

FSIS Process
for
Evaluating the Equivalence
of
Foreign Meat and Poultry Food Regulatory Systems

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INTRODUCTION

Preface

Meat and poultry products exported from another nation must meet all safety standards applied to foods produced in the United States. However, under international law, food regulatory systems in exporting countries may employ sanitary measures¹ that differ from those applied domestically by the importing country. The reasons for such differences include the absence or very low prevalence of particular food safety hazards,² the selection of alternative controls, and national choices about management of food risks. The United States makes determinations of equivalence by evaluating whether foreign food regulatory systems attain the appropriate level of protection³ provided by our domestic system. Thus, while foreign food regulatory systems need not be identical to the U.S. system, they must employ *equivalent* sanitary measures that provide the *same* level of protection against food safety hazards as is achieved domestically.

The Food Safety and Inspection Service (FSIS) evaluates foreign food regulatory systems for equivalence through document reviews, on-site audits, and port-of-entry reinspection of products at the time of importation. Judgments of system equivalence are necessary for FSIS and the American consumer 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 disease from imported products, they simultaneously demand access to the abundant variety of affordable international foods. The degree to which consumers will trust food from an exporting country is directly related to how effectively food production is regulated by the foreign system. Thus, trust becomes an equivalence issue with both food safety and trade implications.

|| *The confidence of consumers in the quality (including safety) of their food supply depends in part on their perception as to the effectiveness of food control measures.*⁴ ||

¹ *Sanitary Measure*: 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 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.

² *Food Safety Hazard*: A biological, chemical, or physical property that may cause a food to be adulterated or otherwise unsafe for human consumption; must be of such a nature that its prevention, elimination, or reduction to acceptable levels is essential to the production of a safe food.

³ *Appropriate level of protection*: A societal judgment of what risk from food safety hazards is acceptable to the majority.

⁴ Codex Alimentarius Commission, Principles for Food Import and Export Inspection and Certification, Guide Line (CAC/GL) 20-1995, at 1.1.

Purpose

This paper presents the evaluation process FSIS now applies to initially determine and periodically verify whether foreign meat and poultry food regulatory systems provide food safety protections equivalent to U.S. domestic regulatory programs. The process presented in this document implements, in part, USDA regulations that require evaluation of a foreign meat and poultry inspection system to determine whether that country is eligible to import products into the United States.⁵ Agency regulations also set forth specific evaluation criteria that are applied by FSIS during this process to make equivalence determinations.⁶ The evaluation process described here represents FSIS's current thinking as to how equivalence decisions with respect to food safety measures should be made. This process will evolve and mature as the United States and its foreign trading partners gain more experience in applying the principles of equivalence internationally.

Scope

The scope of this paper is limited to equivalence under the "SPS Agreement" as is explained in the following section. While non-food safety concerns such as misbranding and economic adulteration are generally not covered by the SPS Agreement, FSIS nevertheless applies an equivalence process analogous to that described in this paper to evaluate whether foreign food regulatory systems meet *all* the equivalence criteria set forth in USDA regulations.

BACKGROUND

SPS Agreement, World Trade Organization

Food safety equivalence evaluations are based upon provisions in the Agreement on the Application of Sanitary and Phytosanitary Measures, which appears in the Final Act of the Uruguay Round of Multilateral Trade Negotiations, signed in Marrakech 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, as a signatory to the Agreement, is a Member of the WTO. The SPS Agreement requires each Member to accept as equivalent the food regulatory system of another country if it has been demonstrated to furnish the same level of public health protection as is provided by its own system.

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.⁷

⁵ 9 CFR 327.2 (a)(2) for meat and 9 CFR 381.196 (a)(2) for poultry

⁶ 9 CFR 327.2 (a)(2) (i)-(iv) for meat and 9 CFR 381.196 (a)(2) (i)-(iv) for poultry

⁷ Article 4.1, "Agreement on the Application of Sanitary and Phytosanitary Measures."

The burden for demonstrating equivalence rests with the exporting country and the importing country is free to set any level of protection it deems appropriate to control or eliminate a food safety hazard. Importing countries have the right to decide whether a foreign food regulatory system is (1) equivalent to its own, (2) is inadequate to achieve its appropriate level of sanitary protection, or (3) that inadequate evidence has been provided to demonstrate equivalence. If the exporting country objectively demonstrates that the appropriate level of protection has been met, the importing country is obliged to accept its food regulatory system as equivalent.⁸ The recognition of equivalence does not necessarily require importing and exporting countries to enter into a formal agreement.

Codex Alimentarius

A central purpose of the SPS Agreement is to encourage the development of international food safety standards that Members will adopt domestically for “harmonization” and the facilitation of international trade. The fact that a Member’s standard may differ from international standards does not, in itself, create any adverse presumption that it is failing to meet its international 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.

For SPS purposes, this international benchmark is the Codex Alimentarius, a code of food standards for all nations. 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 (CAC) is responsible for making proposals to the Directors-General of the Food and Agriculture Organization (FAO) and the World Health Organization (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.

U.S. Laws and Regulations

In 1994, the United States adopted the SPS Agreement with passage of the Uruguay Round Agreements Act. This legislation provided U.S. administrative agencies a standard that must be met when determining equivalence.

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.⁹

⁸ This decision process is equally applicable to individual sanitary measures.

⁹ Sec. 492, “The Uruguay Round Agreements Act,” (P.L. 103-465; December 8, 1994).

The Act also amended other legislation to comport with SPS requirements. Among these were equivalence amendments to the Federal Meat Inspection Act (FMIA)¹⁰ and the Poultry Products Inspection Act (PPIA).¹¹

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.¹²

In July 1995, FSIS implemented the FMIA and PPIA amendments cited above with a direct final rule¹³ that deleted existing regulatory language requiring foreign 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 9 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:

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.¹⁴

Agency regulations further specify that determinations of eligibility must be based upon equivalence evaluations.¹⁵ Consequently, FSIS has developed the process described in this paper to conduct equivalence evaluations of foreign 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.¹⁶ Each of these regulatory criteria constitutes a sanitary measure as defined by the SPS Agreement.¹⁷ The criterion for evaluating alternative sanitary measures is whether they achieve the same level of sanitary protection provided under the United States requirement.¹⁸ Evaluations of alternative sanitary measures are made by determining whether they are at least as effective as the U.S. requirements in controlling food safety hazards. These evaluations employ evolving international concepts of the linkage between a sanitary measure and the appropriate level of protection it is intended to achieve. The following section summarizes these concepts.

¹⁰ 21 U.S.C. 620(e)

¹¹ 21 U.S.C. 466

¹² Amendment to §20(e) FMIA. The PPIA was amended by §431(k) with essentially the same language.

¹³ 60 FR 38667; Friday, July 28, 1995.

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

¹⁵ Ibid., footnote 5.

¹⁶ Ibid., footnote 6.

¹⁷ Ibid., footnote 1.

¹⁸ Ibid., footnote 12.

CONCEPTS OF EQUIVALENCE

Equivalence is the relationship between three interlinking components: sanitary measures, appropriate level of protection, and food safety objectives. Cumulatively, these components provide sufficient data to evaluate the equivalence of different food regulatory systems, parts of systems, or individual sanitary measures.

Sanitary Measures

National food regulatory systems employ sanitary measures to control food safety hazards in a manner that achieves an appropriate level of protection for consumers. Sanitary measures are defined by their intent to protect human life or health from risks arising from an additive, contaminant, toxin, or disease-causing organism in a food or from a disease or pest carried by an animal or a product thereof. 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 or would 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 effects 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 Codex. 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

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 describes significant administrative actions proposed to implement the Uruguay Round Agreements. It represents an authoritative expression by the Administration concerning its views 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.

than Codex provides if a greater level of protection is deemed appropriate. For the purposes of judging equivalence, the sanitary measures that comprise a food safety control system can be broadly categorized as:

- ? Infrastructure; including legislative base authority and administrative regulatory systems, documentation of systems, performance, decision criteria and action, laboratory capability, and provisions for certification, audit and enforcement.
- ? Specific Requirements; individual facilities (e.g. construction), equipment (e.g. design of food contact machinery), processes (e.g. retorting of cans, HACCP plans for a specific product), procedures (e.g. post mortem meat inspection procedures) and tests (e.g. tests for microbiological or chemical hazards).

Appropriate Level of Protection

Importing countries may set any level of protection they deem appropriate and establish sanitary measures accordingly to abate or eliminate food safety hazards. While sanitary measures are objectively based upon scientific or technical knowledge about controlling food safety hazards, an importing country's appropriate level of protection is a societal choice that may be objective or subjective.

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

Food Safety Objective

Sanitary measures applied to control food safety hazards are often narrowly focused and specific while the appropriate level of protection they are intended to achieve may be expressed as broad regulatory or societal goals relating to food safety risks. Consequently, an FSO may be developed to explain how a measure attains or contributes to attainment of the public health protection deemed appropriate. These statements may include quantitative as well as qualitative descriptions of the intended objective.

FSO's are not SPS components, as the Agreement makes no mention of them. They are, nonetheless, useful and relevant for equivalence purposes because they facilitate the comparison of different sanitary measures. An FSO should not, however, be visualized as a standard to be achieved or by which equivalence is judged—FSO's are appropriate for equivalence purposes 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.

²¹ Ibid. at A.3.

It must be noted that the term “Food Safety Objective” is used within the Codex international community to describe two separate activities. While these activities are related, they are particular in purpose and must be distinguished. The Codex Committee on Import and Export Food Inspection and Certification Systems (CCFICS) has commissioned a paper from New Zealand titled “Proposed Draft Guidelines for the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.” An important component of this paper is the concept of an FSO as a bridge between sanitary measures and the appropriate level of protection they are intended to achieve.

Another use of the FSO concept has been proposed in a paper titled “Recommendations for the Management of Microbiological Hazards for Food in International Trade.” This paper was prepared by the International Working Group on Management of Microbiological Hazards as a discussion paper for the Codex Committee on Food Hygiene (CCFH). The CCFH draft defines FSO as “a statement based on a risk analysis process which includes an expression of the level of a hazard(s) in food that is tolerable in relation to an appropriate level of consumer protection. When justified by the risk assessment, the FSO should include expression of the level of the hazard as a maximum tolerable concentration and/or frequency.”

The two Codex definitions of FSO have separate intent. The CCFICS definition is broadly constructed for use by exporting and importing countries in equivalence determinations under the SPS Agreement. The CCFH definition is more narrowly focused on the management of a particular food safety hazard, i.e., pathogenic microorganisms, and incorporates the requirement for a “target” to control these hazards in food. Thus it represents a subset of the more general CCFICS application of an FSO.

THE FSIS FOOD SAFETY EQUIVALENCE EVALUATION PROCESS

Introduction

Evaluations of equivalence between different sanitary measures require exporting and importing countries to cooperate in a series of steps that meet mutual international obligations. The steps that countries choose will depend on circumstances and trading experience between the two nations. Moreover, where sanitary measures differ, the FSO may still be evident and understood by both countries, while in other cases the FSO may need to be further explained by the importing country. A reasonable series of steps that countries may take to determine equivalence is as follows.

- ? An importing country provides notice that it will require a particular sanitary measure to achieve a level of protection it deems appropriate.
- ? An exporting country requests an explanation of the importing country’s appropriate level of protection that is achieved by application of an identified sanitary measure.
- ? The importing country provides that explanation, which may be facilitated by expression of an FSO for that measure.

- ? The exporting country uses that explanation as a guide to develop sufficient evidence to demonstrate the equivalence of an alternative sanitary measure, obtains clarification from the importing country if necessary, and develops a case for equivalence of a different sanitary measure in terms of achieving the importing country's appropriate level of protection.
- ? The importing country 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 importing country'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.

The importing country retains the absolute right to decide whether the exporting country's sanitary measure is equivalent to its own. Exporting countries should be rigorous in seeking importing country determinations of equivalence well before any alternative sanitary measure is implemented. Unilateral action by an exporting country could lead to serious equivalence difficulties with importing countries and a possible disruption of trade.

The foregoing steps provide a structure for the three-part process FSIS now employs to evaluate equivalence. As is explained in the following sections, this process is utilized for initial evaluations of equivalence wherein an exporting country is found eligible to ship meat and/or poultry to the United States, for periodic verifications that eligible countries remain equivalent, and to evaluate individual sanitary measures.

Initial System Equivalence

Applications from foreign countries for an initial determination of equivalence must contain sufficient technical and scientific evidence for FSIS to evaluate whether sanitary measures of the foreign food regulatory system are equivalent to the U.S. system. This evaluation involves a document review and an on-site review.

FSIS does not conduct inspections in foreign countries. After a country is determined 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. Countries must also be certified periodically as continuing to operate an equivalent residue control program. FSIS experts review the country's program to assure that approved analytical methods are used, that foreign officials are knowledgeable about the use of chemical compounds in their country, and that the country tests for those compounds with potential for getting into the U.S. food supply.

Verification of Continuing Equivalence

Prior to the SPS Agreement, FSIS evaluated foreign food regulatory systems under provisions in U.S. inspection laws that required them to have programs “at least equal to” the U.S. system.²² Because the eligibility of countries to export meat or poultry to the United States was initially evaluated on a case-by-case basis through analysis of applications followed by on-site audits, all “at least equal to” countries that were eligible for export of meat or poultry to the United States when the Uruguay Round Agreements Act was passed in 1994 were automatically judged to be “equivalent.”

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

1. The first part is a recurring document analysis wherein the fundamental laws, regulations and implementing policies of an exporting country’s food regulatory system are reviewed in parallel with U.S. government issuances to ensure that an appropriate legal and regulatory structure remains in place.
2. The second is on-site food regulatory system audits conducted first for initial system equivalence determinations in each country that applies for export meat or poultry to the United States and generally repeated annually.
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; they are not necessarily indicators for specific sanitary measures.

Document Analysis

The purpose of recurring document analysis is threefold: first is to verify that the fundamental laws, regulations and implementing policies of an exporting country continue to provide for 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 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 industry oversight, verification and enforcement of requirements.

System Audits

The system audit provides a transparent, collaborative forum with international trading partners to verify continuing equivalence. These audits are generally conducted annually in exporting countries by FSIS technical experts. The purpose of a system audit is to evaluate the foreign inspection program, not to inspect individual foreign establishments.

During the system audits, FSIS, in part, seeks evidence that the exporting country has instituted sanitary measures adequate to provide the *same* level of protection for American

²² Ibid. The poultry requirement was “same as” rather than “at least equal to” because of different language in the FMIA and PPIA.

consumers 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 microbial testing programs and (2) oversight, 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. Exporting countries must meet this fundamental level of protection to establish and maintain equivalence.

An FSIS foreign inspection system equivalence audit consists of three phases.

1. First, FSIS conducts a document analysis as described above. 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 to each country. This plan is transmitted to the exporting country for comments at least 30 days before implementation. The audit protocol is sufficiently detailed to inform the exporting country of the audit objectives, scope and criteria, who will be visiting, what they wish to see, where they wish to go, and when they wish to do so. Special emphasis is given to changes in foreign food regulatory systems that have occurred since the last audit either through initiative of the exporting country or in response to new U.S. requirements.
2. Second, FSIS dispatches an auditor (or in some cases an audit team) to the exporting country's inspection headquarters and/or to sub-offices as agreed in the audit protocol. Discussions are held with exporting country auditors and other officials as appropriate to determine if the exporting country's system of oversight and compliance is being implemented as written, and to identify significant trends or changes in establishment operations, oversight, and compliance. FSIS auditors examine a sample of available records that document the exporting country's oversight and enforcement activities, and accompany exporting country officials on field visits to a representative sample of establishments that are eligible for export to the United States. Exporting country officials conduct an evaluation at each selected establishment to verify that it continues to achieve the level of protection required by the United States. Particular attention is paid to how the foreign food regulatory system ensures that eligible establishments have addressed food safety hazards, some of which may be different from those encountered in the United States. FSIS auditors observe these activities and correlate findings made by exporting country officials.²³ A sample of laboratories and other facilities is also reviewed in this manner. At conclusion of its visit, the FSIS auditor(s) meets with exporting country representatives to provide an overview of conditions observed during the audit and to ensure that observations noted are clearly understood by both parties.
3. Third, FSIS conducts a post-audit evaluation of all data collected on-site and advises the exporting country in writing of any system equivalence issues to be resolved. When

²³ Other alternatives may be selected by agreement between FSIS and the exporting country. For example, the establishment audits could be conducted jointly by FSIS and foreign auditors or FSIS could conduct the audits with correlation by foreign auditors or supervisory personnel. These variables are resolved collaboratively on a country-by-country basis.

evaluating audit data, FSIS will base its equivalence judgments on how sanitary measures of the foreign inspection system compare and relate to those used in the U.S. and whether the foreign food regulatory system cumulatively provides the same level of protection.

A draft audit report is sent to the exporting country for review and comment after an on-site visit. 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.

Port-of-entry Reinspection

FSIS relies on its baseline determination that a foreign country is equivalent coupled with annual system audits to provide assurance that products shipped to the United States are—and continue to be—safe as well as wholesome, correctly labeled and properly packaged. As a further check on the equivalence of a foreign food regulatory system, FSIS randomly samples meat and poultry products for reinspection as they enter the United States and ensures that exporting country certificates are authentic and accurate.

Port-of-entry reinspection is directed by the Automated Import Information System (AIIS), a centralized computer database that stores reinspection results from all ports-of-entry for each country and for each establishment. Reinspection of products is performance-based in that better performing foreign establishments have their products reinspected less frequently. Additionally, FSIS randomly samples products at ports for drug and chemical residues. An annual import residue plan sets the initial sampling rate for each country based on its volume of product exported to the United States. Compounds included in the plan reflect testing done in the U.S. domestic residue program. Decisions about product acceptability are based on U.S. tolerances.

The AIIS receives and stores daily reinspection results from all ports-of-entry and continuously updates compliance histories for every establishment exporting to the United States. If a problem is found at one point, FSIS can quickly locate and hold other shipments from the same 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 AIIS also determines the type of reinspection based on compliance history of the establishment and country for that specific product. AIIS data provides a record of how each exporting country maintains inspection controls.

FSIS has about 75 inspectors who carry out reinspection in approximately 150 official import establishments. At these establishments, all incoming lots of meat and poultry are reinspected for transportation damage, labeling, proper certification, general condition, and accurate count. Products that pass reinspection are stamped with the USDA mark of inspection and are allowed to enter U.S. commerce for distribution and use as if they were produced domestically. If they do not meet U.S. requirements, they are stamped "U.S. Refused Entry" and must be exported, destroyed, or converted to animal food.

Specific Sanitary Measures

FSIS has successfully used the equivalence evaluation process described in this paper to ensure that exporting countries establish and maintain a food regulatory system appropriate to achieve the same level of protection provided by domestic inspection.²⁴ In addition, these evaluation procedures have proven effective in verifying equivalent foreign implementation of specific sanitary measures such as those in USDA's Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems final rule (PR/HACCP final rule).²⁵

For example, in August 1996, FSIS provided a copy of the newly promulgated PR/HACCP final rule and a summary of its principal sanitary measures to each country listed as eligible for export of meat or poultry to the United States. FSIS conducted two public hearings in early October 1996 to brief interested parties on equivalence issues generally and in particular on implementation of equivalent PR/HACCP sanitary measures by eligible exporting countries. In late October 1996, FSIS followed-up these meetings with a cable to all exporting countries restating the need for equivalent implementation of PR/HACCP sanitary measures and requesting that each country provide information by the end of 1996 as to how it intended to achieve the same level of protection.

Beginning in January 1997, FSIS sought from each exporting country specific documentation of what sanitary measures it had implemented to be equivalent with PR/HACCP final rule requirements for U.S. domestic establishments. Many countries have implemented measures identical to the U.S. requirements, and equivalence is not an issue. Where alternative sanitary measures have been offered, FSIS has conducted appropriate scientific and technical evaluations to determine whether the proffered alternatives are equivalent. In cases where exporting countries have not adequately demonstrated equivalence, additional information has been requested. If ultimately, a foreign country's alternative sanitary measure were deemed not equivalent, FSIS would be obliged to initiate rulemaking that would terminate its eligibility for export to the United States. Equivalence decisions based on foreign food regulatory system documentation of specific sanitary measures are subsequently verified by on-site audits.

²⁴ For example, Agency 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 by (1) document analysis and (2) system audit. Some indications of equivalence would also be obtained from (3) port-of-entry reinspections of product. Each additional regulatory criterion would be evaluated in the same manner; cumulatively they provide evidence of system equivalence—and thus eligibility. All foreign food regulatory system sanitary measures—whether they be for food safety or other consumer protections—fall within one or more of the regulatory criteria set forth in Sections 327.2 and 381.196 and each must be evaluated for equivalence using procedures described in this document.

²⁵ 61 FR 38806; Thursday, July 25, 1996.

Conclusion

FSIS applies a rational evaluation process to determine the initial eligibility of foreign inspection systems or alternative sanitary measures and to verify annually that equivalence is maintained. Cumulatively, the evaluation process summarized in this document complies with international obligations under the SPS Agreement, comports fully with U.S. laws, and effectively implements FSIS inspection regulations by ensuring that American consumers receive the same level of protection in imported meat and poultry as is achieved domestically.