United States Department of Agriculture

FOOD SAFETY AND INSPECTION SERVICE
Office of International Affairs

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PROCESS FOR EVALUATING THE EQUIVALENCE OF FOREIGN MEAT AND POULTRY FOOD REGULATORY SYSTEMS

1. INTRODUCTION

Imported meat and poultry products must meet all safety standards applicable to similar products produced in the United States. In doing so, foreign meat and poultry food regulatory systems may apply *equivalent* sanitary measures to eliminate or abate food safety hazards if those measures provide the *same* "level of public health protection" achieved by U.S. measures. The concept that different sanitary measures can achieve the same level of protection is called equivalence.

The Food Safety and Inspection Service (FSIS) evaluates foreign meat and poultry food regulatory system equivalence through a process that consists of (1) document analysis, (2) on-site audit, and (3) port-of-entry product reinspection. Judgments of system equivalence are necessary for FSIS and the American public to develop and maintain trust in imported meat and poultry products. While consumers increasingly express concern that the worldwide integration of food production may expose them to hazards from imported products, they simultaneously demand access to the abundant variety of affordable international foods. The degree to which consumers trust imported food is directly related to perceptions of how effectively food production is regulated by the foreign system and how well USDA verifies the safety of imported meat and poultry food products. Thus, trust becomes an equivalence issue with both food safety and trade implications.

2. PURPOSE AND SCOPE

This paper revises and replaces a March 1999 document titled "FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems." On March 12, 1999, FSIS published a Notice in the *Federal Register* announcing availability of the "FSIS Process…" document and solicited public comments. [1] The Notice also announced a public meeting that FSIS held on April 14, 1999, to introduce the equivalence evaluation process and take oral comments.

On December 17, 1999, FSIS published a response to public comments. [2] In that *Federal Register* Notice, the Agency agreed to incorporate suggested changes where appropriate in the next edition of its "FSIS Process…" document and pledged to continue equivalence activities in a transparent manner. This revised paper presents the evaluation process FSIS applies to initially determine and periodically verify whether foreign meat and poultry food regulatory systems are equivalent to U.S. domestic regulatory programs. The process described in this document is essentially unchanged from the March 1999 version, but has been expanded in certain areas pursuant to public comments on the earlier version. The paper itself has been reformatted in a manner similar to Codex Alimentarius publications.

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[1] 64 FR 12281; March 12, 1999

[2] 64 FR 70690; December 17, 1999

The process presented in this document implements FSIS regulations that require an evaluation of foreign inspection systems to determine whether countries are eligible to export meat and poultry products to the United States. [3] Agency regulations also set specific evaluation criteria that are applied by FSIS during this process to make equivalence determinations. [4]

3. DEFINITIONS

Appropriate level of protection [5]	The level of protection from a food safety hazard that is deemed appropriate by a country in establishing a sanitary measure to protect human life or health within its territory. Also referred to as the "acceptable level of risk," which is a societal judgment of what risk from food safety hazards is acceptable to the majority.
Equivalence [6]	Equivalence is the state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing country, achieve, as demonstrated by the exporting country, the importing country's appropriate level of sanitary protection.
Food Safety Hazard [7]	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse human health effect.
Regulatory Objective [8]	An explanation of how a sanitary measure attains or contributes to attaining the level of protection from a food safety hazard that is deemed appropriate by a country within its territory.
Sanitary Measure [9]	Any measure applied: (a) to protect animal life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; (b) to protect human or animal life or health from risks arising from additives, contaminants, toxins

[3] 9 CFR 327.2 (a)(2) for meat and 9 CFR 381.196 (a)(2) for poultry

[4] 9 CFR 327.2 (a)(2) (i)-(iv) for meat and 9 CFR 381.196 (a)(2) (i)-(iv) for poultry

[5] Adapted from a Codex Committee on Food Inspection and Certification Systems (CCFICS) document titled "Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems" (ALINORM 03/30A, Appendix II)

[6] Ibid.

[7] Codex Alimentarius Commission: Procedural Manual

[8] Food Safety and Inspection Service; bridging concept formerly referred to as "Food Safety Objective." This explanation includes quantitative or qualitative descriptions of what the sanitary measure is intended to achieve.

[9] Agreement on the Application of Sanitary and Phytosanitary Measures; Appendix A

or disease-causing organisms in foods, beverages or feedstuffs; (c) to protect human life or health from risks arising from diseases carried by animals, or products thereof, or from the entry, establishment or spread of pests; or (d) to prevent or limit other damage from the entry, establishment or spread of pests. Sanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.

4. BACKGROUND

This section summarizes the legal basis for equivalence determinations, first in the context of international agreements, then more specifically in U.S. meat and poultry inspection laws and regulations.

4.1 SPS Agreement, World Trade Organization

International food safety equivalence is a concept introduced by the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement), which appears in the Final Act of the Uruguay Round of Multilateral Trade Negotiations, signed in Marrakesh on April 15, 1994. The SPS Agreement became effective in January 1995 concurrently with establishment of the World Trade Organization (WTO), which superseded the General Agreement on Tariffs and Trade (GATT) as the umbrella organization for international trade. The United States is a signatory to the SPS Agreement and a Member of the WTO.

The SPS Agreement requires an importing Member country to accept the sanitary measures of an exporting Member country as equivalent to its own if the exporting country demonstrates that its sanitary measures attain the same level of protection.

> *Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.*[10]

[10] Article 4.1, "Agreement on the Application of Sanitary and Phytosanitary Measures."

The burden for demonstrating equivalence rests with an exporting country. The importing country has a sovereign right to set any level of protection it deems appropriate to eliminate or abate a food safety hazard within its territory. If an exporting country objectively demonstrates that its sanitary measures achieve the levels of protection set domestically by an importing country, the importing country is obliged to accept the exporting country's measures as equivalent.

The recognition of equivalence does not require importing and exporting countries to enter into a bilateral agreement or any formal agreement. Mutual recognition is not a component of Article 4.1 and *quid pro quo* is not a criterion for equivalence. Equivalence under Article 4.1 means the unilateral evaluation by an importing country of an exporting country's sanitary measures.

The SPS Agreement also regards equivalence as a way to encourage the development of international food safety standards for "harmonization" between Members and the facilitation of trade. The fact that a Member's standard may differ from international standards does not, in itself, create an adverse presumption that it is failing to meet its SPS obligations. In other words, the SPS Agreement preserves each Member's right to make independent judgments about food safety risks and to set standards that may be higher or lower than an international benchmark.

4.2 Codex Alimentarius

The SPS Agreement states that Members shall harmonize sanitary measures applied within their territory by basing them on international standards, guidelines, or recommendations where they exist. This requirement for harmonization applies in particular to the standards, guidelines and recommendations established by the Codex Alimentarius Commission for food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice. Codex standards are scientifically defensible and widely accepted as benchmarks against which national measures and regulations are evaluated.

Codex was developed by an international commission established in 1962 when the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) recognized the need for universal standards to guide the world's growing food industry. The purpose of Codex Alimentarius is to promote the elaboration and establishment of definitions and requirements for foods, to provide harmonization for public health purposes, and to facilitate international trade.

The Codex Alimentarius Commission is responsible for making proposals to the Directors-General of the FAO and the WHO on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Program. The Commission establishes subsidiary bodies in the form of Codex Committees for the preparation of draft standards for submission to the Commission.

FSIS has referred to work done by the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) in the development of this equivalence evaluation process document.

4.3 U.S. Laws and Regulations

Prior to the SPS Agreement, FSIS evaluated foreign meat and poultry food regulatory systems under U.S. inspection laws that required them to be "at least equal to" the U.S. system. The eligibility of countries to export meat or poultry products to the United States was initially evaluated on a case-by-case basis through analysis of applications followed by on-site audits. In 1994, the United States adopted the SPS Agreement with passage of the Uruguay Round Agreements Act. Subsequently, all "at least equal to" countries that were eligible to export meat or poultry products to the United States were automatically judged to be "equivalent."

The Uruguay Round Agreements Act provided U.S. administrative agencies a standard that must be met when determining the equivalence of alternative sanitary measures.

> *An agency may not determine that a sanitary or phytosanitary measure of a foreign country is equivalent to a sanitary or phytosanitary measure established under the authority of Federal law unless the agency determines that the sanitary or phytosanitary measure of the foreign country provides at least the same level of sanitary or phytosanitary protection as the comparable sanitary or phytosanitary measure established under the authority of Federal law.*[11]

The Act also amended other legislation to comport with SPS requirements. Among these were equivalence amendments to the Federal Meat Inspection Act (FMIA)[12] and the Poultry Products Inspection Act (PPIA).[13]

> *The Secretary [of Agriculture] may treat as equivalent to a United States requirement a requirement described in subparagraph (A) [of this section] if the exporting country provides the Secretary with scientific evidence or other information, in accordance with risk assessment methodologies determined appropriate by the Secretary, to demonstrate that the requirement achieves the level of sanitary protection achieved under the United States requirement. For the purposes of this subsection, the term 'sanitary protection' means protection to safeguard public health.*[14]

In July 1995, FSIS implemented the FMIA and PPIA amendments cited above with a direct final rule[15] that deleted existing regulatory language requiring foreign meat and poultry food regulatory systems to be "at least equal to" the system in the United States. In its place, the final rule substituted the words "equivalent to" as the standard for eligibility. Part 327 (meat) and Part 381 Subpart T (poultry) of Title 9, Code of Federal Regulations (CFR), pertain to eligibility requirements for imported meat and poultry products. For example, Section 327.2 describes the standard for eligibility of foreign countries for importation of meat products into the United States, as follows:

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[11] Sec. 492, "The Uruguay Round Agreements Act," (P.L. 103-465; December 8, 1994).

[12] 21 U.S.C. 620(e)

[13] 21 U.S.C. 466

[14] Amendment to §20(e) FMIA. The PPIA was amended by §431(k) with essentially the same language.

[15] 60 FR 38667; July 28, 1995.

> *Whenever it shall be determined by the Administrator that the* system *of meat inspection maintained by any foreign country, with respect to establishments preparing products in such country for export to the United States, insures compliance of such establishments and their products with requirements* **equivalent** *to all the inspection, building construction standards, and all other provisions of the Act and the regulations in this subchapter which are applied to official establishments in the United States, and their products, and that reliance can be placed upon certificates required under this part from authorities of such foreign country, notice of that fact will be given by including the name of such foreign country in paragraph (b) of this section.* [16]

Agency regulations further specify that determinations of eligibility must be based upon equivalence evaluations. [17] Consequently, FSIS has developed the process described in this paper to conduct equivalence evaluations of foreign meat and poultry food regulatory systems or of individual sanitary measures that vary from U.S. requirements. The criteria for evaluating foreign systems are set forth in Section 327.2 for meat and Section 381.196 for poultry. [18] Each of these regulatory criteria constitutes a sanitary measure as defined by the SPS Agreement. The criterion for evaluating alternative sanitary measures is whether they achieve the same level of sanitary protection provided by the United States requirement. Evaluations of alternative sanitary measures are made by determining whether they are at least as effective as U.S. requirements in controlling food safety hazards. These evaluations employ evolving international concepts that link sanitary measures with the level of protection they are intended to achieve. The following section summarizes these concepts.

5. CONCEPTS OF EQUIVALENCE

Equivalence is based upon an inter-relationship between sanitary measures, regulatory objectives, and levels of protection. Cumulatively, these components provide a framework to evaluate the equivalence of different food regulatory systems, parts of systems, or individual sanitary measures.

5.1 Sanitary Measures

National food regulatory systems apply sanitary measures to eliminate or abate food safety hazards to a degree that achieves the level of protection deemed appropriate within their territory. Sanitary measures are defined by their intent to protect human life or health from foodborne hazards that involve an additive, contaminant, toxin, or disease-causing organism or from a disease or pest carried by an animal or a product thereof.

[16] 9 CFR §327.2(a)(1) [emphasis added]

[17] Ibid., footnote 5.

[18] Ibid., footnote 6.

These measures may take many forms, to include: [19]

- End product criteria.
- A product-related processing or production method.
- A testing, inspection, certification, or approval procedure.
- A relevant statistical method.
- A sampling procedure.
- A method of risk assessment.
- A packaging and labeling requirement directly related to food safety.

Sanitary measures must (1) be based upon scientific principles and (2) be applied by an importing country in a manner that is not arbitrary and would not unjustifiably discriminate between its own industry and that of another country. These measures must be based on an assessment of risk from a food safety hazard, i.e., an evaluation of the potential for adverse affects on human life or health. The term "risk assessment" as used in the SPS Agreement is not limited to quantitative risk assessment, which has been described as a particular type of risk assessment used to evaluate the potential for carcinogenesis. [20]

To the extent deemed appropriate by each Member, sanitary measures should be harmonized with those applied in other countries by basing them on relevant international standards such as the Codex Alimentarius. Countries are not, however, required to harmonize "downward" by accepting a Codex or other international standard that provides a lower level of protection than is deemed appropriate by society. Similarly, Members may establish and maintain higher standards than Codex provides if a greater level of protection is deemed appropriate.

An objective basis for comparison of sanitary measures should be established, and this may include the following elements:

- The regulatory objective of the sanitary measure; i.e., its purpose and how it achieves or contributes to achievement of a level of protection (the ALOP).
- To the extent possible and practical, the level of hazard control that is achieved by the sanitary measure.
- A scientific basis for the sanitary measure, including qualitative or quantitative risk assessment where appropriate.

[19] Administrative Action Statement accompanying "The Uruguay Round Agreements Act," (P.L. 103-465; December 8, 1994); at A.3.b. (see House Report No. 103-826(II) accompanying H.R. 5110). This statement represents an authoritative expression regarding the interpretation and application of the Uruguay Round Agreements, both for purposes of U.S. international obligations and domestic law. Since this Statement was approved by the Congress at the time it implemented the Uruguay Round agreements, the interpretations of those agreements in this statement carry particular authority.

[20] Ibid. at A.9.

5.2 Appropriate Level of Protection (ALOP)

Importing countries may set any level of protection they deem appropriate and establish sanitary measures accordingly to eliminate or abate food safety hazards. While sanitary measures must be based objectively on scientific or technical knowledge about controlling food safety hazards, an importing country's level of protection is a societal choice of what is deemed appropriate. An ALOP may be objective or subjective in its tolerance for particular hazards.

> *The [SPS] Agreement explicitly affirms the right of each government to choose its levels of protection, including a "zero risk" level if it so chooses. A government may establish its levels of protection by any means available under its law, including by referendum. In the end, the choice of the appropriate level of protection is a societal value judgment. The Agreement imposes no requirement to establish a scientific basis for the chosen level of protection because the choice is not a scientific judgment.*[21]

The SPS Agreement defines ALOP as follows:

> *Appropriate level of sanitary or phytosanitary protection - The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".* [22]

Article 2 of the SPS Agreement states that *sanitary measures* employed to meet an importing country's ALOP must be based on "scientific principles." Additionally, Article 5 requires that *sanitary measures* be based on "an assessment, as appropriate to the circumstances, of the risks to human…health."

Neither provision limits a country's right to set its *level of protection* at any point it deems appropriate because that decision is societal, not scientific. For example, an importing country may decide that its tolerance for a particular "hazard" in meat products is zero and put in place sanitary measures designed to achieve zero risk. Where science does play a part is that the hazard must be scientifically supported as a bona fide risk to human health.

5.3 Regulatory Objective (RO)

Sanitary measures applied to control food safety hazards are often narrowly focused and specific while the ALOP they are intended to achieve may be expressed as broad regulatory or societal goals relating to safety in the food supply. Consequently, a Regulatory Objective[23] (RO) may be

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[21] Ibid. at A.3.

[22] Agreement on the Application of Sanitary and Phytosanitary Measures; Appendix A

[23] In the March 1999 version of this document, FSIS used the term "Food Safety Objective" (FSO) to describe this bridging concept. At that time, a consensus definition of the term FSO had not been developed internationally. As no consensus has since been reached, FSIS has decided to withdraw its use of the term FSO until such time as an agreed definition is formulated through the Codex Alimentarius process. This document introduces the term "Regulatory Objective" (RO) to mean an explanation by an importing country of the linkage between sanitary measures and levels of protection.

developed to explain how a sanitary measure attains or contributes to attaining the level of protection from a food safety hazard that the United States deems appropriate. These statements may include quantitative, as well as qualitative descriptions of the intended objective.

The concept of an RO is presented in Article 5.8 of the SPS Agreement, as follows:

> *When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.*

A Regulatory Objective should not, however, be visualized as a standard to be achieved or by which equivalence is judged—ROs have a role in equivalence only as elaborative statements of public intent that describe how sanitary measures achieve, or contribute to the achievement, of a country's appropriate level of protection.

6. INITIAL SYSTEM EQUIVALENCE

FSIS conducts two types of equivalence evaluations: (1) to initially determine whether a foreign food regulatory *system* is equivalent in the case of a country that is not presently eligible to export meat or poultry products to the United States, and (2) to determine whether an *individual sanitary measure* is equivalent in the case of a country that has already established its equivalence and is requesting that FSIS recognize an alternative method of eliminating or abating a particular food safety hazard. This section explains how FSIS initially evaluates system equivalence.[24]

Initial equivalence evaluations of foreign meat and poultry food regulatory systems are a prerequisite for trade. Both the FMIA and the PPIA place a positive requirement on USDA to establish the equivalence of a foreign country's food regulatory system before accepting meat or poultry products from them for sale in U.S. commerce. Additionally, foreign systems must meet all FSIS regulatory requirements for equivalence, which include both food safety sanitary measures and other provisions. [25]

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[24] A subset of the initial system equivalence evaluation process is applied in instances where a country has already been found equivalent to export one commodity (meat, for example) and is applying to extend that eligibility to another commodity (poultry, for example). FSIS uses the process described in this section to evaluate applications for extension of eligibility, but limits the scope of that evaluation to inspection system components particular to the additional commodity.

[25] For example, FSIS regulations require that foreign countries have an "organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and regulations in all establishments throughout the system at which products are prepared for export to the United States." [9 CFR 327.2 (a)(2) (i)(A) for meat and 9 CFR 381.196 (a)(2)(i)(A) for poultry] This regulatory criterion is a "sanitary measure" under the SPS Agreement, and would be evaluated for equivalence through document analysis and verified by system audit. Each additional regulatory criterion would be evaluated in the same manner; cumulatively they provide evidence of system equivalence—and thus eligibility. All of the regulatory criteria set forth in Sections 327.2 for meat and 381.196 for poultry are evaluated for initial equivalence using procedures described in this section of the document.

Any country can apply for eligibility to export meat or poultry products to the United States.[26] Normally, the application process begins with a letter to FSIS from a foreign government asking for approval to export its products for sale in the United States. FSIS responds to these letters with a standard package that contains:

- Questionnaires designed to collect detailed information about the foreign food regulatory system;[27]
- Examples of completed questionnaires that demonstrate how FSIS would answer them; and
- Copies of pertinent U.S. laws, FSIS regulations, and other documents that set forth meat and poultry food regulatory policy.

The initial package provides an applicant country with information about the U.S. meat and poultry food regulatory system and conveys expectations about sanitary measures that FSIS anticipates in an equivalent foreign system. In summary, the initial equivalence package explains by example the level of sanitary protection that FSIS deems appropriate.

Foreign countries often take months to assess the initial equivalence package and complete all necessary questionnaires. Upon request, FSIS provides advice and guidance to foreign governments concerning any portion of the application process. When the completed application is received, FSIS conducts an initial document analysis to compare foreign inspection system sanitary measures with measures FSIS applies domestically. In many cases, further information or clarification is needed. FSIS advises the foreign government of data or other information needed to finish the evaluation, and works collaboratively with its food regulatory officials to facilitate this process.

Upon completion of the document analysis step, FSIS decides whether the foreign food regulatory system documentation (1) meets all U.S. import requirements in the same or an equivalent manner, and (2) cumulatively provides the *same* level of public health protection attained domestically. If this step is satisfactorily completed, FSIS plans an on-site audit of the entire foreign meat and/or poultry food regulatory system.

Initial equivalence audits are conducted by a multidisciplinary team of experts. Composition of the audit team may include a veterinarian, food technologist, microbiologist, chemist, residue technician, compliance officer, the document analysis case officer, and others as needed. In some instances, auditors may possess multiple skills and will perform more than one function. The audit planning process begins with each auditor becoming completely familiar with all documentation submitted by the foreign government. The audit scope includes system records such as country laws, regulations, notices, and other program implementation documents; records of establishment operations, inspection results, and enforcement activities; chemical

[26] FSIS would, as a matter of policy, apply SPS principles to any initial equivalence application regardless of whether the applicant country is a Member of the WTO.

[27] Data is collected in five areas: Animal Disease, Slaughter/Processing, Sanitation, Residue Controls, and Enforcement.

residue controls from farm to slaughter; microbiological and chemical testing programs; laboratory support, sampling programs, testing methodologies, and special U.S. import requirements such as pathogen reduction and HACCP programs.

During the on-site audit, FSIS auditors correlate foreign program documentation with observations about program delivery. Thus the goal of an initial equivalence audit is to verify that the foreign food regulatory system has satisfactorily implemented all the country laws, regulations, and other inspection or certification requirements that FSIS found to be equivalent during the document analysis step. In some cases, more than one on-site audit may be required to fully verify system equivalence.

When both the document analysis and on-site audit steps have been satisfactorily completed, FSIS publishes a proposed rule in the *Federal Register* that announces results of the first two steps and proposes to add the country to its list of eligible exporters in the Code of Federal Regulations. Upon receipt of public comments, FSIS makes a final decision about system equivalence based upon all available information and—if favorable—publishes a final rule in the *Federal Register* announcing country eligibility.

It is important to note that FSIS does not conduct food inspections in foreign countries or certify foreign establishments for export to the United States. After a country is judged to have an equivalent food regulatory system, FSIS relies on it to carry out daily inspection. Foreign establishments desiring to export to the United States must apply to their own national inspection authority, and that country's chief inspection official must certify to FSIS a list of all establishments that meet U.S. import requirements.

No meat or poultry products are accepted from a foreign country until its initial equivalence has been established through document analysis, on-site audit, and rulemaking. The initial equivalence process normally requires three to five years of bilateral resource-intensive work from time of application to completion.

7. ALTERNATIVE SANITARY MEASURES

This section explains how FSIS conducts evaluations of alternative sanitary measures upon request from an exporting country that has an established meat or poultry trade relationship with the United States. Section 6 described the process for determining initial system equivalence in cases where there is no current trade relationship (or in instances where system equivalence exists for one commodity and a request is submitted for extension of eligibility to another commodity). The model that follows would also be applied during an initial equivalence evaluation if the applicant country were to propose alternative sanitary measures as part of its initial equivalence submission.

1. FSIS provides notice both through the WTO and directly to meat and poultry exporting countries that it will require a particular sanitary measure to eliminate or abate an identified food safety hazard in a manner that achieves a level of protection deemed appropriate in the United States. Upon promulgation domestically, the new sanitary measure automatically becomes an import requirement applicable to foreign meat and poultry products.[28]

2. An exporting country must either adopt the FSIS sanitary measure as written or notify the Agency that it proposes to apply a different measure. The exporting country may at this time request that FSIS explain the reason/purpose for the new sanitary measure.

3. Upon request, FSIS will provide an exporting country with a reason/purpose for the new or pre-existing sanitary measure, i.e., the Regulatory Objective it is intended to achieve. This objective may be corroborated by a qualitative or quantitative assessment of risk to the extent it is possible and practical to do so.

4. FSIS and the exporting country would then use an agreed-upon process for exchange of relevant information to facilitate the determination of equivalence.

5. The exporting country develops a submission to demonstrate that its alternative sanitary measure achieves the same level of protection as the U.S. measure.

6. FSIS evaluates evidence provided by the exporting country and (1) recognizes that the exporting country's alternative sanitary measure achieves the same level of protection provided by the U.S. measure *or* (2) requests more information to facilitate further consideration of the submission *or* (3) rejects equivalence of the alternative sanitary measure and provides appropriate reasons for that decision.

7. FSIS notifies the exporting country of its judgment within a reasonable period of time and provides the basis for its decision, should the judgment be that the sanitary measure(s) is not equivalent.

8. An attempt will be made to resolve differences of opinion over the judgment of an equivalence submission, either interim or final.

9. FSIS retains a sovereign right to decide whether the exporting country's sanitary measure is equivalent to its own *provided that* the process is fair and transparent and the decision is based on the best available science. Exporting countries should seek FSIS determinations of equivalence well before any alternative sanitary measure is implemented. Unilateral action by an exporting country could lead to serious equivalence difficulties and a possible disruption of trade.

[28] This process may also begin at any time by application from an exporting country for approval to implement an alternative sanitary measure in lieu of a pre-existing FSIS measure.

10. Following a judgment of alternative sanitary measure equivalence based upon document analysis, FSIS will follow-up with verification on-site during the next regularly scheduled audit to confirm that the measure is being implemented in the manner found to be equivalent. Thereafter, FSIS and the exporting country should advise each other of any changes in their programs or infrastructure that may affect the original determination of equivalence.

8. EQUIVALENCE VERIFICATION

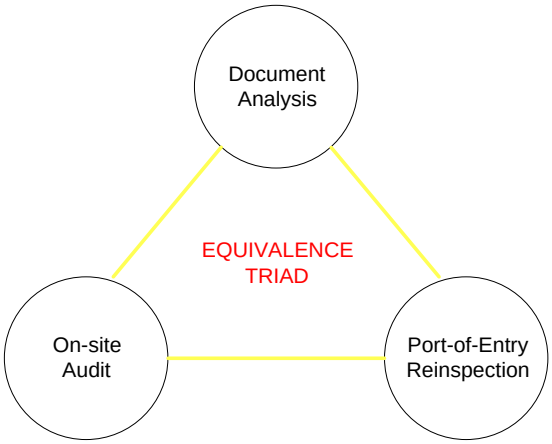
As noted above, initial equivalence applications and alternative sanitary measure proposals both have an equivalence verification component. This section explains how FSIS uses verification as a *recurring* component of equivalence.

FSIS utilizes a three-part process to verify that foreign meat and poultry food regulatory systems continue to be equivalent.

1. The first part is a recurring document analysis wherein the laws, regulations and implementing policies of a foreign food regulatory system are reviewed to ensure that an infrastructure remains in place.

2. The second is on-site food regulatory system audits conducted at least annually in every country that exports meat or poultry products to the United States.

3. The third is continuous port-of-entry reinspection of products shipped from exporting countries. These reinspections provide evidence of how the foreign inspection system is functioning.



8.1 Document Analysis

The purpose of a recurring document analysis is threefold: first is to verify that the laws, regulations, and implementing policies of an exporting country continue to support a food regulatory system with adequate authority and funding to accomplish its mission; the second is to examine written requirements for food production to determine whether the same or equivalent sanitary measures have been mandated for the foreign meat and poultry industry; and the third is to evaluate written regulatory system procedures for foreign establishment oversight, verification and enforcement of requirements.

This recurring analysis focuses on five categories of sanitary measures (termed risk areas): animal disease, slaughter and further processing, sanitation, residue control program, and enforcement. Periodically, one of the five risk areas is selected for in-depth analysis. Questionnaires are sent to every exporting country asking them to provide extensive details about how they regulate for hazards in that category.

Along with answers to the questionnaire, exporting countries are asked to submit current inspection system laws, regulations, and policy issuances associated with the category under analysis. These questionnaires are the same instruments FSIS uses in an initial equivalence evaluation. Thus, the recurring document analysis gradually repeats and updates initial determinations of foreign inspection system equivalence.

8.2 Equivalence Verification System Audits

The system audit provides a transparent, collaborative forum with international trading partners to verify equivalence. These audits are conducted at least annually in exporting countries by FSIS technical experts. The purpose of a system audit is to evaluate the foreign inspection program and verify equivalence, not to inspect individual foreign establishments. This discussion of system audit procedures is also applicable to audits conducted during an initial equivalence evaluation.

During a system audit, FSIS seeks evidence that the exporting country has instituted sanitary measures adequate to provide the *same* level of protection that is ensured by our domestic system. The system audit focuses on two essential components of safe food production: (1) process control, which is an industry responsibility executed through sanitary measures such as sanitation standard operating procedures, HACCP and quality assurance systems, and laboratory testing programs, and (2) regulatory control, which is a government responsibility exercised in a form and at an intensity appropriate to verify the effectiveness of industry process controls, detect noncompliance, and provide necessary enforcement.

Foreign food regulatory system equivalence audits are conducted in four phases: planning, execution, evaluation, and feedback. For example, a system equivalence verification audit would consist of the following activities.

1. PLAN. FSIS prepares a consolidated annual plan to audit each country that exports meat or poultry products to the United States. Individual country audit plans are based, in large part, upon prior experience with the exporting country. For example, all previous FSIS audit reports are reviewed to identify issues for inclusion in the current audit. Port-of-entry reinspection data are also reviewed at this time to determine trends and identify areas of special interest for audit. These documents and data are used by FSIS to develop an audit plan that is customized for each country. The audit plan is transmitted to the exporting country for comment before implementation. Special emphasis is given to adoption of new sanitary measures or food regulatory system changes that have occurred since the last audit either through initiative of the exporting country or in response to new U.S. import requirements. Foreign establishments are statistically selected for on-site audit during subsequent planning. Additional establishments may be added for cause.

2. EXECUTE. An auditor (or in some cases an audit team) is dispatched to the exporting country's inspection headquarters and/or to regional offices as agreed in the audit protocol. Opening discussions are held with exporting country officials to determine if the national system of inspection, verification and enforcement is being

implemented as documented, and to identify significant trends or changes in operations. The FSIS auditor examines a sample of program records that evidence exporting country regulatory activities, and accompanies country officials on field visits to a representative sample of establishments that are eligible for export to the United States. Exporting country officials conduct a review to verify that each selected establishment continues to meet all U.S. meat and poultry import requirements. Particular attention is paid to how eligible establishments address food safety hazards, some of which may be different from those encountered in the United States. FSIS auditors observe establishment activities and correlate review findings made by exporting country officials. Selected microbiological and chemical laboratories are also reviewed. In a closing meeting, the FSIS auditor provides exporting country officials an overview of conditions observed and ensures that audit observations are clearly understood.

3. EVALUATE. FSIS conducts a post-audit evaluation of all data collected on-site. When evaluating audit data, FSIS considers how sanitary measures of the foreign food regulatory system compare or contrast to those used in the U.S., and determines whether the foreign system cumulatively provides the same level of protection.

4. FEEDBACK. FSIS thereafter sends the exporting country a draft audit report and provides them an opportunity to comment on its findings. After consideration of country comments, a final report is prepared. An action plan is mutually developed to address any issues raised by the audit. These issues are tracked by FSIS until resolution and are automatically included as items of special interest in the next audit

All reports of initial equivalence audits and annual equivalence verification audits are posted on the FSIS web site after a final version is delivered to the audited country.

8.3 Port-of-entry Reinspection

The third component of equivalence verification is port-of-entry reinspection, where FSIS randomly samples meat and poultry products as they enter the United States. The purpose of reinspection is to ensure that exporting country certificates are authentic and accurate and that products meet all U.S. food safety and quality standards.

It is important to note that this verification activity is a *re*inspection of products that have already been inspected and passed by an equivalent foreign inspection system. Of note as well is the fact that a majority of imported meat and poultry is bulk raw product that moves on to USDA-inspected domestic establishments for further processing into a variety of finished products. Incoming raw products are routinely screened by U.S. domestic establishments for hazards identified in their HACCP plan, and are included in FSIS domestic inspection activities.

Port-of-entry reinspection is directed by the Automated Import Information System (AIIS), a centralized computer database that stores daily reinspection results from all ports of entry for each country and for each establishment. If a problem is found at one point, FSIS can quickly locate and hold other shipments from the same country and establishment at other entry points.

When a shipment is presented for port-of-entry reinspection, the AIIS scans its existing records to determine if the foreign country, the establishment, and the product are eligible for export to the United States. The shipment is refused entry if any component of eligibility is absent.

Although records are maintained on each establishment, reinspection of products is system-based in that its intent is to verify effectiveness of the foreign inspection system, not determine individual establishment performance. A central purpose of the AIIS is to generate reinspection assignments that FSIS import inspectors perform on each lot of imported product. For example, all product lots are reinspected for general condition, labeling, proper certification, and accurate count. In addition, FSIS uses a statistical sampling system to generate other types of inspection (TOI) that are applicable to the product. Under this system, the AIIS identifies foreign meat and poultry shipments by the same HACCP processing categories applied to products in U.S. domestic establishments. [29] These are:

03B Raw Ground
03C Raw Not Ground
03D Thermally Processed, Commercially Sterile
03E Not Heat Treated, Shelf Stable
03F Heat Treated, Shelf Stable
03G Fully Cooked, Not Shelf Stable
03H Heat Treated, But Not Fully Cooked, Not Shelf Stable
03I Products with Secondary Inhibitors, Not Shelf Stable

Port-of-entry sampling is allocated by country, process category, and in some cases species. Each imported product shipment is identified by a unique "shipping mark" that is entered into the AIIS for initial identification and subsequent tracing into U.S. commerce channels. When a lot of imported product is statistically selected for reinspection, several types of inspection may be performed. These include a physical examination of the product for visible defects and an examination of container condition. At set intervals, FSIS also collects samples for microbiological analyses, food chemistry analyses, and samples to be analyzed for drug and chemical residues.

Although the Animal and Plant Health Inspection Service (APHIS) has lead responsibility for assuring that meat and poultry products are eligible for importation under animal disease restrictions, FSIS is the second line of defense to prevent entry of products carrying animal disease organisms that could be transmitted to domestic animals. To that end, the AIIS is programmed to assure that products restricted under APHIS regulations are not allowed to enter the United States.

If a shipment fails reinspection, the result is recorded in the AIIS. Thereafter, the AIIS automatically generates an increased rate of reinspection. For example, a failure for physical defects results in the next ten shipments being selected for reinspection. In the case of a

[29] 9 CFR 417.2(b)

laboratory analyses failure, the next fifteen consecutive lots are selected for repeat analysis. Products that fail reinspection are refused entry into the United States and must be re-exported, converted to non-human food, or destroyed.

Products that pass reinspection are stamped with the official mark of inspection and are allowed to enter U.S. commerce. Under U.S. meat and poultry inspection laws, reinspected and passed imported articles are, upon entry into the United States, deemed and treated as domestic articles in commerce.

9. CONCLUSION

FSIS has developed and is presently applying a fair and transparent process to evaluate the initial equivalence of foreign meat and poultry food regulatory systems and the equivalence of alternative sanitary measures. This process includes reliable methods to verify that equivalence is maintained. The equivalence evaluation process summarized in this document complies with the SPS Agreement and provides assurance that imported meat and poultry products meet all U.S. import requirements.