

ENFORCEMENT QUESTIONNAIRE

Sample Response

The following responses to the questions and requests for information made in this questionnaire serve as an example to all foreign governments of how the United States expects the applicant to fill out the questionnaire. In order to answer the questions from your perspective, we have answered the questions as if the U.S. is applying for eligibility to ship meat products to Country-X.

For each question and request, we have cited the sections in our regulations or other reference material that governs our response(s). In addition, we have provided examples of any forms, charts, or other documents applicable to each question or comment.

(Questions A through L address compliance and M through P address economic fraud.)

A. Program Organization

- 1. For each of the products under this application, what national and other government agencies enforce the relevant laws and regulations relating to compliance activities? Compliance activities include the investigation of violations of inspection laws; controlling violative products through detentions, civil seizures, and voluntary recalls; and assuring that appropriate criminal, administrative, and civil sanctions are carried out? Include organizational charts for each of these agencies.**

REGULATORY AGENCIES

U.S. Department of Agriculture, Food Safety and Inspection Service

U.S. Department of Agriculture, Office of Inspector General

U.S. Department of Agriculture, Office of the General Counsel

U.S. Department of Justice

REGULATORY AUTHORITIES

Federal Meat Inspection Act (21 U.S.C. 601 et seq.)

Poultry Products Inspection Act (21 U.S.C. 451 et seq.)

References: Federal Meat Inspection Act (21 U.S.C. 641-676)

Poultry Products Inspection Act (21 U.S.C. 460-467)

Organizational charts—USDA and DOJ.

Organizational charts for FSIS, USDA; EPA, FDA; APHIS, and OIG are attached.

(See Attachments).

2. What is the functional relationship among these government agencies and between these agencies and any separate activities at state, provincial, or local levels?

FSIS' District Enforcement Operations (DEO) works with the Office of Inspector General and the Office of the General Counsel when violations of the Federal Meat Inspection Act are found. Recommendations for legal action are forwarded by USDA's Office of the General Counsel to the Department of Justice. DEO also works with the Food and Drug Administration and with state and local food safety and public health offices to investigate sanitation and other violations and control products implicated in food poisoning outbreaks.

Reference: FSIS, Office of Field Operations, District Enforcement Operations Federal Meat Inspection Act (21 U.S.C. 601 et seq.)

3. What personnel, training, equipment/resources, and other facilities are utilized to enforce and fulfill the responsibilities of the meat and/or poultry inspection system regarding the investigation of violations of inspection laws; controlling violative products through detentions, civil seizures, and voluntary recalls; assuring that appropriate criminal, administrative, and civil sanctions are carried out; and other compliance activities for each of the products under this application?

FSIS' DEO personnel supplement in-establishment inspection by monitoring meat and poultry products as they move through channels of distribution outside of official establishments. DEO compliance officers investigate violations of the inspection laws; control adulterated and misbranded products through detentions, civil seizures and voluntary recalls; and assure that appropriate criminal, administrative, and civil sanctions are carried out. The Federal Meat Inspection Act and the Poultry Products Inspection Act provide the primary legal authority and mission for DEO.

Approximately 140 geographically dispersed compliance officers explain inspection and other requirements to industry officials, review records, and maintain a nationwide monitoring program to prevent adulterated or misbranded meat and poultry products from reaching consumers.

All firms and individuals that process, store or distribute meat and poultry products are subject to random reviews. Where prior history or known risks identify a need for closer monitoring of a particular firm or individual, FSIS' Planned Compliance Program provides a systematic method for determining frequency of follow-up reviews.

During a typical review, compliance officers contact industry management officials and discuss applicable FSIS requirements. Inventories of meat and poultry products are observed to see if they comply with Federal regulations, and appropriate records concerning the sale, purchase, shipping or storage of products are examined. Additional investigations may occur when evidence of a violation is found. Certain significant

alleged violations are referred to USDA's Office of Inspector General for further investigation.

Cases involving major violations of Federal laws are referred to USDA's Office of the General Counsel for review. The Office of the General Counsel, in turn, forwards cases to the Department of Justice for further review and legal action.

Under the HACCP system requirements, FSIS has integrated its compliance staff into the field regulatory staff and assigned new roles to compliance officers to create a team approach to enforcement. In the past, compliance officers were primarily responsible for products in distribution channels and generally contacted establishments only when following up on violations involving products that had already been distributed in commerce. Under the HACCP system, compliance officers assist inspectors in documenting failures of establishment control systems and help to ensure appropriate due process when enforcement actions are needed, including suspending the use of the inspection marks and formally closing establishments, i.e., withdrawing inspection.

Compliance Officers are required to take the following courses:

Basic Compliance Officer

This 10-day course is designed for the newly appointed Compliance Officer. The subjects covered are criminal law, the Federal Meat Inspection Act, the Poultry Products Inspection Act and the Egg Products Inspection Act regulatory authority; administrative, civil authority and rules of practice; strict liability/specific intent; investigation planning; communication, listening and interviewing skills; dealing with informants; surveillance techniques; search and seizures; evidence procedures; violation report preparation and processing; grand jury testimony; federal court procedures; fundamentals of court testimony; due process procedures; civil liabilities and Federal Tort Claims Act; and administrative adjudication procedures.

Advanced Compliance Officer

This 9 1/2-day course is designed for Compliance Officers who have had at least three years of experience as Compliance Officers with FSIS. The subjects covered are advanced investigatory techniques; advanced interviewing; aspects of white collar crime; orientation to financial investigation; financial research and analysis; document review; indicators of financial fraud; conspiracy; principles of extortion and entrapment; and Indian Country law.

*References: FSIS, Office of Management, Human Resources Division
FSIS, Office of Field Operations, District Enforcement Operations*

B. Livestock and Poultry Husbandry

- 1. What animal species are used for human food in your country? The list should include domesticated and wild animals or fowl, such as cattle, swine, horses, kangaroos, camels, deer, donkeys, ducks, and geese.**

Regarding beef species, cattle, sheep, swine, goats, equines, and some exotic animals are used for human food.

*References: Federal Meat Inspection Act (21 U.S.C. 641-676)
9 CFR Section 352.3
FSIS Directive 6200.1*

- 2. For each applicable animal species at each stage of development, what types of movement take place between producers/facilities? The list should include movement through sales yards, from farm to farm, from weanling to yearling facilities, from farm to direct slaughter, from hatchery to feeders, and other types of movement or animal transfer.**

CATTLE

Cow/Calf Operations, typically 30 head each, wean and raise the calves to 500#. The Stocker Calves are then sold (they are grouped according to size into groups of 200 – 300 calves and moved via truck to a Stocker/Grazer Operation where they are grazed on wheat (pasturage). At 750 to 850#, the Feeder Cattle are delivered, via truck, to a Feed Lot Operation and feed for 120 to 240 days until they reach 1100 (heifers) or 1200 (steers) pounds. They are then sold via packer buyers to the packing/slaughter house for slaughter and packaging. GIPSA, USDA is the government agency that administers the laws that police the costs that the packers pay for the cattle. Dealers are required to be licensed and, therefore, fall under GIPSA authority.

SWINE

Piglets are weaned (5-9 days) and raised to 35# at Farrowing Operations (sows produce a litter every 4 months). The Feeder Pigs are then sold to a Feeder Pig Operations where they are fed until they reach 225# to 250#. The swine are then sold under contract to a packer/slaughter operation or sold through a marketing operation. Some operations are farrowing/feeder operations of 50 or less piglets. They sell them through a marketing agent, who groups them into larger groups by size, to packer/slaughter operations. GIPSA, USDA is the government agency that administers the laws that police the costs that the packers pay to the swine. Dealers are required to be licensed and, therefore, fall under GIPSA authority.

*Reference: National Livestock Packers Association
Grain Inspection Packers & Stockyards Administration*

3. How does your country ensure that sick, diseased, or dead animals (or the meat from these animals) are not slaughtered, processed, packaged, and/or commingled with carcasses or product eligible for export?

CFR 9, section 309.1 states that all livestock offered for slaughter in an official establishment shall be examined and inspected (ante-mortem inspection) on the day of and before slaughter. Part 9, Ante-Mortem Inspection, Title 9.1 states that ante-mortem inspection shall be performed only on lots identified for slaughter by the establishment. Title 9.3 states that the establishment must provide sufficient employees to move, segregate, restrain, identify, and dispose of animals as requested by the inspector. Title 9.4 states that ante-mortem inspections must be made by an official Veterinarian or an inspector under the supervision of a Veterinarian. Title 9.5 states that the inspection must be performed when the animal is at rest and when in motion. Title 9.6 states that animals showing signs of abnormalities or diseases shall be segregated into designated (suspect) pens for examination by an official veterinarian. Suspect animals must be tagged as such. Title 9.7 states that adequate identification and control over inspected animals shall be established.

Delayed-slaughter animals, according to Title 9.8, must be must be held and slaughtered under an identification and control system that uses self-locking or sealing tags, or similar devices, that are kept under the inspector's custody for cattle. On swine, a tattoo or other suitable device is to be used on mechanically dehaired swine.

Title 9.14, Suspects, states that animals with signs of abnormalities or diseases shall be restrained and closely examined by an official veterinarian. Animals with abnormalities that require a detailed postmortem inspection are handled as "suspects." Suspect animals must be identified with a "U.S. Suspect" tag and slaughtered separately. Form MP 402-2 must be completed for each animal tagged and is given to the post-mortem inspector before slaughter.

Title 9.15 states that when ante-mortem inspection of abnormal animals reveals a dying condition, a disease or condition requiring carcass condemnation on post-mortem inspection, or a disease or condition requiring further observation or treatment, such animals must be identified as "U.S. Condemned" and must be withheld from slaughter. Condemned animals must be either promptly killed by establishment employees and disposed of as required, or must be held for observation and/or treatment in a separate, identified facility. Dead-on-arrival (DOA) carcasses shall be identified and disposed of as required by the regulations. Livestock DOA's must be tagged as "U.S. Condemned." Title 9.17 of the regulations, states that all downers must be examined by an official veterinarian to extent necessary to determine whether to condemn, pass for slaughter as a suspect, or held for further observation. Sick, dying, or animals treated with a drug or chemical (and presented for slaughter too early) are not covered under the emergency slaughter provisions of Section 311.27 and must not be slaughtered without an inspector present. Immature, diseased, weak, and uncoordinated calves must not be slaughtered for human food. Livestock with an eye, or associated structure, missing must be treated as suspect. Tuberculosis reactor, suspect, or exposed animals must be identified before ante-mortem inspection. Condemned or DOA animals must be given a complete post-mortem examination in the inedible room. Animals with central nervous system disorders or rabies must be condemned. Animals with vesicular diseases are to be

reported to officials of animal disease control, who will diagnose and dispose of the animal and instruct the facility concerning disinfection. Screwworm infestation must be investigated on animals with wounds infested by maggots. Experimental or research animals must not be slaughtered without proper, headquarters authority.

Part 11, Post-Mortem Inspection, states that the Federal meat and poultry inspection acts require a post-mortem inspection to be performed by an inspector on each carcass of livestock or poultry. Carcasses and/or parts with abnormalities or diseases must be handled as required by the regulations. The disposition of abnormalities or diseases not specifically covered by the regulations or other instructions is left to the judgement of the official veterinarian. Cadavers must be condemned and recorded on the proper government form.

Part 14, Inedible and Condemned Product, states that all condemned carcasses, parts, and unborn calves must be visually controlled, or must be under Government lock or seal until denatured, tanked, incinerated or, if eligible for animal food, properly identified with approved material. Title 14.2 states that inedible and condemned material must not accumulate from one day to the next except for an emergency situation. Title 14.3 states that the material must be segregated and isolated to prevent contamination of edible product, facilities, equipment, and ingredients used for preparing such product. If the method of collection and handling does not identify the products as inedible, Title 14.4 states that the establishments must further identify the products by an approved identifying agent. Unborn animals and the associated products must be handled in an enclosed inedible product area, according to Title 14.9. A government lock or seal must be used to lock or seal of the area when it is not under an inspector's visual supervision.

The identification, marking, tagging, and storage of product saved for animal food is covered in Titles 14.20 through Title 14.23. All products save for animal food must be promptly handled and properly identified while an inspector is on duty. Such product must be kept under Government lock or seal is kept overnight at the establishment. Condemned carcasses, parts, and livers that are eligible for animal or fish food must be branded as "U.S. Condemned" and be under visual control or under official lock or seal until properly slashed and identified. Inedible material that is saved for animal food and packed in a properly marked liquid-tight containers, may be stored in edible product freezers if it is separate and does not interfere with edible product handling. Title 14.18 states that establishments that wish to save inedible and/or condemned material for animal or fish food must have separate and adequate equipment. Stomachs, intestines, washed paunches, and denuded tripe can be stored or shipped as certified animal food without denaturing or identifying treatment if its identity is maintained and it is accompanied by the appropriate official form.

Inedible product not rendered within the establishment must be properly identified before the inspector's duty tour is completed. Titles 14.6 and 14.8 state that the inspector must lock or seal conveyors, charging and discharging lids or valves of rendering tanks, and equipment used for conveying or processing condemned product. If such product is hashed or ground upon removal from the truck or container used for condemned product,

it is not required that the tanks and equipment be locked or sealed. When rendering facilities are not provided, condemned material shall be denatured and held in watertight metal containers in a suitable inedible product room pending daily (or equivalent) removal to the rendering establishment(s)

Title 14.12 states that establishments wanting to ship inedible and condemned material must obtain a letter from the animal and poultry disease control officials of the state(s) involved. The letter must certify that the removal of the material is acceptable and is filed in the inspector's files. Rendered animal fat (see Title 14.13) that is non-federally inspected or inedible that is offered for interstate or international movement without an official government permit, must be denatured. Title 14.5 states that establishment management must request government permission to receive dead animals other than DOA's on premises. 9 CFR sections 325.20 and 325.21 state that dead, dying, disabled, or diseased livestock or parts of a carcass may be unloaded enroute in case of an emergency and reloaded onto another vehicle if the carrier reports the facts to the FSIS Compliance Staff. All such vehicles must be leak-proof and constructed and equipped so as to permit thorough cleaning and sanitizing. The vehicles must be cleaned and disinfected prior to use for edible product.

In addition, compliance officers conduct planned and random reviews at renderers, pet food manufacturers, 4-D operations (for dead, dying, diseased, and disabled animals) to ensure that the products are properly denatured/decharacterized and determined as inedible to preclude their use as human food.

*References: Titles 14.12, 14.13, and 14.5
Titles 14.2, 14.3, 12.4, 14.6, 14.8, and 14.9
9 CFR sections 309.1, 325.20, and 325.2
Titles 14.20 through Title 14.23
Part 11
Titles 9.3, 9.4, 9.5, 9.7, 9.8, 9.15 and 9.17*

C. Livestock and Poultry Controls

- 1. What type of identification program do you have for each species? Describe the program(s) in detail, including a description of the health records kept for vaccinations; records kept for government subsidies, taxes, or loans; residue or other trace-back records; and other identification activities.**

The United States does not have a uniform, comprehensive system for animal identification. There are, however various sampling programs. FSIS Directive 7220.1 states that sausages identified in 9 CFR sections 319.141, 319.142, 319.144, and 319.160 of the meat inspection regulations must comply with the applicable standards if the product name is to include the name of the species involved. Title 18.12 states that boneless meat and bulk-packed ground product must be sampled by an inspector for species identification whenever the character of the product, condition of the container, or lack of proper identification is in question or suspect. The sampling is to include

domestic and imported product from warehouses, other establishments, and any other source. Samples are sent to USDA microbiological laboratories. According to Section 909.10, inspectors must be concerned about the species or part identification of product during the breaking and boning of meat carcasses. Special products testing, as described in FSIS Directive 10230.2, includes cooked, ready-to-eat products for species identification.

FSIS Directive 10230.1, Species Identification Sampling for Cooked Product, provides the procedures, policy, and actions to take when undeclared species are found. Guidelines are provided to establishment operators. The presence of animal tissue that consumers could not reasonably expect to be in the product will result in the product being adulterated and/or misbranded. The meat/poultry portion of the food product is a valuable ingredient and, for the purposes of inspection, usually characterizes the product. The substitution of any of this ingredient with other substances is prohibited by the Federal Meat Inspection Act and the Poultry Products Inspection Act. Product suspected of being adulterated and/or misbranded due to the presence of undeclared animal tissue is sampled and tested to ascertain whether such tissue is present. In addition, it must be further inspected. To this end, FSIS has developed laboratory testing procedures for cooked (Enzyme Linked Immunosorbent Assay) and uncooked (SIFT) product, based on antibody-antigen reactions.

Sample collection, for monitoring purposes, of cooked product is generated from Headquarters. In addition, if an inspector deems it necessary, (s)he may collect additional samples. If a positive is found during this regular in-establishment monitoring program, the establishment will receive an official "letter of notification" that identifies the problem and the actions to be taken. The inspector-in-charge (IIC) of the establishment must then sample each lot of "like" product or the establishment may rework or relabel the product. Either way, the establishment is required to either voluntarily hold and segregate all "like" product or voluntarily recall all "like" product shipped from the establishment. Product found to contain undeclared species from sampling the "like" product on hand at the establishment must either be reworked or relabeled. If product is later found to be adulterated, it may be subject to retention, detention, or seizure action.

In addition, the IIC at the establishment must request that establishment operators evaluate all aspects of how the product was made and prepare a letter to the District Office identifying the precautions that will be taken to guard against a recurrence of the problem. The IIC also advises the establishment that subsequent production lots of the product will be tested, and held pending the results of the test.

Following a positive SIFT result, the IIC must retain production lot(s) of questionable "like" products and submit verification samples for testing. The IIC will continue to sample and retain subsequent products until 5 consecutive day of negative results have been received. If a positive is received during the above sample and retain mode, applicable product will be reworked or relabeled, other cooked products prepared with the same species will be sampled and retained, and all other cooked products prepared at the establishment will be sampled. These same procedures will take place when positive results are received from samples taken by the inspector of suspect product.

*References: FSIS Directives 10230.1 and 10230.1
Title 18.12
9 CFR Section 909.10
FSIS Directive 7220.1*

- 2. Are sales yards and poultry producers required to be licensed? Indicate record-keeping requirements, such as sales transactions and listing animal owners and/or buyers.**

Auction markets are under the authority of the USDA, Grain Inspection Packers and Stockyards Administration. Animals going through auction markets must be identified according to the identity of the current owner. The U.S. government does not license animal producers. Some States have recordkeeping/identification requirements and there are some animal health requirements for some species.

References: 9 CFR 309.1 and Title 21.15

- 3. Are health certificates required for the movement of livestock or poultry? Who prepares the health certificates and who is required to check the animals before, during, and/or after transporting them?**

For intrastate movement of livestock or poultry, no health certificate is required. For interstate movement of livestock or poultry, a standard health certificate by a licensed veterinarian is needed. In addition, for quarantined animals associated with animal health concerns, APHIS would handle the certification and oversight. For international movement of livestock or poultry, an international health certificate made out by a licensed veterinarian and also endorsed by a salaried veterinarian of the Federal Government is needed from the country where the animals originated. Many countries require an import permit that is issued by the Federal Government of the importing country.

Health Certificates are required by most foreign governments, as indicated in FSIS Directive 5110.1 and are prepared by U.S. Government Veterinarians. In some cases, where necessary, licensed and properly trained U.S. Government inspectors prepare the health certificate.

*References: 9 CFR, subchapter B, C, and D
9 CFR, Part 93
FSIS Directive 5110.1*

- 4. Are livestock or poultry imported from other countries? If so, what records are kept? Are there health or other restrictions?**

Yes. Live animals received from other countries must meet U.S. requirements. Live animal disease protection would fall under the purview of APHIS, who would restrict product importation, as needed. For each load, an Import permit (See Attachment of VS

Form 17-129), Health Certificate (signed by foreign government Veterinarian), declaration (providing information port of entry, importer, broker, animal origin, species, breed, import purpose, quantity, and name and location of animal destination), or affidavit is presented by the importer (or agent) to the U.S import inspector and kept on file for future use. The Health Certificates must show that the animal is free or comes from an area that is free from foot-and-mouth disease, rinderpest, contagious pleuropneumonia, surra, tuberculosis, and brucellosis for ruminant and cattle.

References: 9 CFR Parts 92 and 93.

5. What procedures and records are required for the movement of dead, diseased, 'downer', or otherwise unsound animals and/or poultry either from farm to slaughter or between other facilities? For example, are health papers required or is the hauler required to have a special license?

FSIS Directive 8420.1 dated 11-7-85 states disabled livestock will be handled in a humane manner from the time they enter the establishment premises until the time they are slaughtered. The Directive references the Humane Methods of Slaughter Act of 1978 and 9 CFR 304.2, 308.1, 308.3, 309.1(b), 309.2(b), 314.1, 314.3, Part 313, 329.6, and 352.10. It also references FSIS Directives 5400.5 dated 11/21/97 and 8820.1, Rev. 2, dated 9/6/96.

9 CFR Section 311.1 provides for the disposal of diseased or otherwise adulterated carcasses and parts. Section 311.1(a) states that the carcasses or parts of carcasses of all animals slaughtered at an official establishment and found at the time of slaughter or at any subsequent inspection to be affected with any of the diseases or conditions named in this part shall be disposed of according to the section pertaining to the disease or condition: Provided, That no product shall be passed for human food under any such section unless it is found to be otherwise not adulterated. Products passed for cooking or refrigeration under this part must be so handled at the official establishment where they are initially prepared unless they are moved to another official establishment for such handling or in the case of products passed for refrigeration are moved for such refrigeration to a freezing facility approved by the Administrator in specific cases: Provided, That when so moved the products are shipped in containers sealed in accordance with section 318.10(c) of this subchapter or in a sealed means of conveyance as provided in section 325.7 of this subchapter. Owing to the fact that it is impracticable to formulate rules covering every case and to designate at just what stage a disease process or a condition results in adulteration of a product, the decision as to the disposal of all carcasses, organs, or other parts not specifically covered in this part shall be left to the veterinary medical officer. The veterinary medical officer shall exercise his judgment regarding the disposition of all carcasses or parts of carcasses under this part in a manner that will ensure that only wholesome, unadulterated product is passed for human food.

Section 311.1(b) states that in cases of doubt as to a condition, a disease, or the cause of a condition, or to confirm a diagnosis, representative specimens of the affected tissues,

properly prepared and packaged, shall be sent for examination to one of the laboratories of the Biological Control Section of the Program.

Section 309.2 provides for livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise. Section 309.2(a) states that any livestock which, on ante-mortem inspection, do not clearly show, but are suspected of being affected with any disease or condition that, under Part 311 of this subchapter, may cause condemnation of the carcass on post-mortem inspection, and any livestock which show, on ante-mortem inspection, any disease or condition that, under Part 311 of this subchapter would cause condemnation of only part of the carcass on post-mortem inspection, shall be so handled as to retain its identity as a suspect until it is given final post-mortem inspection, when the carcass shall be marked and disposed of as provided in Parts 310 and 311 of this subchapter, or until it is disposed of as otherwise provided in this part.

Section 309.2(b) states that all seriously crippled animals and animals commonly termed "downers," shall be identified as U.S. Suspects and disposed of as provided in section 311.1 of this subchapter unless they are required to be classed as condemned under section 309.3.

Section 309.2(c) states that livestock which have reacted to a test for leptospirosis, or anaplasmosis, but which show no symptoms of the disease, shall be identified as U.S. Suspects and disposed of as provided in section 311.10 of this subchapter.

Section 309.2(d) states that livestock that are known to have reacted to the tuberculin test shall be identified as U.S. Suspects and disposed of as provided in section 311.2 of this subchapter, except that livestock bearing an official "USDA Reactor" or similar State reactor tag shall not be tagged as U.S. Suspects.

Section 309.2(e) states that any cattle found on ante-mortem inspection to be affected with epithelioma of the eye or of the orbital region to a lesser extent than as described in section 309.6 shall be identified as a U.S. Suspect and disposed of as provided in section 311.12 of this subchapter.

Section 309.2(f) states that cattle found on ante-mortem inspection to be affected with anasarca to a lesser extent than as described in section 309.8 shall be identified as U.S. Suspects and disposed of as provided in section 311.8 of this subchapter or paragraph (g) of this section.

Section 309.2(g) states that any livestock suspected of being affected with anasarca may be set apart and held for treatment under Program or other responsible official supervision approved by the area supervisor. If at the expiration of the treatment period the livestock upon examination is found to be free from disease, it may be released for any purpose. Otherwise, it shall be identified as U.S. Suspect and disposed of as provided in section 311.8 of this subchapter or condemned and disposed of as provided in section 309.8, whichever is appropriate.

Section 309.2(h) states that all hogs suspected on ante-mortem inspection of being affected with swine erysipelas shall be identified as U.S. Suspects and disposed of as provided in section 311.5 of this subchapter or paragraph (i) of this section.

Section 309.2(i) states that a hog suspected of being affected with swine erysipelas may be set apart and held for treatment under Program or other responsible official supervision approved by the area supervisor. If at the expiration of the treatment period

the animal upon examination is found to be free from disease, it may be released for any purpose. Otherwise, it shall be identified as U.S. Suspect and disposed of as provided in section 311.5 of this subchapter, or condemned and disposed of as provided in section 309.13, whichever is appropriate.

Section 309.2(j) states that any livestock which is affected with vesicular exanthema or vesicular stomatitis, but which has recovered to the extent that the lesions are in process of healing, the temperature is within normal range, and the livestock shows a return to normal appetite and activity, shall be identified as U.S. Suspect and disposed of as provided in section 311.32 of this subchapter, except that if desired, such livestock may be set apart and held under supervision of a Program employee or other official designated by the area supervisor for treatment. If the livestock is set aside for treatment, the U.S. Suspect identification device will be removed by a Program employee, following such treatment, if the livestock is found to be free from any such disease. Such livestock found to be free from any such disease may be released for slaughter or for purposes other than slaughter, provided that in the latter instance, the operator of the official establishment or the owner of the animal shall first obtain permission from the local, State, or Federal livestock sanitary official having jurisdiction over the movement of such livestock.

Section 309.2(k) states that livestock which are offered for ante-mortem inspection under this part, and which are regarded by the inspector as immature, shall be identified as U.S. Suspects and, if slaughtered, the disposition of their carcasses shall be determined by the post-mortem findings in connection with the ante-mortem conditions. If not slaughtered as suspects, such livestock shall be held under supervision of a Program employee or other official designated by the area supervisor, and after sufficient development may be released for slaughter or may be released for any other purpose, provided they have not been exposed to any infectious or contagious disease. If such exposure occurs, permission should be obtained from the nearest Veterinary Services unit of the Animal and Plant Health Inspection Service prior to release of such livestock.

Section 309.2(l) states that livestock previously condemned for listeriosis, if released for slaughter under section 309.13(b) shall be identified as a U.S. Suspect in accordance with section 309.13(c).

Section 309.2(m) states that each animal required by this part to be treated as a U.S. Suspect shall be identified as such by or under the supervision of a Program employee with an official device in accordance with section 309.18. No such device is to be removed except by a Program employee.

Section 309.2(n) states that each animal identified as a U.S. Suspect on ante-mortem inspection shall be set apart and shall be slaughtered separately from other livestock at that establishment unless disposed of as otherwise provided in this part.

Section 309.2(o) states that each animal identified as a U.S. Suspect on ante-mortem inspection, when presented for slaughter shall be accompanied with a form MP 402-2 on which the inspector at the establishment shall record the U.S. Suspect identification number and any other identifying tag numbers present and a brief description of the animal and of the disease or condition for which the animal was classed as a suspect, including its temperature when the temperature of such animal might have a bearing on the disposition of the carcass on post-mortem inspection.

Section 309.2(p) states that when any animal identified as a U.S. Suspect is released for any purpose or reason, as provided in this part, the official identification device shall be removed only by a Program employee and he shall report his action to the area supervisor. When a suspect is to be released under the provisions of this part for a purpose other than slaughter, the operator of the official establishment or the owner of the animal shall first obtain permission for the removal of such animal from the local, State or Federal livestock sanitary official having jurisdiction.

Records are required, as stated in sections 381.175 and 320.1, of any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter. Records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, must provide following information with respect to each transaction in which any livestock or carcass, part thereof, meat or meat food product is purchased, sold, shipped, received, transported, or otherwise handled by said person in connection with any business subject to the Act:

The name or description of the livestock or article; the net weight of the livestock or article; the number of outside containers (if any); the name and address of the buyer of livestock or article sold by such person, and the name and address of the seller of livestock or articles purchased by such person; the name and address of the consignee or receiver (if other than the buyer); the method of shipment; the date of shipment; and the name and address of the carrier.

*References: 9 CFR Sections 311.1, 311.5, 381.175, and 320.1
9 CFR Sections 309.2 and 309.1
FSIS Directive 8420.1*

D. Slaughter Facilities

- 1. What are the various types of facilities where animal slaughter can take place? For each type of slaughter facility, such as pet food slaughter establishments, rendering establishments, local slaughtering facilities, and export establishments, indicate the percentage of the total number of animals slaughtered.**

Types of operations are:

*(S): Slaughter; (P): Processing; (B):Boning; (E): Edible fat processing;
and (I) inedible fats rendering*

*Total number of birds (young chicken) slaughtered for fiscal year 1995=7,512,916,376
Total number of steers and heifers slaughtered for fiscal year 1995 = 28,807, 882
Total number of hogs (barrows and gilts) slaughtered for fiscal year 1995 = 89,530,876*

LIVESTOCK SLAUGHTER

Livestock Slaughter: Number, United States (1,000 Head):

	<i>Cattle</i>	<i>Calves</i>	<i>Hogs</i>
<i>July 97</i>	<i>3,181.3</i>	<i>134.4</i>	<i>7,311.5</i>
<i>June 98</i>	<i>3,109.2</i>	<i>116.4</i>	<i>7,730.1</i>
<i>July 98</i>	<i>3,038.6</i>	<i>133.3</i>	<i>8,268.6</i>
<i>Jan-July 97-X</i>	<i>21,381.2</i>	<i>902.15</i>	<i>1,450.9</i>
<i>Jan-July 98-X</i>	<i>20,715.1</i>	<i>829.25</i>	<i>6,676.3</i>

*Note-Excludes slaughter on farms. Totals may not add due to rounding.
Accumulated totals and percentages based on unrounded data.*

Commercial Red Meat Production, United States (million pounds):

	<i>Beef</i>	<i>Veal</i>	<i>Pork</i>
<i>July 97</i>	<i>2,256</i>	<i>27</i>	<i>1,354</i>
<i>June 98</i>	<i>2,249</i>	<i>20</i>	<i>1,444</i>
<i>July 98</i>	<i>2,213</i>	<i>21</i>	<i>1,529</i>
<i>Jan-July 97-X</i>	<i>14,779</i>	<i>192</i>	<i>9,636</i>
<i>Jan-July 98-X</i>	<i>14,891</i>	<i>147</i>	<i>10,647</i>

*Note-Based on packers' dressed weights and excludes farm slaughter.
Accumulated totals based on unrounded data.*

Classification Of Livestock Slaughtered Under Federal Inspection, U.S. (1,000 head):

<u><i>Cattle-Y</i></u>	<i>July 97</i>	<i>June 98</i>	<i>July 98</i>	<i>Jan-Jul 97</i>	<i>Jan-Jul 98</i>
<i>Steers</i>	<i>1,564</i>	<i>1,569</i>	<i>1,542</i>	<i>10,262</i>	<i>10,058</i>
<i>Heifers</i>	<i>994</i>	<i>948</i>	<i>913</i>	<i>6,645</i>	<i>6,566</i>
<i>All Cows</i>	<i>506</i>	<i>479</i>	<i>481</i>	<i>3,639</i>	<i>3,354</i>
<i>Dairy Cows</i>	<i>227</i>	<i>200</i>	<i>203</i>	<i>1,670</i>	<i>1,545</i>
<i>Other Cows</i>	<i>279</i>	<i>279</i>	<i>278</i>	<i>1,969</i>	<i>1,809</i>
<i>Bulls/Stags</i>	<i>62</i>	<i>54</i>	<i>51</i>	<i>397</i>	<i>343</i>
<i>Total-X</i>	<i>3,127</i>	<i>3,050</i>	<i>2,987</i>	<i>20,942</i>	<i>20,321</i>
<u><i>Hogs-Y</i></u>					
<i>Barrows/Gilts</i>	<i>6,856</i>	<i>7,263</i>	<i>7,773</i>	<i>48,405</i>	<i>53,512</i>
<i>Sows</i>	<i>264</i>	<i>288</i>	<i>309</i>	<i>1,721</i>	<i>1,934</i>
<i>Stags/Boars</i>	<i>50</i>	<i>45</i>	<i>48</i>	<i>346</i>	<i>299</i>
<i>Total-X</i>	<i>7,169</i>	<i>7,596</i>	<i>8,130</i>	<i>50,472</i>	<i>55,745</i>

X-Total and percentages based on unrounded data.

*Y-Species totals and classification reported by meat inspectors, Inspection
Operations FSIS August 21,
1998 NASS, USDA*

Only federally inspected establishments may sell their products in interstate or foreign commerce. The following table shows the numbers and types of meat and poultry, and other slaughter or processing establishments that operate under Federal Inspection, including (as of Sept. 30, 1996):

<u>Type of Est.</u>	<u>Meat</u>	<u>Poultry</u>	<u>Meat &</u>		<u>Other</u>	<u>Total</u>	<u>Percent</u>
			<u>Poultry</u>	<u>sub-total</u>			
<i>Slaughtering</i>	178	118	1	297	6	303	4.7
<i>Processing</i>	1,138	171	3,091	4,400	538	4938	76.0
<i>Slau.&Proc.</i>	433	163	398	994	6	1000	15.4
<i>Subtotal</i>	1,749	452	3,490	5,691	550	6,241	96.1
<i>Fed/State</i>	142	7	106	255	0	255	3.9
<i>Total</i>	1891	459	3,596	5,946	550	6,496	100
<i>Percentages</i>	29.1	7.1	55.3	91.5	8.5	100	

*References: Meat and Poultry Inspection Directory, July 1998, page 62
Federal Register Vol. 62, No. 211, June 10, 1997, Pages 31556 and 31557*

2. What records are kept at the various slaughter-facilities concerning the origin and numbers of livestock and poultry slaughtered?

9 CFR section 309.2 states that each animal identified as a U.S. Suspect on ante-mortem inspection, when presented for slaughter shall be accompanied with a form MP 402-2 on which the inspector at the establishment shall record the U.S. Suspect identification number and any other identifying tag numbers present and a brief description of the animal and of the disease or condition for which the animal was classed as a suspect, including its temperature when the temperature of such animal might have a bearing on the disposition of the carcass on post-mortem inspection.

FSIS Directive 8820.1 states that deficiencies in slaughter operations are recorded on the Inspection Assignment Schedule, FSIS Form 8800-2.

FSIS Directive 6200.1 states that for the FSIS Form 6200 series, Inspector-in-charge (IIC) will complete this form to document the disposition actions on retained carcasses, provide the primary information for the weekly FSIS 6200 forms, and report the slaughter of tuberculosis "suspects" or "exposed" tuberculosis reactors and animals found to have certain reportable diseases.

A livestock and/or poultry weekly summary report is prepared by each establishment's Inspector-In-Charge and submitted to Data Service Center, Des Moines, IA. In addition, a quarterly summary report of all processed products is prepared by establishment management and submitted to Data service Center, Des Moines, IA. Depending on the species slaughtered, a copy of the pertinent FSIS Form(s) is maintained in the FO District Office. Establishment management maintains records of each lot of animals received and slaughtered with information about their point of origin.

The following weekly summary reports (see Attachment) are maintained in the District office:

*FSIS form 6200-10 for Cattle
FSIS form 6200-11 for Hogs
FSIS form 6200-12 for Sheep
FSIS form 6200-15 for Calves
FSIS form 6200-21 for Chicken
FSIS form 7010-1 for processed products which includes fats and oils*

*Reference: MPI/FSIS Inspection Manual, 1995, Section 20.13 and 20.14
FSIS Directive 6200.1
FSIS Directive 8820.1 and 9 CFR section 309.2*

3. What type of inspection is provided at each of the various slaughter-facilities? Indicate if no inspection is provided or if local, state, or national inspection is provided. For each type of inspection, what is the minimum required frequency of inspection?

9 CFR Section 302.1 states that government inspection is required at:

Every establishment, except as provided in section 303.1(a) and (b), or (c) of this subchapter, in which any livestock are slaughtered for transportation or sale as articles of commerce, or in which any products of, or derived from, carcasses of livestock are, wholly or in part, prepared for transportation or sale as articles of commerce, which are intended for use as human food;

Every establishment, except as provided in section 303.1 (a) and (b), or (d) of this subchapter, within any State or organized Territory which is designated pursuant to paragraph 301(c) of the Act, at which any livestock are slaughtered or any products of any livestock are prepared, for use as human food solely for distribution within such jurisdiction; and

Every establishment, except as provided in section 303.1(a) and (b) of this subchapter, that is designated by the Administrator pursuant to paragraph 301(c) of the Act as one producing adulterated products which would clearly endanger the public health.

9 CFR, Part 307, section 4c states that each Federal and State inspected facility is provided with 8 hours of free inspection service per shift. Part 304 indicates that, generally, processing and cold storage operations are inspected under patrol assignment and their frequency varies from location to location depending on various factors like availability of manpower, complexity of operation and compliance history, and geographical location.

9 CFR, Section 351.14 that all processes used in the preparation of certified technical animal fats at any certified establishment shall be subject to supervision by an inspector. Certified establishments shall not prepare any technical animal fat for certification under the regulations in this part, except in accordance with such regulations.

Supervision, ranging from full-time coverage of an entire process to one or more reviews per month, to determine an establishment's compliance with the regulations in this part will be maintained. A circuit supervisor may increase the frequency of reviews whenever he deems necessary to assure the validity of certifications under the regulations in this part. Usual coverage of individual rendering establishments will be as follows:

Coverage shall be at least once a month if the establishment consistently handles only raw materials acceptable under section 351.3 for the preparation of certified technical animal fat and the establishment operator, in writing, certifies that he is maintaining this procedure.

Coverage shall be at least once a week if the establishment consistently handles some raw materials that are acceptable, and some that are unacceptable, under section 351.3, for the preparation of certified technical animal fat, uses separate equipment for processing, and uses separate rooms, compartments, and equipment for receiving and storing the respective types of raw materials and technical animal fats, and the establishment operator, in writing, certifies that he is maintaining this complete physical separation procedure.

Coverage shall be full-time during receiving of raw materials and their preparation into certified technical animal fat, if the establishment handles some raw materials that are acceptable, and some that are unacceptable, under section 351.3, for the preparation of certified technical animal fat, and uses the same rooms, compartments, and equipment, with only time separation between receiving, processing, and storing the respective types of raw materials and technical animal fats.

*References: 9 CFR, Parts 302 and 304, pages 81-91
9 CFR Part 307 section 4c, page 96
9 CFR Section 351.14
35 FR 15556, Oct. 3, 1970, as amended at 36 FR 12002, June 24, 1971*

4. What provisions are there to prevent a slaughter-facility that is required to have government inspection from slaughtering animals when government inspectors are not on duty? What legal authority do you have?

Section 3 of the Federal Meat Inspection Act states that the Secretary shall cause to be made, by inspectors appointed for that purpose, an ante-mortem examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all cattle, sheep, swine, goats, horses, mules, and other equines found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered, the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary as herein provided for.

In addition, Section 4 states that the Secretary shall cause to be made by inspectors appointed for that purpose, as here-in-before provided, a post-mortem examination and

inspection of the carcasses and parts thereof of all cattle, sheep, swine, goats, horses, mules, or other equines to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia as articles of commerce which are capable of use as human food; and the carcasses and parts thereof of all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as "Inspected and passed;" and said inspectors shall label, mark, stamp, or tag as "Inspected and condemned," all carcasses and parts thereof or animals found to be adulterated, and all carcasses and parts thereof thus inspected and condemned shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any such establishment which fails to so destroy any such condemned carcass or part thereof, and said inspectors, after said first inspection shall, when they deem it necessary, reinspect said carcasses or parts thereof to determine whether since the first inspection the same have become adulterated, and if any carcass or any part thereof shall, upon examination and inspection subsequent to the first examination and inspection, be found to be adulterated, it shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any establishment which fails to so destroy any condemned carcass or part thereof. (21 U.S.C. 604.)

Section 6 states that the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and for the purposes of any examination and inspection said inspectors shall have access at all times, by day or night, whether the establishment be operated or not, to every part of said establishment; and said inspectors shall mark, stamp, tag, or label as "Inspected and passed" all such products found to be not adulterated; and said inspectors shall label, mark, stamp, or tag as "Inspected and condemned" all such products found adulterated, and all such condemned meat food products shall be destroyed for food purposes, as herein before provided, and the Secretary may remove inspectors from any establishment which fails to so destroy such condemned meat food products: Provided, That subject to the rules and regulations of the Secretary the provisions hereof in regard to preservatives shall not apply to meat food products for export to any foreign country and which are prepared or packed according to the specifications or directions of the foreign purchaser, when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is to be exported; but if said article shall be in fact sold or offered for sale for domestic use or consumption then this proviso shall not exempt said article from the operation of all the other provisions of this Act. (21 U.S.C. 606.)

9 CFR Section 355.38 states that after an opportunity for hearing before a proper official of the Department has been accorded the operator of an inspected establishment, the inspection, certification, and identification provided for in this part may be withdrawn from such establishment if the operator: (a) Persistently fails to comply with any provision of the regulations in this part or of instructions or directions issued thereunder; (b) makes any willful misrepresentation or engages in any fraudulent or deceptive practice in connection with the making of any application for service; (c) violates section

355.37; or (d) interferes with or obstructs any program employee in the performance of his duties under the regulations in this part by intimidation, threats, or other improper means. Pending final determination of the matter, the Administrator may suspend such inspection, certification, and identification without hearing in cases of willfulness or those in which the public health, interest, or safety requires such action. The operator of the inspected establishment shall be notified of the Administrator's decision to suspend such inspection, certification or identification service, and the reasons therefor, in writing, in the manner prescribed in section 1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to suspend such inspection, certification or identification service shall be effective upon such oral or written notification, whichever is earlier, to the operator of the establishment. If such notification is oral, the Administrator shall confirm such decision and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator of the inspected establishment, in the manner prescribed in section 1.147(b) of the rules of practice (7 CFR 1.147(b)). In other cases, prior to the institution of proceedings for any withdrawal or suspension, the facts or conduct which may warrant such action shall be called to the attention of the operator in writing and he shall be given an opportunity to demonstrate or achieve compliance with the requirements of the regulations in this part and instructions and directions issued thereunder.

9 CFR Section 335.10 states that if the Administrator has reason to believe that the applicant for or recipient of service under Title I of the Act is unfit to engage in any business requiring such inspection because of any of the reasons specified in section 401 of the Act, he may institute a proceeding by filing a complaint with the Hearing Clerk, who shall promptly serve a true copy thereof upon each respondent, as provided in section 1.147(b) of the Uniform Rules of Practice (9 CFR 1.147(b)).

9 CFR Section 305.5 states that the Administrator is authorized to withdraw inspection from an official establishment where the sanitary conditions are such that its products are rendered adulterated, or for failure of the operator to destroy condemned products as required by the Act and the regulations in this subchapter. Inspection may be withdrawn in accordance with section 401 of the Act and the applicable rules of practice.

FSIS Notice 0-93, Inspection Services, dated 3/5/93, provides for the temporary suspension and subsequent withdrawal of inspection services from any recipient or operator of an establishment which produces meat or poultry products under conditions and/or procedures that may endanger public health and safety.

FSIS Directive 5220.1 states that the Compliance Program has basic responsibility for initiating inquiries, assembling documentation, and/or conducting necessary liaison with the Office of the General Counsel regarding formal refusal or withdrawal of inspection service. Procedures are established by departmental rules and regulations. Subtitle A, under Title 7 of the U.S. Code provides general rules of practice which are further defined in section 335.1 et seq., and 381.230 et seq., of the meat and poultry inspection regulations. The Compliance Program should be promptly notified when there is reason to believe inspection service should be refused or withdrawn.

FSIS Compliance Officers from Field Operations have the legal authority to assure that a product is in compliance and take legal action against violations.

*References: 9 CFR, Sections 305.5, 335.10, and 355.38
FSIS Notice 0-93;
FSIS Directive 5220.1
Federal Meat Inspection Act (21 U.S.C. 3,4, and 6)*

- 5. Which export-certified establishments slaughter or receive animal species or carcasses that are not approved for export from your country to the importing country or do not come from export-certified establishments? What procedures and record-keeping practices are in place to ensure that they cannot be included in product that is exported to the importing country? Indicate where the records are kept and how they are accessed?**

The Animal and Plant Health Inspection Service (APHIS) is responsible for assuring that only livestock from an approved country and area can enter United States. There should not be any establishment slaughtering livestock from an unapproved country/area. Compliance reviews each situation as it occurs. Section 30.2 of 15 CFR states that for all shipments to foreign countries or areas, the Shipper's Export Declaration is an export control document. In preparing and filing export declarations for shipments to foreign countries and areas, therefore, the shipper must comply with all pertinent export control regulations as well as the requirements of the statistical regulations of this part.

[This sample response will not include the expected list of export establishments serviced by FSIS that would normally be listed here. However, this response will include the general requirements that ensure that received or imported products are not co-mingled with product eligible for export.]

All products for export shall meet the importing country's requirements. Exporters are responsible for determining that they comply with these requirements and providing the necessary documents. FSIS inspectors verify exporter compliance.

All exportable meat products must comply with the requirements established in FSIS Directives 9020.1, 9040.1, 9060.4, and 9080.1. In addition, FSIS agrees to ensure that establishments comply with specific requirements (see Part 22 of the Regulations) established by and for each country, including any special requirements for maintaining product integrity. These additional conditions, restraints, procedures, and recordkeeping practices required of U.S. establishments that export to Country-X preclude the export of animal species, livestock, carcasses, or slaughtered/processed products to Country-X that are not approved for export. FSIS personnel prevent co-mingling of products and the integrity of specific products through the use of retain tags, seals, labels, and official stamps or marks of inspection.

Retain tags can be used for control of slaughter and processes products within an establishment. 9 CFR Section 355.23 states that a "U.S. Retained" tag must be placed by

an inspector at the time of inspection on all certified products, materials to be used in the preparation of certified products, or containers thereof, whenever such certified products, materials, or containers are suspected of being unsound or otherwise unfit or not in conformity with the requirements contained in this part. Tags can also be placed on product that must be maintained separately from other similar products in an establishment. Retain tags that are placed to control such product can only be removed by an official government inspector.

Retain tags can be used within an establishment or to transport product between official establishments. Section 325.5 covers unmarked inspected product transported under official seal between official establishments for further processing. Any product which has been inspected and passed may be transported from one official establishment to another for further processing without each article being marked with the official inspection legend, if it is so transported in a railroad car, motortruck, or other means of conveyance which is sealed by a Program employee with an official seal of the Department. When articles are offered for transportation under this section, the initial carrier shall require, and the shipper shall make in duplicate and deliver to the carrier, one copy of a certificate/guarantee from the shipper. The guarantee must include the date, name of carrier, establishment number of consignor, point of shipment, establishment number of consignee, destination, car number and initials, and the license number of other means of conveyance. The shipper certifies or guarantees the product was U.S. inspected and passed by the U.S. Department of Agriculture; and that it was not marked "U.S. inspected and passed," but has been placed in the means of conveyance specified above under the supervision of an employee of the Food Safety and Inspection Service, and the means of conveyance has been sealed by him/her with official U.S. Government seals. The guarantee also identifies the product by kind, amount, and weight and is signed by the shipper. The carrier, if different from the shipper, and FSIS are to receive a copy of the document. If the shipper is also the carrier, he shall nevertheless execute and retain the certificate as part of the company records.

Section 325.17 prohibits the loading or unloading of products in sealed railroad cars, trucks, etc., that are en route. Unloading any product from an officially sealed railroad car, truck, or other means of conveyance containing any unmarked product or loading any product or any other commodity in the means of conveyance while en route from one official establishment to another official establishment is not permitted, except that product transported under section 325.5 from one official establishment to another for further processing may be unloaded and stored in transit at any approved warehouse which is operated under the identification service and which has the facilities or a receiving dock for unloading the product directly into such warehouse: Provided, That the product is stored in rooms which are of such size and type as will not result in adulteration or misbranding of the product: And provided further, That the product is transported to and from such warehouse, and under official seal as provided in section 325.5 and stored in such rooms at such warehouse.

Section 318.2 states that all products brought into any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official

establishment and shall be subject to reinspection by a Program employee at the official establishment in such manner and at such times as may be deemed necessary to assure compliance with the regulations and to ensure product integrity/identify. All products, whether fresh, cured, or otherwise prepared, even though previously inspected and passed, shall be reinspected by Program employees as often as they may deem necessary in order to ascertain that they are not adulterated or misbranded at the time they enter or leave official establishments and that the requirements of the regulations in this subchapter are complied with. A U.S. retained tag can be placed by a Program employee at the time of reinspection at any official establishment on all products, as necessary. Such tags shall be removed only by authorized Program employees. If a product is found upon reinspection to be misbranded, it shall be held under a U.S. retained tag, or a U.S. detention tag as provided in Part 329 of this subchapter, pending correction of the misbranding or issuance of an order under section 7 of the Act to withhold from use the labeling or container of product, or the institution of a judicial seizure action under section 403 of Act or other appropriate action. The inspector shall make a complete record of each transaction under this paragraph and shall report his action to the area supervisor.

Section 354.2 covers the designation of official certificates, memoranda, marks, other identifications, and devices for specific purposes of identification and control of the product. An "Official certificate" is any form of certification, either written or printed, used under to certify product with respect to the inspection, class, or condition of products. It can also be used to positively identify products eligible or ineligible for export. An "Official memorandum" is any initial record of findings made by an authorized person in the process of inspecting or sampling and can serve as a record to identify and quantify applicable products. An "Official mark" is the inspection mark, and any other mark, or any variations in such marks, approved by the Administrator and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product, stating that the product was inspected, or indicating the condition of the product, or for the purpose of maintaining the identity of products inspected. An "Official identification" is any symbol, stamp, label, or seal indicating that the product has been officially inspected and/or indicating the identity, class, or condition of the product. The identification can be affixed to any product, or affixed to or printed on the packaging material of any product. An "Official device" is a stamping appliance, branding device, stencil, printed label, or any other mechanically or manually operated tool that is approved by the Administrator for the purpose of applying any official mark or other identification to any product or the packaging material thereof. To ensure the appropriate application of the appropriate memorandum, mark, or identification, subsection 203(h) of the Agricultural Marketing Act of 1946 provides criminal penalties for various specified offenses relating to official certificates, memoranda, marks or other identifications, and devices for making such marks or identifications, issued or authorized under section 203 of said Act, and certain misrepresentations concerning the inspection of agricultural products under said section.

Also of assistance in maintaining product integrity and identity is the use of a food product inspection certificate. Section 354.142 states that, upon request, an inspector is authorized to issue a food product inspection certificate with respect to any inspected and certified edible product after suitable examination of the product has been made by the inspector. The original of each food product inspection certificate is, upon issuance, immediately delivered or mailed to the applicant or person designated by him. Another copy is filed in the office of the FSIS District Manager serving the area in which such certificate was issued. One copy is forwarded to and maintained by the Administrator. These last two copies must be retained until otherwise ordered by the Administrator and are subject to official review.

Product labels can also serve as a means of specifically identifying product. Section 355.32 states that each container of inspected and certified product shall have affixed thereto a label bearing pertinent information, prominently displayed. This information not only identifies the type, class, and ingredients of the product, but also identifies the establishment where it was produced and any other special descriptions as required by the receiver of the product. To ensure that labels are correct and do not misrepresent the product, Section 354.60 provides that any label or packaging material which bears any official identification must be used only in such manner as the Administrator may prescribe and must be approved by the Administrator before it is used. A label that bears official identification must not bear any statement that is false or misleading.

FSIS inspection personnel have access to all pertinent records maintained by each eligible establishment or cold-storage. Section 320.4 states that every person (including every firm or corporation) within any of the classes specified in section 320.1 shall upon the presentation of official credentials by any duly authorized representative of the Secretary, during ordinary business hours, permit such representative to enter his or its place of business and examine the records required to be kept by section 320.1 and the facilities and inventory pertaining to the business of such person subject to the Act, and to copy all such records and to take reasonable samples of the inventory. In addition, Part 22 of the regulations outlines the specific requirements for each country and specifies the records and documents that are to be completed and maintained at the export warehouse/cold-storage and at the establishment for product exported to Country-X.

*References: FSIS Directives 9020.1, 9040.1, 9060.4, and 9080.1
9 CFR Parts 92, 93, and 94, 1998
15 CFR Part 30 and Part 22 of the Regulations
9 CFR Sections 355.23, 325.5, 325.17, 318.2, 354.142, and 354.2
9 CFR Sections 320.4, 355.32 and 354.60*

E. Processing Facilities

- 1. What are the various types of processing facilities. Indicate whether the facility requires inspection and describe what type of inspection is required; such as local, state, or national inspection. What is the minimum required frequency of inspection for each type of facility?**

There are various types of official processing facilities operating under FSIS inspection. These include boning, cutting, grinding, smoking/curing, cooking, salting, packing, rendering, and canning establishments. FSIS regulations (9 CFR 318.4) state that it is the responsibility of the operator of every official establishment to comply with the meat inspection Act and regulations (9 CFR Part 200 to end). The degree or frequency of inspection conducted at each processing facility is fairly consistent, but may vary from one type of processing activity to another depending upon the process activity occurring at the establishment at any particular time. FSIS enforces its inspection laws at a level that protects consumers by ensuring that meat products are wholesome, unadulterated, and properly marked.

Any official establishment that wants to export product out of the U.S. must operate under FSIS inspection laws. Meat processing establishments operating solely under state inspection authority are not eligible to export products out of the United States.

*Reference: 9 CFR 318.4
Federal Meat Inspection Act*

- 2. What receiving and shipping procedures have been instituted to ensure that products designated for shipment to Country-X do not include ineligible product? How is product eligibility and integrity maintained? How are transfer papers, truck seals, inventory records, and inspector presence (at loading and unloading) used to ensure that export shipments do not include ineligible product? Do inspection personnel have access to applicable establishment records?**

Each official establishment must have a quality control (QC) system or plan in place to produce product that meets certain specifications or requirements, e.g., certified for export. The QC system or plan shall ensure that the product, operation, or part of operation, which it concerns, is in control and that the applicable product meets the stated requirements (9 CFR 318.4). This system or plan shall also describe how eligible and ineligible product will be kept separated during production, how eligible product is marked for export, and how oversight and corrective action is taken to assure compliance. FSIS must approve the QC system or plan and monitor it as needed, and has the authority to terminate a QC system or plan if the establishment fails to comply with it.

FSIS regulations (9 CFR Part 316) state that only inspected and passed product shall be marked with an official FSIS inspection legend. For unmarked inspected and passed product, FSIS has the ability and authority (9 CFR 325) to use official Agency seals as a

means to identify inspected and passed product and distinguish it from non-inspected product.

FSIS regulations (9 CFR Part 320) require all official establishments to keep records that will fully and correctly disclose transactions involved with the production and selling of meat and poultry products. Some of the other records required to be kept by official establishments include records of processing procedures, guaranties provided by suppliers or packaging materials, labeling requirements, and shipping documents. FSIS regulations (9 CFR 320.4) require official establishments to provide immediate access of their records to FSIS inspectors and any other authority representing the Secretary of the Department of Agriculture upon request.

*References: 9 CFR Part 316, 320, and 325
9 CFR Section 318.4*

3. What establishments, that are approved to export product to Country-X, process product that is ineligible for export to Country-X? For each establishment, describe the products that are ineligible.

[Although the product descriptions provided in this question are based on FSIS standards, the specific details regarding the establishment are fictitious so as to protect the identity of the establishments and the products they produce. In addition, although the following answer lists only a few establishments, please provide a complete answer for all the establishments that will export to the United States.]

For example:

Establishment # 2459 Western Wild Game, Parlo, TX is approved to export raw wild boar carcasses to the Country-X but is not approved to export swine carcasses to them. They also produce raw wild boar carcasses that are ineligible to export to the EU. Raw swine and wild boar carcasses are livestock that have been humanely and properly slaughtered, dressed or prepared for market, and refrigerated in preparation for shipment.

Establishment # 293, TFC Rushing River, Iowa is approved for the export of pork sausage to Country-X but is not approved to export corned beef products to them. Corned beef products are beef products prepared from beef briskets, navels, clods, middle ribs, rounds, rumps, or similar cuts using one or a combination of the following curing ingredients: common salt, approved sugars (sucrose, cane or beet sugar), maple sugar, dextrose, invert sugar, honey, corn syrup solids, (corn syrup, glucose syrup and fructose), wood smoke, vinegar, flavorings, spices, sodium nitrate, sodium nitrite, potassium nitrate, and/or potassium nitrite. Canned product labeled ``Corned Beef'' is prepared so that the weight of the finished product, excluding cure, salt, and flavoring material, shall not exceed 70 percent of the fresh beef weight. Corned beef other than canned is cured in pieces weighing not less than 1 pound, and if cooked, its weight shall not exceed the weight of the fresh uncured beef. Beef cheek meat, beef head meat and beef heart meat may be used to the extent of 5 percent of the meat ingredient in preparation of this product when trimmed. When beef cheek meat, beef head meat, or

beef heart meat is used in preparation of this product, its presence is reflected in the statement of ingredients. The application of curing solution to beef cuts, other than briskets, which are intended for bulk corned beef does not result in an increase in the weight of the finished cured product of more than 10 percent over the weight of the fresh uncured meat.

Establishment #456, International Foods, Council Plains, Indiana is approved for the export of raw pork carcasses to Country-X but is not approved to export raw beef or pork carcasses and mechanically deboned beef to them. Raw beef and port carcasses are livestock that have been humanely and properly slaughtered, dressed or prepared for market, and refrigerated in preparation for shipment. Mechanically separated (Species) is any finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of livestock carcasses and parts of carcasses and meeting the other provisions of this paragraph. Examples of such product are "Mechanically Separated Beef", "Mechanically Separated Veal", "Mechanically Separated Pork", and "Mechanically Separated Lamb". At least 98 percent of the bone particles present in such product has a maximum size no greater than 0.5 millimeter in their greatest dimension and has no bone particles larger than 0.85 millimeter in their greatest dimension. The product resulting from the separating process has a calcium content not exceeding 0.75 percent, as a measure of a bone solids content of not more than 3 percent, and has a minimum PER of 2.5. Such product also has a protein content of not less than 14 percent and a fat content of not more than 30 percent, or it has been deemed to be product for processing. Such product failing to meet the bone particle size, calcium, or PER requirements of this paragraph shall only be used in producing animal fats. Where such product meets the bone particle size, calcium, and PER requirements of this paragraph, it may also be used in the formulation of meat food products.

References: 9 CFR Parts 318 and 319

- 4. What establishments, that are approved to export product to Country-X, receive domestic product that is not eligible for export to Country-X? For each establishment, describe the products that are received and not eligible for export?**

[Although the product descriptions provided in this question are based on FSIS standards, the specific details regarding the establishment are fictitious so as to protect the identity of the establishments and the products they produce. In addition, although the following answer lists only a few establishments, please provide a complete answer for all the establishments that will export to the United States.]

For example:

Establishments #481C, Brass Incorporated, Turnville, TX, and #9923, Customized Meats, Mnarls, Ohio, are eligible to export dry cured beef from normal cattle to Country-X but also receives local cattle from other growers that are hormone treated whose products are ineligible for export to Country-X. Hormone treated cattle are cattle that are given growth hormones during their development to increase the size and bulk of the animal.

Establishment 3334, Armband Meats Company, Earls, KS is eligible to export dry cured pork to Country-X but also receives domestically produced pork sausage that is not eligible for export to Country-X. Pork sausage is a finely comminuted meat food product prepared from one or more kinds of meat or meat and meat byproducts, by species, containing various amounts of water as provided for elsewhere in this part, and usually seasoned with condimented proportions of condimental substances, and frequently cured. These sausages may contain binders and extenders; e.g., cereal, vegetable starch, starchy vegetable flour, soy flour, soy protein concentrate, isolated soy protein, nonfat dry milk, dry or dried whey, reduced lactose whey, reduced minerals whey, whey protein concentrate, calcium reduced dried skim milk, enzyme (rennet) treated calcium reduced dried skim milk and calcium lactate or dried milk. The finished product contains no more than 3.5 percent of these additives individually or collectively. Two percent of isolated soy protein shall be deemed equivalent to 3 1/22 percent of any one or more of these binders. Sausages do not contain phosphates except that phosphates listed in 318.7(c)(4) of this subchapter may be used in cooked sausage. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of sausage which is not cooked in an amount not to exceed 3 percent of the total ingredients in the formula. Cooked sausages such as Polish sausage, cotto salami, braunschweiger, liver sausage, and similar cooked sausage products may contain no more than 10 percent of added water in the finished product. Sausage may contain Mechanical Separated (Species).

Establishment 123A, Harmon Meats Corp., Maine, Conn. Is approved to export frozen beef carcasses to Country-X but also receives domestically slaughtered and frozen beef carcasses that are not eligible for export to Country-X. Frozen beef carcasses are cattle that are humanely and properly slaughtered, dressed in preparation for market, and frozen before shipment.

References: 9 CFR Parts 318 and 319

- 5. What establishments, that are approved to export product to Country-X, receive imported product that is not eligible for export to Country-X? For each establishment, describe the products that are received and not eligible for export?**

[Although the product descriptions provided in this question are based on FSIS standards, the specific details regarding the establishment are fictitious so as to protect the identity of the establishments and the products they produce. In addition, although the following answer lists only a few establishments, please provide a complete answer for all the establishments that will export to the United States.]

For example:

Establishment #3235, Marllarc Warehouse, Ogden, WA is approved to export raw beef and port carcasses to Country-X if it was produced at an approved slaughter facility but imports raw beef carcasses from Australia and New Zealand that is not eligible for export to Country-X. Raw beef and port carcasses were described in question 3 above.

Establishment # 3367, Townsend Cutters, Friona, LA is approved to export ground pork to Country-X but imports ground beef from Germany that is not eligible for export to Country-X. Ground beef consists of chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. When beef cheek meat (trimmed beef cheeks) is used in the preparation of chopped or ground beef, the amount of such cheek meat shall be limited to 25 percent; and if in excess of natural proportions, its presence shall be declared on the label, in the ingredient statement and otherwise contiguous to the name of the product.

Establishment #67223, Amberly Meats, Harmondale, CA is approved to export country hams to Country-X but also imports country hams from Japan that are not eligible for export to Country-X. Country hams are the uncooked, cured, dried, smoked or unsmoked meat food products made respectively from a single piece of meat conforming to the definition of "ham," (the hind legs of swine) or from a single piece of meat from a pork shoulder. They are prepared by the dry application of salt (NaCl), or by the dry application of salt (NaCl) and one or more of the following optional ingredients: nutritive sweeteners, spices, seasonings and flavorings, sodium or potassium nitrate and sodium or potassium nitrite. The product is not injected with curing solutions nor placed in curing solutions. The product is treated for the destruction of possible live trichinae. The entire exterior of the ham or pork shoulder is coated by the dry application of salt or by the dry application of salt combined with the above optional ingredients. Additional salt, or salt mixed with other permitted ingredients, may be reapplied to the product as necessary to insure complete penetration. When sodium or potassium nitrate, or sodium or potassium nitrite, or a combination thereof, is used, the application of salt is in sufficient quantity to insure that the finished product has an internal salt content of at least 4 percent. When no sodium nitrate, potassium nitrate, sodium nitrite, potassium nitrite or a combination thereof is used, the application of salt shall be in sufficient quantity to insure that the finished product has a brine concentration of not less than 10 percent or a water activity of not more than 0.92. For hams or pork shoulders labeled "country" or "country style," the combined period for curing and salt equalization is not be less than 45 days for hams, and is not be less than 25 days for pork shoulders; the total time for curing salt equalization, and drying is not less than 70 days for hams, and is not less than 50 days for pork shoulders. During the drying and smoking period, the internal temperature of the product does not exceed 95 degrees F, provided that such temperature requirement is not apply to product dried or smoked under natural climatic conditions. For hams or pork shoulders labeled "dry cured," the combined period for curing and salt equalization is not be less than 45 days for hams, and is not be less than 25 days for pork shoulders; and the total time for curing, salt equalization, and drying is not be less than 55 days for hams and is not less than 40 days for pork shoulders. The weight of the finished hams and pork shoulders covered in this section is at least 18 percent less than the fresh uncured weight of the article.

References: 9 CFR Parts 318 and 319

6. What establishments, that are approved to export product to Country-X, receive domestic product that is eligible for export to Country-X? For each establishment, describe the products that are received and eligible for export?

[Although the product descriptions provided in this question are based on FSIS standards, the specific details regarding the establishment are fictitious so as to protect the identity of the establishments and the products they produce. In addition, although the following answer lists only a few establishments, please provide a complete answer for all the establishments that will export to the United States.]

For example:

Establishment 23581, Brauss Inc, Bonne, WI is eligible to export luncheon meat (pork and beef) to the European Union, receives domestic luncheon meat and raw carcasses from other local establishments, and exports the received luncheon meat and luncheon meat made from the received carcasses to Country-X. Luncheon meat is a cured, cooked meat food product made from comminuted meat. Mechanically separated beef and pork may be used if the meat food products required to be prepared from one species does not contain mechanically separated meat of any other species, if the mechanically separated meat has a protein content of not less than 14 percent and a fat content of not more than 30 percent, but may constitute up to 20 percent of the livestock and poultry product portion of any meat food product except in baby, junior, or toddler foodstose listed in paragraph (d) of this section, and if the mechanically separated meat for processing constitutes no more than 20 percent of the livestock and poultry product portion of any meat food product that is subject to a definition and standard of identity or composition which establishes a maximum limit on the fat content. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of luncheon meat in an amount not to exceed 3 percent of the total ingredients.

Establishment # 41140, Goldbrick & Sullivan, Mt. Vernon, VA is eligible to export raw beef parts to Country-X, receives domestic raw beef carcasses and cuts them to specification, and exports the parts from all carcasses sources to Country-X. Beef parts are produced from cut-up raw beef carcasses that have been slaughtered and dressed as indicated in question 3.

Establishment # 77721, Specialty Meats, Dalworth, LA is eligible to export frozen, raw cut-up pork carcasses and beef tamales to Country-X, receives domestic pork beef and beef/pork tamales from local establishments, and exports any and all beef tamales to Country-X. Beef tamales are prepared with at least 25 percent beef computed on the weight of the uncooked fresh meat in relation to all ingredients of the tamales. When tamales are packed in sauce or gravy, the name of the product includes a prominent reference to the sauce or gravy; for example, "Tamales With Sauce" or "Tamales With Gravy." Product labeled "Tamales With Sauce" or "Tamales With Gravy" will contain not less than 20 percent beef, computed on the weight of the uncooked fresh beef in relation to the total ingredients making up the tamales and sauce or the tamales and

gravy. Mechanically separated beef may be used in accordance with the conditions outlined in above.

References: 9 CFR Parts 318 and 319

7. What establishments, that are approved to export product to Country-X, receive imported product that is eligible for export to Country-X? For each establishment, describe the products that are received and eligible for export?

[Although the product descriptions provided in this question are based on FSIS standards, the specific details regarding the establishment are fictitious so as to protect the identity of the establishments and the products they produce. In addition, although the following answer lists only a few establishments, please provide a complete answer for all the establishments that will export to the United States.]

For example:

Establishment # I-119, Niagarian River Falls, NJ is approved to export parboiled roast beef and fresh pork sausage to Country-X, imports these products from Canada, and exports them to Country-X. Parboiled roast beef is prepared so that the weight of the finished product, excluding salt and flavoring material, does not exceed 70 percent of the fresh beef weight. Beef cheek meat and beef head meat from which the overlying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap is used individually or collectively to the extent of 5 percent of the meat ingredients in the preparation of canned product labeled "Roast Beef Parboiled and Steam Roasted." When beef cheek meat, beef head meat, or beef heart meat is used in the preparation of this product, its presence shall be reflected in the statement of ingredients. Fresh pork sausage is sausage (as described above) prepared with fresh pork or frozen pork or both, but not including pork byproducts, and may contain Mechanically Separated pork (as described above), and may be seasoned with the following condimental substances; common salt, approved sugars (sucrose, cane or beet sugar), maple sugar, dextrose, invert sugar, honey, corn syrup solids, (corn syrup, glucose syrup and fructose), wood smoke, vinegar, flavorings, spices, sodium nitrate, sodium nitrite, potassium nitrate, and potassium nitrite. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

Establishment 18233, Morrison Foods Inc., Philadelphia, AR is eligible to export raw beef carcasses and cured beef tongue to Country-X, imports cured beef tongue from Australia, Brazil, New Zealand, and Uruguay, and exports the domestic and imported cured beef tongue, except from Brazil, to Country-X. In preparing "Cured Beef Tongue," the application of the curing solution to the fresh beef tongue does not result in an increase in the weight of the cured beef tongue of more than 10 percent over the weight of the fresh uncured beef tongue. The curing solution consists of

Establishment 12136, Carson Meats, Miami, MN is eligible to export frozen fabricated beef and veal steaks to Country-X, imports raw beef and veal carcasses from France and Denmark, and exports the fabricated beef and veal steaks made from the imported carcasses to Country-X. Raw beef and veal carcasses are described in question 3 above. Fabricated beef and veal steaks prepared by comminuting and forming the product from fresh and/or frozen meat, with or without added fat, of the species indicated on the label. Such products shall not contain more than 30 percent fat and shall not contain added water, binders or extenders. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of fabricated beef steaks only in accordance with the conditions prescribed for chopped or ground beef noted in question 5 above.

References: 9 CFR Parts 318 and 319

8. What controls are in place to ensure that product moving between establishments, as well as product within establishments, is correctly marked as product eligible to be exported to Country-X?

As part of its quality control system or plan, an official establishment must include control procedures in place to ensure that eligible product designated for export will be identified (marked) and kept segregated from ineligible product. FSIS monitors the QC system to assure compliance.

For product shipped between establishments, FSIS, when necessary, will seal containers of product when it is being transferred from one official establishment to another. Also, products brought into an official establishment are subject to re-inspection by FSIS. 9 CFR Section 325.7 states that when product is shipped from one official establishment to another official establishment in the same railroad car or other means of conveyance with other product, such restricted product shall be packed in individual closed containers as hereinafter provided. Containers shall be sealed by firmly applying a pressure sensitive tape around each container in two directions and stamping the intersection of the tape with an official marking device. Alternatively, an inelastic, nonmetallic strap which will retain a legible imprint of the marking device (2 1/2-inch rubber brand) may be used. The imprint of the marking device shall be placed partially on the strap and partially on the container. Such product shall be marked "U.S. passed for cooking" or "pork product ---- degrees F. ---- days refrigeration" or "beef passed for refrigeration," as the case may be. In addition, a "U.S. retained" tag shall be securely affixed to each container of product passed for cooking and of beef passed for refrigeration. The means of conveyance shall not be sealed unless at least 25 percent of the other product in the vehicle is unmarked. For each consignment there shall be promptly issued and forwarded by the inspector to the inspector in charge at destination, a report on the form entitled "Notice of Unmarked Meats Shipped in Sealed Cars," appropriately modified to show the character of the containers, and that the contents are restricted. A duplicate copy shall be retained in the program files.

9 CFR Section 350.3(a) provides for an Identification Service where meat or other product that is federally inspected and passed at an official establishment, or upon importation, under the meat inspection laws, is officially marked to identify it as federally inspected and passed. In order to facilitate the division of such meat or other product into smaller portions or its combination into larger units and still maintain its identity as product which has been federally inspected and passed and so marked, inspectors may supervise the handling of the product and mark such portions or units with the marks of Federal inspection when they determine that the identity has been maintained. There are two ways of identifying product to ensure that a product maintains its eligibility for export. Section 352.1 provides for "Official devices", which is a stamping appliance, branding device, stencil printed label, or any other mechanically or manually operated tool that is approved by the Administrator for the purpose of applying any official mark or other identification to any product or packaging material. Alternately, "Official identification" is any symbol, stamp, label or seal indicating that the product has been officially inspected and/or indicating the condition of the product approved and authorized by the Administrator to be affixed to any product, or affixed to or printed on the packaging material of any product. Part 22 of the regulations establishes controls for the positive identification of export-eligible product that is country-specific and designed, depending on the product, to provide assurances that only eligible product will be exported.

*References: FSIS Directive 11040.2
9 CFR Sections 325.7 and 352.1
9 CFR Section 350.3(a)
Part 22 of the Regulations*

9. Are off-hour checks made to determine that processing establishments are not working without proper inspection?

Official establishment cannot produce product without FSIS direct presence or oversight. FSIS has the authority to review official establishments at all times, day and night to assure compliance with the meat and poultry inspection Acts and regulations.

Reference: 9 CFR 306.2

10. Are inspections made of facilities that are not certified to export meat and/or poultry product to ensure that these products do not enter the export system? What controls are used to ensure that the inspection process is effective? For example, the controls may include the use of local stamps to identify local product, denaturing condemned product, or maintaining inventory records at pet food establishments.

In the United States, all official establishments that operate under FSIS laws and regulations are eligible to export product. In the United States, there are meat and poultry facilities that operate solely under the local state laws and regulations and not under FSIS authority. These state facilities can only produce, ship, and sell their

products within the state they reside. Accordingly, these facilities are not eligible to export product to other countries. FSIS works closely with each state inspection governing body to ensure that products produce in these facilities are not shipped to FSIS official establishments. Controls, such as stamping and records of production, are in place and monitored by state inspection officials to assure FSIS that product is maintained within the state and is not exported. Also, FSIS regulations state that product entering an official establishment cannot be transported, sold or received, without bearing an official FSIS inspection legend, which indicates that the product has been inspected and passed by FSIS. FSIS also has the authority to review and re-inspect any product entering an official establishment.

References: 9 CFR Sections 318.1 and 318.2
9 CFR Part 325

F. Warehouse Facilities

- 1. What are the various types of warehouse facilities that are used for meat and/or poultry products? List the types of facilities separately, such as refrigerated, non-refrigerated, export, local, or other type of warehouse facility?**

FSIS Directive 12,600.1 provides for the following types of facilities:

- a. Food Inspection Service Warehouse (I-House) – for assuring the wholesomeness of a food article.*
- b. Cold Storage Warehouse – for assuring the refrigeration or freezing of inspected product.*
- c. Identification Service Warehouse (ID Warehouse) – for assuring the identity of federally inspected and passed product or imported products.*
- d. Import Inspection Warehouse – for inspecting and holding product being imported into the United States.*
- e. Unofficial Warehouse – for fully packaged, marked and labeled product.*
- f. Certified Pet Products Service – for the inspection identification of products for dogs, cats, and other carnivora from an establishment or I-House.*
- g. Technical Animal Fats Service – for certifying animals fats eligible for export from an establishment or I-House..*

In addition, FSIS Directive 12,600.1 states that a warehouse that simply stores frozen or refrigerated, properly packaged, marked and labeled meat and poultry products does not need FSIS approval (=unofficial warehouse). Voluntary services are provided for certifying trichinae-free pork by freezing, refrigerating cysticercus beef, freezing poultry or red meat in accordance with label requirements, and labeling product under the identification service.

*References: FSIS Directives 12,600.1 and 11010.1
9 CFR Sections 327.7, 327.12, and 327.3
9 CFR Sections 311.23, 318.10, 350.3, and 362.2*

- 2. For each type of warehouse, what inspection coverage is provided or required? For example, is an inspector present whenever product enters or leaves the warehouse, or is an inspector present occasionally (at random) and/or on a fee basis? Who performs these inspections? If applicable, describe how the frequency of inspection is risk-based and based on previously recorded findings.**

Inspector coverage and frequency is outlined in the following statements and depends upon the activity occurring in the facility.

Section 325.17 of 9 CFR states that unmarked product in officially sealed railroad cars, trucks, etc. must not be unloaded or added-to enroute except at a warehouse that is operated under FSIS' Identification Service. Title 18.75 of the regulations, Seal Breaking,, states that designated warehouse operators can only break company or warehouse seals on incoming product. Official seals or approved warehouse seals that seal shipments of restricted or certified product must be broken under an inspector's supervision. The inspector would have to be present during this activity in the situation stated above.

Part 22, Export, of the CFR states that all products for export must meet the importing country's requirements, including final inspection at the warehouse. Title 18.12 states that inspectors must sample domestic and imported boneless meat for species identification at locations such as warehouses.

Off-premises freezers are used to freeze meat, meat byproducts, and processed meat products labeled as frozen, according to Title 18.70, Off-Premise Freezing. Product is shipped to these facilities under refrigeration.

Title 18.74, Facilities, Equipment, Sanitation, states that officially approved warehouses must comply to the regulations in areas/rooms where meat products are being handled or stored. The inspector must periodically ensure that the facilities comply with the regulations, depending upon the activities occurring in the facility. Inspectors must verify that establishment responsibilities are carried out. For example, the warehouse must provide monitored/measured refrigeration with cooling coils that are without excessive frost, provide separate and secure areas for freezing pork and cysticercosis beef. Management is responsible for area sanitation. Approved warehouses must have a designated room for the storage of unwrapped product, properly drained rooms with hot and cold water for cleaning, and a product reconditioning room. Approved warehouses, with advanced notice to FSIS, can perform ice glazing.

Title 18.77 states that each lot of product received by a warehouse must be properly identified. Title 18.79 states that approved warehouses must store meat products in an orderly and sanitary manner. For example, air circulation must be adequate and odors

and objectionable conditions must be prevented. In warehouses with voluntary services, per FSIS Directive 12,600.1, the specified area or room must operate under sanitary conditions and be free of odors. Product must be stored in a sanitary manner, away from wall and off the floor. Handling unwrapped product requires the room to be properly drained, hot and cold running water for cleaning, certified potable water, and hand washing facilities. The inspector must have an appropriate work space or office with a locking file drawer or cabinet. The identity of unmarked product must be maintained and certified pet food must be kept segregated from other product.

Title 18.78, Product Reconditioning, states that warehouse reconditioning of contaminated product in an approved warehouse must be performed under the Identification Service. Therefore, an FSIS inspector must be present. FSIS Directive 10240.1 dated December 15, 1994 permits the storage of monitored lots, verification lots, and hold-and-test lots if the warehouse is qualified and receives prior approval under the Identification Service. These lots are monitored by FSIS inspectors as required, depending on the individual situation.

Title 18.81 states that official warehouses must allow inspectors and other authorized USDA employees to enter the warehouse at any reasonable time to review the facilities and the records. A supervisor conducts unannounced biweekly inspections of the premises, operations, inventory, and records. Insanitary conditions and non-compliances are reported and may lead to the removal of the warehouse from the list of approved warehouses or suspension.

The Hazard Communication Program, as stated in FSIS Directive 4791.5 dated January 18, 1995, has limited application for employees in warehouses where work operations only involve handling chemicals in sealed containers. In other situations, FSIS employees are provided training and have access to applicable records and information about the use/precautions/etc. of each chemical.

FSIS Directive 12,600.1 states that FSIS employees develop PBIS monitoring plans for warehouses that identify the various processes that are conducted under inspection within the facility. Only those areas of a warehouse that are designated as applicable to a specified service are subject to review and inspection. Product can, under certain conditions be labeled or relabeled in approved warehouses. Product reconditioning, "ice glazing", cutting, boning, or trimming are not permitted unless all FSIS establishment requirements are met for the area/room and process in question.

The monitoring plans are based on required records, apply only to the specific area or room where the approved activities take place, show that the warehouse service complies with 9 CFR Parts 308 and 381, Subpart H, and are incorporated into the Inspection System Guide and the Performance Based Inspection System in the form of inspection tasks. Inspection tasks, depending on the complexity and frequency of operations, are assigned according to previous findings. Inspection results (findings) are recorded into an FSIS database and are referenced prior to the assignment of new tasks. In facilities that operate infrequently, the inspector chooses the tasks to perform based upon past

experience and personal judgement. Warehouses that handle exposed product will have more critical control points and tasks than those that only handle product in sealed containers.

*References: 9 CFR Section 325.17
FSIS Directives 12600.1, 10240.1, and 4791.5
Titles 18.12, 18.70, and 18.74 through 18.81
Part 22 of the Regulations*

3. What records are kept of product movement between and within warehouse facilities? For example, does the warehouse keep inventory or transportation records? How do inspectors access or review these records?

Title 18.76 of the regulations states that warehouses that receive unpackaged but federally marked product should record the date of arrival, the identity of the carrier, shipper, official establishment, and warehouse customer, a description of the meat, the quantity of the lot, and the warehouse lot number. Approved-warehouse to approved-warehouse shipments require a warehouse certificate or shipping form to accompany the shipment. The form must include information pertaining to product identity and history.

The records requirements for approved warehouses is specified in Title 18.80, Records. Warehouse operators must stamp the incoming or certification with same warehouse lot number that must be stamped on the product cartons and cross-reference this number on all applicable paperwork. They must file copies of all incoming and outgoing certification and forms and hold for two years. In addition, a warehouse must provide an up-to-date inventory of stored products. All lot and product information must be readily available to the inspector. Warehouse records and certifications are subject to criminal and other enforcement penalties for such offenses as willful, false entries, false representation, and unauthorized use of official marks and identification.

FSIS Directive 12,600.1 states that, in warehouses approved for voluntary services, records must be maintained. FSIS requires that warehouses keep a copy of the current approved application/approval form(s), product receipts (including dates, lot numbers, origin establishment/location, storage purpose, and warehouse location), a current inventory of product by lot, shipment records (including destination and the other items listed for product receipts), letters of guarantee (including water potability and sewage certificate), records of product origination when relabeling, and all certificates for two years. All records must be made available to FSIS personnel.

Title 18.70 states that approved freezing facilities will be responsible for identifying each lot of product by number and for moving the product into the freezing area immediately after its arrival. Designated employees shall keep the following records and make them available to the IIC upon request.

- (a) Product arrival date and time.*
- (b) Product temperature just prior to entering freezer.*
- (c) Daily log of freezer temperatures while product is in storage.*

(d) Time and date product is reshipped.

The freezing establishment will notify the IIC prior to the product leaving the freezer establishment so that the IIC can make arrangements for product inspection.

*References: FSIS Directive 12,600.1
Titles 18.70, 18.76, and 18.80*

4. What type of warehouse is required to be licensed? List each type of warehouse with the government agency that requires the licensing.

The following types of warehouses are required to be licensed/approved by FSIS and are given an establishment number for identification purposes:

*Food Inspection Service Warehouse (I-House)
Cold Storage Warehouse
Identification Service Warehouse (ID Warehouse)
Import Inspection Warehouse*

Off-Premises Freezers are cold storage warehouses that are approved to receive product from slaughter and processing establishments that is required to be frozen.

Bonded Warehouses are import inspection warehouses that are legally bonded and able to hold product detained or held by Customs.

All approved warehouses are determined compliant to the regulations via an FSIS review, as per FSIS Directive 915.4, according to the type of service provided by FSIS.

FSIS Directive 8070.1 dated December 19, 1994, states that State compliance programs that are equal to federal compliance programs must require the registration (form submission, licensing, permits, etc.) of warehouse facilities engaging in intrastate (federal = interstate and international) commerce. Shipping permit numbers, as required by 9 CFR 325.8 and 325.11, as stated in Part 25, Transportation, are requested by the official warehouse or establishment.

Title 18.79 states that an approved warehouse must promptly advise FSIS when it discontinues meat storage.

FSIS Directive 12,600.1 requires that warehouses receiving certain FSIS services are required to meet additional requirements and be specifically approved for the particular service. Freezing pork for trichinae control, as provided in section 318.10 of 9 CFR, requires that freezer time/temperature monitors or product time/temperature monitors (for internal temperature) are provided, that product is kept segregated under official lock or seal, that accurate room or compartment thermometers are provided, that accurate internal product thermometers are used, and that post-freezing-process pork be kept under close program supervision, in a locked cage (or equivalent) until shipped from the warehouse.

Refrigerated beef, when used to control cysticercus, is another specific service that requires the product, as provided in section 311.23, to be identified with retain tags, held

under FSIS control during specific time/temperature requirements, and held in an approved locked cage or equivalent.

Food Inspection or Voluntary Inspection Service requires that the warehouse comply with all the applicable regulations. This service permits product processing and requires that the warehouse use its assigned establishment number with the official inspection legend on the product

*References: FSIS Directives 915.4, 8070.1 and 12600.1
Title 18.79
9 CFR Sections 325.8, 325.4, 318.10, and 311.23*

5. What types of product are kept in each warehouse? For example, is it export- product, local product, pet meats, orange juices, and/or vegetables? (Explain.)

FSIS Directive 12,600.1 and Notice 64-85, Identification state the following:

Food Inspection Service Warehouse (I-House) – for all types of meat and poultry products, including products that need to be cut-up or further processed, including preparation, labeling, and certification. Warehouse facilities may preclude the storage of some products. For example, the warehouse may not have a freezer capable of freezing product within a given, required time period.

Cold Storage Warehouse – for meat and poultry products that are or need to be refrigerated and/or frozen to meet labeling, processing, or other requirements, including trichinae pork and cysticercus beef. The products are stored or held will depend on the capability and extent of the freezing and/or cooling facilities.

Identification Service Warehouse (ID Warehouse) – for all types of meat and poultry products that have maintained product identity and may need to be divided into smaller units or combined into larger units and need to be positively identified. Products that need to be exposed for cutting or further process are not permitted unless the warehouse also has the above Food Inspection Service.

Import Inspection Warehouse – for all products subject to port-of-entry inspection or held by U.S. Customs. A bonded U.S. Customs Service warehouse would be certified by the U.S. Customs Service as such.

Warehouses may be only one or any combination of the above, depending on the products or services they choose to handle or perform, respectively.

References: FSIS Directive 12,600.1 and Notice 64-85, Identification

G. Transportation Vehicles

- 1. What type of meat and/or poultry transporters or shippers are required to be licensed? For example, are meat or pet food transporters licensed? What government agencies oversee licensing?**

Section 322.4 of the regulations, Clearance of Vessels and Transportation Without Certificate Prohibited, states that export vessels or carriers will not be provided clearance to export product unless an official export certificate covering the specified product is issued. Question 3 below contains references and information on the requirements that must be met regarding the shipping vehicle or container before a certificate can be issued.

Shippers of inedible product, in containers such as railroad cars, trucks, or tankers, must have a permit from the appropriate District Office, per 9 CFR 325.11 (e) (1).

FSIS Directive 11010.1 dated December 23, 1993 states that the transport of condemned material over public streets and highways requires permission from State and local authorities.

References: FSIS Directive 11,010.1 and 9 CFR Section 322.4

- 2. What controls are in place to ensure that product being moved between facilities or outside the country maintains its original identity? For example, random checks, truck seals, and/or special labeling requirements may be used to ensure product integrity?**

Adulterated or misbranded product is controlled in intrastate distribution through the use of detentions, recalls, and seizures according to FSIS Directive 8070.1 dated 12/19/94. Part 325 of the regulations states that seals must be used to maintain the identity of unmarked or restricted products and that the breaking of the seals without proper authority is prohibited. MP Form 408 accompanies the product and is securely attached to the inside of the vehicle. In addition, official seals that are affixed to secure product must be accompanied by M P Form 408-3, Warning Tag. Part 18 of the regulations, Reinspection and Preparation of Product, dated December 5, 1994, states that denatured and certified byproducts must be shipped under establishment seal and MP Form 508.

Part 11 of the regulations states that product that is retained for further inspection, product identity and wholesomeness needs to be maintained. This can be accomplished through the use of government locks or seals and/or retain tags.

Title: 14.7 states that the identity of inedible product is maintained by recording tag numbers, seal numbers, time-of-seal-breaking, and the inspectors identity.

Section 325.21 states that all vehicles used for transporting dead, dying, disabled, or diseased livestock or carcass parts must be leak-proof and constructed and equipped so as to permit thorough cleaning and sanitizing.

FSIS Directive 12,600.1 states that the identity of unmarked product must be maintained and that unwrapped product (or certified pet food) must be kept segregated from other product. Part 18 of the regulations states that unmarked product would be held under security (for example: caged and locked, separate rooms and locked, cross taped and stamped) in a manner that would maintain product identity. Only properly identified product is allowed to be shipped and unmarked or unlabeled product is shipped under government seals.

Sections 350.3 (a) and 362.2 (c) state that federally inspected and passed product (including imported product) must be officially marked and identified. When such product is divided into smaller units and its identify needs to be maintained, inspectors supervise product handling and mark the smaller units with the mark of federal inspection, as appropriate (see above reference and Notice 64-85, Identification 8/30/85). FSIS Directive 12,600.1, Voluntary Reimbursable Inspection, states that this maintenance of product identity is even ensured when the identified smaller portions are combined into larger units, repackaged, or relabeled.

In the preparation and packaging of export product, the identity of the product is maintained conclusively and the preparation of domestic product is adequately protected, as per 9 CFR 318.8 (b). Section 354.2 (c) defines “official mark” as an inspection mark that may state the condition of the product or the purpose of maintaining the particular identity of the product(s). The identity of canned product must be maintained throughout all stages of handling to insure the correct labeling of the containers, as per 9 CFR 318.14 (c)(4). Before an export certificate is issued, the identity of the product and its eligibility for export is positively determined through government inspection.

Title: 18.77 states that each lot of product received by a warehouse must be properly identified, that unwrapped marked product must be properly segregated and identified, and that the applicable lot number must be stamped on every carton.

Section 318.10 (c)(2)(vi) of 9 CFR states that refrigerated pork must be transported between establishments in sealed vehicles such as railroad cars, motor-trucks, trailers or closed containers. Part 22, EXPORT, of the regulations states that swine must be identified and product identity must be maintained until packed for export. Part 18, Section 52, Facilities, Equipment, states that to ensure product identity during the re-inspection and preparation of product, establishments must provide separate equipment.

*References: FSIS Directives 8070.1 and 12600.1
Federal Meat Inspection Act (21 U.S.C. 11, 18, and 22)
9 CFR Sections 325.21, 350.3, 362.2, 318,8 354.2, 318.14, and 318.10
FSIS Notice 64-85
Titles 14.7 and 18.77*

3. What temperature and product handling requirements apply to transported meat and/or poultry products during shipment?

Federal Register; July 25, 1996, Vol. 61, No. 144 (9 CFR Part 304, et al.) states that product will not be shipped unless it is 40°F or less. The transport vehicle must also have an environmental temperature of 40°F or less. In addition, product packages must be intact before shipping and the vehicle must be clean after each use and before loading the product.

FSIS Directive 11000.1 dated 12/23/93 states that transport vehicles must be suitably constructed to ensure that product will reach its destination in a clean condition and that the product is protected against weather and road contamination. The vehicles must be free of objectionable odors and foreign materials and must have suitable provisions (such as lining, paper, and burlap) to ensure that the product is not contaminated from outside and other sources. Handling and rinsing of lye and soda solution cleaners must be correct and thorough. The interiors of vehicles that may be used for inedible product must be inspected for cleanliness before edible product can be transported. Vehicles hauling exposed product must have interior surfaces that are clean and intact and have closed doors that produce a dust-proof seal

FSIS Directive 5400.1 Rev.2, dated 3/23/95 states that vehicles must be in good repair to protect the type of product to be transferred. They must be clean and free of objectionable odors and foreign material. FSIS Directive 8140.1 dated August 30, 1995 states that establishment management is responsible for ensuring that the vehicles are clean and adequate to maintain product wholesomeness.

The inspection procedures outlined in FSIS Directive 9040.1 dated 8/12/93 state that export re-inspections examine shipping cartons for signs of poor product handling and storage during the transport of fresh, frozen, processed, and canned product.

*References: Federal Register; July 25, 1996, Vol. 61, No. 144
FSIS Directives 9040.1, 8140.1, 5400.1, and 11,000.1*

4. What provisions are used to handle product from transportation vehicles that have been in an accident or are significantly damaged? For example, is the product returned to the establishment of origin and/or denatured at the site of accident?

FSIS Directive 8420.1 dated 11-7-85 states that inspection personnel have the authority to inspect, pass, or condemn meat and poultry products at federally inspected establishments only, including warehouses that are approved for the specific service. Product may be detained or seized at other locations. Accidents involving federally inspected and passed products require that the FSIS inspector call the appropriate Compliance Program officer and provide pertinent product, accident, and shipment information. The compliance officer must monitor the subsequent movement of the product to ensure that it is reinspected in an official establishment or that other

appropriate disposition occurs as required. Inspectors need not be present at the accident site unless expressly requested by the compliance officer.

Title 18.85 of the Regulations states that product that has been shipped and returned to any official establishment (i.e. more than one carrier and/or > 24 hrs. from origin est.) is subject to specific requirements. The establishment is responsible for designating an appropriate (temperature, cleanliness, equipment, etc.) area to receive the product, for ensuring that the product is moved to the designated areas as soon as is possible, and for securing FSIS inspector permission and approval for the location of the designated area and the sorting, handling, and removal of the product. The FSIS inspector must examine/inspect all of the product and determine its disposition or the action to be taken. These actions include, but are not limited to, releasing marked and wholesome product into intrastate and/or interstate commerce or finding the product adulterated, misbranded, unwholesome, or unidentifiable and, therefore, condemned, destroyed, or processed into pet food.

*References: FSIS Directive 8420.1
Title 18.85 of the Regulations*

H. Export Procedures

1. What procedures are used to obtain export certificates or other documents? Does the inspector that signs the documents see the product being certified?

FSIS Directive 9020.1 states that exporters of meat and poultry products, including horsemeat, casings, pharmaceutical products, and inedible products, must apply for an export certificate by completing FSIS Form 9060-6, Application for Export Certificate. The application must be completed prior to the issuance of an export certificate. ()

When certifying inspected and passed fresh meat and poultry products or processed meat and poultry products for export, the inspector issuing the export certificate will organoleptically examine shipping cartons in the lot for signs of poor product handling and storage (e.g., torn, damp or damaged cartons; off-condition odor, etc.). If the lot does not show signs of poor product handling and storage, the shipping cartons will be stamped with the export mark and FSIS Form 9060-5, Meat and Poultry Export Certificate of Wholesomeness, will be issued. According to FSIS Directive 9040.1, if the lot shows signs of poor product handling and storage, a condition of container examination will be performed by the inspector in accordance with FSIS Directive 7520.2, and as directed by the Field Operations supervisor.

References: FSIS Directives 9020.1 and 9040.1

- 2. What procedures are used to determine that the product being exported is eligible for shipment to Country-X? For example, are the boxes labeled as product being exported to Country-X or are special can-codes used? How is product traced back to the origin establishment?**

When the exporter completes the FSIS Form 9060-6, Application for Export Certificate, the exporter must state that the product being exported meets the foreign country requirements; and that it has been slaughtered, processed, packaged, labeled, and handled according to the requirements of the country to which it is being exported. If the inspector issuing the export certificate desires, he/she may request additional documentation reinforcing the exporter's claim. The FSIS/Home Page contains a reference library that details foreign country requirements for all of those countries requiring additional certification and/or handling in addition to U.S. domestic requirements. All product is properly identified by the producing establishment.

*References: FSIS Form 9060-6
FSIS/Home Page/Export Library*

- 3. What means of conveyance is used for exporting product? For example, are bulk shipments, individual container shipments, or air cargo used to convey product for export?**

An exporter may choose the means of conveyance for exporting product. Steamships, sailing vessels, railroad cars, trucks, etc. may be used. However, 9 CFR, Section 327.8 states that the means of conveyance and the devices used to move and hold or handle product must be maintained in a sanitary manner.

Reference: 9 CFR 327.8

- 4. How does the government inspector verify that the product noted on the certificate, and other documents, matches the product being loaded for export?**

All exports of meat products from the U.S. are accompanied by a health certificate (FSIS Form 9060-5) which bears an official USDA seal printed on the certificate. In addition, the certificate includes an enlarged USDA seal (watermark on the top portion of the certificate) and a unique and traceable export certification number. These forms are secured and controlled by a FSIS inspector. They are not accessible to any other person, unless by written agreement. Each of the cartons carrying the product is stamped with an export box stamp that bears the same unique number that appears on the export certificate. The export box stamp that appears on the product cartons serves to link the product to the certificate. The product presented for inspection must be that product identified on the certificate.

References: 9 CFR Sections 322.1 and 312.8

I. Imported Meat

- 1. If meat or poultry is imported, what type of import inspection program do you have? Describe your import inspection program, including the specific measures used to substantiate product identity and inspection procedures. Does the program verify that tariffs or duties have been paid?**

The principle underlying FSIS import inspection activities is the systems approach. FSIS relies on its initial determination of a foreign country's eligibility along with reviews to provide assurance that product shipped to the United States are and continue to be safe, wholesome, properly labeled and packaged. To verify the effectiveness of the system, FSIS randomly samples meat and poultry products for reinspection as they enter the United States. Reinspection is directed by the AIIS which stores reinspection results from all ports of entry for each country and for each establishment. Reinspection is performance-based; better performing foreign establishments have their products reinspected less frequently at the port of entry. All lots are reinspected for transportation damage, labeling, proper certification, general condition, and accurate count.

In addition, the AIIS assigns various type of inspections which can include examination of the product for defects, net weight checks, examination of condition of containers, incubation of shelf stable canned products, laboratory analyses for food chemistry for processed product, and laboratory analyses for chemical residues, microbiological contamination, and species tests. Products that pass reinspection are stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they are stamped "U.S. Refused Entry", and must be exported, destroyed, or converted to animal food.

Reinspection occurs at one of four frequency levels. At the normal level, all lots are reinspected. At the Skip 1 level, one of every four lots is reinspected; at the Skip 2 level, one of every 12 lots is reinspected. Shipments subject to tightened-and-hold inspection are held pending test results.

*References: Import Inspection Manual
Importing Meat and Poultry to the United States (A Guide for Importers and Brokers)*

- 2. If imported meat or poultry is to be used in Country-X product, how will the inspector know that the imported meat or poultry came from Country-X certified establishments?**

When imported meat and poultry product is presented for reinspection an assignment is issued by the AIIS. Only establishments that have been certified by the foreign governments for export to the United States would be listed as eligible in the AIIS.

References: *Import Inspection Manual*
Importing Meat and Poultry to the United States (A Guide for Importers and Brokers)

3. What records are kept concerning imported meats. For example, is the country of origin, establishment number, quantity, product type, and date of production recorded?

The following records are kept on imported meats at the official establishment where prepared or received:

Form 9530-1, Imported Meat and Poultry Product Reinspection Record. This form is filled out at port-of-entry and includes all pertinent product information that identifies the product being inspection for accountability and trace-back purposes. The form also contains the findings of the reinspection.

Form 9540-1, Import Inspection Application, must accompany each import shipment and must be completed fully and accurately. The form provide all the pertinent information concerning the product imported and must be signed by an authorized individual.

Foreign Health Certificate must accompany each import shipment and must be completed fully and accurately. The form must certify to the wholesomeness and proper processing of the product in question and be signed by a Veterinarian.

The initial entry and reinspection results for all product presented for reinspection are stored in the AHS database system.

References: *Import Inspection Manual*
Importing Meat and Poultry to the United States (A Guide for Importers and Brokers)

J. Pet, Zoo Animal, and Fur Feed Production:

1. What is the extent of the fur industry?

The fur producing animal industry (for pelt) is relatively small compared to food animals producing industry. The animals raised especially for fur are mink and foxes. Rabbits are primarily raised for food. In 1997, the industry produced 2.84 million pelts valued at \$94.1 million.

There were 401 mink farms producing pelts in 1997. Leading States were Utah with 125 farms, Wisconsin with 69 farms, and Minnesota with 39 farms. There were 29 farms those also raised foxes in 1997.

References: Mink. July 1998. National Agriculture Statistics Service, USDA, Washington, DC. LV Gn 3 (7-98)
Fur Commission (www.furcommission.com)
21 CFR, Part 500
American Association of Feed Control Official Publication (published yearly)
USDA/FSIS/ Administrative Management, Human Resources Division, 1993 (Revised). Identification, control, and Destruction of Condemned Meat Material.

2. What is the source of feed for fur animals? For example, is the feed processed from imported product or from domestic product?

Feed is rarely imported. The farms use processed product from Purina or Mink feed Cooperatives in Utah. They use processed protein sanitized by rendering. Some use fresh unprocessed protein from products such as ground dried fish heads and entrails.

References: Mink. July 1998. National Agriculture Statistics Service, USDA, Washington, DC. LV Gn 3 (7-98)
Fur Commission (www.furcommission.com)
21 CFR, Part 500
American Association of Feed Control Official Publication (published yearly)
USDA/FSIS/ Administrative Management, Human Resources Division, 1993 (Revised). Identification, control, and Destruction of Condemned Meat Material.

3. What controls, if any, are placed on the movement of fur feeds? Describe these controls in detail.

*There is no control for unprocessed protein in the U.S. Some States have local regulations for odor and discharge.
FDA regulates ingredients (drugs) that go into the feed for pet animals, which is also fed to fur animals. Individual States require labeling (%) for protein, fat and fiber. Manufacturers normally follow the procedures and the formulation of the American Association of Feed Control Official Publication for the preparation of fur and other feeds.*

Reference: Mink. July 1998. National Agriculture Statistics Service, USDA, Washington, DC. LV Gn 3 (7-98)
Fur Commission (www.furcommission.com)
21 CFR, Part 500
American Association of Feed Control Official Publication (published yearly)
USDA/FSIS/ Administrative Management, Human Resources Division, 1993 (Revised). Identification, control, and Destruction of Condemned Meat Material.

4. What is the source of food for carnivorous pets and zoo animals?

Pet animals, including carnivore pets, are fed with food produced by Ralston Purina, ConAgra, and Cargill. They operate under FDA regulations and guidance provided by the American Association of Feed Officials Publication. The ingredients (for approved drugs) added to a feed are periodically sampled and analyzed by FDA for quality. Pet food manufacturers use byproducts, trimmings, and poor quality protein; much of which comes from inedible products from egg breaking establishments, poor quality eggs, and condemned poultry. Since many animals in a zoo are exotic, they are carefully fed with a controlled diet, consisting of (horsemeat) good quality protein and minerals. Some carnivorous animals are fed with approved pet food or inspected horsemeat.

References: Mink. July 1998. National Agriculture Statistics Service, USDA, Washington, DC. LV Gn 3 (7-98)
Fur Commission (www.furcommission.com)
21 CFR, Part 500
American Association of Feed Control Official Publication (published yearly)
USDA/FSIS/ Administrative Management, Human Resources Division, 1993 (Revised). Identification, control, and Destruction of Condemned Meat Material.

5. What controls are places over these feeds? Describe these controls in detail.

Feed manufacturers such as Ralston Purina, ConAgra, Cargill etc operate under FDA regulations and guidance provided by the American Association of Feed Officials Publication. The ingredients (for approved drugs) added to a feed are periodically sampled and analyzed by FDA for quality. Additionally, if adulteration, contamination, misbranding or death of a pet due to feed from any manufacturer is reported, FDA investigates, analyzes the feed, and disposes of it, as it deems appropriate (like destruction of feed with peanut meal with aflatoxin). Individual States control labeling information on protein, fat and fiber content in feed.

Reference: *Mink. July 1998. National Agriculture Statistics Service, USDA, Washington, DC. LV Gn 3 (7-98)*
Fur Commission (www.furcommission.com)
21 CFR, Part 500
American Association of Feed Control Official Publication (published yearly)
USDA/FSIS/ Administrative Management, Human Resources Division, 1993 (Revised). Identification, control, and Destruction of Condemned Meat Material.

6. Where applicable, what controls are maintained on the production and handling of animal feeds in U.S.-certified establishments? Describe these controls as they apply to animals that are used for their fur, kept as pets, or confined in a zoo.

All animal feed producers including Ralston Purina, ConAgra, Cargill operate under FDA regulations and guidance provided by the American Association of Feed Officials Publication. The products from feed mills are periodically sampled and analyzed by FDA for quality.

9 CFR Section 325.11 states that inedible products (including condemned products as specified in section 314.11 of this subchapter) which were prepared at any official establishment, or at any State inspected establishment in any State and which have the physical characteristics of a product fit for human food, may be transported from an official establishment or in commerce, without denaturing as required by this subchapter, if the following conditions are met:

The shipper must have obtained a numbered permit for such activity from the appropriate Regional Director, as identified in section 301.2 of this subchapter. Such permit may be obtained upon written application to the appropriate Regional Director and his determination that the proposed transportation would be authorized under this paragraph (e). The application shall state the name and address of the applicant, a description of the type of his business operations, and the purpose of making such application.

Such inedible products may be transported under this paragraph (e) only if consigned to a manufacturer in the United States of articles other than for human food and if the product is for use solely by the consignee for manufacturing articles not for human food. Such products may not be transported in commerce to any consignee other than the one to which they were originally shipped unless prior notice of the diversion is given to the appropriate Regional Director and a record identifying the new consignee is maintained by the shipper as required by section 320.1 of this subchapter.

When transported from an official establishment or in commerce under this paragraph (e), the outside container of such inedible products shall be marked conspicuously with the words "Inedible -- Not Intended for Human Food" in letters not less than 2 inches high, in the case of containers, such as cartons, drums, tierces, barrels, and half barrels, and not less than 4 inches high in the case of tank cars and trucks used to transport such products not in other containers.

Such inedible products shall be transported from an official establishment or in commerce under this paragraph (e) only in railroad cars, trucks, or containers which bear unofficial seals applied by the shipper, which shall include the identification number assigned to the permit holder and an individual seal serial number assigned by the shipper; and the product so transported shall be accompanied by an invoice or bill of lading specifying the permit holder's identification number. The consignee in the United States must retain a record of the identification and serial numbers shown on the seals in his records as prescribed in Part 320 of this subchapter.

Any diversion, or effort to divert, undenatured, inedible product contrary to the provisions of this paragraph (e) or other violation of the provisions of this section may result in the revocation of the permit for shipment of inedible products under this paragraph (e), at the discretion of the Administrator.

A feed that is produced by an approved feed manufacturer can be used for feeding pets, fur or zoo animals.

References: *Mink. July 1998. National Agriculture Statistics Service, USDA, Washington, DC. LV Gn 3 (7-98)*
Fur Commission (www.furcommission.com)
21 CFR, Part 500
9 CFR Section 325.11
American Association of Feed Control Official Publication (published yearly)
USDA/FSIS/ Administrative Management, Human Resources Division, 1993 (Revised). Identification, control, and Destruction of Condemned Meat Material.

7. How are establishments required to denature or otherwise identify product that is not fit for human consumption? What authority is used to mandate this process?

Besides tagging and denaturing the product with stain, products that do not pass USDA/FSIS inspection are placed in a bin for condemned product and placed in a designated area in every establishment. Only the inspector in charge has the authority to open the area and dispose of the product (for fat rendering or burning).

Reference: *Mink. July 1998. National Agriculture Statistics Service, USDA, Washington, DC. LV Gn 3 (7-98)*
Fur Commission (www.furcommission.com)
21 CFR, Part 500
American Association of Feed Control Official Publication (published yearly)
USDA/FSIS/ Administrative Management, Human Resources Division, 1993 (Revised). Identification, control, and Destruction of Condemned Meat Material.

K. General

- 1. What laws prevent your inspection system from certifying establishments as eligible to export product to Country-X when it is known that the establishment is owned by someone convicted of a criminal act? Explain the authority that is mandated and the controls that are used.**

Section 401 of the Federal Meat Inspection Act (FMIA) authorizes the Secretary of Agriculture to withdraw or to refuse to provide inspection services with respect to any establishment if he determines the applicant or recipient is unfit to engage in any business requiring inspection because the applicant or recipient has been convicted, in any Federal or State court, of any felony or one or more misdemeanors under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food, or fraud in connection with transactions in food; or any felony, involving fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting the public health. Applicants and other recipients of Federal inspection services are required to provide the USDA sufficient information to control for the potential involvement of such persons as owners, partners, officers or owners of 10% or more of the voting stock of the establishment.

References: Federal Meat Inspection Act (21 U.S.C. 601 et seq.)

- 2. Are all wages and expenses of inspection personnel paid by the national government? Who pays for overtime incurred by the inspector? If industry pays for the overtime, how is the money distributed to the government inspectors? For example, are the inspectors paid directly by the establishment or through the national government?**

Yes, except for authorized overtime, which is paid for by the establishment receiving the inspection services. The payment procedures are as follows: The USDA bills the establishment, which makes payment to the Department. The USDA's National Finance Center then distributes overtime pay to the appropriate inspector in the usual manner. Government inspectors are assigned wage grades and tours of duty depending on the nature and complexity of the work. Inspectors are paid directly by the government for travel time, expenses during travel and official work requirements, normal work hours, and premium time or overtime. All expenses, fees, overtime, etc. are paid directly to the government by the establishment. No monies are paid directly to government inspectors or other official employees.

*Reference: FSIS Directives 5110.1 and 4551.1
FSIS Directives 4550.4 and 4550.1
FSIS Directive 4530.3*

- 3. Who monitors product integrity when the product to be exported is not under the normal product controls established for the inspector? For example, what inspection staff monitors product during transportation, in warehouses, or when establishments are not working?**

Import Inspectors and Compliance Officers are authorized under Section 327 of the FMIA to monitor product during transportation, in warehouses, and in commerce.

*References: Federal Meat Inspection Act (21 U.S.C. 2 through 6 and 401)
9 CFR Section 350.3*

- 4. What authority do your inspectors have over export-product that is not within an officially inspected establishment? If product outside of official establishments is found to be ineligible for export, what action is taken? For example, does the inspector retain the product, destroy the product, or require it to be re-inspected?**

FSIS Compliance Officers have authority to monitor the product being so held for sale and to detain, seize, or require it to be reinspected or voluntarily destroyed.

References: Federal Meat Inspection Act (21 U.S.C. 402 & 403)

- 5. Which agency in the national government investigates and prosecutes businesses, organizations, individuals, or inspection employees that are suspected of illegal activities?**

Initially FSIS Compliance Officers investigate; if necessary, officials from the USDA Office of the Inspector General and the USDA Office of the General Counsel may be brought in; and ultimately if necessary prosecutors from the US Department of Justice.

FSIS Directive 922.6 provides an outline of the policy and procedure for the disposition of cases involving alleged violations of the Federal Meat Inspection Act.

The Federal Meat Inspection Act (FMIA) authorizes the Secretary to issue a written notice of warning for minor violations whenever he believes that the public interest will be adequately served through such administrative action. Prior to submitting a case for prosecution, the person(s) against whom such proceeding is contemplated must by law be given reasonable notice of the alleged violation and an opportunity to present his views orally or in writing. In practice this is known as a "Notice of Intent to Prosecute."

The FSIS Compliance Program is responsible for (1) Issuing letters of warning involving alleged violations that appear to be minor, and (2) Submitting cases to the Office of the General Counsel (OGC) for clearance that appear to involve more than minor violations, but which, for other reasons, do not warrant legal action. All reports by the Office of the Inspection General (OIG) containing evidence of violation of the Acts are submitted to

OGC before issuance of warning letters. The basis for handling cases in this manner includes:

- (1) Evidence would not support prosecution;*
- (2) Violator cooperated with the Government in some manner to assure future compliance;*
- (3) Person or firm is out of business;*
- (4) Further investigation would not develop evidence required to support prosecution; or*
- (5) Violation is minor in nature.*

*References: Federal Meat Inspection Act (21 U.S.C. 601 et seq)
Title 18 of the Criminal Code
FSIS Directives 1232.1 and 1232.2
FSIS Directive 922.6*

6. What type of program do you have for testing product to ensure that the product content is limited to the animal species designated on the package or label? Describe the program in detail and address the following related questions:

Federal inspectors carry out species sampling on a randomized basis for both domestic and imported product. Species testing procedures are defined for fresh and cooked product. Samples are sent to an “accredited” laboratory for comparability analysis; only one lab in the United States has been approved to test for species identification: ABC RESEARCH CORPORATION, 3437 SW 24th Avenue, Gainesville, FLA 320607.

The following letter was sent to all eligible countries in June of 1999:

Dear CVO:

The Food Safety and Inspection Service (FSIS) requires that foreign countries conduct species verification testing of all fresh and cooked products intended for export to the United States. Species verification testing for fresh meat was initiated in 1981 and species verification testing for cooked meat products was initiated in 1988. The purpose of this letter is to clarify our policy for exempting foreign countries from routine species verification testing. No response is required.

In the past, FSIS has provided an exemption from the species testing requirement if the exporting country satisfactorily demonstrated that the country had controls in place to assure that commingling of species did not occur. To request an exemption, an exporting country must write to FSIS and respond to the conditions for exemption noted below. The conditions for exemption that must be met include all of the following:

CONDITIONS FOR EXEMPTION FROM ROUTINE
SPECIES VERIFICATION TESTING

1. *Carcasses and products are transported between establishments in devices which are sealed with a tamper detectable inspection seal by the Inspection Service at the originating establishment and broken by the Inspection Service at the receiving establishment.*
2. *Brands and sealing devices used by the Inspection Service to identify and seal product are kept under Inspection Service security.*
3. *Establishments are under continuous Inspection Service supervision while operating. No operations may take place without Inspection Service supervision.*
4. *Only one species of livestock or meat is allowed in the slaughter or processing areas at one time.*
5. *Product must be exported to the United States in a cargo container sealed by the Inspection Service.*

Alternatively, you may implement a different measure that you believe is equivalent to our requirement. If you elect to demonstrate how your alternative measure is equivalent to our requirement, please provide information and data that supports the different requirement.

Your request for exemption should be directed to:

*International Policy Division
Food Safety and Inspection Service, USDA
1400 Independence Avenue, SW
Room 4434 South
Washington, DC 20250*

If you need more information or have any questions, please contact Mr. Mark Manis at (202) 720-6400; fax (202) 720-7990.

Sincerely,

*Mark Manis, Director
International Policy Division
Office of Policy, Program Development and Evaluation*

*References: Federal Meat Inspection Act (21 U.S.C. 20)
9 CFR Section 927.2, Part 319, Sections 317.8 and 317.2
FSIS Notice 14-91
FSIS Directives 5400.1, 10230.2, and 10230.1*

a. How many samples are taken?

A ½ pound sample from 1 unit per lot.

b. Who takes the samples?

Federal inspectors.

c. Where are the samples taken?

Domestic product: *at the producer's establishment.*

Imported product: *at the port-of-entry in the import establishment.*

d. What techniques are used in selecting and collecting the samples?

Random samples are selected and collected so as not to contaminate or bias the sample in any way. Sampling tools are clean and free of contaminants that could affect the results of the sample and the samples are kept separate and apart from and other samples and from contact with any other substances or materials that may bias the test results in any way.

Fresh product is tested using a SIFT kit, where available. If not available, the sample is submitted directly to the laboratory.

Cooked product of non-shelf stable items are sampled by immediately placing 1/2 sample in a clean plastic bag. Shelf-stable product is sampled by selecting 1 unit of product.

Reference: ABC Research Corporation, Gainesville, Florida

e. What laboratory support do you have for species testing? For example, where are the labs located, what methodology is used, and what is the source of the reagents? Describe the applicable program in detail.

Only one lab in the United States has been approved to test for species identification: ABC RESEARCH CORPORATION, 3437 SW 24th Avenue, Gainesville, FLA 320607. ABC makes there own antibody reagents and purchases the other reagents from reliable commercial sources.

(For sampling methodology and details, see Attachment)

f. How is the test information used? For example, is product held (not exported) until satisfactory results are received and recalled if found unsatisfactory? Describe the applicable process in detail.

The Laboratory conducting the testing reports species violations to the appropriate inspection officials for corrective and/or enforcement action. Product is detained, retained, or recalled, as appropriate.

7. How do you monitor the flow of product throughout the inspection system? What controls do you have in-place to ensure that your export inspection program is adequately implemented and maintained? Include a diagram of these activities.

Under traditional slaughter inspection, Federal inspectors follow the regulatory procedures for antemortem and postmortem inspection of slaughtered animals set forth in 9 CFR Parts 309 and 310. Section 309.1 states that ante-mortem inspection shall be made in pens on the premises of the establishment at which the livestock are offered for slaughter before the livestock shall be allowed to enter into any department of the establishment where they are to be slaughtered or dressed or in which edible products are handled. Section 310.1 states that a careful post-mortem examination and inspection shall be made of the carcasses and parts thereof of all livestock slaughtered at official establishments. Such inspection and examination shall be made at the time of slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for making such inspection and examination at a later time.

The monitoring of the flow of processed product through the processing parts of the inspection system is handled traditionally under the other applicable parts of 9 CFR Sections 301 through 417. Section 307.4 states that no operations requiring inspection shall be conducted except under the supervision of a government Program employee. All slaughtering of animals and preparation of products shall be done with reasonable speed, considering the official establishment's facilities. Official establishments, importers, and exporters shall be provided inspection service. Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take into account the efficient and effective use of inspection personnel. Establishments shall maintain consistent work schedules. Any request by an establishment for a change in its work schedule involving an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change.

FSIS Directive 9040.1 dated 8/12/93 states that exporters requesting USDA certification for product intended for export must agree prior to the certification that the product will be subject to re-inspection before being exported, so that the product's identity and eligibility for export may be determined. FSIS may perform more in-depth re-inspection procedures at any time in response to complaints from countries receiving United States product.

Under the Pathogen Reduction; HACCP final rule, Federal inspectors follow the regulatory monitoring and oversight process described in detail in the Reference Guide: "HACCP Regulatory Process for HACCP-based Inspection," (January 1998). Section 417.2 states that the contents of an establishment's HACCP plan includes a list of the food safety hazards identified in accordance with paragraph (a) of this section, which

must be controlled for each process and a list of the critical control points for each of the identified food safety hazards, including, as appropriate:

Critical control points designed to control food safety hazards that could be introduced in the establishment: and,

Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

Include all corrective actions that have been developed in response to any deviation from a critical limit at a critical control point;

Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring;

List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use.

FSIS Directive 12,600.1, states that establishments may apply for a voluntary inspection service that specifically ensures that product is properly monitored. Identification Service (ID service) is a service that is provided to assure that the identity of federally inspected and passed meat and poultry products is maintained, throughout the division of such meat or poultry or other product into smaller portions, its combination into larger units, or repackaging and relabeling of product in which the integrity of the immediate container has not been compromised. Title 22 of the regulations states that all products for export shall meet the importing country's requirements. Exporters are responsible for determining that they comply with these requirements and providing the necessary documents. FSIS Veterinarians certify that the product is wholesome and meets specific country requirements. FSIS Directive 9060.4 states that Export Certification ensures that boxes are marked for export, that certified product is properly recertified, and that certificates and stamps are secure and safe from unofficial use. Certification of the product by the inspector indicates that the inspector has:

- a. Officially authenticated that the product described was inspected and passed, sound, wholesome, and correctly labeled at the time the certificate was issued.*
- b. Determined that all applicable foreign country requirements have been met.*

*See Generic HACCP Plans for Fully Cooked, Not Shelf Stable product and for Beef Slaughter product, as an examples of required flow charts developed by each establishment for each product they produce.
(See Export Inspection System Attachment.)*

*References: FSIS Directives 12600.1 and 9040.1
9 CFR Sections 309.1, 310.1, 417.2, 307.4
9 CFR Parts 401, 301, 417, 309, and 310
Title 22 of the Code of Federal Regulations
FSIS Issuances, HACCP 11 and 13*

8. Who supplies official brands, locks, seal and documents?

Section 316.4 states that the operator of each official establishment or official import inspection establishment shall furnish such ink brands, burning brands, and any other device for marking products with official marks as the Administrator may determine is necessary for marking products at such establishment. All official devices for marking products with the official inspection legend, or other official inspection marks, including self-locking seals, shall be used only under supervision of a Program employee, and, when not in use for marking shall be kept locked in properly equipped locks or compartments, the keys of which shall not leave the possession of a Program employee, or the locker or compartment shall be sealed with an official seal of the Department. FSIS provides the official documents used in inspecting and reporting inspection activities in an official establishment. FSIS Directive 5400.5 provides the procedures, forms, and instructions that are appropriate for use under a PR/HACCP inspection system. FSIS Notice 43-97 provides for new locks. Official locks can only be replaced, if necessary, by the Inspectors-in-charge (or higher authority) from a specified FSIS service center.. Keys for the new locks are available from the district offices and all replacement locks are keyed-alike.

*References: 9 CFR Parts 309, 310 and Section 316.4
FSIS Notice 43-97
FSIS Directive 5400.5*

9. What controls are placed on official brands, locks, seals and documents?

They are secured under lock and key by the Inspector-in-Charge. Section 316.4 states that all official devices for marking products with the official inspection legend, or other official inspection marks, including self-locking seals, shall be used` only under supervision of a Program employee, and, when not in use for marking shall be kept locked in properly equipped lockers or compartments, the keys of which shall not leave the possession of a Program employee, or the locker or compartment shall be sealed with an official seal of the Department. FSIS Directive 2400.1 states that inspectors maintain an inventory and accountability records of badges, identification cards, accountable forms, credit cards, and other program equipment showing current status. FSIS Notice 43-97 states that official government locks and keys are considered accountable property. In addition, lost or stolen locks and keys must be reported immediately, via Form AD-112, to the appropriate District Office and the Administrative Services Division.

References: 9 CFR Section 316.4
FSIS Directive 2400.1 and FSIS Notice 43-97

L. Refused Entries

1. What records are kept of meat or poultry shipments that are refused entry into your country from other countries?

*Before disposition, Form 9530-1, Imported Meat and Poultry Reinspection Record;
Form 9840-3, Refused Notification;*

Form 9840-2, Establishment Refused Entry Log;

Form 9135-1, Notice of Shipment of Refused Entry Product, for Country-X only;

*Form 7512, Customs Form Transportation Entry and Manifest of Goods Subject to
Customs Inspection and Permit (Country-X only.);*

*After disposition, Form 9840-4, Voluntary Destruction of Imported Meat and Poultry
Product.*

FSIS Form 9530-1, "Defects in Container Condition"

FSIS Form 5110-1, "Services Rendered"

FSIS Form 9540-1, "Import Inspection Application and Report"

FSIS Form 9840-4, "Voluntary Destruction of Meat and Poultry Product"

MP Form 32, "United States Refused Entry"

*Customs Form 3499, "Application and Approval to Manipulate, Examine, Sample or
Transfer Good"*

*Customs Form 4613, "Order to Destroy and Record of Destruction of Forfeited,
Abandoned, or Unclaimed Merchandise"*

*Customs Form 7512, "Transportation Entry and Manifest of Goods Subject to Customs
Inspection and Permit"*

References: *Import Inspection Procedures Manual, Part 7, Sections 1 –3
Import Inspection Procedures Manual, Part 8, Sections 1, 4, 11, and 12*

2. What control procedures are in place to prevent this product from being re-exported to Country-X or mixed with other product being exported to the Country-X?

Product is stamped "U.S. Refused Entry" and retained in a separate area. Part 7, Section 3 of the IIPM states that imported meat and poultry products that do not comply with U.S. requirements are not allowed to enter U.S. commerce and will be identified as "U.S. Refused Entry Product." When this occurs, the broker/applicant has 45 days to either destroy, re-export, or convert the refused entry product to animal food. In certain cases, however, noncomplying product (the entire lot or partial lot) can be brought into compliance with U.S. requirements under the supervision of an FSIS inspector. Each shipping container and each carcass or parts of carcass, as applicable, of refused entry product shall be legibly stamped once with "U.S. Refused Entry"; unless the broker/applicant has requested either an appeal or further reinspection of the product to bring it into compliance with U.S. requirements. The location of the "U.S. Refused

Entry" imprint must be such that the refused entry product is easily identifiable. The import establishment shall designate an employee(s) to stamp refused entry products. Inspectors shall have control over the "U.S. Refused Entry" stamps at all times and keep an accurate count of the number of units stamped for each refused entry occurrence. For each lot of refused entry product, the import establishment shall inform the inspector as to the temporary storage location of the product. Each lot of refused entry product must be stored intact and segregated from other product at the import establishment, and be easily accessible for review by an inspector until properly disposed. On the days assigned to the import establishment, the inspector shall check all stored refused entry product and enter the verification dates onto FSIS Form 9840-2.

Reference: Import Inspection Procedures Manual, Part 3, Section 3

3. What procedures are in place to trace product and monitor shipments that are refused entry into your country from other countries?

A record of product refused entry into the United States is kept in the Automated Import Information System (AIIS). Refused product is stamped as such and can be identified through the forms noted in question 1. Product presented for importation must be accompanied by an import application and product certification, whereby the product is properly identified and can be matched with AIIS data on the product, such as origin establishment and country, product type, and rejection history.

In addition, FSIS Compliance Officers monitor refused entry products to ensure that they are re-exported within 45 days. If not re-exported within 45 days, action is initiated to seize the product.

*References: Import Inspection Manual, Part 2, Sections 1-2
Import Inspection Manual, Part 7, Section 3
Import Inspection Manual; Part 8, Sections 1 & 12.*

M. Control of Deceptive Labeling, Packaging, and Documentation

1. For each of the products under this application, what national and other government agencies enforce the relevant laws and regulations relating to the control of economic fraud? Include organizational charts for each of these agencies.

For Meat Products, the Food Safety and Inspection Service (FSIS) and the Federal Trade Commission (FTC) enforce the relevant laws and regulations. FSIS is a public health agency in the U.S. Department of Agriculture. FSIS protects consumers by ensuring that meat and poultry products are safe, wholesome, and accurately labeled. FSIS protects the consumer and other meat, poultry, and egg products producers from fraudulent practices that might give an unfair economic advantage to one producer over another or might misrepresent a product in economic value. Section 362.4 allows for the

withdrawal or denial of inspection service based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food, or fraud in connection with transactions in food, or any felony indicating a lack of the integrity needed for the conduct of operations affecting the public health.

Within FSIS, food inspectors and compliance officers collect samples of product for submission to FSIS laboratories to test for a variety of “economic” non-compliances, such as testing for species substitutions and/or the addition of water, filler, soy, and preservatives (such as sulfite, niacin, benzoate, etc.). The compliance program has the authority to institute legal proceedings against an establishment for alleged violations for cases involving economic fraud. They also initiate criminal cases involving misbranded products. For example, labeling ungraded beef as USDA Choice or non- Kosher as Kosher product.

The Enforcement Program of the Federal Trade Commission enforces orders that cover a wide variety of products, services, and consumer protection issues. It also administers and enforces more than a dozen statutes and rules. The Program works to improve compliance with orders and rules, seeking significant penalties when appropriate, and working cooperatively to ensure future compliance by companies that have acted in good faith and committed only technical or inadvertent violations.

*References: “Protecting the Public From Foodborne Illness: The Food Safety and Inspection Service (Backgrounder, January 1995)
9 CFR Section 362.4
<http://www.ftc.gov/>
<http://www.fsis.usda.gov/OM/ofo.pdf>
FSIS Directives 8100.1 and 8110.1*

[Charts or outlines of organizations are attached]

2. What is the functional relationship among these government agencies and between these agencies and any separate activities at state, provincial, or local levels?

The Federal Trade Commission (FTC) has broad jurisdiction over deceptive commercial practices involving false advertising associated with any product placed in interstate commerce, including misleading or false labels such as those on meat, poultry, or egg products that might be due to economic fraud. FSIS ‘s jurisdiction is more narrowly confined to labels on meat products. Both the FTC and FSIS may have preemptory rights over state and local governments in the United States with respect to such matters in certain circumstances; and they also work cooperatively with such governments on public health matters whenever appropriate

References: <http://www.ftc.gov/>
<http://www.fsis.usda.gov/OM/ofof.pdf>

3. What personnel, training, equipment/resources, and other facilities are utilized to enforce and fulfill the responsibilities of the meat and/or poultry inspection system regarding the control of economic fraud?

FSIS employs and trains approximately 7,936 Federal inspectors, including approximately 120 import inspectors, and approximately 175 compliance officers who have responsibilities related to the control of economic fraud.

References: <http://www.fsis.usda.gov/om/stats.htm>
<http://www.fsis.usda.gov/OM/ofof.pdf>

4. What actions are taken when deceptive labeling, packaging, or invoicing practices are discovered? What program official is responsible for taking this action?

Inspectors-in-charge have the authority to retain product and to order an appropriate investigation by compliance staff who may then refer the matter for appropriate enforcement action to the District Manager with jurisdiction. Section 329.2 states that any authorized representative of the Secretary shall detain any article or livestock to be detained under this part, by affixing an official "U.S. Detained Tag" (FSIS Form 8400-2) to such article or livestock. TITLE: 17.16, ACCEPTANCE; RESPONSIBILITY, states that all packaging materials must be safe for the intended use and may not cause adulteration of edible products. In addition, all packaging materials shall be identified by a brand name or supplier identification on shipping cases, invoices, or bills of lading which can be traced back to a particular material. The establishment is required to receive written guaranties from the suppliers of their food contact packaging materials. Official establishments shall retain in their files written guaranties that the materials are in compliance with the Federal Food, Drug and Cosmetic Act (FFDCA) as amended and all applicable food additive regulations. A guaranty is not required for packaging materials not in direct contact with meat or poultry products. The identity of all food contact packaging materials must be traceable to the applicable guaranty. USDA- issued acceptance letters for packaging materials may not be substituted for a guaranty. FSIS will permit use of a material on the basis of the supplier's guaranty unless there is a specific reason to doubt the acceptability of the material. The inspector should be alert to the use and performance of all food contact packages and packaging materials. The inspector may inspect and disallow the use of packaging material, and may retain any product in it if there is reason to doubt the acceptability of the packaging materials. Section 355.34 states that no certified product and no container thereof shall be labeled with any false or deceptive term, and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of the origin, quality, or quantity of the product shall appear on any label.

Title 18.80, Records, states that willful, false entries in warehouse records or certificates are subject to penalties of 18 U.S.C. 1001. Criminal penalties are also contained in the Agricultural Marketing Act (7 U.S.C. 1622(h)) and the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) for specified offenses, including certain false representation and unauthorized use of official marks or other identification devices.

Section 355.37 states that any statement of certification provided for by section 355.32(a)(4) must not be altered, defaced, imitated, or simulated in any respect or used for the purpose of misrepresentation or deception. Section 355.32 contains all the required information that must be on a product label.

*References: TITLE 17.16, Labeling: Acceptance; Responsibility
TITLE 18.80, Records
9 CFR Sections 355.34, 355.37, and 329.2*

5. What official review and approval of meat and poultry product labels is required prior to their use in your country?

9 CFR Section 355.34 states that no label shall be used on any container of certified products until it has been approved by the Administrator. Inserts, tags, liners, pasters, and like devices containing printed or graphic matter for use on, or to be placed within, containers and coverings of certified products shall be submitted for approval, except that inspectors in charge may permit the use of such devices if they contain no reference to the certified products and bear no misleading feature. Stencils, labels, box dies, and brands may be used on shipping containers, including tierces, barrels, drums, boxes, crates, and large- size fiberboard containers, without approval by the Administrator, provided the markings are applicable to the certified products, are not false or deceptive, and are used with the approval of the circuit supervisor.

Section 317.6 states that labels shall be used only on products for which they are approved, and only if they have been approved for such products: Provided, That existing stocks of labels approved prior to the effective date of this section and the quantity of which has been identified to the circuit supervisor as being in storage on said date at the official establishment or other identified warehouse for the account of the operator of the official establishment may be used until such stocks are exhausted, but not later than 1 year after the effective date of this section unless such labels conform to all the requirements of this part and Part 319 of this subchapter. Part 317 details all aspects of labeling meat products. Section 317.4 states that no labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to Food Safety and Inspection Service, and approved. The management of the official establishment or establishment certified under a foreign inspection system must maintain a copy of all labeling used, along with the product formulation and processing procedure. Such records shall be made available to any duly authorized representative of the Secretary upon request.

On December 29, 1995, (60 FR 67444), effective July 1, 1996, FSIS expanded the categories of products for which labeling can be approved generically by industry. For example, the rule allows Federal establishments to design and use labeling that conforms to the regulatory requirements for meat, poultry, and egg products that have standards of identity and composition defined in the regulations (9 CFR 319 and 381) or in the Food Standards and Labeling Policy Book. These labels do not require submittal to FSIS for approval prior to use. In addition, FSIS amended the Federal meat and poultry products inspection regulations to permit the submission of only sketch labeling, except for temporary approvals, in those instances where labeling is required to be submitted for approval and to require retention of certain labeling records.

The Agency also maintains a prior label approval system for reviewing and approving sketches and temporary labeling for certain categories of meat and poultry products that are not defined by standards of identity and composition; products that are prepared using novel production methods; products that are formulated with novel additives or ingredients; or products whose labeling bears nutrition, health, quality, or other types of claims. The final rule on PLAS also indicated that the Agency would implement a Generic Labeling Audit System (GLAS) to determine the extent to which Federal establishments are applying labeling regulations and policies in approving generic labeling, in compliance with the regulations. The Agency is currently developing this audit system. The prospective goals of PLAS include developing and implementing GLAS simultaneously to conducting PLAS, and to devote more time to devising a prior approval system that will be more consistent with Hazard Analysis and Critical Control Point (HACCP) systems and the labeling concepts of the future. The division will continue to review and approve labeling in a timely and efficient manner and accommodate representatives of industry and other representatives who wish to meet with staff members for consultation on any issues relating to labeling, standards, or ingredients. Labeling approvals are handled on a first-come, first-served basis, as they are delivered to the LCRD, including expedited labeling, labeling mailed directly to the division, and labeling delivered in person by representatives of the industry. As needed, representatives of industry and other representatives will have the opportunity to arrange appointments with division staff on a time-available basis to discuss novel product and ingredient issues and appeals, and to receive regulatory guidance. The LRB will continue, to the extent possible, to accommodate emergency situations regarding labeling approvals on a case-by-case basis. The Agency believes this procedural change will result in a more productive use of LCRD staffing resources, and most importantly, improve the quality of meat, poultry, and egg products labeling.

*References: 9 CFR Sections 355.34, 317.4, and 317.6
Federal Register of July 27, 1998 (Volume 63, Number 143)
Federal Register of December 29, 1995 (Volume 60 Number 250)*

6. How do you ensure the accuracy of packaging and labeling materials, health certificates, invoices, and export documentation? Describe the process in detail.

9 CFR section 320.1 states that every person, firm, or corporation within specified categories is required by the Act to keep records, including invoices, that will fully and correctly disclose all transactions involved in his or its business subject to the Act. These categories include:

Any person that engages, for commerce, in the business of slaughtering any cattle, sheep, swine, goats, horses, mules, or other equines, or preparing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food;

Any person that engages in the business of buying or selling (as a meat broker, wholesaler, or otherwise), or transporting in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any such animals;

Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules, or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter.

The records that are required include records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, giving the following information with respect to each transaction in which any livestock or carcass, part thereof, meat or meat food product is purchased, sold, shipped, received, transported, or otherwise handled by said person in connection with any business subject to the Act:

The name or description of the livestock or article;

The net weight of the livestock or article;

The number of outside containers (if any);

The name and address of the buyer of livestock or article sold by such person, and the name and address of the seller of livestock or articles purchased by such person;

The name and address of the consignee or receiver (if other than the buyer);

The method and date of shipment;

The name and address of the carrier.

Shipper's certificates and permits are required to be kept by shippers and carriers. A record of seal numbers is required to be kept by consignees of inedible products shipped under unofficial seals, as well as a record of new consignees of inedible products.

Records of processing procedures for cooked beef and roast beef are required.

Records of canning procedures and operations are required. Records are also required for: sample results and calculation results as required by processing procedures to destroy trichinae; nutrition labeling; calcium content in meat derived from advanced meat/bone separation machinery and meat recovery systems; all labeling, along with the product formulation and processing procedures; and guaranties provided by suppliers of packaging materials

As described in detail in Part 22 of the regulations, all products for export shall meet the importing country's requirements. Exporters are responsible for determining that they

comply with these requirements and providing the necessary documents. These requirements include a review of applicable labels and labeling requirements, packaging materials and specifications, incoming and outgoing health certificates, export documents, and product invoices. Inspectors are required to verify the accuracy of these determinations, including verification that the product was correctly processed and packaged according to country-specific or FSIS requirements. The labeling and packaging of all products is checked periodically, based on the performance of previous checks in each establishment. Inspectors insure that packaging materials are USDA-accepted and properly used. Letters of guaranty are on file certifying that packaging material that contacts product meets all requirements. Certificates, including Health Certificates, are completed under FSIS security. They are thoroughly proofread, minor alterations are initialed, and unused space is cancelled. Unusable certificates are voided.

With regards to the reinspection of export product at certified warehouses, Title 18.5, LOT INSPECTION; SAMPLING, requires the sampling of finished product to assure compliance with regulations, approved fabrication procedures, and labeling.

FSIS Directive 5400.1, Inspection System Guide, provides tasks to observe lots of received product for grade labeling and identification and to verify recording such product into the establishment's inventory record. It also provides for a review of records that provide information on supplies of nonmeat ingredients and/or packaging material. The inspectors also determine if nonmeat ingredients are properly identified and labeled and if restricted materials such as binders, extenders, etc., are stored in an acceptable manner and have a current and accurate inventory.

For imported products, port-of-entry re-inspection includes a review of the accuracy of packaging and labeling materials, health certificates, invoices and export documentation.

*Reference: 9 CFR Part 322
Import Inspectors Procedures Manual, Parts 5 & 8
FSIS Directive 5400.1, Inspection System Guide*

7. What regulations, policies, guidelines, and other requirements pertain to the labeling and invoicing of products? Briefly describe the intent of each regulation, policy, guideline, and requirement.

9 CFR section 320.1 provides for the record keeping requirement of all official establishments.

9 CFR section 325.11 provides labeling and invoice requirements for the denaturing and identification of inedible materials/product.

9 CFR section 317.024 provides invoicing and guarantee information for packaging materials.

TITLE: 18.20 provides labeling and invoicing requirements for non-meat ingredients and additives.

FSIS Directive 9080.1 provides labeling and invoicing requirements specific to export product.

FSIS Directive 5720.2 provides invoicing/recordkeeping requirements for cooperative inspection programs run by individual States.

For labeling queries:

9 CFR section 355.37 provides for the prevention of altered, defaced, imitated, or simulated labels for the purpose of misrepresentation or deception.

9 CFR section 355.35 provides label information to be displayed on the principal panel of the primary container.

9 CFR section 355.34 requires official approval of all product labels.

9 CFR section 355.33 provides for the embossing of the official establishment number onto metal containers.

9 CFR section 355.32 provides for the prominent display of information required on all inspected and certified product labels.

9 CFR section 354.60 provides requirements for labels and packaging material that bears any official identification.

9 CFR section 354.46 establishes that misrepresentation and deceptive or fraudulent acts or practices in connection with labeling and invoicing is subject to regulatory and judicial action.

9 CFR section 335.12 provides for withholding the use of official marks or identification by written notification to those whose product markings, labeling, or container size/form is false or misleading.

9 CFR section 327.15 establishes information required on the outside containers of foreign products, including marking/labeling, and the application of official inspection legends.

9 CFR section 327.14 provides for country of origin and other labeling and marking requirements on imported product.

9 CFR section 319.1 establishes labeling requirements for product in which standards of identity or composition are prescribed.

9 CFR section 318.4 provides labeling and invoicing requirements for establishments operate under the, soon to be outdated, FSIS Partial Quality Control program.

9 CFR section 318.23 provides for labeling requirements of heat-processed products.

9 CFR part 318 provides labeling requirements for various meat products.

9 CFR section 317.9 provides labeling requirements for equine products.

9 CFR section 317.8 provides prohibitions and requirements for product labeling and on product containers.

9 CFR section 317.7 provides permission for printing labels for foreign commerce.

9 CFR section 317.5 provides for the use of generically approved labeling.

9 CFR part 317 also provides for exemptions from nutritional labeling, special dietary-use labeling, and labeling for nutrient content claims.

FSIS Directive 7239.4 establishes requirements for the nutritional labeling of children's food.

References: See above listing

N. Product Standards and Formulations

- 1. How do you ensure that products exported to the Country-X meet Country-X standards? For example, how do you control and verify the quantity and/or percent of meat/poultry, added water, fat, or microorganisms in a product?**

In the United States, Federal inspectors verify the adequacy of process controls established by producers to assure that all applicable standards are met. FSIS Directive 7220.1 provides standards and formulations for various products produced by official establishments. Part 22 of the regulations provides the requirements that establishments must meet and inspectors must verify for product intended for shipment to specific countries. FSIS Directive 9080.1 describes special requirements which foreign countries may prescribe in addition to USDA requirements. FSIS Directive 9060.4 provides instructions to FSIS inspection personnel on the preparation of official export certificates, MP Forms 130 and continuation sheet, 414-3, 415-3, 415-4, 415-5, and USDA/FSIS Letterhead Certificate, the marking of boxes for export shipment, the re-certification of certified product, and the security of certificates and stamps. FSIS Directive 9040.1 provides responsibilities and procedures for re-inspecting and certifying product for export. These responsibilities and procedures apply whether the product is located at the establishment where produced, or off site, such as in a cold storage facility. FSIS Directive 9020.1 describes FSIS' responsibilities regarding exports, provides general requirements for export certification of meat and poultry products, and provides instruction on applications for export certificates.

The control and verification of microorganisms in or on a product, as stated in FSIS Directive 5400.5, is accomplished by way of the E. coli testing and Salmonella testing programs on raw product and Listeria testing on cooked products. FSIS Directive 10,240.2 states that FSIS will verify the adequacy of an establishment's HACCP system by determining whether each HACCP plan meets the requirements of 9 CFR Part 417, and all other applicable regulations. Verification activities include, but are not limited to, collecting and testing ready-to-eat product for microbial hazards. If samples test positive for a microbial hazard, action will be taken on product represented by the samples. Inspection personnel will determine whether the establishment is continuing to ship product that may be injurious to health and, if so, will withhold inspection. As provided in 9 CFR 417.6(e), the establishment's HACCP plan may be determined to be inadequate because adulterated product was produced or shipped. Note, the cause of a positive finding in ready-to-eat product varies from case to case, based on the pathogen or toxin found and the type of processing involved. For example, in many cases a positive result for Salmonella could indicate that critical limits in a HACCP plan were not met, while a positive for Listeria monocytogenes could indicate that there is a sanitation problem. Before deciding on a course of action, FSIS will consider the entire situation. This includes whether some or all other processes functioning under the same HACCP plan have been affected, what pathogens or toxins are involved, whether there have been any other incidents of contamination in the establishment associated with the pathogen or toxin, and whether there has been persistent and recurring noncompliance

in the establishment. FSIS Directive 10240.1 provides instructions, procedures, and actions pertaining to the FSIS Microbiological Monitoring Program. Information is provided on the current sampling and testing program for Listeria monocytogenes and Salmonella and provides inspection personnel with special instructions for sampling of cooked, ready-to-eat meat and/or poultry products for L. monocytogenes and Salmonella and for actions to be taken when samples test positive for these organisms.

*References: FSIS Directives 7220.1, 9080.1, 9040.1, 9020.1, and 5400.5
 FSIS Directives 10240.1 and 10240.2
 Part 22 of the Code of Federal Regulations
 9 CFR Part 417 and Section 417.6*

2. What are the microbiologic standards, if any, for raw product and for meat and/or poultry products after thermal, or other, processing? How are these standards used as a measure of effective and safe processing?

There is zero tolerance standard for E.coli O157:H7 in raw ground beef. As stated in 9 CFR section 310.25, FSIS has established Salmonella performance standards and m/M evaluation criteria for generic E.coli for carcasses and raw ground products under the PR/ HACCP rule. FSIS Directive 10240.1 and 9 CFR sections 318.2 and 318.9 state that cooked, ready-to-eat products should be free of bacterial foodborne pathogens, e.g., Salmonella, Listeria monocytogenes, E.coli O157:H7.

For E. coli testing of carcasses after slaughter, the evaluation criteria are:

EVALUATION OF E. COLI TEST RESULTS

<i>Type of Livestock</i>	<i>Lower Limit of Marginal Range</i>	<i>Upper Limit of Marginal Range</i>	<i>Number Tested(n)</i>	<i>Maximum Number Marginal Permitted</i>
<i>Cattle</i>	<i>Negative</i>	<i>100 CFU/cm²</i>	<i>13</i>	<i>3</i>
<i>Swine</i>	<i>10 CFU/cm²</i>	<i>10,000 CFU/cm²</i>	<i>13</i>	<i>3</i>

Test results that do not meet the criteria described above are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate.

For Salmonella testing of raw product, the performance standards are:

SALMONELLA PERFORMANCE STANDARDS

<i>Class of product</i>	<i>Performance Standard (percent positive for Salmonella)</i>	<i>(n) Number of samples tested</i>	<i>Maximum number of positives (c) to achieve Standard</i>
<i>Steers/heifers</i>	<i>1.0%</i>	<i>82</i>	<i>1</i>
<i>Cows/bulls</i>	<i>2.7%</i>	<i>58</i>	<i>2</i>
<i>Ground beef</i>	<i>7.5%</i>	<i>53</i>	<i>5</i>

Hogs	8.7%	55	6
Fresh Pork Sausages	30.0%	53	18
Broilers	20.0%	51	12
Ground chicken	44.6%	53	26
Ground turkey	49.9%	53	29

Regarding enforcement, FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard. If the first set of results meets the performance standard, the establishment is returned to ongoing random testing. If the first set of results fail to meet the performance standard, the establishment is required to take immediate corrective action and is placed on establishment specific targeted testing. A second set of samples should be collected. If the second set of results meets the performance standard, the establishment is returned to ongoing random testing. If the second set of results fail to meet the performance standard, the establishment is required to reassess its HACCP plan and is placed on establishment specific targeted testing. A third set of samples is collected. If the third set of results meets the performance standard, the establishment is returned to ongoing random sampling. If the third set of results fail to meet the performance standard, FSIS will suspend inspection services until the establishment submits satisfactory written assurances to the inspection authority that establishment deficiencies have been corrected.

*References: 9 CFR Section 310.25
Federal Register: July 25, 1996 (Volume 61, Number 144)
FSIS Directive 10240.1
9 CFR Sections 318.2 and 318.9*

3. What are the specific inspection-program responsibilities regarding the control of processed products?

9 CFR Section 304.3 states that before being granted Federal inspection, an establishment will develop written sanitation Standard Operating Procedures, conduct a hazard analysis, and develop and validate a HACCP plan. Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, conducted a hazard analysis, and developed and validated a HACCP plan. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan. In addition, before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan.

Establishments are required to validate that corrective measures are effective and that the HACCP plan measures process control. Establishments and FSIS are required to verify the adequacy of the HACCP system. Section 416.17 states that FSIS must verify

the adequacy and effectiveness of the SSOP and the procedures specified therein. Such verification may include:

Reviewing the SSOP;

Reviewing the daily records documenting the implementation of the SSOP and the procedures specified therein and any corrective actions taken or required to be taken;

Direct observation of the implementation of the SSOP and the procedures specified therein and any corrective actions taken or required to be taken; and

Direct observation or testing to assess the sanitary conditions in the establishment.

9 CFR Section 417.8 states that FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

Reviewing the HACCP plan;

Reviewing the CCP records;

Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

Reviewing the critical limits;

Reviewing other records pertaining to the HACCP plan or system;

Direct observation or measurement at a CCP;

Sample collection and analysis to determine the product meets all safety standards; and

On-site observations and record review.

9 CFR Parts 318 and 319 state that meat products produced by establishments must be sampled periodically for laboratory testing to assure compliance with all applicable identity and composition standards, chemical and biological residue control standards, and microbiological performance standards.

*References: Federal Register: July 25, 1996 (Volume 61, Number 144)
9 CFR Section 304.3
9 CFR Parts 318 and 319
9 CFR Section 310.25 and Parts 416 and 417*

4. Who develops processing procedures for individual establishments, and how are these procedures approved?

As noted in question 3. above, 9 CFR Section 304.3 indicates that each establishment is responsible for developing its own processing procedures, including a HACCP plan describing the process controls appropriate to those procedures. HACCP plans are developed through an extensive process of performing a thorough hazard analysis, setting critical limits, and establishing effective corrective actions. 9 CFR Part 417 states that establishments are required to validate that corrective measures are effective and that the HACCP plan measures process control. Establishments and FSIS are required to verify the adequacy of the HACCP system, based upon the specific processes

and procedures that take place in each establishment. i.e. HACCP plans and the analysis of hazards, including processing procedures and hazards, are specific to each establishment and are, therefore, assessed accordingly. Each establishment as well as FSIS personnel assess (verify) whether the HACCP system adequately addresses the control of processes within the establishment.

References: *Federal Register: July 25, 1996 (Volume 61, Number 144)*
9 CFR Section 304.3
9 CFR Part 417

5. How can inspectors or visiting program officials readily determine that approved processing procedures are in use? For example, are processing activities, procedures, and observations documented and are they filed with the inspection official at the processing facility?

All production processes and controls are documented in the HACCP plan that must include record keeping; including the records associated with plan validation, verification and a corrective action planning. These are available to FSIS upon request.

References: *Federal Register: July 25, 1996 (Volume 61, Number 144)*
9 CFR Part 417

6. How are raw materials, formulations, yields, and product identification evaluated or controlled?

Regulations in 9 CFR Part 318 describe the standards of identity for evaluating and controlling raw materials, ingredients, formulations, and yields for selected products. 9 CFR Part 417 requires that establishments conduct a hazard analysis covering all aspects of an establishment, including the control of the processing and movement of raw materials, the accuracy of product formulations and yields, and the identity of products, ingredients, additives, etc.

FSIS Directive 10230.1 states that inspection program employees must inspect products as often as they deem necessary to ascertain that they are not adulterated or misbranded when they leave the establishment and that they comply with the requirements of the regulations. Product suspected of being adulterated or misbranded shall be retained by the employee for further inspection and, if found to be adulterated or misbranded, is subject to condemnation and disposal. FSIS Directive 7236.2 states that FSIS inspectors assigned to establishments subject to or participating in the nutrition labeling program must continue to observe and monitor product formulations and processing procedures to assure conformance with general labeling requirements. FSIS Notice 78-110 states that, the identity of the ingredients be sufficient to assure that (1) the meat and/or poultry product formulations are accurate, (2) the meat and/or poultry product labels reflect all required ingredient in correct order of predominance, and (3) restricted ingredients are used according to regulations. 9 CFR Section 354.71 states that no official identification or any abbreviation, copy, or representation thereof may be affixed to or placed on or caused to be affixed to or placed on any product or container thereof except by an

inspector or under the supervision of an inspector. All such products shall have been inspected and certified. The inspector shall have supervision over the use and handling of all material bearing any official identification. In addition, each container of inspected and certified products to be shipped from one official establishment to another official establishment for further processing shall be marked for identification.

*References: 9 CFR Parts 318 and 417
MPI Notice 78-110
FSIS Directive 7236.2*

7. How do you control the use and storage of restricted ingredients? Describe the controls in detail.

Procedures for tagging chemicals, non-chemical ingredients, or other food additives deemed "unfit or otherwise unacceptable" are described in 9 CFR Section 318.15. When any chemical, preservative, cereal, spice, or other substance is intended for use in an official establishment, it shall be examined by a Program employee and if found to be unfit or otherwise unacceptable for the use intended, or if final decision regarding acceptance is deferred pending laboratory or other examination, the employee shall attach a "U.S. retained" tag to the substance or container thereof. The substance so tagged shall be kept separate from other substances as the circuit supervisor may require and shall not be used until the tag is removed, and such removal shall be made only by a Program employee after a finding that the substance can be accepted, or, in the case of an unacceptable substance, when it is removed from the establishment.

FSIS Directive 5400.1 specifies inspector tasks related to the receiving and control of incoming products and materials. Inspectors must ensure that restricted materials such as binders, extenders, etc., are stored in an acceptable manner, with current and accurate inventory maintained as applicable. Such materials must be stored on racks or closely arranged and frequently moved to facilitate cleaning and inspection. The use and recordkeeping of restricted materials and ingredients, such as weighing, handling, and storage, in an establishment is periodically monitored, observed and verified by FSIS inspectors.

Title 18.21 of the regulations states that each restricted ingredient must be properly identified and individually weighed into separate containers in single batch formula amounts. If a mixture is prepared containing both restricted and nonrestricted ingredients (excluding non-fat dry milk (NFDM), cereal, soy products). "Single- batch" formula amounts of the mixture are weighed. Each container must bear (a) product name; (b) each ingredient listed in predominant order; (c) percent of restricted ingredients; (d) net weight of mixture and total weight of batch; (e) a statement including that "the establishment certifies that a sample of the lot has been chemically analyzed, found acceptable and within label's limitation, and that "X" pounds of the mixture in "X" pounds of raw product will produce a finished product complying with regulations." Source ingredients for any mixture shall be available for sampling before mixing. Finished mixture shall be available for verification sampling before use.

Title 18.32 of the regulations states that establishment management is expected to (1) control all restricted ingredients and procedures--curing, smoking, chilling, etc.--to assure product compliance, and (2) adopt uniform procedures to prevent product variations. FSIS inspectors must assure that product meets regulation requirements. They should (1) know the establishment's production practices and control procedures to evaluate their effects on finished product; (2) frequently observe amount of ingredients used; and (3) calculate percent of curing solutions injected into product to assure restricted ingredients are properly used, and pumping procedures are uniform.

FSIS Directive 4110.2 states that establishments must submit processing procedures so that the inspector can monitor the use of restricted ingredients and processing procedures.

*References: 9 CFR Section 318.15
FSIS Directive 5400.1
FSIS Directive 4110.2
Titles 18.21 and 18.32*

8. What enforcement and regulatory actions are taken when manufacturers fail to comply with product standards or approved formulations? How is the product handled, controlled, and identified?

Compliance failures are first brought to the attention of establishment management for corrective action. A recurring pattern of such failures are brought to the attention of FSIS compliance officers for investigation and enforcement action by the appropriate District Manager. Product may be tagged as detained and retained or, if appropriate, recalled. A continuing pattern of serious failures may lead to prosecution for economic fraud in the proper circumstances, under the appropriate parts of Section 1 of the FMIA or Section 9 of the PPIA.

FSIS Directive 5400.1 provides for inspection tasks that the Performance Based Inspection System periodically requires of FSIS inspectors. Inspectors must ensure that the establishment has properly identified facilities for retained product of a size commensurate with need and that the security of retained product is maintained pending disposition. Facilities must provide appropriate refrigeration for the retained product, if required. If results do not meet compliance standards, inspectors initiate appropriate action. For returned product, inspectors ensure that the returned goods are received into the designated area and not diverted to edible usage until they are released by FSIS personnel. Inspectors ensure the proper disposition of returned goods and that appropriate corrective and preventive actions are taken, as required. In regards to restricted product, "Passed for Cooking" product is under the direct control of FSIS until the applicable treatment accomplished. "Passed for Refrigeration" or "Passed for Heating" product is under direct control of FSIS until the applicable treatment is accomplished. The establishment is responsible for contacting FSIS prior to initiating applicable treatment.

In regards to product having Trichinae Treatment, the inspector must ensure that all applicable products are treated to destroy trichinae by approved methods (heating, freezing, curing, etc.) as required and have approved and documented controls in place to certify treatment (inventory, security, recording devices, records, hi-lo thermometers, etc.). If the results do not meet compliance standards, inspectors must initiate appropriate action. Inspectors also verify instrument accuracy with over/under thermometer and check to determine that regulated control procedures are on file, adhered to, and properly recorded. Inspectors ensure that Trichinae-treated or-tested (certified) pork is segregated and properly identified and used in all applicable products.

Section N., question 2 of this questionnaire provides the enforcement actions that FSIS initiates when designated raw products “fail” the Salmonella performance standards (as specified in 9 CFR 310.25). Three consecutive failures result in the suspension of the government inspection service.

*References: Federal Meat Inspection Act (21 U.S.C. 1)
FSIS Directive 5400.1, Process No. 08
9 CFR 310.25*

O. Sampling Program

1. What kinds of sampling or testing programs are in place to evaluate the occurrence of fraudulent practices?

Section 355.26 of 9 CFR states that samples of certified product, water, chemicals, flavoring, or other articles are taken for examination as often as inspection deems necessary. FSIS Directive 7221.1 states that when an audit request is received by an inspector to select finished product labels for review, samples are gathered to determine if the label accurately reflects the finished product. Section 318.2 states that all products are sampled and reinspected as often as is deemed necessary to ensure that products are not adulterated or misbranded, using a statistically sound sampling plan. The sampling plans are developed for individual products.

FSIS Directive 10,230.1 requires that cooked products or like-products are sampled for species identification and outlines the actions to be taken when an undeclared species is found. Inspection program employees inspect product as often as they deem necessary to ascertain that the products are not adulterated or misbranded. This includes the substitution of another ingredient for a particular valuable ingredient. The identity of the finished product and its ingredients must be as described on the label. FSIS has also developed in-establishment testing procedures capable of identifying pork, poultry, and beef in uncooked, formed meat and poultry products.

FSIS Directive 5400.1 establishes a list of tasks/activities that an inspector is scheduled to perform in response to a performance based system. The Directive states that the ingredients in processed sausage must be properly identified and that the sausage must be blended and formulated as per the label. In addition, samples must be taken to

determine if the rework used in cooked sausage meet the levels and parameters specified in Title 18.24 (a) (5). Samples are taken to determine that natural and artificial casings are properly identified. Samples are taken by inspectors to determine the yield in pre-cooking operations of brown and serve sausages. Samples are taken to determine the internal temperature of cooked and smoked products and the “shrink” associated with cooking and chilling product. Samples are taken to determine the formulation of pickling and water-based (for tenderization, marination, curing, etc.) solution with restricted and other ingredients. Inspectors verify the formulation and addition of other ground ham or trimmings to ground ham. The Directive lists tasks/activities that require internal product temperature checks to be taken on cooked products. Net weights and drain weights are checked. Cooler shrink is check on chilled product. Samples are taken to determine if the meat, poultry, and/or nonmeat ingredients are properly identified and formulated as shown on the posted formula and product standard. Calculations from selected product samples ensure that cooked meat/poultry substituted for fresh meat/poultry meets the standard. Samples are taken to ensure that fill weights, meat content formulation, and non-meat ingredients are in compliance. Samples are selected to check carcasses and parts to be boned for foreign material and defects. Samples are taken to check the pH of shelf-stable acidified products that are not heat-treated. The moisture/protein ratio is checked on applicable products through regular, systematic sampling. Random samples are taken to determine the percent fat and percent added water in applicable products.

FSIS Directive 7330.1 requires FSIS to monitor the levels of fat and added water in finished cooked sausage products. FSIS Directive 7140.3 requires a determination of the amount of added water in fresh sausage. FSIS Directive 7310.6 requires that establishments monitor product processes to ensure compliance with the regulations. Section 319.107 states that the weight of cured pork bellies must not exceed the weight of uncured pork bellies. FSIS Directive 10,520.1 requires pumped bacon to be sampled for nitrosamines. The sampling and analysis program used depends on test results and the processing procedures used. Cured pork products, according to FSIS Directive 7110.2, are sampled and analyzed under the PFF (protein, fat free) sampling program. FSIS Directive 8821.1 requires that boneless manufactured meat be reinspected.

FSIS Directive 917.1 states that District Offices must initiate surveillance procedures to sample and test for residues in meat and poultry, using established sampling programs for violative residue findings and actual violations. FSIS Directive 10,530.3 describes the Contamination Response System and requires that FSIS respond to a sampling program designed to detect, monitor, reduce, and control residues from animal drugs, pesticides, and other chemicals and contaminants in meat and poultry products. FSIS 10,520.1 requires the development of sampling plans to detect specific residues in response to residue contamination of product.

*References: FSIS Directives 7221.1, 10230.1, 5400.1, 7330.1, and 10520.1
FSIS Directives 7110.2, 8821.1, 917.1, and 10530.3
Title 18.24 of the Code of Federal Regulations
9 CFR Sections 355.26, 318.2, and 319.107*

2. What laboratory procedures are used by your inspection officials to determine compliance with product standards and formulations? What procedures are used to evaluate fraudulent practices? Identify the approved procedures and methods.

FSIS Notice 17-96 dated 7-12-96 and FSIS Directive 10,240.1 require that all samples of cooked, ready-to-eat products to be analyzed for Salmonella or Listeria monocytogenes are sent to one of the FSIS Technical Support Laboratories. Some ready-to-eat products are also tested for E. coli 0157:H7 and/or staphylococcal enterotoxin. Raw ground or comminuted beef or veal is tested for E. coli 0157:H7. FSIS Directive 10,210.1 lists all the directed sampling programs (chemical, residue, microbiological).

(See Attachment)

SIFT Kits are used by inspectors to test raw meat tissues for species identification as initial screen tests. Presumptive positive samples indicating product adulteration are then sent on to an appropriate FSIS Technical Support Laboratory for further analytical confirmation. Cooked meat species identification can be performed by FSIS laboratories or by one of the FSIS recognized laboratories listed below:

ABC RESEARCH CORPORATION

*Ms. Karen B. Little
3437 SW 24th Avenue
Gainesville, FL 32607
352-372-0436*

ELISA Technologies, Inc.

*Mr. Bruce W. Ritter
Progress Center
One Progress Blvd, B-28
Alachua, FL 32615
904-462-4546*

QCm, Inc.

*Mr. Brian Bannach
1205 Industrial Highway
Southampton, PA 18966
215-355-3900*

Inspectors also use various screen tests (STOP, CAST, and FAST) in the establishments to test slaughter animal carcasses for the presence of antimicrobial residues. Screen test positive tissues are sent to FSIS Technical Support Laboratories for further analytical confirmation testing.

FSIS also requires chemical analyses of certain products to ensure that they meet product standards. 9 CFR sections 319.000, 319.5, and 318.24 state that "Mechanically Separated (Species)" shall have been produced by an establishment under an approved

*plant quality control system. The Administrator shall receive, evaluate, and approve requests for plant quality control in accordance with section 318.4(d)(1) and (2) and (e) of this subchapter. Such a plant quality control system shall provide the controls and information necessary to assure that the product will meet the requirements described in section 319.5(a) and to enable establishment personnel and program employees to monitor the system for effectiveness. The system shall include a written description of the methods used by the establishment to maintain uniformity of the raw ingredients used in manufacturing product, to control the handling and processing of the raw ingredients and the finished product, and shall contain provisions for chemical analyses of the product and other procedures to determine and assure compliance with standards for the product. For purposes of this paragraph, a lot shall consist of the "Mechanically Separated (Species)" designated as such by the operator of the establishment or his or her agent from the product produced from a single species of livestock in no more than one continuous shift of up to 12 hours. All units of any lot must be available for inspection by program employees. Analysis of a sample of at least 1 pound from each lot to verify contents of fat, protein, and calcium in "Mechanically Separated (Species)" shall be performed by the operator of the establishment or his or her agent to assure that finished product will meet the requirements in section 319.5(a), except that such analyses with respect to fat, protein, and calcium content shall be required to be performed with respect to only one randomly selected lot of every five lots if the preceding ten analyses and all such analyses performed by the Department during the preceding ten analyses period establish compliance with the requirements of section 319.5(a), and that no analyses with respect to fat or protein content shall be required where the finished product is represented as product for processing. An analysis of a sample of at least 1 pound to verify essential amino acid content and/or protein efficiency ratio in "Mechanically Separated (Species)" shall be performed by the operator of the establishment or his or her agent at the rate of at least one per month during production to assure that finished product meets the requirements of section 319.5(a), except that such analyses with respect to essential amino acid content and/or protein efficiency ratio shall be required to be performed only once every 6 months if the preceding three analyses and all such analyses performed by the Department during the preceding three analyses period establish compliance with the requirements of section 319.5(a). Finished product samples shall be analyzed in accordance with "Official Methods of Analysis of the Association of Official Analytical Chemists", (AOAC), " *** CHANGE 9-6, * * * 15th edition, 1990, sections 960.39, 976.21, 928.08 (Chapter 39), and 940.33 (Chapter 45), which is EFF. DATE 6/30/94 *** incorporated by reference, or if no AOAC method is available, in accordance with the "Chemistry Laboratory Guidebook," U.S. Department of Agriculture, Washington, DC, March 1986 edition, sections 6.011-6.013, Revised June 1987 (pages 6-35 through 6-65). *** CHANGE 94-6, The "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. EFF. DATE 6/30/94.*

Part 18 of the regulations, Re-inspection and Preparation of Product states that an effective AQC program must assure process control and compliance with yield requirements determined by chemical analysis. In corned beef hash, for example,

although inspection control is the principal basis for determining compliance with regulations, results of chemical analysis can be used to supplement this control. The results of analysis for fat and moisture are to be used as a basis for determining whether or not product is in compliance with respect to these components (and is an indicator of economic fraud and fraudulent practices) since limits on these are based on finished product. For ham trimmings, to be labeled as ham, cannot contain excess shank meat. The fat content will not exceed 35%. It will consist of at least 65% lean meat as determined by chemical analysis.

FSIS Notice 52-95 informs inspection personnel of what analyses may be requested on an FSIS Form 10,600-1, Domestic Chemical Laboratory Report, dated 6/94, and when inspector-generated samples are warranted. When completing an FSIS Form 10,600-1, Domestic Chemical Laboratory Report, dated 6/94, inspection personnel should request only those analyses necessary to determine compliance of a product with a specific standard or regulatory requirement that cannot be determined by formulation verification. Example: to determine compliance of cooked frankfurters, the analyses requested should be limited to fat and added water. Compliance of other ingredients or factors, such as maximum internal temperature, sodium nitrite, ascorbate, soy protein, or other non-meat proteins, should be determined by in-plant verification tasks rather than by chemical analysis. Routine food chemistry sampling is directed by the Performance Based Inspection System, the Protein-Fat-Free Compliance Monitoring System, and the Bacon Nitrosamine Monitoring System.

FSIS Notice 51-95 states that establishment management must control any product found contaminated with lead shot and immediately notify inspection personnel for proper disposition. Inspection personnel must ensure that such product is under control and, because lead shot is often embedded below the surface, require that establishment management follow the provisions of FSIS Directive 7310.4, Revision 2, dated 12/28/93, Foreign Particle Contamination of Meat or Poultry Products. However, FSIS Directive 7310.4, Revision 2, dated 12/28/93 is not applicable to product contaminated with subdivided lead shot (See Part VI. E. of FSIS Directive 7310.4). Because a magnet attracts steel but not lead, it can be used in most cases to discern lead shot from steel shot. If there is any doubt as to whether or not the shot consist of lead or other toxic substance, it is establishment management's responsibility to make that determination including, if necessary, chemical analysis. It is reasonable to conclude that lead shot in ground, emulsified, or chopped meat has been subdivided. Therefore, unless establishment management can demonstrate to inspection personnel's satisfaction that all lead shot is intact, such product is subject to condemnation.

FSIS Directive 7140.3 states that if fresh sausage is suspected of containing excess added water, the inspection service is to take three samples and submit them for chemical analysis.

FSIS Directive 10530.2 ensures that livestock and poultry produced for slaughter do not contain violative levels of chemical residues. Contaminants may leak into water supplies because of improperly protected toxic waste dumps, chemical spills or other reasons.

Since such contaminants are often colorless and tasteless, they can only be discovered through laboratory analysis. As a preventive measure, water given to an animal must be tested for contaminants twice a year at the expense of the applicant. If the water tested is found to be contaminated, such water must not be used for an animal covered by an official memorandum-of-understanding (MOU). An animal that has consumed contaminated water must not be sent to slaughter until it is determined that the animal does not have any violative levels of chemical residues.

FSIS Directive 10530.1 states that an integral part of FSIS's inspection program is the National Residue Program (NRP) which includes monitoring, surveillance, and the Contamination Response System (CRS). Under the NRP, FSIS samples, detects, reduces, and controls residues of drugs, pesticides, and other potentially hazardous chemical adulterants in meat and poultry products. In addition to utilizing regulatory control measures, NRP promotes residue prevention through interagency programs for producer education and through incentives for producers and processors to develop residue quality assurance programs. Samples of meat and poultry are collected for analysis at federally inspected slaughtering establishments producing domestic products and at ports of entry receiving import shipments. The presence of violative residues leads to the investigation and control of the movement of suspected and known adulterated product and to the identification of producers marketing animals with adulterating residues. When a potential or known residue crisis is identified under the NRP, CRS is activated. The CRS utilizes the resources of all relevant FSIS headquarters and field units through an interdisciplinary team whose goal is immediate action for problem resolution. The NRP demands a concerted effort by all programs within FSIS.

*References: FSIS Notices 17-96 and 52-95
FSIS Directives 7140.3, 10,210.1, 10,240.1, 10,240.2, and 10,010.1
USDA/FSIS Microbiology Laboratory Guidebook, 3rd edition, 1998
Test Antimicrobial Screen Test (FAST) for Detection of Antibiotic and
Sulfo-amide Residues in Livestock Kidney Tissues, A Self-
Instructional Guide, 1994, USDA, FSIS
Part 18 of the Regulations
9 CFR Sections 319.000, 319.5, and 318.24
FSIS Directives 10530.1 and 10530.2*

3. What additional reasons would you have, if any, for sampling product intended for export to Country-X?

Product is inspected to ensure that only normal-appearing cartons/containers are shipped from an establishment, according to section 318.309 of 9 CFR..

The United States reviews the applicable chemical and biological residue standards of each of the foreign countries to which it exports meat, poultry, and egg products and, when necessary to meet another importing country's level of protection, the US institutes an appropriate testing program taking such samples as may be needed. (See, e. g., the US-EU Agreement regarding residue controls.)

Species verification is required of product imported into the U.S. and exported from the U.S., for example:

9 CFR Section 319.6(a) states that meat food products required to be prepared from one species shall not contain Mechanically Separated (Species) of any other species. Section 319.500 states that meat pies such as "Beef Pie," "Veal Pie," and "Pork Pie" shall contain meat of the species specified on the label, in an amount not less than 25 percent of all ingredients including crust and shall be computed on the basis of the fresh uncooked meat. Section 319.312 states that "Pork with Barbecue Sauce" and "Beef with Barbecue Sauce" shall contain not less than 50 percent meat of the species specified on the label, computed on the weight of the cooked and trimmed meat. Section 319.304 states that meat stews such as "Beef Stew" or "Lamb Stew" shall contain not less than 25 percent of meat of the species named on the label, computed on the weight of the fresh meat. Section 319.15 fabricated beef steaks, veal steaks, beef and veal steaks, or veal and beef steaks, and similar products, such as those labeled "Beef Steak, Chopped, Shaped, Frozen," "Minute Steak, Formed, Wafer Sliced, Frozen," "Veal Steaks, Beef Added, Chopped-Molded-Cubed- Frozen, Hydrolyzed Plant Protein, and Flavoring" shall be prepared by comminuting and forming the product from fresh and/or frozen meat, with or without added fat, of the species indicated on the label.

*Reference: 9 CFR Sections 318.309, 319.304, 319.312, 319.500, 319.6
FSIS Notice 26-86
FSIS Directives 5400.1, 5400.5, and 7220.1*

4. What is the significance or impact of laboratory findings in determining product acceptability?

FSIS Directive 5400.1 states that if the results of the above sample-checks do not meet compliance standards, then inspection program officials are to initiate appropriate corrective actions.

Product may be detained, retained, destroyed or recalled for failure to meet applicable standards.

*References: FSIS Directive 5400.1
Federal Meat Inspection Act (21 U.S.C. 1)*

P. Inspection Controls

1. What inspection or other procedures are used to ensure that meat and/or poultry products prepared for export to Country-X meet the established criteria?

Part 22, Subpart 22-B, states that all products must meet the importing country's requirements and that exporters are responsible for determining that the product complies with the requirements and providing the necessary documents.

When off-premises freezers are used, Part 18 of 9 CFR, required inspectors to visit the facilities as often as it is necessary to ensure the proper handling of the product. The freezers are required to meet applicable facility and product handling requirements. In addition, section 325.3 of 9 CFR, requires that any product destined for export, must meet the same certification requirements as domestic product when transported within the United States. Section 322.3 states that the transfer of product from vehicle to vehicle must be performed, as needed, under supervision of a USDA inspector. The inspector ensures that product identity is maintained, that the product is or remains eligible for certification, and that it is handled in a sanitary and proper manner, as per Part 350 of the regulations.

Section 322.1 requires that the outside container of inspected and passed product must be marked with an official export stamp (see also FSIS Directive 9020.1), bearing the number of the export certificate (see also section 316.13 (c)). Page 70 of FSIS Directive 7220.1, Rev. 3, dated 3/23/94, requires that products for export must bear labeling acceptable to the country of destination. Establishment management must adequately assure inspection personnel that product ingredients are of domestic origin, if the "Product of U.S.A." label is used.

Section 318.8 safeguards foreign countries from products made from preservatives and other substances not permitted in that country by requiring that product packaging and preparation meet foreign purchaser specifications, do not conflict with the country's laws, and meet export labeling requires. The inspector-in-charge is responsible for ensuring that the identity of the product is maintained conclusively. The contents of any product container must not be removed prior to exportation unless a program employee supervises the process. Repackaging or product destruction is also supervised by the program employee.

FSIS Directive 9020.1 dated 5/15/84 provides the general requirements for export product regarding product eligibility, inspection requirements, and labeling. Product is eligible if it is federally inspected and meets importing country requirements, reinspected immediately prior to exportation (FSIS Directive 9040.1 and section 322.2), marked and labeled as required, accompanied by inspection and other certificates, and handled in a sanitary manner. Minimum inspection requirements that the establishment must perform involve adequate space for inspection, freedom from dust, vermin, rodents, odors..., proper equipment services, adequate lighting, adequate hand/equipment cleaning/sanitizing facilities and equipment, an approved exposed product examination area, and trained personnel to assist the government inspector. Labels are approved only if they meet the specifications of the foreign purchaser, do not conflict with any laws of the destination country, and do not misbrand the product.

Special export requirements are outlined in FSIS Directive 9080.1 dated 9/6/84. Establishment construction, equipment, and procedures must meet importing country requirements. Specified requirements must be met and the establishment must be officially approved (via an FSIS survey and form approval) before it can produce and export a country's product.

The inspection of establishments and facilities that produce and export product to other countries is based on inspector discretion and knowledge and on the performance and compliance of the establishment/facility. FSIS Directive 5400.1 establishes a list of tasks that can be performed by inspection personnel, including obtaining pertinent information concerning product, carrier, and producer identity and verifying or ensuring that the product meets all foreign requirements, the product is of current production, export facilities are acceptable according to the product to be produced and exported, personnel are adequately trained, proper sampling of the product is performed, containers are in an acceptable condition, frozen samples (when taken) remain in an acceptably frozen state, only product in good condition is exported, slaughter dates are provided, export stamps are used properly, product certification is completed under FSIS security, and copies of the certification are distributed appropriately.

An official export-product certificate is required before a vessel, having on board any product for export to a foreign country, receives clearance, as per section 322.4 of 9 CFR. Section 322.2 states that only one certificate can be issued for each consignment and that the certificate must bear a serial number and contain adequate information to track the product, the exporter, and the consignee. Section 354.140 also requires that each certificate show the appropriate information for tracking the production and handling of the product.

FSIS Directive 9060.4 states that export-product certificates indicate that the inspector has officially authenticated that the product was inspected and passed (see also section 322.2), sound, wholesome, correctly labeled, and meets all the applicable foreign country requirements. Section 312.8 (b) states that the certificate certifies that ante- and post-mortem inspections were performed, the animals/carcasses were in healthy and sound condition, and that the product was inspected and passed as provided by USDA laws and regulations and was sound and wholesome. FSIS Directive 9040.1 states that product identity and eligibility for export will be determined upon reinspection and that the level of inspection can be increased in response to consumer complaints from foreign countries. Product lots are individually inspected, where a lot can consist of only one type of product and originate from only one establishment. Provisions are in place to remove and test samples from the lot. Sensory evaluations by inspectors are used to locate off-condition and/or improperly handled or stored product.

Finally, section 322.2 of 9 CFR states that carriers of export product can only receive clearance if a copy of the certificate (or a prescribed certificate reference) has been presented to Customs. Copies are also kept at prescribed office locations.

*References: Parts 18, 22, and 350 of the Code of Federal Regulations
9 CFR Sections 325.3, 322.3, 322.1, 316.13, 318.8, 322.2, and 322.4
9 CFR Sections 354.140 and 312.8
FSIS Directives 7220.1, 9040.1, 9080.1, 5400.1, and 9020.1
FSIS Directive 9060.4*

2. What is the frequency of supervisory visits to the slaughter or processing facility? What areas are reviewed and how are the findings reported? What follow-up procedures are in place?

Title 6.7, Supervisory Visits, states that supervisors are responsible for inspection and all activities that might affect inspection in establishments under their supervision. Supervisors must visit official establishments during “other-than-normal” operating hours to observe sanitation, evidence of unauthorized operations, and other applicable activities. Title 18.81, Inspection, states that supervisors must visit warehouses and other re-inspection facilities, unannounced, on a biweekly basis. The supervisor checks records, files, premises, operations, sanitation, and inspection procedures. The findings are reported to the District Manager, kept on file, and can become evidence for withdrawal of service, if necessary.

References: Titles 6.7 and 18.81 of the Code of Federal Regulations

3. In establishments that export to Country-X, how do you ensure that establishments and specific areas of operation are adequately staffed with assigned inspectors? For example, how would you determine staffing needs based on an evaluation of facilities and operating practices?

Section 310.1 of 9 CFR establishes staffing standards on the basis of the number of carcasses to be inspected per hour. Multiple inspector lines are also based on a rotation of inspectors to different inspection stations to equalize workloads and maximize efficiency. The inspector-in-charge of an establishment has the authority to reduce slaughter line speeds because of deficiencies in carcass preparation/presentation and because animal health needs may require more extensive inspection. Tables are provided that indicate maximum slaughter speeds and the number of inspectors to use per station. These standards, for cattle, are provided for inspection using the viscera truck, for inspection using the viscera table (tongue-in presentation of heads), and for inspection using the viscera table (tongue-out presentation of heads). In swine, staffing standards are based upon the observation, rather than the palpitation, of the spleen, liver, heart, lungs, and mediastinal lymph nodes. As in cattle, the standards depend on the distance an inspector has to walk and on the use of a mirror.

FSIS Directive 4312.1, Position Management, requires that managers develop and maintain staffing patterns. Supervisors are required to identify needed changes in workflow, job content, and staffing to more effectively accomplish the work of the unit and organization. They also recommend any necessary adjustments in the staffing pattern to the District Office. The Personnel Division provides managers and supervisors with guidance and assistance and monitors the structure and content of positions. In addition, Personnel issues approved staffing patterns for FSIS employees every six-months. FSIS Directive 4300.5, Details of Personnel, requires that FSIS provide needed assistance when a shortage of personnel or an exceptional volume of work requires additional personnel at an establishment or establishments. FSIS must also meet staffing needs due to unforeseen workloads, changes in Agency mission or

organization, unanticipated absences, and situations where employees are unable to work at their regular assignment.

The staffing of Veterinary Medical Officers is dictated by FSIS Directive 1030.3, VMO Staffing Guidelines. The Directive provides a uniform procedure for documenting VMO staffing requirements. The numeric guidelines and factors are validated against information provided by each District Office, provided to the Resource Management Staff in Washington, D.C. In addition, inspection circuits are maintained by providing a detailed listing of all in-establishment inspectors for each circuit for each establishment, including a profile of circuit/establishment staffing, as required in FSIS Directive 1010.2 Rev. 1, Circuit Maintenance Guidelines.

In order to effectively and efficiently utilize FSIS resources, second shift staffing needs are determined using FSIS Notice 41-95, Guidelines for Approving A Second Shift For Establishments. Section 307.4 (c) of 9 CFR states that additional shifts must meet requirements as determined by the Administrator or his designee. In addition, staffing needs can be met by cross-utilizing trained State inspectors or inspectors from other federal agencies, such as the Agricultural Marketing Service. FSIS Directive 5110.2 states that cross-utilization should be used to avoid dual staffing with grading services. FSIS Directive 5720.2 states that for Cooperative Inspection Programs, the cross-utilization of State personnel should be used for the effective use of personnel and to avoid dual staffing.

If an establishment has compliance problems, FSIS Directive 8830.1, PEA Stages I, II, II, requires that District Managers (DM) make the necessary staffing adjustments of Inspectors-in-Charge, Circuit Supervisors, and inspectors to assure compliance with progressive enforcement requirements, as needed. The DM will arrange for details of qualified inspection personnel into applicable establishments and remove any rotation schedule or pattern, where applicable.

FSIS Directive 10,530.1, National Residue Program, requires that District Managers determine in-establishment staffing needs and set priorities to assure adequate residue monitoring and surveillance. The Circuit Supervisor must monitor in-establishment staffing needs and set priorities to assure an adequate residue control system.

The FSIS Notice dated 1-13-99 provides information to inspection personnel for planning and executing inspection activities, depending on whether the establishment has implemented HACCP or not (i.e. patrol assignment configurations). The directive affects the assignment of inspection tasks and, therefore, staffing needs.

In Cooperative Inspection Programs, FSIS Directive 5720.2 states that staffing patterns must be described by the applicable resource management personnel and that they are to have enough employees to carry out the responsibilities assigned to all organizations, units, and functions. According to FSIS Directive 5710.1, when a State inspection program is designated for Federal inspection, surveys must be performed of all known

establishments to identify the minimum staffing required to operate under Federal inspection.

Section 327.2 of 9 CFR requires that for inspection systems that export to the United States, the organization and staffing of the inspection system, including all establishments, must ensure the uniform enforcement of the requisite U.S. laws and regulations.

*References: 9 CFR Sections 310.1, 307.4, and 327.2
FSIS Directives 4312.1, 1030.3, 4300.5, 1010.2, and 5110.2
FSIS Notice 41-95
FSIS Directives 8830.1, 10530.1, 5720.2, and 5710.1*

4. What corrective and preventative actions do you take when unacceptable products intended for export to Country-X are found?

FSIS Directive 5400.1, Rev. 2, Inspection System Guide requires all official establishments and facilities to take corrective and preventative actions in all slaughter and processing areas, whether the product is domestic or export product. These actions are required for: facilities, equipment, water supply, and sewage; sanitation of facilities, equipment, and personal hygiene; slaughter operations, rodent and pest control, receiving and control of incoming products and materials; product handling and preparation; marking, branding, labeling, and packaging; retained, returned, and restricted product; finished product storage and shipping; control of inedible and condemned material; and residues, sampling, and product analysis. The government inspector and supervisor determine if the results of a corrective action meet compliance standards. If the standards are not met, then they are required to take appropriate action. Regulatory actions include process deficiency reports, tagging of equipment or areas, retention of product, letters of warning, and suspension and withdrawal of inspection services.

FSIS Directive 8800.1, Rev. 2 states that one of the principal components of FSIS' Performance Based Inspection System (PBIS) is a Corrective Action System (FSIS Directive 8820.1), requiring that deficiencies and the respective corrective actions are documented. Inspectors are also required to initiate corrective actions by the establishment when deficiencies are found. The Corrective Action System provides procedures applicable to slaughter and processing operations in official establishments. The System involves the performance of scheduled inspection tasks, to identification and classification of deficiencies and deviations, proper documentation and notification, initiating corrective and preventative actions, and FSIS verification of the establishments actions.

FSIS Directive 8830.1 states that establishments that demonstrate an unwillingness or inability to maintain facilities and operations in compliance with FSIS regulatory requirements, when corrective action procedures have not achieved the desired results of regulatory compliance, a Progressive Enforcement Action (PEA) system must be

initiated. PEA increases the inspection presence and procedures at a particular establishment in response to specific deviations.

In reference to Sanitation Standard Operating Procedures (SSOP), Section 416.15 of 9 CFR requires that official establishments take appropriate corrective action(s) when either the establishment or FSIS discovers that the SSOP program fails to prevent the direct or adulteration of product(s). These corrective actions include product disposition, preventing a recurrence of the problem, SSOP reevaluation and modification, and restoration of sanitary conditions (also see PR/HACCP final rule). FSIS Directive 5400.1 states that corrective actions are an indication of an adequate SSOP program. In addition, the establishment must identify the individuals who are responsible for taking appropriate corrective actions, when needed, and for recording the corrective actions taken on a daily basis, as stated in the Federal Register, July 25, 1996, Volume 61, Number 144.

Under the HACCP environment (the PR/HACCP final rule), 9 CFR Section 417.3 states that establishments must identify and take corrective action for any deviation from a set critical limit. Sections 417.2 (c) and 417.3 require HACCP plans to describe the corrective actions that will be taken (see Principle No. 5 of the seven principles of HACCP) and define corrective actions as procedures to follow when a deviation occurs. These actions must ensure that no unwholesome or adulterated product enters commerce, the cause of the deviation is identified and eliminated, the applicable critical control point is under control after the action is taken, and measures are taken to prevent a recurrence of the deviation. FSIS Directive 5400.5 requires inspectors to identify the relevant section or page of an establishment's document if they fail to follow the corrective action procedure(s) specified in its HACCP plan. Basic compliance checks on whether an establishment has failed to institute a PR/HACCP system, as per the regulations, is indicated by their failure to identify the corrective action(s) to be followed in response to a deviation. Establishments are required to document when a failure occurs. They must ensure that proper corrective action is taken. Failure to document the action violates the HACCP regulation, subjecting the establishment to appropriate regulatory action, as stated in the Federal Register, July 25, 1996, Volume 61, Number 144.

In addition, PR/HACCP regulations require that establishment verify that their HACCP plans are effective. Part of the verification procedure is reviewing the corrective action records. Section 417.3 states that all corrective actions must be documented and are subject to verification and records retention.

With respect to Salmonella Testing, the Federal Register date July 25, 1996 (Vol. 61, Number 144), states that FSIS determines when corrective actions or regulatory actions are required. Only raw meat products are tested for Salmonella. If inadequate corrective actions are taken after failing the performance standards for Salmonella, found in 9 CFR, Section 310.25 (b), or if the establishment simply ignores the failure, FSIS conducts another series of tests. If the second set fails and the establishment does not reassess its HACCP plan, or a third series of test fail, then FSIS suspends inspection

services in that establishment. The suspension remains in effect until the establishment demonstrates its ability to meet the performance standard.

Facilities outside of an official establishment must have a monitoring plan, set up by the inspector surveying the establishment, as per FSIS Directive 9080.1 dated 9/6/84. When a deficiency is found, the designated person at the facility would be required to initiate an appropriate corrective action(s).

Finally, FSIS regulations, Part 22, allow for the addition of specific corrective action provisions applicable to a specific country's exports. For example, Title 22.24, states that Country-Y has specific requirements that must be met before an establishment can regain its eligibility (when lost) to produce and export product to Country-Y. The establishment must provide evidence that all the necessary corrective actions have been taken and the appropriate inspection personnel have been notified. In addition, the evidence that was provided must be verified by government officials.

*References: FSIS Directives 5400.1, 8800.1, 8820.1, 8830.1, 9080.1, and 5400.5
9 CFR Sections 416.15, 417.2, 417.3, 310.25
Part 22 of the Code of Federal Regulations (Ex. Title 22.24)
Federal Register, July 25, 1996, Volume 61, Number 144*

5. What procedures are used to advise importers, custom officials, and/or inspection personnel that misbranded and/or adulterated products have been exported to your country? Who in your country is advised of this product and what initial and follow-up actions are required? What inspection controls ensure that this product does not enter consumer channels?

FSIS Directive 8040.1, Reports of Apparent Violations requires documenting reports of apparent violations of the Federal Meat Inspection Act and related laws and regulations. FSIS Form 8000-8 is used to report minor or technical violations. FSIS Form 8050-1 is used to report findings and evidence to support criminal, civil, or administrative actions. Exhibits in support of a violation are numbered and listed on FSIS Form 8000-7. FSIS Directive 8100.1, Planned Compliance Program, establishes that violations are assigned a risk category based on specific criteria. The criteria addresses current and past violations, incidents of unsound product into consumer channels, incidents of product adulteration, mis-branding, and other operational non-compliances, and consumer deaths. In addition, the Compliance Program can deviate from the risk categories whenever it is deemed necessary.

FSIS Directive 8110.1, Compliance Program – Documentary Evidence, establishes procedures for obtaining and preserving documentary and other non-meat evidence through a chain of custody. As referenced in FMIA Section 202, 21 U.S.C. 642, and Section 320.4, the regulations authorize representatives of the Secretary to examine facilities, inventory, and records, to copy all such records, and to take samples of the inventory from persons, firms, and corporations engaged in certain meat and poultry operations. Evidence obtained by the Compliance Program may be used in a court of law. Such evidence is required to be carefully protected to prevent loss, breakage,

alteration, or unauthorized handling. Evidence is properly identified and the information is maintained on an up-to-date database.

Domestic and exported product violations/incidents are handled the same, except that, for product exported to a foreign country, the International Policy Division and the Foreign Review Staff within FSIS are notified for policy and audit considerations.

*References: FSIS Directives 8040.1, 8100.1, and 8110.1
Federal Meat Inspection Act, Section 202
9 CFR Section 320.4*

Q. Salmonella Testing

- 1. What are the laws, regulations, and official directives that mandate a pathogen reduction program that systematically seeks to reduce pathogenic microorganisms in raw meat and/or poultry? The program documents must describe and mandate that the program will:**
 - a) be supported by analytical test results, nationwide microbiological baseline surveys, and other scientific data.**
 - b) include performance standards for appropriate target pathogens.**
 - c) employ microbiological testing as an indicator of pathogenic microorganisms.**

Salmonella is supported by the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; final rule (PR/HACCP) and the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Technical Corrections and Amendments (Technical Amendments). These regulations address the development and implementation of national performance standards for Salmonella from data collected from FSIS' Nationwide Microbiological Baseline Data Collection Programs and Nationwide Microbiological Surveys. These regulations are found in Title 9, U. S. Code of Federal Regulations, Section 310.25 (9 CFR 310.25) for Cattle and Swine. FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations, dated 11-21-97, addresses compliance with the PR/HACCP regulations and corrective actions when a noncompliance is found and the prevalence of Salmonella exceeds the established maximum number. FSIS Directive 10,230.5, Self-Instruction Guide for Collecting Raw Meat and Poultry Product Samples For Salmonella Analysis, dated 2-4-98, is used by inspection personnel when collecting samples of raw meat and poultry products for Salmonella analysis. In addition, helpful reference material is located in the Federal Register, Volume 61, Number 144.

a) The above Nationwide Programs and Surveys established raw product performance standards for Salmonella, as specified in 9 CFR 310.25 (b) Table 2. In each establishment, FSIS samples and tests raw product for the presence of Salmonella to determine if the applicable national pathogen reduction performance standard has been exceeded, as per section 310.25 (b) (1). FSIS' "Sample Collection Guidelines and

Procedure for Isolation and Identification of Salmonella from Meat and Poultry Products” is used to select and collect samples that are periodically taken in each establishment. Ongoing Salmonella testing under the PR/HACCP final rule currently applies only to raw product from slaughter establishments and establishments producing raw ground products.

b) The PR/HACCP regulations mandate the performance standards to be used on cattle, as per section 310.25 (b), Table 2. The performance standard for steers/heifers is 1.0% positive for Salmonella with the number of samples to be tested equaling 82 and the maximum number of positives to achieve the standard equaling 1 positive. The performance standard for cows/bulls is 2.7% positive for Salmonella with the number of samples to be tested equaling 58 and the maximum number of positives to achieve the standard equaling 2 positives. For ground beef, the numbers are 7.5%, 53, and 5, respectively. The numbers for hogs are 8.7%, 55, 6 and for fresh pork sausages, 30%, 53, 18, respectively.

c) Salmonella testing is used as a measure of the effectiveness of an establishment’s sanitation and HACCP plan. The PR/HACCP regulation is used by FSIS to control establishment processes and to reduce the pathogens prevalent in meat and poultry products. FSIS regulations, 9 CFR 310.25 (b) (3) and (3) (i), state that when FSIS determines that the establishment has not met the performance standard (see above), the establishment must take immediate action to meet the standard. A failure by the establishment to meet the standard (section 310.25 (b) (3) (ii) and (iii) of 9 CFR) constitutes a failure by the establishment to maintain sanitary conditions and a failure to maintain an adequate HACCP plan.

FSIS Directive 10,230.5 states that Salmonella test results are used to verify that establishments are meeting the pathogen reduction performance standards. The standards provide a direct measure of the establishment’s progress in controlling and reducing the most significant hazards associated with raw meat and poultry products. Salmonella test results indicate the introduction or presence of a pathogenic organism. FSIS requires (FSIS Directive 10,230.5, page 3-1 through 3-3) samples to be collected from chilled carcasses or after the final grinding process.

For Salmonella to be an indicator of pathogenic organisms, section 310.25 (b) (2) states that product will be sampled on an unannounced basis and that the frequency and timing of the sampling will be based on previous test results and other pertinent performance information on the establishment being tested. FSIS Directive 10,230.5, page 3-1, requires that samples are to be taken at random on each day the designated product is produced until a complete set (i.e. steers/heifers = 82 samples, cows/bulls = 58 samples) of samples is taken and analyzed. Inspectors are sent FSIS Form 10,210-7 (Sample Collection Request) when Salmonella testing is needed. In addition, FSIS has determined (see section 310.25 (b) (3) of the PR/HACCP regulations) that if an establishment fails the performance standards for raw product, then they must take immediate action to meet the standard. If the next series of tests fail to meet the standard, the establishment must re-assess its HACCP plan for the product in question and take appropriate corrective

actions. If the establishment fails to meet the standard on the third series of tests or fails to re-assess its HACCP plan, FSIS will suspend inspection services for that product.

*References: FSIS Directives 5000.1 and 10230.5
9 CFR Section 310.25
Federal Register, Volume 61, Number 144
Federal Register, Volume 62, Numbers 92, 212, and 220*

- 2. What are the laws, regulations, and official directives that mandate an effective enforcement program? The program documents must describe and mandate that:**
- a) establishments utilize available process control methods and technologies as necessary to achieve applicable pathogenic reduction performance standards.**
 - b) the foreign inspection system takes effective enforcement action, including suspension and withdrawal of inspection of those establishments which fail to meet the pathogen reduction performance standards or which fail to take corrective actions based on the results of the foreign inspection system's microbiological testing program.**

Enforcement regulations and provisions are found in 9 CFR 310.25 (b) (3); FSIS Directive 5000.1; the Federal Register, Volume 61, Number 144; FSIS Directive 10,011.1, Enforcement Instructions for the Salmonella Performance Standards, dated 9-9-98; and 9 CFR 305.5 (a) and 335.11 (a).

a) Section 310.25 (b) (3) of 9 CFR requires that establishments take immediate corrective action to meet performance standards when they have not been met. In addition, establishments are required to re-assess their HACCP plans and take appropriate corrective action when a second set of tests does not meet the standards. The PR/HACCP final rule requires establishments to identify chemical, biological, and physical hazards and to develop appropriate preventative measures. Biological hazards include pathogenic microorganisms and are required to be controlled through the use of appropriate preventative measures. Section 417.2 of 9 CFR and FSIS Directive 5000.1 (page 10) require establishments to monitor each critical control point so that corrective actions can take place following a deviation from an established critical limit. If the Salmonella performance standard is not met, the hazards identified as biological hazards would provide an action point from which to take immediate action or from which to re-assess the HACCP plan.

b) In general, as stated in 9 CFR 335.11 (a) and 305.5 (a), the Administrator of FSIS has the authority to withdraw inspection service if an establishment fails to destroy condemned meat products and to withdraw inspection from establishments where sanitary conditions render product adulterated or there is a PR/HACCP system failure. In regards to Salmonella standards, FSIS Directive 5000.1, pages 38-39 and 9 CFR

310.25 (2) and (3) require FSIS to sample and test raw meat products in individual establishment for the presence of Salmonella. In addition, FSIS inspectors have the authority to suspend inspection services if the establishment fails to re-assess its HACCP plan or take appropriate corrective action when two successive sets of Salmonella test results fail to meet the standard. Inspectors may also suspend inspection services if the establishment fails to meet performance standards on three successive sets of Salmonella test results.

The performance standards and the above approach to enforcement ensure that each establishment is consistently achieving an acceptable level of performance with regard to controlling and reducing harmful bacteria on raw meat and poultry products. FSIS Directive 10,011.1, page 6, states that ongoing random testing is used to assess the overall compliance of a product or an establishment with the Salmonella performance standards and identifies individual products and/or establishments that need to be targeted. Targeted product and/or establishment testing is used to further assess specific concerns and failures to meet Salmonella performance standards.

Section 310.25, (b) (3) (iii) states that noncompliance with the Salmonella standard may constitute a failure to maintain sanitary conditions or an inadequate HACCP plan and would result in the suspension of inspection services.

*References: Federal Register, Volume 61, Number 144
9 CFR Sections 310.25, 417.2, 305.5, and 335.11
FSIS Directives 5000.1 and 10011.1*

Remember: Cite the section in your regulations or other reference material that governs your response(s) to each question or request. In addition, provide examples of any forms, charts, or other documents applicable to each question or comment.