



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2014-0039]

Document Reviews of Foreign Food Regulatory Systems: New Web-based Self-Reporting Tool

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Response to comments; notice of availability.

SUMMARY: FSIS is making available to the public its new Web-based Self-Reporting Tool (SRT) that it will be sending to foreign countries to report information on their food regulatory systems for the purpose of establishing that the systems are, or continue to be, equivalent to that of the United States' system. The Agency will send a letter to foreign countries with instructions on how to access and use the Web-based SRT. FSIS is also responding to the comments on its document review process for determining and verifying equivalence that the Agency received in response to the Federal Register notice that it published on January 25, 2013, on the use of the SRT. FSIS evaluates the information provided in the SRT and uses it, along with the results of on-site systems audits and port-of-entry (POE) reinspections, to make a determination on equivalence.

DATES: On February 17, 2015, FSIS will make available to the public the new Web-based SRT. To ensure that a complete and up-

to-date SRT is being considered as part of FSIS's annual assessment of country performance, countries that are currently eligible to export meat, poultry, and egg products to the United States must submit their completed SRTs to FSIS before May 18 of 2015 and annually before May 18 thereafter. FSIS will send SRTs to all countries currently eligible to export meat, poultry, and egg products to the United States on December 1 of each year in the future.

Countries applying for initial equivalence determinations after [INSERT DATE OF PUBLICATION] must submit their completed SRTs within one year of receiving the SRT.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel L. Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

#### Background

In a notice published in the Federal Register of January 25, 2013 ([78 FR 5409](#)) (hereafter "the Federal Register notice"), FSIS described how it conducts ongoing equivalence verifications of the food regulatory systems of countries that export meat, poultry, or processed egg products to the United States. FSIS uses a three-part approach that includes (1) document reviews, (2) on-site system audits, and (3) POE reinspections. FSIS determines the scope and frequency of on-site systems audits

based on its analysis of the results of its document reviews and ongoing assessment of a country's performance. This performance-based approach allows FSIS to direct its audit resources to foreign food regulatory systems that appear to pose a greater risk to public health than other foreign systems.

FSIS invited interested persons to submit comments on its new methodology by March 26, 2013. FSIS received approximately 31 comments from foreign countries, trade consulting groups, consumer groups, private citizens, a trade association representing the meat industry, and a member of the U.S. Congress. Twelve of those comments concerned the Agency's document review process. In this notice, FSIS is responding only to the comments that it received on its document review process. A summary of comments on the Agency's document review process and the Agency's responses are below. The Agency will address the other comments in a future Federal Register document.

On the basis of information provided by commenters, FSIS's experience in conducting document reviews, and the Agency's analysis of available SRT data, FSIS has decided to make two changes to its document review process. The changes are explained below and are discussed in more detail in the Agency's responses to comments.

#### Improvements to the Document Review Process

A foreign country interested in exporting to the United States is required to submit information concerning its food regulatory system to FSIS (see 9 CFR 327.2(a)(2)(iii), 381.196(a)(2)(iii), and 590.910). As explained in the January 2013 Federal Register notice, FSIS uses the equivalence questionnaire, called the SRT, to collect this information for the Agency's document review of the food regulatory system of foreign countries that are listed in the regulations as eligible to export meat, poultry, or egg products to the United States and for countries interested in becoming eligible (78 FR 5411). The SRT is a repository for key documents about a foreign food safety inspection system (e.g., inspection system laws, regulations, and policy issuances) that FSIS uses, in addition to on-site audits, to verify whether the laws, regulations, and implementing policies of a foreign country establish an inspection system that is equivalent to the U.S. system. It also allows FSIS to evaluate whether a country maintains system effectiveness and to assess any impacts that an administrative or legislative change has had on a foreign food regulatory system. FSIS conducts a document review at least annually.

The information in the SRT allows FSIS to conduct a comprehensive assessment of a foreign country's food safety regulatory system. These comprehensive assessments inform the Agency's determination of whether a country's system should be

found equivalent and the country eligible to export product into the United States. FSIS also assesses information in the SRT on an ongoing basis to verify whether a country maintains equivalence.

In the past, the SRT was available in a Microsoft Word format, and once completed by the country, it was submitted to FSIS along with corresponding supporting documentation either by mail or e-mail communication. A PDF copy of the Microsoft Word version of the SRT is available on FSIS's Web site at:

<http://www.fsis.usda.gov/wps/wcm/connect/7893547e-d0d2-4fa9-a984-fdc17228bfcd/SRT.pdf?MOD=AJPERES>. On February 17, 2015,

FSIS will launch a Web-based version of the SRT within its Public Health Information System (PHIS) to more efficiently capture up-to-date information about foreign food regulatory systems. PHIS is a comprehensive Web-based data-analytics and inspection system that automates and replaces many of FSIS's paper-based processes.

The Web-based SRT will be beneficial for countries exporting meat, poultry, and egg products to the United States; countries interested in exporting product to the United States and applying for equivalence; and FSIS personnel. With the Web-based SRT, countries can link supporting documentation to each question. With the Microsoft Word version, the supporting documentation is provided as a supplement to the SRT. As a

result, during the review process, FSIS must sift through documents to match up information with the corresponding questions in the SRT. FSIS anticipates that use of the Web-based SRT will decrease the time it takes the Agency to review an SRT submission and thereby allow for a quicker response to an equivalence request.

Using PHIS as a platform for the SRT allows for a more secure exchange of information between FSIS and foreign countries because countries will be accessing the SRT through a secure USDA Web site that requires a unique ID and password acquired through an authentication process. To guarantee that the security of the Web-based SRT in PHIS is maintained and to gain access to the system, each potential user will have to register for a USDA eAuthentication (eAuth) Level 2 account and complete the authentication process. FSIS will send a letter to foreign countries with instructions on obtaining an eAuth account and using the Web-based version of the SRT. FSIS strongly encourages countries to use the Web-based SRT. However, the use of the Web-based SRT is voluntary, and FSIS will continue to accept the current Microsoft Word version of the SRT. To ensure that the transition to the Web-based SRT is as seamless as possible, FSIS pre-entered into PHIS the SRT responses and supporting documentation that countries actively exporting meat, poultry, or egg products to the United States

have provided to FSIS. FSIS requests that countries review the pre-entered responses for completeness and accuracy.

In addition to a Web-based version of the SRT, foreign countries will note that the revised SRT asks fewer and more targeted questions necessary for FSIS to verify system equivalence. FSIS expects countries to answer all the targeted questions in the SRT to facilitate the review process. FSIS may not be able to make an equivalence determination without answers to all of these questions.

The SRT also includes questions for FSIS to use in assessing how frequently to conduct on-site audits of the country. FSIS refers to these questions as level of advancement (LOA) questions. As explained in the Federal Register notice, the sum of the LOA responses is one of the factors that FSIS considers as part of an annual analysis of country performance to determine the frequency and scope of on-site audits (78 FR 5412). FSIS uses the results from the analysis to place exporting countries into one of three categories, based on food safety performance, with corresponding audit frequencies: Well-performing countries are to be audited every three years. Average-performing countries are to be audited every two years. Adequately-performing countries are to be audited every year. Thus, the completeness of a country's SRT contributes to FSIS's assessment of that country's performance and to FSIS's

determination of the appropriate audit frequency for that country. Countries with incomplete SRTs will not be considered "well-performing" because they will not have provided the Agency enough information to give the Agency confidence in their food safety systems. FSIS will provide more information on LOAs in a subsequent Federal Register notice that addresses all comments received in the January 2013 Federal Register notice and provides additional updates on the FSIS equivalence determination process.

To ensure that a complete and up-to-date SRT is being considered as part of FSIS's annual assessment of country performance, countries must submit their completed SRTs to FSIS before May 18, 2015, and on an annual basis moving forward. If a country submits partial or inaccurate information, FSIS personnel will follow up with additional questions until all outstanding issues are resolved. FSIS must have complete and accurate information to verify that the foreign country's food regulatory system is robust, transparent, and science-based. If a country does not provide FSIS with documentation showing its system is equivalent, or if it continues to submit inadequate documentation, FSIS will not have sufficient information to determine the viability of the food safety system and may have to pursue a series of actions directed at product presented for reinspection (e.g., intensified testing for microbial

adulterants, indicator organisms, chemical residues, or species) to address the absence of a government-supplied explanation of inspection system controls. In addition, FSIS likely would begin refusing to list establishments newly certified by the foreign government, or to relist certified establishments, because of a lack of confidence in the government-supplied explanation of its inspection system. FSIS may conduct specially designed in-country audits to obtain information. FSIS may, within a reasonable period of time, refuse entry to products exported from that country. Finally, if it becomes necessary, FSIS will take steps to remove the country from the list of countries eligible to export meat, poultry, or processed egg products.

Any country can apply for eligibility to export meat, poultry, or egg products to the United States. The application process begins with a letter to FSIS from a foreign country asking for consideration to export its products for sale in the United States. FSIS responds to these letters with a standard package that contains information on the SRT and information on gaining eAuthentication. More information on how to apply for initial equivalence is available on FSIS's Web site at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence/equivalence-process-apply-for-initial-equivalence>.

FSIS asks that a foreign country applying for initial equivalence submit a complete SRT to FSIS in PHIS within one year of receiving the questionnaire. If FSIS needs additional information, or if FSIS's regulations change, the Agency will request that the country update its SRT to provide additional information to demonstrate that the country has an equivalent food regulatory system to the United States' system. If FSIS's document review supports that the foreign country's food regulatory system may be equivalent to the United States' system, the Agency will conduct an on-site audit.

However, if a foreign government applying for initial equivalence does not submit a complete SRT or fails to respond to additional requests for information within one year of receiving the SRT, FSIS will not be able to determine that the country maintains an inspection system equivalent to FSIS's system and will discontinue its analysis.

FSIS will accept information submitted in any one of the three official languages of the World Trade Organization (WTO) - English, French, or Spanish. Please note that it may take the Agency a longer period of time to review documents submitted in French or Spanish because the information will have to be translated.

Summary of Comments

Comment: Several commenters were pleased to see improvements in the document review process; however, they asked FSIS to provide more guidance on how the SRT will be used. They also asked the Agency to share the content of the SRT with the public. A few commenters asked FSIS to clarify whether the document review process is limited to the information collected in the SRT, or if it also includes information from other sources. The commenters asked FSIS to explain how data outside the SRT would be used in the document review process, how the Agency would validate the quality of data, and how often FSIS would collect and use the data. One commenter stated that both the National Advisory Committee on Meat and Poultry Inspection's (NACMPI's) recommendations and the Codex document cited in the Federal Register notice (78 FR 5409) support third-party audits as a means of informing importing countries about the knowledge, experience, and confidence of an exporting country's food regulatory system.

Response: The SRT is used to inform a determination that a country has or has not met the United States' level of protection and is eligible to export product into the United States. It is reviewed on an ongoing basis to verify whether the country maintains equivalence. FSIS requires countries to update the SRT at least annually and as changes are made in the foreign country's food regulatory system.

FSIS personnel may review outside information, such as third-party audit reports, in preparation for an on-site audit (see FSIS Notice 35-14, Ongoing Foreign Equivalence Verification Audits). The outside information could affect the scope of an on-site audit.

Comment: Two commenters were concerned about the amount of time it takes to complete the SRT. One commenter asked FSIS to reduce the number of questions in the SRT. Another commenter requested that FSIS limit the level of detail required for responses. The commenter stated that the SRT focuses too much on individual components of the foreign inspection system, rather than taking a more holistic approach to assessing whether defined food safety outcomes are met. The commenter recommended that FSIS focus more on an evaluation of whether food safety and suitability outcomes have been achieved rather than whether various activities and processes have been replicated. The commenter suggested that FSIS change the design of the SRT so that it is more like the "outcome-focused" design of the United States Food and Drug Administration's (FDA's) International Comparability Tool.

Response: FSIS reduced the number of questions in the SRT to focus on those most necessary to determine or to verify whether a country's food regulatory system is equivalent and those necessary to help inform the necessary on-site audit

frequency. In the past, the SRT included approximately 500 questions. The new, streamlined version has approximately 200 questions. Foreign countries may receive fewer questions depending on the number of classes of products produced.

In addition, the Web-based version of the SRT is more accessible. Foreign countries will be able to log onto PHIS at any time to view and update their responses and supporting documentation. Countries will also be able to view the status of their individual SRT, as well as a date and time stamp for each status update.

FDA's International Comparability Tool does not provide the information that FSIS needs to verify that a foreign country's food regulatory system is equivalent to FSIS's system. The SRT focuses on individual components of a foreign food regulatory system and compares them to components within FSIS's regulations because the Acts and regulations (9 CFR 372.2, 381.196, and 590.910) require that foreign countries maintain equivalent requirements to those that apply to United States domestic meat, poultry, and egg products.

Comment: A few commenters stated that FSIS's review of information in the SRT should not be a substitute for on-site audits by FSIS because countries may not always report information fully or accurately. The commenters argued that FSIS will be forced to rely more heavily on self-reported data from

countries, as well as POE reinspections, and that these data sources are not an adequate substitute for in-person inspection.

Response: The SRT is not a substitute for on-site audits. The SRT is one of three components to FSIS's equivalence process. As mentioned above and in the January 2013 Federal Register notice, the SRT provides FSIS with initial information that is verified through periodic on-site audits and POE reinspections (78 FR 5411). FSIS will get more accurate information through the SRT that will better inform FSIS's audit scheduling. In addition, information from the SRT may be used to inform reinspection assignments. For example, based on information from the SRT, FSIS may perform targeted testing for residues or pathogens in product from certain countries.

It should also be noted that every country now eligible to export meat, poultry, or egg products to the United States has a food inspection system that FSIS has determined to be equivalent to the FSIS domestic inspection system. FSIS is committed to protecting the health of U.S. consumers, and it will continue to make every effort to ensure that meat, poultry, and egg products imported into the United States are as safe as products produced in this country.

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Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices.

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Done in Washington, DC on: February 18, 2015.

Alfred V. Almanza

Acting Administrator.

[FR Doc. 2015-03576 Filed 02/20/2015 at 8:45 am; Publication Date: 02/23/2015]