

RICHARD L. FRANK  
ARTHUR Y. TSIEN  
STEPHEN D. TERMAN  
MARSHALL L. MATZ  
MICHAEL J. O'FLAHERTY  
DAVID L. DURKIN  
BRETT T. SCHWEMER  
TISH E. PAHL  
EVAN P. PHELPS  
GARY H. BAISE  
FREDERICK H. BRANDING\*  
BRUCE A. SILVERGLADE  
JOLYDA O. SWAIM  
STEWART D. FRIED  
ROGER R. SZEMRAJ  
EDWARD J. FARRELL  
ELLIOT BELLIOS  
LADD WILEY  
JOHN G. DILLARD  
J. MASON WEEDA\*  
KRISTEN L. O'BRIEN



OLSSON FRANK WEEDA TERMAN MATZ PC

2000 PENNSYLVANIA AVENUE NW  
SUITE 3000  
WASHINGTON, DC 20006

(202) 789-1212 • FAX (202) 234-3550  
WWW.OFWLAW.COM

**John G. Dillard - Principal**  
**Direct (202) 518-6349 / jdillard@ofwlaw.com**

DARREN H. WEBB\*

COUNSEL  
ANDREW S. M. TSUI\*

OF COUNSEL  
KENNETH D. ACKERMAN  
NANCY A. NORD  
EDWARD R. TEITEL, MD, JD\*  
PARKER DOUGLAS\*

SENIOR POLICY ADVISORS  
JOHN R. BLOCK  
JAY VROOM  
ELIZABETH H. STOWER  
MOLLY S. O'CONNOR

SENIOR SCIENCE ADVISOR  
NINA V. FEDOROFF, PhD

SENIOR TECHNICAL ADVISOR  
J. J. CAPONE, MS, PhD

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## **MEMORANDUM**

April 3, 2020

### **BY ELECTRONIC MAIL**

FROM: Olsson Frank Weeda Terman Matz PC

RE: COVID-19: Food Industry Update

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OFW is continuing its efforts to provide timely updates on the actions of food-related regulatory agencies in response to the SARS-CoV-2 (COVID-19) pandemic caused by the coronavirus.

Below is a summary of the statements provided by relevant federal agencies regarding COVID-19 as well as some recent regulatory developments taken in response to the outbreak.

### **U.S. Department of Agriculture Food Safety and Inspection Service (FSIS)**

#### **Leadership – Industry Conference Call (4/1/20)**

On April 1, 2020, FSIS leadership hosted a conference call for industry to provide an update on FSIS's response to the COVID-19 outbreak. Moving forward, FSIS will be hosting these calls every week at 1 PM for the duration of the outbreak.

#### **Inspection Matters**

Administrator Paul Kiecker opened the meeting by extending thanks to the industry for working with FSIS to keep meat and poultry production moving forward under difficult circumstances.

Mr. Kiecker said he welcomes ideas and suggestions for keeping production going during the pandemic, but he asked that companies think through any proposals in a HACCP lens. The more research that an establishment can do to support their proposal, the easier and quicker it will be for FSIS to approve a plan.

Next, Mr. Kiecker discussed issues regarding the availability of inspectors during the COVID-19 outbreak. He emphasized that the agency is advising inspectors to stay home when they are sick. FSIS leadership is passing along COVID-19-related guidance through emails and weekly town hall meetings. Of note, FSIS has updated their guidance regarding face masks. While FSIS is not requiring inspectors to wear face masks, inspectors may choose to wear their own. Also, if an establishment requires an inspector to wear a face mask, inspectors are expected to comply.

Mr. Kiecker noted that FSIS has been taking steps to ensure the agency can meet inspection needs. During the past week, Consumer Safety Inspectors, Front Line Supervisors, and headquarter employees have been performing inspections as needed. The agency also has more reserves that it can call upon.

He acknowledged there will be more difficult weeks ahead, but encouraged everyone to keep lines of communication open, especially in instances where there has been an employee in an establishment that has tested positive. He noted that he heard from several sources that companies were concerned that if they reported an instance of a sick employee to inspectors that the establishment would be shut down by FSIS. He reiterated that FSIS will not be shutting down establishments because someone reported a positive test. He also noted that local health authorities should be notified so that they can provide guidance on how to protect other employees in the establishment.

Mr. Kiecker also requested that very small establishments could help out in preserving inspection resources by speaking with their inspectors to determine if there are ways to schedule slaughter activities such that slaughter requiring inspection (as opposed to exempt custom slaughter activities) is conducted one or two days a week. This would free up the inspector to work in other establishments on the days when inspection is not required.

Dr. Phil Bronstein (Assistant Administrator of the Office of Field Operations ) warned that there may be staffing issues in higher risk areas (e.g., New York). While the agency would normally have inspectors travel from other regions to fill temporary gaps, inspectors traveling to high risk areas will be required to quarantine for 14 days once they return, which would hinder their availability for inspection.

### Questions

FSIS leadership fielded several questions from industry participants:

- *What are the current recommendations for establishments if employees notice an inspector is exhibiting symptoms (e.g. coughing, looking unwell)?*
  - Establishment management should notify the inspection supervisors onsite or reach out to the District Office if they notice an ill inspector. Likewise, FSIS inspectors will notify plant management if they observe employees showing symptoms.

- If inspectors need to leave mid-shift because they are experiencing COVID-19 symptoms, FSIS instructions are for the Inspector-in- Charge to address staffing with the inspectors currently in the establishment. If that is not possible, the agency will make plans to replace the inspectors as soon as possible.
- *If an establishment cuts back, or ceases, production, will they lose the ability to have inspection once they are ready to return to normal production levels?*
  - FSIS has no plans to reposition permanent inspection positions – the agency will have the same level of coverage as it did previously.
- *How should an establishment handle cleaning and disinfection when there is a positive employee? Some of the [guidance from CDC](#) recommends opening outside doors and windows to increase airflow – this is not realistic in a production environment. Is this a requirement for FSIS?*
  - Establishments are not required to ventilate areas where a sick employee has worked. The establishment’s SSOPs and HACCP plan should be used to determine how to undertake cleaning and sanitation activities. FSIS also recommends that establishments contact their local health authorities for instruction.
  - Dr. Kis Robertson Hale (Deputy Assistant Administrator of the Office of Public Health Science) recommended that establishments follow the spirit of the CDC guidance by cleaning and removing organic matter thoroughly and focusing on areas where the sick individual was present.
  - Dr. Hany Sidrak (Deputy Assistant Administrator of the Office of Field Operations) noted that an establishment’s approach will depend on their facility and where the sick individual worked. He noted that researchers are seeing good results from disinfectants and that the virus is not terribly hardy.
- *Who do I notify if I intend to change my production schedule?*
  - Whatever methods/communications channels are normally used to communicate schedule changes should be used. This would typically be with an in-plant supervisor.
- *If CDC recommends that everyone wear face masks/coverings, where will inspectors get their masks?*
  - Mr. Kiecker noted that FSIS will evaluate any guidance changes from CDC. He said the agency will determine what types of masks are appropriate and take steps to procure the masks. He left open the possibility that FSIS would require establishments to provide masks for the inspectors.
    - In a follow-up comment, one participant asked that Mr. Kiecker request that food manufacturers receive consideration in receiving masks from the federal stockpiles after health workers are addressed because companies are not presently able to access masks.
- *What do we do if an inspector refuses to submit to a forehead temperature reading?*

- Dr. Bronstein said that establishment management should contact an inspection supervisor immediately if an inspector refuses to submit to a forehead temperature screening. He also noted that he understands plants are seeking out alternatives to forehead thermometers due to shortages, but at this time they would only allow forehead thermometers.
- Dr. Bronstein also noted that some establishments are evaluating using infrared cameras to measure temperature. These can allow temperatures to be evaluated without an individual getting close to employees or inspectors. He noted that some inspectors may take issue with appearing before a camera and establishments may want to have a forehead thermometer to use as a backup.
- *Is FSIS able to publicly share its pandemic response plan?*
  - At this point, FSIS is not planning to publicly share it, but the agency will evaluate whether to share it moving forward.

### **Constituent Update – Clarification on Temporary Labeling**

On Friday, March 27, 2020, FSIS released a [Constituent Update](#) with further clarification on the agency's exercise of enforcement discretion with respect to nutrition information on products that were originally labeled for foodservice that are now being re-directed to retail sales (this action was originally announced in a [March 23, 2020 Constituent Update](#)). FSIS will not require that establishments submit applications for temporary label approval if the only defect on the product label is that it does not include nutrition facts.

In the original announcement, FSIS stated that, with respect to products labeled for foodservice at a federal establishment, the enforcement discretion only applied to products labeled on or before March 23rd. However, after receiving feedback, FSIS has clarified that establishments can continue to produce products for retail using foodservice labeling (e.g., missing nutrition facts) until May 26, 2020. FSIS expects establishments to use this time to update their labels if necessary.

### **Food and Drug Administration**

#### **Updated FAQ Guidance**

The U.S. Food and Drug Administration (FDA) has updated its [FAQ guidance](#) for the food industry with respect to COVID-19. Some of the responses relevant to food and feed manufacturers is included below:

- *A worker in my food production/processing facility/farm has tested positive for COVID-19. What do I need to do to continue operations while protecting my other employees?*

All components of the food industry are considered critical infrastructure and it is vital for the public health that they continue to operate.

If an employee is confirmed to have COVID-19, employers should inform fellow employees of their possible exposure to COVID-19 in the workplace but maintain confidentiality about individual employees' identities. Ill workers should follow the CDC's [Steps to help prevent the spread of COVID-19 if you are sick](#).

Food production/processing facilities/farms 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. These decisions will be based on public health risk of person-to-person transmission – not based on food safety.

For food safety, food facilities should be vigilant in their hygiene practices, including frequent and proper hand-washing and routine cleaning of all surfaces.

Businesses should consult the CDC's [Interim Guidance for Business and Employers to Plan and Respond to Coronavirus Disease 2019](#), which is frequently updated. The Occupational Safety and Health Administration (OSHA) also issued Guidance on [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' risk of exposure to SARS-CoV-2 (COVID-19).

The Food and Beverage Issues Alliance has developed [protocols](#) for (1) when an employee of a firm is a confirmed or presumptive case of COVID-19 and (2) when a facility employee/facility visitor/customer has been in close contact with an individual with COVID-19. This protocol is specific to food manufacturing facilities, distribution centers, and wholesale and retail outlets.

- *If a worker in my food processing facility has tested positive for COVID-19, should I test the environment for the SARS-CoV-2 virus?*

Currently there is no evidence of food or food packaging being associated with transmission of COVID-19. Therefore, we do not believe there is a need to conduct environmental testing in food settings for the virus that causes COVID 19 for the purpose of food safety. Cleaning and sanitizing the surfaces is a better use of resources than testing to see if the virus is present.

Facilities are required to use personnel practices that protect against contamination of food, food contact surfaces and packaging and to maintain clean and sanitized facilities and food contact surfaces. Although it is possible that the infected worker may have touched surfaces in your facility, FDA-regulated food manufacturers are required to follow Current Good Manufacturing Practices (CGMPs). Maintaining CGMPs in the facility should minimize the potential for surface contamination and eliminate contamination when it occurs. With the detection of the coronavirus in asymptomatic people and studies showing survival of coronavirus on surfaces for short periods of time, as an extra precaution, food facilities may want to consider a more frequent cleaning and sanitation schedule for high human contact surfaces.

- *Is FDA providing flexibility regarding the nutrition labeling of packaged food for restaurants and other businesses?*

As a result of the COVID-19 pandemic, restaurants and food manufacturers may have food not labeled for retail sale that they wish to sell at retail. The FDA has released a [guidance document to provide restaurants and other businesses with flexibility regarding nutrition labeling](#) so that they can sell certain packaged food during the COVID-19 pandemic.

### **FDA Center for Veterinary Medicine Briefing for Animal Food Stakeholders**

On March 31, 2020, FDA's Center for Veterinary Medicine (CVM) hosted a stakeholder call for the animal food industry to discuss COVID-19-related questions.<sup>1</sup> We have summarized some of the highlights of the call below:

#### Dr. Steve Solomon (Director, CVM)

- Dr. Solomon opened the call by noting that CVM is coordinating with state and local governments as well as FDA's human food counterparts in CFSAN to cooperate during the COVID-19 outbreak. They are also working with the animal food sector to deal with potential animal food or ingredient shortages to understand if there will be supply chain issues.
- Dr. Solomon also noted that CVM has received concerns from animal food facilities about shortages of disinfectants, cleaners, and personal protective equipment (PPE); they have passed on these concerns to FDA leadership.

#### Dr. Tim Schell (Director, CVM Office of Surveillance and Compliance)

- Dr. Schell opened by stating that there is no evidence that the coronavirus can be spread through animal food, and thus, CVM does not anticipate market withdrawals or recalls because animal food was produced in a facility where sick employees had worked.
- Dr. Schell also noted that there are no animal food shortages in the country. FDA is working with industry to monitor any animal food or ingredient shortages.

#### Jenny Murphy (Deputy Director for Food, CVM Office of Surveillance and Compliance)

- CVM has been working with the Department of Homeland Security (DHS) to ensure animal food workers are well-represented on DHS' list of essential critical infrastructure workforce, along with other stakeholders within the food and agriculture sector.<sup>2</sup> Ms. Murphy noted that inclusion on the DHS list of critical infrastructure workforce is not

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<sup>1</sup> A transcript of the call is available [here](#).

<sup>2</sup> Animal food is included in the food and agriculture sectors in DHS' Memorandum of Identification of Essential Critical Infrastructure Workers During COVID-19 Response, available at <https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce>.

binding on state and local governments. These governments are entitled to develop their list of essential workers (e.g., those exempt from stay-at-home orders) as they see fit.

- Ms. Murphy addressed the issue of documentation of “essential” status. She said she is aware that some employers are providing their workers with a letter explaining they are essential and attaching it to the state’s list of essential workers. However, she noted that if a company has a question on this matter, it should be directed to the state government.
- She recommended that facilities follow their CGMPs to cleaning their facility to prevent the spread of COVID-19. She noted this is the time to consider sanitizing food contact surfaces and equipment that workers may come into contact with. Facilities should be using sanitizer products identified by EPA as effective against SARS-CoV-2.
- She also recommended that facilities conduct an evaluation to identify and implement operational changes that increase employee separation (if possible) to at least six feet apart, per CDC recommendations. If it is not possible, workers should be encouraged to maintain effective hygiene practices to reduce the spread of the virus.
- If an employee tests positive, the facility should follow CDC’s guidelines regarding cleaning and sanitizing the premises. They should also follow protocols established by local and state health authorities. At this time, CVM is not recommending environmental testing for the coronavirus.

Michael Rogers (Office of Regulatory Affairs, Assistant Commissioner for Human and Animal Food Operations)

- Mr. Rogers noted that FDA has postponed all domestic and foreign routine surveillance inspections at food manufacturers and farms. FDA is only focusing on mission-critical inspections – those for which there is a potential threat to public health, human or animal. Also, FDA will be pre-announcing most onsite inspections that they conduct during the COVID-19 outbreak.
- Examples of mission-critical inspections 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. State governments are also following this approach with respect to inspections that are conducted for FDA under contract.
- FDA will revisit this approach on a periodic basis, but does not expect to re-commence routine inspections while the COVID-19 crisis is ongoing.

## **Menu Labeling Flexibility for Covered Establishments During Pandemic**

FDA has issued a guidance to chain restaurants and similar retail food establishments (“covered establishments”) that sell standard menu items covered under the menu labeling provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide flexibility regarding these menu labeling requirements during the COVID-19 pandemic. *See generally* [Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar Retail Food Establishments During the COVID-19 Public Health Emergency: Guidance for Industry \(Apr. 2020\)](#).

Specifically, to help covered establishments address temporary business practice changes as a result of the COVID-19 public health emergency, FDA does not intend to object if covered establishments do not meet the menu labeling requirements under section 403(q)(5)(H) of the FD&C Act (21 U.S.C. § 343(q)(5)(H)) and its regulation at 21 C.F.R. § 101.11 during the duration of the ongoing pandemic. The guidance is effective *immediately* and is intended to stay effective throughout the duration of this public health emergency.

FDA is aware that some covered establishments are temporarily changing business practices as a result of the pandemic. For example, some dine-in operations are switching to takeout only, which may require changes in online ordering portals and printed menus. Additionally, some of these establishments may be experiencing temporary disruptions in the food supply chain, which may lead to different menus or substitutions that could affect the accuracy of the nutrition information provided. To give flexibility to these chains covered by menu labeling requirements, FDA will not object if establishments do not meet menu labeling requirements during this public health emergency.

FDA’s menu labeling regulation essentially require that restaurants and similar retail food establishments that are part of a chain with 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items, provide nutrition information (including calorie declarations) for standard menu items on menus and menu boards.

Although already effective, comments on the guidance may be submitted to FDA in accordance with the agency’s [good guidance practices](#).

## **Department of Homeland Security**

On Thursday, April 2, 2020, the Department of Homeland Security’s (DHS) Cybersecurity and Infrastructure Security Agency (CISA) held a call to discuss the most recent developments around the coronavirus pandemic, supply chain issues, and DHS’ response. This call will be held every Tuesday and Thursday at 3:00 PM (eastern) to provide updates on the coronavirus response until further notice.

Bradford Willke, Assistant Director (Acting) for Stakeholder Engagement at CISA opened the call. He thanked everyone for calling in and noted how valuable the previous calls have been for

the government teams. He reported that callers can find numerous Go-To-Resources on the CISA Dashboard. He advised callers to go back and listen to the previous call at approximately 6:32 to 12:40 timestamp for helpful summaries. He gave updates on infection both globally (750k) and in the U.S (106k). He went on to say that the feedback given after the previous call was extremely helpful and that, as a result, he would be opening the call to questions immediately.

### Question and Answer

- The U.S. Postal Service has begun to reduce mail services. Does the CISA have an update?
  - CISA has been monitoring the supply particularly the segments serviced by FedEx and UPS to ensure distribution and understands how critical that “last mile” is in the chain. CISA asked for incidents of items not being delivered to be forwarded to them.
- The U.S. and Mexico have different approaches to the classifications of essential employees and it is affecting workers traveling between the borders. Does the CISA have any guidance?
  - At this time a Standard Work Visa is required to satisfy both requirements. The government is looking for alternatives to improve the situation.
- Are there lists of state registries of businesses that are exempted from state “stay-at-home” orders?
  - You should work through your local government officials regarding who is exempted. The National Governors Association does have great resources involving these issues.
- On a previous call there was a mention of a Food Supply Task Force being established; is there an update on that?
  - The task force is going to operate as a part of the Supply Chain Task Force and is currently being established.
- There have been conflicts between current regulations regarding essential employees and the CARES Act paid medical leave and similar employee benefits. Is there any guidance on resolving those?
  - Please report specific conflicts or incidents that are arising. The CARES Act was just enacted and the government team is looking at resolving conflicts.
- We are looking into getting PPE, particularly masks manufactured for our employees. We understand the N-95 masks are preferred. However, is there any guidance or helpful information on alternative masks or components such as cotton, 2-ply or 3-ply?
  - Reach out to the CDC and FEMA; they are in the best position to assist.
- What is the current strategy regarding PPE and its allocation?

- The government is trying not to disrupt the normal allocation of PPE in the supply chain. We are working on improving distribution by coordinating shipments and getting them onto planes versus boats to speed up supply. We are working with distributors to inform them of the hot spots of coronavirus so they can allocate their supply as needed.

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We trust this update is useful. Please let us know if you have any questions.