



## Label Backlog Update and Tips for the Label Approval Process

FSIS is currently experiencing a delay of 22-24 business days in evaluations for labels that require review prior to use. The agency will continue to provide frequent backlog updates and suggestions via the *Constituent Update* to assist industry in streamlining label submissions. By highlighting common mistakes observed during the label evaluation process and providing industry with suggestions for correcting these mistakes, FSIS is hopeful that it will achieve a faster, more efficient label evaluation process and a quicker turnaround of label applications.

**TIP: Only submit labels that require approval by the Labeling and Program Delivery Staff (LPDS).**

FSIS regulations only require four categories of labels to be submitted to the LPDS for approval, as described in 9 CFR 412.1. These categories include:

- 1) intended for temporary approval,
- 2) for poultry products produced under religious exemption,
- 3) for products for export with certain labeling deviations from domestic requirements, and
- 4) with special statements and claims as described in 9 CFR 412.1(c).

All labels that do not fit into one of the four categories noted above are eligible for generic approval, meaning that these labels are not required to be submitted to LPDS for approval prior to use, but must comply with all applicable regulations including 9 CFR Part 317 or 381. More information about generic labeling can be found at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Labeling-Policies#Generic>.

Additionally, certain changes to labels previously approved by LPDS bearing special statements or claims may be made without submitting the label to LPDS (e.g., change in brand name, net weight changes, or updating the values in the nutrition facts panel). These types of label changes may be made generically for labels previously approved by LPDS with special statements and claims, provided the change is unrelated to the special statement or claim. For example, an establishment may change the address line and net weight on a label submitted and approved with a "natural" or "gluten free" special statement or claim because these changes would be unrelated to the claims. In comparison, if the establishment modified the product formula to include a new ingredient not included in the previously approved formula, the label would need to be resubmitted for approval because a formulation change of this type could affect an ingredients-based special statement or claim.

Continues on Page 2

### In This Issue

- 1 Label Backlog Update and Tips for the Label Approval Process
- 1 Export Requirements Updates
- 2 FSIS Announces Industry Testing of PHIS Export Component
- 3 FSIS Announces New Date for PHIS Export Component's Second Country Group
- 4 Reminder: Consumer Food Safety Education Conference to Be Held March 6-8, 2019

### Export Requirements Updates

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

- Canada
- European Union
- Hong Kong
- Japan
- Morocco
- New Caledonia
- Republic of Korea
- South Africa
- Ukraine
- Western Samoa

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

# ...Label Backlog Update

Continued from Page 1

For assistance in determining which labels must be submitted to LPDS for approval, including what types of statements are considered “special statements or claims,” please see the FSIS Compliance Guidance for Label Approval at: <https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES>. Additional guidance is available through the Generic Labeling Advisor, which is accessed through the online Label Submission and Approval System (LSAS). The Generic Labeling Advisor is a tool that asks the submitter a series of questions and allows the submitter to determine if a label can be generically approved based upon the answers given by the system.

Labels may also be submitted through [askFSIS](#) for a determination from a staff officer as to whether the label requires LPDS approval. Although label approvals are only granted through LSAS, utilizing [askFSIS](#) is an efficient way to verify if a label must be submitted for approval without contributing to the label backlog. Additionally, the [askFSIS](#) response will provide written documentation if the label is eligible for generic approval.

Labels that are eligible for generic approval may be voluntarily submitted to LPDS for evaluation; in this case, the company should add “generic” to the box for other claims in the application, and answer “yes” when prompted in LSAS when asked if the label is being submitted for voluntary review. When a label eligible for generic approval is submitted and not marked for voluntary label evaluation, LPDS will return the label to the submitter with an explanation of why the label does not require evaluation and move the label out of the higher priority review queue into the lower priority voluntary review queue. Note that labels submitted for voluntary label evaluation will receive lower priority than those requiring approval and, therefore, may take longer to be reviewed.

FSIS looks forward to working with industry on this issue to facilitate faster turnaround times, fewer label resubmissions, and an overall decreased label backlog.

## FSIS Announces Industry Testing of PHIS Export Component

FSIS is announcing that industry can volunteer to test the Public Health Information System (PHIS) export component for establishments that will begin shipping to the 21 countries identified below and previously announced in the [Dec. 14, 2018 Constituent Update](#). Testing will be from March 4, 2019 to April 4, 2019. If you have an interest in testing, please continue to send your name and other contact information to: [PHISTechnicalQA@fsis.usda.gov](mailto:PHISTechnicalQA@fsis.usda.gov).

Testing will include establishments exporting to Angola, Antarctica, Aruba, Bhutan, Botswana, Bouvet Island, Brunei Darussalam, Christmas Island, Comoros, Eritrea, Falkland Islands, Faroe Islands, French Southern and Antarctic Islands, Greenland, Guernsey, Heard Island and McDonald Islands, Isle of Man, Jersey, Lesotho, Liechtenstein, Vietnam.

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

Assistant Administrator  
Carol Blake

Deputy Assistant Administrator  
Aaron Lavallee

Director  
Roxanne Smith

Editor  
Veronika Pfaeffle

# FSIS Announces New Date for PHIS Export Component's Second Country Group

FSIS is announcing a new implementation date for the second group of countries that will be included in the Public Health Information System (PHIS) export component, FSIS' electronic export application and certification system. On May 20, 2019, FSIS will begin issuing FSIS Export Certificates of Wholesomeness for Meat and Poultry (FSIS Form 9060-5) and Siluriformes Fish (FSIS Form 9060-5S) for the following countries through the PHIS export component on FSIS-controlled security paper:

Angola, Antarctica, Aruba, Bhutan, Botswana, Bouvett Island, Brunei Darussalam, Christmas Island, Comoros, Eritrea, Falkland Islands, Faroe Islands, French Southern and Antarctic Islands, Greenland, Guernsey, Heard Island and McDonald Islands, Isle of Man, Jersey, Lesotho, Liechtenstein, and Vietnam.

Previously, FSIS had announced an implementation date of March 4, 2019, in a [Dec. 14, 2018 Constituent Update](#). However, FSIS is announcing a new date to ensure the PHIS export component, exporters and countries are adequately prepared.

As noted in the [Dec. 14, 2018 Constituent Update](#), FSIS implemented the PHIS export component on June 29, 2018, with 16 countries\* that do not maintain export library requirements. FSIS is incrementally adding countries to the PHIS export component and has chosen to include one country with export library requirements in the second group: Vietnam. Vietnam will receive country-specific letterhead certificates listed in the export library with ink signatures, as is done currently, and 9060-5 certificates generated by PHIS with ink signatures – signatures on letterhead certificates and the 9060-5 will match. Other countries included in the second group that do not maintain export library requirements will receive the 9060-5 with a digital signature, as shown in FSIS' April 2018 World Trade Organization notification ([G/SPS/N/USA/2954/Add.1](#)).

U.S. exporters that ship meat or poultry products to the countries in the second group should follow published FSIS guidance for submitting applications for export certification in the PHIS export component (PHIS Industry User Guide): [https://www.fsis.usda.gov/wps/wcm/connect/475cd9e6-50ca-44c4-8fa5-5f3c4cee02a1/PHIS\\_Industry\\_User\\_Guide\\_20180622.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/475cd9e6-50ca-44c4-8fa5-5f3c4cee02a1/PHIS_Industry_User_Guide_20180622.pdf?MOD=AJPERES). More information and resources can be found on FSIS' PHIS export component web page at: <https://www.fsis.usda.gov/wps/portal/phis/topics/international-affairs/exporting-products/phis-export-component>.

\*Afghanistan, Andorra, Bahamas, Bolivia, Burundi, Cape Verde, Cook Islands, Ethiopia, French Guiana, Gambia, Guinea, Liberia, Mozambique, San Marino, Tanzania, and Uganda.

# Reminder: Consumer Food Safety Education Conference to Be Held March 6-8, 2019

The Partnership for Food Safety Education will be holding its 2019 Consumer Food Safety Education conference from March 6-8, 2019, in Orlando, Florida. The conference, "From Consumers to Chefs: Food Safety Education Matters," will focus on take-away strategies for changing people's food safety knowledge and behaviors. More than 400 health and food safety educators are expected to attend to explore influences on consumers, how to effect behavior change, and discuss strategies to engage everyone in modeling proper food preparation and good hand hygiene practices. Information on how to register can be found at: <https://cfsec2019.fightbac.org/>