



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2020-0016]

Availability of FSIS Import Guidance

AGENCY: Food Safety and Inspection Service, Agriculture (USDA).

ACTION: Notice of availability and response to comments.

SUMMARY: In July 2017, FSIS published and requested comment on guidance for importing meat, poultry, and egg products into the United States. FSIS is announcing updates to this guidance and responding to comments received on the guidance. FSIS intends for this guidance to help U.S. importers, customs brokers, official import inspection establishments, and other interested persons understand and comply with FSIS import requirements. The guidance represents current FSIS thinking, and FSIS will update it as necessary to reflect comments received and any additional information that becomes available.

ADDRESSES: A downloadable version of the FSIS import guidance is available to view and print at <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/guidelines>. No hard copies of the compliance guideline have been published.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by

telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) is the public health regulatory agency responsible for ensuring that domestic and imported meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged. FSIS inspects imported meat, poultry, and egg products under the authority of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (EPIA) (15 U.S.C. 1031 et seq.). Imported meat, poultry, and egg products must originate from eligible countries and from establishments or plants (for egg products) that are certified to export to the United States (21 U.S.C. 620, 466, and 1046). A country becomes eligible following an equivalence determination process completed by FSIS in coordination with the country's central competent authority (CCA). Foreign establishments or plants become eligible when the CCA certifies to FSIS that the establishments or plants meet requirements that are equivalent to FSIS requirements. All imported shipments of meat, poultry, and egg products must be presented to FSIS for inspection, with certain exceptions, as detailed in the guidance (i.e., a meat, poultry, or dried egg

products shipment that does not exceed 50 pounds, or a liquid egg products shipment that does not exceed 30 pounds, for personal consumption only).

Updated Guidance

On July 7, 2017, FSIS announced the availability of and requested comments on import guidance that summarized existing requirements for importing meat, poultry, and egg products into the U.S. and best practices for complying with those requirements (82 FR 31549). FSIS has updated the guidance based on comments received. Specifically, FSIS revised and reorganized a section on industry supply chain best practices; clarified approaches to levels of reinspection; added information about generic labeling approvals, food defense, slaughter dates on import certification, and barcoding; and made minor editorial changes to improve the guidance's clarity.

This guidance represents current FSIS thinking, and FSIS will update it as necessary to reflect comments received and any additional information that becomes available. The updated guidance is posted at:

<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/guidelines>.

Comments and Responses

FSIS received public comments from one trade association and two non-profit consumer groups. The following is a summary

of the comments and the Agency's responses.

Product Lot Grouping & Certification

Comment: The trade association asked that FSIS use an updated FSIS import application and "physical manifest" as a cross-reference when lots on the foreign inspection certificate and import inspection application misalign.

Response: FSIS regulations require that foreign inspection certificates accompany each consignment of meat, poultry, or egg products offered for import into the United States and thoroughly identify the product (by species, process category, number of units, lot weight, etc.) certified by the foreign CCA as meeting all applicable FSIS requirements (9 CFR 327.4, 381.197, 557.4, and 590.915). Thus, the foreign inspection certificate is the primary lotting reference for FSIS import inspectors. FSIS acknowledges the importance of complete import documentation for meeting all commercial and government requirements, but the import inspection application and a "physical manifest" are not adequate to rectify misaligned lotting.

Barcoding

Comment: A trade association requested that the guidance reference the use of barcodes as an alternative identifier when shipping marks are missing or illegible and recommended that the guidance include a link to FSIS instructions on this topic.

Response: FSIS agrees with this recommendation. The use of barcodes is currently an option when shipping marks are missing or completely illegible and FSIS has updated the guidance to note this option. To use the barcode option, countries must first submit a barcoding plan to FSIS to be approved for this process, so that FSIS can verify that imported products meet requirements. FSIS is currently engaging with countries and industry to develop and verify alternative identification (e.g., barcode) processes. FSIS is also implementing a pilot to apply the official import mark of inspection to imported product (currently for raw meat shipments exported to the United States from participating establishments in Australia) using barcodes instead of shipping marks on shipping containers.

Level of Reinspection (LOR) applicability

Comment: The trade association requested clarification on whether levels of reinspection (LOR), such as normal, increased, or intensified, apply to lab sampling only, or other types of inspection (TOI) also (physical exams, container condition, etc.).

Response: Normal, increased, and intensified LORs can apply to any TOI. FSIS clarified this in the guidance.

Sampling

Comment: The trade association asked whether imported products shipped after a related shipment fails a specific lab

analysis would be subject only to intensified sampling for the same lab analysis, or the full range of TOI (e.g., product exam, condition of container, sampling, etc.).

Response: Future associated shipments are subject only to the specific TOI failed in the original shipment. FSIS has clarified this in the guidance.

Generic Labeling

Comment: A trade association and non-profit consumer group requested guidance about how generic labeling approval (i.e., labeling that does not need to be submitted to FSIS for review) would be applied to imported shipments.

Response: Any entity responsible for designing or modifying meat or poultry labels may use generic approval of labels, including foreign exporters and U.S. importers, provided the label is eligible for generic labeling approval. In August 2017, FSIS published a compliance guide on generic labeling to assist industry in realizing the efficiencies of generic labeling. The guideline is available at <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling>. FSIS also held a webinar for trading partners, foreign exporters, and U.S. importers in February 2018 to provide guidance on generic labeling (<https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newletters/constituent-updates/archive/2018/ConstUpdate011218>).

FSIS updated the import guidance to indicate that the generic labeling approval process applies to labels from foreign establishments, provided the label is eligible for generic labeling approval.

Tray Packs and Palletized Shipments

Comment: A non-profit consumer group requested information on labeling requirements for imported tray packs and single pallets in the guidance document, and a trade association requested that FSIS consider expanding its policy of permitting application of shipping marks to the outside of pallets in certain cases to include shipments destined for processing as an intact unit. The trade association noted that, currently, palletized, consumer-packaged, fully marked and labeled products may be presented with the shipping mark and shipping container label applied to the outside of the pallet, rather than to individual tray packs or cartons, when only one type and size of product is presented as a lot, and the entire pallet will be distributed to retail or the end user as an intact unit.

Response: This proposal is currently under consideration within FSIS but is outside the scope of this guidance. Imported tray packs are subject to immediate container labeling requirements found in 9 CFR 327.14. Pallets are subject to labeling requirements if the pallets themselves are the outside or shipping container (e.g. shrink-wrapped pallet) of the

shipment (9 CFR 327.15, 9 CFR 301.2). Regarding an expansion of the policy allowing the shipping or identification mark and label on pallets of the products referenced above, FSIS is considering the proposal for the shipping or identification mark and label to be applied to the outside of pallets of product destined for further processing as an intact unit.

Cooked meat/poultry requirements

Comment: A non-profit consumer group requested that FSIS include requirements for imported cooked meat and poultry from countries with exotic animal disease outbreaks in the guidance document.

Response: Animal disease restrictions are under the jurisdiction of the Animal and Plant Health Inspection Service (APHIS) and can be found in 9 CFR part 94. Since announcing the draft import guidance, FSIS has published a new Import Library on its Web site. The Import Library provides links to country-specific pages for equivalent countries that can export to the United States detailing the eligible species, process categories, product categories, and product groups the country can export. The information detailed on the country-specific pages aligns with the FSIS product categorization guide and the Public Health Information System (PHIS) (<https://www.fsis.usda.gov/wps/wcm/connect/abf595d-7fc7-4170-b7be-37f812882388/Product-Categorization.pdf?MOD=AJPERES>).

Each eligible country page will also list any applicable APHIS animal disease restrictions, and includes direct, disease-specific links to APHIS' Web site and regulations. FSIS has updated the import guidance to include reference to the Import Library, which can be found online at <https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/eligible-countries-and-products>.

Imported carcasses

Comment: A non-profit consumer group requested FSIS include requirements for reinspecting imported carcasses in the guidance document.

Response: Section VI of FSIS Directive 9900.2, available at <https://www.fsis.usda.gov/wps/wcm/connect/e262834a-80f7-4502-bf1d-1a79b03899cd/9900.2.pdf?MOD=AJPERES>, includes FSIS inspection program personnel (IPP) instructions for reinspecting imported carcasses. FSIS did not update the import guidance with this information because this guidance is intended for importers and foreign countries, not FSIS inspection program personnel.

Prohibiting imports of beef derived from cattle subject to certain pre-slaughter restraints

Comment: A non-profit consumer group requested that FSIS prohibit the import of beef from cattle slaughtered using "shackle/hoist" and "shackle/drag" methods, which are not

permitted in the United States, specifically from South American countries.

Response: Prohibiting entry of a product derived from a specific method of slaughter is a matter of equivalence, not import inspection. Equivalence is the process of determining whether a country's food safety inspection system achieves FSIS's appropriate level of public health protection as applied domestically in the United States. Additionally, the foreign food safety inspection system is to provide standards equivalent to FSIS to ensure other non-food safety requirements (such as humane handling, accurate labeling, and assurance that meat, poultry, or egg products are not economically adulterated) are met.

As part of the equivalence process, FSIS completes a review of a country's laws, regulations, policies, and procedures pertaining to its food safety inspection. This review includes assessment of humane handling and slaughter, animal disease restrictions, and postmortem inspection. FSIS assesses the supporting documents to determine whether each country's food safety inspection system provide standards equivalent to FSIS regarding these and other factors of inspection. If FSIS concludes that these documents support that the country maintains a food safety inspection system that provides an equivalent level of protection, then FSIS conducts an on-site

verification audit of the country's food safety inspection system. The purpose of the audit is to verify that the inspection system is implementing its laws, regulations, policies, and procedures as described in its documents. Information on the equivalence process is available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/Equivalence/equivalence-process-overview>.

At the time of this Notice, Argentina, Brazil, Chile, and Uruguay are South American countries that maintain equivalence with the United States for certain meat products. FSIS auditors have determined that slaughter establishments that produce eligible meat products in these countries comply with the animal welfare, humane slaughter, and postmortem inspection requirements of the government's requirements, which are equivalent to FSIS requirements.

FSIS Changes

Based on further internal review, FSIS has updated the guidance as follows:

Slaughter dates: FSIS added language to reflect that slaughter dates may be required on the official inspection certificate when FSIS has first determined that a country's system is equivalent to the United States, or FSIS reinstates a country's equivalence status.

Reinspection failures and appeals: FSIS added language to

clarify the existing policy on intensified rates of reinspection when a shipment fails reinspection, to align with current PHIS programming. FSIS also added a sub-section for establishment appeals of inspection decisions.

Equivalence page: FSIS has updated links in the guidance to the current FSIS equivalence page.

Food defense: FIS has added a section on food defense.

Industry Supply Chain Best Practices: FSIS has expanded and revised the industry supply chain best practices section.

Siluriformes: FSIS has added regulatory references for Siluriformes throughout the guidance.

Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this notice is not a "major rule," as defined by 5 U.S.C. 804(2).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations,

Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service, which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Done at Washington, DC:

Paul Kiecker,

Administrator.

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