

Saqib: Welcome and thank you for joining today's egg products regulatory updates and how it impacts or changes imports and exports. Before we begin, please ensure you have opened the WebEx chat panel by using the associated icon located at the bottom of your screen. If you require technical assistance, please send a chat message to the event producer. To submit a written question for the panelists, please select All Panelists from the dropdown menu in the WebEx chat panel, type your question in the message box provided and press Enter on your keyboard to send it. All audio lines will remain muted until the Q&A session. We will give you instructions on how to ask questions on the audio line at that time with that, I'll turn it over to Shannon McMurtry. Shannon, please go ahead.

Shannon McMurtr...: Thank you, [Saqib 00:00:46]. Good afternoon, everyone. This is Shannon McMurtry. I'm the deputy assistant administrator for the FSIS Office of International Coordination. And I appreciate you taking time out of your busy schedule to join us this afternoon for our webinar focused on the egg products rule and talking a little bit more in depth about how the egg products final rule ... how those regulatory updates will impact exports and imports back and forth from the United States, or into the United States.

We hope that there's a lot of interest in this. We've hopefully organized what we think will be an informative and helpful presentation for you today. We look forward to your questions at the end. And certainly after the fact, if there's additional questions, we'll provide an email address where you can provide those. So with that again, welcome this afternoon. I'm going to turn it over to my colleague, Vicki Levine, in the Office of Policy and Program Development to give a brief overview of the rule to kick us off. Vicki, it's all yours.

Vicki Levine: Thank you, Shannon. Next slide, please. As Shannon said, my name is Vicki Levine and I'm a program analyst with the Regulations Development Staff. Next slide, please. Next slide, please. Thank you. So, hang on one second, everybody. Okay, sorry about that. So, let me provide you with an overview of this afternoon's webinar. First, we're going to go over amendments to the egg product inspection regulations, including general requirements, the Sanitation Standard Operating Procedure Regulations to be implemented on October 29th of this year. The Hazard Analysis and Critical Control Point Requirements to be implemented on October 31st, 2022, other egg product regulatory oversight changes to be implemented by October 30th, 2023, egg products guidance, and implementation of the final rule. Then we'll briefly talk about exports and use of the FSIS PY 200 form, and finish up with a discussion of import issues, including stamping imported egg products with the import Mark of Inspection changes, just the weight limits for small importations for importer's personal use, display for laboratory analysis, and the amount of time extended for importers to dispose of egg products identified as refused entry.

Next slide please. On February 13th, 2018, FSIS proposed to amend the egg products inspection regulations. The rule proposed to require plans to develop and implement hazard analysis and critical control point systems, HACCP, and

Sanitation Standard Operating Procedures, otherwise known as sanitation SOPs. And all sanitation requirements consistent with the meat and poultry regulations. They proposed to specify that egg products are required to be processed to be edible without additional preparation to achieve food safety, provide for generic label approval, and amend the required features. And eggs products under the rules of practice that govern administrative enforcement actions initiated by the agency. Redefine the agency's interpretation of contentious inspection, and change jurisdiction over egg substitutes and freeze dried egg products. On October 29th, 2020, the final rule was published in the federal register.

So let's discuss some of the changes to the egg products regulations resulting from the final rule. Next slide, please. For importers and exporters, relevant regulations that were amended include 9 CFR 590.200, Record Keeping Requirements, 9 CFR 590.411, Label Approval, 9 CFR 590.412, Approval of Generic Labels, and 9 CFR 590.570(B) Control Packages and Pasteurized Egg Products. Next slide, please.

FSIS has added to meet record keeping requirements to the egg products regulations. For example, persons engaged in the transporting, shipping, or receiving of any products in commerce, or holding such articles received, must maintain records documenting the date of production and quantity of egg products delivered, and sold, and to [inaudible 00:05:59], and the date of receipt and quantity of egg products purchased overseas, and from home. These records must be kept for two years and made available to an authorized representative of the secretary for official review and copying. These requirements were effective on December 28th, 2020. Next slide, please.

FSIS has revised the requirements of 9 CFR 594.11, which is the Egg Product Label Approval Regulations, to require egg products plants to comply with the label approval provisions governing meat and poultry products in 9 CFR 412.1. Only labels intended for temporary approval, labels for products exported with labeling deviations, and labels containing special statements and claims as described in 9 CFR 412.1(E) need to be submitted for approval. FSIS has revised 9 CFR 594.12 stating that plants, including official plants certified under a foreign inspection system in accordance with 9 CFR 590.910 may comply with the generic labeling regulations in 9 CFR 412.2. Under 412.2, egg products plants may use generically approved labels without submitting them to the agency, except for those labels I've mentioned above, provided the labels display all the required, mandatory features in a prominent manner, and are not otherwise false or misleading. Next slide, please.

The presence of pathogenic organisms in egg products, for example, salmonella, and listeria monocytogenes, render those products adulterated, and FSIS treats them like ready-to-eat products. When the HACCP regulations take effect, the prescriptive time temperature requirements in 9 CFR 590.570(B) will be removed and replaced with a performance standard requiring egg products to be processed such they do not require additional pasteurization ... excuse me,

additional preparation to ensure food safety. The finished product will also have to be free of detectable pathogens. [inaudible 00:08:28] that do not develop new or modified procedures under HACCP they continue to follow the pasteurization time and temperature combinations found in the food safety guidelines for egg products. Combinations in the compliance guidelines will assist small and very small businesses and identifying validated procedures. Materials are posted on the agency's website. Next slide, please.

Next slide, please. On October 29th, 2021, egg products plants will be required to develop and implement written sanitation SOPs, since they voluntarily choose to develop and implement written sanitation SOPs, before this date. Sanitation SOP requirements define the results to be achieved by sanitation, but not the specific means to achieve those results. Sanitation SOPs describe all the procedures a plant will conduct daily, before, and during operation sufficient to prevent direct contamination or adulteration of product. Plants can meet the sanitation requirements in different ways, but the required results are the same for all plants. FSIS inspectors will verify that plants are following their written SOPs. If a plant is not following a sanitation SOPs, FSIS inspectors will document the non-compliance in a noncompliance record. Next slide, please.

Next slide, please. The HACCP requirements will take effect on October 31st, 2022, two years from the date of publication of the final rule. I know that the slide says October 30th, but that is incorrect. The HACCP regulations will be effective on October 31st, 2022. HACCP is a flexible system that will enable plants to tailor their control systems to the needs of their particular plants and processes. Plants will be required to develop and implement that HACCP system for food safety that is designed to prevent, eliminate, or reduce to an acceptable level the occurrence of biological, chemical, and physical hazards that are reasonably likely to occur in the plant's process. Specifically, plants will have to develop and implement HACCP plans that incorporate controls that are necessary to produce safe egg products. Next slide, please.

Next slide, please. On October 30th, 2023, FSIS will assume regulatory authority over egg substitutes and freeze dried egg products, including those that are imported, which pose the same risks as egg products and will be inspected in the same manner, enhancing the existing food safety system. These products are similar, if not identical to currently amenable egg products, and are subject to the same food safety risks during processing. FSIS is requiring that these products being produced under FSIS inspection and jurisdiction. Next slide, please.

Products remaining under FDA jurisdiction under the new rule are imitation egg products, dietary foods, dry egg custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, French toast, sandwiches containing eggs or egg products, and cooked eggs for cooked egg products. Next slide, please.

So now, we'll talk about egg products guidance. Next slide, please. FSIS developed the food safety guidelines for egg products to help all egg products

plants meet the new regulatory requirements. It does not impose new regulatory requirements. Establishes may continue to use former regulations of safe harbors. Safe harbors are recognized procedures that had been used as scientific support for a validated HACCP system. Former regulations that can be used as safe harbors include pasteurization, cooling, freezing, defrosting, and heat treatment operations. FSIS could incorporate many of the procedures from new technology, no objection letters and waivers as additional safe harbors that establishments may use. These procedures include time temperature combinations for various egg product formulations, extended freezing times, and holding egg products for enzyme modification processes. In addition, FSIS calculated a variety of time temperature combinations for several types of [inaudible 00:13:41] egg product. Next slide, please.

In addition, FSIS has provided a Hazard and Controls Guide. This guide identifies relevant processing steps, potential hazards for each of the steps, and controls frequently used to address these hazards. This guide is not regulatory, and it's meant only to provide assistance and examples of common steps, hazards, and frequently used controls. Since this guideline only provides common steps in hazards, additional steps in hazards may be identified based on each plant's unique process. In addition, plants may identify additional controls, not included in this guide that are still valid options. Next slide. Now I'd like to turn this over to my colleague, Dawn Sprouse, to discuss implementation.

Dawn Sprouse: Good afternoon. Next slide, please. Official plants may begin operating under HACCP and sanitation SOP regulations at earlier dates, provided FSIS has verified that they are compliant with the regulations. The plant will provide written notification to the district manager that they wish to opt into either SSOPs, or HACCP and SSOP. A plant is not able to opt into HACCP only, without first implementing SSOP.s The district will then work with the frontline supervisor to review the programs and plans to determine regulatory compliance. Inspection training needs will be determined as well. Once regulatory compliance is met, a tentative date can be set for implementation. Required training for inspection personnel will also need to take place prior to implementation. Egg product plants will be staffed with CSIs, and once sanitation SOPs and HACCP are implemented by the plant, districts will then make determinations regarding placing the plant on a patrol assignment or creating a new patrol assignment. I will now turn it over to my colleague, James Chisholm, with the Office of Policy and Program Development staff.

James Chisholm: Thank you very much, Dawn. This is James Chisholm. I'm with the Import/export Policy Development staff on the export side. I'd like to point out the one caveat here with the implementation of the new final egg rule. Next slide, please. Next slide, please. With the issuance of the FSIS Directive 5030.1, it has canceled out the Directive 5040.1 for the uses of the FSIS form PY 200 egg products, or certificates. And in other words, the use of the FSIS form will no longer be utilized by OFO for official exports. Additionally, with the updated guidance in the 9 CFR 590.410, labeling requirements that are now set into place will no longer require the need of PY-200 for egg products inspection to accompany the

shipment, and for the application of government seals. However, for exports to the European Union, there is still an exception, and the requirements for those shipments to have PY-200 accompany them. For exports to the EU, establishments will now be responsible for requesting and obtaining the PY-200 to be submitted with the export documentation package that accompanies each egg product export to the EU. Next slide, please.

For EU samples, there'll still be submitted under the voluntary Egg Products Protection Program to and through AMS to the National Laboratory for Analysis. Upon receipt of the results from the laboratory analysis, IPP determines a lot of product that's available for certification. Each shipment consigned to a destination within the European Union must be accompanied by the FSIS form [inaudible 00:17:51], egg products that can hold the FSIS letterhead, and a copy of the PY-200 that identifies the lab results. This exception retains the import, and involves PY-200, and the PY-200 should be utilized by establishments to relay their sample results, until a new procedure has been agreed upon by the USDA and the EU Commission. With that, I'd like to turn it over to my colleague in the Import Department, Michelle [Kemper 00:18:16]. Thank you.

Michelle Kemper: Hello, I work with Import/export of Policy Development staff with Imports. And next slide, please. Imported egg products found acceptable upon re-inspection must be stamped with the official import Mark of Inspection US inspected and passed, as described and 9 CFR 590.940(A). The requirement is not apply to egg products imported from Canada. Important egg products were not stamped before December the 28th, 2020. Next slide, please.

The inspection legend may be placed on containers of egg products before completion of the official import inspection as described and 9 CFR 590.940(E). The official import inspection establishment must have submitted a pre-stamping procedure for egg products to the frontline supervisor for approval, and received a signed letter from the district manager approving the pre-stamping procedure. FSIS Directive 9900.3 pre-stamped the imported product is an excellent resource for information on the imported products. Next slide, please.

Imported egg products that are refused entry into the United States must be disposed of within 45 days as described and 9 CFR 590.945(A3). The amended regulation extends the amount of time allowed for disposal from 30 days. Next slide, please.

Small importations of liquid, frozen, or dried egg products for importer's personal use, display, or laboratory analysis cannot exceed 50 pounds for each type of product as described and 9 CFR 590.960. The amended regulation extends the amount of liquid and frozen egg products from 30 pounds. Next slide, please.

All conveyances containing imported liquid egg products must be sealed by inspection authorities in the exporting country as per 9 CFR 590.935(B).

Examples include bulk tanker shipments, trailers containing packaged liquid, and frozen egg products, and undenatured, and edible liquid and frozen egg products. Next slide, please.

A foreign inspection certificate is required for bulk shipments of imported unpasteurized egg products. A placard with the date of loading as described in 9 CFR 590.410(C) does not apply to bulk shipments of imported unpasteurized egg products. Next slide, please.

Okay, here we have some additional guidance that we believe is very helpful. You have the FSIS Import Compliance Guide web link there. And then we have also included the 9000 series for the export/import directives that will also be very helpful in regards to this new information. Next slide, please. And any questions about these regulations can go to Ask FSIS. And here we have the web link, as well as the phone number you may use to contact our offices. Shannon, back to you.

Shannon McMurtr...: Thank you, Michelle, and thank you to all our speakers today from the Office of Policy and Program Development for giving us a clearer picture of the implications of the egg rules relative to exports and imports. At this point in time, I think we'll turn it back over to Saqib, our moderator, and he will give some final instructions for how to open it up to questions that may be on the phone line, or coming through the chat box. Saqib, I'll turn it over to you.

Saqib: Ladies and gentlemen, to submit written questions, please select All Panelists in the dropdown menu in the WebEx chat panel, before you type your question in. And press Enter on your keyboard to send it. If you'd like to ask a question on the audio line, please press #2 on your telephone keypad. When your line is unmuted, you will hear a notification. At that time, please state your name and your question. Once again, that command on your telephone keypad is #2 for the audio line questions. Thank you.

At this time, we do not have any questions on either queue. Once again, folks, please be sure to select All Panelists in the dropdown menu in the WebEx chat panel before you type your question in. And press Enter on your keyboard to send it. If you'd like to ask your question on the audio line, please press #2 at this time. Okay, it does not look like ... We do not have any questions in either queue at the time.

Once again, ladies and gentlemen ... okay, it looks like ... Ladies and gentlemen, please be sure to select All Panelists in the dropdown menu in WebEx before you type your question. And press Enter on your keyboard to send it. For audio line questions, please press #2. It looks like we do have a question that has just come in. It reads, "I have a question about the PY-200 note on export requirements to the EU. I haven't seen the need for a PY-200 when exporting to the EU. Is that for specific egg products or categories?"

James Chisholm: This is James. Currently with the European Union, for any egg products going over to European Union, PY-200 is required documentation to show the sample results received from the National Laboratory through AMS.

Saqib: Okay, and we do not have any questions on either queue at this time. Once again, folks, please be sure to select All Panelists in the drop down menu in the WebEx chat panel before you type your question. And press Enter on your keyboard to send it. For audio line questions, please press #2 on your telephone keypad at this time. We do have another question that has come in. That is, "Are we going to get copies with the presentation with links?" I'm guessing it should read, "Are we going to copies of the presentation with the links?"

Shannon McMurtr...: Hi, this is Shannon. We're looking at potentially posting this webinar online. So, we'll either post it, or we'll look at how we can send out links to those that registered after the fact.

Saqib: Okay. The next question that has come in is the same, regardless of the slides. Folks, once again, please be sure to select All Panelists in the dropdown menu in the WebEx chat panel before you type your question in. And press Enter on your keyboard to send it. If you'd like to ask a question on the audio line, please press #2 at this time. Thank you. We do have another question that has come in. "To confirm, the exports changes have already gone into effect."

Vicki Levine: Yes, that is correct.

Saqib: Once again, folks, please be sure to select All Panelists in the dropdown menu in the WebEx chat panel before you type your question. And press Enter on your keyboard to send it. If you'd like to ask your question on the audio line, please press #2 at this time, thank you. We do not have any questions in either queue at this time. Oh, it looks like we do have a question that has come in. It reads, "Do freeze dried egg products have to be destroyed if salmonella is detected? Can it be part of the process in a product subjected to adequate lethal process?"

Vicki Levine: I can't tell you what process would be acceptable, but if freeze dried products are found to be positive, you could work with our staff or MIS, which of course the name is totally escaping me at the moment. But you would work with them to work out a process that might be able to make the products usable.

Saqib: The next question is, "Could you please provide further clarification on the export mark for packaging? Are all packages in a shipment required to carry the mark?" Folks, should I repeat that question?

James Chisholm: No, this is James. I'll see if I can't do a little bit of clarification on this, and maybe my colleagues want to step in. Currently, since FSIS took over the regulations of egg products, the CFR does state that there is a requirement for an export mark on every package. However, at this point time, it has not necessarily been applied or applicable for all exports leaving the country. So, I know that's kind of

a vague answer. However, I would pay close attention to constituent updates to see if that does change, and that there is more enforcement action on whether every package is required to bear the mark of inspection or not here in the near future.

Shannon McMurtr...: And this is Shannon. I'll just add to that to say it's always advisable to consult the Export Library for any additional or nuanced instructions for a particular market, as well as work with your importer. We do our very best to keep track of foreign import requirements, and line them up with our requirements, our domestic and our export requirements. But it is always useful to check with your importer to make sure we've captured all the requirements, and you're doing what's necessary to get your product into a foreign country.

Saqib: Okay. The next question is, "Foreign companies and countries must be equivalent to FSIS regulations before being able to export egg products to the US Connect?"

Shannon McMurtr...: This is Shannon, and I think that's correct. Yes, I think it was supposed to be Correct rather than Connect. But yes, foreign countries must be determined equivalent. We don't determine individual companies or establishment as equivalent. We determined the foreign countries as equivalent. And then, they certify the individual establishments to us, and we post the eligible countries, and eligible establishments on our Import Library website. So yes, they must be equivalent before they can send product to the United States for import.

Saqib: Okay, next question is, "Is there any change to the use of FSIS Form 9065 EP for exports?"

Shannon McMurtr...: James, do you have that one?

James Chisholm: No, there has not, that I know of, anything for exports has changed their identifies on the 9065. No new form has been updated, or [inaudible 00:32:05].

Saqib: Okay. With that, there are no further questions at this time. Ladies and gentlemen, once again, please be sure to select All Panelists in the dropdown menu in the WebEx chat panel before you type your question in. And press Enter on your keyboard to send it. If you'd like to ask your question on the audio line, please press #2 on your telephone keypad. When your line is un-muted, please state your name, and your question. Once again, that command is #2 on your telephone keypad for audio line questions. Thank you. We do not have any further questions at this time.

Shannon McMurtr...: Okay then, this is Shannon McMurtry. If there's no other questions, I'll just say thank you to everybody for taking time out this afternoon to participate in this webinar. We appreciate it, and we hope that this was informative and helpful to those of you dealing with the export and import of egg products. I don't have



anything else, Saqib, unless you want to run through any final announcements for wrapping up the call.

Saqib: That is it. Ladies and gentlemen, with that, that concludes our conference. Thank you for using AT&T Events Services. You may now disconnect.

Shannon McMurtr...: Thank you.