

Foreign Site Ranking and Selection Process for Foreign Audits

Introduction

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) has updated the methodology for determining how many and which specific foreign sites (Central Competent Authority's – CCA – offices, laboratories, and establishments) FSIS visits during ongoing equivalence audits. This methodology replaces the methodology in *Performance-Based Approach to Foreign Country Equivalence Verification Audits and Point-of-Entry (POE) Reinspection*. FSIS will implement this updated methodology during the audit planning process as described in [FSIS Directive 9770.1, Determining Initial and Reinstating the Equivalence of Foreign Food Safety Inspection Systems](#) and [FSIS Directive 9780.1, Verifying the Ongoing Equivalence of Foreign Food Safety Systems](#).

FSIS utilizes the *Methodology on How to Classify Foreign Countries for Prioritizing On-Site Equivalence Verification Audits* and the instructions in [FSIS Directive 9780.1](#) to develop the audit schedule that identifies which countries will be audited each year.

During on-site verification audits, FSIS visits foreign sites associated with the system of providing government oversight and inspection (including microbiological and residue testing) for meat, poultry, and egg products intended for export to the United States. The purpose of the audit is to verify that the implementation of the equivalence components of the country's food safety inspection system remains consistent with its design as documented by the CCA in the Self-Reporting Tool (SRT). FSIS is to plan the audit to assess how a country's food safety inspection system is working. FSIS uses a risk-based approach to assess the food safety inspection system as a whole, by verifying controls and by recognizing that any findings identified during the audit need to be considered in the context of the overall food safety inspection system.

This methodology applies to on-site verification audits associated with initial, reinstatement, expansion of initial, and ongoing equivalence determinations.

Methodology for Selecting and Prioritizing Specific Foreign Sites

During the audit planning process, FSIS utilizes a risk-based approach to prioritize all foreign sites that are associated with providing government oversight and inspection for products intended for export to the U.S. [Appendix A](#) provides the risk determinates to prioritize foreign sites. In some countries, the number of potential foreign sites is few enough that FSIS may elect to audit all the sites.

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

- Those foreign sites associated with one or more incidents of illnesses in the U.S. attributed 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 establishments with three or more public health lot failures since the last audit of the foreign country's food safety inspection system; and
- Regional offices overseeing high priority establishments.

Within this highest-priority category, FSIS ranks foreign sites highest based on the number of priority incidents they experienced, and then on how recent the incidents were.

FSIS's medium priorities for audits are:

- Those foreign sites 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 a risk footprint in the 90th percentile for the country's food safety program (See [Appendix B](#) for information concerning how FSIS determines risk footprints);
- Those establishments with no more than two public health lot failures since the last on-site verification audit;
- Those sites that had significant prior findings during the last audit cycle; and
- Newly-certified establishments, establishments not previously audited, establishments with administrative issues of concern to FSIS, establishments that have been recently renovated, certified source establishments, regional offices not previously audited, and newly-accredited laboratories.

Within this medium-priority category, FSIS ranks foreign sites highest based on the number of priority incidents they experienced, and then on how recent the incidents were. When further refinement of establishments is necessary within this category, FSIS ranks establishments based on their average risk footprint.

FSIS's low audit priorities are CCA offices and laboratories previously audited, and establishments without any of the "high" or "medium" risk determinants. FSIS prioritizes establishments within this low-priority category according to their average risk footprint.

The number of foreign sites, including establishments, is determined by available resources (e.g., time, money, staffing availability, personnel security, geographical considerations, and the need to visit establishments representing different product categories). FSIS is to audit the highest prioritized sites in descending order until the determined number is reached as described in [Directive 9770.1](#) and [Directive 9780.1](#).

Appendix A

Table 1. Risk Determinants for Foreign Establishments, Offices, and Laboratories

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	CCA offices and laboratories previously audited
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 footprint in the 90 th percentile (Appendix B)	Establishments are ranked by average risk footprint
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	
3 or more public health lot failures since the last audit	Significant prior findings last audit cycle	
Regional offices overseeing high priority establishments	Newly certified establishments Establishments not previously audited Establishments with administrative issues of concern to FSIS Establishments recently renovated Certified source establishments	
	Regional offices not previously audited	
	Newly accredited laboratories	

Appendix B: Risk Footprints

A **risk footprint** is each individual certified establishment’s impact on the final risk volume score of the country. 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/product group/species combination (as described in [FSIS Product Categorization Guide](#)). Table 1 contains hazard coefficient (HC) 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

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/wps/wcm/connect/2d081ff1-cdc3-4975-94d4-948930b6e141/RBI_Elicitation_Report.pdf?MOD=AJPERES and https://www.fsis.usda.gov/shared/PDF/Elicitation_Memo_092205.pdf?redirecthttp=true.

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.

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

Table 2. Country “X” Import Volume

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

² Staff in the Office of Investigation, Enforcement and Audit (OIEA), 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.

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" =

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

Risk Volume Score =

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

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

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

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

Table 3 demonstrates the distribution of the risk-volume score (3,853) for Country “X” among establishments. For example, establishment X-YZ accounts for 26% (1,000 / 3,853) of the risk-volume and as such has the second highest risk footprint even though the establishment only accounts for 1.2% (10,000 / 833,518) of the import volume in pounds. This is primarily due to the import of raw ground beef from this establishment, which presents a significantly higher hazard coefficient than other products received from this country.

Table 3. Ranking of Establishments by Risk Footprints

Establishment	Establishment Risk Volume Score	% of Country X’s Risk Volume	Risk Footprint Rank
X-CD	296	8%	4
X-EF	1,464	38%	1
X-GH	162	4%	5
X-HI	878	23%	3
X-JK	53	1%	6
X-YZ	1,000	26%	2

The ranking of establishments by their risk footprints, as demonstrated in Table 3, is calculated for each of the three 12-month cycles. The average of the ranking of the establishments by their risk footprints for the three 12-month cycles is used to calculate the average risk footprint rank for each establishment.