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Food Safety and Inspection Service

1400 Independence Avenue, SW. Washington, D.C. 20250

TO: See Distribution

The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that meat, poultry, and egg products imported and sold in U.S. commerce are safe, wholesome, and correctly labeled and packaged. FSIS enforces, among other laws, the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.). As a possible result of the impact that highly-pathogenic avian influenza (HPAI) has had on U.S.-sourced egg products, FSIS has seen a recent increase in egg products offered for import into the United States from ineligible sources. FSIS also has seen an increase in egg products labeled with incorrect product names that are not eligible to be imported into the U.S. but that somehow entered this country. This letter provides information to each foreign country's Central Competent Authority (CCA) on:

- egg products under FSIS jurisdiction;
- foreign country eligibility;
- plant eligibility;
- misbranded egg products;
- · the U.S. import process; and
- enforcement provisions for ineligible or misbranded egg products that arrive at the borders of the United States or enter U.S. commerce.

Foreign countries that export egg products to the United States are required to establish and maintain inspection systems that are equivalent to those of the United States. FSIS audits eligible foreign inspection systems and reinspects all egg products offered for import to ensure that the products are wholesome, not adulterated, and properly labeled.

Egg products under FSIS jurisdiction: FSIS regulations (9 CFR 590.5, 590.570, and 590.575) identify egg products under FSIS jurisdiction, including:

- Egg albumin, dried;
- Egg albumin other than dried;
- Dried egg whites;
- · Pasteurized Frozen Whole Egg with citric acid;
- Plain Pasteurized Frozen Whole Egg without added ingredients;
- Pasteurized Liquid Yolk with 10% salt;

- Pasteurized Frozen Scrambled Egg Mix with Whole Egg and pepper, starch, and dried milk;
- Frozen Yolks with 10% sugar added;
- Frozen Egg Whites with whipping aids (such as sodium sulfate or triethyl citrate);
- Pasteurized Enzyme Modified Dried Egg Product with Egg Yolks and xanthan gum and citric acid to preserve color, and less than 1% silicon dioxide as an anticaking agent and phospholipase;
- Spray Dried Albumin; and
- Spray Dried Egg Whites with calcium citrate and salt (or other added ingredients).

The list above is not all inclusive. Questions about whether or not FSIS has jurisdiction over egg products not listed in this letter should be referred to FSIS's Office of International Coordination, at internationalcoordination@fsis.usda.gov, which will direct the inquiry to the appropriate egg product subject matter experts in FSIS.

Foreign Country Eligibility: FSIS regulates the importation of egg products, which must come from countries that have food safety systems for egg products that are determined by FSIS to be equivalent to that of the United States (21 U.S.C. 1046, 9 CFR 590.910(a)). There are two countries authorized to export egg products to the United States, Canada and The Netherlands.

To determine whether a country maintains an equivalent inspection system, FSIS conducts a thorough document review of that country's relevant laws, regulations, and other official publications and one or more on-site audits of the country's relevant inspection system. If FSIS concludes that the system is equivalent based on that review, FSIS proposes to list the country in the egg products inspection regulations as eligible to export egg products to the United States. FSIS then requests and evaluates the comments it receives in response to the proposal and determines whether to finalize a determination that the country's system is equivalent. If FSIS concludes that the country's system is equivalent, the Agency publishes a final rule listing the country in FSIS's regulations as eligible to export egg products to the United States. More information regarding the equivalence process can be found at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence/equivalence-process-overview.

Plant Eligibility: Plants that are eligible to export egg products to the United States must be certified by the foreign country's CCA as being in compliance with all equivalent U.S. requirements.

Misbranded Egg Products: For FSIS-regulated egg products, the use of the generic term "Bird" to identify the type of poultry from which the egg products originated from is unacceptable, and product under FSIS jurisdiction labeled with that term will be considered misbranded. If the egg products are processed from the shell egg of a turkey,

goose, duck, or guinea (not domesticated chicken), then the name of the type of poultry must be included as part of the common or usual product name (e.g., Pasteurized Frozen Whole Goose Egg with citric acid). If the egg products are processed from the shell egg of a domesticated chicken, the word "egg" must appear as part of the common or usual product name, but the word "chicken" need not appear.

FSIS has identified the following egg products descriptions that have appeared on ineligible or misbranded imported egg product labels. These egg product descriptions are not a recognized common or usual name for any egg products that are under FSIS jurisdiction, and, thus, they are neither acceptable, nor can they be used, to label, invoice, or certify egg product shipments to the United States. Each foreign country's CCA needs to take steps to prevent shipment of these and other ineligible or misbranded products to the United States.

- Bird Egg Yolks Dried (because the word "bird" does not specify the type of poultry)
- Bird Egg Yolk Other than Dried (because the word "bird" does not specify the type of poultry)
- Bird Egg Not in Shell Dried, Not Yolk (because the word "bird" does not specify the type of poultry)
- Bird Egg Not in Shell Not Dried (because the word "bird" does not specify the type of poultry)
- Not Dry/Yolk (because the type of poultry, if not produced from chicken eggs, and an accurate and acceptable product description is not specified)
- Food Preparation product (because FSIS determined that the product was an FSIS-amenable egg product based on the product formulation)
- Protein Concentrates and Textured Protein Substances (because FSIS determined that the product was an amenable egg product based on the product formulation)

Import Process: Foreign inspection certificates issued by the CCA of the exporting country are required to accompany all egg products shipments to the United States. Upon arrival at the designated FSIS-approved inspection location, FSIS inspection program personnel reinspect all egg product shipments before they are allowed into U.S. commerce. Every lot of product is given a visual inspection for appearance and condition, is checked for certification and label compliance, and is subject to FSIS sampling for analysis. Shipments that pass reinspection are allowed to enter U.S. commerce and are treated as domestic product.

USDA's Animal and Plant Health Inspection Service (APHIS) may apply animal disease restrictions to some egg products. These egg products would require an APHIS Veterinary Service permit before FSIS inspects the product. Importantly, imported egg products that require an APHIS Veterinary Service permit for entry into the United States must still be reinspected by FSIS at an approved inspection location.

Egg substitutes, imitation eggs, and similar products that are not considered egg products are under the jurisdiction of the Department of Health and Human Services' Food and Drug Administration.

Enforcement Provisions: FSIS refuses the entry of egg product shipments presented for import reinspection that are ineligible, misbranded, or otherwise in violation of the EPIA, as well as the implementing regulations for the Act (9 CFR 590.925). Furthermore, beginning on May 1, 2016, FSIS may request that the importer of record voluntarily recall from U.S. commerce any egg product that is ineligible or misbranded and that inappropriately entered the United States after that date. FSIS will notify CCAs of such an action.

Through this letter, CCAs are notified that FSIS is taking new steps to better ensure that egg products are not adulterated, ineligible, or misbranded upon entry into the United States. FSIS looks forward to working with foreign governments, industry, and all interested stakeholders in implementing these changes.

Sincerely.

Jane H. Doherty

International Coordination Executive Office of International Coordination

¹ The FSIS amenable egg product component of the exempted food must still come from an approved source (*see* http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/imported-food-products-containing-a-small-amount-of-meat-poultry-or-processed-egg-product-ingredients) or eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs.

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