Tips for Faster Label Approval Process

Labels are currently taking **about 13-15** business days to evaluate.

TIP: When submitting a label for approval that bears text in a foreign language, including the English translation in the application will result in a faster label evaluation process.

Establishments often include foreign language on domestic product labels to reach a diverse group of customers. The foreign language may be a translation of information already on the label or a stand-alone statement about a specific characteristic of the product, such as flavor profile or quality claim. A translation is only required on the final label when one of the required features is in a foreign language; otherwise, an English translation is not required on the final label applied to product. However, the label application must include the translation for FSIS to thoroughly evaluate the label. As part of the label approval process, FSIS must determine whether all the information on the label is truthful and not misleading, which means that the translation needs to be included in the label application. The translation may be included as a separate attachment in the application, or it may be included elsewhere within the application if it is easily accessible to the staff officer who is evaluating the label application. If the entire label includes both English and a foreign language translation, the submitter may simply stipulate in the application that all foreign language is a direct translation of English on the label. If a translation is not provided with the application, then the application will be returned, which will unnecessarily delay the evaluation time.

Note that the addition of foreign language to labels is not considered a special statement or claim; therefore, the label does not require approval by FSIS unless other information on the label places it into one of the categories of labels described in 9 CFR 412.1 that require FSIS evaluation.

For additional information about special statements or claims requiring FSIS approval, please see the "FSIS Compliance Guideline for Label Approval" at https://www.fsis.usda.gov/wps/wcm/connect/45a29f18-52cc-4012-8790-ab7ea9f980c9/LSAS-Industry-User-Guide-063015.pdf?MOD=AJPERES.

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:

Canada
China, People's Republic of
Republic of Cote d'Ivoire
Ghana

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

Reopening the Public Health Information System Industry Test Environment

On January 27, 2020, FSIS will add the People's Republic of China to the Public Health Information System (PHIS) Export Component as Phase 3 of the country rollout. In preparation for the rollout, FSIS will reopen the Industry Test Environment (ITE) on Monday, January 6, 2020. The ITE will remain open until further notice for industry users that wish to test the User Interface (UI) or develop and/or continue developing XML schema to communicate with PHIS.

On January 6, 2020, the ITE will reopen with new requirements for the People's Republic of China. New features added to PHIS will include a third method to add attestations and other letterhead statements (this method is in addition to the attachments and cut/paste options that became available in June 2018) and product-based prompts for additional information (based on country requirements identified in the Export Library) while completing the application wizard. As an example, users would be prompted to provide slaughter information when preparing certificates for export to the People's Republic of China. The ITE will be refreshed with production data on January 27, 2020. Users will be required to set up their establishment and corporate information in the ITE.

As a reminder, each establishment in PHIS is required to have an establishment administrator listed in the establishment profile on the contacts page; each establishment is responsible for managing establishment access, including approving and removing privileges. The establishment administrator is first added by the FSIS In-Plant Program Personnel (IPP). All roles in PHIS must be roles recognized by PHIS; for example, if you want to submit an export application, your role must be export applicant or broker – export coordinator or docket clerk roles are not allowed to conduct business in PHIS. Information regarding these processes is available in the user guide, "PHIS Industry User Guide June 2018", which is available on the FSIS website.

Additionally, all parties that want to and/or are required to conduct business in PHIS (via export) are required to have electronic Authentication (eAuth) Level 2, which is managed by the U.S. Department of Agriculture. You can register online and find the steps to complete the eAuth Level 2 process at: https://www.eauth.usda.gov. Electronic Authorization is required for both the ITE and production environment.

For export policy questions, please go to: https://askfsis.custhelp.com. For technical questions concerning the XML schema development, please contact the FSIS Service Desk at 800-473-9135, select prompt 1, followed by prompt 3. Other questions concerning the PHIS export can be submitted to PHISTechnicalQA@fsis.usda.gov.

FSIS encourages all users who are not familiar with PHIS Export Component to use the ITE opportunity to test their export application process.

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 Directive 9510.1 Rev. 1 - Importation of Undenatured Inedible Meat, Fat, Rendered Fat, Poultry, and Egg Products

Docket No. FSIS-2018-0048 - Updated Labeling Guideline on Statements That Bioengineered or Genetically Modified Ingredients or Animal Feed Were Not Used in the Production of Meat, Poultry, or Egg Products

Docket No. FSIS-2016-0021 - Food Safety and Inspection Service Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission