

SLAUGHTER/PROCESSING 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 United States 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.

A. Program Organization

- 1. For each of the products under this application, what governmental agencies enforce the relevant laws and regulations relating to the testing, approval, and control of: (a) additives (including the use of irradiation), (b) packaging materials, (c) nonfood compounds, (d) residues, and (e) slaughter/processing requirements (canning, de-boning, grinding, etc.)? Include organizational charts for each of these agencies.**

ADDITIVES

REGULATORY AGENCIES

*U.S. Department of Health and Human Services, Food and Drug Administration
U.S. Department of Agriculture, Food Safety and Inspection Service*

REGULATORY AUTHORITIES

*Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
Poultry Products Inspection Act (21 U.S.C. 451 et seq.)*

PACKAGING MATERIALS

REGULATORY AGENCIES

*U.S. Department of Health and Human Services, Food and Drug Administration
U.S. Department of Agriculture, Food Safety and Inspection Service*

REGULATORY AUTHORITIES

Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.)

Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
Poultry Products Inspection Act (21 U.S.C. 451 et seq.)

NONFOOD COMPOUNDS

REGULATORY AGENCIES

U.S. Department of Health and Human Services, Food and Drug Administration
U.S. Department of Agriculture, Food Safety and Inspection Service

REGULATORY AUTHORITIES

Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.)
Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
Poultry Products Inspection Act (21 U.S.C. 451 et seq.)

RESIDUES

REGULATORY AGENCIES

U.S. Environmental Protection Agency
U.S. Department of Health and Human Services, Food and Drug Administration
U.S. Department of Agriculture, Food Safety and Inspection Service

REGULATORY AUTHORITIES

Federal Fungicide, Insecticide and Rodenticide Act (7 U.S.C. 135 et seq.)
Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
Poultry Products Inspection Act (21 U.S.C. 451 et seq.)

SLAUGHTER/PROCESSING REQUIREMENTS

REGULATORY AGENCIES

U.S. Department of Agriculture, Food Safety and Inspection Service
U.S. Department of Health and Human Services, Food and Drug Administration

REGULATORY AUTHORITIES

Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
Poultry Products Inspection Act (21 U.S.C. 451 et seq.)
Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.)

Organizational charts are attached for each of the agencies mentioned above.
(See Attachments - EPA; USDA, FSIS; HHS, FDA)

References: Federal Meat Inspection Act (21 U.S.C. 601-624)
Poultry Products Inspection Act (21 U.S.C. 451-467)
Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.)
Federal Fungicide, Insecticide and Rodenticide Act (7 U.S.C. 135 et seq.)

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 and the Food and Drug Administration share responsibilities for protecting the public health with regard to human foods. FSIS is responsible for the safety and wholesomeness of meat, poultry, and egg products. The Food and Drug Administration is responsible for the safety and wholesomeness of all other foods. The Environmental Protection Agency regulates pesticides and their use and establishes tolerance levels for pesticides in food, including meat and poultry.

References: Organizational charts for USDA, HHS, and EPA
Internet Homepages for FSIS and FDA

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: (a) additives (including the use of irradiation), (b) packaging materials, (c) nonfood compounds, (d) residues, and (e) slaughter/processing requirements (canning, de-boning, grinding, etc.) for each of the products under this application?

Under its statutes, FSIS inspects all meat and poultry sold in interstate and foreign commerce, including imported products. Approximately 7400 Federal inspectors carry out inspection laws in about 6200 establishments. Inspectors check animals before and after slaughter, visually examining over 6 billion poultry carcasses and 125 million livestock carcasses each year. They prevent diseased animals from entering the food supply and examine carcasses for visible defects that can affect quality and safety. FSIS also inspects products during processing, handling, and packaging to ensure that they are safe and truthfully labeled. Among other things, FSIS also sets standards for certain slaughter and processing activities, such as establishment sanitation and thermal processing. The training courses described below provide knowledge, skills and ability to enforce and fulfill the responsibilities of the meat and/or poultry inspection program regarding additives (including the use of irradiation), packaging materials, nonfood compounds, residues, and slaughter/processing requirements (canning, de-boning, grinding, etc.). These courses are mandatory.

Slaughter inspectors are required to complete the following courses before they are assigned to an establishment:

Basic Livestock Slaughter Inspection

This 11-day course is designed for the newly hired livestock slaughter inspector. The following subjects are covered: the Federal Meat Inspection Act, as amended; safety; sanitation; Performance-Based Inspection System; Sanitation Standard Operating Procedures; humane slaughter; antemortem and postmortem inspection procedures; control of restricted products; control of condemned and inedible products; microbiology; epidemiology of foodborne disease (microbiology); HACCP Systems; wellness training; interpersonal relations skills; and other related areas. Off-line inspection procedures are covered in the Advanced Livestock Slaughter Inspection course.

Basic Poultry Inspection

This 8-day course is designed for the recently hired poultry inspector. The subjects covered are the Poultry Products Inspection Act and inspection regulations; wellness training; poultry antemortem and postmortem inspection; poultry anatomy; food microbiology; integrity; Performance-Based Inspection System and sanitation; HACCP concepts and trends; safety; streamlined inspection system presentation; interpersonal skills; and other related areas.

Sulfa On Site Training Qualification Laboratory

This 1-day teaching laboratory is designed to train personnel to perform the FSIS-approved SOS thin-layer chromatography testing method in a high-volume swine slaughter establishment. Trainees practice analysis of swine urine samples and complete the first half (18 samples) of the SOS User Qualification series. Trainees (except certain supervisory personnel) are required to complete the second half (18 samples) of the SOS User Qualification series upon return to their official duty station.

Inspectors being cross-trained are required to take the following course:

Livestock Slaughter Inspection Cross-Training

This 8-day cross-training course is for the inspector who has a poultry inspection background. The following subjects are covered: the Federal Meat Inspection Act, as amended; sanitation; Performance-Based Inspection system (PBIS); Sanitation Standard Operating Systems (SSOPs); humane slaughter; antemortem and postmortem inspection procedures; control of restricted products; control of condemned and inedible products; and other related areas. Off-line inspection procedures are covered in the Advanced Livestock Slaughter Inspection course.

Veterinary Medical Officers must complete the following courses before they are assigned to an establishment:

Veterinary Medical Officer (Red Meat Technical)

This course is for recently hired veterinary medical officers who have red meat inspection responsibilities and other veterinarians who are being cross-trained in red meat inspection. It is conducted at a designated field training station by a designated trainer using computer-based technology. The course includes scientific and technical subjects such as preoperational and operational sanitation; Performance-Based Inspection System; Sanitation Standard Operating Procedures; labeling and net weights; food microbiology; humane slaughter; livestock antemortem and postmortem inspection procedures; food animal diseases; pathology; veterinary dispositions; carcass and boneless meat reinspection; control of condemned and inedible materials; control of restricted products; viscera separation; Veterinary Services; tuberculin reactor procedures; and other related areas.

Veterinary Medical Officer Intern (Red Meat Technical)

This 9-day course provides an in-depth study of the responsibilities of the entry-level medical officer and other veterinarians who are being cross-trained in red meat inspection. The course includes lecture and laboratories that cover scientific and technical topics such as microbiological etiologies; red meat disposition; veterinary correlation and case studies; pathology; parasitology; food animal diseases; animal disease/disposition workshop; biological residues workshop; pathogen reduction; epidemiology of foodborne disease; HACCP trends and update; establishment performance system (IPPS) reviews; granting/refusing/withholding/withdrawing inspection; computer lab—World Wide Web applications; inspector-in-charge responsibilities; and other related areas.

Veterinary Medical Officer (Red Meat Technical)

This course is designed for recently hired veterinary medical officers who have poultry inspection responsibilities and other veterinarians who are being cross-trained in poultry inspection. It is conducted at a designated field training station by a designated trainer using computer-based training technology. The course includes scientific and technical subjects such as preoperational and operational sanitation; facilities; labeling and net weights; poultry anatomy; antemortem and postmortem inspection procedures; moisture control; packing room procedures; inspection of poultry giblets and necks; biological residues; turkey slaughter; cumulative sum; streamlined inspection system; streamlined inspection system presentation; avian diseases; food microbiology; pathology; veterinary dispositions; poultry parasitology; and other related areas.

Veterinary Medical Officer Intern (Poultry Technical)

This 9-day course provides an in-depth study of the responsibilities of the entry-level veterinary medical officer and other veterinarians who are being cross-trained in poultry inspection. The course includes lectures and laboratories that cover scientific and technical topics such as microbiological etiologies, poultry disease/disposition correlation; poultry postmortem trim and carcass disposition correlations (wet lab); pathology; parasitology; food animal diseases; residue workshop; pathogen reduction; epidemiology of foodborne disease; HACCP trends and update; establishment performance system reviews; granting/refusing/withdrawing/withholding inspection; veterinary case studies; computer lab—World Wide Web applications; inspector-in-charge responsibilities; and other related areas.

Inspectors must complete the following course before they may be assigned to a HACCP establishment:

Pathogen Reduction and HACCP

This 8-day course is designed for inspection employees and supervisors; compliance officers and supervisors; and district office personnel. The training focuses on the following topics: FSIS philosophy and operations; principles and application of HACCP; working knowledge of HACCP systems development and the relationship to good manufacturing practices and sanitation standard operating procedures; regulatory and operational requirements for E. coli testing; regulatory and operational requirements for Salmonella testing; system's approach to inspection; changes made to the PBIS system; determining an establishment's compliance or noncompliance with pathogen reduction and HACCP requirements; obtaining technical assistance and guidance; and information and techniques for use in building effective relationships, managing conflict, and communicating more effectively.

New supervisors and managers are required to take the following course:

Supervision and Management

This course is delivered through computer-based training technology and written lesson plans at a designated veterinary field training station. Topics include supervision of the performance system; systems thinking; supervising and managing in a Pathogen Reduction/HACCP environment; employee relations; labor management relations; Agency mission and organization; relationship between red meat, poultry, processing, enforcement, in-distribution, and industry; regulatory process; personnel matters and benefits; time and attendance reporting and travel voucher completion; overview of Fair Labor and Standards Act; intermittent use; integrity/conflict of interest; equal employment opportunity; sexual harassment; career ladder; merit promotion; reassignments; safety and health; performance appraisal procedures/process; awards and recognition; and position management and classification.

Training for State and Local Officials:

The Food Safety and Inspection Service also provides training to state and local regulators about meat and poultry processing. One of the ways FSIS is accomplishing this is to provide a series of satellite teleconferences, cosponsored by the Association of Food and Drug Officials, aimed at state and local sanitarians. The interactive broadcasts provide training in the risks associated with new processing and packaging methods and in monitoring traditional processing methods that pose a significant risk to public health. Process areas emphasized in the next session are Cooking and Cooling. Past teleconferences have emphasized Fabrication and Curing, and Emerging Pathogens and Grinding and Cooking of Ground Beef. Future teleconferences are planned in the areas of smoking, stuffing, packaging, labeling, and HACCP.

During fiscal year 1996, FSIS conducted training for 1,708 students through 92 courses at the Donald L. Houston Center for Meat and Poultry Inspection Sciences, located in College Station, Texas. The curriculum included basic entry-level courses for food inspectors and veterinarians, inspection and industry personnel, and courses on supervision and management, interpersonal skills, State training in processing and slaughter, advanced food inspector slaughter, advanced veterinary medical officer, processing (basic, advanced and canning), and residue testing qualification. The courses were completed by 899 FSIS food inspectors, 464 FSIS veterinarians, 158 State veterinarians and inspectors, and 175 other personnel.

*References: Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
Poultry Products Inspection Act (21 U.S.C. 451 et seq.)
Federal Fungicide, Insecticide and Rodenticide Act (7 U.S.C. 135 et seq.)
Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
FSIS, Office of Management, Human Resources Division
FSIS, Office of Field Operations*

4. Within the Meat and Poultry Inspection Program, who is responsible for setting and implementing microbial guidelines in the products produced?

The Office of Public Health and Science within FSIS has the responsibility for establishing microbial guidelines for meat, poultry, and egg products. FSIS inspectors are responsible for implementing the established guidelines or providing oversight to ensure established guidelines are implemented by official establishments.

*References: OPHS Functional Statement
OFO Functional Statement*

B. Additives**1. What authority determines if food additives are safe for human consumption?**

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture shares responsibility with the Food and Drug Administration (FDA) for the safety of food additives. All additives to be used in food products and packaging materials are initially evaluated for safety by FDA, and if an additive is to be used in meat and poultry, it must also be evaluated for safety by FSIS. FSIS ensures that all ingredients and other articles used in the preparation of any product shall be clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated. Official establishments shall furnish inspectors accurate information on all procedures involved in product preparation including product composition and any changes in such procedures essential for inspectional control of the product. No substance may be used in the preparation of any product unless it is approved. FSIS ensures that establishments adhere to the standards of identity or composition for specific products and that they are properly prescribed.

*References: Federal Food, Drug and Cosmetic Act, 1958 Food Additive Amendment
21 CFR Parts 1 to 184
Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
9 CFR Sections 318.6 and 318.7, and Part 319
FSIS Directive 11000.1*

2. What authority exists for enforcing and controlling the level and use of additives, including the use of irradiation, in meat and/or poultry products?

FDA's Food, Drug, and Cosmetic Act and related regulations (21 CFR Parts 1 to 184) provide the legal authority under which all food additives including irradiation are regulated. Accordingly, before a food additive can be marketed, a manufacturer must file a petition with FDA showing that tests prove that the substance is safe. Once approval is given, FDA declares the types of food in which it can be used, the approved level of usage, and the related labeling directions.

FSIS' meat and poultry inspection acts and related regulations (9 CFR Part 318.6, 318.7, and 319) provide the requirements for ingredients, food additives and other articles used in the preparation of meat and poultry products. Also, the regulations require certain information on labels of meat and poultry products so that consumers will have complete information about a product. In most cases, ingredients must be listed on the product label in order by weight, from the greatest amount to the least. Additives such as spices, flavorings, and colors may be listed as such without naming each one.

The Food, Drug, and Cosmetic Act does allow two groups of additives [those identified as "generally recognized as safe" (GRAS) and "prior sanctioned substances"] to be exempt from the testing and approval process required by FDA. This includes additives

such as spices and flavorings that are considered harmless and those that were approved prior to the 1958 Food Additives Amendment. FDA, however, continues to test the exempt additives to assure they meet current food safety standards.

*References: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
21 CFR Parts 1 through 184
9 CFR Parts 318 and 319*

3. What are the permitted additives for meat and/or poultry and what are the allowable tolerances and limits for each additive? (Provide a comparison between your country and what is allowable in the Country-X.)

Food additives used in meat and poultry products are classified as either direct or indirect. Direct additives are those substances added directly to foods for a specific purpose, and by law, they must be named on labels of meat and poultry products. Indirect additives are substances that may be present in food in very small amounts as a result of some phase of production, processing, storage, or packaging. The meat regulations (9 CFR 318.7) provide a Substance Table that lists the approved direct food additives, the products in which they are allowed, and the allowable amounts. For example, the substances specified in the following partial chart are acceptable for use in the preparation of products, provided they are used for the purposes indicated, within the limits of the amounts stated and under other conditions specified in this part and part 317 of this subchapter. In addition to the substances listed in the following chart, part 319 of this subchapter specifies other substances that are acceptable in preparing specified products.

Class of substance	Substance	Purpose	Products	Amount
Acidifiers.....	Acetic acid.....	To adjust acidity.....	Various ⁽²⁾	Sufficient for purpose ⁽³⁾
	Citric acid.....	"....."	"....."	"....."
	Glucono delta-lactone....	"....."	"....."	"....."
	Lactic acid.....	"....."	"....."	"....."
	Phosphoric acid.....	"....."	"....."	"....."
Anti-coagulants.....	Tartaric acid.....	"....."	"....."	"....."
	Citric acid.....	To prevent clotting.....	Fresh blood of..... livestock.	0.2 percent with or without water. When Water is used to make a solution of citric acid added to blood of livestock, not more than 2 parts of water to 1 part of citric acid shall be used.
	Sodium citrate.....	To prevent clotting.....	"....."	Not to exceed 0.5 percent based on the ingoining weight

		of the product. When water is used to make a solution of sodium citrate added to blood of livestock, not more than 2 parts of water to 1 part of sodium citrate shall be used.
Antifoaming agent... Methyl polysilicone.....	To retard foaming.....	Soups.....10 parts per million
		Rendered fats..... “ .
		Curing pickle.....50 parts per million.

A copy of the above regulations containing the complete list of approved substances is provided with this document in attached CFRs.

References: 9 CFR Section 318.7

4. What controls are in place in establishments to ensure that only additives approved for use in meat and poultry establishments in the Country-X are used and that respective Country-X tolerances and limits for each additive are not exceeded?

Meat and poultry establishments operating under FSIS laws and regulations are responsible for ensuring that only approved food additives and their allowable amounts are used in the production of meat and poultry products. Accordingly, the regulations (9 CFR 318.7) require that no product shall contain any substance that would render it adulterated or misbranded. FSIS has the authority to collect and test samples of product and food additives (9 CFR 318.9) to ensure that product is safe, wholesome, and accurately labeled.

In addition, FSIS Directive 5000.1 states that the approved use of direct or indirect food or color additives is a potential food safety hazard that must be addressed, where applicable, in an establishment's HACCP plan. FSIS Directive 11,000.1 states that control over nonfood compounds and chemical substances used in the preparation of food products should begin at the time of delivery of these materials to the establishment. When such chemical compounds are delivered to the establishment, the inspector must determine their acceptability and assure that they are used for the accepted purpose. Most accepted compounds and substances which must be evaluated prior to use are listed in the FSIS publication "List of Authorized Proprietary Substances and Nonfood Compounds" (formerly the "List of Chemical Compounds" - Miscellaneous Publication No. 1373). Letters indicating acceptability are issued to permit use of materials accepted between revisions of the publication. Therefore, for materials classified in categories described in the publication, letters dated prior to the date of the current publication are not valid as proof of authorization unless otherwise stated in the publication. Proprietary substances included in the publication can be generally classified as food processing chemicals such as scald media, tripe processing agents, and fruit and vegetable washing agents; smoke flavoring agents; rendering agents; and

denaturants. The nonfood compounds can be generally classified as maintenance and cleaning compounds; sanitizing and pesticide compounds; water treatment compounds; and lubricants.

Specifically, for approved substances, 9 CFR Section 318.7 states that no substance may be used in the preparation of any product unless it is approved in paragraph (c)(4) of this section or elsewhere in Part 318 or in Part 319 of this subchapter, or by the Administrator in specific cases. Approval of new substances or new uses or new levels of use of approved substances may be granted by the Administrator if:

? *The substance has been previously approved by the Food and Drug Administration (FDA) for use in meat or meat food products as a food additive, color additive, or as a substance generally recognized as safe and is listed in Title 21 of the Code of Federal Regulations, Parts 73, 74, 81, 172, 173, 179, 182 or 184.*

? *Its use is in compliance with applicable FDA requirements; and*

? *The Administrator has determined that:*

The use of the substance will not render the product in which it is used adulterated or misbranded or otherwise not in compliance with the requirements of the Act; and

Its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the stated technical effect as determined in specific cases.

Whenever the Administrator determines that approval of a new substance or new use or new level of use of an approved substance should be granted, the Administrator may issue a final rule amending the chart of approved substances to include the additional substance or new use of the substance, and any technical effect or change in level of use of the substance.

No product shall bear or contain any substance which would render it adulterated or misbranded, or which is not approved in Part 318 or Part 319 of this subchapter, or by the Administrator in specific cases.

*References: 9 CFR Sections 318.7 and 318.9
FSIS Directives 5000.1 and 11,000.1*

5. What are the testing frequencies and laboratory testing procedures used to test meat and/or poultry products and their ingredients for additives? (Provide a list of the additives that are tested for each applicable product or ingredient.)

The answer to Question 3 above provides a listing (or references to the Substance List) of the products and additives allowed in meat products (see 9 CFR Sections 318.7 and 318.9). The only products that are routinely checked, are products in which additives contain or alter the quantity of nitrites, nitrosamines, and/or moisture/fat/protein/salt. Each time a sample is taken for moisture/fat/protein/salt, each substance is analyzed from the same sample and 10,000 to 12,000 samples of product are analyzed each year. Product is analyzed for nitrites through the Automated Import Inspection System on imported product at the rate dictated by the products imported and the results of previous

tests. For domestic product, nitrites are only analyzed if the inspection personnel suspect a problem with the product. Product is analyzed for nitrosamines at a rate of approximately 10 samples per year. The laboratory testing procedures used for these substances is detailed in the corresponding attachments. (See Attachments)

Products are analyzed for other additives according to need. Inspection personnel in establishments request that product be analyzed for a particular additive through the use of a laboratory analysis request form indicating a Type 30 sample request. Requests for analyses are usually made because inspection personnel suspect that the ingredients added are incorrect or are not supported by labeling claims. Other requested analyses are designated by sample type. Type 39 samples are samples that are requested by Compliance officers and Type 42 samples are those that are initiated by consumer complaints and requested by the Office of Public Health and Safety, FSIS. Binders and extenders are also sampled on a random basis, as determined by establishment history and performance and other applicable factors.

Nutrition verification samples are checked, domestically, at a rate of not more than 50 sample products a month, usually about 40. The samples are targeted. That is, if we receive complaints or concerns about the accuracy of labels from competitors, the label review staff, the FSIS hotline, consumers, or consumer organizations then those products are sampled. Product is sampled at random in many instances, especially when we do not receive sufficient complaints. All of the labeled nutrients are analyzed at the Eastern Laboratory. The methods are those designated by OPHS in the Analytical Chemistry Laboratory Guidebook, Food Chemistry, Spring 1993. Imported products are also checked at a rate of 50 samples per year, taken in a one-month period. The samples are chosen from a listing of the number of lots of applicable products that are received at the various ports-of-entry. Sampling is, therefore, based on the likelihood of sampling highly imported products at specific entry points. The system is flexible and can vary according to the needs, pressures, and resources of the Agency. Whether the product is imported or domestic, nutritional verification sample requests are directed from OPPDE/Labeling, Product and Technology Division in Washington. The laboratory testing procedures used for these nutrients is detailed in the attachments. (See Attachments)

*References: 9 CFR Sections 318.7 and 318.9
Import Inspection Manual
Analytical Chemistry Laboratory Guidebook*

6. What type of laboratory facility is used for the analyses (private, government, or company) of additives?

FSIS has three government laboratories that it uses for testing of meat and poultry products for various disciplines. These field service laboratories are as follows:

*Eastern Laboratory
Patrick C. McCaskey, Director
Tel: (706) 546-3576
FAX: (706) 546-3383*

Mailing Address:

*Eastern Laboratory
Russel Research Ctr., Suite 205
950 College Station Road
Athens, GA 30605*

This lab coordinates and conducts laboratory analytical services in support of the Agency's farm-to-table strategies in the disciplines of chemistry, microbiology, and pathology in meat, poultry, and egg products.

*Midwestern Laboratory
James Hess, Director
Tel: (314) 263-2680
FAX: (314) 263-2679*

Mailing Address:

*Midwestern Laboratory
Bldg. 105-D, Room 344
4300 Goodfellow Road
St. Louis, MO 63120*

This lab coordinates and conducts laboratory analytical services in support of the Agency's farm-to-table strategies in the disciplines of chemistry and microbiology in meat, poultry and egg products.

*Western Laboratory
Joseph Chiu, Director
Tel: (510) 337-5031
FAX: (510) 337-5036*

Mailing Address:

*Western Laboratory
620 Central Avenue
Building 2A
Alameda, CA 94501-3874*

This lab coordinates and conducts laboratory analytical services in support of the Agency's farm-to-table strategies in the disciplines of chemistry and microbiology in meat, poultry and egg products.

References: <http://www.fsis.usda.gov/OPHS/ophswho.htm> - FSL

7. How are test results reported? Who receives these reports when allowable tolerances are exceeded? What preventative and corrective actions are taken to resolve problems revealed by test results?

All laboratory test results are provided to FSIS for review. When allowable tolerances are exceeded, FSIS' food safety laws prohibit the selling of any adulterated or mislabeled meat or poultry product. Under a Hazard Analysis and Critical Control Point (HACCP) program, an establishment HACCP plan must identify all significant biological, chemical and physical hazards for each processing step and each ingredient. They must also, if possible, identify measures to prevent hazards from compromising the safety of your finished product. HACCP defines a preventive measure as "Physical, chemical, or other means that can be used to control an identified food safety hazard." Food additives, under specific circumstances, can be considered a chemical hazard within an establishment's HACCP plan. The HACCP plan under which official meat and poultry establishments operate must describe the corrective action to be taken when a deviation (non-compliance) occurs and ensure that measures are taken to prevent recurrence (9 CFR 417.3). The establishment must also monitor the applicable critical control points and provide verification procedures to ensure that the hazard and its monitoring frequency is adequate to maintain compliance. Chemical hazards are, therefore, addressed and corrected by the establishment. In addition, official establishments are required to document and maintain records regarding deviations and have these records readily available to FSIS employees.

Furthermore, FSIS Directive 5000.1 states that if an establishment makes production or other changes that could reasonably affect whether a food safety hazard exists, the establishment must reassess the adequacy of their hazard analysis.

FSIS will verify the adequacy of HACCP plans through activities such as reviewing plans and critical control points, reviewing and determining the adequacy of corrective and preventive actions, reviewing establishment's records, direct observation and measurements, and sample collection and analysis (9 CFR 417.8). The FSIS verification will ensure that each HACCP plan meets all applicable regulations. In addition, FSIS will verify that an establishment performs adequate and appropriate sample collection and analysis to determine that the product(s) meets all safety standards. FSIS Directive 5000.1 states that finding a noncompliance with requirement(s) supports the withholding of inspection to prevent the production of such products until the failure is remedied. Inspection program personnel who determines that an establishment has failed to meet one or more of these requirements is to take the following steps:

- 1. Advise establishment management orally of the findings on which the intended action is based and (as soon as possible where practicable and by the end of his or her tour of duty) confirm with a copy of the NR that documents the noncompliance finding(s).*
- 2. a. Refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness."*

b. *Identify all possibly adulterated livestock and/or poultry products as "U.S. Retained."*

3. *Notify the District Office of the action(s) taken, and if the establishment does not initiate action immediately to bring itself into compliance, the Office will assign a Compliance Officer to the case. The District Office and the Compliance Officer will then take further action, as necessary, to correct the noncompliance.*

References: 9 CFR Sections 417.3 and 417.8
FSIS Directive 5000.1 and 7410.2
Federal Register: July 25, 1996 (Volume 61, Number 144)

8. How is the purity of additives determined and verified? Who sets the standards and what are the analytical methods used? Does the supplier certify, in writing, that a particular standard of purity is being met?

Manufacturers of food additives must provide sufficient detailed information (e.g., research documents, test and safety reports) to FDA regarding the safety and any other claims of an additive intended for use in food products. In addition, when establishing the purity of a food additive, manufacturers must describe the analytical methods used to evaluate the purity and conduct applicable validation tests. When food additives are used in meat and poultry products and there is a claim regarding the purity of an additive, FSIS has the authority to evaluate and verify any claims made by the manufacturer.

When a particular standard of purity is stated on the product's label, the supplier must provide to the establishment a letter of guarantee addressing such claims. FSIS Directive 7140.1 states that a letter of guarantee from the manufacturer is used as the basis for allowing non-meat ingredients to enter a meat establishment.

In addition, since packaging materials could pose chemical hazards, an establishment may require a letter of guarantee from the supplier that the packaging materials are all food grade. This requirement would be subject to establishment and Agency verification.

Unless specified in FSIS regulations, letters of guarantee (including those that address labeling claims) are kept by the establishment and are available to FSIS personnel upon request.

References: <http://www.fda.gov/>
9 CFR Section 318.7
FSIS Directives 5400.1, 5930.1, and 7140.1
Federal Register: July 25, 1996 (Volume 61, Number 144)

C. Control of Packaging Materials

- 1. What laws and regulations control the adequacy and use of primary and secondary packaging materials as acceptable for use with product prepared for consumption in Country-X? What part of the government is responsible for implementing and maintaining Country-X, or equivalent, standards?**

The Food and Drug Administration (FDA) has the primary responsibility for approving materials used in the packaging of food products. FDA requires the use of safe materials, which mean articles manufactured from or composed of materials that do not contaminate the food product. If materials used are considered to be food additives or color additives as defined in Section 201(s) or (t) of the Federal Food, Drug, and Cosmetic Act, they are "safe" only if they are used in conformity with regulations established pursuant to Section 409 or Section 706 of the Act and 21 CFR Part 7. Other materials are "safe" only if, as used, they are not food additives or color additives as defined in Section 201(s) or (t) of the Federal Food, Drug, and Cosmetic Act and are used in conformity with all applicable regulations of the FDA.

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) works with FDA to ensure that only safe materials are used in the packaging of meat and poultry products. Both FDA and FSIS are responsible for implementing and maintaining these standards. FSIS implements packaging requirements in 9 CFR Parts 317 and 318.

*References: Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.)
Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
9 CFR Parts 318 and 317
21 CFR Part 7*

- 2. What procedures, tests, and/or criteria are used to determine material and chemical acceptability and to ensure that only authorized and approved packaging materials are used in each exporting establishment?**

Manufacturers of packaging materials used in direct contact with food products must obtain approval for use from FDA. FDA classifies such packaging materials as "indirect" food additives because minute amount of substances making up the packaging material may diffuse into the food product. It is the manufacturer's responsibility to clearly demonstrate to FDA the safety of using the packaging material. Manufacturers must conduct, as necessary, appropriate tests and/or examinations to assure the packaging materials do not contaminate food products when in direct contact.

Specifically, 9 CFR section 318.4 states that it shall be the responsibility of the operator of every official establishment to comply with the Act and the regulations in this subchapter. In order to carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to assure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of

its products strictly in accordance with the sanitary and other requirements of this subchapter. The effectiveness of such measures will be subject to review by the Department. FSIS verifies that the establishment complies with this requirement.

Section 317.24 states that edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for their intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).

FSIS monitors the use of packaging material in official establishments to assure that the requirements are met, and may question the basis for any guaranty. Official establishments and packaging suppliers providing written guaranties to those official establishments will be permitted an opportunity to provide information to designated Department officials as needed to verify the basis for any such guaranty. The required information will include, but is not limited to, manufacturing firm's name, trade name or code designation for the material, complete chemical composition, and use. Selection of a material for review does not in itself affect a material's acceptability. Materials may continue to be used during the review period. However, if information requested from the supplier is not provided within the time indicated in the request -- a minimum of 30 days -- any applicable guaranty shall cease to be effective, and approval to continue using the specified packaging material in official establishments may be denied. The Administrator may extend this time where reasonable grounds for extension are shown, as, for example, where data must be obtained from suppliers.

The Administrator may disapprove for use in official establishments packaging materials whose use cannot be confirmed as complying with FFDCA and applicable food additive regulations. Before approval to use a packaging material is finally denied by the Administrator, the affected official establishment and the supplier of the material shall be given notice and the opportunity to present their views to the Administrator. If the official establishment and the supplier do not accept the Administrator's determination, a hearing in accordance with applicable rules of practice will be held to resolve such dispute. Approval to use the materials pending the outcome of the presentation of views or hearing shall be denied if the Administrator determines that such use may present an imminent hazard to public health.

Periodically, the Administrator will issue to inspectors a listing, by distinguishing brand name or code designation, of packaging materials that have been reviewed and that fail to meet the requirements of paragraph (a) of this section. Listed materials will not be permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of paragraph (a), the material will be deleted from the listing.

Nothing in this section shall affect the authority of Program inspectors to refuse a specific material if he/she determines the material may render products adulterated or injurious to health.

All exposed edible product and its packaging materials are removed, tightly covered, or stored in closed containers whenever residual or contact pesticides are used in the vicinity of packaging materials. In contrast, all edible products and their packaging materials must be removed from rooms before fumigation, except packaged products.

When rodent evidence is discovered in production or production-related area-- processing room, ingredient storage area, cooler, or any area where meat or poultry product is accessible--the inspector shall stop operations and movement of any material into or out of the area, and shall require management to:

1. Examine all products, packaging materials, and containers for rodent damage or contamination.

2. Destroy or decharacterize rodent damaged or contaminated product, carcass, parts, packaging materials and containers, and any open dry ingredient container.

3. Remove accumulations of equipment, paper, or other debris providing harborage in involved area, and wash and sanitize all equipment.

4. Survey premises and outside areas; eliminate all suspected harborages (outside premises, maintenance areas, etc); close all possible rodent access points, and arrange all dry storage material to facilitate cleaning.

Finally, the inspector may allow operations to resume after all actions are successfully completed.

FSIS laboratories test and review various nonfood compounds and packaging materials that are used in federally inspected establishments. Title 23.2 states that packaging materials, in general, need not be sampled. However, establishment management must maintain a file containing guaranties for all food contact packaging materials in the establishment. The inspector will permit use of materials on the basis of such guaranties unless there is a specific reason to doubt the acceptability of the materials. If there is any doubt about the acceptability of a food contact packaging material, the inspector should contact his/her supervisor and report the incident.

Title 17.16 states that all packaging materials must be safe for the intended use and may not cause adulteration of edible products. 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 inspector 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. Since certain materials may fail to perform as expected (e.g., transfer color or odors or otherwise affect the characteristics of meat products, acceptance by the inspector must be based on performance under actual packaging conditions. The inspector may inspect and disallow the use of packaging material, and may retain any packaged product in it if there is reason to doubt the acceptability of the packaging materials.

When the inspector questions the acceptability of a material, assistance may be requested from the appropriate FSIS office. The inspector should provide the supplier's name,

brand name or other designation for the material, and the condition of use of the material. The inspector may also request assistance for problems relating to mechanical failure of materials (e.g., defective seals in cans, pouches, semirigid containers and other similar materials).

FSIS Notice 31-98 states that, in some situations, condensation clearly adulterates product, creates insanitary conditions, and/or interferes with inspection. For example, condensate from a loading dock ceiling or wall drips onto boxes of product and breaks down and compromises the packaging of the product. FSIS inspectors document such condensation as a noncompliance, where applicable..

FSIS Directive 8820.1 states that packaging materials that are in use or are ready for use, and are in violation of FSIS regulations should be identified by the inspector as a major deficiency and the inspector will determine if official control action is warranted.

FSIS Directive 7410.2 provides guidelines for complying with the packaging monitoring requirements contained in Section 317.24 Regulations. Official establishments must receive from the suppliers of their packaging materials and retain in their files, written guaranties that the materials comply with the FFDCA, as amended, and all applicable food additive regulations. Such guaranties establish that the described packaging materials are in compliance unless the inspector has specific reasons to believe otherwise. FSIS will monitor the use of packaging materials in official establishments to ensure that the written guaranties can be substantiated. In addition, the FSIS Packaging Monitoring Program involves a series of limited surveys of official establishments selected on a random basis. Inspectors at the selected establishments are requested to provide information on a specified number of packaging materials. Using the information received from inspectors, FSIS reviews the material and requests additional information from establishment management and/or suppliers to confirm compliance with applicable regulatory criteria.

Under the PR/HACCP final rule, FSIS Directive 5000.1 states that reassessments of the HACCP plan and hazard analysis may be needed when different packaging materials are used. For example, in many operations, the packaging step could pose chemical hazards from the packaging materials. A preventive measure could be a letter of guarantee from the supplier that the packaging materials are all food grade. Any changes to the HACCP plan are subject to verification by FSIS personnel

*References: 9 CFR Sections 318.4 and 317.24
21 CFR Sections 7.12 and 7.13
Titles 8.08, 8.50, 17.16, 23.1, and 23.2
FSIS Notice 31-98
FSIS Directives 8820.1, 5000.1, and 5400.1
Federal Register: July 25, 1996 (Volume 61, Number 144)*

3. To what extent are manufacturers required to guarantee the composition of the packaging material they manufacture?

Manufacturers of packaging materials must provide a letter of guarantee stating that the materials are composed of acceptable substances. The letter of guarantee must be supported by appropriate tests, and/or examinations to assure the composition of the packaging material is safe and suitable when in direct contact with food products and the food products are not contaminated.

9 CFR Section 317.24 states that packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name and firm name the material is marketed to the official establishment. The guaranty shall state that the material's intended use complies with the FFDCa and all applicable food additive regulations. The guaranty must identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and any other pertinent limits specified under the FFDCa and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty may be limited to a specific shipment of an article, in which case it may be part of or attached to the invoice covering such shipment, or it may be general and continuing, in which case, in its application to any article or other shipment of an article, it shall be considered to have been given at the date such article was shipped by the person who gives the guaranty. Guaranties consistent with FDA's regulations regarding such guaranties (21 CFR 7.12 and 7.13) will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department officials upon request. While in the official establishment, the identity of all packaging materials must be traceable to the applicable guaranty. The guaranty by the packaging supplier will be accepted by FSIS inspectors to establish that the use of material complies with the FFDCa and all applicable food additive regulations.

Title 23.2 states that packaging materials, in general, need not be sampled. However, establishment management must maintain a file containing guaranties for all food contact packaging materials in the establishment. Title 17.16 states that official establishments are 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 products. Examples of these are shipping cartons which are not the immediate container, netting placed over sealed plastic wrap, labels applied to cans or other containers after the food is sealed inside, and strapping or tape used where food contact is not expected. The guaranty {See 9 CFR 317.20} need not be in any specific format, but must include the following:

1. a statement that the material complies with the Federal Food, Drug and Cosmetic Act and any applicable regulations,
2. the brand name or code designation of the material,
3. the name of the supplier,
4. the conditions of use of the material, including temperature and other pertinent limits, and
5. the signature of an official of the supplier. USDA- issued acceptance letters for packaging materials may not be substituted for a guaranty.

References: 9 CFR Sections 317.20 and 317.24
21 CFR Sections 7.12 and 7.13
Titles 23.2 and 17.16
Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)

4. How are exporting establishments kept abreast of the current list of approved packaging materials and manufacturers? How often is the list updated?

FSIS publishes on an annual basis a list of FDA approved packaging materials that can be used in the production of meat products. FSIS Directive 7410.2 states that FSIS will periodically issue to inspectors a listing, by distinguishing brand name or code designation and by the supplier's name and address, of packaging materials that have been reviewed and have failed to meet the requirements of the FFDCa, as amended. Materials listed are those not permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of the FFDCa, a letter will be issued to the packaging material supplier superseding the listing. This letter will serve as proof of acceptability until a subsequent listing is issued. Upon receipt of notification by the Headquarters IO office or the FSIS listing, the IIC will take the following actions:

1. *Follow instructions given in the notification of unacceptable materials, which will be sent by the Headquarters IO Office.*
2. *Review the FSIS listing to determine if any listed materials are in use at the establishment. The inspector should not allow materials listed in the FSIS listing to be used in official establishments unless notified otherwise. Unless an imminent hazard to public health exists, no product recalls or repackaging should be required. The disposition of materials already in the establishment, which appear in the FSIS listing, and of food products packaged in such materials, will be handled on a case-by-case basis in the notification.*

FDA lists the approved substances that are used in packaging materials and lists the substances in 21 CFR of the regulations. The list is updated annually. Packaging material manufacturers submit applications for approval of new substances or substances not listed in 21 CFR and, once approved or cleared for use, provide establishments with a letter of guaranty that the packaging material was produced from approved substances. Interested parties should contact the U. S. Food and Drug Administration, Center for Food Safety & Applied Nutrition, Office of Premarket Approval.

References: FSIS Directive 7410.2
21 CFR Parts 5, 25, 170, 171, and 174
<http://vm.cfsan.fda.gov/~dms/opa-toc.html>

D. Control of Nonfood Compounds

- 1. What laws and regulations control the use of nonfood compounds (such as cleaning/sanitizing compounds and pesticides) in establishments where the food products under this application are prepared for consumption in the Country-X?**

The Toxic Substances Control Act (TSCA) provides for the protection of human health and the environment from unreasonable risks arising from the manufacture, distribution, use, or disposal of chemicals. (40 CFR Parts 700-1517)

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) sets forth the procedures, requirements, and criteria for the registration of pesticide products. (40 CFR Parts 150-189).

The Federal Meat and Inspection Act (FMIA) provides for the protection of the health and welfare of consumers by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. (9 CFR Parts 300, 416, and 417)

References: Toxic Substances Control Act
Federal Insecticide, Fungicide, and Rodenticide Act
Federal Meat Inspection Act (21 U.S.C. 601 et seq.)

- 2. What are the procedures used for approving nonfood compounds and how does the government ensure that only approved nonfood compounds are received and used in each establishment exporting to Country-X?**

Two government agencies have the responsibility of approving and controlling the use of nonfood compounds in all establishments preparing meat, poultry, and egg products. The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) has the primary responsibility for authorizing and enforcing the use of non-food compounds in establishments producing meat, poultry, or egg products. Accordingly, FSIS publishes an annual list of approved nonfood compounds (Publication Number 1419, see attached List of Proprietary Substances and Nonfood Compounds.) Compounds not listed in this publication must be submitted to FSIS and evaluated prior to being used. Following approval, FSIS provides to its inspectors a certificate of approval and such certificate must be on file at the establishments until a revised edition of Publication 1419 is published.

FSIS administers the FMIA and the corresponding regulations to ensure the safety of meat intended for human consumption. FSIS enforces the use of non-food compounds by having FSIS inspectors in meat establishments review the packaging labels to ensure that they are an approved compound listed in Publication Number 1419. Examples of non-food compounds include cleaning compounds and compounds for laundry use, hand washing and sanitizing compounds, solvent cleaners, and lubricants on equipment.

The Environmental Protection Agency (EPA) of the United States government has the responsibility for assuring that all pesticides sold in the United States are registered. EPA is also responsible for establishing tolerances for pesticides and for revoking tolerances for cancelled pesticides. Accordingly, EPA administers the FIFRA and TSCA and the regulations issued under them. USDA and EPA work closely together to ensure that establishments adhere to FDA tolerances.

*References: Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
Federal Insecticide, Fungicide and Rodenticide Act
Toxic Substances Control Act*

3. To what extent are manufacturers required to guarantee the composition and/or strength of the nonfood compounds they manufacture?

Manufacturers are required to obtain approval from U.S. government authorities for the non-food compounds they produce and clearly demonstrate that the composition of the product is exactly what the label indicates.

*References: Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
Federal Insecticide, Fungicide and Rodenticide Act
Toxic Substances Control Act*

4. How are exporting establishments advised of recently approved (or unapproved) nonfood compounds and manufacturers? Is an updated list or notice provided and how often is the list or notice updated?

FSIS annually publishes a list of approved nonfood compounds (Publication Number 1419) and distributes this list to FSIS inspectors located in all applicable establishments including all exporting facilities. Establishments requesting to use a non-food compound not listed in Publication 1419 must obtain a certificate of approval from FSIS prior to such use.

*References: List of Proprietary Substances and Nonfood Compounds,
Publication number 1419*

E. Processing Requirements (Canning, Deboning, Grinding, etc.)

- 1. What is the organizational name, function, responsibility, and authority of those responsible for approving the formulations, methods of preparation, and product standards of processed products, including thermally processed products?**

Processed products destined for export must be prepared and processed in accordance with the requirements stated in FSIS regulations (9 CFR 317, 318, and 319). Official establishments have the responsibility to furnish FSIS inspectors with accurate information on all procedures involved with the preparation and processing of meat. FSIS inspectors, who have the authority to approve or deny the preparation/processing procedures, monitor all processing activities. FSIS' Processing Operations Staff provides guidance to inspectors related to the processing of meat products.

FSIS inspectors and the Processing Operations Staff operate through and receive authority from the applicable regulations found in Title 9 of the Code of Federal Regulations.

Part 317 provides regulations on labeling, marking devices, and containers. 9 CFR Section 317.1 states that when, in an official establishment, any inspected and passed product is placed in any receptacle or covering constituting an immediate container, there shall be affixed to such container a label as described in section 317.2 except that the following do not have to bear such a label. Folders and similar coverings made of paper or similar materials, whether or not they completely enclose the product and which bear any written, printed, or graphic matter, shall bear all features required on a label for an immediate container. No covering or other container which bears or is to bear a label shall be filled, in whole or in part, except with product which has been inspected and passed in compliance with the regulations in this subchapter, which is not adulterated and which is strictly in accordance with the statements on the label. No such container shall be filled, in whole or in part, and no label shall be affixed thereto, except under supervision of a Program employee.

Part 318 provides regulations on the entry of product and other articles into an establishment and the re-inspection and preparation of meat products. 9 CFR Section 318.1 states that no product shall be brought into an official establishment unless it has been prepared only in an official establishment and previously inspected and passed by a Program employee, and is identified by an official inspection legend as so inspected and passed. Notwithstanding the foregoing provisions of this subparagraph, product imported in accordance with Part 327 of this subchapter and not prepared in the United States outside an official establishment, may enter any official establishment subject in other respects to the same restrictions as apply to domestic product. Products received in an official establishment during the Program employees absence shall be identified and maintained in a manner acceptable to such employee. Product entering any official establishment shall not be used or prepared thereat until it has been reinspected in accordance with section 318.2. Any product originally prepared at any official

establishment may not be returned into any part of such establishment, except the receiving area approved under section 318.3, until it has been reinspected by the inspector.

Part 319 provides regulations on product definitions and standards of identify or composition. 9 CFR Section 319.1 states that labels for products for which standards of identity or composition are prescribed in this part shall show the appropriate product name, an ingredient statement, and other label information in accordance with the special provisions, if any, in this part, and otherwise in accordance with the general labeling provisions in Part 317 of this subchapter, and such products shall be prepared in accordance with the special provisions, if any, in this part and otherwise in accordance with the general provisions in this subchapter. Any product for which there is a common or usual name must consist of ingredients and be prepared by the use of procedures common or usual to such products insofar as specific ingredients or procedures are not prescribed or prohibited by the provisions of this subchapter.

*References: 9 CFR Parts 317, 318, 319
9 CFR Sections 317.1, 318.1, and 319.1*

2. What is the approval process for thermal and other processing procedures/activities (schedules) that require government approval? What documentation formally states that a thermal, or other, processing schedule is approved?

Prior to the processing of canned product for distribution in commerce including product to be exported, the producing establishment shall have on file a process schedule for each canned product produced. Process schedules are developed or determined by a processing authority. For thermal processing activities, FSIS defines a process authority as a person or organization having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform applicable functions.

For non-thermal processing activities, FSIS defines process schedule as a written description of processing procedures, consisting of any number of specific, sequential operations directly under the control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production. FSIS defines processing authority as a person or organization with expert knowledge in meat production process control and relevant regulations.

FSIS recognizes the processing authority as the approving official for process schedules. Complete records concerning all aspects of the development or

determination of a process schedule are provided to the FSIS inspector or other agency employee upon request.

References: 9 CFR Sections 318.300, 318.301, and 318.302

3. Where applicable, how do you verify that specific and/or approved processing schedules and/or procedures are being followed? How often are records reviewed and how are process deviations handled?

Where applicable, establishments are required to have a process schedule and any other record related to the production for each process. This information shall be made available to the FSIS employee upon request. Establishments shall review all processing and production records to ensure completeness and to determine if all products received the process schedule. The person conducting the review shall sign all records and these records shall be made available to the FSIS employees for review. The FSIS employee will review processing records for verification.

Canned Products - Prior to the processing of canned product for distribution in commerce including product to be exported, the producing establishment shall post in a conspicuous place near the thermal processing equipment or provide the FSIS inspector with a list of process schedules (including alternate schedules) along with any additional applicable information, such as the retort come-up operating procedures and critical factors. Letters and other written communications from a processing authority recommending all process schedules are maintained on file in the establishment. Process deviations are evaluated and approved by the processing authority and the process schedule is amended accordingly.

Cooked Beef, Roast Beef, and Cooked Corned Beef Products - For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) procedures, FSIS requires an establishment to develop and have on file (and available to FSIS inspectors) a process schedule. Each process schedule must be approved in writing by a processing authority (i.e. the equipment manufacturer or processing experts) for safety and efficacy in meeting the performance standards established for the product in question. A processing authority must have access to the establishment to evaluate and approve the safety and efficacy of each process schedule.

*References: 9 CFR Sections 318.300, 318.302, 318.306 and 318.307
9 CFR Sections 318.302, 318.304, and 318.308*

4. Where applicable, what are the requirements to ensure that rigid, and other, product containers are properly closed and/or sealed? Is lead solder used in can seams?

FSIS regulations (9 CFR 318.301) require official establishments to have their closure technician visually examine the double seams formed by each closing machine head and

record the observations of at least one container from each closing machine head. The regulations also require visual examinations to be performed by closure technicians with sufficient frequency (at least every 30 minutes during continuous operation) to ensure proper closure.

Lead solder is not permitted for use in the manufacture of food cans in the United States. The Food and Drug Administration (FDA) of the U.S. government has the responsibility to approve materials used in the development of food containers such as cans and pouches. FSIS works closely with FDA to assure that food containers are made of approved materials.

*References: 9 CFR Section 318.301
Toxic Substances Control Act*

5. What are the requirements and procedures to ensure that thermal, dry cured, or other processing systems are properly constructed, instrumented, and operated?

FSIS regulations (9 CFR 318.302 and 318.311) contain the procedures and requirements concerning the proper construction, instrumentation, and operation of thermal and other heat processing systems. Official establishments including exporting facilities or establishments having thermal or other heat processing systems are responsible for all operations and other facets of this equipment and the safety of food produced from this equipment. In addition, all operators of thermal processing systems and container closure technicians shall be under the direct supervision of a person who completed a school of instruction that is recognized as adequate for properly training supervisors of canning operations. FSIS ensures adherence to FSIS regulations through period verification of an establishments HACCP plan. The HACCP plan is required to include any hazards associated with thermal and other heat processing systems. See Section J. of this questionnaire.

References: 9 CFR Sections 318.302 and 318.311

6. What are the record-keeping requirements to document the adequacy of each approved process. What records ensure the adequacy of other critical control factors in thermal, or other, processing operations?

FSIS regulations (9 CFR 318.306 and 318.307) state that, at a minimum, the following processing and production records shall be maintained: date of production; product name and style; container code; container size and type; and process schedule(s) including minimum initial temperature(s). In addition, the measurements made to satisfy the critical factors specified in process schedules shall be recorded. Furthermore, where applicable, the following information and data shall be recorded for processing in steam:

- a) Batch Still Retorts: Record the retort number for each retort batch and the approximate number of containers or crates per load, product initial temperature, time steam on, the time and temperature vent closed, the start of*

the process timing, the steam off, and the actual processing time. Also, the indicating temperature device and temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

- b) Batch Agitating Retorts: Record the information required for batch, still steam retorts in paragraph (a) above, the functioning of the condensate bleeder(s) and the retort or reel speed.*
- c) Continuous Rotary Retorts: Record the retort system number, the approximate number of containers retorted, product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the times the first can enters and last can exits the retort, the retort or reel speed at intervals not to exceed 4 hours, indicating temperature device(s) and recorder(s) at the times the first can enters the retort and thereafter with sufficient frequency (not exceeding 30 minutes) to ensure compliance, and the times the first can enters the retort and thereafter concerning the condensate bleeders.*
- d) Hydrostatic Retorts: Record the retort system number, the approximate number of containers retorted, product initial temperature, time steam on, the time and temperature vent(s) closed, time process temperature reached, the times the first can enters and last can exits the retort and, if specified in the process schedule, measurements of the temperatures in the hydrostatic water legs. In addition, other temperature recording devices or instruments as well as container conveyor speeds or rotative chain speeds are checked every 4 hours.*

Similar requirements must be recorded for processing in water, steam/air mixtures, and atmospheric cookers. Other records must be kept as specified in 9 CFR 318.307.

References: 9 CFR Sections 318.306 and 318.307

7. What are the food processing standards for processing meat and poultry products to render them shelf-stable? What are the allowable limits for pH and A_w ?

For each given product to achieve shelf stability, it must be produced in accordance with the applicable process schedule. Process schedules are the responsibility of official establishments and must be produced by an authorized processing authority. The pH and A_w limits are specified within each process schedule, where applicable.

References: 9 CFR Sections 318.300 and 381.300

8. What are the procedures used to incubate cans, pouches, or their equivalent from lots of shelf-stable processed products prior to shipping and/or during shipping?

Official establishments must provide incubation facilities that include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations and a means to prevent unauthorized entry into the facility. The incubation procedures are contained in FSIS regulations.

References: 9 CFR Section 318.309

9. What are the standards for non-retorted foods that do not require refrigeration?

Processing standards for non-retorted products that do not require refrigeration such as dry, cured hams and dehydrated meats are contained in Title 9, Part 319 of the Code of Federal Regulations.

For example, if the product was dry cured hams, Section 319.106 would apply. The standards for dry cured ham include:

The product in question uncooked, cured, dried, smoked or unsmoked meat food products made respectively from a single piece of meat conforming to the definition of "ham," as specified in section 317.8(b)(13) of this subchapter, or from a single piece of meat from a pork shoulder. They are prepared in accordance with paragraph (c) of this section by the dry application of salt (NaCl), or by the dry application of salt (NaCl) and one or more of the optional ingredients as specified in paragraph (d) of this section. They may not be injected with curing solutions nor placed in curing solutions.

The product must be treated for the destruction of possible live trichinae in accordance with such methods as may be approved by the Administrator upon request in specific instances and none of the provisions of this standard can be interpreted as discharging trichinae treatment requirements.

The entire exterior of the ham or pork shoulder shall be coated by the dry application of salt or by the dry application of salt combined with other ingredients as permitted in paragraph (d) of this section.

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 shall be 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 shall not be less than 45 days for hams, and shall not be less than 25 days for pork shoulders; the total time for curing salt equalization, and drying shall not be less than 70 days for hams, and shall not be less than 50 days for pork shoulders. During the drying and smoking period, the internal temperature of the product must not exceed 95 degrees F., provided that such temperature requirement shall 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 shall not be less than 45 days for hams, and shall not be less than 25 days for pork shoulders; and the total time for curing, salt equalization, and drying shall not be less than 55 days for hams and shall not be less than 40 days for pork shoulders.

The weight of the finished hams and pork shoulders covered in this section shall be at least 18 percent less than the fresh uncured weight of the article.

The optional ingredients for products covered in this section are:

Nutritive sweeteners, spices, seasonings and flavorings.

Sodium or potassium nitrate and sodium or potassium nitrite if used as prescribed in this section and in accordance with section 318.7(c)(4) of this subchapter.

*References: 9 CFR Part 319
9 CFR Section 318.7*

10. What are the refrigerated storage standards for products requiring refrigeration?

There are no specific storage standards for meat and meat products requiring refrigeration other than at official establishments. 9 CFR Section 308.9 states that products shall be protected from contamination from any source such as dust, dirt, or insects during storage, loading, or unloading at and transportation from official establishments. This includes temperature abuse.

References: 9 CFR Section 308.9

F. Testing/Monitoring Programs

- 1. What microbiological monitoring programs cover applicable meat and poultry products. Describe these programs in detail and provide examples of the data that is recorded. How is the data used/analyzed?**

Depending on the situation, such as the incidence or prevalence of a pathogen and the introduction of processing/testing procedures to control the situation, the following microbiological monitoring programs have been implemented:

Testing/Monitoring programs

Product

Listeria monocytogenes

<i>or Salmonella</i>	<i>Cooked, roast, or corned beef, sliced ham, sliced luncheon meat, large and small diameter comminuted products such as bologna and salami, cooked poultry, meat and poultry salads and spreads, beef jerky</i>
<i>E.coli 0157:H7</i>	<i>Cooked meat patties, raw ground or comminuted beef or veal, dry and semi-dry fermented product</i>
<i>Listeria mono., Salmonella and Staphylococcal enterotoxin</i>	<i>Dry and semi-dry fermented product</i>

Over the years, FSIS has conducted numerous programs to assist and support meat and poultry inspection programs, such as:

*Determination of microbial load in poultry chill water;
Introduction of methodology and technology for better detection of pathogens;
Introduction of techniques and methodology for safe meat and poultry production.*

The data generated by each program is carefully collected, recorded, processed, and analyzed to determine the effectiveness of an operating procedure or for instituting measures for the production of safe meat and poultry. The following microbiological surveys provide examples of the type and quantity of data collected.

*References: FSIS Directive 10320.2 (Procedure for Collecting and Submitting Domestic Samples for Microbiological Analysis
FSIS Directive 10,010.1 (Microbiological Testing Program for Escherichia coli 0157:H7 in Raw Ground Beef)
Nationwide Beef Microbiological Baseline Data Collection Program: Steers and Heifer, Oct. 1992-Sept. 1993.
Nationwide Beef Microbiological Baseline Data Collection Program: Cows and Bulls, Dec. 1993-Nov. 1994.
Nationwide Broiler Chicken Microbiological Data Collection Program: July 1994-June 1995.
Nationwide Pork Microbiological Baseline Data Collection Program: Market Hogs, April 1995-March 1996.
Nationwide Raw Ground Chicken Microbiological Survey, May 1996.
Nationwide Federal Establishment Raw Ground Beef Microbiological Survey, August 1993-March 1994
Nationwide Raw Ground Turkey Microbiological Survey, May 1996
Nationwide Young Turkey Microbiological Baseline Data Collection Program, Aug. 1996- July 1997
FSIS Directives 10,240.1, 10,240.2, 10,210.1*

2. How are microbial guidelines and monitoring programs used as a measure of effective sanitation? Specify what guidelines or programs apply to each product under this application. Describe guidelines not covered in 1. above.

In addition to conducting pre-op and post-op sanitary procedures as specified in an establishment's Standard Sanitary Operating Procedures (SSOP), E. coli testing on carcasses and Salmonella testing on raw carcasses and ground meat are routinely performed to help ensure that slaughter and production procedures are under adequate control and the meat is safe for human consumption. Additionally, many processed products and partially cooked or fully cooked products (salami, Bologna, roast beef, beef jerky, ham, TV dinners, canned meat and soups) are tested for pathogens such as Salmonella, Listeria monocytogenes, and Staphylococcal-enterotoxin. These pathogens have been shown to cause human illness. Cooked or ready-to-eat products must be free of enteric pathogens.

Although E. coli testing, as a measure of the process control of fecal contamination, is not part of SSOP, 9 CFR Section 310.25 states that each official establishment that slaughters cattle and/or swine shall test for Escherichia coli Biotype 1 (E. coli). Furthermore, establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number. From this, FSIS can determine the presence or absence of fecal contamination and is authorized to require that establishments adjust their HACCP plan to correct any such non-compliances. Product contamination, fecal or otherwise, is a sanitation concern.

Section 310.25 also provides raw meat product performance standards for Salmonella. An establishment's raw meat products, when sampled and tested by FSIS for Salmonella, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2 - SALMONELLA PERFORMANCE STANDARDS

<i>Class of product</i>	<i>Performance Standard (percent positive for Salmonella)^a</i>	<i>Number of samples tested (n)</i>	<i>Maximum number of positives to achieve Standard (c)</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>
<i>Hogs</i>	<i>8.7%</i>	<i>55</i>	<i>6</i>
<i>Fresh pork sausages</i>	<i>30%</i>	<i>53.</i>	<i>18</i>

FOOTNOTE a: Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys.

FSIS samples and tests 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. The frequency and timing of such testing is based on the establishment's previous test results and other information concerning the establishment's performance. The effectiveness of an establishment's HACCP plan is measured by Salmonella test results. Failure by the establishment to reassess its HACCP plan for that product and take appropriate corrective actions or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services.

*References: Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems: Final Rule, U.S. Department of Agriculture, Food Safety and Inspection Service.
9 CFR Parts 416 and 417
9 CFR Section 310.25*

3. What other (non-microbiological) monitoring procedures are used to ensure the proper preparation, processing, and handling of product, e.g., the incubation of cans or pouches of shelf stable processed products prior to shipping and/or during shipping?

Inspectors in processing establishments follow FSIS regulations and directives for evaluating the raw meat, ingredients, spices, containers, labels, and processing methods before a product is made. During production, they actively monitor each and every step of a production process and, if necessary, stop production or require a corrective action/procedure.

Canned products are sampled and incubated as specified in FSIS Directives. Depending on the product, the response to a given number of defective cans of product found in a lot (swollen or defective cans) depends on the particular FSIS Directive. In one case, a sample may be taken and the lot released before the laboratory results are completed. In another case, the lot kept under Hold and Test Mode until the results of the test results are shown to be satisfactory. Depending on the situation and the test results, part or all of the lot is reprocessed or condemned.

There are also different directives that apply to the different self-stable meat items (i.e. pouched).

*References: FSIS Directive 7520.2
9 CFR Section 318.305*

4. For each of the products under this application, what procedures do you follow for analyzing can or container defects, e.g., how are lots of shelf stable product examined for “condition of container” prior to shipping?

The FSIS laboratory analysts are trained in analyzing defective canned product due to incorrect or under-processing or due to container defects. Additionally, samples are chosen at random from every lot, prior to shipping, and are physically examined at the establishment by the inspector.

*References: 9 CFR Sections 318.308 and 318.309
FSIS Directive 7520.2
USDA/FSIS Microbiol. Laboratory Guidebook, 3rd ed, 1998, Chapter 10*

5. What are the criteria for “Potable” water? What requirements do you have for ensuring that potable water is used during the canning and processing of meat and poultry products? What requirements do you have for the water used to clean and rinse processing equipment?

Potable water means that it has been approved by a State health authority or other agency or laboratory acceptable to the Administrator as safe for drinking and suitable for food processing; i.e free of pathogens and chemicals as specified by the United States Public Health Service for water quality and standard.

The water is collected at the establishment site and tested once a year by a municipal or public health laboratory if the water is supplied by the municipal authority. If the water is supplied from a different source (private well), then the supply of water is tested twice a year by a public health laboratory.

The requirement for using potable water in canning operations is specified. Only potable water can be used in a processing or slaughter operation.

*References: MPI Regulations 381.50, 318.305, and 318.35
FSIS Notice 7-98*

6. How are privately owned laboratories involved in microbiologic testing to determine and/or monitor the compliance meat and poultry of products?

Since all establishments are privately owned, they employ the services of private laboratories to monitor the compliance of various government requirements, such as the presence of pathogens or residual chemicals in products. The results are monitored and reviewed by FSIS inspectors.

FSIS does its own monitoring by collecting samples that are analyzed in FSIS laboratories.

Reference: 9 CFR Part 417

7. For the testing and monitoring programs stated above, what procedures or guidelines are used when corrective actions are required? What are the action levels for these programs?

For establishments under the HACCP regulations:

FSIS Directive 10240.2 states that if the sample tests positive for microbial hazards, the District Office (DO) provides the Inspector-in-Charge (IIC) with the information necessary to complete a Noncompliance Record (NR)(FSIS Form 5400-4). The IIC documents the procedure as unscheduled on the Procedure Schedule and, in Block 8 on the NR, records ISP code 05B02. No trend indicators are checked. In Block 10 on the NR, the IIC includes:

- a. the sample collection date,*
- b. the product name, and*
- c. the organism or toxin found.*

The IIC provides a copy of the NR to the establishment and sends a copy to the DO.

Program Personnel Responsibilities - The IIC, DO, and Emergency Response Division coordinate regarding the necessity of product retention, seizure, or recall. The DO will instruct inspection and enforcement personnel as necessary.

If product from the sampled lot is in the establishment, inspection personnel will verify that the establishment prevents product from entering commerce in accordance with 417.3(a)(4) or (b)(3). If necessary inspection personnel will retain that product.

Inspection personnel will release the product if the establishment can treat it in a manner so that it is no longer adulterated, or condemn the product if the establishment fails to treat it in a manner so that it is no longer adulterated. (See FSIS Directive 5000.1 Part II III.B. 3.a.(3) & b. and Part III III.B.2.).

Inspection personnel will perform an O2 procedure on the products HACCP plan and procedures 01B01 and 01C01 on the establishment s SSOP covering the time period from when the sample was collected to the present. (See FSIS Directive 5400.5).

If the IIC determines, based on the available information, that the establishment is continuing to produce and ship product that may be injurious to health, he or she should withhold the marks of inspection and inform the DO.

Inspection personnel will verify that the establishment performs the necessary corrective and preventive actions in accordance with 416.15 and 417.3 (See FSIS Directive 5000.1 Part II III.B.3. and Part III III.B.).

The DO will make a determination, based on consideration of the policy issues discussed in paragraph VI., regarding the necessity of enforcement actions and instruct inspection and enforcement personnel as needed.

For establishments not under the HACCP regulations:

FSIS Directive 10,240.1 establishes the sampling if product produced under a non-HACCP environment.

For ROUTINE MICROBIOLOGICAL SAMPLING - MONITORING PHASE

A. Monitoring Samples. Those establishments that produce certain cooked, ready-to-eat meat and/or poultry products are subject to routine sampling and testing under FSIS's Microbiology Monitoring Program for the presence of microbiological contaminants. Examples of these types of products include cooked sausages such as frankfurters and bologna, cooked roast beef, cooked corned beef, sliced canned ham, sliced canned luncheon meat, jerky, cooked poultry, and poultry and meat salads and spreads.

1. When the IIC receives a Request for Sampling, FSIS Form 10210-2, the IIC should:

a. Notify establishment management that samples of product will be collected and tested for microbiological contaminants under the Monitoring Program.

b. Advise establishment management that if intact sample units are collected, the entire sampled production lot may be held at the discretion of establishment management pending results of the monitoring sample, and if not held, the lot could be subject to voluntary recall, detention or seizure if the samples are positive for microbiological contaminants. If non-intact samples are taken, the lot does not need to be held pending test results.

2. The IIC will collect either non-intact or intact samples depending on the packaging practices of the establishment.

3. If the establishment is producing product units of more than 3 pounds, the IIC will select a non-intact-sample. One sample consisting of 1/2 to 1 pound from the bulk pack or large piece should be collected. The non-intact sample should be taken aseptically. The IIC will submit this sample to an FSIS laboratory.

4. If the establishment is producing product units of 3 pounds or less, the IIC will select intact samples. If the intact product unit weighs 1 pound or less, 6 intact product units will be collected. If the intact product unit weighs more than 1 pound but not more than 3 pounds, 2 intact product units will be collected. The IIC will submit these samples to an FSIS laboratory.

B. Initial Monitoring Sample Result from Intact Samples--Positive Finding.

1. The Microbiology Division will notify the Processing Operations Staff when an initial monitoring sample tests positive for microbiological contaminants. The Processing Operations Staff will notify the appropriate Regional Office.

2. The Regional Office will:

a. Immediately advise the IIC and the establishment orally of the positive finding followed by written notification.

b. Provide the establishment management an opportunity to respond to the Notice by submission of a corrective action letter outlining a corrective action plan to the IIC, with a copy to the Regional Director and the Area Office. The corrective action letter should outline what actions the establishment intends to take to correct the situation. The letter should also state whether product will be voluntarily held at the establishment until FSIS laboratory results are received.

c. Notify the Processing Operations Staff and the Emergency Programs Staff if the lot represented by an initial intact monitoring sample has left the establishment.

3. *The IIC should:*

a. *Advise the establishment to stop cooking like product until a corrective action plan is implemented. Like product produced after notification should be considered suspect unless and until the IIC has been informed adequate corrective action has been taken to prevent production of contaminated product.*

b. *Review and discuss with establishment management the establishment's corrective action letter.*

c. *Retain the lot of product represented by the initial monitoring sample if the lot has not left the establishment.*

d. *Notify the Regional Office if the lot is represented by an intact sample and has left the establishment.*

e. *Advise establishment management that the establishment is now under the Hold and Test Restriction as described in section IX.*

C. *Initial Monitoring Sample Result from Non-Intact Samples-- Positive Finding. When a positive finding is reported, follow the procedures given in Paragraph VIII., Verification Sampling and Procedures.*

D. *Intact Samples of Non-Like Product.*

When the Microbiology Division notifies the Processing Operations Staff that microbiological contaminants have been found in an intact monitoring sample, action will be initiated to order the collection of a set of intact monitoring samples of non-like product.

VERIFICATION SAMPLING AND PROCEDURES

A. *Verification sampling is only instituted in those establishments in which non-intact samples were taken under the monitoring program and found to be positive for microbiological contaminants. Verification sampling is intended to determine whether intact samples of product from those establishments are also positive for microbiological contaminants.*

B. *Verification Samples Where Corrective Action Taken. After the establishment's corrective action plan has been implemented and cooking of like product has resumed, the IIC will collect samples from the next production lot of like product.*

C. *Verification Samples Where Corrective Action Not Taken. If the establishment does not implement a corrective action plan and/or does not stop cooking like product upon notification by FSIS, the IIC will collect samples from a production lot with a production code similar to the code of the product selected for sampling under the Monitoring Program. If no similar product is available for sampling, the IIC will collect samples from the next production lot of like product.*

D. *Product Units Weighing 15 Pounds or Less. If units of product subject to verification sampling weigh 15 pounds or less, the IIC will collect six intact units.*

E. *Product Units Weighing More Than 15 Pounds. If the units of product subject to verification sampling weigh more than 15 pounds, the IIC will select six units of product and collect 1 pound of product from each of the six units. These samples must be taken aseptically. If desired by establishment management, establishment employees may collect the samples from the six units selected by the IIC under the IIC's supervision.*

F. The IIC will submit all samples to an FSIS laboratory.

G. The IIC should advise establishment management that if the lot represented by the verification samples is not voluntarily held, it may be subject to voluntary recall, detention or seizure if a sample is positive for microbiological contaminants.

H. Verification Sampling--Negative Finding.

If verification samples test negative, the verification lot under voluntary hold will be released. The establishment will return to routine sampling under the Monitoring Program.

I. Verification Sampling--Positive Finding.

1. If verification samples test positive, the IIC will:

a. Retain as suspect the lot represented by the verification sample if the lot has not been shipped from the establishment. The establishment will be given a reasonable opportunity to propose disposition of the lot to prevent its condemnation and destruction.

b. Inform his/her supervisor if any portion of the lot has been shipped from the establishment.

c. Place subsequent production of like product on the hold-and-test restriction as described in Paragraph IX.

HOLD AND TEST RESTRICTION

A. Application. The hold and test restriction is instituted by the IIC after intact monitoring samples or verification samples have tested positive for microbiological contaminants. Subsequent production of like product will be tested and retained at the establishment until five consecutive production lots of like product are found to be free of microbiological contaminants.

B. Responsibilities.

1. The IIC will collect five intact samples from each lot of like product. A lot under the hold-and-test restriction is defined as all like product prepared from one day's production or as described in Section VI.E.2. The IIC will submit these samples to either a recognized laboratory or an FSIS laboratory. If the samples are sent to a recognized laboratory, five additional audit samples per lot of like product must be collected and sent to an FSIS laboratory.

2. If samples are sent to an FSIS laboratory, the Area Office will advise the IIC and establishment management of the test results and the disposition of each lot.

3. If samples are sent to a recognized laboratory, the IIC will receive the results directly from the recognized laboratory. The IIC should advise establishment management of the test results.

4. If any hold and test lot tests positive for microbiological contaminants, the affected lot will be held at the establishment pending disposition.

5. If the results are negative, the affected lot is released.

6. When like product is released from the hold and test restriction (after five consecutive negative tests), samples of like product no longer need to be taken except as directed by the Monitoring Program.

PREVIOUSLY DISTRIBUTED 'SUSPECT' PRODUCT

A. *The lot represented by a positive intact sample under the Monitoring Program or verification sample will be considered to be suspect and may be subject to voluntary recall, detention or seizure.*

B. *The Emergency Programs Staff will:*

1. *Notify the establishment when a voluntary recall of affected product is advised.*
2. *Coordinate activities related to the voluntary recall, including issuing a press release, in accordance with FSIS Directive 8080.1, Rev.1.*

RECALLED PRODUCT

In the event of a product recall by the establishment, the IIC will:

- A. *Retain all product that is returned to the establishment.*
- B. *Supervise the identification and separation of product by name and production code.*
- C. *Supervise the disposition of the recalled product as directed by the Regional Office.*

MICROBIOLOGICAL INCIDENT SURVEILLANCE SAMPLE (MISS) PROGRAM

A. *The MISS Program is a component of FSIS's Microbiological Monitoring and Surveillance Program. The MISS Program is initiated at establishments where a problem has been noted through monitoring or other sources to determine whether the noted problem has been corrected.*

B. *In particular, the MISS Program is initiated whenever an establishment shows a pattern of violative sample results or otherwise at the discretion of FSIS. The MISS Program covers all products including those incriminated in the Monitoring Program, and the results are used to evaluate potential problems.*

C. *Under the MISS Program, the IIC will:*

1. *Select MISS Program samples for a designated period of time as directed by the Regional Director.*
2. *Advise establishment management that any lot of product where intact samples are taken and found to be positive may be subject to voluntary recall, detention, or seizure if the lot is shipped prior to receipt of sample results. If non-intact samples are taken, the lot does not need to be held pending test results.*

D. *The Regional Office will notify the IIC of test results.*

E. *If test results are negative, the IIC will release any lot represented by the MISS sample that has not left the establishment and sampling continues under the MISS Program.*

F. *If test results are positive, the IIC will:*

1. *Retain any product represented by the MISS sample that has not left the establishment.*

2. *Notify the Regional Office if product represented by the MISS sample was from product packed in a consumer size retail package and the product has left the establishment.*

FSIS Directive 10210.1 provides a unified sampling form. The purpose of the Directive provide instructions to inspectors for the use of a unified sampling form to be used for all directed sampling programs (microbiological, chemical, and residue).

FSIS Directive 10,010.1 provides instructions for the microbiological testing program for E. coli 0157:H7 in raw ground beef. In domestic establishments, if a sample is confirmed positive, inspection personnel condemn the sampled lot, unless it is fully cooked in accordance with 9 CFR 318.23 or processed in an equivalent manner to that required by the regulations. In addition, the inspector is to collect subsequent samples from new lots on a daily basis until 15 consecutive samples have tested negative and is to direct questions through supervisory channels. In retail outlets, positive results require that compliance officers collect samples on a daily basis until 15 samples have tested negative. If a sample of imported product is confirmed positive, the foreign establishment is placed on intensified inspection as explained above. The import inspector is to collect samples from the next 15 consecutive shipments of ground beef shipped to the United States from that establishment. These samples must test negative before intensified inspection can be lifted.

*References: FSIS Directives 10,010.1, 10,240.1, 10,240.2, and 10,210.1
9 CFR Sections 417.3 and 416.15*

- 8. For each product, how many samples are analyzed per year for microbiologic characteristics, pathogens, and foreign particle contamination before, during, and after processing under each testing program? Describe the statistical analysis used to determine the frequency and type of sample taken. Provide a copy of at least one full year's data (from current year) from each program.**

FSIS Directive 10,010.1 states that microbiological testing of ground beef for E. coli 0157:H7 is performed among approximately 1900 establishments and 100,000 retail outlets. Each month, FSIS randomly selects an appropriate number of inspected establishments and retail outlets for sample collection. In addition, an appropriate number of samples are taken from imported ground beef product(s) upon FSIS import inspection and at state inspected establishments by state program personnel. [The applicant would herein provide current test results covering one full year, as applicable]. FSIS bases its sampling plan on information from Centers for Disease Control and Prevention (CDC) sentinel sites, historic data of outbreaks of food borne illnesses, and information developed by the Office of Public Health and Science (OPHS). If an establishment or retail outlet initiates its own routine sampling program, has a certification from suppliers that the product was tested, or, in the case of inspected establishments, uses in-establishment validated pathogen reduction interventions on beef carcasses, FSIS will not collect samples.

Generic E. coli is tested at a rate of 1 sample for every 300 cattle and 1 sample for every 1000 swine in every slaughter establishment in the United States. Establishments are required to collect the samples according to FSIS regulations and have them analyzed in a laboratory shown to perform a AOAC approved or internationally recognized method of analysis to measure the process control of fecal contamination in each establishment. Test records are maintained in the establishments and are readily available for government review. This program is more thoroughly explained in Section I. (Generic E. coli Testing) of this questionnaire. [Where applicable, the applicant should provide one full year's worth of data reflecting the test results from each establishment being certified to export to the U.S.]

Raw carcasses and ground beef products are tested for Salmonella according to FSIS' Salmonella Testing Program, as detailed in the Enforcement Questionnaire, Section Q. Salmonella Testing. During 1998, the following data was compiled from large establishments (and a few volunteer small establishments) and quantifies the pass/fail results from the first sample set of samples.

Summary Of Passed/Failed Sets By Product Category:

<u>Product Class</u>	<u>Set Size</u>	<u># Passed Sets</u>	<u># Failed Sets</u>
Cows/Bulls	58	4	1
Steers/Heifers	82	2	0
Hogs	55	14	6
Ground Beef	53	19	6
Broilers	51	86	9
Ground Turkey	53	14	1

(Set Size is the number of samples required to complete one set of samples for the given product class.)

The sampling of cans or other product is random and the number of samples taken depends on the production volume. From each lot, 6 samples are taken and incubated in the establishment, if it is a canned product. If abnormal cans are found, they are sent to an FSIS laboratory for examination. For other products, samples are sent directly to the laboratory for testing. Routine, on-going samples are taken from product as described in 1. above. The frequency and type of sample taken is based on numerous factors, such as the number of establishments involved in the program, the capability of the laboratories, and the number of problems that were observed. The sampling programs are historically based and are designed to be responsive to current needs. The trigger point for all the programs is well below necessary contamination levels. The guidelines for sample collection and analysis used are:

*References: MPI Regulation 23.3 (c)
MPI Regulation 318.14
FSIS Directives 7520.2, 7530.1, 10,600.1, 7520.2, and 10,230.5
FSIS Directives 10,010.1, 10,210.1, 10,240.1, and 10,240.2.*

9. For each microbiologic characteristic that is not part of a routine, on-going sampling program, how many samples are analyzed per year and how are the results reported? Provide a summary of most recent full year's data.

Sampling that is part of a baseline study or survey in non-routine/non-on-going and usually covering a period of one year or less. Non-routine sampling is also generated for extraneous materials and other contaminants by FSIS inspectors, the FSIS Compliance program, or consumer complaints. A summary of the raw product nationwide baseline studies and surveys is as follows:

<u>Project Name</u>	<u>Start Date</u>	<u>End Date</u>	<u>Testing For:</u>
Baseline-Steer/Heifer	10/92	9/93	Aerobic Plate Count Total Coliform E. coli (Biotype 1) Clostridium perfringens Staphylococcus aureus Listeria monocytogenes Campylobacter jejuni/coli Salmonella spp
Survey-Federal Ground Beef	8/93	3/94	Same, Baseline-Steer/Heifer
Baseline-Cow/Bull	12/93	11/94	Same, Baseline-Steer/Heifer
Baseline-Broilers	7/94	6/95	Same, Baseline-Steer/Heifer
Survey-Ground Chicken	3/95	5/95	Same, Baseline-Steer/Heifer
	9/95	11/95	Same, Baseline-Steer/Heifer
Survey-Ground Turkey	3/95	5/95	Same, Baseline-Steer/Heifer
	9/95	11/95	Same, Baseline-Steer/Heifer
Baseline-Market Hogs	4/95	3/96	Same, Baseline-Steer/Heifer
Survey-Raw Pork Sausages	3/96	7/96	Same, Baseline-Steer/Heifer
Baseline-Turkeys*	8/96	7/97	Same, Baseline-Steer/Heifer
Sponge Baseline-Cattle	6/97	5/98	Salmonella, generic E. Coli
Sponge Baseline-Swine	6/97	5/98	Salmonella, generic E. Coli
Sponge Baseline-Turkey	7/97	6/98	Salmonella, generic E. Coli
Baseline Campylobacter-Chickens	1/99	in progress	Campylobacter

*Attachment Enclosed.

A summary of the Ready-To-Eat non-routine testing studies is as follows:

<u>Date Started</u>	<u>Project Name</u>	<u>Testing for:</u>
July '83	Cooked, Roast & Corned Beef	Salmonella, Listeria monocytogenes
April '86	Sliced Ham & Luncheon Meat	Salmonella, Listeria monocytogenes, S. aureus
March '88	Small Diameter Cooked Sausage	Salmonella, Listeria monocytogenes

March '88	Large Diameter Cooked Sausage	Salmonella, Listeria Monocytogenes
October '88	Jerky	Salmonella, Listeria monocytogenes, S. aureus
March '89	Cooked Poultry	Salmonella, Listeria Monocytogenes
May '89	Salads, Spreads, & Pate	Salmonella, Listeria monocytogenes, S. aureus
May '90	Imported Cooked Product	Salmonella, Listeria Monocytogenes
March '94	Cooked Paties	E. coli O157-H7
September '94	Fermented Sausages	Salmonella, Listeria monocytogenes, Staphylococcus enterotoxin, E. coli O157-H7
October '94	Raw Ground Beef	E. coli O157-H7
November '95	Pasteurized Egg Products	Salmonella
February '97	Imported Fermented Sausages	Salmonella, Listeria monocytogenes, Staphylococcus enterotoxin, E. coli O157-H7

These studies were implemented using a zero tolerance performance standard.

In addition to the above, canned products are not routinely tested for gram negative organisms such as E.coli, Salmonella, or Shigella, since these organisms are heat sensitive and canned products are heat processed. However, if it has been determined that there has been some processing deviation, then a statistically determined, random number of cans are incubated at the establishment. Depending on the appearance of the incubated cans, the inspector will send a can to the laboratory. Tests are performed to determine the nature of organism that is present in the can. The type of organism found determines the type of defect in the can or the deviation in the processing. For shelf stable canned products, tests for heat resistant organisms, organisms causing flat-sour spoilage, and some pathogens (Listeria mono.) are also carried out.

The result is sent to the District Office (DO) electronically. The DO alerts the inspector and Compliance, and appropriate action is taken. Depending on the degree of public health risk from the product, the product is; (a) recalled and destroyed; (b) recalled for reprocessing/repackaging; or (c) allowed for use for pet food, fertilizers etc.

Product sampling in response to consumer complaints depends on the nature of the complaint. If the complaint involves an alleged foodborne illness, product samples are analyzed only when the consumer has a laboratory-confirmed diagnosis or more than one complaint from unrelated sources is reported about a product. If a consumer has a laboratory-confirmed illness, the product is analyzed for the same organism that the consumer tested positive for (ie. if the consumer tested positive for E. coli O157:H7, the product will be analyzed for E. coli O157:H7). If there is more than one illness complaint reported about a particular product, which is rare, the Food Health and Safety Division

(FHSD) usually requests a sanitation series be run on an intact, like-coded product sample. The sanitation series includes analysis for Enterococci, Coliforms, E. coli, Salmonella, S. aureus, APC at 35 degrees and at 20 degrees, and gas forming anaerobes.

If a consumer complaint involves finding a foreign object in a product, product samples are requested only if a Compliance Officer is unable to identify the foreign object or more than one complaint about a particular product has been reported. The product and foreign object are usually sent to the lab to identify the foreign object. Sometimes additional like-coded product samples are analyzed to determine whether they also contain extraneous materials.

For the past two years approximately 50 to 60 product samples per year were analyzed in response to consumer complaints (out of approx. 400 consumer complaints per year). This number includes complaints involving both extraneous materials found in products and alleged foodborne illnesses.

The results are reported directly to FHSD and the ADME (Assistant District Manager for Enforcement) from the district where the complaint originated. If the results are negative, a record is made of the results and the case is closed. If the results indicate a potential food safety hazard, the Emergency Response Team is notified to evaluate the need for a product recall.

CY 1998 Raw Ground Beef Survey Samples
Analyzed for Ecoli O157:H7

<u>Project</u>	<u>Number Analyzed</u>	<u>Total Negative</u>	<u>Total Positive</u>
<i>Raw Ground Beef - Federal</i>	4258	4246	12
<i>Raw Ground Beef - Import</i>	13	13	0
<i>Raw Ground Beef - Retail</i>	3731	3729	2
<i>Raw Ground Beef - State</i>	55	55	0

*References: FSIS Directives 7520.2, 7530.1, and 10,210.1
 FSIS Directive 10320.2 (Procedure for Collecting and Submitting Domestic Samples for Microbiological Analysis
 FSIS Directive 10,010.1 (Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef)
 Nationwide Beef Microbiological Baseline Data Collection Program: Steers and Heifer, Oct. 1992-Sept. 1993.
 Nationwide Beef Microbiological Baseline Data Collection Program: Cows and Bulls, Dec. 1993-Nov. 1994.
 Nationwide Broiler Chicken Microbiological Data Collection*

Program: July 1994-June 1995.
Nationwide Pork Microbiological Baseline Data Collection
Program: Market Hogs, April 1995-March 1996.
Nationwide Raw Ground Chicken Microbiological Survey,
May 1996.
Nationwide Federal Plant Raw Ground Beef Microbiological Survey
August 1993-March 1994
Nationwide Raw Ground Turkey Microbiological Survey, May 1996
Nationwide Young Turkey Microbiological Baseline Data Collection
Program, Aug. 1996- July 1997
Nationwide Raw Ground Beef Survey for E. coli O157:H7, July 1999

G. Laboratories

- 1. How many laboratories are used to perform microbiologic testing? For each laboratory, indicate whether it is a federal, private, or 'other' type of laboratory and describe the tests that are performed there.**

There are 3 (three) FSIS laboratories which perform microbiological testing. They are all government (Federal) laboratories, each having specialized testing abilities. Together, the combined FSIS laboratories perform various microbiological tests; e.g. isolation and identification of pathogens such as Salmonella, Shigella, Clostridium, E.coli, Listeria monocytogenes, and Bacillus from raw or processed meat and poultry products including canned, frozen, vacuum packaged and dried product. Additionally, they detect and identify residual antibiotics in meat and poultry and perform extraneous material analysis including evaluation of disinfectants and sanitizers.

In addition, there are Recognized Laboratory Programs for species testing. The FSIS recognized laboratories are as follows:

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*

*References: <http://www.fsis.usda.gov/index.htm>
<http://www.fsis.usda.gov/OA/programs/programs.htm>
<http://www.fsis.usda.gov/OPHS/ophshome.htm>.
MPI Manual, 23.10 (Microbiology)
Meat and Poultry Inspection Directory, July 1998*

**2. Is each laboratory approved to perform applicable microbiologic testing?
What is the approval process?**

Yes, all FSIS laboratories are capable of performing applicable testing. All of the scientists in FSIS laboratories are trained and qualified. In addition to bi-annual meetings for laboratory personnel, the scientists attend annual professional meetings. Additionally, the analysts are tested for their skill ability. The testing procedures, as approved by the FSIS, Microbiology Division, are used in all 3 laboratories. The scientists are trained in ISO 2500 procedures.

APHIS conducts laboratory approvals for specific diseases (See Attachment). For example, for Bluetongue, Bovine Leukosis, and Equine Infectious Anemia, APHIS has written policies and procedures for the approval of laboratories to conduct official tests for these diseases through the use of officially approved and licensed diagnostic test kits. Requests for laboratory approval are made through the appropriate Area Veterinarian-in-Charge.

*References: <http://www.fsis.usda.gov/OPHS/ophshome.htm#MD>
<http://www.fsis.usda.gov/OPHS/ophswho.htm#FSL>
APHIS, Veterinarian Services Memorandum No. 555.8 dated 4/10/97.*

3. What are the requirements and qualifications of the microbiology supervisor and of the bench microbiologist? If you have a microbiology staff at headquarters, describe and list their functions and responsibilities.

*A bench microbiologist, starting at the GS-5 level, should have a Bachelor's degree with 20 hours of course work in the area of microbiology.
A supervisory microbiologist should have a bachelors degree and 8-10 years of bench experience. Usually, a microbiology supervisor, in charge of a laboratory, has a graduate degree (see FSIS Position Description Manual).*

The headquarter's staff consists of approximately 12 microbiologists headed by a Director of the Division. The three Branches at Headquarters and their functions are:

- a. Emerging Microbial Issues Branch: Develops programs for monitoring foodborne pathogens in meat, poultry, and egg products and also for obtaining baseline data.*
- b. Special Projects and Outbreak Support Laboratory: Conducts studies to support meat and poultry inspection program, investigates outbreaks and analyzes epidemiological samples.*
- c. Quality Assurance Branch: Performs quality control of commercially available screen test kits used by field inspectors and provides/prepares inter-laboratory check samples(for antibiotic analysis).*

The last two Branches have laboratories. They are located in Athens, GA. Additionally, FSIS has three field laboratories for testing routine microbiological samples. They are located in Athens, GA; St. Louis, MO; and Alameda, CA.

*Reference: Meat and Poultry Inspection Directory, 1998
FSIS Position Description Manual*

4. Are standardized analytical methods used in the laboratories? Are the analytical methods AOAC approved or internationally recognized? Describe the microbiologic procedures/methods and provide a copy of the worksheets that are used.

Yes, the standardized analytical methods have been tried and approved by AOAC or found suitable through collaborative studies conducted by FSIS. Additionally, FSIS laboratories use those methods that were developed and tested by FSIS scientists and are included in the FSIS Microbiology Laboratory Guidebook, 3rd edition, 1998.

Reference: FSIS Microbiology Laboratory Guidebook, 3rd edition, 1998.

5. How do the quality control or quality assurance programs in approved laboratories ensure accurate and consistent analyses? Describe how the government ensures that the programs produce accurate results and provide examples of the data obtained from this program.

On a quarterly basis, all FSIS laboratories are supplied with check samples by a reputable private laboratory and each FSIS laboratory has to qualify; i.e. successfully isolate and identify the agents (Salmonella, E.coli, Listeria etc.) in the check samples supplied by the private laboratory. Internal Quality Assurance Programs are in place for meat species identification, staphylococcal enterotoxin analysis, and antibiotic residue identification and quantification. All analytical protocols of the methods in the Microbiology Laboratory Guidebook (MLG) include quality control measures that ensure the accuracy and reliability of performance.

References: *FSIS Microbiology Laboratory Guidebook, 3rd edition, 1998.*
<http://www.fsis.usda.gov/OPHS/ophshome.htm#MD>
<http://www.fsis.usda.gov/OPHS/ophswho.htm#FSL>

6. If applicable, how does the government ensure that the results of analyses performed at privately owned laboratories are accurate?

The three recognized noted in question 1. above for cooked meat species identification are subjected to the same quality assurance program check samples as the FSIS Field Services Laboratories. The FSIS Accredited Laboratory Program (ALP) regulations (FSIS Directive 3300.4 and 9 CFR Part 318) require that a non-Federal laboratory successfully analyze an initial set of accreditation check samples before accreditation by FSIS. The Quality Assurance Branch, Chemistry and Toxicology Division:

A. Sends laboratories an initial set of accreditation check samples to analyze and return the results.

B. Insures that laboratories analyze the initial check samples and meet specific regulatory performance standards. Laboratories have two opportunities to correctly analyze the check samples to demonstrate analytical proficiency.

C. Notifies laboratories of the results of the performance evaluation. Laboratories that successfully analyze the samples receive accreditation.

D. Denies FSIS accreditation when a laboratory fails two performance evaluations. Informs laboratories of the mandatory 60-day waiting period and the procedure for reapplying for accreditation after the 60-day waiting period.

Although FSIS Notice 26-94 suspends the routine collection of "split" official food chemistry samples that are to be analyzed by FSIS Accredited Laboratories for determining the acceptability of accredited laboratory performance, the Agency will continue to use its interlaboratory check sample program and other quality assurance systems to monitor accredited laboratory performance.

References: *MPI Manual 23.11 and 23.12*
<http://www.fsis.usda.gov/OPHS/ophshome.htm#MD>
<http://www.fsis.usda.gov/OPHS/ophswho.htm#FSL>
<http://www.fsis.usda.gov/ophs/acclab/alpinfo.htm>
FSIS Directive 3300.4 and FSIS Notices 26-94
9 CFR Part 318

H. Control of Non-compliant Product

- 1. What procedures and instructions do you follow for the control and disposition of product that does not comply with Country-X, or equivalent, standards?**

FSIS has a Compliance Program headquartered in Washington, D.C. with approximately 140 compliance officers stationed throughout the country. In addition, there are 18 Assistant District Managers for Enforcement, one in each of the 18 District Offices.

There are also Supervisory Compliance Officers stationed across the country. Compliance officers conduct systematic reviews of all classes of persons, firms, and corporations dealing in meat, poultry, and egg products intended for either direct human consumption or other use (but ultimately distributed in consumer channels), i.e freezer warehouses, institutions, etc. Compliance officers have the authority to detain products believed to be adulterated or misbranded. Compliance officers document information and develop case files for alleged violations of the various inspection Acts. Samples are collected in the marketplace to ensure compliance with labeling requirements. Product integrity is monitored outside normal inspection controls. Where necessary, administrative actions are initiated to suspend or withdraw inspection service for insanitary conditions, HACCP System failures, failure to test and record E. coli test results, failure to meet performance standards for Salmonella spp, unfitness to operate (felony convictions or two misdemeanors involving transactions with food, inhumane slaughter, assaults or threats, intimidation, or interference with government officials), and failure to control condemned products.

When imported meat, poultry, or egg products as well as product produced in this country are found to be unsafe, non-wholesome, or incorrectly labeled or otherwise found to be in violation of the FMIA, PPIA, or EPIA or any other law, FSIS will detain such product. Detained product not eligible to be brought into compliance with U.S. law is subject to condemnation and disposal. Condemned product is destroyed in the presence of an FSIS inspector by incineration, denaturing, or other acceptable means. Such product may be eligible for further processing into animal food, or inspected and passed by FSIS personnel strictly for cooking, depending on the circumstances.

*References: 9 CFR Parts 314, 315, 318.8, 325, and 329
FSIS Directives 8110.1, 8100.1, 8070.1, and 8040.1*

2. If applicable, who authorizes the reprocessing of non-compliant product and how is the integrity of the product maintained?

FSIS personnel or any authorized representative of the Secretary of Agriculture has the authority to allow the reprocessing of non-compliant product, provided such product is eligible to be brought into compliance with U.S. law. Non-compliant product subject to reprocessing is identified and maintained under control until such product has been brought back into compliance.

References: 9 CFR Part 315

3. What procedures do you follow to certify acceptable products or re-certify previously non-compliant products for export?

Acceptable product and re-certified (reprocessed) product meeting FSIS laws and regulations and determined to be U.S. inspected and passed product may be used for domestic or export commerce. FSIS inspectors do certify product for export as meeting the requirements of the importing country. Products containing certain preservatives

and other substances not permitted in domestic product may be exported provided the product meets the laws and regulations of the importing country and are appropriately approved and identified.

*References: 9 CFR Part 325
9 CFR Sections 318.8*

4. What tests are performed and what do you do with the results when cans and other product containers are submitted to a laboratory because they are swollen or otherwise defective?

*For processed product, FSIS requires finished product inspections to be conducted in accordance with FSIS regulations -- 9 CFR 318.309. Accordingly, canned products identified as being defective, e.g., swollen, leakers, are sent to an FSIS laboratory for microbiological testing. Defective cans are opened aseptically and tested for the detection of aerobes. Cans are also incubated at 35°C and 55°C to detect mesophilic and thermophilic organisms. The presence of mesophilic gas-forming anaerobes warrants further tests for *Clostridium botulinum*. Emptied cans examined for leaks by vacuum analysis and can seams are analyzed by magnified examination of cross-sections and separation of body and cover hooks.*

The inspector may inspect and disallow the use of any packaging material, and may retain any product in it if there is reason to doubt the acceptability of the packaging materials. When the inspector questions the acceptability of a material, assistance may be requested from the applicable FSIS office. The inspector should provide the supplier's name, brand name or other designation for the material, and the condition of use of the material. The inspector may also request assistance for problems relating to mechanical failure of materials (e.g., defective seals in cans, pouches, semirigid containers and other similar materials) from the appropriate FSIS office.

*References: 9 CFR 318.309
FSIS Directive 7520.2
Part 17 of the Regulations*

5. What are the procedures for investigating consumer complaints or consignor/ consignee complaints?

FSIS works collaboratively with other federal and local government agencies, producing establishments, and consumers to investigate possible foodborne illness associated with meat, poultry, or egg products. FSIS has agency compliance officers and epidemiologists stationed across the United States to help provide assistance during these investigations. Samples of the product and/or the foreign object are submitted to an FSIS laboratory for analysis. A follow-up review is conducted at the producing establishment so that corrective and preventative measures can be implemented, if necessary.

Title 20.3 states that the complaint report should provide the nature of the hazard and the name, address and telephone number of the person who can furnish additional information. It should include, if available, product involved; where ingested; time of ingestion and onset of illness; number of persons involved; name and establishment number of processor; processing, packaging, and handling procedures; and other pertinent information. The reporting procedures include:

- 1. Inspectors report actual or potential health hazards or consumer complaints involving adulteration or misbranding to supervisors.*
- 2. Supervisors notify local health officials and exchange information relative to the problem. Supervisors relay all information (including health official contact) to area supervisors.*
- 3. Area supervisors notify the District Office and the District Office initiates the investigation.*

*References: Title: 20.3 Food Poisoning; Adulteration; Misbranding
FSIS Directives 10630.1, 10625.1, and 10610.1*

6. What actions are taken to protect the Country-X and other consumers when violative product has already left the processing establishment? Provide a copy of the directives and procedures used for recalling product.

If product is found to be directly connected with a consumer illness or injury or has the potential to cause illness or injury, FSIS works closely with the producing establishment to recall the product and remove it from commerce. Accordingly, if the product is identifiable by the public, FSIS will release a public notification advising consumers of the violative product. FSIS compliance officers conduct effectiveness checks at consignees to assure that the recalled product is being removed from consumer.

Regarding canned product, FSIS requires producing establishments to prepare and maintain a recall procedure for the handling and returned of volatile canned product. These procedures shall be made available to FSIS inspectors upon request.

FSIS Directive 8080.1 establishes that recalls are actions to effect the removal of product from trade and/or consumer channels. Recalls are voluntary actions by manufacturers and/or distributors to protect the public health from products that are adulterated or misbranded. A recall may be an alternative to an FSIS detention or seizure action to remove or otherwise correct violative, distributed products. Therefore, although recalls are voluntary, FSIS must oversee all such recall activities and coordinate any FSIS actions with the recall taken by the manufacturing distributor.

A recall may be undertaken at any time by a manufacturer or distributor on its own initiative, or at the request of FSIS. A request by FSIS that a firm recall a product is reserved for urgent situations and is to be directed by FSIS to the firm that has primary

responsibility for the manufacturing and marketing of the product that is to be recalled. In all cases involving firm-initiated recalls, the firm is requested to notify the District Office, FSIS, or other inspection personnel in the region where the establishment is located within 24 hours of the firm's initiating action to recall a product from the marketplace. FSIS will give recalls priority attention at all levels of the Agency and will:

- 1. Assess the public health hazard presented by a product being recalled, or considered for recall, whether firm- initiated or requested by FSIS, and classify it as one of the following:*
 - a. Class I. Involves a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.*
 - b. Class II. Involves a potential health hazard situation where there is a remote probability of adverse health consequences from the use of the product.*
 - c. Class III. Involves a situation where the use of the product is not likely to cause adverse health consequences.*
- 2. Initiate the following FSIS recall oversight under the following circumstances:*
 - a. When the firm initiates the recall, by reviewing their recall strategy and suggesting changes as deemed necessary, and coordinating with them any action taken or planned by FSIS.*
 - b. When FSIS requests the recall, by notifying the firm and by confirming in writing FSIS's determination of the need to immediately begin a recall. Such notification will specify the violation, the health hazard classification, the recommended recall strategy and any other instructions appropriate to the conduct of the recall.*
- 3. Monitor the recall operation by developing and implementing a recall monitoring program which will include:*
 - a. Reviewing periodic recall status reports received from the recalling firm and/or reviewing documentation of the recall operation and its effectiveness during visits to the firm.*
 - b. Conducting effectiveness reviews to verify that consignees have received notification and have taken appropriate action.*
 - c. Reviewing the recall firm's determination as to when its recall is complete and providing written notification to the firm when FSIS officially terminates its recall oversight.*

4. *Maintain working relationships with other Federal, State and local agencies, and foreign governments for the purpose of obtaining information and cooperation in recall situations.*

5. *Pursue, if necessary, legal action and/or other measures.*

The purpose of these steps is to assure that a recall is conducted in a manner that achieves the orderly return or other appropriate disposition of violative product to the extent necessary to protect the consuming public from products that present real or potential health risks or gross consumer deception. These steps include:

A. Health Hazard Evaluation. An evaluation of the health hazard presented by a product being considered for recall, or being recalled, will be conducted by a team of FSIS experts in cooperation with other individuals or agencies as deemed necessary. The evaluation will include at least the following factors:

- 1. Nature of the violation or defect.*
- 2. Whether any illnesses or injuries have already occurred from the use of the product.*
- 3. Assessment of the likelihood of occurrence of the hazard.*
- 4. Assessment of the consequences (immediate or long range) of occurrence of the hazard.*

B. Recall Classification. A recall classification will be assigned to product recalls based on the health hazard evaluation, or the assessment of the nature of the deception or other defect. FSIS will assign the classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being considered for recall or being recalled.

C. Recall Strategy.

1. A recall strategy will be developed to assist in the conduct of a recall. The strategy takes into account the following factors:

- a. Recall classification assigned by FSIS.*
- b. Depth of recall.*
- c. Extent of notification being made to the trade or public.*
- d. Action plan to coordinate the removal and return or correction of the product from the marketplace.*
- e. Effectiveness reviews.*

2. *Elements of a recall strategy will include:*
 - a. *Results of the health hazard evaluation.*
 - b. *Ease in identifying the product.*
 - c. *Degree to which the product's deficiency is obvious to the consumer.*
 - d. *Degree to which the production remains unused in the marketplace.*
 - e. *Amount of product involved.*
 - f. *Area of distribution.*
 - g. *Action taken or planned by the recalling firm.*

D. Recall Recommendation. The EEPS Staff will prepare the Recall Recommendation for submission to the Deputy Administrator, IO. The Recall Recommendation will include:

1. *Health Hazard Evaluation.*
2. *Recall Classification.*
3. *Recall Strategy.*

FSIS Directive 10240.2 states that, under the PR/HACCP inspection system, in situations where recall, retention, or seizure is necessary, FSIS may determine that more product or less product than that produced from clean-up to clean-up under the HACCP plan is represented by the sample. FSIS will consider such factors as the establishment's coding of products; the pathogen; the process; the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; SSOP records as required in 416.16; and whether some or all of the processes functioning under the same HACCP plan have been affected. The IIC, DO, and Emergency Response Division coordinate regarding the necessity of product retention, seizure, or recall. The DO will instruct inspection and enforcement personnel as necessary.

FSIS Directive 8080.1 is included as an Attachment to this document.

*References: 9 CFR section 318.311
FSIS Directives 10240.2, 9050.1, and 8080.1*

I. Generic Escherichia coli (E. coli) Testing

- 1. What are the laws, regulations, and official directives that mandate that export establishments validate their process controls through microbiological testing during slaughter operations to prevent fecal contamination? 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) identify sample sites, frequency of sampling, and sampling techniques.**
 - c) use approved analytical methods.**
 - d) require the use of reputable laboratories which adhere to quality control/quality assurance programs.**
 - e) require that results be recorded and used to control fecal contamination by the establishment.**

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) address the process control of fecal contamination during the slaughter process. 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 in the process control of fecal contamination in slaughter establishments.

a) The generic E. coli testing program for cattle and swine is supported and mandated in the United States by section 310.25 (a) of 9 CFR. The Nationwide Microbiological Baseline Data Collection Programs were initiated by FSIS to develop and maintain a general, ongoing microbiological profile of carcasses for selected microorganisms and to document changes in their profiles over time. Generic E. coli was and is used as the indicator microorganism for the process control of fecal contamination, as mandated in 9 CFR 310.25 (a) (1). These programs were used to develop the evaluation criteria specified for cattle in section 310.25 (a) (5), using the excision method of sample collection. In addition, these programs are being used to develop evaluation criteria for different sampling parameters, such as the sponge sample collection tool.

The methodology used to determine the process control of fecal contamination is found in E. coli-1, "Guidelines for Escherichia coli Testing for Process Control Verification in Cattle and Swine Slaughter Establishments," (E. coli-1 Guidelines), pages 22-24. Test results must be recorded, as required. The quantitative analysis for generic E. coli (biotype I) results in test results in which all cfu/cm² values are recorded, even if below 1 cfu/cm². Statistical process control techniques or m/M evaluation criteria (PR/HACCP

final rule) are used to evaluate the test results to determine when corrective actions are needed to maintain the process control of fecal contamination.

b) The sampling sites on each chilled cattle carcass are the flank, the brisket, and the rump (see 9 CFR 310.25 (a) (2) (ii) and the diagram in the E. coli-1 Guidelines for cattle and swine). The sampling frequency, based on production volume, is one sample/test per 300 cattle carcasses slaughtered or, at least, one sample/test per week (see 9 CFR 310.25 (a) (2) (iii), (iv), and (v)). In swine, the ham, belly, and jowl areas are sampled at a rate of 1 test per 1000 carcasses slaughtered. The sampling technique used by most establishments is the sponge method of sample collection, as mandated in 9 CFR 310.25 (a) (2) (ii). At each sample site, a 100 cm² surface area (10 cm by 10 cm) is sponged (see E. coli-1 Guidelines, page 3). The three samples are collected on the same sponge, resulting in a consolidated sample being sent for analysis. Carcasses are selected for sampling on a random basis. The E. coli-1 Guidelines (pages 6 – 10) indicate that samples are collected using aseptic techniques, using the same side of the sponge for the flank and brisket areas and the opposite site of the sponge for the rump area. The sampling sponge is placed back into the sample bag it was removed from prior to performing the test. The three sponge sites per carcass are thereby consolidated into one test sample. Each test sample is analyzed separately.

The excision method of sample collection involves excising 20 cm² from each of the sample sites. This technique is described in the E. coli-1 Guidelines, pages 18-24. The evaluation criteria established from the excision method of sample collection are provided in 9 CFR 310.25 (a) (5).

c) The analytical methods used by the United States are mandated in section 310.25 (a) (3) of 9 CFR and found in the E. coli-1 Guidelines, pages 12-13. The quantitative analysis for generic E. coli (biotype I) begins no later than the day after the sample has been collected, using one of the quantitative methods found in the Official Methods of AOAC International or using a scientifically validated alternate method. The United States allows the use of AOAC 17.2.01-17.2.02, AOAC 17.3.07, AOAC 17.4.01, AOAC 17.3.04, or 17.3.09.

d) According to the Federal Register, Volume 21, Number 144, pages 38853 and 38854, each establishment is responsible for the accuracy of the tests performed to detect generic E. coli. If samples are not analyzed at the establishment, the establishment must ensure that the laboratory is reputable and adheres to a Quality Control or Quality Assurance Program. The E. coli-1 Guidelines describe how best to sample and test for generic E. coli and how to record and interpret test results, as required in 9 CFR Section 310.25

FSIS regulations, 9 CFR 310.25 (a) (2) (I), require each establishment prepare and maintain written specimen collection procedures. These procedures include the designation of a responsible employee, the location(s) in which sampling will take place, the process used to achieve random sampling, and the procedures used to handle samples

to ensure sample integrity. These requirements, with suggested procedures, are outlined in the *E. coli-1 Guidelines*.

e) The recording and evaluation of test results used by the United States are mandated in section 310.25 (a) (4) and (5) of 9 CFR and found in *E. coli-1 Guidelines*, pages 12-13, 22-24. Over a period of one year, FSIS has required slaughter establishments to collect test results from each applicable slaughter class. The following explanation currently applies to the excision method. The criteria for the sponge method will be set up in a similar manner. The information covering the sponge method will provide the percentage of each class that tested at or below a specific number of cfu/cm². Under a 3-class-attributes sampling plan, the 80th and 98th percentile figures will be used to define cut-off values, *m* and *M* respectively, for establishing performance/evaluation criteria. There will be 3 classes of results, acceptable (results ≤ *m*), marginal (results > *m* and ≤ *M*), and unacceptable (results > *M*), with *m* < *M*. FSIS has shown that slaughter establishments that are performing at the acceptable performance level (*m*) will, with an 80% probability, have 3 or fewer results above *m* within every 13 samples tested. Using a moving window of results, FSIS can provide a continuous picture of establishment performance regarding the presence of fecal contamination on cattle carcasses. Therefore, the presence of more than three marginal or unacceptable results within any 13 consecutive samples will indicate a failure of process control for fecal contamination. In addition, the occurrence of one unacceptable test result, at any time, will result in a process control failure. At no time does the count begin anew and each time a process control failure occurs, corrective action will be required by the establishment.

For the excision method, for cattle, *m* = negative or zero and *M* = 100 cfu/cm². This means that marginal values are between 0 and 101 (see *E. coli-1 Guidelines*, Page 23). For swine, *m*=10 and *M*=10,000.

At this time, however, FSIS is using statistical process control techniques to determine if process control is maintained during slaughter operations when samples are taken using the sponge method. Statistical process control involves an initial data evaluation to determine slaughter process capabilities, followed by observations of subsequent data to determine whether the process is in control and whether the observed variations are within normal and acceptable limits. These techniques are used to check for unreasonable high test results and trends so that corrective actions can be taken where indicated.

Regardless of the type of sampling method (excision or sponge), establishments are required to maintain accurate records of all test results (even if less than 1 cfu/cm²). Results must be recorded on a process control chart or table, showing the most recent 13 results, by type of livestock slaughtered. Results are kept one year and made available to inspection personnel upon request. The charting of results is explained in the *E. coli-1 Guidelines*, pages 22-24.

*References: 9 CFR Section 310.25
FSIS Directive 5000.1
Federal Register, Volume 61, Number 144
E. coli – 1 Guidelines*

- 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 take action to prevent product contamination and take corrective action when contaminated product is found.**
 - b) the foreign inspection system takes effective enforcement action, including suspension and withdrawal of inspection of those establishments which fail to control fecal contamination or fail to take corrective actions based on the results of the establishment's microbiological testing program.**

The enforcement program for control of fecal contamination, using generic E. coli as the indicator organism, is mandated in 9 CFR 310.25 (a) (6) and (7) of the PR/HACCP final rule. In addition, FSIS Directive 5000.1 outlines compliance requirements and enforcement actions for 9 CFR 310.25.

a) FSIS Directive 5000.1, pages 32-34, states that the establishment is required to initiate corrective action immediately after being notified of the noncompliance and that inspectors must document and notify the establishment as soon as possible, by the end of the tour of duty. FSIS Directive 5400.5, Inspection System Activities, dated 11-21-97, page 4 states that it is the responsibility of establishment management to prevent contamination and adulteration and to take actions that bring the establishment into compliance by controlling the immediate situation and preventing recurrence of the problem.

b) FSIS Directive 5400.5, page 5, states that the distribution of adulterated or misbranded product is prohibited and that compliance with FSIS regulations is required. When the establishment fails to prevent contamination and adulteration or to take actions that bring the establishment into compliance, FSIS will take further action, as necessary. In regard to E. coli testing, 9 CFR 310.25 (a) (6) and (7) states that test results that fail to meet established evaluation criteria indicate possible process control failures and require further action to ensure compliance. Inspection operations will be suspended if the establishment fails to implement and maintain the E. coli testing program by properly testing for generic E. coli and recording the results. The establishment is provided written notification first.

Depending on the noncompliance, FSIS regulations under 9 CFR, Part 335, provide for the refusal or withdrawal of inspection service and for withholding the use of marking, labeling, or product containers. Section 335.13 provides for the refusal or withdrawal of inspection service under the Federal Meat Inspection Act for failure to maintain sanitary

conditions. The control of fecal contamination by testing and record keeping is part of an establishment's control of contamination on the slaughter line.

*References: 9 CFR Section 310.25 and Part 335
FSIS Directives 5000.1 and 5400.5
Federal Register, Volume 61, Number 144
E. coli – 1 Guidelines*

J. HACCP Plans

- 1. How does the government inspection system describe, specify, and mandate a system whereby meat and poultry establishments must identify and evaluate the food safety hazards that can affect the safety of their products, institute controls necessary to prevent those hazards from occurring or keeping them within acceptable limits, monitor the performance of controls, and maintain records routinely? How is this system firmly established in the government's requisite laws and regulations?**

The PR/HACCP rule is mandated for cattle, swine, and poultry slaughter and processing operations by 9 CFR Part 417. Every official establishment, as stated in section 417.2, must prepare a flow chart and conduct a hazard analysis of establishment operations and processes. Each establishment must develop and implement a written HACCP plan based on the seven principles of HACCP and covering each product produced by the establishment. A Hazard Analysis (Principle #1) must be performed and Critical Control Points (Principle #2) must be identified and listed for each of the identified hazards. Critical limits (Principle #3) must be assigned to each critical control point. Monitoring Requirements (Principle #4) are established for each critical control point. Corrective Actions (Principle #5) must be developed in response to any deviation of a critical limit. A recordkeeping system (Principle #6) must be developed to document the HACCP system and monitor each critical control point. Verification Procedures (Principle #7) must be established to ensure that the HACCP system is working correctly.

Section 417.3 also requires that the HACCP plan must identify and describe the corrective action to be followed in response to a deviation from a critical limit and requires that responsibility is assigned for taking corrective action. Section 417.4 requires that establishments validate their HACCP plans to determine if they are functioning as intended. Initially, an establishment must repeatedly test the adequacy of each CCP, critical limit, monitoring and recordkeeping procedure, and corrective action. Records are also reviewed in the context of other validation activities. Ongoing verification activities must be performed to calibrate monitoring instrumentation, observe monitoring activities and corrective actions, and review the records generated. Establishments must also ensure that the records are properly maintained (see also section 417.5). Every establishment must reassess or re-evaluate its HACCP plan at a minimum of once a year and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan as mandated in section 417.7 of the PR/HACCP final rule. Only trained individuals (as per section 417.7) may perform the reassessment.

Section 417.5 of 9 CFR states that establishments must maintain the records that document its HACCP plan. These records must include written documentation of the hazard analysis (including supporting documentation), the written HACCP plan (including decision-making documents on CCPs, critical limits, monitoring and verification procedure selections, and procedure frequency determinations), the CCP-monitoring records (including designated quantifiable values/dates/times), the calibration of process-monitoring instruments, the corrective actions taken, the verification procedures used (including results), and the applicable product code(s) and product name, identity, or slaughter production lot. Each record must include the date the record was written. Each entry on each record must be written when the specific event occurs, include the date and time of the occurrence, and be initialed by the individual establishment employee making the entry. These records must be reviewed by the establishment prior to shipping the applicable product. The above records must be retained according to whether the product is frozen, preserved, or shelf-stable (retain 2 years) or the product is refrigerated (retain 1 year). Slaughter-activity records must be retained for 1 year. All records must be retrievable-for-review by FSIS inspection personnel within 24 hours. All records must be available for official review and copying.

In section 417.6, the regulations state that an establishment's HACCP system is inadequate if the HACCP plan does not meet all of the requirements set forth in 9 CFR Part 417, establishment personnel are not performing the tasks specified in the HACCP plan, the establishment fails to take appropriate corrective actions, the HACCP records are not properly maintained, or adulterated product is produced or shipped.

Section 417.7 states that only successfully trained and qualified establishment individuals may develop establishment HACCP plans or reassess and modify HACCP plans. The course instruction must apply the seven HACCP principles to meat and/or poultry product processing and include the development of a HACCP plan for a specific product and information on reviewing records.

References: 9 CFR Part 417

2. How does the government inspection system verify the effectiveness of processes and process controls designed to ensure food safety? How does the government inspection system ensure that the government will:

- a) carry out a general review of establishment plans to identify, evaluate, and prevent food safety hazards?
- b) continuously verify establishment production, processes, and controls?

Section 417.8 of 9 CFR mandates that FSIS verify the adequacy of the HACCP plan for each applicable establishment by determining if the plan meets all the requirements of 9 CFR Part 417 and any other applicable regulation. The verification may include a review of an establishment's HACCP plan, CCP records, corrective actions, critical limits, and other HACCP plan/system records. It may also include the direct observation

or measurement of a CCP, a determination of safety-standard compliance through sample collection and analysis, and on-site observations (including a review of the applicable records).

Section 304.3 of 9 CFR requires that establishments that are to be granted Federal inspection must first perform a hazard analysis and develop a HACCP plan. Within 90 days, the establishment must validate its HACCP plan. These conditions also apply whenever an establishment produces a new product for commercial distribution.

a) FSIS Directive 5400.5, Inspection System Activities, dated August 24, 1998, page 3-1, provides for regular performance and production based reviews of food safety hazards. Inspection personnel are required to ensure that the establishment conducts an initial hazard analysis, including a product flow chart and an intended-use/end-user (consumer) list of the finished product. Inspection personnel ensure that establishments with 1 or more food safety hazards have a written HACCP plan for each product or process. They ensure that HACCP activities include a validation process, identifying/monitoring of CCPs, establishing critical limits for each CCP, corrective actions that address non-conformities, a hazard reassessment process, new-product hazard analyses, a CCP monitoring/recordkeeping system, verification procedures (including frequency), and the identification of a responsible establishment official.

b) FSIS Directive 5400.5 provides instructions to FSIS inspectors on how to verify the effectiveness of an establishment's processes and process controls under its required HACCP plan. Two components of the U.S. Performance Based Inspection System (PBIS) are designed to assist inspection personnel in determining if an establishment is meeting HACCP plan requirements and if the HACCP plan is operating adequately. The first component is the Inspection System Guide (ISG). The ISG includes all in-establishment procedures, grouped by activity, and broken down into specific tasks that are performed by inspection personnel. The second PBIS component is the automated work-scheduling system that incorporates previous findings to assign and prioritize the inspector's duty assignments.

Activity 03 pertains to HACCP systems and includes all of the requirements listed above under 9 CFR Part 417, 9 CFR section 304.3, and FSIS Directive 5000.1, Part III. These requirements cover basic compliance checks, slaughter operations, and checks covering product that is raw ground, raw not-ground, thermally processed/commercially sterile, not-heat-treated shelf-stable, heat-treated shelf-stable, fully-cooked not-shelf-stable, heat-treated not-fully-cooked not-shelf-stable, and not-shelf-stable with secondary inhibitors.

Reports are created by the PBIS system based on the data entered into the computer system. The data includes information from reports generated by inspection personnel on the establishment's failures to comply with the regulations and noncompliance trend indicators. The reports support supervisory and management decision-making.

References: 9 CFR Part 417
9 CFR Section 403.3
FSIS Directives 5000.1 and 5400.5

- 3. How does the government inspection system ensure an effective enforcement program? How does the government enforcement program ensure that:**
- a) the establishments take action to correct process deviations that result in food safety hazards, determine how non-compliant product would be handled, ensure that no safety hazards exist after the corrective actions are taken, and define measures to prevent recurrence?**
 - b) the appropriate government regulatory agency takes effective enforcement actions, as required; including suspension, withdrawal of inspection, and, in the case of falsification of records, criminal prosecution?**

Pursuant to the Federal Meat Inspection Act (sections 8 and 21), if an establishment fails to develop and implement a HACCP plan or otherwise operate in accordance with 9 CFR part 417 requirements, the product produced may be considered adulterated (see also 9 CFR section 417 (2) (e)). Section 305.5 (a) authorizes the withdrawal of inspection from an establishment in which conditions result in adulterated product.

a) FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations, dated 11-21-97, pages 11-12, states that inspection program personnel will determine if an establishment complies with all the requirements of 9 CFR Part 417, as listed above. It states that inspection personnel will advise establishment management, refuse to identify product as passed or wholesome, retain adulterated product, and/or notify the District Office of the action(s) taken to correct the non-compliance. If an establishment fails to initiate corrective action immediately, inspection personnel must notify the District Office and work with the assigned (by the District Office) Compliance Officer to develop a case file and take further action as necessary. Easily resolved issues that can be corrected immediately need not go through these steps and management can be given an opportunity to bring the establishment back into compliance.

FSIS Directive 5000.1, page 12, states that inspection program personnel will perform procedures to verify (see 9 CFR 417.8) the adequacy of an establishment's HACCP plan(s). This verification, as mandated in sections 417.3 (a) and (c) and 417.5 (a) (3), includes correcting process deviations, handling non-compliant product, ensuring that no safety hazards are present after the corrective action is taken, and defining the measures needed to prevent a recurrence of the deviation(s). Compliance determination procedures involve either reviewing particular features of a HACCP plan (such as correlating records entries with random observations or measurements) or reviewing the implementation of a HACCP plan for a particular product. Inspection personnel are

required to ensure that establishments validate the adequacy of their HACCP plan(s) and verify that the plans have been effectively implemented (see section 417.4).

b) FSIS Directive 5000.1, page 18, states that the withdrawal of inspection due to an inadequate HACCP plan or system can occur only when inspection personnel have documented that a HACCP system did not prevent the production and distribution of adulterated product and the violations include failures of the establishment to comply with requirements for monitoring CCPs, responding to deviations from critical limits, and documenting the verification and review of production records. Inspection personnel follow the same steps as outlined in 3.a. above. For non-compliance issues that do not meet the above conditions, inspection personnel are required to take appropriate official control of the product or situation, advise establishment management, review and verify the documentation of the establishments corrective actions (see FSIS Directive 5400.5), and determine if the establishment's noncompliance history warrants the involvement of a Compliance Officer from the District Office.

Notice 12-98, Notification to Establishments of Intended Enforcement Actions, dated August 24, 1998, states that if the Inspector-in-Charge determines that a HACCP system is inadequate, (s)he must notify establishment management and base the notification on recurring noncompliances as documented on Noncompliance Reports. If at any time, inspection personnel determine that adulterated product was shipped, inspection personnel will withhold inspection in accordance with FSIS Directive 5000.1, Part Two, section III. C.

c) Section 310.25, (b) (3) (iii) states that failure to maintain an adequate HACCP plan would result in the suspension of inspection services.

*References: Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
9 CFR Part 417 and Section 310.25
FSIS Directive 5000.1 and FSIS Notice 12-98*

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 request.