



Label Backlog Update and Tips for the Label Approval Process

FSIS is currently experiencing a delay of **about 20-21** business days in evaluations for labels that require review prior to use. By providing industry with label application submission tips and suggestions via the *Constituent Update*, FSIS is hopeful that it will achieve a faster, more efficient label evaluation process.

TIP: The fastest way to obtain a label approval is to ensure the application includes a label with all of the required features and documentation necessary to support any statements or claims on the label.

FSIS receives and reviews a high volume of labels every week. Accurate and complete label application submissions will ensure that reviews are carried out in a timely manner. When only minor modifications are needed, labels may be approved by FSIS as “sketch modified” rather than returned to the submitter. However, if the label modifications necessary for FSIS to approve a label are too numerous or complex, or if the modification cannot be made by FSIS without additional information (e.g., the product formula in the application does not match the ingredients statement on the label), then the label application must be returned to the submitter. FSIS must also return label applications submitted without the necessary supporting documentation for special statements or claims on the label.

NOTE: A label application that is resubmitted, after being returned by FSIS during initial review, will automatically be placed at the top of the label evaluation queue and FSIS will review them within a few days. Even so, the quickest way to obtain label approval is by initially submitting a complete label application, which would include a fully compliant label and any necessary supporting documentation.

FSIS will continue to provide weekly updates regarding the label turnaround time, as well as suggestions to assist industry to streamline label submissions. For more information about the mandatory label features and considerations relating to each feature, please see the following guidance: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/label-submission-checklist>.

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Export Requirements Update

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

Brazil

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

FSIS to Implement PHR Update for Scheduling PHREs

FSIS uses a number of decision criteria described in Directive 5100.4 to prioritize establishments for Public Health Risk Evaluations (PHREs). At the meeting of the National Advisory Committee on Meat and Poultry Inspection (NACMPI) in January 2013, FSIS presented its plans to implement a food safety assessment (FSA) scheduling criterion called Public Health Regulations (PHRs). In June 2013, FSIS implemented the PHR criterion. Periodic re-analysis of the PHRs is one of the recommendations from the 2013 NACMPI report.

This year, FSIS has analyzed the most current data and is revising the list of PHRs as well as the thresholds used to prioritize establishments for PHREs and to alert inspection personnel of elevated PHR noncompliance levels.

On July 1, 2019, FSIS will post on its website the fiscal year (FY) 2020 list of PHRs and their corresponding thresholds. A detailed report on how FSIS determines PHRs and their thresholds will be posted later in July. The agency will implement this updated set of PHRs at the start of FY 2020.

Policy Update

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 update was recently issued:

Docket No. FSIS-2019-0007 - Retail Exemptions Adjusted Dollar Limitations

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
Buck McKay