



FSIS Announces Proposal to Expand Generic Label Approval

FSIS is proposing to amend its inspection regulations pertaining to the generic approval of meat, poultry, and egg product labels. Labels that have been generically approved do not need to be submitted to or reviewed by FSIS before they can be used on product in commerce. Under FSIS regulations, certain categories of labels must be submitted to FSIS for review and approval before use. All other labels may be “generically approved” if they meet all applicable requirements and are, therefore, not required to be submitted to FSIS before use.

[Under this proposed rule](#), labels on products for export that deviate from FSIS requirements but meet the requirements of the foreign country would be deemed generically approved. In addition, the proposed rule would extend generic approval to the following labeling claims:

- Claims in a label’s ingredients statement that designate ingredients as certified “organic” (e.g., organic garlic) under the Agricultural Marketing Service National Organic Program;
- Geographic landmarks on product labels, such as a foreign country’s flag, monument, or map; and
- “Negative” claims on product labels that identify the absence of certain ingredients or types of ingredients (e.g., “No MSG Added,” “Preservative Free,” “No Milk,” “No Pork,” or “Made Without Soy”).

The proposed rule would also permit generic label approval for products that receive voluntary FSIS inspection (e.g., exotic species under 9 CFR part 352) on the same basis as amenable meat, poultry, and egg products. Lastly, under the proposed rule, FSIS would no longer evaluate generically approved labels voluntarily submitted to FSIS for review.

FSIS is seeking public comments on the proposal until November 13, 2020. Comments may be submitted online via the federal eRulemaking portal, available at <http://www.regulations.gov>; by mail sent to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, D.C., 20250-3700. All items submitted by mail or electronic mail must include the agency name and docket number FSIS-2019-0019.

FSIS will consider the comments received and respond to them as it works on finalizing the rule.

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USDA Modernizes Egg Products Inspection

On September 9, 2020, FSIS announced that it is modernizing egg products inspection methods for the first time since Congress passed the Egg Products Inspection Act (EPIA) in 1970. The Egg Products Inspection Regulations final rule aligns the egg products regulations to be consistent with current requirements in the meat and poultry products inspection regulations.

“Requiring egg product plants to develop food safety systems and procedures similar to meat and poultry requirements is a significant milestone in modernizing our inspection system,” said FSIS Administrator Paul Kiecker. “FSIS is continuing to carry out its public health mission to prevent foodborne illness.”

Under the new rule, federally inspected egg products plants are required to develop and implement Hazard Analysis and Critical Control Points (HACCP) systems and Sanitation Standard Operating Procedures (SSOPs). FSIS will continue to test for *Salmonella* and *Listeria monocytogenes* (Lm) in egg products. FSIS requires that plants produce egg products that meet food safety standards and are edible without additional preparation and nothing in the final rule changes those requirements.

Under the HACCP system, plants will be able to tailor a food safety system that best fits their particular facility and equipment. Furthermore, by removing prescriptive regulations, egg products plants will have the flexibility and the incentive to innovate new means to achieve enhanced food safety.

In addition, FSIS will be assuming regulatory authority over egg substitutes and freeze-dried egg products, which pose the same risk as egg products and will be inspected in the same manner, enhancing the existing food safety system.

The agency has also realigned the regulations governing the importation and inspection of foreign egg products more closely with the regulations governing the importation of foreign meat and poultry products. FSIS will notify foreign countries of the regulatory changes. Countries that have ongoing equivalence and most countries that have requested initial equivalence for egg products already have HACCP implemented for egg products for their domestic products.

A pre-publication copy of the rule can be viewed at <https://www.fsis.usda.gov/wps/wcm/connect/9c7eca7a-29dd-49ca-ae0b-e3faece17d52/2005-0015.pdf?MOD=AJPERES>.

FSIS Constituent Update is prepared by the Congressional and Public Affairs Staff, Office of Public Affairs and Consumer Education

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Tips for Faster Label Approval Process

Labels are currently taking **about 5-7** business days to evaluate.

TIP: Ensuring that safe handling instructions on labels comply with all requirements of the applicable regulation will minimize unnecessary label returns and time-consuming modifications.

Safe handling instructions (SHI) are required on meat and poultry labels if the meat or poultry component of the product is raw or partially cooked (i.e., not ready-to-eat) and if the product is destined for household consumers or institutional uses (9 CFR 317.2(l) and 381.125(b)). Meat and poultry products intended for further processing at another official establishment and those for export only are exempt from this requirement.

SHI may be located on any panel of a package; however, they must be prominent and conspicuous. The instructions, which consist of a heading, rationale statement, and four handling statements each accompanied by a specific graphic illustration, must all be set off by a border and appear in one color type printed on a contrasting single-color background. FSIS has observed many label application submissions in which SHI are displayed with no border, in three colors instead of two, or with the text and background color reversed within the SHI box (e.g., the heading and rationale statement are white text on a black background, while the four handling statements are black text on a white background.) FSIS permits changes to the “Keep refrigerated or frozen” statement and icon if specific handling information on the product label conflicts with the safe handling instructions. For example, if the label on a frozen product states, “Do not thaw product, cook from frozen,” or “Do not thaw,” then the safe handling statement may be changed to “Keep Frozen.” If a product is shelf stable and states, “No refrigeration necessary,” or “Refrigerate after opening,” the icon of the refrigerator and the entire statement about refrigeration can be eliminated. No other changes to the safe handling instructions are permitted on meat or poultry labels.

NOTE: Labels for Siluriformes fish products must also bear SHI because these labels must comply with the meat labeling regulations in 9 CFR 317, Subpart A; however, references to meat or poultry must be replaced with the word “fish” (9 CFR 541.7(c)).

Additionally, the first statement in the SHI is not sufficient to replace the mandatory handling statement (e.g., Keep refrigerated), which is placed on the principal display panel and required by 9 CFR 317.2(k) and 381.125(a).

For a link to a sample image of the safe handling instructions for meat/poultry see https://www.fsis.usda.gov/wps/wcm/connect/8b783c38-cd3c-4413-9c23-dac20d2e001e/Safe_Handling2.gif?MOD=AJPERES.

For a link to the safe handling text, including the Spanish translation, see https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/teach-others/download-materials/image-libraries/safe-handling-label-text/CT_Index.

FSIS will continue to provide updates regarding label turnaround time, as well as suggestions to assist industry to streamline label submissions in its *Constituent Update*.

Export Requirements Update

The Library of Export Requirements has been updated for the following countries:

Cuba
Korea, Republic of

For a complete list of countries, visit <https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products>.

FSIS Posts After-Action Review Report for Foodborne *Salmonella* Dublin Outbreak

FSIS has posted an after-action review report of an outbreak of *Salmonella* Dublin illnesses associated with ground beef. From September–December 2019, FSIS, the Centers for Disease Control and Prevention (CDC), public health officials in several states, and USDA’s Agricultural Marketing Service (AMS) investigated an outbreak of 13 *Salmonella* Dublin illnesses linked to ground beef sold at multiple retail stores. An automated alert from the National Center for Biotechnology Information (NCBI) gave FSIS an early notification of the outbreak. The source establishment of some of the implicated beef was determined by obtaining a consumer’s purchase history through shopper cards and by using retail grinding records. Multiple hospitalizations and one death were reported, highlighting the severity of disease caused by *Salmonella* Dublin.

The purpose of FSIS after-action review reports is to share lessons learned from outbreak investigations with industry and public health partners to help prevent illness and improve response. FSIS also promotes [studies](#) under its food safety research priorities to gain a better understanding of pathogen factors associated with disease severity.

To view the full after-action report, please visit <https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/foodborne-outbreak-investigation/outbreak-salmonella-ground-beef-2019>.

To view additional reports and learn more about outcomes of FSIS outbreak investigations, please visit FSIS’ [Foodborne Outbreak Investigation Outcomes – Response and Prevention page](#).

FSIS to Post Updated Dataset on Import Refusals

On September 15, 2020, FSIS will update the publicly posted dataset on import refusals for products that the agency regulates. Federal law requires every commercial shipment of imported meat, poultry, and egg products to be re-inspected prior to product entering U.S. commerce. FSIS re-inspects each shipment to verify labeling, proper certification, general condition, and any signs of tampering and to identify product adulterated by transportation damage. FSIS also performs additional activities on a random and/or for-cause basis, such as physical product examination and laboratory sampling for pathogens and chemical residues.

Any product that does not meet FSIS requirements is refused entry, and the importer has up to 45 days (30 days for egg products) to have the product destroyed for use as human food, re-exported/returned to the foreign country, converted to animal food, or brought into compliance with FSIS requirements, if applicable (e.g., relabeled, remarked, or issued a replacement certificate).

This dataset is updated around the 15th of each month and contains each shipment with product that was refused entry. To access these datasets or view more information about them, please visit the [FSIS Datasets page](#).

FSIS to Hold Animal Raising Claims and Negative Claims Webinar

FSIS will host a webinar on animal raising claims and negative claims (on non-use of GMO ingredients) on September 17 at 2:00 p.m., ET. The webinar will provide an overview on documentation needed to support animal raising claims made on meat or poultry products and will include a discussion about updates made to the [Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions](#) posted in December 2019. FSIS updated the guideline in response to comments received on the previous version of the guideline posted in October 2016.

The webinar will also provide updated information for factual statements concerning the non-use of bioengineered or genetically modified ingredients on labels of meat, poultry and egg products. The December 2019 [Labeling Guideline on Statements That Bioengineered or Genetically Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products](#) includes changes made based on comments on the guideline posted in August 2016.

To access the webinar, go to <https://fsis-usda.webex.com/fsis-usda/j.php?MTID=m25528890545e59f85d559ae30d45b1fa> and follow the on-screen instructions. If a password is requested, enter the password "fsis". You can also call into the meeting by dialing 888-844-9904 and entering the access code 2956126. For questions, contact Gianfranco Santaliz at 301-504-0878 or gianfranco.santaliz@usda.gov.

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

Reminder: Upcoming FSIS Public Meetings

FSIS is hosting multiple public meetings in the coming weeks. Below is a list of the upcoming virtual meetings.

- USDA FSIS Virtual Public Meeting: Salmonella - State of the Science (September 22, 2020)
 - The public meeting has reached its capacity for oral comments. Interested parties can still submit written comments at <http://www.regulations.gov>.
- National Advisory Committee on Meat and Poultry Inspection Public Meeting (September 24 – 25, 2020)
- Food Safety: Consumer Outreach and Education Today and for the Future (October 6, 2020)
 - The public meeting has reached its capacity for oral comments. Interested parties can still submit written comments at <http://www.regulations.gov>.

Additional information on the upcoming meetings and details on how to register can be found at <http://www.fsis.usda.gov/meetings>.

Policy Updates

FSIS notices and directives on public health and regulatory issues are available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations>. The following policy updates were recently issued:

FSIS Notice 43-20 - USDA Material Management Service Center End of Fiscal Year Supplies Inventory and Reconciliation Closure

FSIS Notice 44-20 - Cut-Off Dates for Fiscal Year 2021 Purchases

Docket No. FSIS-2005-0015 - Egg Products Inspection Regulations

FSIS Directive 7120.1 Revision 53 - Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products