Self-Reporting Tool

To be eligible to export meat, poultry, or egg products to the United States, countries must maintain food safety inspection systems that achieve an equivalent level of public health protection to the FSIS inspection system. The Codex standard *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CXG 53-2003) defines equivalence as "the state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing country, achieve, as demonstrated by the exporting country, the importing country's appropriate level of sanitary protection." This definition is consistent with the principle of equivalence as provided in the *Agreement on the Application of Sanitary and Phytosanitary Measures* of the World Trade Organization. Furthermore, the definition of sanitary measure in the Codex standard includes "all relevant laws, decrees, regulations, requirements, and procedures." Therefore, a country that wishes to export meat, poultry, or egg products to the United States must provide objective data that the country's laws, regulations, requirements, and procedures provide a level of public health protection equivalent to the FSIS inspection system. If the exporting country does not have this objective data, FSIS would recognize as equivalent the implementation of FSIS sanitary measures to assure the eligibility of products intended for export to the United States.

To determine whether a country's documented food safety inspection system achieves an appropriate level of public health protection, FSIS assesses *Self-Reporting Tool* (SRT) responses and supporting documentation provided by the country's national government authority responsible for ensuring the safety, wholesomeness, and accurate labeling of meat, poultry, and egg products intended for export to the United States (i.e., the Central Competent Authority [CCA]). SRT questions are based on regulatory-focused food safety objectives and reflect the equivalence criteria used by FSIS to determine whether a country's documented food safety inspection system is equivalent to the FSIS inspection system. The SRT is designed for countries that want to export the following products to the United States: meat (including beef, veal, pork, sheep [including lamb and mutton], goat, and Siluriformes fish); poultry (including chicken, turkey, duck, goose, guinea, squab, and ratites [emu, rhea, and ostrich]); or egg products[1] from domesticated chicken, turkey, duck, goose, or guinea. SRT questions are arranged into six (6) components:

1. Government Oversight (e.g., Organization and Administration, Enforcement Authority, Government Inspection Personnel–Training/Staffing)
2. Government Verification of Food Safety and Other Consumer Protection Requirements (e.g., Humane Handling, Ante-mortem Inspection, Post-mortem Inspection, Product Standards and Labeling)
3. Government Sanitation Verification
4. Government Hazard Analysis and Critical Control Point (HACCP) System Verification
5. Government Chemical Residue Program
6. Government Microbiological Pathogen and Process Control Programs

For FSIS to determine equivalence, the CCA must provide complete responses to all SRT questions applicable to its food safety inspection system governing the meat, poultry, or egg products the country intends to export to the United States. Complete responses include a narrative, accompanied by supporting documentation, describing how the country's food safety inspection system is implemented. In addition, SRT responses need to cite where in the supporting documentation the information can be found. For example, answers should include the article, clause, section, or chapter from the relevant supporting documentation. Types of supporting documentation the CCA should provide include, but are not limited to, the following:

- Food safety and inspection laws and legislation;
- Regulations, policies, standards, decisions, annexes, and decrees;
- Inspection procedures, manuals, and directives;
- Control programs;
- Inspection training programs;
- Mechanisms for documenting compliance/noncompliance;

[1] Egg product means any dried, frozen, or liquid eggs, with or without added ingredients.

- Enforcement and compliance programs; and
- Government chemical residue and microbiological sampling programs and results.

The following chart identifies which SRT questions the CCA needs to answer, with supporting documentation, based on the specific products the country is currently eligible to export or requesting eligibility to export to the United States. To view which products a country is currently eligible to export to the United States, refer to the individual country page in the FSIS Import & Export Library. For more information on product categorization, refer to the FSIS Product Categorization (Import) guideline.

Products	SRT Question Numbers
Standard SRT questions to be answered for **all** products	1, 2, 3, 4, 5, 6, 7, 9, 13, 14, 15, 16, 18, 23, 24, 25, 26, 34, 35
Raw-Intact and Raw-Non Intact Beef and Veal	10, 11, 12, 17, 22, 27, 29
Raw-Intact and Raw-Non Intact Pork	10, 11, 12, 22, 27
Raw-Intact and Raw-Non Intact Lamb, Mutton, or Goat	10, 11, 12, , 22, 27
Raw-Intact and Raw-Non Intact Poultry and Ratites	10, 11, 12, 22, 27, 28
Raw-Intact and Raw-Non Intact Siluriformes Fish	20, 21
Thermally Processed/Commercially Sterile Meat and Poultry Products	33
Not Heat Treated-Shelf Stable Meat and Poultry Products	30, 31, 32
Heat Treated-Shelf Stable Meat and Poultry Products	30, 31, 32
Fully Cooked-Not Shelf Stable Meat and Poultry Products	30
Heat Treated-Not Fully Cooked-Not Shelf Stable Meat and Poultry Products	32
Product with Secondary Inhibitors-Not Shelf Stable Meat and Poultry Products	30, 32
Egg Products	30
Cell-Cultured[2] Meat and Poultry Food Products	8, 19

The SRT provides bulleted guidance under each SRT question to aid CCAs in providing complete SRT responses and supporting documentation that adequately demonstrate that the country's documented food safety inspection system achieves an equivalent level of public health protection to the FSIS inspection system. The bulleted information is not intended to be prescriptive in nature but rather it is guidance to foreign countries on the information to be included in the response to each individual SRT question. When responding to SRT questions, the CCA can provide responses and supporting documentation that demonstrate that the CCA implements regulations and procedures consistent with FSIS regulations and procedures or alternative measures that achieve an equivalent level of public health protection.

Submission of SRT Responses and Supporting Documentation

To submit SRT responses and supporting documentation, the CCA can either upload the information into FSIS' web-based Public Health Information System (PHIS) or submit SRT responses and supporting documentation to FSIS' Office of International Coordination (OIC) through email at internationalcoordination@usda.gov.

If SRT responses and supporting documentation are submitted to FSIS outside of PHIS, FSIS uploads the documentation in PHIS. It is important for countries to verify the accuracy and completeness of the English translated documents in PHIS because FSIS uses the English translated version of SRT responses and supporting documentation in PHIS when making equivalence determinations.

[2] Cell-cultured meat and poultry food products are "meat food products" and "poultry food products" as defined in Title 9 of the U.S. Code of Federal Regulations (9 CFR) 301.2 and 9 CFR 381.1, respectively. Cell-cultured food products include any meat or poultry product comprised of or containing cultured animal cells.

If issues are identified or clarification is needed during FSIS' review of the country's submitted SRT responses and supporting documentation, FSIS will send the CCA a request for additional information and may propose a technical call between FSIS and the CCA.

Ongoing Equivalence Verification

To maintain current eligibilities, FSIS requires countries with ongoing equivalence to provide updates to their previous SRT responses to include all applicable information and any updates, changes, or revisions of the foreign country's food safety inspection system, such as revised laws, regulations, or inspection procedures. FSIS requires this update annually, or as changes are made to your regulatory system to verify that your foreign country's food regulatory system continues to be robust, transparent, and science-based (80 FR 9428). No later than May 18th of each year, CCAs of countries currently eligible to export to the United States and wishing to continue exporting meat, poultry, or egg products to the United States must either provide updated SRT responses and supporting documentation or communicate to FSIS that the SRT responses in PHIS are accurate and complete by providing an answer to SRT Question #34. Also, no later than May 18th of each year, the CCA must verify in PHIS whether the English translated documents are accurate and complete by providing an answer in SRT Question #34. CCAs in countries with current eligibility to export meat, poultry, or egg products to the United States must notify FSIS of any changes to laws, regulations, procedures, or other supporting documentation affecting products intended for export to the United States prior to implementation. FSIS will review the changes to determine if the country's food safety inspection system will remain equivalent once the changes are implemented.

In addition, the CCA must provide the following no later than May 18th of each year:

- An up-to-date list of all establishments certified by the CCA as eligible to export to the United States (hereafter referred to as certified establishments).
    - For more information on how to complete and submit an up-to-date list of all certified establishments used in the production of products eligible to export to the United States, refer to FSIS Guidance for Foreign Countries – Suggested Reporting Table for the Certified Establishment List.

- An updated official government chemical residue sampling plan and the previous year's results.
    - For more information on how to submit annual official government chemical residue sampling plans and results and for an example of the information FSIS needs to evaluate this information, refer to the FSIS Guidance for Foreign Countries: Suggested Reporting Tables for Official Government Chemical Residue Sampling Programs.

- An updated official government microbiological sampling plan and the previous year's results for the following: **(A)** *Salmonella* in raw meat and poultry products; **(B)** *Listeria monocytogenes (Lm)* and *Salmonella* in ready-to-eat (RTE) meat, poultry, and egg products; **(C)** *Lm* on food contact surfaces or non-food contact surfaces in certified establishments producing RTE meat or poultry products exposed to the post-lethality processing environment; and **(D)** Shiga toxin-producing *Escherichia* (*E.*) *coli* (STEC), including serogroups O157, O26, O45, O103, O111, O121, or O145, in raw beef products.

    NOTE: The CCA should provide indicator organism results for intestinal or fecal contamination if the official government sampling plan includes monitoring for indicator organisms.
    - For more information on how to submit annual official government microbiological sampling plans and results and for an example of the information FSIS needs to evaluate this information, refer to the FSIS Guidance for Foreign Countries: Suggested Reporting Tables for Official Government Microbiological Sampling Programs.

Annually, FSIS will provide CCAs of countries currently eligible to export to the United States and wishing to continue exporting meat, poultry, or egg products to the United States with the following:

- A request for additional information regarding issues identified or clarification needed following review of SRT responses, supporting documentation, and official government microbiological and chemical residue sampling plans and results, if needed;

NOTE: When FSIS requests additional information, CCAs should revise SRT responses, as needed, to address the requests for information or clarification, including providing supporting documentation.

- A report of the previous year's FSIS point-of-entry (POE) import reinspection results;
- A summary of any changes to the process categories, product categories, product groups, or species of meat, poultry, or egg products the country is eligible to export to the United States since the previous year's annual documentation package; and
- Notification of any new FSIS policies that CCAs need to address or other information that CCAs need to include as part of their annual submission by May18th of the following year, if applicable.

Component 1: Government Oversight

1. **How does the CCA ensure that the laws and regulations governing inspection of meat (including beef, veal, pork, sheep [including lamb and mutton], goat, and Siluriformes fish); poultry (including chicken, turkey, duck, goose, guinea, squab, and ratites [emu, rhea, and ostrich]); and egg products (from domesticated chicken, turkey, duck, goose, or guinea) are enforced?**

   To respond to this question sufficiently, the CCA must:

   - Describe the legal framework that gives the CCA the authority and ability to administer the food safety inspection system. Include the name of the CCA and a brief explanation of the CCA's organizational structure.
   - Provide an organizational chart and a description of how to trace the linkage of authority from the CCA to local government inspection personnel.
   - Describe the CCA's authority and responsibility to enforce the laws and regulations governing meat, poultry, or egg products inspection. In addition, describe the CCA's authority to take enforcement measures, as appropriate.
     - Include supporting documentation demonstrating that the CCA has an effective enforcement program to address the following: (1) insanitary conditions or practices; (2) product adulteration or misbranding; (3) conditions that preclude the CCA from determining that product is not adulterated or misbranded; or (4) inhumane handling or slaughtering of animals.
     - Include how (i.e., actions taken) and under what circumstances the CCA implements additional enforcement measures in certified establishments (e.g., withdrawal of inspection for failure to maintain a HACCP plan).

   For cell-cultured meat and poultry food products:

   - Indicate whether the CCA with oversight over the preharvest[3] cell production phase is the same as the CCA for the harvest[4] and postharvest[5] product production phases.
     NOTE: If the country has more than one CCA overseeing the production of cell-cultured livestock and poultry food products, then the country must provide responses to SRT Questions #1 through #9 for each CCA.

2. **How does the CCA ensure that no meat, poultry, or egg products intended for export to the United States are adulterated or misbranded (i.e., properly labeled and packaged), and that only eligible meat, poultry, or egg products are certified for export to the United States?**

   To respond to this question sufficiently, the CCA must:

   - Describe the CCA's legal authority and responsibility to ensure that **adulterated** or **misbranded** product is not prepared for export to the United States.
     - Define adulterated and misbranded as it relates to meat, poultry, or egg products (i.e., statutory or regulatory definition).
   - Describe the CCA's authority for certifying meat, poultry, or egg products for export to the United States,

[3] FSIS considers the preharvest production phase to include collection and storage of living cells from amenable species and subsequent introduction to inputs (e.g., amino acids, glucose, and inorganic salts) and other factors that encourage their growth, multiplication, and differentiation into various cell types in a controlled environment (e.g., bioreactor).
[4] FSIS considers harvest to begin when the cell-culture establishment commences the process of removing the cells from the controlled environment, thereby halting their ability to further grow, multiply, or differentiate into various cell types.
[5] FSIS considers postharvest to include distribution of raw harvested cells in commerce or processing of the harvested cells into finished products that contain ingredients, such as spices, flavorings, binders or other ingredients.

including an export certification procedure that ensures these products meet FSIS import requirements. Furthermore, identify which type of government inspection personnel (i.e., government inspector, licensee, or contract employee)[6] is performing export certification procedures for product intended for export to the United States, including signing the export certificate. Lastly, describe how the CCA maintains control over export certificates, stamps, and seals.

- Describe how and at what frequency government inspection personnel are verifying during export certification that adulterated or misbranded product is not being exported to the United States.
- Describe how and at what frequency government inspection personnel review and confirm acceptable testing results from all samples of products (i.e., establishment testing and government verification testing) tested for adulterants as defined by FSIS prior to signing the export certificate.

  NOTE: This applies to confirmation of acceptable testing results for the following sampled products: raw non-intact beef product or raw intact beef product intended for raw non-intact use (or where intended use is unknown) that is tested for STEC; RTE meat, poultry, or egg products tested for *Lm* or *Salmonella*, or STEC (relative to RTE beef products, if applicable); RTE product that passed over food contact surfaces that have been tested for the presence of *Lm* or *Salmonella*; and livestock carcasses and parts subject to both routine and suspect chemical residue testing for veterinary drugs, pesticides, or, if applicable, environmental contaminants.
- Describe the CCA's authority and ability to detain or seize adulterated or misbranded products and to require that establishments have written recall procedures. Identify whether recalls of adulterated or misbranded product are carried out by the CCA or the establishment.
- Describe how recalls are carried out when product identified as adulterated or misbranded is in the distribution phase to the United States. Additionally, describe whether the CCA requires certified establishments to notify the CCA of the production of or shipment of adulterated products within a certain time (e.g., within 24-hours). Furthermore, in the event adulterated or misbranded products are shipped to the United States, describe the CCA's procedures for informing FSIS and include a timeframe of when FSIS will be notified.

3. How does the CCA ensure that source meat, poultry, or egg products used in processing operations originate from certified establishments in countries that the United States has determined have an equivalent meat, poultry, or egg products inspection system (i.e., eligible countries)?

NOTE: Source is defined as materials that originate from a certified establishment in an eligible country and that are used to further produce a meat, poultry, or egg product intended for export to the United States.

To respond to this question sufficiently, the CCA must:

- Describe how and at what frequency government inspection personnel verify source materials originate from a certified establishment in a country eligible to ship meat, poultry, or egg products to the United States and operating under a food safety inspection system determined to be equivalent by FSIS.
- Describe how and at what frequency government inspection personnel verify that harvested cells or cell-cultured meat and poultry food products used as source materials for further processing originate from a certified establishment in a country eligible to export cell-cultured meat or poultry food products to the United States.
- Describe the CCA's requirements for the quality and appearance of shell eggs used to produce egg products for export to the United States.

4. How does the CCA ensure that the same set of laws, regulations, and policies are applied consistently to all establishments certified to export meat, poultry, or egg products to the United States?

NOTE: A certified establishment is an establishment that the CCA determines as meeting FSIS import

[6] For definitions of these terms, please refer to SRT Question #5.

requirements and, therefore, eligible to produce products intended for export meat, poultry, or egg products to the United States.
NOTE: A decertified establishment is an establishment that the CCA determines as not meeting FSIS import requirements and, therefore, not eligible to export meat, poultry, or egg products to the United States.
NOTE: A source establishment is a certified establishment that provides raw materials to other certified establishments for the production of processed products intended for export to the United States. Product from certified establishments that are not eligible to export product directly to the United States due to animal disease restrictions, regionalization, product ineligibility, or other reasons may be able to be used as source material for processed products (e.g., when product will be fully cooked to destroy causative agents related to restricted animal diseases). However, source establishments must meet all FSIS import requirements, be from an equivalent country, be certified by the CCA, and be identified as a source establishment on the certified establishment list.

To respond to this question sufficiently, the CCA must:

- Describe how and at what frequency CCA supervisory personnel verify that certified establishments meet FSIS import requirements.
- Describe the processes that the CCA follows to certify establishments as meeting FSIS import requirements, and to decertify establishments that no longer meet FSIS import requirements.
- Describe how and at what frequency the CCA disseminates information regarding FSIS import requirements from headquarters to government inspection personnel and certified establishments, including how the CCA communicates any changes to FSIS import requirements in a timely manner. Further, describe how the CCA remains aware of FSIS import requirements as they change over time.

5. How does the CCA ensure that government inspection personnel assigned to certified establishments are employees of and paid by the government?

NOTE: The term "government inspection personnel" (referenced throughout this SRT) refers to inspectors meeting the criteria in a, b, or c below. When responding to this SRT question, use the terms and definitions below to identify the type of government inspection personnel assigned to perform inspection duties when an establishment is producing product intended for export to the United States.

a. **Government Inspector:** A government inspector is a permanent or intermittent employee of the CCA of a foreign government, eligible to perform all applicable inspection duties, including:
    - ante-mortem inspection of livestock and poultry;
    - post-mortem inspection of every livestock carcass, head, and viscera and every poultry carcass and viscera;[7]
    - sanitation and HACCP verification activities in all meat, poultry, or egg product establishments;
    - export verification activities; and
    - official government verification sample collection activities in meat, poultry, or egg product establishments.

[7] Under alternative poultry inspection systems, similar to FSIS' New Poultry Inspection System (NPIS), the visual inspection of each carcass by government inspection personnel also serves as the inspection of the viscera if the inspector's condemnation of a carcass requires condemnation of the corresponding viscera. For countries that implement an alternative poultry inspection system, provide a response that describes the requirements and procedures of your alternative poultry inspection system under SRT Question #12.

NOTE: FSIS would recognize as government inspectors those inspectors that work for another part of the foreign government outside the CCA, but under delegated authority from the CCA, provided the CCA has authority and oversight over the inspection.

b. **Licensee (Limited Government Inspector):** An inspector employed under individual contract by the government and who is eligible to perform all applicable inspection duties, including:
   - ante-mortem inspection of livestock and poultry;
   - post-mortem inspection of every livestock carcass, head, and viscera and every poultry carcass and viscera;
   - sanitation and HACCP verification activities in all meat, poultry, or egg product establishments;
   - export verification activities; and
   - official government verification sample collection activities in meat, poultry, or egg product establishments.

   NOTE: Typically in this situation, the licensee (limited government inspector) is under direct supervision of the government, meaning that a government inspector is on the premises while licensees (limited government inspectors) are performing inspection duties (other than official government verification sample collection activities) for product intended for export to the United States continuously throughout slaughter operations and at least once per shift during processing (i.e., non-slaughter) operations and are ensuring licensees are effectively performing inspection duties. Typically, criterion b is not equivalent when a limited government inspector performs inspection activities (other than official government verification sample collection activities) without direct supervision from an onsite government inspector continuously during slaughter operations and at least once per shift during processing operations.

c. **Contract Employee (Private Contractor):** An employee employed by a third-party organization contracted to conduct inspection activities on behalf of the government. The operator is authorized by the government to perform all applicable inspection duties, including:
   - ante-mortem inspection of livestock and poultry;
   - post-mortem inspection of every livestock carcass, head, and viscera and every poultry carcass and viscera;
   - sanitation and HACCP verification activities in all meat, poultry, or egg product establishments;
   - export verification activities; and
   - official government verification sample collection activities in meat, poultry, or egg product establishments.

   NOTE: Typically in this situation, the contract employee (private contractor) is under direct supervision of the government, meaning that a government inspector is on the premises while contract employees are performing inspection duties (other than official government verification sample collection activities) for product intended for export to the United States continuously during slaughter operations and at least once per shift during processing (i.e., non-slaughter) operations, and are ensuring contract employees are effectively performing inspection duties. Typically, criterion c is not equivalent when a contract employee performs inspection activities (other than official government verification sample collection activities) without direct supervision from an onsite government inspector continuously during slaughter operations and at least once per shift during processing operations.

To respond to this question sufficiently, the CCA must:

- Identify which of the criteria above describes the type of government inspection personnel utilized by the CCA for inspection of establishments producing meat, poultry, or egg products intended for export to the

United States.
    - For countries utilizing licensees or contract employees, describe how and at what frequency the CCA ensures that inspection activities (other than official government verification sample collection activities) are being conducted under the direct authority of a government agency when producing product intended for export to the United States.
- Describe how all government inspection personnel are paid. This may include direct or indirect payment by the government, such as payment through a third party.
- Describe the CCA's conflict-of-interest controls to ensure that government inspection personnel act in the public's interest.

6. How does the CCA ensure that government inspection occurs continuously during slaughter operations, and at least once per production shift during the processing of meat, poultry, or egg products intended for export to the United States?

NOTE: Processing operations include all non-slaughter activities, including but not limited to, boning, cutting, slicing, grinding, injecting, pumping, filleting, breading, adding ingredients through other mechanical means, formulating, assembling, packaging, and labeling meat or poultry food products. For egg products, processing operations include the manufacturing of egg products, including but not limited to, breaking eggs, filtering, blending, mixing, pasteurizing, stabilizing, storing, cooling, freezing, drying, packaging, labeling, and final product examination.

NOTE: In slaughter operations, FSIS requires continuous government inspection during slaughter activities to ensure that every livestock carcass, head, and viscera and every poultry carcass and viscera[8] are inspected.

NOTE: In processing operations (i.e., non-slaughter), FSIS requires that government inspection personnel (i.e., government inspector, licensee, or contract employee) be on the premises and performing inspection activities at least once per production shift during processing operations. The requirement for government inspection once per production shift during processing operations is not the same as inspection once daily. In processing establishments, if an establishment has more than one production shift per day during which it produces product for export to the United States, government inspection personnel (i.e., government inspector, licensee, or contract employee) must be present at least once during each production shift.

To respond to this question sufficiently, the CCA must:

- Describe how the CCA ensures that qualified government inspection personnel provide inspection coverage at each of the certified establishments continuously during slaughter operations, and at least once per production shift during processing operations when producing meat, poultry, or egg products intended for export to the United States. Include how the CCA ensures that there are enough qualified government inspection personnel to cover during planned or unplanned government inspection personnel absences.

7. How does the CCA ensure that government inspection personnel have appropriate educational credentials, disciplinary backgrounds, and training to carry out assigned inspection tasks?

To respond to this question sufficiently, the CCA must:

- Describe the minimum qualifications for government inspection personnel (e.g., educational credentials, training, and experience requirements) for both veterinarians and non-veterinarians. Include whether official veterinarians in certified establishments are required to possess a doctoral degree in veterinary medicine or equivalent degree.

[8] See footnote 7

- Describe how and at what frequency government inspection personnel are trained on requirements consistent with FSIS import requirements.

8. How does the CCA ensure adequate oversight of facilities that perform the collection, growth, and differentiation of livestock and poultry cells before cell harvest for use in the production of cell-cultured meat or poultry food products?

NOTE: The response to this question will be assessed in consultation with the U.S. Food and Drug Administration (FDA).

To respond to this question sufficiently, the CCA must:

- Indicate whether the CCA will require pre-market consultation through the U.S. FDA or whether the CCA will implement its own pre-market consultation and approval process. If the CCA will require pre-market consultation through the U.S. FDA, indicate how the CCA will verify that the establishment has satisfactorily gone through the pre-market consultation process. Additionally, indicate whether the CCA will review and provide concurrence with the results of the U.S. FDA's pre-market assessment.
- Describe the requirements and verification activities related to preharvest controls, including initial cell and tissue collection, development and maintenance of qualified cell banks, and the proliferation and differentiation of cells through the time of harvest. Include:

  NOTE: This question does not need to be answered if all preharvest establishments producing cells for production of cell-cultured food products will go through the U.S. FDA pre-market consultation process.

  - How the CCA conducts pre-market food safety assessments[9] of the preharvest production process, including any substances (including direct ingredients, nutrients, medium management substances, growth factors, any structural materials, and any other substances) used, of cultured animal cells used as human food;
  - How the CCA ensures that the laws and regulations governing the preharvest process for cultured animal cells consumed as human food are enforced;
  - How the CCA ensures the substances used in the cell culture food production process are safe and authorized for their intended use;
  - How the CCA ensures that condition of establishments' personnel practices, construction, facilities, and equipment are adequate to prevent the contamination or adulteration of the preharvest cell cultures;
  - How the CCA ensures that certified establishments develop, implement, and maintain operational sanitation procedures sufficient to prevent contamination or adulteration of the preharvest cell cultures;
  - How the CCA ensures the establishment personnel working in the preharvest environment receive good manufacturing practice and food safety training;
  - How the CCA ensures that certified establishments develop, implement, and maintain a food safety program to ensure that food safety hazards are identified and prevented or controlled when producing preharvest cultured animal cells, including adventitious agent[10] hazards associated with cell procurement, contamination of production inputs, environmental and equipment contamination, and handling at harvest;
  - How the CCA oversees procurement, identification, and establishment of animal cell lines used for human food production;

[9] A pre-market food safety assessment process evaluates the safety of the cultured animal cell material (including cells and any preharvest inputs) used as food before it enters the market. The pre-market process allows developers to work with the CCA on a product-by-product basis and informs them of issues they must consider to produce safe food. As part of the pre-market process, the CCA evaluates the production process and the cultured cell material made by the production process, including the establishment of cell lines and cell banks, manufacturing controls, and all components and inputs.

[10] Adventitious agents are replicative agents such as eukaryotes, prokaryotes, or viruses and additionally prions.

- How the CCA oversees the establishment of animal cell banks used for human food production;
- How the CCA oversees the process of culturing animal cells for consumption as human food, including proliferation (biomass accumulation), differentiation, and harvest; and,
- How the CCA ensures that cell material at the point of harvest prior to conventional food processing for use as human food is safe and correctly characterized with respect to species or other properties, including
  - Whether any substances used in production are intentionally or unintentionally present, and if so, whether there is an adequate margin of exposure to ensure safety; and
  - Whether specifications are set for contaminants such as toxic metals that may be present through bioaccumulation or introduction from substances used in the culture process.

9. How does the CCA ensure adequate oversight of laboratories that perform analyses of official government samples of meat, poultry, or egg products intended for export to the United States, including oversight to ensure that laboratories conducting analyses of official government samples implement general quality assurance and quality control procedures in accordance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards?

NOTE: The CCA must provide information for laboratories that perform analyses of official government samples collected as part of official government chemical residue and microbiological sampling programs for products intended for export to the United States.

To respond to this question sufficiently, the CCA must:

- Describe the CCA's oversight of laboratories responsible for analyzing official government samples, including whether the CCA has the legal authority and responsibility to approve and disapprove laboratories conducting testing of official government samples of product intended for export to the United States.
- Provide a list of laboratories that perform official government chemical residue or microbiological analyses. Identify whether laboratories conducting official government analyses are official government laboratories or third-party laboratories (e.g., international (foreign), private, or establishment laboratories) and which type of analyses are performed at each laboratory (i.e., chemical residue or microbiological). If a third-party laboratory is used, briefly describe the interaction and oversight by the government. Include documentation demonstrating that the third-party laboratory reports test results directly to the government, as well as documentation demonstrating the degree of oversight by the government, such as annual audits, to ensure laboratory procedures are followed in accordance with ISO/IEC 17025 standards.
- Describe the CCA's requirements for ensuring that official laboratories implement procedures consistent with ISO/IEC 17025 standards.
- Describe the CCA's requirements for ensuring that laboratory personnel are properly trained in the chemical residue and microbiological analyses performed (ISO/IEC 17025:2017(E), Section 6.2).
  - Indicate whether official laboratories are required to monitor laboratory performance through proficiency testing or other interlaboratory comparisons (ISO/IEC 17025:2017(E), Section 7.7).
- If the laboratory is not ISO-accredited, describe how laboratory management and technical requirements comply with ISO/IEC 17025 standards including the following:
  - Sample handling after collection and during transport to official laboratories;
  - Sample receipt and storage prior to analyses at the laboratory;
  - Calibration and maintenance of laboratory equipment necessary for chemical residue and microbiological analyses (ISO/IEC 17025:2017(E), Section 6.4);
  - Internal quality control parameters, including positive and negative assay controls where appropriate, to assure the quality of the results for the analyses performed (ISO/IEC 17025:2017(E), Section 7.7); and
  - Reporting and recordkeeping capabilities that can clearly track and link a test result to the correct

establishment, including traceability from sample collection, to receipt by the laboratory, through reporting back to the CCA (ISO/IEC 17025:2017(E), Sections 7.5 and 8.4).

- Describe how official government test results are reported directly from the laboratory performing the analysis to the CCA in a timely manner. In addition, describe how the CCA notifies establishments when official government test results are found positive for microbiological pathogens or violative for chemical residues.
- Describe how the CCA ensures that samples with violative or unacceptable test results are not resampled or retested.

Component 2: Government Verification of Food Safety and Other Consumer Protection Requirements

10. How does the CCA ensure that animals are handled and slaughtered humanely?

To respond to this question sufficiently, the CCA must:

- Identify and describe the CCA's laws and regulations requiring that livestock and poultry are handled and slaughtered humanely.
- Describe how and at what frequency government inspection personnel verify that livestock and poultry are handled and slaughtered humanely, including how livestock are rendered insensible to pain (e.g., stunning by captive bolt, gunshot) prior to shackling, hoisting, and cutting the animal and how and at what frequency government inspection personnel verify that birds are thoroughly bled and not breathing prior to entering the scalder.
- Describe the enforcement actions the CCA takes when certified establishments do not comply with humane handling and slaughter requirements.
- Describe how and at what frequency the CCA verifies that certified establishments take effective actions after instances of noncompliance.

11. How does the CCA ensure that government inspection personnel perform ante-mortem inspection of all livestock and poultry prior to slaughter?

To respond to this question sufficiently, the CCA must:

- Identify and describe the CCA's laws and regulations for ante-mortem inspection of livestock and poultry.
- Describe how government inspection personnel perform ante-mortem inspection of all livestock and poultry during slaughter operations when producing products intended for export to the United States.
- Identify which type of government inspection personnel (i.e., government veterinarian, government inspector, licensee, or contract employee) is performing ante-mortem inspection of livestock and poultry in certified establishments. Furthermore, identify whether a government veterinarian oversees ante-mortem verification activities.
- Identify which ante-mortem disease conditions are condemnable.
- Describe how and at what frequency government inspection personnel verify that dead, dying, and diseased animals are condemned and not used to manufacture meat and poultry products intended for export to the United States.
- For cattle (including calves), describe how and at what frequency government inspection personnel verify that non-ambulatory disabled cattle are condemned or physically segregated before, during, and after entry into the slaughter establishment's rooms or compartments where cattle eligible for the production of products intended for export to the United States are being slaughtered, dressed, processed, handled or stored to prevent comingling and preclude their eligibility for export to the United States.
- Describe how and at what frequency government inspection personnel verify that animals displaying

clinical signs of central nervous system disorders (e.g., rabies, listeriosis, bovine spongiform encephalopathy [BSE], scrapie) are condemned and not used to manufacture meat products intended for export to the United States.

- For swine, identify whether the CCA utilizes an alternative swine slaughter inspection system similar to FSIS' New Swine Slaughter Inspection System (NSIS). If using an alternative swine slaughter inspection system, describe how and at what frequency government inspection personnel verify that certified establishments:
    - Sort fit from unfit animals prior to government ante-mortem inspection;
    - Dispose of carcasses and parts with condemnable conditions;
    - Identify animals or carcasses, that they have sorted and removed for disposal before government inspection, with a unique tag, tattoo, or similar device; and
    - Maintain records documenting the total number of animals and carcasses sorted and removed per day and the reasons for their removal.

12. How does the CCA ensure that government inspection personnel perform post-mortem inspection of every livestock carcass, head, and viscera and every poultry carcass and viscera during and after the slaughter of livestock and poultry?

NOTE: In this SRT question, the term "on-line" refers to government inspection personnel working on the production line and performing post-mortem inspection procedures on every livestock carcass, head, and viscera and every poultry carcass and viscera.[11] The term "off-line" refers to government inspection personnel performing verification activities throughout the establishment (e.g., HACCP, sanitation, zero tolerance). Off-line government inspection personnel do not remain on the production line performing inspection activities throughout the day. Off-line government inspection personnel are also referenced in SRT Question #22.

To respond to this question sufficiently, the CCA must:

- Identify and describe the CCA's laws and regulations for post-mortem inspection of every livestock carcass, head, and viscera and every poultry carcass and viscera[12] at the time of slaughter. Furthermore, identify which type of government inspection personnel (i.e., government inspector, licensee, or contract employee) is performing post-mortem inspection of livestock and poultry in certified establishments.
- For livestock, describe how on-line government inspection personnel perform post-mortem inspection of every livestock carcass, head, and viscera and the point in the slaughter process where government inspection personnel examine each carcass, head, and viscera. Include how on-line government inspection personnel perform post-mortem inspection activities to ensure that every livestock carcass, head, and viscera are free of visible fecal material, ingesta, and milk; and the actions taken when on-line government inspection personnel observe contamination (i.e., fecal material, ingesta, or milk) on livestock carcasses, heads, or viscera.
- For poultry, describe how on-line government inspection personnel perform post-mortem inspection of every poultry carcass and viscera.[13]
- Describe how on-line government inspection personnel verify that poultry carcasses with visible fecal contamination do not enter the chiller; and the actions taken when on-line government inspection personnel observe fecal material on poultry carcasses.
- For poultry, identify whether the CCA utilizes an alternative poultry slaughter inspection system similar to FSIS' New Poultry Inspection System (NPIS). If using an alternative poultry slaughter inspection system, describe how and at what frequency government inspection personnel verify that certified establishments 1) conduct carcass and viscera sorting activities, 2) dispose of carcasses and parts with

[11] See footnote 7
[12] See footnote 7
[13] See footnote 7

condemnable conditions, and 3) perform appropriate trimming and reprocessing tasks before carcasses are presented for government inspection.

- For swine, identify whether the CCA utilizes an alternative swine slaughter inspection system similar to FSIS' New Swine Slaughter Inspection System (NSIS). If using an alternative swine slaughter inspection system, describe how and at what frequency government inspection personnel verify that certified establishments 1) prepare carcasses and parts for government post-mortem inspection (e.g., incise mandibular lymph nodes and palpate the viscera to detect the presence of animal diseases (e.g., *Mycobacterium avium*); and 2) maintain records documenting that products resulting from their slaughter operations meet FSIS' definition of ready-to-cook (RTC) pork product, which is any slaughtered pork product sufficiently free from bile, hair, scurf, dirt, hooves, toenails, claws, bruises, edema, scabs, skin lesions, icterus, foreign material, and odor that is suitable for cooking without need of further processing.
- Identify which animal disease conditions are condemnable during post-mortem inspection. In addition, describe how and at what frequency government inspection personnel verify the proper disposition of livestock and poultry identified with these conditions.
- Describe the maximum line speed rate and government staffing standards for on-line government inspection personnel in meat and poultry slaughter establishments.

13. How does the CCA ensure that a representative of the government inspection system makes periodic supervisory visits to each certified establishment to evaluate the performance of government inspection personnel?

To respond to this question sufficiently, the CCA must:

- Describe how and at what frequency the CCA evaluates the performance of government inspection personnel in certified establishments, including the position and level of government for the person conducting performance reviews of government inspection personnel.
- Identify the inspection topics evaluated during these supervisory review visits. These visits should include reviews of government inspection personnel's knowledge of U.S. import requirements and verification of the following: animal welfare, ante-mortem, post-mortem, sanitation standard operating procedure (Sanitation SOP) and sanitation performance standards (SPS), HACCP, labeling verification, export certification, import inspection to ensure source materials originate from certified establishments in eligible countries, separation of products eligible for export to the United States from ineligible products, control over condemned materials, official government sample collection practices, and enforcement of FSIS import requirements.

14. How does the CCA ensure complete separation of meat, poultry, or eggs products eligible for export to the United States from meat, poultry, or egg products that are ineligible?

NOTE: Any meat, poultry, or egg products intended for export to the United States cannot be produced in an establishment or part of an establishment that is not certified by the CCA as eligible to export to the United States.

NOTE: If a certified establishment also produces meat, poultry, or egg products not intended for export to the United States, the products not intended for export to the United States must be produced separately by either time or space.

To respond to this question sufficiently, the CCA must:

- Describe how the CCA ensures that meat, poultry, or egg products intended for export to the United States are produced separately (by time or space) from products not intended for export to the United States.
- Describe how and at what frequency government inspection personnel verify the separation of meat, poultry, or egg products eligible for export to the United States from products that are ineligible .

15. How does the CCA ensure that meat, poultry, or egg products intended for export to the United States meet FSIS labeling requirements?

NOTE: For labels that require FSIS approval, foreign establishments can submit applications for FSIS approval by completing FSIS Form 7234-1, *Application for Approval of Labels, Marking or Device*, and then mailing the paper form. Mailing instructions are located under Label Application Guidance on the FSIS website. For more information on U.S. labeling requirements, please refer to FSIS Guideline for Label Approval and Check List for Mandatory Features on a Label.

NOTE: FSIS will no longer evaluate generically approved labels[14] that foreign establishments voluntarily submit for review.

To respond to this question sufficiently, the CCA must:

- Describe how and at what frequency government inspection personnel perform labeling verification activities to ensure that U.S. labeling requirements are met, and all labels are accurate and truthful (e.g., verification of all required labeling features including accuracy of net weights, ingredients statements, and nutrition label information, when applicable).
- Describe how and at what frequency government inspection personnel verify that all ingredients and processing aids used in the production of product intended for export to the United States are considered safe and suitable as per FSIS' list of safe and suitable ingredients and regulations.

  NOTE: For more information on which ingredients FSIS identifies as safe and suitable, please refer to the complete list of safe and suitable ingredients and the list in 9 CFR 424.21(c) of additional acceptable food ingredients. Additional information is also available in FSIS Directive 7120.1, *Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products*, and FSIS Guidance on the Determination of Processing Aids.
- Describe how and at what frequency government inspection personnel perform verification activities to ensure that allergens are clearly identified and labeled.

  NOTE: FSIS recognizes the major food allergens designated by the U.S. Food and Drug Administration's (FDA) Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and subsequent amendments. These allergens include wheat; crustacean shellfish (e.g., crab, lobster, shrimp); eggs; fish; peanuts; milk; tree nuts (e.g., almonds, pecans, walnuts); sesame, and soybeans.
- Describe how and at what frequency government inspection personnel perform species verification activities (e.g., species verification testing or verification of product formulation).
- Describe how and at what frequency the CCA ensures that labels with special statements and claims (9 CFR 412.1(c)(3)) or labels used for cell-cultured food products have been approved by FSIS before exporting products to the United States.

  NOTE: Labels for cell-cultured food products are required to be submitted for FSIS approval.
- Describe how the CCA ensures that meat and poultry products with a U.S. standard of identity are accurately labeled.

  NOTE: For more information on the U.S. labeling requirements for standards of identity, please refer to 9 CFR part 319 (meat products) and 9 CFR part 381 subpart P (poultry products), and to the FSIS Food Standards and Labeling Policy Book.
- Describe how and at what frequency the CCA verifies that not ready-to-eat (NRTE) meat or poultry products are labeled with safe handling instructions and that NRTE products that are not shelf stable are labeled with special handling statements, such as keep refrigerated or keep frozen.

  NOTE: For more information on the FSIS labeling requirements for safe handling instructions and special handling statements, refer to 9 CFR 317.2 (k-l) (meat products) and 9 CFR 381.125 (a-b)

[14] Generically approved labels are labels that bear all applicable mandatory labeling features (i.e., product name, handling statement, ingredients statement, the name and place of business of the manufacturer, packer or distributor, net weight, legend, safe handling instructions, and nutrition labeling) in accordance with FSIS labeling requirements and do not bear special statements and claims as defined in 9 CFR 412.1(e).

(poultry products).

- Describe the actions the CCA takes when certified establishments do not comply with labeling requirements.

16. How does the CCA ensure that meat, poultry, or egg products intended for export to the United States are not restricted by the USDA Animal and Plant Health Inspection Service (APHIS)?

To respond to this question sufficiently, the CCA must:

- Identify and describe any APHIS disease restrictions for meat, poultry, or egg products (including cell-cultured food products) that the country is currently exporting to the United States or intends to export to the United States.
- Describe how the CCA is notified of updates or changes to APHIS restrictions, and how these changes are communicated to government inspection personnel in certified establishments and to the officials responsible for the certification of products intended for export to the United States.
- Describe how government inspection personnel verify during the export certification process that APHIS-restricted products are not shipped to the United States.

17. How does the CCA ensure that beef products are not contaminated with specified risk materials (SRMs) associated with bovine spongiform encephalopathy (BSE)?

NOTE: FSIS considers the following materials from cattle to be SRMs: (1) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from cattle 30 months of age and older and (2) The distal ileum of the small intestine and the tonsils from all cattle.

To respond to this question sufficiently, the CCA must:

- Describe how the CCA defines SRMs and identifies affected tissues.
- Describe the CCA's requirements concerning the identification, removal, and disposal of SRMs.
- Describe how and at what frequency government inspection personnel verify adequate identification, removal, and disposal of SRMs.

18. How does the CCA ensure control over condemned animals, which can include portions of inspected carcasses and parts or inedible material, until destroyed or otherwise denatured?

NOTE: Condemned means any animal carcass, part of an animal carcass, or animal-based product inspected and determined to be unfit for human food.

NOTE: Inedible material includes animals condemned either at ante-mortem or post-mortem inspection, SRMs, diseased parts, tissues that are inedible by definition (e.g., tonsils and lungs), and inedible shell eggs and egg products.

NOTE: The denaturing of meat, poultry, or egg products includes the addition of a chemical substance (e.g., charcoal or dye) to ensure that the products cannot be used for human food.

To respond to this question sufficiently, the CCA must:

- Identify and describe the CCA's laws and regulations for identifying, handling to prevent cross-contamination, and controlling inedible material to ensure that it is not used to manufacture meat, poultry, or egg products intended for export to the United States.
- Describe how and at what frequency government inspection personnel verify that condemned and inedible material is destroyed or denatured before leaving the establishment.

19. How does the CCA ensure the implementation and maintenance of a food safety inspection system for cell-cultured meat or poultry food products that prevents food safety hazards that can arise after harvesting the cells for further processing?

To respond to this question sufficiently, the CCA must:

- Describe the CCA's requirements for postharvest production of cell-cultured meat and poultry food products.
- Describe how and at what frequency the government inspection personnel verify certified establishments meet requirements for postharvest production of cell-cultured meat and poultry food products.
- Describe any enforcement actions by the CCA or any follow-up necessary when a certified establishment does not meet requirements for postharvest production of cell-cultured meat and poultry food products.

Component 3: Government Sanitation Verification

20. How does the CCA ensure that Siluriformes fish are raised and transported under sanitary conditions?

To respond to this question sufficiently, the CCA must:

- Describe how and at what frequency the CCA verifies that Siluriformes fish intended for export to the United States are raised in a sanitary manner. Include how the CCA ensures that Siluriformes fish do not grow or live under conditions that would render the fish unsound, unwholesome, unhealthful, or otherwise inedible (e.g., preharvest standards).
- Identify whether Siluriformes fish intended for export to the United States will be wild-caught or farm-raised, or both.
- Identify whether the CCA collects either routine or "for cause" official government samples of feed, Siluriformes fish, or source water to verify that Siluriformes fish are being raised under conditions that will yield safe, wholesome products. Additionally, describe the official government sample collection procedures and sampling frequencies. If samples are not collected by the CCA (e.g., by producers or establishments), describe how and at what frequency the CCA ensures that samples are collected appropriately. Furthermore, if product sampling results indicate the conditions in which the fish were raised as the source of contamination, describe how the CCA ensures contaminated or adulterated Siluriformes fish is not used in the production of Siluriformes fish product for export to the United States.
- Describe the CCA's requirements for ensuring that Siluriformes fish are transported from the point of harvest to the processing establishment in a sanitary manner, including requirements for the sanitation of containers used to transport Siluriformes fish to the establishments (e.g., a holding tank in a boat transporting live fish).
- Describe how and at what frequency the CCA verifies that Siluriformes fish are transported to the establishment in a sanitary manner.

21. How does the CCA ensure that only Siluriformes fish that have died under the controlled circumstances of commercial fishing are eligible for export to the United States?

To respond to this question sufficiently, the CCA must:

- Describe the CCA's requirements to ensure separation between slaughtered Siluriformes fish and fish products and any fish that have died other than by slaughter.
- Describe how and at what frequency government inspection personnel verify that establishments are properly identifying, sorting, and disposing of Siluriformes fish that have died from circumstances other

than under the controlled circumstances of commercial fishing (e.g., dead Siluriformes fish that exhibit signs of spoilage or decomposition).

22. How does the CCA ensure that livestock and poultry are slaughtered and processed in a sanitary manner?

To respond to this question sufficiently, the CCA must:

- Describe the CCA's requirements for sanitary dressing of livestock and poultry throughout slaughter operations, include whether establishments are required to develop, implement, and maintain written procedures in their HACCP plans, Sanitation SOPs, or other prerequisite programs to prevent contamination of livestock carcasses and parts by enteric pathogens, fecal material, ingesta, and milk; and poultry carcasses by enteric pathogens and fecal material.
  NOTE: The term "sanitary dressing" refers to the practice of handling carcasses by establishment employees and machinery, throughout the slaughter process, in a manner that produces a clean, safe, wholesome meat or poultry food product in a sanitary manner.
- Describe how and at what frequency government inspection personnel perform sanitary dressing verification activities.
- Describe how and at what frequency off-line government inspection personnel perform zero tolerance verification activities to ensure the following: livestock carcasses are free of visible fecal material, ingesta, and milk at or immediately after the final rail; head, cheek, and weasand meat are free of visible fecal material, ingesta, and milk at the end of the harvesting process (e.g., at the packaging step or when the product is placed into a container for storage); and poultry carcasses are free of visible fecal material prior to entering the chiller. Include the point in the slaughter process where the off-line government zero tolerance verification activity is performed and the actions taken when government inspection personnel observe fecal material, ingesta, or milk on livestock carcasses, head, cheek, or weasand meat; or fecal material on poultry carcasses or viscera.

23. How does the CCA ensure that the construction and condition of facilities and equipment in certified establishments is adequate to prevent the contamination or adulteration of meat, poultry, or egg products intended for export to the United States?

To respond to this question sufficiently, the CCA must:

- Describe the CCA's requirements for construction and condition of facilities and equipment in certified establishments.
- Describe how and at what frequency government inspection personnel verify that construction and condition of facilities and equipment in certified establishments are sufficient to prevent product contamination or adulteration (e.g., pest management program; construction; separation of edible materials from inedible materials; employee hygiene; sanitation of equipment and utensils; adequate lighting, drainage, and ventilation; and water potability).
- Describe the actions the CCA takes when certified establishments do not comply with requirements for construction and for condition of facilities or equipment.
- Describe how and at what frequency the CCA verifies that certified establishments take effective actions after instances of noncompliance.

24. How does the CCA ensure that certified establishments develop, implement, and maintain daily pre-operational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of meat, poultry, or egg products intended for export to the United States?

To respond to this question sufficiently, the CCA must:

- Describe the CCA's requirements for certified establishments to implement daily sanitation procedures sufficient to prevent direct contamination or adulteration of product.
- Describe how and at what frequency government inspection personnel verify that certified establishments develop, implement, and maintain daily pre-operational and operational sanitation procedures.
- Identify which type of government inspection personnel (i.e., government inspector, licensee, or contract employee) is performing sanitation verification activities in certified establishments.
- Describe the CCA's sanitation recordkeeping requirements for certified establishments, including a description of the records certified establishments are required to maintain to demonstrate adequate implementation of their sanitation procedures (e.g., sanitation monitoring records and corrective action records).
- Describe how and at what frequency government inspection personnel review sanitation records of certified establishments.
- Describe the actions the CCA takes when certified establishments do not comply with the sanitation requirements.
- Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions to restore sanitary conditions and implement preventive measures, as applicable, after instances of noncompliance.

Component 4: Government HACCP System Verification

25. How does the CCA ensure that certified establishments develop, implement, and maintain a HACCP system to ensure that food safety hazards are identified and prevented or controlled when producing meat, poultry, or egg products intended for export to the United States?

To respond to this question sufficiently, the CCA must:

- Identify whether the CCA requires that each certified establishment develop, implement, and maintain a HACCP system which incorporates the seven principles of HACCP to identify and prevent or control hazards.
  NOTE: The seven principles of HACCP include: (1) conduct a hazard analysis; (2) identify critical control points; (3) establish critical limits for each critical control point; (4) establish critical control point monitoring requirements; (5) establish corrective actions; (6) establish record keeping procedures; and (7) establish procedures for verifying the HACCP system is working as intended.
- Identify whether the CCA requires specific controls for relevant hazards to be incorporated in the HACCP plan as a critical control point (CCP).
- Identify whether the CCA requires certified establishments to 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 keep them within acceptable limits, and routinely monitor and maintain records for the performance of controls.
- Describe how and at what frequency the CCA verifies that certified establishments properly identify hazards reasonably likely to occur and develop CCPs.
- Describe how the CCA requires and verifies that certified establishments maintain in-plant implementation data, and scientific or technical support to validate the adequacy of their HACCP systems in controlling the food safety hazards identified in the hazard analysis.
- Describe how the CCA requires certified establishments to perform ongoing verification activities, such as calibration of process monitoring equipment, direct observation of monitoring activities and corrective actions, and review of records, to ensure the adequacy of their HACCP systems.
- Describe how and at what frequency the CCA verifies that certified establishments implement ongoing verification activities to ensure the adequacy of their HACCP systems.

- Describe how and at what frequency the CCA conducts an ongoing review of HACCP plans and verifies the effectiveness of the HACCP plans.
- Describe whether the CCA has the regulatory authority to require that certified establishments take corrective actions when a CCP does not control an identified hazard. Furthermore, describe the corrective action requirements when establishment monitoring or verification, or government verification, shows that a deviation has occurred (e.g., identify and eliminate the cause of the deviation, determine that the CCP is under control after taking corrective actions, establish measures to prevent recurrence, and ensure appropriate product disposition).
- Describe how often certified establishments are required to reassess their HACCP plans and under what circumstances reassessment is required.
- Describe the CCA's HACCP recordkeeping requirements, including a description of the records certified establishments are required to maintain to demonstrate adequate implementation of their HACCP systems.
- Identify which type of government inspection personnel (i.e., government inspector, licensee, or contract employee) is performing HACCP verification activities in certified establishments.
- Describe how and at what frequency government inspection personnel verify that certified establishments review records associated with the production of product intended for export to the United States to ensure that all HACCP requirements are met (e.g., all critical limits at all CCPs have been met, and any required corrective actions have been taken) prior to shipping the product into commerce (i.e., establishments conduct pre-shipment review).[15]
- Describe how and at what frequency government inspection personnel verify that certified establishments are receiving and confirming acceptable testing results from all samples (i.e., establishment testing and government verification testing) of products tested for adulterants as defined by FSIS prior to completing and signing the pre-shipment review record.

  NOTE: This applies to confirmation of acceptable testing results for the following sampled products: raw non-intact beef product or raw intact beef product intended for raw non-intact use (or where intended use is unknown) that is tested for STEC; RTE meat, poultry, or egg products tested for *Lm*, *Salmonella*, or STEC (relative to RTE beef products, if applicable); RTE product that passed over food contact surfaces that have been tested for the presence of *Lm* or *Salmonella*; and livestock carcasses and parts subject to both routine and suspect chemical residue testing for veterinary drugs, pesticides, or, if applicable, environmental contaminants.
- Describe how and at what frequency government inspection personnel perform HACCP verification activities (e.g., verification of monitoring, verification, recordkeeping, corrective actions requirements) in certified establishments.
- Describe the actions the CCA takes when certified establishments do not comply with the HACCP requirements.

Component 5: Government Chemical Residue Program

26. How does the CCA ensure the implementation and maintenance of an official government chemical residue sampling program that prevents and controls all specific chemical compounds of concern in the foreign country and in the United States?

To respond to this question sufficiently, the CCA must:

[15] Pre-shipment review, as described in 9 CFR 417.5(c), requires a review of records associated with a specific production of product or establishment designated lots before it is shipped into commerce. The review includes a check of any records associated with the HACCP system, including prerequisite programs, that are tied to the specific production lot that is being shipped. Pre-shipment review ensures that all applicable prerequisite programs have been implemented, that all critical limits at all CCPs have been met, and that any required corrective actions have been taken.

- Identify and describe the CCA's official government chemical residue sampling program. Include the following:
    - Proposed number of samples for each production class and compound tested;
    - Type of tissue (e.g., muscle, liver, or kidney) and sample collection procedures for each production class and compound tested; and
    - Established tolerances or action levels used to take regulatory action for a violative sample (e.g., maximum residue limit (MRL)) for each chemical compound tested.
- Describe the process and frequency of reassessment of the official government chemical residue sampling program to determine whether the production classes and compounds tested should be modified. Include the following:
    - Indicate whether the results from previous sampling programs are evaluated to determine when changes are required;
    - The rationale or criteria used to develop the proposed number of samples for each production class (e.g., statistical basis, etc.); and
    - The rationale or criteria used to determine whether a compound is included or removed from the testing program.
- Provide the screening and confirmation analytical methodology (e.g., LC-MS/MS, GC-MS) for each of the chemical compounds tested as part of the official government chemical residue sampling program. For reference, current FSIS analytical methods can be found in the FSIS Chemistry Laboratory Guidebook. Include the limit of detection for both screening and confirmation methods, as applicable.
- Identify whether all official government chemical residue sampling is done by government inspection personnel (i.e., government inspector, licensee, or contract employee). If official government chemical residue sampling is performed by the establishment, please include a description of how and at what frequency the CCA verifies that samples are collected appropriately.
- Describe how the CCA ensures that lotting procedures are defined so that if there is a violative sample result, all affected product can be identified. Include a description of how the CCA ensures establishments are able to identify the origin of the product or animal associated with the violative result.
- Confirm whether the CCA requires individual livestock carcasses subjected to routine official government chemical residue testing to be held pending acceptable test results when used for product intended for export to the United States.
- Describe how the CCA reviews official government chemical residue test results to ensure that product intended for export to the United States does not contain a chemical residue that exceeds an established U.S. tolerance or action level, or contain a chemical compound with no approved use in the production class tested. For reference, information regarding FSIS' current sampling plan for chemical residues can be found on the FSIS Sampling Program web page under the "Annual Sampling Reports" section; the acceptable tolerance levels set by the United States Food and Drug Administration for veterinary drugs can be found at 21 CFR part 556; and the acceptable tolerance levels set by the United States Environmental Protection Agency for pesticides can be found at 40 CFR part 180.

    NOTE: FSIS considers adulterated any product produced using source materials with chemical residue results that exceed established U.S. tolerances or action levels. Generally, if there is no established U.S. tolerance or action level set for a specific veterinary drug or pesticide residue, FSIS would consider the product adulterated if any level is detected. Therefore, FSIS generally does not evaluate risk on a case-by-case basis for veterinary drug or pesticide residue test results. However, there are some environmental or industrial contaminants, such as metals, mycotoxins, and dioxins, where no tolerances are set, so when FSIS detects the contaminant, the level detected is evaluated on a case-by-case basis to determine if the product is injurious to health and thus adulterated.
- Describe how the CCA notifies establishments when an official government chemical residue result exceeds established criteria, including when the result for product intended for export to the United States exceeds an established U.S. tolerance or action level, or contains a chemical compound with no approved use in the production class tested.
- Describe the actions the CCA takes when an official government chemical residue result exceeds

established criteria, including when the result for product intended for export to the United States exceeds an established U.S. tolerance or action level, or contains a chemical compound with no approved use in the production class tested.
- Describe how and at what frequency the CCA verifies that certified establishments take effective actions when established chemical residue criteria are not met.

For cell-cultured meat and poultry food products:

- Describe how the CCA verifies that chemical substances[16] used in production that may be of toxicological concern based on the pre-market safety assessment (see footnote 6) do not adulterate product intended for export to the United States.

Component 6: Government Microbiological Pathogen and Process Control Programs

27. How does the CCA ensure that meat or poultry slaughter establishments verify process control using microbiological analyses for indicators of intestinal and fecal contamination?

To respond to this question sufficiently, the CCA must:

- Describe how the CCA requires and verifies process control in certified slaughter establishments.
- Identify whether sampling for microbiological indicators of process control is performed by government inspection personnel (i.e., government inspector, licensee, or contract employee) or by the establishment. If sampling is performed by the establishment, include a description of how and at what frequency the CCA verifies that samples are collected appropriately.
- Identify and describe the CCA's testing requirements for using indicator organisms to monitor process control in certified establishments. Include the following:
    - Microbiological indicator organism chosen (e.g., Enterobacteriaceae or generic *E. coli*);
    - Frequency of sampling;
    - Points in the process where sampling will occur (e.g., pre-evisceration, pre-chill, or post-chill);
    - Sampling methodology; and
    - Process control criteria used to evaluate the results.
- Identify whether the microbiological methods of analysis used for official government samples of indicator organisms conform to FSIS Microbiology Laboratory Guidebook (MLG) methods or internationally recognized method standards (e.g., ISO methods for Enterobacteriaceae or generic *E. coli*).
    NOTE: If the official method includes the use of a commercial detection kit, the commercial detection kit must have been validated by an external validating organization such as Association of Analytical Collaboration (AOAC) International, Association Française de Normalisation (AFNOR), NordVal, Microval, or Spanish Association for Standardization and Certification (AENOR).
- Describe the CCA's requirements for certified establishments to maintain process control records for monitoring of indicators of intestinal and fecal contamination.
- Describe how and at what frequency government inspection personnel verify that certified establishments restore process control when microbiological process control criteria are exceeded.
- Describe actions the CCA takes when established microbiological process control criteria are not met.
- Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions when established microbiological process control criteria are not met.

28. How does the CCA ensure the reduction of *Salmonella* in raw meat and poultry products through

[16] Substances may include, but are not limited to, antibiotics, recombinant growth factors, hormones, peptides, small molecule agonists, or other relatively exotic elements.

sampling and other verification activities?

To respond to this question sufficiently, the CCA must:

- Describe how and at what frequency the CCA verifies that establishments reduce and control *Salmonella* in raw meat and poultry.
- Describe the CCA's requirements for poultry on-line reprocessing (OLR) and poultry off-line reprocessing (OFLR).
- Describe how and at what frequency the CCA verifies that all poultry carcasses, parts, and giblets are chilled immediately after slaughter operations so that there is no outgrowth of pathogens, unless such poultry is frozen or cooked immediately at the establishment.
- For certified poultry slaughter establishments, identify whether the CCA requires the establishment to develop, implement, and maintain written procedures for chilling in its HACCP plans, Sanitation SOPs, or other prerequisite programs that address the potential for pathogen outgrowth, the conditions affecting carcass chilling, and the length of time necessary for adequate chilling.
    - Describe how and at what frequency government inspection personnel verify that certified establishments develop, implement, and maintain these procedures in their HACCP plans, Sanitation SOPs, or other prerequisite programs.
- Describe how the CCA provides for an official government microbiological sampling verification program for *Salmonella* in raw meat and poultry. Include a written sampling plan with instructions for sample collection and testing to address the following:
    - Frequency of sampling;
    - Points in the process where sampling will occur; and
    - Sampling methodology.
    - Describe the CCA's performance standard criteria for evaluation of *Salmonella* verification sampling results, including how the CCA assesses on an ongoing basis whether certified establishments meet such performance standards for chicken and turkey carcasses, chicken parts, and comminuted chicken and turkey.
    - Describe the CCA's performance standard criteria for evaluation of *Salmonella* results, including how the CCA assesses on an ongoing basis whether certified establishments meet such performance standards for beef carcasses (cow/bull, steer/heifer) and raw ground beef.
- Identify whether official government verification sampling for *Salmonella* in raw meat and poultry products is performed by government inspection personnel (i.e., government inspector, licensee, or contract employee) or by the establishment. If official government verification sampling is performed by the establishment, include a description of how and at what frequency the CCA verifies that samples are collected appropriately.
- Identify whether the microbiological methods of analysis used for official government samples of *Salmonella* conform to FSIS MLG methods or internationally recognized method standards (e.g., ISO methods). Additionally, identify any circumstances where culture confirmation is not performed on screen positive results from samples collected as part of official government microbiological sampling, and how the CCA will respond to a screen positive result if culture confirmation is not performed.

  NOTE: If the official method includes the use of a commercial detection kit, the commercial detection kit must have been validated by an external validating organization such as AOAC International, AFNOR, NordVal, Microval, or AENOR.
- Describe actions the CCA takes when performance standard criteria are not met.
- Describe how and at what frequency the CCA verifies that certified establishments take effective actions when performance standard criteria are not met, including whether the CCA conducts follow-up sampling.

29. How does the CCA ensure through sampling and other non-sampling verification activities that certified establishments control contamination from STEC in raw beef products intended for export to

the United States?

To respond to this question sufficiently, the CCA must:

- Identify whether the CCA considers STEC an adulterant in raw non-intact beef products (e.g., mechanically tenderized beef, raw ground beef products) or raw beef products intended for raw non-intact use (e.g., beef manufacturing trimmings and other raw ground beef components such as head meat, cheek meat, weasand meat, and heart meat).
- Describe how and at what frequency government inspection personnel verify that certified establishments producing raw beef products adequately address STEC in their HACCP plans, Sanitation SOPs, or prerequisite programs.
- Describe the CCA's official government verification sampling program for STEC[17] in raw beef manufacturing trimmings, raw ground beef products, and other raw ground beef components (head meat, cheek meat, weasand meat, or heart meat). Include a written sampling plan with instructions for sample collection and testing to address the following:
    - Frequency of sampling;
    - Points in the process where sampling will occur;
    - Sampling methodology;
        NOTE: For analyses of raw beef products using an N60 sampling method, confirm that the entire sample is analyzed, not just a portion of the N60 trim pieces equaling a specific weight (e.g., 325g or 375g).
    - Target pathogens for each analysis; and
    - Criteria used to evaluate the results.
- Identify whether official government verification sampling for STEC in raw beef manufacturing trimmings, raw ground beef products, and other raw ground beef components is performed by government inspection personnel (i.e., government inspector, licensee, or contract employee) or by the establishment. If official government verification sampling is performed by the establishment, include a description of how and at what frequency the CCA verifies that samples are collected appropriately.
- Identify whether the microbiological methods of analysis used for detection of STEC in official government samples conform to FSIS MLG methods or internationally recognized method standards. Additionally, identify any circumstances where culture confirmation is not performed on screen positive results from samples collected as part of official government microbiological sampling, and how the CCA will respond to a screen positive result if culture confirmation is not performed.
    NOTE: If the official method includes the use of a commercial detection kit, the commercial detection kit must have been validated by an external validating organization such as AOAC International, AFNOR, NordVal, Microval, or AENOR.
    - Describe which STEC characteristics are used to define adulterants (e.g., presence/absence of virulence genes (*stx*, *eae*), O-antigens).
- Describe how the CCA ensures that all certified beef slaughter establishments are included in the official government verification sampling for STEC in raw beef manufacturing trimmings.
- Describe how the CCA ensures that lots are defined to establish microbiological independence so that if there is a STEC positive sample result, all affected product intended for export to the United States can be identified.
- Indicate whether the CCA requires establishments to sample and test raw beef products for STEC. If so, describe how and what frequency government inspection personnel verify that establishments collect samples appropriately.
- Describe the actions the CCA takes when STEC positive results are found through official government or establishment microbiological verification sampling programs.

[17] FSIS currently defines STEC as an *E. coli* isolate with the presence of *stx* and *eae* genes and the presence of one of the following serogroups: O157, O26, O45, O103, O111, O121, or O145.

  - Identify whether the CCA verifies that establishments that implement their own STEC verification sampling programs define, investigate, and respond to recurring positives (i.e., periods of time in which slaughter establishments experience a high rate of STEC positive results in production lots of raw beef trimmings containing the same source materials [e.g., raw beef trimmings from a specific slaughter date]).
- Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions to prevent recurrence of STEC in response to positive samples from official government or establishment verification sampling programs. For example, verification activities can include: increased frequencies of inspector verification tasks (e.g., increased sanitary dressing verification); follow-up sampling; or routine sampling of every lot for the presence of STEC.
  - If the CCA requires follow-up sampling, provide the frequency and duration of the follow-up sampling, and identify whether the CCA or the establishment conducts the follow-up sampling. If the CCA requires the establishment to collect follow-up samples, describe how and at what frequency the CCA verifies that the establishment conducts sampling and that results are acceptable.
- Identify any additional STEC controls required and verified by the CCA in establishments producing raw beef products intended for export to the United States.

30. How does the CCA ensure through sampling and other non-sampling verification activities that RTE meat, poultry, or egg products are not contaminated with microbiological pathogens or their toxins, including *Lm* and *Salmonella?*

NOTE: RTE products are meat, poultry, or egg products that are edible without further preparation to achieve food safety.

NOTE: RTE products may include products produced under the following HACCP categories: Not Heat Treated-Shelf Stable; Heat Treated-Shelf Stable; Fully Cooked-Not Shelf Stable; Products with Secondary Inhibitors-Not Shelf Stable. For more information on how FSIS defines these HACCP process categories, refer to the FSIS Product Categorization (Import) guideline.

To respond to this question sufficiently, the CCA must:

- Identify whether the CCA considers RTE product containing *Lm*, *Salmonella*, or other pathogens (e.g., STEC in dry, semi-dry, or fermented RTE beef products); and RTE product that comes into direct contact with a food contact surface (FCS) contaminated with *Lm* or *Salmonella*, to be adulterated.
- Describe how the CCA enforces a zero tolerance approach to control *Lm*, *Salmonella,* and other pathogens in RTE product destined for export to the United States.

  NOTE: FSIS considers all RTE products to be adulterated if they contain pathogens of public health concern (depending on the type and level) or their toxins that can cause illness in humans. There are some pathogens where any level would make the product adulterated (e.g., *Lm*, *Salmonella*, and STEC) because it would be injurious to health. Other pathogens are only a public health concern when multiplication occurs at levels that could lead to toxin formation (e.g., *Staphylococcal* (*S.*) *aureus*, *Clostridium perfringens* (*C. perfringens)*, and *Clostridium botulinum* (*C. botulinum).*
- Identify whether the CCA maintains laws, regulations, or inspection procedures regarding application of high pressure processing (HPP) treatments to products intended for export to the United States. For reference, HPP is an antimicrobial treatment that is capable of either reducing or eliminating biological food safety hazards on meat, poultry, or egg products.

For meat and poultry products:

- Describe the CCA's government non-sampling verification activities for certified establishments producing RTE meat and poultry products intended for export to the United States, including the following:

  - Describe how and at what frequency government inspection personnel verify that certified establishments adopt *Listeria* control measures.
  - Describe how and at what frequency government inspection personnel verify that certified establishments producing RTE meat and poultry products implement control measures to prevent adulteration of RTE products, whether exposed to the post-lethality processing environment or not. Include how and at what frequency government inspection personnel verify that certified establishments identify and implement procedures in their HACCP plans, Sanitation SOPs, or other prerequisite programs to control pathogens of concern in RTE product.
  - Describe how and at what frequency government inspection personnel verify that certified establishments are meeting lethality and stabilization requirements for RTE products. Include whether the CCA maintains performance standard requirements for pathogens or their toxins in RTE meat and poultry products (e.g., at least a 6.5-log reduction in *Salmonella* in cooked beef products, at least a 7-log reduction in *Salmonella* in cooked poultry products, and no more than a 1-log multiplication of *C. perfringens* and no multiplication of *C. botulinum* in RTE meat and poultry products).
- Describe the CCA's official government sampling verification activities for *Lm* and *Salmonella* in RTE products intended for export to the United States. Include a written sampling plan with instructions for sample collection and testing to address the following:
  - Frequency of sampling;
  - Points in the process where sampling will occur;
  - Sampling methodology;
  - Target pathogens for each analysis; and
  - Criteria used to evaluate the results.
- Describe official government sampling verification procedures for *Lm* on food contact and non-food contact surfaces in certified establishments producing RTE meat and poultry products exposed to the post-lethality processing environment and intended for export to the United States. Include the frequency of sampling and the sampling methodology.
- Identify whether official government sampling for *Lm* and *Salmonella* in RTE products or the RTE production environment is performed by government inspection personnel (i.e., government inspector, licensee, or contract employee) or by the establishment. If official government verification sampling is performed by the establishment, include a description of how and at what frequency the CCA verifies that samples are collected appropriately.
- Describe how the CCA ensures that RTE meat and poultry products both exposed and not exposed (e.g., cook-in-bag) to the post-lethality processing environment are included in its official government sampling program.
- Describe how the CCA ensures that lots are defined to establish microbiological independence so that if there is a positive sample result for *Lm*, *Salmonella*, or other pathogens, all affected product intended for export to the United States can be identified.
- Identify whether the microbiological methods of analysis used for official government samples of *Lm* and *Salmonella* conform to FSIS MLG methods or internationally recognized method standards. Additionally, identify any circumstances where culture confirmation is not performed on screen positive results from samples collected as part of official government microbiological sampling, and how the CCA will respond to a screen positive result if culture confirmation is not performed.

  NOTE: If the official method includes the use of a commercial detection kit, the commercial detection kit must have been validated by an external validating organization such as AOAC International, AFNOR, NordVal, Microval, or AENOR.
- Describe the CCA's requirements for certified establishments to implement testing of food contact surfaces for *Lm* or *Listeria* species as an indicator for *Lm* based on risk. Include how and at what frequency government inspection personnel review and verify the establishment's sampling procedures, testing methods, and testing results.
- Describe the actions the CCA takes when insanitary conditions or *Lm*, *Salmonella*, or other pathogens of

public health concern are found through official government or establishment microbiological verification sampling programs.

- Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions when insanitary conditions or *Lm*, *Salmonella*, or other pathogens of public health concern are found through official government or establishment microbiological sampling programs. For example, verification activities can include: increased frequencies of inspector verification tasks (e.g., increased sanitation or HACCP verification); follow-up sampling; and routine sampling of every lot for the presence of *Lm* and *Salmonella*.
    - If the CCA requires follow-up sampling, provide the frequency and duration of the follow-up sampling, and identify whether the CCA or the establishment conducts the follow-up sampling. If the CCA requires the establishment to collect follow-up samples, describe how and at what frequency the CCA verifies that the establishment conducts sampling and that results are acceptable.

For egg products:

- Describe how the CCA ensures that establishments implement time and temperature parameters for cooling, and pasteurization or other heat treatments that are effective in eliminating microbiological hazards in egg products intended for export to the United States.
- Describe the official government microbiological sampling verification program for *Salmonella* and *Lm* in finished egg products (rather than source materials) in certified establishments. Include a written sampling plan with instructions for sample collection and testing to address the following:
    - Frequency of sampling;
    - Points in the process where sampling will occur;
    - Sampling methodology;
    - Target pathogens for each analysis; and
    - Criteria used to evaluate the results.
- Identify whether official government verification sampling for *Salmonella* and *Lm* in finished egg products is performed by government inspection personnel (i.e., government inspector, licensee, or contract employee) or by the establishment. If official government verification sampling is performed by the establishment, include a description of how and at what frequency the CCA verifies that samples are collected appropriately.
- Identify whether the microbiological methods of analysis used for official government samples of *Lm* and *Salmonella* conform to FSIS MLG methods or internationally recognized method standards. Additionally, identify any circumstances where culture confirmation is not performed on screen positive results from samples collected as part of official government microbiological verification sampling, and how the CCA will respond to a screen positive result if culture confirmation is not performed.

  NOTE: If the official method includes the use of a commercial detection kit, the commercial detection kit must have been validated by an external validating organization such as AOAC International, AFNOR, NordVal, Microval, or AENOR.
- Describe whether the CCA requires certified egg product establishments to develop and implement *Salmonella* sampling programs for pasteurized liquid, frozen, and dried egg products. Describe how and at what frequency the CCA verifies establishment sampling procedures and testing results.
- Describe how the CCA ensures that lotting procedures are defined to establish microbiological independence of production lots so that if there is a positive sample result, all affected product intended for export to the United States can be identified.
- Describe the actions the CCA takes when *Lm* or *Salmonella* positive test results are found through official government or establishment microbiological sampling programs.
- Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions to prevent recurrence of *Lm* or *Salmonella* in response to positive samples from official government and establishment testing.

31. **How does the CCA ensure that RTE shelf-stable meat and poultry products that do not rely on cooking alone to achieve lethality, such as fermented, acidified, salt-cured or dried meat and poultry products, achieve adequate lethality and shelf-stability to prevent contamination with microbiological pathogens or their toxins (e.g., *Salmonella, Lm* and STEC (in beef products), *C. perfringens, C. botulinum*, and *Staphylococcus aureus* (*S. aureus*))?**

    NOTE: This question applies to products produced under the Heat Treated-Shelf Stable or Not Heat Treated-Shelf-Stable HACCP categories. For more information on how FSIS defines these HACCP process categories, refer to the FSIS Product Categorization (Import) guideline.

    To respond to this question sufficiently, the CCA must:

    - Provide documentation that describes how the CCA defines the shelf stability of meat and poultry products intended for export to the United States.

        NOTE: FSIS defines shelf stability as the condition achieved when: 1) meat or poultry products can be stored under ambient temperature and humidity conditions; 2) the package integrity is maintained during storage, shipping, and display at retail and in the home; and 3) the product will not spoil or become unsafe throughout the manufacturer's specified shelf-life.
    - Provide all supporting documentation, including inspection procedures and frequencies, used by the CCA to verify the following:
        - At least a 5-log reduction in *Salmonella* and STEC (for products containing beef), and sufficient reductions in *Lm* during lethality;
        - The prevention of the growth of spore-forming bacteria (i.e., *C. perfringens* and *C. botulinum*) by maintaining critical operational parameters (low pH, relatively low water activity); and
        - The prevention of the growth of *S. aureus* during the processing and no growth of *S. aureus* during the storage of shelf stable product (pH, water activity, etc.).

32. **How does the CCA ensure that heat-treated NRTE meat and poultry products are properly stabilized to prevent outgrowth of microbiological pathogens or their toxins (e.g., *C. perfringens* and *C. botulinum*), and properly labeled to ensure adequate cooking by the consumer?**

    NOTE: NRTE products are meat and poultry products that may or may not have received an adequate lethality treatment for *Salmonella,* and may appear RTE (e.g., chicken kiev). Furthermore, products that receive a full lethality treatment may be classified as NRTE product if they are not defined by a standard of identity to be fully cooked (e.g., hotdogs or barbecue) **and** are not edible without further preparation to achieve food safety.

    NOTE: NRTE products may include products produced under the following HACCP categories: Not Heat Treated-Shelf Stable; Heat Treated-Shelf Stable; Heat Treated but not Fully Cooked-Not Shelf Stable; Products with Secondary Inhibitors-Not Shelf Stable. For more information on how FSIS defines these HACCP process categories, refer to the FSIS Product Categorization (Import) guideline.

    To respond to this question sufficiently, the CCA must:

    - Describe how and at what frequency the CCA verifies that certified establishments are properly stabilizing and preventing the growth of spore-forming bacteria (i.e., *C. perfringens* and *C. botulinum*) in NRTE product intended for export to the United States.

33. **How does the CCA ensure that the processing of thermally processed/commercially sterile (e.g., canned) meat and poultry products addresses *C. botulinum* and the finished products are commercially sterile?**

    NOTE: Address the types of processing systems your country uses to produce thermally processed/commercially sterile (TP/CS) meat or poultry products for export to the United States (e.g.,

batch steam still, batch steam agitating, continuous rotary, hydrostatic, batch still pressure processing in water, batch agitating pressure processing in water, pressure processing with steam/air mixture in batch retorts, atmospheric cookers, and other systems such as cascading water or aseptic systems).
NOTE: FSIS considers the implementation of requirements consistent with the FSIS canning regulations (see 9 CFR part 431) as providing an equivalent level of sanitary protection when producing TP/CS meat and poultry products for export to the United States.

To respond to this question sufficiently, the CCA must:

- Describe how and at what frequency the CCA ensures that certified establishments producing TP/CS products for export to the United States address *C. botulinum*, incipient spoilage (i.e., spoilage occurring before the thermal process is initiated), post-processing contamination, and non-pathogenic spores (e.g., thermophilic spoilage) that are a source of abnormal containers. Furthermore, include any strategies for reducing or eliminating these hazards.
- Describe how and at what frequency the CCA verifies adequate thermal processing and commercial sterility of containers for the following:
    - For low-acid products (i.e., a canned product in which any component has a pH value above 4.6), the process achieves a probability of 10^-9 that there are spores of *C. botulinum* in a container of the product that are capable of growing, or, a 12D reduction of *C. botulinum*, assuming an initial load of ≤ 1000 spores per container.
    - For acidified low-acid products (i.e., a canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process) or products in which pathogen growth is controlled by factors other than thermal or other sporicidal processing, the process prevents multiplication of *C. botulinum* in the food under the conditions in which the food is stored, distributed, and held.
    - All products are rendered free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50°F or 10°C) at which the product is intended to be held during distribution and storage (e.g., process schedules ensure at least a 5D reduction of *C. sporogenes*).
- Describe how and at what frequency the CCA verifies that establishments certified to export TP/CS meat and poultry products to the United States address the following:
    - Containers are airtight (hermetically sealed) and protect the contents of the container against the entry of microorganisms during and after processing;
    - Containers are cleaned and examined prior to filling;
    - Containers, closures and flexible pouch roll stock are stored and handled in a sanitary manner to prevent damage to the hermetic condition of the sealed containers;
    - Container closures (e.g., can, glass jars, semi-rigid and flexible containers) are examined (e.g., visual, teardown, or physical examination) by trained closure technicians at a frequency sufficient to ensure proper closure;
    - Finished products are stored and handled in a manner to prevent damage to the hermetic condition of the sealed containers;
    - Process schedules are developed by a processing authority prior to the processing of canned product for export to the United States;
    - Critical factors specified in the process schedule are measured, controlled, and recorded (e.g., initial temperature, retort processing time and temperature);
    - Operations in thermal processing areas include the posting of process schedules; development of a retort traffic control system to prevent product from bypassing the retort, such as placement of heat sensitive indicators to indicate adequate thermal processing; determination and recording of initial temperature at the start of the processing cycle; accuracy of timing devices (e.g., analog and digital clocks); and measurement of pH with a pH meter;
    - Equipment and procedures for heat processing systems include:
        - Instruments and controls common to different thermal processing systems (e.g., indicating temperature devices, temperature/time recording devices, steam controllers, air

valves, and water valves);
        - Engineering design standards for each retort used (e.g., batch steam still, batch steam agitating, continuous rotary, hydrostatic, batch still pressure processing in water, batch agitating pressure processing in water, pressure processing with steam/air mixture in batch retorts, atmospheric cookers, and other systems such as cascading water or aseptic systems);
        - Examinations of all instrumentation and controls upon installation, on an annual basis, and following an extended shutdown to ensure the design of all equipment, instrumentation, and controls is sound, and that equipment maintenance is up-to-date;
        - The recording and retention of maintenance records;
        - Requirements for container cooling and cooling water, both single pass and recycled or reused cooling water (e.g., potable, chlorinated, cooling canals cleaned at an adequate frequency to prevent insanitary conditions); and
        - Handling processed containers in a manner that will prevent damage to the hermetic seal area.
    - Processing and production records include, at a minimum, the date of production; product name and style; container code; container size and type; the process schedule, including the minimum initial temperature; measurement of critical factors, and record requirements specific to each retort type;
    - Maintenance of records, including but not limited to, thermal process records, critical factor control records, closure evaluation records, and records associated with the development of the process schedule (e.g., venting schedules, heat distribution data, heat penetration data);
    - Records review and maintenance includes reviewing processing records and container closure records; maintaining records identifying initial distribution of the product; and retaining processing and production records;
    - Processing deviations identified in-process or through record review are handled according to the establishment's HACCP plan, or alternative documented procedures to ensure that TP/CS product being exported to the United States is safe for human consumption and shelf-stable;
    - Finished product inspection procedures are developed and implemented to ensure that only normal appearing containers are exported to the United States; and
    - Direct supervisors of thermal processing operators and closure technicians possess knowledge and training specific to canning operations.
- Describe the actions taken by the CCA in response to processing deviations (i.e., deviation identified in process or through records review) and the identification of abnormal containers, including how the CCA controls TP/CS products identified to be abnormal, under-processed, or contaminated post-processing. In addition, describe how the CCA verifies corrective actions.

34. Has the CCA reviewed the SRT responses and supporting documentation for accuracy and completeness, including all English translated documents, as part of its annual submission by May 18th of each year?

NOTE: To maintain current eligibilities, FSIS requires countries with ongoing equivalence to provide updates to their previous SRT responses to include all applicable information and any updates, changes, or revisions of the foreign country's food regulatory system, such as revised laws, regulations, or inspection procedures. FSIS requires this update annually, or as changes are made to your regulatory system to verify that your foreign country's food regulatory system continues to be robust, transparent, and science-based (80 FR 9428). If there were changes to laws, regulations, or inspection procedures since your previous SRT submission, please provide the updated SRT responses and supporting documentation as part of your annual submission.

NOTE: In the SRT response to this question, verify whether your country's current SRT responses and supporting documentation are accurate and up-to-date, including whether documents were correctly translated into English, where applicable.

NOTE: All translated documents will be uploaded for review in the document section of PHIS with the

word TRANSLATED in all capital letters at the beginning of the title**.** Countries unable to access PHIS can contact FSIS' OIC through email at internationalcoordination@usda.gov to obtain access to the system.

35. **For countries requesting initial, reinstatement, or expansion of equivalence, identify the HACCP process category, product category, product group, and species of the products that your country intends to export to the United States.**

    NOTE: For more information, refer to the FSIS Product Categorization (Import) guideline.