

Methodology on How to Classify Foreign Countries for Prioritizing On-Site Equivalence Verification Audits

Introduction

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) has updated the methodology for prioritizing countries for scheduling on-site equivalence verification audits. This methodology replaces the methodology in *Performance-Based Approach to Foreign Country Equivalence Verification Audits and Point-of-Entry (POE) Reinspection*.

FSIS conducts on-site equivalence verification audits of those countries that are eligible or interested in obtaining market access to export meat, poultry, or egg products to the United States. FSIS continuously evaluates and verifies the ongoing equivalence of exporting countries' food safety inspection systems through a three-part process: (1) recurring document reviews; (2) on-site verification audits; and (3) point-of-entry (POE) reinspection of each shipment of meat, poultry, and egg products. FSIS requires an on-site equivalence verification audit of exporting countries at least once every three years from the date that FSIS published the last audit report of that exporting country. Typically, FSIS does not schedule on-site equivalence verification audits until at least one year after FSIS publishes the last audit report. FSIS also requires newly determined equivalent countries to have an on-site equivalence verification audit within one year from the effective date listed in the final rule granting equivalence. In addition, FSIS requires an on-site equivalence verification audit be performed within six months of the date of reinstating an inspection system when an on-site verification audit was not a prerequisite for reinstatement.

Methodology for Prioritizing Exporting Countries

This methodology institutes a risk-based approach that utilizes public health risk determinants to prioritize foreign countries (high priority, medium priority, and low priority). FSIS will implement this methodology to prepare the annual on-site verification audit schedule, as described in [FSIS Directive 9780.1, Verifying the Ongoing Equivalence of Foreign Food Safety Inspection Systems](#). By considering a country's public health risks during the audit planning process, FSIS maximizes the effectiveness of its audit resources to ensure that only wholesome, unadulterated products enter U.S. commerce. [Appendix A](#) provides public health risk determinants to prioritize exporting countries.

FSIS's highest priorities for on-site verification audits are:

- Those countries with one or more incidents of illnesses in the U.S. attributable to export products, public health recalls, or public health alerts where preventative measures have not been verified;

- Those with one or more POE positive test results for *Listeria monocytogenes* (Lm) or *Salmonella* in ready-to-eat (RTE) meat, poultry, or processed egg products or Shiga toxin-producing *Escherichia coli* (STEC) test results in raw beef or veal products;
- Those with lot failures of POE for violative residues; and
- Those with three or more public health lot failures since their last on-site verification audit, and countries with findings from the last on-site verification audit which were classified as significant/systemic.

Within this highest-priority category, FSIS ranks at the top countries with one or more attributed U.S. illnesses, public health recalls, or public health alerts. Within this highest-priority category, FSIS also ranks countries based on the number of priority incidents they experienced, and then on how recent the incidents were. FSIS will audit these countries within 24 months from when FSIS publishes the last audit report.

FSIS's medium priorities for on-site verification audits are:

- Those countries where preventative measures were verified in the previous on-site verification audit associated with one or more incidents of illnesses in the U.S. attributed to export products, public health recalls, or public health alerts;
- Those with no more than two public health lot failures since the last on-site verification audit;
- Those with a risk volume in the 90th percentile of exporting countries (See [Appendix B](#) for information concerning how FSIS determines risk volume scores); and
- Those with trends in Other Consumer Protection (OCP) Types of Inspection (TOI) failures at POE since their last on-site verification audit, and countries with findings from the last on-site verification audit which were not classified as significant/systemic.

Within this medium-priority category, FSIS ranks countries higher based on the number of priority incidents they experienced, and then on how recent the incidents were. When further refinement of countries is necessary within this category, FSIS ranks countries based on their average risk volume score. FSIS will audit these countries within 30 months from when FSIS publishes the last audit report.

FSIS's low audit priorities are countries without any of the "high" or "medium" risk determinants, and FSIS prioritizes these countries according to their average risk volume score. FSIS will audit these countries within 36 months from when FSIS publishes the last audit report.

This methodology does not apply to countries that have not exported any eligible meat, poultry, or egg products within three or more years. FSIS considers countries that are not actively exporting products to the U.S. as inactive. FSIS requires these countries to obtain a reinstatement of equivalence determination prior to resuming exporting products to the United States.

Appendix A

Table 1. Public Health Risk Determinants for Foreign Countries

High Priority	Medium Priority	Low Priority
One or more incidents of illnesses in the U.S. attributed to export products, recalls, or public health alerts where preventative measures were not verified since the last audit	Preventative measures were verified in the previous audit associated with one or more incidents of illnesses in the U.S. attributed to export products, recalls, or public health alerts	No previous audit findings
One or more POE positive test results for <i>Lm</i> or <i>Salmonella</i> in RTE meat and poultry, and processed egg products since the last audit	Average risk volume Score in the 90 th percentile (Appendix B)	Country not actively exporting product to the U.S. resulting in limited to no recent POE inspection data
One or more POE positive test results for STEC in raw beef and veal product	No more than 2 public health lot failures since the last audit	Country exporting low volume of product to the U.S.
Lot failures at POE for violative residues	Trends identified in OCP TOI failures at POE	Ordered by average risk volume score
3 or more public health lot failures since the last audit	Findings from the last audit not classified as significant/systemic	
Findings from the last audit classified as significant/systemic		

Appendix B: Risk Volume Score

Calculation of an exporting country's risk volume score considers product type and import volume, according to the following formula:

$$\text{Risk Volume Score} = \sum (\text{Volume Risk Units} \times \text{Hazard Coefficient for the Product Type})$$

The Volume Risk Units (VRU) for exporting countries are currently defined as the *square root* of the total import volume for a particular process category/product category/species combination (as described in [FSIS Product Categorization Guide](#)). Table 1 contains hazard coefficients for various product categories:

Table 1. Hazard Coefficient by Product Type¹

Class#	Product Category	Hazard Coefficient
1	Raw ground, comminuted, or otherwise non-intact beef	10
2	Raw ground, comminuted, or otherwise non-intact chicken	10
3	Raw ground, comminuted, or otherwise non-intact turkey	10
4	Raw ground, comminuted, or otherwise non-intact poultry—other than chicken or turkey	10
5	Raw ground, comminuted, or otherwise non-intact meat—other than beef or pork	9.7
6	Raw intact turkey	9
7	Raw intact chicken	8
8	Raw intact poultry—other than chicken or turkey	8
9	Raw ground, comminuted, or otherwise non-intact pork	8
10	Raw otherwise processed meat	7
11	Raw otherwise processed poultry	7
12	Raw intact beef	5
13	Raw intact meat—other than beef or pork	5
14	Raw intact pork	4
15	RTE fully-cooked meat (Post Lethality Exposed)	3
16	RTE fully-cooked poultry (Post Lethality Exposed)	3
17	RTE acidified / fermented meat (without cooking)	2
18	RTE acidified / fermented poultry (without cooking)	2
19	RTE dried meat	2
20	RTE dried poultry	2
21	RTE salt-cured meat	2
22	RTE salt-cured poultry	2
23	RTE meat fully cooked (Not Post-Lethality Exposed)	1
24	RTE poultry fully cooked (Not Post-Lethality Exposed)	1
25	Thermally Processed / Commercially Sterile Product	1

FSIS applies a hazard coefficient of 10 for process categories, product categories, product groups or species not identified in the above chart. For example, fish of the order Siluriformes and egg products are not identified in the chart and FSIS applies a hazard coefficient of 10 for these products.

¹ This chart is based on the results of an expert elicitation conducted by RTI International (RTI) for FSIS. The purpose of the expert elicitation was to collect data on the relative risks posed to public health by various types of processed meat and poultry products, and can be found at:

https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/RBI_Elicitation_Report.pdf and
https://www.fsis.usda.gov/shared/PDF/Elicitation_Memo_092205.pdf

Example: Table 2 lists the import values for Country “X” in a 12-month period² in 2012:

Table 2. Country “X” Import Volume

Year	Country	Process Category	Product Category	Product Group	Species	Presented Net Weight (lbs.)
2012	Country “X”	Thermally Processed/ Commercially Sterile	Thermally Processed, Commercially Sterile	Sausage	Pork	87,362
2012	Country “X”	Not Heat Treated - Shelf Stable	RTE acidified / fermented meat (without cooking)	Sausage/Salami - Not Sliced	Pork	536,038
2012	Country “X”	Heat Treated - Shelf Stable	RTE dried meat	Ham - Not Sliced	Pork	6,522
2012	Country “X”	Not Heat Treated - Shelf Stable	RTE dried meat	Jerky	Beef	192,882
2012	Country “X”	Not Heat Treated - Shelf Stable	RTE acidified / fermented meat (without cooking)	Sausage/Salami - Not Sliced	Beef	714
2012	Country “X”	Raw - Non Intact	Raw ground, comminuted, or otherwise non-intact beef	Ground Beef	Beef	10,000
						833,518

The country risk volume score for the 833,518 lbs. of product imported from Country “X” for that 12-month period is calculated as follows:

Risk Volume Score for Country "X" =

$$\begin{aligned}
 &VRU(\textit{Thermally Processed, Commercially Sterile Pork Sausage}) \times \\
 &HC(\textit{Thermally Processed, Commercially Sterile Pork Sausage}) \\
 &+VRU(\textit{RTE acidified fermented meat (without cooking) Pork Salami}) \times \\
 &HC(\textit{RTE acidified fermented meat (without cooking) Pork Salami}) \\
 &+VRU(\textit{RTE dried meat Ham}) \times HC(\textit{RTE dried meat Ham}) \\
 &+VRU(\textit{RTE dried meat Jerky}) \times HC(\textit{RTE dried meat Jerky}) \\
 &+VRU(\textit{Raw ground, comminuted, or otherwise non – intact beef Ground Beef}) \times \\
 &HC(\textit{Raw ground, comminuted, or otherwise non – intact beef Ground Beef})
 \end{aligned}$$

² Staff in the Office of Investigation, Enforcement, and Audit, Management Control and Audit Division (MCAD) uses three 12-month cycles starting from 60 days prior to the request date to provide the data in order to account for dispositions.

Risk Volume Score =

$$\sqrt{87,362} \times 1 + \sqrt{536,038} \times 2 + \sqrt{6,522} \times 2 + \sqrt{192,882} \times 2 + \sqrt{714} \times 2 + \sqrt{10,000} \times 10$$

$$\text{Risk Volume Score} = 296 + 1,464 + 162 + 878 + 53 + 1,000$$

$$\text{Risk Volume Score} = 3,853$$

The Country Risk Volume Score for Country “X” in a 12-month period in 2012 is 3,853.

The risk volume score for a country is calculated, as demonstrated above, for each of the three 12-month cycles. The average of the risk volume scores for the three 12-month cycles is used to calculate the average risk volume score for each country.