

Defend Our Pet

by Mr. Mike Floyd

MR. FLOYD: First, I would like to thank the FDA and CVM for the opportunity on the behalf thousands and thousands of pet families across the United States, Canada, South Africa and the rest of the world for the opportunity that has been a long time coming.

On March 16 of last year Menu Food announced the precautionary recall of pet foods that were causing illnesses in pets. That recall over time became the largest pet food

recall in world history and I say world because it was not just the United States.

This news was not exactly startling information to many of us whose pets had been dying and becoming ill for months. We knew something was going on but we had a lot of questions.

As of May of last year to give you an idea of the scope the FDA had a registry for listing pets who were affected by this recall. At that time over 8,000 pets and pet families were recorded in that registry with over 4,000 deaths. For those of you who own pets you know that is more than just a loss of a little animal.

So it is important to remember that I am here today speaking not just for my self. I am here for Miriam in St. Petersburg, Florida and her little Molly. I am here for Diane in Prescott, Arizona and her two little kittens, Jennifer in Bastrop, Texas and her little cat Timber, Clare and Sophie in Georgetown, South Carolina, Tammy in Ukiah, California and Melissa in Suquamish, Washington, Sandy in Juno, Alaska. All across this nation pet families were affected.

The goal of Defend Our Pets which we started in April of 2007 is to do everything possible legally and on a regulatory basis to try and prevent this kind of disaster

from ever happening again. Simple thing to say, but a very difficult thing to get accomplished.

We now have about 2,200 active members and including support from actors and others from Act For Animals and many other groups focusing on the right of our companion animals. In January of 2008 we were proud to be named an advisory member to the Pet Food Committee of AAFCO. This was the first consumer representation on any AAFCO committee in a long time.

We would like to express our thanks to Ricky and to others for the warmth and understanding of our welcome to that group, without exception they have been very helpful and very cooperative.

When the recall was first announced, the natural reaction was to ask what had happened. All we knew was that our pets were suffering and dying very rapidly. Over a period of time we discovered that some Chinese companies and individual had deliberately -- please notice that word, deliberately introduced a chemical called melamine into some wheat flour in order to sell it in the United States as wheat gluten with a greatly inflated and overstated protein content.

It turns out that test used to determine the protein content of wheat gluten examines nitrogen omissions

under the certain test protocols. By adding a relatively small amount of melamine to their wheat flour the Chinese companies were able to get a greatly inflated test score and a higher price for their product.

It also happens, not that they cared, that melamine in the presence of cyanuric acid crystallizes in animals' kidneys causing renal blockage, kidney failure and death, but they did get a higher price. The head of one of these Chinese companies has already been executed.

In addition two Chinese companies along with two key executives of ChemNutra in Las Vegas and we will get back to that, which is the largest importer of Chinese food stuffs has been charged under a Federal indictment in a Kansas City Federal Court.

After we discovered what had happened, we began to look at how could this have happened? Who was minding the store and protecting us and our companion animals who cannot protect themselves? We discovered that virtually the entire infrastructure of pet food quality control in the United States is mostly smoke and mirrors bounded by good intent and frustrated and limited by lack of funding.

You will hear from the Pet Food Institute and the APPMA and others from the industry that the pet food industry is among the most regulated groups in the United States and

approaches the same regulations imposed on human food. This statement is utter and complete nonsense.

Regulation and enforcement of pet food quality due to neglect and abuse has been almost 100 percent voluntary and self regulated. The industry through its lobbying efforts has virtually written the existing regulations themselves. Where was the pet food consumer represented? No where.

And lest we forget the protection of the American consumer is the greatest reason for the regulations in the first place and we seem to lose track of that. They, after all, through their purchases and taxes pay a lot of the salaries here in this building.

This leads us to what I refer to as the “chain of greed” in terms of how could this happen? The first link, and to this we will certainly take some responsibility, is with the consumer in a day when their funds are torn and diminished and devalued they have to look for value in all of their purchases and that includes pet food, so we will take some responsibility for the chain of greed.

Retailers who complain loudly and strongly, “We do not make the stuff, we just sell it.”, are liars. They do make it through co-makers like Menu Foods. In an attempt to avoid responsibility on their part it is and will be found to

be criminal.

The store brand foods, why does a company like some of the biggest retailers and the largest retailer in this country need a store brand pet food period, to increase market share and to increase profits. It is all about the money.

The next chain are the pet food manufacturers including co-makers like Menu Foods who are under constant pressure from retailers to reduce cost. They eventually turn to third and fourth level suppliers of pet food ingredients. It is at this point that Menu Foods turns to Chinese “wheat gluten” that was selling 20 percent below the open market price and distributed in the United States by a company called ChemNutra out of Las Vegas.

Number four in the link of the chain of greed are the Chinese companies who are operating under a virtually nonexistent pet food safety system, they look for anyway possible to increase profits and not all of these have proven to be legal or safe.

Next is the Chinese Government itself who really does not care. As long as the product is being exported, their attitude is that is up to the company importing the product to check for safety. Millions and millions of lives are at stake and what has happened are denials, lies and

refusals for large scale inspections.

There are currently 300 -- and we are going to talk a little bit but very briefly about what can be done. There are currently 327 official ports of entry; 327 including and we will get back to this, Las Vegas, Nevada. Only about 1 percent or just over 1 percent of all food and food stuffs imported are ever inspected at all; 1 percent.

Some ports of entry are known to be tougher than others. Importers trying to avoid inspection will usually circumvent the tough ports and go to the ones with somewhat easier reputations. A ship load of ingredients coming from China going to Long Beach, California or the Bay Area will be put on plane and flown to Las Vegas to avoid and change the port of entry.

Ingredients now with more sensitivity --ingredients are flown to other intermediary countries and that list is long and may change hands five or six times in order to cloud the country of origin. This is not an easy thing to deal with. It is a little bit like laundering money.

Ever wonder why a company like ChemNutra who is the largest importer of food stuffs from China chose to have their headquarters in the middle of the desert in Las Vegas, Nevada? It seems just a little bit of a coincidence.

The FDA inspections of pet food companies and the

pet food products also amount to about 1 percent of production, while the increase in foreign imports of ingredients has increased at the rate of in excess of 10 percent per year. That is right 10 percent per year. The actual number of Field Agents from the FDA and CVM out in the field conducting inspections has decreased.

The American consumer today gets approximately 15 percent of all the food they eat from foreign sources. In the area of human food many of these are labeled as made in and fill in your own country. In pet food that does not happen; why? The answer is, "I do not know." Why is there so little regulation and enforcement? Mostly it is money.

While the FDA and CVM have been able to get small budget increases in the 3 or 4 percent range and there are ways of quoting those numbers, the fact is that much of those funds have been diverted to other sources through general appropriations. The actual amount of money spent on food control has not increased, even though foreign imports have skyrocketed. And with food costs going higher and higher here in the United States the outlook for decreasing foreign food imports is not likely.

Someone said if you took all of the products made in China off of Wal-Mart's shelves, they would have to close the store and that is true. We have sold out our birthright.

Okay, we sold it out to make a few dollars but, it is time to get it back.

This chain of death and greed led to the demise of over 4,000 pets early last year. Thousands of other families including some who can very little afford it have spent thousands of dollars so far in veterinary bills to try and keep their pets alive. If you do not believe me go to our website and look at the pictures of the dead and dying, read some of the stories that make me cry every night and maybe we will get some action.

We have waited a year for this meeting and I cannot tell you how excited we are to finally be able to say, "help." Many of the people here are in positions to do just that. We are watching.

Let's talk about "free trade." Multinational companies in the United States and others including me at various times during my study of economics, have pushed for free trade. Multinational companies here in the United States and you can name most of them because they are very large and well-known companies, want to go to overseas to the excess in the case of China and I am just using them as an example. They want to go to China in order to access the Chinese consumers, cheaper Chinese labor and zero governmental

influence. The trade off is that Chinese companies are allowed to import into the United States virtually without inspection. So that is where it started.

The top countries importing food are Canada, Mexico, China and Thailand. Canada has one of the best records of not having import refusals. The others read like a litany of countries that we hear of on the news all the time with problems. This is a report that was issued by the CRS last year Congressional Research Service. I encourage you all to look into it for issues on this subject.

Lastly, I want to cover labeling. This is a six-page document taken from the FDA website. There are six pages to define how to read a pet food label. Labeling is number and key ingredient. A label should be to make it easier for the consumer to make an intelligent choice when selecting a food their companion animal.

The opposite is the case. For those who remember the code breakers at Bletchley Park during World War II would have had a severe challenge in trying to figure out what and what percentage of things are in pet food.

No one to date could tell what percentage of any pet food ingredient is constituted in any pet food. Why? Maybe it is because we desire to keep the consumer ignorant.

Lastly I will cover some recommendations. I want to mention people who are responsible for this meeting whom we think from the bottom of our hearts, Senator Richard Durbin from Illinois, Congresswoman Rosa DeLauro of Connecticut, Congressman John Dingell of Michigan and without their help this meeting would not be possible.

In the last several months we have done surveys and the surveys are available but I am short on time so I will not mention but one aspect and that is 98.9 percent of all pet food consumers demanded country of origin labeling; 98.9 percent consumers demanded so why do we not have it? We have it in human food and its time.

That statement can be so simple as saying, the ingredients in this pet food were not all obtained from sources in whose quality controls were certified by the FDA. You do not have to have a listing by each ingredient. The result of that frankly I do not think hurts the pet food industry at all, because what will happen you can guarantee they will stop using the foreign ingredients in order to avoid that label.

Pet food families are willing to pay a higher price. It is not about price and we surveyed that and we proved it. We will pay the higher price for quality and safety. Pet food sales will actually go up if they listen

but they are stuck in the past. Now we will pay more for top quality products and sales will go up.

Let me briefly and in conclusion recap by giving you certain recommendations. First of all there needs to be mandatory recalls and not just voluntary. We need to have that as part of the new regulations. The Food Registry established in the law and remember this law, not opinion, needs to be expanded to improve testing.

Country of origin labeling is an absolute must but it can be done in a very simple form. The entire six page thing about pet food labeling needs to be eliminated. Simply stated quote the percentage of ingredients on all the cans, simple. Why not do it? Because then it might violate some proprietary recipe. There is no such thing as proprietary rules protecting the manufacturer when it comes to pet food and safety.

It is imperative that words marketing such as premium, natural, organic and holistic be eliminated until such time as they are given regulatory meaning. The name of the actual manufacturer must appear on the pet food label. It does not at present.

Lumping the pet food requirements of the FDAAA with the AFSS would be in our opinion unwise and travesty and diminution of the effort to protect companion animals. The

claim of balanced and long term nutrition is not justified by six months worth of feed testing. That is clear.

The FDA should ban the import of any food stuffs from any countries not in compliance with U.S. Standards; period. The FDA should impose user fees on foreign imports to fund the hiring of additional inspectors. The industry opposes this because frankly we feel they want it from appropriations which will be syphoned off of other areas and no new inspectors will be hired. Using user fees to hire inspectors guarantees the increase in inspections.

By products should be defined as to content and process and not include euthanized animals which is the case at present. Consumer education has to be expanded in order to closely examine any pet food industry grants to veterinary schools, retailers should be subject to FDA inspection and penalties just like manufacturers.

And lastly close down ports of entry because if we cannot inspect 327 ports of entry and we cannot, we make sure that pet food or food imports in general are only allowed to come in through maybe 15 or 20 and not 327. We can inspect and control that but you cannot control 327.

Lastly, this law provides 24 months from the date of enacting for these changes to be put into place and 8 months of that has all ready passed. We have 16 months left.

January 20th of this year Defend Our Pets purposed within AAFCO the creation of a task force to come up (with(?))recommendations. Right now AAFCO has responded although nothing has been done. There has not been a single meeting of that task force and the reason is that they say that they are waiting for the FDA to ask them in other words the two bodies are not communicating. The task force admits that AAFCO but the FDA according to AAFCO has not asked AAFCO to proceed. They are waiting. Gentlemen and ladies they are waiting.

Could the pet food disaster of 2007 happen again? You bet and it could be tomorrow. In the meantime more of furry little family members die every day. Thank you.

DR. DUBBIN: Thank you Mr. Floyd. We now have, it is now, well my watch is blurry but I did not buy it that way.

Open Public Comments

DR. DUBBIN: We now have an opportunity to make public comments. There are microphones on either side of the aisle ways. I will remind you of a ground rule that I mentioned earlier that when you mention your name that you spell it for sake of our transcriber to make sure of accurate name spelling and that would be helpful. With that I open up the floor to questions or comments of the panel, of the

speakers and to the FDA in general.

(Pause)

DR. LITTLE: I am a consulting veterinarian from South Dakota. I just have a question on the survey that was referred to by Mr. Floyd and is that survey being used as part of the comments and if so how is that validated and how was it sampled? I know in the upper Mid-West where I am from there are many families that maybe cannot afford to pay more for food so I am curious as to how that was distributed.

DR. DUBBIN: Mr. Floyd has just stepped out of the room. I think that according to the ground rules questions -- if he could answer that directly if he were here, but he is not. If it is directed to the panel then that question will get put in the docket to be discussed later. Is that how it works, Dan?

(Nodding of head)

DR. DUBBIN: Okay, so when Mr. Floyd comes back or if he comes back, we can ask him that question again. Thank you Dr. Little. Are there any other comments or questions for this period?

Mr. Floyd we have a question on the floor about the survey. Could you make a comment about that?

MR. FLOYD: What one second?

DR. ERIC DUBBIN: Mr. Little asked about the

validation of the survey. Mr. Little would you ask your question again because I do not remember it completely.

DR. LITTLE: You had referred to a survey and some of the results -- summarized some of the results. I was just asking for the validation of that survey. Whom was it distributed to and how was it validated? My specific concern is that I am from South Dakota, the upper Mid-West, and in those areas it is hard for me to believe that there would not be more push back on pet food price.

MR. FLOYD: That is a very good question and I will be the first to admit that the survey sampling was biased. It certainly was. It was an open survey on the internet. It was publicized throughout the pet food support groups, et cetera, all of them on the internet, et cetera.

There were about 2500 responses but is there some bias there? I think that many of them had lost pets, I am certain there was some bias. Hope that answers your question. I am not claiming that it had 100,000 responses and it was done through *Time Magazine* or the *New York Times*. It was done on the internet. It is still there and you are welcome to go check it, as are a number of other surveys.

DR. DUBBIN: Thank you for that response Mr. Floyd. Do we have any other comments or questions in this public comment period?

(No response)

DR. DUBBIN: I see no one coming up. I would like to turn the microphone over to Dr. Dan McChesney for some closing remarks.

Closing Remarks

by Dr. Dan McChesney

DR. McCHESNEY: Thank you Eric. Just want to follow-up on the question that Dr. Little asked that any of the speakers today or anyone in the audience that submits comments to the docket and the information is on the agenda, all of the comments will be considered. So to go to Dr. Little's question, if Mr. Floyd submits the survey information in his presentation today into the docket we will surely consider it and look at it and give you the information.

I think that what we heard today and we heard from a professional organization, state association, a feed control official and a consumer who himself and his group are very active in pushing pet food safety based on the recall and what I heard were at least a couple of themes. One, there seems to be a call for clarification of the label both from the AVMA and the consumer.

They would like a label that is easier to read and the claims on the label have been validated and the data to

validate those claims is adequate. There was information requested on caloric content that would be something more useful for the consumer or more easily understood in relation to the way people feed their pets.

Many of you in this room know that the qualifiers used for lite or or reduced calorie for pet food is based within a certain product. So if I am making a product and my original product has 1500 calories per serving or whatever the unit is, I can make a lite product by having a few hundred calories less like 1000 calories or 1200 calories. Where someone else's product, my compatriot over here, could make a product whose original product is only 1200 calories which is the same as my lite product but that would be his regular product and his lite product may be 800 calories.

So there is really not current firmness lite is across the industry. It is based on the relative product and that I do not think was mentioned in the AVMA comments, so if some of you were more in line with the human side of the house you might not have caught that.

The reason to push for calories is that the labeling is not consistent across the product lines; it is relative within the product lines. So that really makes calories important because you could feed a lite product of one company that could easily be as many calories as a non-

lite product. That is a little bit of background on calorie content. I think the point there is that both consumers and the professional association saw a need for increased clarified labeling that provides more information to the consumer in a more understandable way.

We heard from AVMA that they would like claims on pet food products more substantiated. I think that was a theme that we also heard from the consumer groups.

Emergency preparedness was another point that was put forth and we agree with that and we are working on that.

As for the states I think that an important point that was made by AAFCO today was that there are multiple layers in the safety system. There is the Federal system, but there are also the states both on the pet food and total animal feed safety side, that do play a very important role in pet food safety and in the safety of all animal feed products. A lot of the states probably do more inspections and more oversight than the FDA does.

We also heard that AAFCO currently has their Offical Publication that list names of common ingredients and there are probably several thousand ingredients in the book. The FDA has an MOA to use those as common and usual names. I think that we would like comments from the group on that to this docket. Is that appropriate and would that meet the

standards definitions and ingredient definitions? Would that be an appropriate use of those?

We heard from Mr. Floyd that there is a need for increased oversight over the pet food industry and a need to protect the American consumer. I think the second point there, the need to protect the American consumer was one that Dr. Acheson made this morning when he talked about the shift in philosophy from being a relatively responsive agency to one where we are pushing prevention, intervention and then response really as the last thing. We want to go toward the prevention side of the house and that is what is behind this meeting and that is what is also behind the overall food protection plan, moving toward prevention and that would be my way of saying how we would protect the American consumer.

We heard from Mr. Floyd that his members strongly support country of origin labeling. The one thing I got today from that, I mean I have heard that before, but the one thing I found interesting is that most times people think of country of origin labeling and obviously you put the country on it and that is difficult for a complete food product because you can have sources from many countries. I did find it interesting that his proposal was basically to put a disclaimer on the label that the ingredients were not coming from a certain country or coming from a county not FDA

inspected or FDA approved and that is, I thought, a rather novel approach.

He again emphasized simplifying the labeling and I think that he also mentioned reviewing qualifiers although he did not mention why that but he did talk about a whole variety of other qualifiers that we see on pet food. I think that goes back to if we have qualifiers, there seems to be a request that these qualifiers have data to support whatever they are claiming.

The other point that we heard today was from Mr. Floyd and was not to combine the pet food part with the animal feed safety system. I think that is an interesting view. We will surely consider that and obviously the regulations were written for the pet food side and not the other.

We were also asked to ban products not meeting U. S. Standards and as you heard Dr. Acheson say, that is really one of the approaches we are taking in China with the Memorandum of Agreement we have with China. We are starting to work on aquaculture products and vegetable proteins coming in because of that. The idea there is that these products under this agreement will have to meet U.S. requirements before they are allowed in. That is something that is being developed but I will not kid you, it is a long arduous road

and as we all know the United States depends heavily on imported food from around the world.

The other thing was consumer education and we truly embrace that. We agree that there needs to be more consumer education on food protection, food handling and reading of labels.

I think the plea we heard to simplify the label where it takes six pages to explain a label and I know the folks who wrote that and it is well written and it is understandable but it is very detailed and you have to think about it. We have to ask ourselves is that what we want our labels or do we want to just pick something up and read it and say, oh yeah, I know what is in it. I think that most of us would prefer the, oh yeah, I know what is in it and what it means and how I can use it. That is not a criticism of pet food or any other industry, it is just a statement that I think when we pick things up and read them we would like to know how we use, what we get and what we are doing with it.

I think that is good input and I think that we have heard that multiple times today and we will surely look into that.

I think that with that I will add that I would like to thank you all for coming and probably Eric, I should give everyone one last chance to make a comment if they would like

before we adjourn for the day and either catch their flight home early or enjoy what over the past week or so a rare nice sunny day in Washington.

(No response)

DR. McCHESNEY: Thank you

(Meeting adjourned at 10:53 a.m.)