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# Small Plant News



Volume 7 | Issue No. 3

## *Generic Labeling: Why It Is Important to You*

*By Natasha Williams, OOEET*

You've probably heard by now that FSIS has expanded the circumstances in which labels may be considered generically approved, and that's good news for meat and poultry processors. It is important that you understand why.

This final rule allows establishments to label a broader range of products without first submitting the label to the Agency for review.

At the same time that FSIS made this change, it also amended its regulations to combine the previous regulations that provided for labeling approval (9 CFR 317.4 and 381.132) and generically approved labeling (9 CFR 317.5 and 381.133) into one new part.

The new regulations can now be found in 9 CFR, Part 412. The labeling approval regulations are in 9 CFR 412.1, while the approval of generic labels is now in 9 CFR 412.2.

Under the generic approval final rule, establishments are

still required to submit the following types of labels to FSIS for review:

- (1) Labels for temporary approval;
- (2) Labels for products produced under a religious exemption;
- (3) Labels for products for export with labeling deviations; and
- (4) Labels with special statements and claims.

With this rule, statements on labels that are defined in FSIS' regulations or the "Food Standards and Labeling Policy Book" with the exception of "natural" and negative claims (see examples below), can be generically approved.

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# Generic Labeling: Why It Is Important

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The following is a list of some common label statements and claims that would NOT require submission to the Labeling and Program Delivery Staff (LPDS):

- Statements about allergic ingredients (e.g., “Contains Soy”);
- Foreign language on domestic products;
- Green/Environmental Claims such as “Packaging Made with Recycled Materials”;
- “Halal,” “Kosher” (not certified);
- “Handcrafted,” “Handmade,” “Hand Slaughtered,” and “Hand Crafted Style”; and
- The statement of limited use, e.g., “For HRI Use Only.”

Examples of labels with special statements or claims that continue to be required to be submitted to FSIS’ LPDS for review are:

- Statements that identify a product as “Organic” or containing organic ingredients;
- Implied nutrition claims such as “Heart Smart,” “Baked not Fried,” and “Made Without Butter”; and
- Negative claims such as “Gluten Free,” “No Animal Byproducts,” “No MSG,” and “No Preservatives.”

A label compliance guide outlining what constitutes a special statement or claim that would require submission to the Agency is available at [www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES).

Also included in that guidance is information on certain types of label claims that are approved generically and do not need to be submitted for review.

Will the generic labeling rule cost money? No. It will not create any additional costs for small and very small plant owners and operators.

If anything, the rule should allow establishments to save money. FSIS predicts industry will realize a cost savings (discounted at 7 percent) of \$10.1 million as a result of being able to generically approve an additional 584,000 labels over a 10-year period.

Curious about what the FSIS inspector in your establishment is required to do with your labels under the rule?

FSIS inspection program personnel will continue to verify

labels as part of the General Labeling Task in the Public Health Information System (PHIS), including comparing final labels to actual product formulations to verify that labels are in compliance with FSIS regulations.



The rule has not changed the process for generic approval; it just expanded the types of labels that can be generically approved. Although not submitted to FSIS, generically approved labels have always been approved by FSIS if they are in compliance with applicable regulations. With the new rule, more types of labels are generically approved.

The generic labeling rule creates a win-win situation for everyone involved. Small and very small plants will not have to wait on LPDS sketch approval to release products into the marketplace, provided that the label does not meet any of the four criteria requiring label approval.

This rule will minimize the amount of label submissions to FSIS

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# Generic Labeling: New Rule, New Way

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headquarters, which will increase the availability of the FSIS labeling staff not only to answer your questions but also to prioritize the review of your labels that do require review by FSIS.

Would you prefer to have FSIS approve some of your labels, despite the new rule?

Well, this is completely okay. However, the FSIS labeling staff will give first priority to labels that fall into at least one of the four categories of labels requiring LPDS approval: temporary label approval, products produced under religious exemption, products for exports with labeling deviations, and labels bearing special statements or claims. Consequently, you may have a longer wait time if you choose to submit labels that do not require LPDS review.

We strongly encourage you to consider the benefits of the rule because labels that do not require LPDS sketch approval are generically approved by their compliance with applicable FSIS labeling regulations and may be used immediately by the establishment.

When submitting a label to LPDS that may be generically approved, establishments should note in their labeling application that they are requesting voluntary review. Establishments submitting labels that can be generically approved through the FSIS Web-based Label Submission and Approval System (LSAS) should type “generic” in the box titled “Other claim description” in Step 3: Special Claims Information of the LSAS label submission process.

## Food Defense Update

FSIS has updated its booklet, *Food Defense Guidelines for the Transportation and Distribution of Meat, Poultry, and Processed Egg Products*.

The booklet addresses security measures specifically identified to prevent intentional contamination resulting from criminal or terrorist acts. They apply to all points of shipment—from processor to delivery at the retail store, restaurant, or other facility servicing consumers. FSIS encourages all operators to develop a written food defense plan.

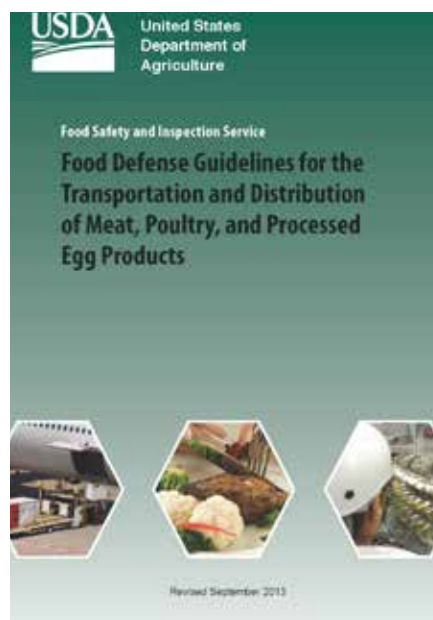
The booklet is available online at [www.fsis.usda.gov/wps/wcm/connect/4f9d737a-1f3e-49ff-851b-](http://www.fsis.usda.gov/wps/wcm/connect/4f9d737a-1f3e-49ff-851b-)

When submitting labels via paper application, establishments should type “Generic” after “Other claims” in Block 10 of FSIS Form 7234-1.

To access the final rule in its entirety, go to [www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules).

Still have questions regarding the process? The labeling staff is hosting a series of webinars to answer any questions or concerns you may have. Check the weekly *Constituent Update* at [www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/constituent-updates-2014](http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/constituent-updates-2014) to find out the dates for the webinars, as well as the call-in information.

For immediate assistance on the new rule and any other questions, contact the Small Plant Help Desk at (877) 374-7435 or [InfoSource@fsis.usda.gov](mailto:InfoSource@fsis.usda.gov). We are available Monday through Friday from 8 a.m. – 4 p.m. ET.



[74884fa946bd/Transportation\\_Security\\_Guidelines.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/resources-and-information/food-safety-resources-svsp-outreach/svsp-brochure).

Hard copies may be ordered through the online brochure at [www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/resources-and-information/food-safety-resources-svsp-outreach/svsp-brochure](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/resources-and-information/food-safety-resources-svsp-outreach/svsp-brochure) or by contacting the Small Plant Help Desk at (877) 374-7435 or [InfoSource@fsis.usda.gov](mailto:InfoSource@fsis.usda.gov).

## Commonly Asked Questions & Answers

**Q** *Is the establishment required to review all records associated with all products if the pre-shipment review covers multiple products that may not have been produced under the same process category and may have different control measures?*

**A** The establishment will need to review any records associated with The Hazard Analysis and Critical Control Point system (HACCP) that are tied to the specific production of that lot of product that is shipped. Every prerequisite program may not apply to a specific production, so it will be the responsibility of the establishment to evaluate its production and recordkeeping systems to determine how the review of the applicable records will be accomplished during the pre-shipment review procedure.

As the notice explains, Inspection Program Personnel (IPP) are to be aware of the establishment's HACCP system associated with the production of a specific product so that they can understand which programs are part of the HACCP system and which bear on the determination whether product is adulterated.

The establishment should be able to explain to IPP how the establishment will perform the review of prerequisite program records generated in support of the food safety system. The establishment can perform the review of its records in stages and by multiple employees. If a prerequisite program is not product specific, and the program does not have a bearing on whether product is adulterated, then the establishment does not need to review those records as part of pre-shipment review. Rather, the establishment should review those records as part of its ongoing HACCP verification activities.

**Q** *A corporation has a computer system for paperless records: HACCP, Sanitation Standard Operating Procedures (SSOP), Quality Assurance, and lab*

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*records. It sells one of its establishments and the establishment's entire product inventory is shipped to one of the corporation's other facilities. What are the regulatory requirements for providing copies of the sold plant's historic and existing records to the new owner?*

**A** As long as the seller has HACCP records for its product inventory as required by 9 CFR 417.5(e), then it is not required by our regulations to provide any records to the new owner. The USDA/FSIS office in the establishment or District Office will retain USDA records if needed for review in the event of recalls or other trace-back scenarios. In the event the new owner is allowed to maintain establishment number and name, then records should be available to FSIS to discern identification of the producer and production dates of product in commerce.