

Risk-Based Approach to Foreign Country Audits and Port-of-Entry Reinspections

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Proposed Risk-Based Approach

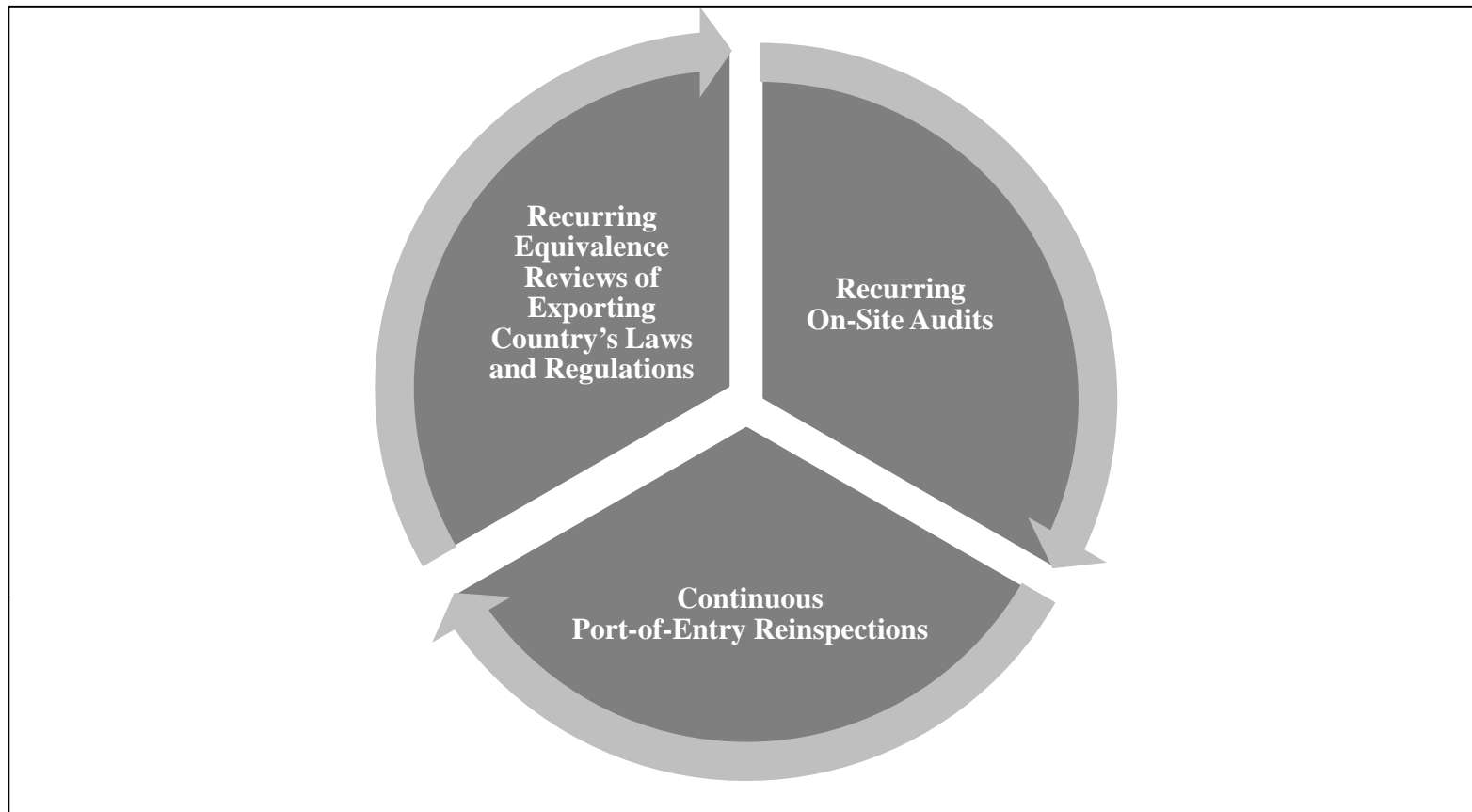
FSIS developed a risk-based approach to foreign country audits and port-of-entry (POE) reinspections/sampling in order to:

- Focus resources on those imported products that are expected to pose the greatest threat to public health
- Improve linkage between foreign country audit findings and POE reinspections
- Increase harmonization of domestic and international approaches

Background

- US imports 4 billion pounds of meat, poultry, and processed egg products annually
- In order to export to the US, FSIS must first deem a foreign country's food safety system equivalent to the US system through:
 - Initial review of a country's laws and regulations
 - Initial on-site country audit
- To ensure continued safety and wholesomeness of products from that country, FSIS conducts:
 - Recurring review of the exporting country's laws/regulations
 - Recurring on-site audits in the foreign country
 - POE reinspection and sampling of imported products

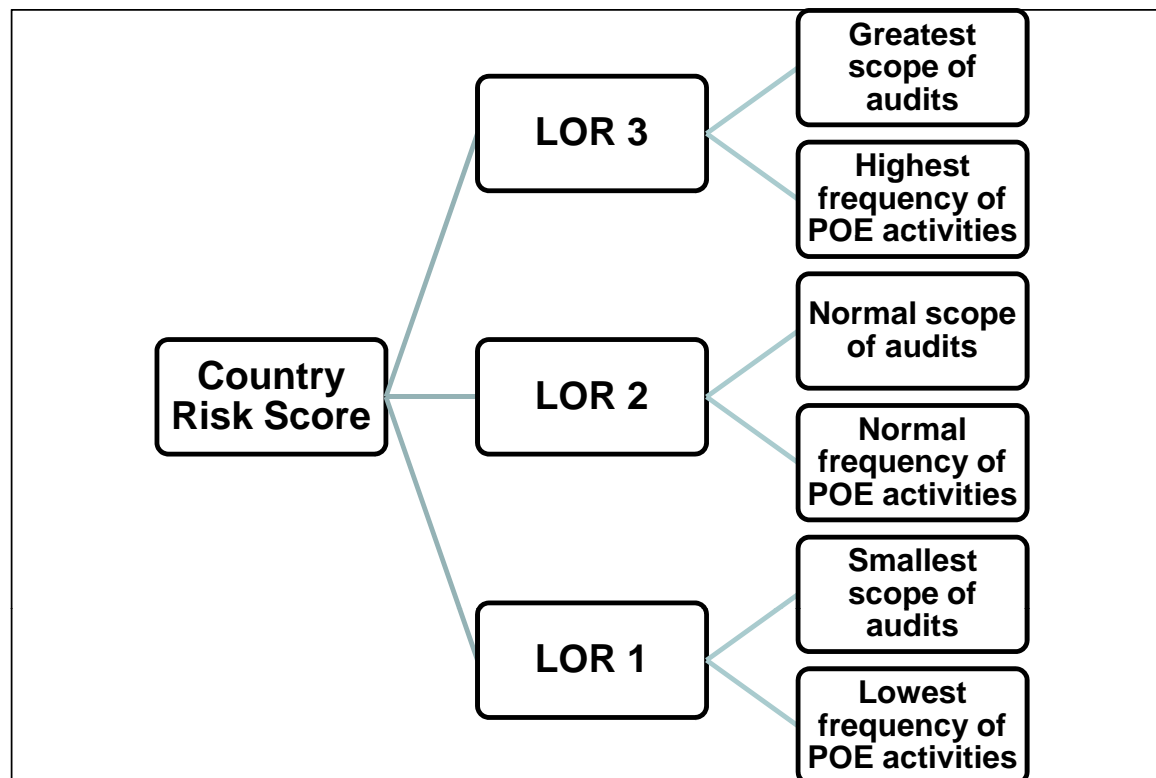
Maintaining Equivalence



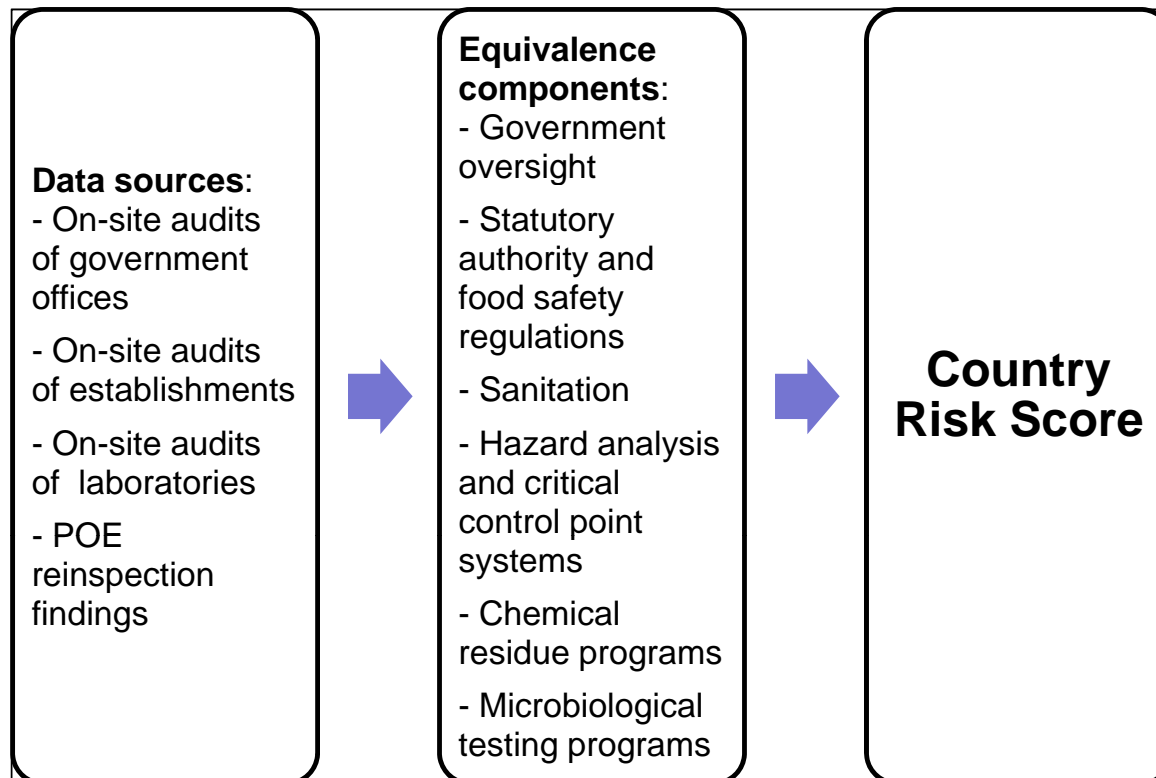
Methodology

- Calculate a country risk score for each eligible exporting country
- Assign each eligible exporting country to one of three levels of risk (LOR) based on its country risk score
- Use the country's LOR to determine:
 - The scope of on-site audits in that country
 - The frequency of POE reinspections and laboratory testing on imports from that country

Country Risk Levels



Factors Considered in Assigning the Country Risk Score



Scoring Methodology

- Develop a country-specific score for each of the 6 equivalence components, based on data from each of the 4 data sources
- Use statistical techniques to combine a country's scores from each of the 6 equivalence components
- Calculate a z-score for each country
 - Statistically-derived z-scores allow country comparisons
 - Current z-score cut points: -1.5, 1.5 (cut points may be adjusted as additional data are collected)
- Assign each country a risk score, based on its z-score
 - Country risk score = 0.9, 1.0, or 1.1
 - The country risk score determines a country's LOR
 - The country risk score modifies the number of POE samples

Example Country Risk Scores

Country	Z-Score	Country Risk Score
Brazil	2.68	1.1
Mexico	1.94	1.1
Iceland	0.38	1
Argentina	-0.06	1
Belgium	-1.69	0.9

Note: The z-scores and associated country risk scores shown above are for demonstration only. They do not reflect actual scores.

Foreign Country Audits

- Country placed in 1 of 3 LORs
 - Countries in Level 3: higher scope of on-site audits
 - Countries in Level 1: smaller scope of on-site audits
- To determine which establishments to visit in each country, FSIS will consider the following:
 - Inherent risk of product(s) from each establishment
 - Volume exported
 - Establishment performance (i.e., positive results reported for previous POE samples)
- Foreign country audits will target higher risk establishments, based on larger volumes and/or “riskier” products

POE Verifications and Reinspections

POE Verifications (All shipments)	POE Reinspections (Risk-based approach used to set sample sizes)
Eligible country	Physical reinspections
Eligible establishment	Condition of containers
Eligible product	Laboratory sampling
Proper certification	- Microbiological
Transportation damage	- Food chemistry
Proper labeling	- Species verification
Shipping marks	- Residue sampling
General condition	
Box count	

Physical Reinspections

- Current approach: Frequency of reinspections is based on:
 - Exporting country
 - HACCP category
 - Product species
 - Number of lots presented
- Proposed approach: Adjust sample size based on country risk score
 - Risk-based sample size =
current sample size X country risk score

Condition-of-Container Reinspections

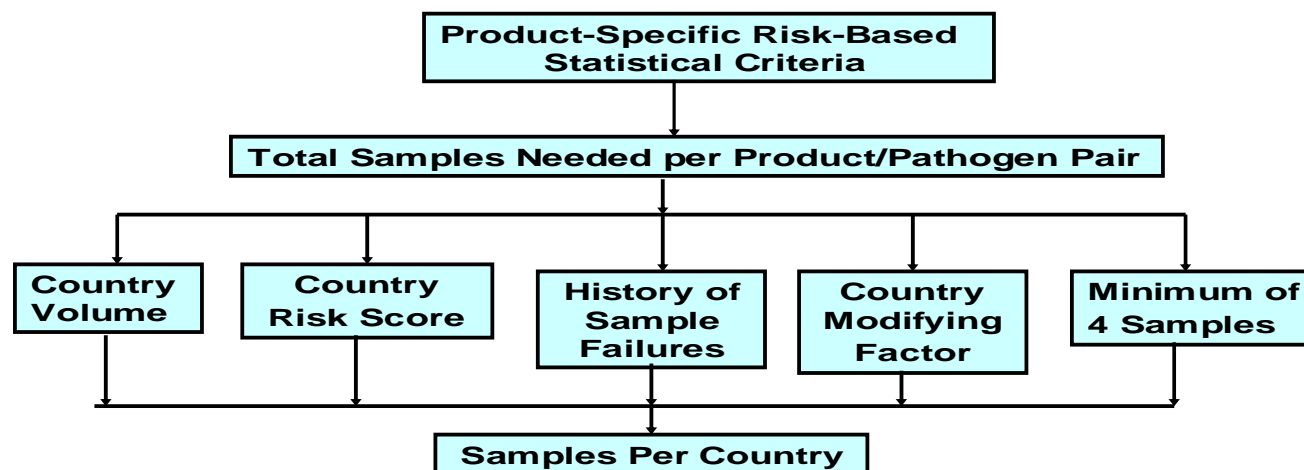
- Current approach: Similar to approach for physical reinspections
- Proposed approach:
 - Use past POE findings to calculate a condition-of-container (coc) risk score for each eligible country
 - Adjust sample size based on coc risk score
 - Risk-based sample size =
current sample size X coc risk score

Laboratory Sampling: Microbiological Testing

- Establish total sample size for each pathogen/product pair, considering all countries collectively
 - E. coli in imported raw ground beef
 - E. coli in imported raw ground beef components
 - L. monocytogenes in imported RTE products
 - Salmonella in imported RTE products
- Apportion total sample size for each product/pathogen pair among exporting countries

Process for Determining Number of Samples per Country

Distribution of Samples Among Countries



Other Sampling

- Food chemistry sampling/Species verification:
 - Utilize approach similar to approach for physical reinspections
- Residue sampling:
 - No change under risk-based approach (sampling established by National Residue Program)

Conclusion

Proposed risk-based approach will:

- Focus FSIS resources on countries/products that are expected to pose the greatest threat to public health
- Improve linkage between audit findings and POE reinspections
- Increase harmonization of domestic and international approaches

Thank You