FSIS Expands PHIS Export Component, Invites Industry Testing

FSIS began implementing the Public Health Information System (PHIS) Export Component on June 29, 2018, with 16 countries, territories and dependencies (Phase I), and added 21 additional countries, territories, and dependencies on May 20, 2019 (Phase II). On January 27, 2020, FSIS will add China (Phase 3) to the PHIS Export Component.

Information about this effort and the PHIS Export Component is available on the FSIS website at https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/phis/phis.

In preparation for this transition, the agency has made the test environment available for those that will be impacted by this phase and want to test the user interface of the export module of PHIS, and/or would like to develop systems to electronically communicate through web services/ machine to machine, to PHIS for ease in submitting batch export applications. The environment will be available now through December 15, 2019 and will then be available again from January 6, 2020 onward. If you are interested in testing this module or have questions, please contact our Export Support Team by sending an email to PHISTechnicalQA@fsis.usda.gov.

Information on the PHIS Export Component (recorded webinars, user guides, HELP videos, questions and answers, etc.) is available on the FSIS website at https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/phis/phis. FSIS would like to remind all parties that want to do business in PHIS that they are required to have electronic Authentication Level 2, which is managed by the U.S. Department of Agriculture. You can register online and find the steps to complete the electronic Authentication Level 2 process at https://www.eauth.usda.gov. If you are new to PHIS, you must be added to the contacts page by your FSIS inspector or have your PHIS establishment administrator give and approve your export role. Information regarding these processes is available in our user guide, PHIS Industry User Guide June 2018, which is available on the FSIS website.

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 functionality can be submitted to PHISTechnicalQA@fsis.usda.gov.

Export Requirements Update

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

Australia
Bahrain
Barbados
Colombia
Costa Rica
Korea, Republic of
Mexico

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

FSIS Finalizes Changes to Publication Method for Lists of Eligible Exporting Countries

FSIS is announcing a final rule that will change how the agency publishes information on the foreign countries eligible to export meat, poultry, and processed egg products to the United States.

FSIS will post on its website the lists of foreign countries eligible to export agency-regulated products to the U.S. instead of publishing the list in the Code of Federal Regulations. The criteria FSIS uses to evaluate whether a foreign country is eligible to export meat, poultry, or processed egg products will not change.

The information on equivalence determinations will still be found in the *Federal Register* and the list of eligible countries will still be found on the FSIS website. The public will still be able to comment on equivalence determinations.

With the final rule, the agency is also amending it regulations to remove references to the lists.

The rule will allow FSIS to be transparent and efficiently communicate equivalence determinations by maintaining a single list of exporting countries on its website.

The online lists are maintained at http://www.fsis.usda.gov/importlibrary.

NARMS to Publish the 2016-2017 Integrated Summary

The National Antimicrobial Resistance Monitoring System (NARMS) is an inter-agency surveillance program conducted by FSIS, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and state and local health departments to monitor antibiotic resistance in bacteria in people, food-producing animals, and raw retail meats. The NARMS program provides information to assess the nature and magnitude of antibiotic resistance in bacteria moving through the food supply and causing illnesses in people. FSIS monitors changes in antimicrobial resistant bacteria that have been recovered from Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) sampling and cecal sampling.

With the release of the 2016-2017 data, NARMS is publishing a NARMS Integrated Summary, instead of the long-form Integrated Report. The 2016-2017 NARMS Integrated Summary describes the most important trends in antimicrobial resistant *Salmonella, Campylobacter*, generic *E. coli,* and *Enterococcus* in a bulleted list. This summary is the first time that NARMS will provide genomic information for *Campylobacter* and *E. coli* retail meat and food animal isolates in addition to *Salmonella*.

Tips for Faster Label Approval Process

Labels are currently taking **about 12-14** business days to evaluate.

TIP: Label applications approved within the Label Submission and Approval System (LSAS) are electronically dated and stamped with either a Sketch Approval stamp or Temporary Approval stamp, as appropriate. The automatically generated eight-digit label application number is also the label approval number and is found in the Summary section of LSAS. The Summary section is part of the official label record and must be maintained by the establishment and made available to FSIS personnel upon request (9 CFR 412.1(a)).

When FSIS evaluated only paper label applications (prior to the launch of LSAS in 2016), every approved paper application was manually stamped with an approval number. Now that all labels are approved electronically through LSAS, the label application number for an approved label application serves as the official means to identify an approved application. This application number is located in the Summary section of LSAS and may include information about the application that is not found anywhere else, such as reasons for temporary approval or conditions/modifications required for the approval. A complete record of labeling is required by 9 CFR 320.1(b)(10) and includes the following: a copy of the final label that is in use, the product formulation, the processing procedure for the product, and any supporting documentation needed to show that the label is consistent with the federal meat and poultry regulations and policies on labeling, as required in 9 CFR 412.1.

Supporting documentation may include a prior approval from FSIS, including the Summary section for labels approved in LSAS. FSIS inspection program personnel performing the General Labeling task assigned in the Public Health Information System (PHIS) require access to the establishment's complete label record. The establishment may access the Summary section in LSAS by selecting "Summary" under the "Available Actions" pull down menu and a copy of the Summary section should be included in the record of labeling.

The LSAS User Guide includes additional information and screen shots of the information contained in the Summary section in LSAS: https://www.fsis.usda.gov/wps/wcm/connect/45a29f18-52cc-4012-8790-ab7ea9f980c9/LSAS-Industry-User-Guide-063015.pdf?MOD=AJPERES.

For more information about required label records, please go to https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/labeling-and-establishment-responsibilities.

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*.

FSIS Posts Next Set of Establishment Specific Datasets

FSIS is preparing to publish the next set of establishment specific datasets as announced in the Federal Register on July 14, 2016 (Docket No. FSIS-2014-0032). Prior to publishing these datasets, FSIS is making sample datasets available. The next sample dataset and corresponding data documentation is on risk-based Listeria monocytogenes sampling results, which can be found on the Establishment-Specific Datasets: Laboratory Sampling Data web page at https://www.fsis.usda.gov/wps/portal/fsis/topics/ data-collection-and-reports/data/datasets-laboratory-sampling. Please visit https://www.regulations.gov/ and follow the online instructions at that site for submitting comments to Docket FSIS-2014-0032 for this sample dataset and data documentation by January 3, 2020. FSIS intends to publish the final dataset on January 10, 2020. Additional details can be found in the FSIS Establishment-Specific Data Release Strategic Plan.