## FDA Coronavirus Disease 2019 (COVID-19) Briefing for Animal Food Stakeholders March 31, 2020 3:00 pm EDT

## **Transcript**

Coordinator:

Welcome and thank you for standing by. All participants will be able to listen-only until the question-and-answer portion of today's conference. To ask a question, please press star 1. Today's conference is being recorded. If you have any objections, please disconnect at this time. I would now like to turn the conference over to Ms. Siobhan Delancey. Miss, you may begin.

Siobhan Delancey: Thank you, (Julie). Thank you all for joining us for today's stakeholder call. My name is Siobhan Delancey. I'll be serving as your moderator today and the purpose of the call is to communicate with our FDA animal food stakeholders and other interested parties to discuss animal food safety questions related to COVID-19.

On the call FDA animal foods program leadership from our Center for Veterinary Medicine and Office of Regulatory Affairs will provide an overview of current activities, acknowledge stakeholder concerns and highlight important FDA resources in response to the COVID-19 pandemic.

I'm joined today by Dr. Steven Solomon, the Director of FDA's Center for Veterinary Medicine, Dr. Tim Schell, Director of CVM's Office of Surveillance and Compliance, Ms. Jenny Murphy, Deputy Director for Food in the Office of Surveillance and Compliance and Mr. Michael Rogers, Assistant Commissioner for Human and Animal Food Operations from FDA's Office of Regulatory Affairs.

And as previously mentioned following the formal remarks, we'll open-up the call for a question-and-answer session and at this time I'd like to turn the call over to our first speaker, Dr. Steve Solomon.

Steve Solomon:

Thanks, Siobhan. Good afternoon, everyone and thank you for joining us for today's call. As mentioned I'm Steve Solomon. I'm the Director of the FDA's Center for Veterinary Medicine. As you all well know, these are very difficult times as we all face unprecedented challenges brought-on by the COVID-19 pandemic.

It's impacting our lives, our families, our communities and our work. First let me assure you that the FDA is committed to protecting the health of the American people and facing any challenges that might arise during this crisis. That has never been more true than it is today. You're committed to ensuring the safety of the food supplies for both animals and humans in that the food supply chain is not disrupted.

The Secretary of Health and Human Services declared a public health emergency on January 31st, 2020 and FDA stood-up to maintain its incident management command structure since the beginning of February. The Center for Veterinary Medicine is part of FDA's incident management group to coordinate actions across all FDA-regulated products and in fact all government in a collaborative response to address COVID-19.

We're working to coordinate the state and local governments as well since the COVID-19 situation is so fluid and impacts different areas of our country differently at any given time. Recognizing the close relationship between the human and animal food sectors, we're closely coordinating with our colleagues at the Center for Food Safety and Applied Nutrition or CFSAN in the Office of Food Policy and Response or OFPR.

In the animal food sector these actions include but aren't limited to working with industry on potential animal food or ingredient shortages so we all can keep abreast of supply chain issues should they emerge. Providing guidance on issues that relate to work or health, at the facilities to any impact on your products.

Ensuring the animal food sector and all its forms is represented on the critical infrastructure list so you can continue your vital work. Modifying our (inspectional) approaches to keep your workers an FDA staff safe while still ensuring the safety of the animal food supply.

Let me emphasize how much FDA appreciates the animal food industry's engagement in the COVID-19 response and the service you are providing. We appreciate the partnership all of you have demonstrated as we face COVID-19 challenges together. Addressing this crisis as a collaborative team effort that involved an all-of-government approach as I mentioned.

It also involves public-private collaboration and that's why CVM is teamingup with all of our partners at this critical time. Keeping the lines of communication open and strong is critical as the situation is constantly evolving. We don't know what form the next challenge will take.

I want you to know that FDA and CVM are here to help. As Michael Rogers will tell you more about shortly, the FDA's halted routine foreign and domestic inspections in standpoint for the time being. We've issued enforcement discretion for the on-site audit provisions for both our preventive control regulations both from the human and animal side and the foreign supplier verification program.

We have issued guidance to relax the terms of the veterinarian/client/patient relationship with DCPR. What's pertinent to the animal food sector is that subject to your state's veterinarian/client/patient relationship rules of providing veterinarians with greater flexibility to use telemedicine during the COVID-19 outbreak are temporarily suspending the animal examination and premise visit requirements to authorize veterinary feed-directed drugs.

We're also working hard to make sure our employees stay safe and the vast majority of staff are teleworking except central employees whose jobs require being on-site. However, we continue to do all mission-critical to the greatest extent of continuing our usual mission-related activities.

We recently received reports that you have potential concerns with shortages of disinfectants, cleaners, personal protective equipment and transportation availability. We'll talk and pass these concerns on and questions to the folks in the U.S. government who are coordinating these type of efforts and Siobhan Delancey will discuss this later in the call.

Before I turn this call over to Dr. Tim Schell, let me again thank you for taking the time to join us today. Thank you for your hard work and thank you for your continued partnership and commitment to producing safe animal food during these challenging times. Dr. Schell?

Tim Schell:

Thank you, Dr. Solomon. I'm Tim Schell. I'm the Director of TVM's Office of Surveillance and Compliance. We want you to know that we are committed to ensuring that the food supply is safe and the food supply chain is not disrupted. First let's talk about animal food safety.

I know there have been lots of questions from consumers about the safety of the food supply and whether the food supply is the source of COVID-19. There's no evidence of food or food packaging being associated with transmission of COVID-19 neither humans or animals. This is not a food-borne gastrointestinal virus like norovirus or Hepatitis A or (macro real) pathogen that may cause gastrointestinal issues.

The virus that causes COVID-19 is one that causes respiratory illness and is not known to be transmitted by exposure to food, including animal food. It is much more likely that an infected person will spread the virus through person-to-person transmission than from contaminated food or food packaging.

A second possible method of transmission is that a person can get COVID-19 by touching a frequently-contacted surface such as a counter or object such as a doorknob that have the virus on it and then touching their own mouth, nose or eye.

Because of the way the virus spreads - primarily from person to person and then potentially from contaminated surfaces - we do not anticipate that animal food products would need to be recalled or be withdrawn from the market should a person who works in an animal food facility be contaminated or because confirmed to be positive for COVID-19.

Now let's shift the focus on the food supply. There's no nationwide shortages of food for humans or animals. Animal food production and manufacturing are widely dispersed throughout the United States and there are currently no widespread disruptions reported in the supply chain.

We are continuing to put this message out to the public. FDA is working with our partners in the animal food industry to monitor the food supply chain for any shortages. We are greatly appreciative for the information you all primary through industry trade associations have been providing to us on the current status of the food supply chains.

No shortage of finished food or ingredients used in manufacturing animal food are being reported. We will be continuously working to monitor the situation. We know that there have been reports of empty pet food aisles or delays ordering from home-based delivery services. Based on our ongoing communication with both the human food and animal food industries, we understand that this is largely an issue of unprecedented demand, not a lack of capacity to produce a process.

So manufacturers and retailers alike are working around the clock to replenish shelves. We, all of us, must continue to reassure and remind American consumers including pet owners and farmers that there is no need to horde animal food particularly pet food. Families should only buy what they need to feed their pets on normal cycles in which they buy pet food.

Often a single bag of pet food could last a few weeks. We want consumers to be confident in the safety of their animal food and we want them to have access to the food they need for the animals they are caring for including pets and farm animals.

I'd like to reiterate our appreciation for the industry cooperation in monitoring the food supply and ask that we continue to work closely together to address the challenges that lie ahead and now I'll turn it over to Jenny Murphy.

Jenny?

Jenny Murphy: Thank you, Dr. Schell. I'm Jenny Murphy and I'm the Deputy Director for Food at CVM's Office of Surveillance and Compliance. For the past few

years, FDA has been discussing the importance of food safety particularly after the passage of the Food Safety Modernization Act or FSMA.

Many of you have heard CVM express why we believe so passionately in food safety. While not every human or animal needs to use all FDA-regulated products such as drugs or devices, every human and animal has to eat to survive and it's our role to make sure that food is safe.

And as time of the COVID-19 pandemic we - regulators and industry - have a role in ensuring that animal food is both safe and available. To ensure that animal food production continues, FDA has been working with the Department of Homeland Security or DHS to ensure animal food is well-represented on DHS' essential critical infrastructure workforce.

Animal food is represented as part of the food and agriculture sector. DHS' what's called their Memorandum of Identification of Essential Critical Infrastructure Workers During COVID-19 Response can be found on DHS' Cyber and Infrastructure Security Agency's Website which is www.cisa.gov.

In the first version of this list which was released by DHS in mid-March, we received a few questions on whether the descriptions in that food and agriculture sector sufficiently represented the animal food industry.

DHS is updating this list on an as-needed basis and FDA was able to work with DHS to get updates to the list to address the concerns we had received. A new version of this list was released on March 28th with some additional edits to the food and agriculture section.

FDA is very grateful for DHS' quick work on the revision. We believe the current list under the food and agriculture section is wide enough to address

all the various animal food industry sectors including livestock food, pet food, renderers, ingredient manufacturers, food packaging, transportation and retail facilities such as pet food stores and feed and grain stores.

Now please recognize that the DH list in its entirety is not meant to be binding for state and local governments and is meant to serve as a tool for them to build their own list. One question that has come-up is what type of documentation workers should provide to show they are essential, critical infrastructure workers especially as more states and localities have put-in shelter-in-place orders?

That decision is a decision for an individual state but we have heard that many employers are providing their own letters of documentation to their employees and attaching the state or local government listing of essential, critical infrastructure workers. If you have questions or concerns within your state, you should work directly with your state government.

If you are unsure of how to reach your state government, we recommend that you use the Association of American Feed Control Officials or AAFCO directory for State Feed Control Officials which can be found on AAFCO's Website at www.aafco.org under the tab titled regulatory. From there you can find your state feed control official contact using the map of the United States.

Now I'm going to shift gears to talk about the health of animal food facility workers. While the normal conversations between FDA and the animal food industry focus-on animal food safety, these are definitely different times so today I'm going to focus-on the health and safety of animal food facility workers.

We deeply care about what's happening for workers in animal food facilities. Animal food facilities should be taking steps to ensure the safety of their workforce. Some steps that can be taken to clean a facility or equipment to prevent the spread of COVID-19 include the following current good manufacturing practice or CGMP requirements for food safety to maintain clean food contact surfaces.

While not required under the CGMPs and the preventive control for animal food regulation, this is the time to consider sanitizing food contact surfaces and equipment that workers may come into contact with.

Facilities should be using EPA (unintelligible) sanitizer products in their cleaning and sanitizing practices. EPA has a list of EPA-registered disinfectant products for COVID-19 on their disinfectants for use against SARS, CO-V2 list that have qualified under EPA's emerging viral pathogen program for use against SARS, CO-V2 which is a coronavirus that causes COVID-19.

To prevent the spread of COVID-19, CDC is recommending individuals employ social distancing or maintaining approximately 6 feet from others when possible. In animal food production and processing facilities and retail food establishments such as again, pet food stores and the feed and grain stores should conduct an evaluation to identify and implement operational changes that increase employee separation.

However, we do recognize that social distancing to the full 6 feet will not be possible in some animal food facilities. When it's impractical for employees in these settings to maintain social distancing, your workers should maintain effective hygiene practices to reduce the chance of spreading the virus.

CDC regularly updates its interim guidance for businesses and employers to plan and respond to coronavirus disease 2019, COVID-19 which includes updates to cleaning and disinfecting guidance and best practices for conducting social distancing among others.

I'm sure many of you have questions on what to do if a worker tests positive for COVID-19. If you have a worker who tests positive, there are recommendations on what you should do to continue operations while at the same time protecting your other employees.

OSHA has issued a guidance of preparing workplaces for COVID-19 that includes information on how a COVID-19 outbreak could affect workplaces and steps all employers can take to reduce workers' exposure for that risk.

Animal food facilities need to follow protocols including cleaning protocols set by local and state health departments which may vary depending on the amount of community spread of COVID-19 in a given area.

The employer should inform fellow employees of their possible exposure to COVID-19 in the workplace but maintain confidentiality about individual employees' identities. (VIQ) employees should follow the CDC's guidelines on what to do if you are sick with coronavirus disease 2019 COVID-19.

While the primary responsibility in this instance is to take appropriate actions that protect other workers and people who might have come in contact with the ill employee, facilities should redouble their cleaning and sanitation efforts to control any risk that might be associated with workers who are ill regardless of the type of virus in the facility.

Recently FDA received questions on the need to conduct environmental testing if a worker has tested positive in a food facility because there is currently no evidence of food or food packaging being associated with transmission of COVID-19. We do not believe there is a need to conduct environmental testing in a food facility setting for the virus that causes COVID-19 for the purposes of animal food safety.

Cleaning and sanitizing surfaces such as with more frequent cleaning and sanitation schedule is a better use of resources than testing to see if the virus is present. Now just a few more points on questions the FDA has received on what to do if a worker tests positive.

As Dr. Schell mentioned earlier, FDA does not anticipate that animal food products would need to be recalled or withdrawn from the market because COVID-19 as there is currently no evidence to suggest transmission through animal food or animal food packaging.

Regarding facility closure, if a worker tests positive, you will need to follow protocols set by local and state health departments which may vary depending on the amount of community spread of COVID-19 in a given area. These decisions will be based on public health risk, a person-to-person transmission, not based on food safety.

Now I'm going to turn the program over to Mr. Michael Rogers to discuss updates on foreign and domestic infections.

Michael Rogers:

Thank you and good afternoon, everyone. My name is Michael Rogers and I am the Assistant Commissioner for Human and Animal Food Operations in FDA's Office of Regulatory Affairs and I oversee the portfolio of the

organization that conducts the inspections and investigations of farms that manufacture human and animal foods as well as feeds and farms.

I'd like to give you a sense of what the industry should expect to see for the foreseeable future related to our current approach for inspections in the domestic and foreign arena that complement the recommendations from the White House, the Department of State's Foreign Travel Warnings, the CDC and some of the local social distancing measures being adopted by many of the states to reduce the community spread of COVID-19.

So regarding inspections, the FDA has issued statements that outline our current approach for domestic and foreign inspections that ensures the continued safety of imported animal food and animal food produced in the United States as well as takes into account the safety and well-being of our workforce and the employees across the animal food industry.

So I'll draw your attention to recent statements by our FDA Commissioner Dr. Stephen Hahn, one on March 10th that addressed farm inspections and another on March 18th covering inspections in the domestic arena and have posted on FDA's Internet site.

So presently for all inspections - domestic and foreign - for all programs, we have postponed all domestic and foreign routine surveillance inspections of firms that manufacture human and animal foods and farms and we're only focusing-on those inspections that are considered as mission-critical when there is a potential threat to public health, human or animal.

And provided that they can be accomplished in a safe manner for our staff, their families and industry. It is also important to mention that we have been getting this mission-critical work done in a variety of program areas.

Some examples of inspections that would meet that mission-critical threshold include inspections and follow-up to an animal food that was shown to be causing death or illnesses, following-up on a Class 1 recall and in some cases conducting inspections at firms with a poor regulatory track record when it comes to animal food safety. I'll refer to those as compliance follow-up inspections.

We plan to revisit this approach on a periodic basis but we do not plan to proceed with routine surveillance inspections until this crisis has passed. We're also aware that many firms are taking into account the local and state measures to reduce the community spread of COVID-19 and our approach for domestic inspections should help reduce the burden on industry during this time as well.

We have received some comments from industry regarding if this is the approach that the states are taking for the inspections that they conduct and I can say that this is the approach that the states are following for the inspections that the states conduct for FDA under contract and partnerships.

We also go recognize that the states conduct many inspections outside of this process and some are solely under the state's jurisdiction, for example intrastate facilities. We would however expect that the states would be using the same mission-critical criteria to conduct this work as well as take into account the measures within their state to reduce the spread of COVID-19.

During this time while we're only focusing on that mission-critical and while many of our workforce are following shelter-in-place restrictions within their states, our efforts to continue to protect the public health continue.

For that routine work, we will be initiating what we're calling an enhanced remote official establishment inventory assignment that is focused-on contacting registered firms remotely, identifying who we are through a standard script and it's really focused-on validating the information that we have on file about firms as well as get a sense of what they're operating status is.

We also plan to share with firms how to access the latest information that the FDA has posted for COVID-19 as well as direct them to a set of questions and answers that have been developed.

We have implemented one change to our procedures for domestic inspections that we will conduct again only those mission-critical inspections and that is that we plan to pre-announce all of our domestic inspections. As you are aware, the majority of our inspections in the domestic arena are unannounced and we're taking this approach at this time to make it easier on industry to promote efficiency as well as help identify the operating status of firms that we plan to inspect.

Let me close by saying that we and I'll say the regulators and the industry are all in this together to achieve our shared vision for safe animal food and I don't think it's an overstatement when you think about the fact that we're all working from home. Our kids are not attending school.

We've seen disruptions to our vacations and graduations. We've seen the impact in our communities and with our neighbors and we're all quite frankly anxious about the unknowns related to this global pandemic so from that standpoint I can't think of a time when that statement was more relevant so we are in fact all in this together.

I'll also add that the safety of the animal food supply is a shared responsibility between the regulators and industry and a key assurance is the fact that the preventive controls for animal food (pool) provides the platform for safe animal food and preventing hazards and emphasizes the need to rely on animal food safety plans.

You know, during this period quite frankly I think we'll be leveraging even more as well as the industry has to ensure that the animal food supply was is safe while we at the FDA do our part. You should know that FDA will be doing all that we can and we know that industry will as well to accomplish our shared goal of ensuring that the animal food supply is safe.

You should know that the animal food is safe and will continue to be with all of our combined efforts. Thanks for your time and I'll turn this back over to our operator and I'll be available to address your questions later. Thank you.

Steve Solomon:

This is Steve Solomon. Again I think I'll close-out on that before we go to Qs and As so thank you, Michael. Well put. Before we start our question-and-answer session, let me once again thank all my FDA colleagues for the good information you've provided today and Michael when we reiterated, this is a critical time for all of us and we at the FDA appreciate all that you and the industry are doing to ensure the safety and security of animal food.

I also want to mention that while FDA including CVM are devoting significant resources to COVID-19 response, we want you to know at this time we're continuing a lot of our normal business functions and still operating. Our complaint and emergency response team and our Division of Compliance is ready to respond to any animal food outbreak or (unintelligible) issue.

Our premarket animal food review process including review of food additives, (unintelligible) definitions is fully operating and reviewing submissions and we're continuing our hiring informed boarding initiative with the funds we received for Fiscal Year '20.

CVM also continues to work on drug approvals and post-market animal drug surveillance and the client's issues. They're also monitoring and taking actions against fraudulent products being marketed to be effective against or to treat or to prevent COVID-19 in both humans and animals.

As I mentioned at the beginning FDA is part of a whole-of-government response. Overall leadership with government coordination is now with the Federal Emergency Management Agency or FEMA. Just about every government agency has an emergency operation center working on this issue.

FDA's Website points you to where information on COVID-19 is posted, how to direct questions to a Website for our partners from USDA, CDC and other agencies. Let me turn the call back to our moderator Siobhan Delancey who will give you more details and resources to help you and she'll help us with the question-and-answer portion of the program. Thanks for your attention today. Siobhan?

Siobhan Delancey: Thank you, Dr. Solomon. In a few minutes we'll start the question-and-answer session. Right now operator can you let participants know how they can enter the queue to ask questions and then I will go over the resources that are available?

Coordinator: Certainly, thank you. If you would like to ask a question, please press star 1.

You will be prompted to record your name and your affiliation. Please

unmute your phone when recording your information and to withdraw your question, press star 2. Once again to ask a question, it is star 1.

Siobhan Delancey: Thank you and while we're waiting for the callers to enter the queue, here is some additional information on resources. If you are experiencing issues regarding your supply chain including ingredients, packaging and personal protective equipment, delivery of goods or business continuity, please contact the FEMA national business emergency operation center at <a href="mailto:nbeoc@fema.dhf.gov">nbeoc@fema.dhf.gov</a>.

This is a 24/7 operation and they can assist in directing your inquiry to the proper contact. Similarly should you contact FEMA if you're having problems with transportation or moving food or getting food through areas that have been post quarantine, CVM has received a few questions on transportation concerns and that's forwarded then to FEMA.

And FDA also has a wealth of resources on its main coronavirus page at fda.gov/coronavirus. CVM also has a coronavirus page for questions that are specific to animal foods, animal drugs and animal safety and this can be accessed through the banner on the main CVM page at fda.gov/animal-veterinary.

Much of the information presented here on the call today is found currently on FDA's Website including in our FAQs. Please check the FAQs frequently to see if your question has already been answered. You may want to look at both the human food FAQs and CVM's page for animal food.

If your question is not answered in the FAQs, the best way to ensure your animal food safety questions are getting through to FDA. (Unintelligible)

miss them via e-mail to <a href="mailto:askcvm@fda.hhs.gov">askcvm@fda.hhs.gov</a>. Operator, we're now ready for our first question.

Coordinator: Thank you. Our first question comes from Cole Harrington with Harrington

Films. Your line is open.

Cole Harrington: Hello. I'm asking what is FDA guidance and how does it differ legally than in

FDA regulation or rule that was passed in accordance with the Administrative

Procedures Act. You guys mentioned guidance several times on the phone

call so I'd just love to have clarity, please.

Siobhan Delancey: Can you tell me how your question is related to COVID-19?

Cole Harrington: You mentioned guidance in COVID-19 on the conference call.

Siobhan Delancey: Yes, we're here today to discuss guidance that is specific to COVID-19.

Your question does not pertain to COVID-19, we'll go to the next caller.

Cole Harrington: Correct, so what is ...

Siobhan Delancey: Operator, could we have the next caller please?

Cole Harrington: ... wow. I'm asking what COVID-19's guidance is and how that differs

within regulations. That's a pretty simple question. Could you help me?

Siobhan Delancey: Yes, all of our guidances are listed on the main coronavirus page once again that is fda.gov/animal-veterinary and operator, please we'll take the next

question.

Coordinator: Thank you. Our next question is from Sheea Rogers with House-Autry Mills.

Your line is open.

Sheea Rogers: Be an issue with taking temperatures for each employee. Is that like an

OSHA issue or could we take the temperatures of the employees to ensure that

they're okay before starting work? Hello?

Jenny Murphy: This is Jenny and I'll take a crack at that response. I believe those are

probably local and state requirements and not specific to FDA requirements. I

would check the CDC guidelines for employee, for businesses that have

operations and then check with your local and state health department on what

the specific requirements are for your region. There have been reports I

believe, I know it's harder to find those, the you know, touch thermometers

but I would contact your local and state agency for that is that's their

guidance.

Sheea Rogers: Thank you. Siobhan, I think that's it for me, if we want to take the next

question.

Coordinator: Once again to ask a question, please press star 1. One moment.

Siobhan Delancey: And again we do have several resources that are available. If you missed

some of the Websites that were listed today, or you have additional questions,

you can send those to <u>askcvm@fda.hhs.gov</u> and thank you for joining today's

call. A recording and transcript will be posted to FDA's Website in the next

few days and again if you have additional questions or need more information,

please send that request to <u>askcvm@fda.hhs.gov</u>. At this time operator we'll

go ahead and close the call. Thank you to everyone for joining.

Coordinator: Thank you for your participation. You may disconnect at this time.

**END**