United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

NOV 14 2003

Ms. Shashi Sareen
Director
Export Council of India
Ministry of Commerce and Industry
3rd Floor NDYMCA Cultural Centre Building,
1 Jai Singh Road, New Delhi – 110 001

Dear Ms. Sareen:

This responds to your inquiry about the export of Indian meat and poultry products to the United States. Before India can export meat and poultry products to the United States, its export inspection system for meat and poultry products must undergo a rigorous and sometimes lengthy review to determine whether it is equivalent to the U.S. domestic system of inspection. We appreciate this opportunity to work collegially with you to expedite the review of India's meat and poultry inspection system.

Enclosed are copies of five questionnaires that India must complete and submit to the Food Safety and Inspection Service (FSIS) for a determination of initial equivalence to export meat and poultry products to the United States. For your information and convenience, we have completed one set of these questionnaires with answers that apply to the U.S. domestic system. The five questionnaires and other supporting documentation are contained on the enclosed CD-ROM. We hope that the U.S. answers will assist you in completing your questionnaires and give you a better understanding of the U.S. domestic inspection system.

General Requirements for Initial Equivalence

The initial determination of equivalence by FSIS will begin with a review of your responses to the five enclosed questionnaires. Please provide citations to relevant laws and regulations for answers to each question. In addition, please submit copies of the pertinent laws, regulations, and administrative instructions that govern your inspection system for exported meat and poultry products.

To assist your government in its response to the enclosed questionnaires, we are enclosing a copy of Title 9, Code of Federal Regulations (CFR), Chapter I, (January 2003). These regulations, which are issued by the Animal and Plant Health Inspection Service (APHIS), state requirements for the importation of animal products from countries that have certain animal diseases. Updates are available online at http://www.aphis.usda.gov/vs/ncie/country.html.

We direct your attention to Parts 94.9 and 94.10 of these regulations. Part 94.10 lists countries where hog cholera is not present. Part 94.9 sets forth requirements for the importation of pork products to the United States from countries that have hog cholera. Since India is not listed in Part 94.10, it is considered to have hog cholera. Therefore, pork products from India, which are offered for importation into the United States, would remain subject to the restrictions in Part 94.9 of APHIS regulations.

In addition, Part 94.6 of the APHIS regulations sets forth requirements for importing poultry from countries where Exotic Newcastle Disease (END) or *Salmonella enteritidis* is considered to exist. Because END and *Salmonella enteritidis* are known to exist in India, poultry imported from India to the United States must comply with the requirements of Part 94.6. For specific information on APHIS requirements, we suggest that you contact Dr. Masoud Malik, at the National Center for Import and Export, Veterinary Services, APHIS, United States Department of Agriculture, 4700 River Road, Unit 38, Riverdale MD 20737-1231. FSIS will work cooperatively with him regarding such animal health matters.

To further assist your government in responding to the enclosed questionnaires, we have also provided a copy of Title 9, CFR, Chapter III, the mandatory meat and poultry inspection regulations administered by FSIS. We direct your attention especially to Part 327 and Part 381 Subpart T that concern imported meat and poultry products. We have also included a comprehensive list of additional reference materials that are available to help applicants obtain export eligibility. Furthermore, as previously mentioned, we are enclosing a CD-ROM containing the five questionnaires and other regulatory information.

Document Review

When we have received all of your completed questionnaires, we will coordinate a technical review within USDA and may request additional information from you during this process. During this technical review, FSIS will work cooperatively with APHIS, which approves the entry of meat and poultry products according to the disease status of the exporting country.

On-Site Audit

Once the technical review has been satisfactorily completed, FSIS will request permission to conduct an on-site audit of your export meat and poultry inspection system. A multi-disciplinary team composed, typically, of a veterinarian, chemist, microbiologist, compliance officer, food technologist, and equivalence officer will conduct this audit. The audit team will evaluate all aspects of your country's export inspection program including training, facilities and equipment, laboratories, and individual establishments. This audit allows FSIS to identify any areas that require more detailed evaluation and to observe the daily operation of your export inspection system. After this on-site audit is completed, FSIS will make an equivalence determination based on a review of the documents and the on-site audit results.

Determination of Equivalence

If your export inspection system is found to be equivalent to the U.S. domestic inspection system, FSIS will publish a proposed rule in the *Federal Register* to list your country as eligible to export meat and poultry products to the United States. After the public has had 60 days to comment on this proposed rule, FSIS will review the public comments and make a final determination of initial equivalence. This determination to list your country as equivalent and, therefore, eligible to export meat and poultry products to the United States will be published as a final rule in the *Federal Register*, along with FSIS' responses to the public comments. At that time, your inspection service may certify establishments for export of meat and poultry products to the United States.

It is important for you to understand that the initial equivalence process outlined in this letter is required by U.S. inspection laws and USDA implementing regulations. Based upon our experience with other countries, this full process, which must be followed for every applicant country, will require about three years of mutual effort to reach completion.

I trust this letter helps to clarify the process for gaining initial equivalence for the export of meat and poultry products to the United States. If you have any further questions, please contact Ms. Shannon McMurtrey, Senior Equivalence Officer, Office of International Affairs. Her telephone number is (202) 690-4036, the fax number is (202) 720-7990, and her e-mail address is Shannon.McMurtrey@fsis.usda.gov.

Sincerely,

Sally Stratmoen JD

Sally Stratmoen, Director
International Equivalence Staff
Office of International Affairs

Enclosures

cc:
Chad Russell, Counselor, U.S. Embassy, New Delhi
Michael Riedel, Agriculture Attaché, U.S. Embassy, New Delhi
Dr. V.S. Seshadri, Minister of Commerce, Embassy of India
Mr. Rajnath Singh, Union Minister for Agriculture, Ministry of Agriculture
Mike Conlon, FAS Area Director
Amy Winton, State Department
Linda Swacina, Deputy Administrator, FSIS
Karen Stuck, Assistant Administrator, OIA
Don Smart, Director, Review Staff, PEER
Sally Stratmoen, Director, IES, OIA
Clark Danford, Director, IEPS, OIA
Shannon McMurtrey, IES, OIA
Country File

SLAUGHTER/PROCESSING QUESTIONNAIRE

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.

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

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?

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

B. Additives

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

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?

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 United States.)

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

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.)

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

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?

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?

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 the United States? What part of the government is responsible for implementing and maintaining the United States, or equivalent, standards?

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?

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

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

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 United States?

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 the United States?

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

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?

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?

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?

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?

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?

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

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?

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?

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?

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

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

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?

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.

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?

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?

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?

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

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?

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.

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.

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.

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

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.

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.

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.

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

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 the United States, or equivalent, standards?

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

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

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?

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

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

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.

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.

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?

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?

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?

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.

ENFORCEMENT QUESTIONNAIRE

For each question and request, cite the sections in your regulations or other reference material that governs your response(s). In addition, provide examples of any forms, charts, or other documents applicable to each question or comment. (Questions A through L address compliance and M through P address economic fraud.)

A. Program Organization

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

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

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

B. Livestock and Poultry Husbandry

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

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

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

C. Livestock and Poultry Controls

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

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

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

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

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

D. Slaughter Facilities

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

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

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

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

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

E. Processing Facilities

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

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

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

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

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

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

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

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

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

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

F. Warehouse Facilities

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

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

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

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

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

G. Transportation Vehicles

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

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

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

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

H. Export Procedures

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

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

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

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

I. Imported Meat

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

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

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

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

1. What is the extent of the fur industry?

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

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

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

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

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

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

K. General

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

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

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

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

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

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

    a. How many samples are taken?

    b. Who takes the samples?

    c. Where are the samples taken?

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

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

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

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

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

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

L. Refused Entries

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

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

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

M. Control of Deceptive Labeling, Packaging, and Documentation

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

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

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

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

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

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

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

N. Product Standards and Formulations

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

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

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

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

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

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

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

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

O. Sampling Program

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

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

3. What additional reasons would you have, if any, for sampling product intended for export to the United States?

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

P. Inspection Controls

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

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

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

4. What corrective and preventative actions do you take when unacceptable products intended for export to the United States are found?

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

Q. Salmonella Testing

1. What are the laws, regulations, and official directives that mandate a pathogen reduction program that systematically seeks to reduce pathogenic microorganisms in raw meat and/or poultry? The program documents must describe and mandate that the program will:

    a) be supported by analytical test results, nationwide microbiological baseline surveys, and other scientific data.
    b) include performance standards for appropriate target pathogens.
    c) employ microbiological testing as an indicator of pathogenic microorganisms.

2. What are the laws, regulations, and official directives that mandate an effective enforcement program? The program documents must describe and mandate that:

    a) establishments utilize available process control methods and technologies as necessary to achieve applicable pathogenic reduction performance standards.
    b) the foreign inspection system takes effective enforcement action, including suspension and withdrawal of inspection of those establishments which fail to meet the pathogen reduction performance standards or which fail to take corrective actions based on the results of the foreign inspection system's microbiological testing program.

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

SANITATION QUESTIONNAIRE

For each question and request, cite the sections in your regulations or other reference material that governs your response(s). In addition, provide 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 prevention and control of contamination? Include organizational charts for each of these agencies.

2. What is the functional relationship among these government agencies and between these agencies and any separate activities at state, provincial, or local levels? For example, if different agencies/authorities apply different laws/regulations at different stages in the movement of product to the consumer, how do these agencies/authorities cooperate and work together to help prevent and control contamination?

3. What personnel, training, equipment/resources, and other facilities are utilized to enforce and fulfill the responsibilities of the meat and/or poultry inspection system regarding the prevention and control of contamination for each of the products under this application?

B. Regulations and Guidelines

1. What regulations, directives, and guidelines control and prevent the contamination of meat or poultry products in the building and construction of official establishments, including:

    a. materials and surface finish of walls, ceilings, and floors?
    b. building ventilation systems?
    c. lighting at product inspection sites (i.e. level of illumination)?
    d. lighting in rooms/hallways, at equipment, etc. (i.e. level of illumination)?
    e. separation of toilet soil lines and plant drainage lines?
    f. room/environmental temperature controls (i.e. such as in further processing rooms and finished product storage areas or rooms)?

2. In approving blueprints for official establishments, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products?

3. In approving the facilities and equipment of official establishments, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products?

4. In using construction and maintenance materials that are toxic free and have appropriate surface finishes, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products?

5. In securing and maintaining potable water supplies, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products?

6. Within your pest control program(s) for insects and rodents, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products?

7. When handling "ready-to-eat" products, what regulations, directives, and guidelines address the control and prevention of contamination of meat or poultry products? This information should include provisions to separate raw products from cooked products.

8. What requirements are there to prevent the contamination/adulteration of foods after processing? For example, are employees handling this product required to wash their hands with soap and hot water before entering the processing room?

9. What requirements are there to prevent contamination/adulteration of foods during the processing procedure, e.g., by temperature abuse, before the processing standard has been fully met?

C. <u>Sanitation Standard Operating Procedures (SSOP)</u>

1. What are the laws, regulations, and official directives that mandate that export establishments take responsibility for sanitation? Describe these requirements in detail.

2. What are the laws, regulations, and official directives that mandate that export establishments determine those aspects of establishment sanitation that pose a risk of causing direct product contamination. The government documents, in the form of a written SSOP or the equivalent, must describe and mandate:

    a) the process whereby establishments identify areas of risk of direct product contamination.
    b) the process whereby establishments identify cleaning procedures, including frequency and accountability for cleaning.
    c) the process whereby establishments identify corrective actions to be taken.

3. What are the laws, regulations, and official directives that mandate that export establishments have an effective enforcement program? The program documents must describe and mandate that:

    a) establishments take action to prevent product contamination and take corrective actions when insanitary conditions or contaminated products are found.
    b) the foreign inspection system takes effective enforcement action, including the suspension and withdrawal of inspection of those establishments that fail to prevent product contamination or take corrective actions.

D. Other Procedures

1. In maintaining sanitation during fabrication, further processing, and other operations, what are the procedures for the detection and control of contamination of meat and poultry products?

2. In product shipped from one official establishment to another, what are the procedures for the detection and control of contamination of meat and poultry products?

3. In monitoring and controlling product temperature and condition during the preparation, shipment, or storage of product destined for export to the United States, what are the procedures for the detection and control of contamination of meat and poultry products?

4. During maintenance work, product may be exposed to environmental contaminants (such as a paint solvent or styrene monomer floor topping). During maintenance work, what are the procedures for the detection and control of contamination of meat and poultry products?

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UNITED STATES
CRITERIA FOR ASSESSING THE
ADEQUACY OF THE RESIDUE CONTROL PROGRAM
for Meat, Poultry and Egg Products

Definitions

Residue program: A combination of educational, research and regulatory enforcement activities designed to provide: (1) a structured process for identifying and evaluating drugs, pesticides and other chemical compounds of concern by slaughter class and/or egg product; (2) capability to analyze compounds of concern reliably; (3) appropriate regulatory follow-up of reports of violative tissue residues in meat, poultry and egg products; and (4) collection, analysis, and reporting of the results of these activities.

Residue plan: The anticipated testing regimen to analyze compounds of concern reliably for specific slaughter classes and/or egg products for a specified time period.

I. Background

The purpose of this section is to obtain general information about animal husbandry, availability of drug usage, agricultural chemicals and incidence of environmental contaminants and pesticides. This information will be used to determine equivalency with the United States' residue control program.

A. Provide total population figures of food animal by each species.

B. Do animals slaughtered for export to the U.S. originate in another country other than the native country? Are egg products exported to the U.S. produced from eggs originating in other countries?

C. Describe the husbandry practices commonly used for each species of animals slaughtered for export to the U.S. Information should describe such factors as:
   1. Type of housing used for rearing animals; for example, confinement versus pasture (free-range), individual stalls or cages, group pens, etc.
   2. Unique weather conditions which may require special housing
   3. Type of feed given to animals (commercial source or farmers mix/grow their own)
   4. Typical age of animals when slaughtered
   5. Treatment for internal and/or external parasites (identify animal diseases or conditions commonly requiring treatment)
   6. Marketing practices
      a. average number of animals in slaughter lot
      b. slaughter lots comprised of animals from one farm or from several farms/growers

D. What measures are taken to prevent exposure of food animals to pesticides?

E. What measures are taken to prevent exposure of food animals to environmental or industrial contaminants?

II. Organization and legal authority

The purpose of this section is to describe the specifications of the legal basis and the organization of the government's activities to prevent contamination of food products with chemical residues.

A. Are the preventative measures taken to satisfy the U.S. requirements handled through a central (National), regional (local) or special export residue program?

B. Identify and summarize the laws and regulations concerning:
   1. Approval and use of food animal drugs and agricultural chemicals
      a. Provide lists of the following types of substances, specified by chemical names, permitted for use in your country:
         (1) drugs permitted for therapeutic and preventative use in each species of food animals
         (2) prohibited substances
         (3) pesticides permitted for use in or on each species of food animals, permitted for crops used in feed processing and storage facilities, or permitted for use in meat processing facilities.
         (4) environmental or industrial chemicals that are potential contaminants to food producing animals
      b. For each drug and chemical listed in your residue plan, identify:
         (1) the species;
         (2) the target tissue used as analytical control;
         (3) a list of the Maximum Residue Limits (MRL) [tolerance or action limits]

   2. Specify the procedures used to approve the use of each substance listed in II.B.1.a. (For example, available by veterinary prescription only, limited availability to authorized distributors, detailed directions for use, penalties for misuse, withdrawal times, extra and/or off label use, etc.)

C. Briefly summarize the procedures employed for enforcing the above laws and regulations.

D. Provide a simple organizational chart and relationship to the meat inspection system for:
   1. compound approval
   2. residue program design
   3. sample collection
   4. laboratory support
   5. enforcement

III. Residue Plan Design

The purpose of this section is to obtain information to understand the basis for your annual residue plan and the process used to design the residue plan.

A. Submit a copy of your annual residue plan, which clearly identifies all sampling plans (monitoring, surveillance or any other special testing programs in place) and identifies the target tissue to be analyzed, by species, for each specific residue compound. Identify whether this is implemented on a calendar year or fiscal year.

B. Describe the design of the sampling plan for animals to be tested for residues. Indicate whether the sampling plan is based on random sampling and the statistical significance expected of the residue conclusions or whether the sampling plan is based on non-statistical design principles. In both cases, indicate the objectives of the sampling program.

C. What criteria are used to determine whether a compound is included or deleted from your testing program?

D. What is the process for reassessing the residue plan? How are data reviewed and analyzed to evaluate the progress?

IV. Residue Plan Operations

The purpose of this section is to obtain information on the basis and actual operation of your residue plan.

A. Describe the implementation of your plan, providing any supplemental information that will help describe what you want to accomplish with the residue plan.

B. Provide a summary of the instructions that are provided to the field personnel that describe sampling procedures, including but not limited to sample selection, collection, identification and security.

C. What is the average time it takes from sample collection until final results are available to the inspector (or person responsible for action)?

D. Describe the control procedures for separating product destine to the U.S. in the case when domestic tolerances are higher.

E. How are individual animals selected for sampling? How do you select the days on which samples are taken?

F. Do inspection personnel use in-plant-screening methods? If so, what are these tests and how are they used (monitoring/surveillance, animal selection, etc.)? Describe the validation of these tests for the intended purpose.

V. Compliance and enforcement

The purpose of this section is to obtain information about actions taken to deal with residue findings as they occur.

A. What actions are taken when positive or violative results are determined for:
   (1) drugs permitted for therapeutic and preventative use in each species of food animals
   (2) prohibited substances
   (3) pesticides permitted for use in or on each species of food animals, permitted for crops used in feed processing and storage facilities, or permitted for use in meat processing facilities
   (4) environmental or industrial chemicals that are potential contaminants to food producing animals

B. What documentation of enforcement actions is maintained?

VI. Laboratories

The purpose of this section is to obtain information on the general capabilities of analytical laboratories and their ability to assure the validity and reliability of test data.

A. Organization and characteristics of your laboratory facilities. Provide:
   (1) An organization chart of the laboratory facilities.
   (2) Information on personnel qualifications.
   (3) Information on facilities and equipment.

B. Laboratory procedures
   1. Identify the analytical method used for each compound. Include:
      (a) Target analyte(s)
      (b) Target tissue/species
      (c) Performance standards

   2. Explain the process to insure that samples and their associated documentation are not interchanged.

   3. Explain how records are maintained.

   4. How are test results reported (include content and format.)

   5. Are corrective actions conducted for noted deficiencies?

   6. Does the laboratory participate in proficiency testing? If yes,

(a) List the proficiency testing programs
(b) Provide the most recent proficiency test report(s), including whether it passed or failed.

7. Is the laboratory accredited? If yes, please provide:
   (a) The name of the accrediting body
   (b) When was the laboratory last accredited?
   (c) What compound (class of compound) was the laboratory accredited for?

ANIMAL DISEASE QUESTIONNAIRE

For each question and request, cite the sections in your regulations or other reference material that governs your response(s). In addition, provide 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 is the functional and organizational relationship between your national program for animal health and the national program for meat and/or poultry inspection? Include an organizational chart for the animal health agency.

2. In the field and at headquarters, how many persons are assigned to the national meat and/or poultry inspection program? List the separate areas of responsibility and denote the number of persons in each area.

3. What are the different kinds of inspection programs that are the responsibility of your national meat and/or poultry inspection agency? (For example, fish inspection, game-animal inspection, animal food manufacturing, and non-meat food products.)

4. What applicable state, provincial, or other local government inspection programs do you recognize as being pertinent to the national meat and/or poultry inspection program? Describe each of these programs and indicate what products are covered under each program. What establishments, under these programs, export product to countries other than the United States? In addition, describe any local non-government inspection programs you may recognize.

5. From what countries do you import raw meat from livestock or poultry? Indicate the product type(s) and the temperature condition (chilled, frozen, etc.) during shipment after each country listed.

6. With regard to funding your national meat and/or poultry inspection program:

    a. Are public funds used for salaries of inspectors and supervisors?

    b. On what basis, if any, are fees assessed to certified establishments?

    c. Are farmers or livestock producers assessed a fee?

7. What are your training requirements for supervisors, veterinarians, processing inspectors, on-line inspectors, and other inspection and supervisory personnel?

B. Disease

1. What are the most common causes of carcass condemnation during ante- and post-mortem inspection? Indicate the product species associated with each cause.

2. What disease conditions require (in order to detect the condition) the use of additional procedures? Describe these procedures.

3. What regulatory or other written authority provides for the inspection of the causes and conditions listed in questions B.1. and B.2.?

4. What type of product disposition is provided and/or mandated for each of the above causes of condemnation or disease condition?

5. What regulatory or other written authority provides for the in-plant control of condemned and inedible product, ingredient, additive, or other applicable material?

6. According to regulatory and other written authority, what animal organs and parts are considered inedible in their natural state, e.g., lungs, thyroid glands, etc.?

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