



Pacific Horticultural and Agricultural Market Access Program (PHAMA)

Technical Report 29: Assistance with Regulatory Requirements
for Re-establishing Meat Exports to American Samoa
(SAMOA08)

30 OCTOBER 2012

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Date: 30 October 2012

Reference: 42444103

Status: FINAL

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Abbreviations

Abbreviation	Description
APHIS	Animal and Plant Health Inspection Service
ASG-PAQ	American Samoa Government Plant and Animal Quarantine Services
BSE	Bovine Spongiform Encephalopathy
FDA	Food and Drug Administration
FMD	Foot and Mouth Disease
FSIS	Food Safety and Inspection Service
ISO	International Standards Organisation
MAF	Ministry of Agriculture and Fisheries (Samoa)
MAWG	Market Access Working Group
NZ	New Zealand
PPQ-VRS	Plant Protection and Quarantine Unit – Veterinary Regulatory Support
SACEP	Samoa Agriculture Competitiveness Enhancement Project
SBS	Samoa Bureau of Statistics
TSE	Transmissible Spongiform
USDA	United States Department of Agriculture
WST	Western Samoa Tala (1 WST= 0.45 USD)

Executive Summary

Exports of meat products to American Samoa ceased in 2003. The trade was never a commercial one, and was based on personal consignments. There is no clear private sector interest in developing a commercial export pathway for meat to American Samoa. However, there is anecdotal evidence of reasonable levels of public interest in resuming access for personal consignments.

United States Department of Agriculture (USDA) import requirements for meat and meat products into American Samoa are:

- All imports of meat (beef, pork, poultry) for commercial or non-commercial purposes are subject to regulation by USDA agency the Animal & Plant Health and Inspection Service (APHIS) requirements regarding recognition of the disease status for the exporting country.
- Samoa's health status is not recognised by APHIS so all imports are currently prohibited. Samoa will need to undertake an approval process by APHIS, which includes a country submission, country visit, and risk assessment.
- Imports of cooked poultry and eggs are considered permissible into American Samoa as small-accompanied personal consignments with verification upon arrival of their cooked state by a border inspector.
- All imports of meat for commercial purposes are also subject to regulation by USDA agency the Food Safety and Inspection Service (FSIS) requirements.

The initial step for re-establishing access for non-commercial consignments is to make an application to USDA APHIS. At this stage Samoa are not in a position to make an application due to a lack of disease survey information and inadequate disease surveillance and response systems. It is not considered appropriate for PHAMA to assist with developing an APHIS application until progress has been made in Samoa to address these and other key elements of country capacity as outlined in the APHIS Recognition of Region questionnaire.

Work will be required to conduct an animal disease survey and strengthen animal disease surveillance legislation, systems and procedures. The USDA approval process is likely to be lengthy and will require commitment from Samoa Government and MAF. Should Samoa wish to pursue the APHIS application the first appropriate step for PHAMA to consider is funding support for animal disease surveys under Component 4 to update the animal health status for the country. It is possible that the World Bank funded Samoa Agricultural Competitiveness Project (SACEP) may be willing to undertake this work under its Livestock Component or at least consider co-funding of it. To confirm this, further discussions will be required with SACEP once their implementation team are established.

At this stage commercial exports to American Samoa cannot be considered due to a lack of meat processing infrastructure and adequate food safety controls for meat. The SACEP project is currently beginning implementation of a 5-year programme of support in the livestock sector and is planning to improve livestock production, sanitary meat controls and invest in processing infrastructure including an abattoir and cold chain. Efforts are also underway to improve the food safety legislation controlling meat production, processing and supply. Should an abattoir and cold chain be successfully established and operated, and there be clear private sector interest in pursuing commercial exports to American Samoa, then PHAMA should consider reassessing the capacity of Samoa to meet USDA requirements. It is unlikely that this will occur for at least several years.

Recommendation:

The Samoan Market Access Working Group (MAWG) is asked to consider approval for PHAMA funding of an animal health disease survey by SPC under Component 4 of PHAMA.

1 Background

Historically, an export pathway for beef and processed meat products has existed between Samoa and American Samoa. However, imports are now prohibited by American Samoa. The detailed reasons for this are unclear to the Samoan MAWG but it is thought to be in part due to the lack of an accredited abattoir facility in Samoa. Samoa Ministry of Agriculture and Fisheries (MAF) officials have indicated that plans for the development of an accredited abattoir have recently been approved.

In 2011 the Samoan MAWG requested an assessment of the situation to determine how PHAMA could provide assistance with the regulatory aspects associated with re-establishing exports of beef and meat products to American Samoa, once the new abattoir is established.

The tasks set by the MAWG were for a PHAMA short-term adviser (STA) to conduct a preliminary visit to Samoa to determine the following:

- The progress of planning for the development of an accredited abattoir facility in Samoa.
- Identification of the adequacy of Samoa food standards relating to the slaughter, handling and processing of beef products and manufactured meat products for export.
- Identification of the beef and manufactured meat products import requirements of American Samoa and the ability of Samoa to comply with these.
- Identification of key American Samoa contacts if and when further dialogue on exports of beef and manufactured meat products are required.
- An assessment of the level of interest and possible volumes of beef and manufactured meat products for export to American Samoa should an accredited abattoir be developed.
- Identification of any training needs and potential funding sources, other than PHAMA, for the required training.
- Identification of any other technical quarantine related issues that will need to be addressed for a successful export pathway for beef and manufactured meat products to be established with American Samoa.

Following this tasking by the MAWG a visit to Samoa was conducted in March 2012 by PHAMA STA personnel, additional follow up was required with American Samoa and United States federal officials to clarify standards with communication exchanges over April to September. This report summarises the findings of that visit and communications, draws conclusions and makes recommendations.

2 Current Situation

2.1 Livestock Production

The livestock sector in Samoa is dominated by smallholder production involving cattle, pigs and poultry. According to a 2009 agricultural census,¹ of an estimated 23,164 households the majority (15,982) own livestock, with approximately 6,000 households owning cattle. Of those households less than 425 owned 20 or more head of cattle. Total cattle herd numbers were estimated at 38,954, with two thirds of these on the capital island of Upolu. Discussions in Samoa suggest that this 2009 population figure may be an over estimate. An agricultural census funded by the World Bank is being conducted in 2012 to define cattle numbers, final figures are not available at time of reporting but indications are that the current cattle population may actually be more between 25,000–30,000 head.

In line with the rest of the agricultural sector in Samoa, production in livestock has been in decline in recent years. The performance and relative contribution of the agriculture sector (including fisheries) to the national GDP has steadily declined from 50.5% in the 1980s to 10% in 2010. The Samoa Government recognises this and has stated policy objectives² to increase productivity to improve national food security and reduce reliance on the importation of livestock products, and to improve marketing and value adding. Intended strategies include the promotion of improved livestock breeding and husbandry, facilitating improved marketing, and improvements in the hygienic controls for meat slaughter and processing. The Samoa Ministry of Agriculture and Fisheries (MAF) has corporate strategies that align with these objectives to improve livestock production.

It is estimated that approximately 7000–9000 cattle are slaughtered each year, with approximately 2000 for retail sale and 5000–7000 for local customary food exchanges between families and communities termed *fa'alavelave*. Only a small number are slaughtered for own household consumption.

It is clear that significant increases in livestock production will be required to meet local demand for meat. The impact of the *fa'alavelave* practice, which often results in the sale of young breeding animals for slaughter, is something that will need to be addressed to improve production.

2.2 Meat Imports

Meat imports into Samoa have been steadily increasing over the past 20 years. Approximately 65% of all meat is now imported (11200 tonnes imports compared to estimated 6000 tonnes domestic production) with an estimated current annual value of WST31 million. The majority of these imports are from Australia and New Zealand and are mainly sheep (4000 tonnes), poultry (6000 tonnes) and beef (1000 tonnes) meats. Local pork still makes up the majority of local pork consumption. Overall per capita meat consumption is increasing and is now at 102 kg.

An analysis funded by the World Bank in 2010³ of the market for meat products in Samoa and the livestock sector concluded that there was positive potential for capturing local demand through increased beef and small stock production, improved marketing and facilitation of slaughter and processing. The same study recommended improvements in regulation of meat hygiene processing

¹ MAF and SBS, Agricultural Census Tabulation Report 2009

² Government of Samoa, Agriculture Sector Plan 2011-2015

³ World Bank, Samoa Livestock production and marketing, Technical Assistance Report 2010

and concluded that an abattoir processing facility could be established based on projected increases in cattle production.

2.3 Meat Exports

Currently no commercial exports of meat occur. There are ad hoc exports of very small amounts of meat products and salted beef as personal consignments to other Pacific countries such as Fiji and Tokelau.

Exports of meat products to American Samoa ceased in 2003 and have not resumed. This trade was never a commercial one, and was based on personal consignments. From discussions conducted in Samoa there is no clear private sector interest in developing a commercial export pathway for meat to American Samoa. However, there is anecdotal evidence of reasonable levels of public interest in resuming access for personal consignments. The number of people departing for travel to American Samoa is between 13,000–15,000 per year. A high proportion of these people would need to take large personal consignments (the amount maximum permitted per traveller would be 22.7 kg) before volumes exported via this pathway were to represent any sort of significant trade.

In its National Export Strategy (2008–2012) the Samoa Government has a stated objective for promoting cattle farming to produce quality local beef to substitute for imports and to become a leading regional exporter of beef including to American Samoa. One of the activities proposed is construction of an abattoir and establishing improved hygienic controls for meat processing. These activities have not been implemented as planned.

After discussions in Samoa it remains unclear as to what if any private sector interest there may be in developing commercial exports. The level of private sector interest may change if SACEP make significant investment in processing facilities and these are operated based on a private sector basis.

It is worth noting that the 2010 World Bank study on the livestock sector concluded that Samoa's livestock sector is unlikely to be competitive in the export meat market and that the focus should be on import substitution.

2.4 Meat Processing Capacity

Samoa currently has no abattoir facilities in which livestock can be hygienically slaughtered and processed. All stock are slaughtered and initially processed on farm. Some carcasses are subsequently processed for the retail market in commercial butchery operations within the town areas but the majority of meat processing is carried out in the open air and not subjected to any refrigeration. An estimated 65% of all animals are slaughtered, distributed and consumed as part of the traditional practice of *fa'alave/ave*. These animals are generally killed and dressed on the ground although some areas do have basic tripod stands for processing off the ground.

Several of the butcheries operating in Apia are of a reasonable standard of construction. There is also a meat processing development unit in the Animal Health and Production unit of MAF formerly used for training but which is now operated by private sector for meat product manufacture (sausages, hams).

There was apparently an abattoir operated in Apia in the 1980s; however, this was closed down over apparent concerns regarding unhygienic practices and maintenance issues. The construction of a new abattoir has been discussed for many years and has been proposed under various sector and

development plans. In 1997 the Samoa Government promulgated the Export of Meat Act to provide regulation for such an abattoir; however, none was built.

The World Bank SACEP project includes in its design planning for investment in a small abattoir facility in the third year of its 5-year (2012–16) programme. Construction of the abattoir will be dependent upon success in increasing cattle numbers and the demonstrated use by farmers on a fee for service basis of two mobile abattoirs to improve hygienic processing standards. Expected throughput of the two mobile units is approximately 700 head in the first two years of the project. Forecast throughput of the abattoir if constructed in the third year of the programme is 1100 head.

The abattoir is intended to be operated as a private independent entity and to be regulated under the draft Samoa Abattoir and Meat Supply Act developed with the assistance of SACEP. The abattoir is intended to be constructed in Upolu and to be built on a modular basis allowing for expansion of its throughput capacity up to a potential 4,500 head per year. It is intended that it be constructed and operated based on international guidelines for good practice. The SACEP has made environmental impact assessments for the abattoir for its waste and other considerations. Construction of the abattoir will form part of the whole of a series of measures by SACEP intended to support the livestock sector in production, marketing and in food safety relating to meat.

Whether the abattoir is constructed and what form its operation will take cannot be known until SACEP implementation is progressed. It is not possible at this stage to determine if the facility and its operation are likely to comply with import requirements of any overseas markets such as American Samoa. Questions remain as to if and when livestock production can be increased to reach the desired throughput levels for domestic demand and any potential export.

2.5 Food Safety Controls for Meat

Food safety controls on meat are currently very limited in Samoa and are certainly not acceptable as a basis for commercial export. The control of slaughter and processing of meat up to the point of retail is the responsibility of MAF through its Animal Health and Production unit (AHP). MAF currently have no legislation to support imposing any meat inspection or sanitary control measures. Meat inspection staff have no formal training in disease recognition or judgements. All meat inspection activities are carried out on a voluntary submission basis by farmers. Farmers bring the carcasses of slaughtered and dressed animals to AHP's office where a cursory inspection is carried out of the carcass often without the viscera being presented. Some retail butcheries request that their suppliers submit all carcasses for AHP inspection, it is not however mandatory. Although AHP inspectors do conduct awareness on hygienic practices and visit some farms at time of slaughter, the majority of meat particularly from *fa'alavelave* is not subject to inspection controls. No structured cold chain for meat storage or transport exists.

No structured bacteriological monitoring is conducted of meat processing operations. However, as an indication of likely contamination levels in the current meat processing system a recent set of microbiology samples taken by MAF from beef carcasses slaughtered for retail showed average coliform counts of over 33,800 colony forming units (CFU) per square cm (more than 100 CFU/square cm is considered unacceptable by the USDA Food Safety and Inspection Service standards). This high rate of carcass contamination is evidence of the current issues in regard to poor slaughter and meat handling practices and the lack of a cold chain from farm to retail. It is worth noting that in terms of capacity to provide potential diagnostic support for future microbiological monitoring of meat the

Samoa Research Organisation of Samoa (SROS) in Apia is an accredited ISO 17025 laboratory for microbiology.

The World Bank SACP project is planning to assist with several areas of improvement in meat control systems. It has assisted in the development of the draft Abattoir and Meat Supply Act, which lays out basic provisions for the slaughter, processing, handling, storage, and transport of meat, including inspection and monitoring activities. The draft act covers domestic meat processing, any exports are to be dealt with under the Export of Meat Act (1997). Both pieces of legislation contain adequate provisions for promulgation of detailed regulations and standards. There is potential scope for these regulations to be developed to a level which could reflect importing country requirements for controls and standards; however, as no regulations have yet to be developed no specific determination can be made at this stage.

Control of meat from the point of sale as a food is the primary responsibility of the Ministry of Health (MOH). The Ministry of Commerce, Industry and Labour (MCIL) currently play a role in setting standards for some foods (such as eggs); however, the MOH is considered the primary agency. The control of food safety is currently conducted under the out-dated Food and Drug Act (1967). This act is currently being reviewed by MOH and stakeholders with the assistance of the World Health Organisation (WHO), and a draft Food Bill (to repeal and replace the food aspects of the old Food and Drug Act) and a draft set of associated Food Standards have been prepared. This legislation will give MOH the primary responsibility for all domestic food safety aspects of any food (including meat) from production, through processing, handling, packaging, storage, transport and sale. It is expected that this legislation will form the overall umbrella for all food safety related legislation and activities, including those of MAF relating to slaughter and meat inspection.

There is some confusion over the exact interrelationship between the various pieces of legislation that are in draft, and the mechanics for their implementation and enforcement. However they do represent a significant improvement in the legislative framework for food safety controls and should provide a relevant set of standards on which to progress improvement in the control of meat hygiene. Whether that level of control would be able to support any particular importing country requirements cannot be determined at this stage.

2.6 Related Donor Activities

The almost complete current lack of sanitary controls for meat and limited disease surveillance monitoring mean that were Samoa to consider pursuing exports of meat to overseas markets such as American Samoa there are a large number of issues that would need to be resolved. These issues and the approval processes involved are discussed in detail in Section 4 of this report. To overcome those issues Samoa will require significant assistance. There are several current or planned donor activities that are of potential relevance.

The World Bank is currently initiating implementation of a 5 year USD 18 million project, the Samoa Agriculture Competitiveness Enhancement Project (SACEP), focused on assisting Samoa Government with implementation of their strategies in the agriculture sector to improve productivity and import substitution. The project will promote the adoption of improved technologies and agricultural practices; and finance investments both on-farm and in strategic marketing infrastructure. Project activities will be grouped into three components: (1) Livestock Production and Marketing; (2) Fruit and Vegetable Production and Marketing; and (3) Institutional Strengthening.

Component 1: Livestock Production and Marketing. The objective of this component will be to encourage interested livestock producers to upgrade livestock, improve husbandry practices and stock management, make productivity enhancing on-farm investments, and improve the quality of meat sold in the local market. The component will comprise a number of activities, including:

- Improving farmer access to superior breeding stock for cattle, pigs, sheep and poultry;
- Financing eligible farm enterprise investments to improve stock handling and livestock housing and provide start-up working capital, through a combination of demand-driven matching grants and bank loans;
- Providing technical advice on breed selection and breeding management, nutrition, animal health and improved husbandry practices;
- Improving livestock nutrition by fostering locally grown feedstuffs and upgrading pastures for cattle and sheep; and
- Improving meat quality and hygiene initially through initiation of a new field slaughter service on Upolu and Savaii, and later by construction of an abattoir on Upolu, all with associated cold chains.
- Training will also be provided in slaughtering and meat processing, meat inspection techniques and standards, and basic microbiology monitoring methods

The SACEP project has begun preliminary activities in the livestock sector by funding a cattle census in 2012 to define populations and production levels. It has also assisted in the drafting of the Abattoir and Meat Supply Act as an instrument to support implementation of the activities to improve hygienic meat processing.

Under Component 3 SACEP will also be providing institutional strengthening support to MAF. The details of this are not yet clear. The project will provide targeted technical assistance from advisers in veterinary regulatory frameworks, ruminant production, small stock production, sanitary slaughter, market linkages and extension management. It is not clear if SACEP will support animal disease survey and monitoring activities as part of its support to MAF.

Overall the SACEP offers an excellent opportunity for relevant assistance to address many of the key issues which if resolved could form the basis for progression of meat production and processing towards any future export potential.

Other organisations are also providing some relevant support that will underpin improvements in food safety control systems. As an example WHO continues to provide technical support for development of food related legislation and standards focusing on the finalisation of the proposed Food Bill and associated Food Standards.

3 Exports to American Samoa

3.1 Trade History

Historically there was a well-established trade in beef and processed meat products with American Samoa. However it is apparent that the trade was never conducted on a commercial basis, and was instead based on large numbers of personal consignments transported by air and sea ferry links predominantly based upon exchanges between familial contacts and community organisations such as church groups. Although it does appear to have been common practice, volumes do not appear to have been large. No official figures are available on the volume of the trade. In general the trade consisted of small consignments (5kg–50kg) of fresh meat (beef, pork, chicken) and processed products such as salted meats and sausages. However it appears that sides of bone-in beef and pork carcasses were also transported at times, and subsequently sold in American Samoa in enterprises such as community or church fund raising events or fares. It does not appear that imports of Samoan meat were ever being offered for commercial sale.

The trade was stopped in the early 2000s by American Samoa based upon concerns that all meat imports into the United States of America (US) and its territories must comply with US federal laws on animal disease status and food safety, and that Samoa did not meet these disease and hygiene requirements. Currently all meat imported into American Samoa comes from either the continental US, New Zealand or Australia.

3.2 Import Requirements

3.2.1 Regulating Agencies

As a territory of the US imports of meat and meat products into American Samoa are subject to US federal import requirements as well as to local territory legislated requirements. All imports must come from countries that comply with US standards and are officially recognised as such. Imports of meat (beef, pork and poultry) and meat products are in the first instance subject to regulation by the United States Department of Agriculture (USDA). Meat from game species (venison or other wild game meats), casings, and processed meat products that only contain a small proportion of meat (less than 2% cooked or 3% raw) can also be subject to separate regulation by the United States Food and Drug Administration (FDA); however, for the commodities traded historically between Samoa and American this is unlikely to apply so this report will only deal with Samoa's ability to comply with USDA regulation.

Regulation by the USDA of imported meat is shared by two agencies, the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS). APHIS is responsible for regulation of animals and animal derived materials to ensure that exotic animal diseases are not introduced. FSIS is the public health agency responsible for ensuring meat and egg products are safe, wholesome, and correctly labelled and packaged.

Standards for imports are set by both these agencies at a federal level, and then overseen at state and territory level by APHIS and FSIS representatives. For American Samoa the decision making level on APHIS and FSIS standards implementation is operated out of USDA's offices in Hawaii and California. Local agencies in American Samoa are charged with border inspection to ensure compliance.

Imports of animals and animal products into American Samoa are also subject to local territory requirements, which are administered by American Samoa Government's Department of Agriculture through the Plant and Animal Quarantine Service (SAG-PAQ). These requirements are codified in the American Samoa Government orders for *Quarantine of Pets and Agricultural products and Animals*, which lay out minimum standards for import of animals and animal products. It includes reference to required disease status for countries of origin in regard to a number of serious animal diseases (such as Foot-and-Mouth Disease (FMD), Rinderpest, hog cholera, swine plague, Newcastle disease amongst others), expected zoo-sanitary certification, and permitting and inspection procedures.

It is worth noting that Section 24.0309 of these orders provides provision for exemption for Samoa, at the discretion of the Director of Agriculture, from certain of the requirements (Sections 24.0307, 24.0308) regarding disease status and quarantine requirements for animals including pets. Discussions with SAG-PAQ suggest that the prior trade between the two countries in meat was conducted under this exemption. However, the exemption appears to have been revoked in the early 2000s once it was realised that USDA regulation was the dominant requirement. Discussions in Samoa indicate that there may still be a very limited number of pets and food animals being sent to American Samoa under this exemption without official permits being issued upon arrival; however, this could not be verified as actually occurring. If such informal trade were occurring it would be in contravention of USDA requirements.

Given the multilayered nature of regulation of imports into American Samoa enquiries were made of American Samoa Government authorities and the USDA to clarify regulatory jurisdictions, import requirements and processes. In communications SAG-PAQ deferred to the APHIS office in Hawaii on determining technical requirements. Feedback was very clear that USDA requirements are the primary requirement for both commercial and non-commercial imports and that Samoa would need to meet those requirements before any trade whether commercial or non-commercial could resume. Samoa is not listed by APHIS as a country with an approved status for diseases of concern to the US (such as FMD, Classical swine fever (CSF), Swine vesicular disease (SVD), Newcastle disease and Bovine spongiform encephalopathy (BSE)) nor is Samoa recognised by FSIS as an approved source for commercial meat exports. Feedback was clear that in the first instance Samoa must satisfy APHIS requirements and obtain country approval for its animal health status. Information was provided by APHIS's Veterinary Regulatory Service (VRS) office in Hawaii regarding the expected approval processes that need to be followed. The APHIS VRS representative advised that the application process would likely be difficult and require considerable commitment by Samoa to see it through. Obtaining such approval will certainly be a lengthy process and require substantial improvements in Samoa's animal health monitoring and meat inspection systems and facilities.

A set of contact details for appropriate USDA and American Samoa Government agencies is attached as Appendix 1 for reference for any future submissions or technical exchanges.

It is worth noting that in June 2012 the import situation was reaffirmed when a large non-commercial consignment of beef and pork was imported into American Samoa from Samoa in an exchange between villages. The Director of Agriculture in American Samoa sought an exemption for the meat to be imported based on non-commercial cultural grounds; however, APHIS VRS staff declined to grant any exemption and rejected the consignment. They emphasised that Samoa did not comply with USDA requirements, and that such requirements applied to all consignments of beef and pork. VRS staff again emphasised that a country application to APHIS was necessary before there would be any change in this situation.

USDA import requirements for meat and meat products into American Samoa from Samoa can be summarised as below:

- All imports of meat (beef, pork, poultry) for commercial or non-commercial purposes are subject to regulation by APHIS requirements regarding recognition of the disease status for the exporting country.
- Samoa's health status is not recognised by APHIS so all imports are currently prohibited. Samoa will need to undertake an approval process by APHIS, which includes a country submission, country visit, and risk assessment.
- Imports of cooked poultry and eggs are considered permissible into American Samoa as small accompanied personal consignments with verification upon arrival of their cooked state by a border inspector.
- All imports of meat (beef, pork, poultry) for commercial purposes are also subject to regulation by FSIS requirements.
- Samoa's meat processing and food safety systems are not recognised as being equivalent to FSIS requirements. Samoa will need to undertake an approval process by FSIS, which includes a country submission, country visit (including inspection of slaughter, processing and cold chain facilities), and a risk assessment.

3.2.2 USDA Approval Process

Should Samoa wish to establish import market access to American Samoa it will need to consider obtaining approval from both USDA agencies APHIS and FSIS. FSIS standards only apply to meat intended for commercial purposes. Meat intended for personal consumption is exempted from FSIS standards; however, all personal consignments of meat must still meet APHIS requirements.

Whether Samoa will wish to seek approval in the future from FSIS for commercial exports is not clear at this stage, and will be very dependent upon successful investment in livestock production systems and processing infrastructure. If in the interim Samoa wishes to regain access for personal consignments of meat for non-commercial purposes it will still need to seek USDA APHIS approval. APHIS VRS staff have noted that this will likely be a difficult and lengthy process for which success is not guaranteed.

Animal Health Status Approval (APHIS)

Samoa will first need to gain recognition from APHIS of its animal disease status. At present APHIS actually officially considers Samoa to be infected with a number of serious animal diseases based upon a lack of available data as to what the actual animal health status of the country is.

The APHIS approval process will be essentially the same regardless of the meat type for which market access is sought although some technical aspects re diseases for evaluation differ slightly. The application can cover multiple species. For this report the aspects relating to beef and pork will be the only ones discussed in any detail.

Samoa will need to make a country application to APHIS for what is termed *Recognition of a Region*. The application is initiated by submission of a country questionnaire that seeks information on:

- Veterinary control and oversight
 - Legal authority for animal health activities

- Organisational structure of veterinary services
- Infrastructure and financial resources
- Disease history and vaccination practices
 - History of disease outbreaks
 - Vaccination practices
- Livestock demographics and traceability
 - Livestock demographics
 - Identification and registration
- Epidemiological separation from potential sources of infection
 - Disease status of adjacent regions
 - Natural man made barriers
 - Import practices and trading partners
 - Requirements for entry
 - Inspection practices and procedures
- Surveillance
 - Active surveillance
 - Passive surveillance
- Diagnostic laboratory capabilities
- Emergency preparedness and response

The submission is intended to allow evaluation of a country's disease status in regard to certain key diseases, and the degree of capacity the country has to prevent entry of disease risks, and to monitor animal health, and respond to disease outbreaks. The diseases APHIS specifically evaluates for are bovine brucellosis, bovine tuberculosis, foot and mouth disease, classical swine fever, Newcastle disease, Rinderpest, swine vesicular disease and transmissible spongiform encephalopathies such as scrapie and BSE.

In making the application there are two options for the questionnaire to be submitted

- Clarification of Information Requested for Recognition of a Region
- Clarification of Information Requested for Recognition of a Historically-free Region

The latter option is available to countries where the diseases under evaluation have not occurred in domestic livestock for the last 25 years, if ever, or in wildlife for at least 10 years. Although as noted below there are a range of issues with Samoa's disease surveillance systems, and only limited testing data is available, if Samoa were to make an application then (based on its situation as an isolated island country, its trading history in imports of animals and meat products predominantly with Australia and New Zealand, and historical trade with American Samoa) this would be the preferred submission option. A copy of the current questionnaire content is attached as Appendix 2 for reference.

The evaluation process consists of initial information gathering for APHIS to make a preliminary assessment of the country capacity, followed by a country visit by veterinary inspectors, and a risk assessment. The likely speed of the process depends very much upon the quality of the information submitted by a country and the ease with which APHIS can at each stage assess compliance or equivalence with their expectations.

Samoa is unfortunately currently in a very weak position in terms of the likelihood of being able to make a successful application. Careful consideration will need to be given to the time and effort that will be involved to progress such an application. Comparison can be made to Vanuatu, which has well-established disease surveillance records and an excellent disease status documented historically. However, APHIS still considers Vanuatu to be infected with significant diseases, and despite several attempts over many years Vanuatu has not been able to change its status with APHIS.

The key issues Samoa faces in making an application are:

Animal Health Legislation

There is only limited animal health legislation in place to outline Samoa's regulatory control of animal disease, veterinary services and biosecurity measures for animals and animal products. The only applicable legislation supporting MAF in animal health and veterinary controls are the basic provisions of the Animal Ordinances 1960 for control of sick animals, and the provisions of the Quarantine (Biosecurity) Act 2005. It is unlikely that APHIS would accept the current legislative controls as adequate particularly given the context of the resourcing constraints that prevent Samoa from demonstrating that it has an effective veterinary services and animal health control activities in place.

Animal Health Surveillance

Although Samoa is not a member of the World Animal Health Organisation (OIE) MAF veterinary staff do enter disease reporting information into the World Animal Health Information System (WAHIS) based on Samoa's historical status and passive surveillance reports. All animal health surveillance in Samoa is essentially passive. There is no structured active or passive disease surveillance conducted for the diseases under evaluation by APHIS. As a result quality information for disease reporting is very limited.

The last significant active disease surveillance work was conducted in 1999 with the assistance of the Secretariat of the Pacific Community (SPC)⁴. That work concluded that Samoa was free of what were then termed OIE "List A" diseases including FMD, Rinderpest, classical swine fever, and Newcastle disease. It confirmed the presence of bovine brucellosis and tuberculosis (which were at the time both the subject of renewed control programmes which have now subsequently lapsed), leptospirosis and trichinosis. The survey also indicated serological evidence for the presence of infectious bovine rhinotracheitis, pestivirus, theileriosis and babesiosis in cattle; Aujeszky's disease in pigs; and infectious bronchitis, infectious bursal disease, infectious laryngotracheitis, avian encephalomyelitis and Marek's disease in poultry.

The survey noted at the time that ongoing surveillance would be necessary to maintain or improve the country's animal health status and that appropriate importation and quarantine procedures must be maintained to retain this disease-free status.

Given the length of time that has elapsed since the SPC survey work and the current lack of disease monitoring systems it is unlikely that APHIS would accept the current level of disease data in regard to the diseases being evaluated for country freedom (such as FMD or other vesicular diseases), or that controls on endemic diseases (such as bovine tuberculosis and brucellosis) are adequate. It is likely that significant active disease survey work will need to be conducted, along with the establishment of effective ongoing disease monitoring systems and control programmes, in order to satisfy APHIS

⁴ SPC, The Animal Health Status of Samoa 1999

requirements. Ultimately APHIS is also likely to expect a period of proven disease surveillance history. To achieve this Samoa MAF would require technical assistance to conduct the disease survey work and some longer-term capacity building.

Actions Necessary

At this point in time Samoa is not in a position to make a country submission to APHIS for evaluation. There will need to be considerable strengthening of the animal health surveillance systems and control programmes with a body disease reporting information built up. An initial step would be to conduct disease surveys that can be used to update the animal health status for Samoa and clarify current status of APHIS target diseases. Such assistance could be sought from SPC's Land Resources Division or via the World Bank SACEP project. SPC funding assistance for the survey work could be considered under Component 4 of PHAMA.

To support any APHIS application there will also need to be improvements in the capacity and operation of MAF's livestock services in regard to animal health activities. Given that commercial export, if it were to be pursued, is unlikely to occur for several years, it will not fall within the scope of PHAMA Phase 1 to support those capacity building activities. However, it is understood that SACEP will be providing a degree of institutional strengthening and operational support to MAF over the next 5 years. The nature of that support in regard to animal health activities still requires definition.

If disease survey work was to be conducted and adequate capacity building occurs with MAL livestock services then an APHIS application could be considered. If and when this could occur would seem mainly dependent upon the degree of assistance that SACEP can provide to support MAL. At this stage opportunity for support from PHAMA Phase 1 would seem limited to the potential support of initial animal disease surveys via Component 4 to update Samoa's animal health disease status.

Recommendation:

That PHAMA consider funding support under Component 4 for SPC to conduct animal health survey work to update Samoa's Animal Health Status in regard to OIE listed diseases.

3.2.3 Food Safety Equivalence Approval (FSIS)

If Samoa were to gain approval from APHIS for recognition of its animal health status as being acceptable, any commercial meat exports to American Samoa would still need approval of FSIS. Gaining this approval will require Samoa to undergo an assessment process to determine *equivalence* of its food safety systems for meat and meat products with USDA required sanitary standards and outcomes.

The FSIS equivalence determination process involves information gathering through a country submission to enable review and assessment of all aspects of that country's food safety legislation, policies, standards, procedures and infrastructure. A copy of the required country submission questionnaire is attached as Appendix 3 for reference. If following that review FSIS deem the country's system as being potentially able to achieve equivalence it will be followed by a country visit to verify standards and outcomes. The visit will include specific site inspections of all establishments involved in the slaughter, processing and cold chain for meat for export. Approval is granted to a country and also specifically to each slaughter and processing establishment. Meat for export can only come from those accredited sources. FSIS will then monitor compliance with expected standards via border

inspections upon import, and will return for regular country visits to audit country systems and establishments. The frequency of those visits depends upon demonstrated compliance history.

Samoa is currently not in a position to consider commercial exports, and is not in a position to make an FSIS application. Samoa will first need to develop sufficient livestock production to meet and then exceed domestic demand, establish adequate food safety controls for the hygienic slaughter, processing, packaging, transport and storage of meat, including the construction of appropriate slaughter and processing facilities. These development aspects are beyond the scope for PHAMA Phase 1 assistance.

It is understood that SACEP will be providing considerable assistance over the next 5 years to Samoa's livestock sector to support improved livestock production and breeding, and improvements in livestock marketing systems. SACEP will also be providing assistance to support improved food safety legislation and controls, and be providing investment in slaughter and processing facilities, initially for mobile facilities with planned later construction of an abattoir based upon adequate increases in production. At this stage it is understood SACEP are focused on domestic meat production as a form of import substitution, improvement in domestic food safety and nutrition, encouragement of local agricultural commerce and livelihoods, and that there is no specific objective in relation to achieving exports.

Should SACEP prove successful in its 5-year plan to improve meat production volumes and the standards and facilities for hygienic processing it may be appropriate to reconsider the future of commercial exports to American Samoa. At which stage PHAMA Phase 2 may wish to reassess the adequacy of Samoa's ability to meet FSIS requirements and assist with a country application.

4 Way Forward

This assessment has provided clarity on the standards applicable for imports of non-commercial and commercial consignments of meat into American Samoa, and the processes necessary to establish market access.

The initial step for re-establishing access for non-commercial consignments is for Samoa to make an application to USDA APHIS. At this stage Samoa is not in a position to make an application to APHIS due to a lack of disease information and animal health surveillance capacity. It is not considered appropriate for PHAMA to assist with developing any such application until progress has been made in addressing the key elements of necessary country requirements as determined by the APHIS Recognition of Region questionnaire.

To do this, work will be required to conduct animal disease survey work and strengthen animal disease surveillance legislation, systems and procedures. The process is likely to be lengthy and will require commitment from Samoa Government and MAF.

Should Samoa wish to pursue the APHIS application the first appropriate step for PHAMA to consider is funding support for animal disease surveys under Component 4 to update the animal health status for the country. It is possible that the World Bank SACEP project may be willing to undertake this work under its Livestock Component or at least consider cofunding of it. Further discussions will be required with SACEP once their implementation team are established.

At this stage commercial exports to American Samoa cannot be considered due to a lack of meat processing infrastructure and inadequate food safety controls for meat. The SACEP project is currently beginning implementation of a 5-year programme of support in the livestock sector and is planning to improve livestock production, sanitary meat controls and invest in processing infrastructure including and abattoir and cold chain. Efforts are also underway to improve the food safety legislation controlling meat production, processing and supply. Should an abattoir and cold chain be successfully established and operated and there be clear private sector interest in pursuing commercial exports to American Samoa then PHAMA should consider reassessing the capacity of Samoa to meet USDA requirements for commercial imports and how it may be able to assist. At this stage it appears unlikely that this need would arise for at least several years.

Recommendation:

The Samoan MAWG is asked to consider approval for PHAMA funding of an animal health disease survey by SPC under Component 4 of PHAMA to update Samoa's animal health status.

5 Limitations

URS Corporation Pty Ltd (URS) has prepared this report in accordance with the usual care and thoroughness of the consulting profession for the use of AusAID and only those third parties who have been authorised in writing by URS to rely on the report. It is based on generally accepted practices and standards at the time it was prepared. No other warranty, expressed or implied, is made as to the professional advice included in this report. It is prepared in accordance with the scope of work and for the purpose outlined in the Contract dated 20 January 2011.

The methodology adopted and sources of information used by URS are outlined in this report. URS has made no independent verification of this information beyond the agreed scope of works and URS assumes no responsibility for any inaccuracies or omissions. No indications were found during our investigations that information contained in this report as provided to URS was false.

This report was prepared between in July 2012 and is based on the conditions encountered and information reviewed at the time of preparation. URS disclaims responsibility for any changes that may have occurred after this time.

This report should be read in full. No responsibility is accepted for use of any part of this report in any other context or for any other purpose or by third parties.

Appendix A

Appendix A USDA and American Samoa Contacts

A.1 USDA Contacts

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Appendix B

Appendix B USDA APHIS Country Questionnaire

Clarification of Information Requested for Recognition of a Historically-free Region

Introduction

This document describes the basic information that the Animal and Plant Health Inspection Service (APHIS) requires to initiate an evaluation of a historically-free region in accordance with title 9, *Code of Federal Regulations*, section 92.2(c). Qualifying regions are those in which the disease under evaluation has not occurred in domestic livestock for at least 25 years, if ever, or in wildlife for at least 10 years. Veterinary authorities seeking APHIS recognition of regions that do not meet these conditions should follow the guidance in 9 CFR 92.2(b).

APHIS recognizes regions (zones) in other countries for the purposes of international trade. A region is defined as a geographical land area identifiable by geological, political, or surveyed land boundaries, which contain an animal subpopulation with a distinct animal health status. Examples include (1) an entire country; (2) part of a country; (3) parts of several countries; and (4) a group of countries. The borders of a region must be clearly defined and the entire region must be accessible to both national veterinary authorities and APHIS personnel.

A regionalization evaluation typically consists of initial information gathering, a site visit, and a risk assessment. Any resulting regulatory action must reflect the risk assessment conclusions. The pace of an APHIS evaluation largely depends on the quality of the information received.

To facilitate the assessment process, please submit all information in English.

1. Scope of the evaluation

- a) Provide a detailed description of the proposed region(s) and maps showing the following:
 - Borders of the region(s)
 - Internal administrative divisions (regional and local)
 - Buffer zones (if any)
 - Main cities and towns
 - Main roads and railways
 - Locations of the following:
 - Headquarters of the veterinary services
 - Regional and local offices of the veterinary services
 - Central and regional official laboratories
 - Approved border inspection posts (airports, seaports, land crossings)
- b) Identify the animal commodities⁵ proposed for export to the United States and estimate the annual volume of export for each commodity.
- c) Specify the disease(s) for which an APHIS evaluation is requested (see Appendix A). 2

⁵ For the purposes of this document, animal commodities are live animals, animal products, and animal by-products.

Appendix B

2. Disease history and vaccination practices

- a) Indicate when each disease under evaluation was last reported in domestic livestock in the region. (Note that this questionnaire may only be used if the disease(s) under evaluation have not been reported for at least 25 years.)
- b) Indicate when each disease under evaluation was last reported in wildlife in the region. (Note that APHIS cannot consider a region historically free if infection has occurred in wildlife in the last 10 years.)
- c) Indicate whether vaccination against the disease(s) under evaluation has occurred in the last 10 years and, if so, provide the following information:
 - Reasons for vaccination
 - Source and type of vaccines used
 - Target populations
 - Recordkeeping requirements
 - Procedures to distinguish vaccinated animals

3. Veterinary control and oversight

The requesting region should provide evidence that the veterinary services in the region have had and continue to have sufficient legal authority, organization, and infrastructure to effectively investigate, diagnose, and report animal diseases, if present.

a) Legal authority for animal health activities

- i. Provide copies (in English) of the legal acts and regulations that afford authority for the official veterinary services to conduct the following animal health activities:
 - On-farm inspections
 - Import, export, and internal movement controls
 - Quarantine of animals or farms
 - Vaccination for the disease(s) under evaluation
 - Surveillance for the disease(s) under evaluation
 - Control and eradication of the disease(s) under evaluation
 - Emergency response activities
 - Seizure, depopulation, and compensation

- ii. Provide copies (in English) of any secondary legislation, enabling regulations, manuals, contingency plans, or guidance documents pertaining to the disease(s) under evaluation.

b) Organizational structure of the veterinary services

- i. Provide an organizational chart of the official veterinary services and describe the chain of command, including to whom the central, regional, and/or local veterinary units report.
- ii. Describe the functions of each unit within the official veterinary services and the division of responsibilities among central, regional, and local veterinary authorities. What procedures are in place to ensure coordination and communication among these entities?

c) Infrastructure and financial resources

- i. Describe the financial resources of the official veterinary services, including the budget for the most recent fiscal year and sources of funding (governmental and nongovernmental).
- ii. If financial or performance audits of the veterinary services are conducted, identify the auditing entity and describe the audit frequency and the results of the most recent audit.

Appendix B

4. Disease reporting

The requesting region should provide evidence that each disease under evaluation has been legally notifiable in the region, for at least the past 10 years.

- a) Describe how notification of the disease(s) under evaluation is ensured within the region, including the methods by which obligated persons are made aware of the reporting requirements and penalties for failure to notify. Provide a copy (in English) of the pertinent legal acts or regulations.
- b) Describe the procedures in place to ensure that the veterinary authorities of the requesting region inform pertinent international entities of a disease outbreak in a timely manner.

5. Disease detection

The requesting region should provide evidence that an effective early detection system has been in place for each disease under evaluation, for at least the past 10 years. An effective early detection system includes, among other things, representative coverage of susceptible animal populations by field services, a training program for detecting and reporting unusual animal health incidents, the ability to undertake effective disease investigation and reporting, and access to laboratories capable of diagnosing and differentiating relevant diseases.

a) Coverage by field services

- i. Complete the table in Appendix B concerning veterinary personnel in the region.
- ii. Indicate the number of private veterinarians and veterinary technicians in the region and the number authorized to conduct official animal health and food safety activities. Describe the procedures for authorization, the policies in place to safeguard against conflicts of interest, and any requirements for official supervision.
- iii. Describe any legal or procedural requirements for routine inspection of livestock premises for animal health, identification, or welfare purposes. Who conducts the inspections and how often do such inspections occur?

b) Training programs

- i. Indicate the minimum qualifications required for veterinary and technical staff employed by the official veterinary services at the central, regional, and local levels. Describe the training requirements for newly recruited and established staff, as well as any pertinent simulation or field exercises conducted in the last 3 years.
- ii. Describe any outreach activities of the official veterinary services designed to increase awareness, recognition, and reporting of the disease(s) under evaluation among producers, industry members, official and private veterinarians, and the general public.

c) Disease investigation and reporting

- i. Describe the type and extent of surveillance activities for the disease(s) under evaluation, in domestic livestock and wildlife. Include both active and passive surveillance, if applicable.
- ii. Indicate the number of suspicious cases of the disease(s) under evaluation reported to the official veterinary services in the past 3 years and describe the follow-up measures taken in each case.
- iii. Provide copies (in English) of any guidance documents for investigation of suspect cases of the disease(s) under evaluation and plans for emergency response.

d) Diagnostic laboratory capabilities

- i. Provide an organizational chart of the animal health laboratory system in the region. Indicate which laboratories conduct screening and/or confirmatory tests for the disease(s) under evaluation. Describe the certification or accreditation requirements for these laboratories.
- ii. Indicate the number of scientists and administrative staff employed in each laboratory, and describe the procedures in place to ensure continued proficiency in diagnostic procedures.

Appendix B

- iii. Indicate the diagnostic tests or procedures used to detect the disease(s) under evaluation. What procedures are conducted for agent isolation, identification, and typing?
- iv. Describe the procedures for reporting test results, including to whom they are reported and the average time between sample collection and reporting. If confirmatory testing is conducted outside of the region, estimate the time required to confirm a diagnosis.

6. Barriers to disease introduction

The requesting region should provide evidence that measures have been in place to prevent introduction of each disease under evaluation, for at least the past 10 years.

- i. Provide a map showing the main geological features of the region. Describe any manmade barriers (e.g., fences, netting) that isolate the region from adjacent regions and indicate how the integrity of these barriers is ensured.
- ii. Provide a map showing the location of all official entry points into the region with veterinary and/or customs inspection. Describe the procedures for veterinary inspection and control of animal commodities that could harbor the disease(s) under evaluation.
- iii. Describe any other procedures at border entry points to exclude prohibited animal commodities (e.g., customs inspections, self-declarations, signs to alert travelers).
- iv. List the countries or regions from which the region under evaluation imports animal commodities that could harbor the disease(s) under evaluation. Indicate the amount and type of such commodities imported from each country or region in the last 3 years.

Appendix A

Select the diseases for which an APHIS evaluation is requested from the table below. Include all diseases potentially affecting the commodities proposed for export in Question 1b, unless APHIS already considers the region free or low risk for a disease.

African horse sickness	Foot and mouth disease
African swine fever	Newcastle disease
Avian influenza	Rinderpest
Bovine brucellosis	Scrapie
Bovine tuberculosis	Swine vesicular disease
Classical swine fever	Other (please specify)
Contagious equine metritis	

Appendix B

Provide the information in the table below concerning veterinary services personnel in the region.

	Veterinarians*		Veterinary technicians		Administrative staff	
	Filled posts	Vacant posts	Filled posts	Vacant posts	Filled posts	Vacant posts
Central service						
Regional service						
Local service						
Border controls						
Laboratory service						

*Veterinarian is defined as having graduated from veterinary school.

Appendix C

Appendix C USDA FSIS Country Questionnaire

United States Department of Agriculture

FOOD SAFETY AND INSPECTION SERVICE

1400 Independence Avenue, S.W., Washington, DC 20250 Tel.: 202-720-3473 Facsimile: 202-690-3856

July 2011

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

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1. INTRODUCTION

Imported meat, poultry, and egg products must meet all safety standards applicable to similar products produced in the United States. In doing so, foreign meat, poultry and egg products 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, poultry, and egg products food regulatory system equivalence through a process that consists of (1) document analysis, (2) on-site audit, and (3) port-of-entry product reinspection. Determinations of system equivalence are necessary for FSIS and the American public to develop and maintain trust in imported meat, poultry, and egg 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, poultry, and egg products. Thus, trust becomes an equivalence issue with both food safety and trade implications.

2. PURPOSE AND SCOPE

This paper revises and replaces the October 2003 document titled “FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems.” This revised paper presents the evaluation process FSIS applies to initially determine and periodically verify whether foreign meat, poultry, and egg products food regulatory systems are equivalent to U.S. domestic regulatory systems. In addition, this document has been revised to include FSIS responsibilities for egg products and to provide current information on how FSIS evaluates country submissions for initial equivalence, how FSIS determines ongoing equivalence of a country’s food regulatory system, and how FSIS evaluates country submissions for equivalence of individual sanitary measures.

3. DEFINITIONS

*Appropriate level of protection*¹ 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.

¹ Adapted from a Codex Committee on Food Inspection and Certification Systems (CCFICS) document titled “Proposed Draft Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems” (ALINORM 03/30A, Appendix II)

<i>Equivalence</i> ²	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.
<i>Food Safety Hazard</i> ³	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse human health effect.
<i>Regulatory Objective</i> ⁴	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.
<i>Sanitary Measure</i> ⁵	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 Ibid.

³ Codex Alimentarius Commission: Procedural Manual

⁴ 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.

⁵ Agreement on the Application of Sanitary and Phytosanitary Measures; Appendix A

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, poultry, and egg products 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.⁶

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

⁶ Article 4.1, "Agreement on the Application of Sanitary and Phytosanitary Measures."

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, poultry, or egg 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.⁷

⁷ 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)⁸ and the Poultry Products Inspection Act (PPIA).⁹

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.¹⁰

In July 1995, FSIS implemented the FMIA and PPIA amendments cited above with a direct final rule¹¹ 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. (The EPIA has always required that countries seeking equivalence to export egg products to the United States be evaluated for equivalence and, thus, no amendments were made to the EPIA or egg products regulations.) Part 327 (meat) and Part 381 Subpart T (poultry), and Part 590 of Title 9, Code of Federal Regulations (CFR), pertain to eligibility requirements for imported meat, poultry, and egg 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.¹²*

Agency regulations further specify that determinations of eligibility must be based upon equivalence evaluations.¹³ Consequently, FSIS has developed the process described in this paper to conduct equivalence evaluations of foreign meat, poultry, and egg products food regulatory systems and individual sanitary measures that vary from U.S. requirements. The criteria for evaluating foreign systems are set forth in section 327.2 for meat, section 381.196 for poultry, and section 590.910 for egg products.¹⁴ Each of these regulatory criteria constitutes a sanitary measure as defined by the SPS Agreement. The criterion for evaluating alternative

⁸ 21 U.S.C. 620(e)

⁹ 21 U.S.C. 466

¹⁰ Amendment to §20(e) FMIA. The PPIA was amended by §431(k) with essentially the same language.

¹¹ 60 FR 38667; July 28, 1995.

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

¹³ Ibid., footnote 5.

¹⁴ Ibid., footnote 6.

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.

These measures may take many forms, to include:¹⁵

- 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

¹⁵ 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.

limited to quantitative risk assessment, which has been described as a particular type of risk assessment used to evaluate the potential for carcinogenesis.¹⁶

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 an appropriate 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.

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.*¹⁷

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".*¹⁸

Article 2 of the SPS Agreement states that *sanitary measures* employed to meet an importing

¹⁶ Ibid. at A.9.

¹⁷ Ibid. at A.3.

¹⁸ Agreement on the Application of Sanitary and Phytosanitary Measures; Appendix A

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 Objective¹⁹ (RO) may be 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 or egg 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

¹⁹ 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.

system equivalence.²⁰

Initial equivalence evaluations of foreign meat, poultry, and egg products food regulatory systems are a prerequisite for trade. The FMIA, the PPIA, and the EPIA place a positive requirement on USDA to establish the equivalence of a foreign country's food regulatory system before accepting meat or poultry or egg products from the country 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.²¹

Any country can apply for eligibility to export meat, poultry, or egg products to the United States.²² 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:

- A self-assessment designed to collect detailed information about the foreign food regulatory system;²³ and
- Access to pertinent U.S. laws, FSIS regulations, and other documents that set forth meat, poultry, and egg products food regulatory policy.

The initial package provides an applicant country with information about the U.S. meat, poultry, and egg products food regulatory system and conveys expectations about sanitary measures that FSIS anticipates in an equivalent foreign system, including the criteria used to evaluate equivalence. 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 the self-assessment. Upon request, FSIS provides advice and guidance to foreign governments concerning any portion of the application process. When the completed application is received,

²⁰ 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.

²¹ 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 and 9 CFR 590.910(a) for egg products] 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, 381.196 for poultry, and 590.910 for egg products are evaluated for initial equivalence using procedures described in this section of the document.

²² 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.

²³ Data is collected in six components: Government Oversight, Statutory Authority and Food Safety Regulations, Sanitation, HACCP, Chemical Residues, and Microbiological Testing Programs.

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, poultry, and/or egg products food regulatory system.

Initial equivalence audits are conducted by a team of experts. Composition of the audit team may include a veterinarian, food technologist, microbiologist, chemist, the document analysis case officer, and others as needed. The audit scope includes verification of system records such as country laws, regulations, directives, notices, and other program implementation documents; records of establishment operations, inspection results, and enforcement activities; chemical residue controls from farm to slaughter; microbiological and chemical testing programs; laboratory support, sampling programs, testing methodologies, and other 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 many 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 publishes a final rule in the *Federal Register* announcing country eligibility. 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.

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 determined to have an equivalent food regulatory system, FSIS relies on the country's food regulatory system to carry out inspection activities. 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 those establishments that meet U.S. import requirements before exporting product to the United States.

No meat, poultry, or egg 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 can take several 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 or egg products 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 countries exporting meat, poultry, and egg products to the United States 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. FSIS will explain the reason/purpose for the new sanitary measure at this time. Upon promulgation domestically, the new sanitary measure automatically becomes an import requirement applicable to foreign meat, poultry, and egg products.²⁴
2. An exporting country must either adopt the FSIS sanitary measure as written or notify the Agency that it proposes to apply an alternative measure. 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.
3. The exporting country develops a submission to demonstrate that its alternative sanitary measure achieves the same level of protection as the U.S. measure.
4. 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.
5. FSIS notifies the exporting country of its decision and provides the basis for its decision, whether accepted or rejected.
6. Following a determination of alternative sanitary measure equivalence based upon document analysis, FSIS will verify the application of the sanitary measure during the

²⁴ 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.

next regularly scheduled on-site 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.

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.

8. EQUIVALENCE VERIFICATION

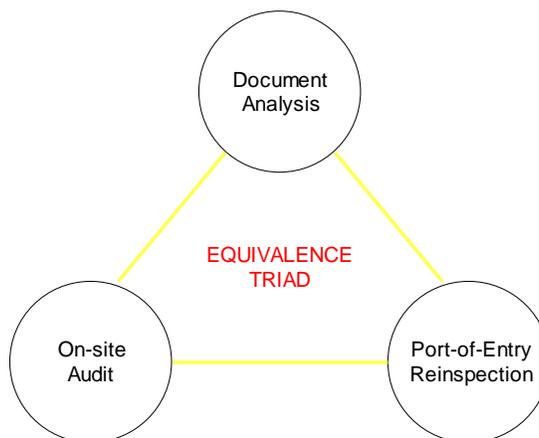
As noted above, initial equivalence applications and alternative sanitary measure proposals both have an equivalence verification component. This section explains how FSIS uses verification as a *recurring* component of equivalence.

FSIS utilizes a three-part process to verify that foreign meat, poultry, and egg products 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 equivalent infrastructure remains in place.

2. The second part is a food regulatory **system audit** conducted periodically for every country that exports meat, poultry, or egg products to the United States to assess the delivery of inspection services by the foreign inspection service and to verify continuing equivalence.

3. The third part 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 Self-Reporting Tool

The first component of equivalence verification is the recurring document analysis of an eligible country's laws, regulations and implementing policies. The purpose of a recurring document analysis is twofold: (1) to verify that the laws, regulations, and implementing policies of an exporting country continue to support the food regulatory system determined to be equivalent with adequate authority to accomplish its mission and (2) to evaluate written regulatory system procedures for foreign establishment oversight, verification and enforcement of requirements.

FSIS carries out the recurring document analysis through its review of responses from eligible exporting countries to FSIS' Self-Reporting Tool (SRT). The SRT complements the required documentation that countries submit as part of the initial equivalence evaluation process. The SRT is provided to every eligible exporting country with a request to maintain up-to-date information about the six components on which initial system equivalence was based: government oversight, statutory authority and food safety regulations, sanitation, HACCP, chemical residues, and microbiological testing programs. Along with responses to the questions in the SRT, exporting countries are asked to submit current inspection system laws, regulations, and policy issuances to support their answers. The SRT also affords countries the opportunity to advise FSIS of any new controls they have implemented (e.g., microbial baseline studies, ongoing risk assessments, internal audit programs) to demonstrate the effectiveness of their food regulatory systems. In summary, the recurring document analysis updates initial determinations of foreign inspection system equivalence and is the first component of the three-part process for verifying continuing system equivalence.

8.2 Equivalence Verification System Audits

The second component of equivalence verification is the conduct of system audits. System audits provide a transparent, collaborative forum with international trading partners to verify equivalence. The purpose of a system audit is to evaluate the foreign inspection program and verify equivalence, not to inspect individual foreign establishments. These audits are conducted periodically in exporting countries by FSIS technical experts. 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 the U.S. 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.** Each year, FSIS prepares a performance-based plan to audit those countries that export meat product, poultry products or egg products to the United States. Individual country audit plans are based, in large part, upon prior experience with the exporting country. 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. In addition, information from the country's SRT is analyzed to determine where the audit focus/resources should be directed. These documents and data are used by FSIS to develop an audit plan that is customized for each country. If it is determined that an on-site audit is needed, the audit

plan is transmitted to the exporting country for comment before implementation. 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, such as verification of corrective actions as a result of a POE violation.

2. EXECUTE (on-site). 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 lead the audit which is intended to verify that each selected establishment continues to meet all U.S. meat, poultry, and egg products import requirements. FSIS auditors visit field offices, observe establishment, microbiological and chemical residue laboratories activities and correlate review findings made by exporting country officials. In a closing meeting, the FSIS auditor provides exporting country officials a preliminary 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 to determine whether the performance of the country's food regulatory system is consistent with the information provided to FSIS via the SRT and in other submitted documents. When evaluating audit data, FSIS determines whether the foreign system cumulatively provides the same level of protection as provided by the U.S. inspection system.

4. FEEDBACK. FSIS sends the exporting country a draft audit report which provides the exporting country an opportunity to comment on FSIS findings. A final report is prepared that includes the exporting country's comments. 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 verification audit.

All reports of initial equivalence audits and periodic equivalence verification audits are posted on the FSIS website 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 (POE) reinspection, where FSIS randomly samples meat, poultry, and egg 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 reinspection 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, poultry, and egg products 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.

POE reinspection is directed by the Automated Import Information System (AIIS), a centralized computer database that stores daily inspection results from all FSIS official import inspection establishments for all shipments of meat and poultry from each country and foreign 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 import 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 systems-based in that its intent is to verify effectiveness of the foreign food regulatory system, not to determine individual establishment performance. A central purpose of the AIIS is to generate reinspection assignments that FSIS import inspectors perform on the imported product. 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 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.²⁵ 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

POE 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 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.

²⁵ 9 CFR 417.2(b)

Although the Animal and Plant Health Inspection Service (APHIS) has lead responsibility for assuring that meat, poultry, and egg products are eligible for importation under animal disease restrictions, FSIS is the second line of defense in preventing 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 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.

In the case of imported egg products, inspection assignments and results are maintained in a separate computer database specifically designed for the egg product groups, including pasteurized, unpasteurized, and dried. The same enforcement actions are taken when a shipment fails reinspection.

Products that pass reinspection are stamped with the official mark of inspection and are allowed to enter U.S. commerce. Under U.S. meat, poultry, and egg products 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 applying a fair and transparent process to evaluate the initial equivalence of foreign meat, poultry, and egg products 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, poultry, and egg products meet all U.S. import requirements.



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