

## Self-Reporting Tool (SRT; v2019-001)

FSIS's last revision to the SRT in 2016 (i.e., 2016 SRT v. 2015.005) significantly decreased the number of SRT questions and clarified the regulatory-focused food safety objectives used by FSIS to evaluate the equivalence of foreign food safety inspection systems. Since releasing the 2016 SRT and through review of SRT submissions and corresponding with Central Competent Authorities (CCAs), FSIS identified additional opportunities to further improve the 2016 SRT. Thus, FSIS developed the 2019 SRT that provides further clarification and guidance on how to respond to individual SRT questions

The 2019 SRT provides bulleted guidance under each SRT question to aid CCAs in providing complete SRT responses that adequately demonstrate that the country's documented food safety inspection system achieves a level of public health protection equivalent to the U.S. inspection system. The bulleted information is not intended to be prescriptive in nature but rather guidance to foreign countries on the type of information CCAs should include in their responses to each individual SRT question.

Additional improvements made to the 2019 SRT include the following:

- A chart that clearly illustrates which SRT questions countries need to answer based on the products the country is currently eligible to export or intends to export to the U.S.;
- A description of the information countries will receive annually from FSIS (i.e., issues identified during FSIS's review of the SRT and official government microbiological and chemical residue sampling and testing programs);
- Links to guidance documents on the [FSIS Equivalence](#) webpage;
- Slight revisions to component names for clarity;
- The incorporation of Siluriformes fish SRT questions; and
- The addition of SRT questions specific to labeling verification (2019 SRT question #15); ready-to-eat (RTE) fermented, salt-cured, or acidified products (2019 SRT question #31); and heat-treated, not-ready-to-eat products (2019 SRT question #32).

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### Self-Reporting Tool

Equivalence with the level of public health protection achieved by the food safety inspection system of the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) is the prerequisite for the export of meat, poultry and egg products to the United States (U.S.). The Codex standard [\*Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems\*](#) (GL53-2003) 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 and egg products to the U.S. must provide objective data that the country’s decrees, regulations, requirements, and procedures have the same effect as the FSIS inspection system, including humane handling and accurate labeling. If the exporting country does not have this objective data, FSIS would consider implementation of U.S. sanitary measures as a reasonable alternative to assure the eligibility of products for export to the U.S.

To determine whether a country’s documented food safety inspection system achieves an appropriate level of public health protection, FSIS assesses the self-reporting tool (SRT) answers 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 (i.e., the Central Competent Authority (CCA)). The 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 U.S. system. The SRT is designed for countries that want to export the following products to the U.S.: meat (including beef, veal, pork, sheep including lamb and mutton, goat, and Siluriformes fish), poultry (including chickens, turkeys, ducks, geese, guineas, ratites, or squabs), or egg products (i.e., dried, frozen, or liquid eggs, with or without added ingredients). The 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 answers 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 U.S. Complete answers include a narrative, accompanied by supporting documentation, describing how the country’s food safety inspection system is implemented. In addition, SRT answers need to cite where in the supporting documentation the information can be found. For example, answers should include the page number, section number, or chapter from the relevant supporting documentation. Types of supporting documentation the CCA should provide include, but are not limited to, the following:

- a. Food safety and inspection laws and legislation
- b. Regulations, policies, standards, decisions, annexes, and decrees
- c. Inspection procedures, manuals, and directives

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- d. Control programs
- e. Inspection training programs
- f. Mechanisms for documenting compliance/noncompliance
- g. Enforcement and compliance programs
- h. Government chemical residue and microbiological sampling and testing programs, and test results.

The following chart identifies which SRT questions the CCA needs to provide answers and supporting documentation for based on the specific products the country is eligible to export or interested in exporting to the U.S. To view which products your country is currently eligible to export to the U.S., refer to [FSIS Import Library- Eligible Countries and Products](#). For more information on product categorization, refer to the [FSIS Product Categorization Guide](#).

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

### Submission of the SRT

To submit the SRT and supporting documentation, the CCA can either upload the information into FSIS's web-based Public Health Information System (PHIS), or submit a Microsoft Word version of the SRT including supporting documentation to the FSIS Office of International Coordination through e-mail at [internationalcoordination@fsis.usda.gov](mailto:internationalcoordination@fsis.usda.gov) or regular mail (1400 Independence Avenue SW, Room 3143-South Building, Washington, DC 20250).

FSIS uploads and maintains all SRT answers and supporting 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 the SRT answers and supporting documentation in PHIS when making equivalence determinations.

If issues are identified during FSIS's review of the country's submitted SRT answers and supporting documentation, FSIS will send the CCA requests for information and may propose a technical call (e.g., teleconference call) between FSIS and the CCA.

### On-going Equivalence Verification

No later than May 18<sup>th</sup> of each year, the CCAs of countries wishing to maintain on-going equivalence and continue exporting meat, poultry, or egg products to the U.S. must either provide updated SRT

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answers, or communicate to FSIS that the SRT answers in PHIS are accurate and complete by providing an answer to SRT question 34. Also, no later than May 18<sup>th</sup> of each year, the CCA should verify in PHIS whether the translated documents were translated correctly into English by providing an answer in SRT question 34. Updates to the SRT are expected whenever the CCA makes changes to its food safety inspection system, including changes implemented because of new or revised FSIS policies, or in response to FSIS requests for information.

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

1. An up-to-date list of all certified establishments eligible to export to the U.S.
  - For more information on how to complete and submit an up-to-date list of all establishments used in the production of products eligible to export to the U.S., refer to [FSIS Guidance for a Suggested Reporting Table for the Certified Establishment List](#).
2. An updated official government chemical residue sampling and testing program, including the previous year's chemical residue test results and a description of your country's responses to violative findings.
  - For more information on how to submit annual Government Chemical Residue Control Program Plans and Residue Control Program Results, refer to [FSIS Guidance for Suggested Reporting Tables of the Government Chemical Residue Control Program](#).
  - For an example of the information FSIS needs to evaluate foreign official National Residue Programs, refer to [Summary of FSIS Government Residue Control Program Frequencies](#).
3. An updated official government microbiological sampling and testing program, including the previous year's test results and a description of your country's responses to positive results for the following: **(A)** *Salmonella* and *Campylobacter* in raw meat and poultry products; **(B)** *Listeria monocytogenes* (*Lm*), *Salmonella*, or other pathogens of public health concern in ready-to-eat (RTE) meat and poultry products, and pasteurized (including heat treated) egg products; and **(C)** Shiga toxin-producing *Escherichia coli* (STEC) in raw beef products.

**NOTE:** The CCA should provide indicator organism results for intestinal or fecal contamination if the official government sampling and testing program includes monitoring for indicator organisms.

  - For more information on how to submit annual official government microbiological sampling and testing program plans and microbiological sampling and testing program results, refer to [FSIS Guidance for Suggested Reporting Tables of the Government Microbiological Sampling and Testing Program](#).
  - For an example of the information FSIS needs to evaluate foreign official microbiological sampling and testing programs, refer [Summary of FSIS Government Microbiological Sampling Programs Frequencies](#).

Annually, FSIS will notify the CCAs of countries wishing to maintain on-going equivalence and continue exporting meat, poultry, or egg products to the U.S. of the following: issues identified during our review of the SRT and official government microbiological and chemical residue sampling and testing programs; a summary of the past year's point-of-entry (POE) results; and any new FSIS policies that CCAs need to address, or information that CCAs need to include, as part of their annual update by May 18<sup>th</sup> of the following year. Additionally, at this time, FSIS will also inform CCAs which categories of meat, poultry, or egg products their country is eligible to export to the U.S.

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### Component 1 Government Oversight

1. **How does the CCA ensure that the laws and regulations governing meat (including beef, veal, pork, sheep, goat, and Siluriformes fish), poultry (including chickens, turkeys, ducks, geese, guineas, ratites, or squabs), and egg products inspection are enforced?**

To sufficiently respond to this question, the CCA must:

- Describe the legal framework that gives the CCA the authority and ability to administer the inspection system. Include the name of the CCA and 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 inspection.
  - Describe the CCA's authority and responsibility to enforce the laws and regulations governing meat, poultry, and egg products inspection. In addition, describe the CCA's authority to require corrective actions in certified establishments and to take additional enforcement measures as appropriate. Include supporting documentation demonstrating that the CCA has an effective enforcement program that requires that certified establishments perform the following: take action to prevent product contamination, take corrective actions when insanitary conditions or contaminated products are found, and take effective preventive measures after instances of noncompliance.
  - 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).
2. **How does the CCA ensure that no meat, poultry, or egg products intended for export to the U.S. are adulterated or misbranded (i.e., properly labeled and packaged), and only eligible meat, poultry, and egg products are certified for export to the U.S.?**

To sufficiently respond to this question, 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 U.S. Define adulterated and misbranded as it relates to meat, poultry, and egg products (i.e., statutory or regulatory definition). Describe how the CCA identifies misbranded or adulterated products and provide information on the enforcement activities the CCA takes when it identifies adulterated or misbranded product.
- Describe the CCA's authority and inspection procedures for certifying meat, poultry, or egg products for export to the U.S., including evidence of a certificate procedure to meet U.S. import requirements. Furthermore, identify who (e.g., government inspector, limited government inspector, contracted employee) is performing export certification procedures for product intended for export to the U.S. 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 both routine government verification activities and export certification, that adulterated or misbranded product is not being exported to the U.S. 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 that is tested for STEC; RTE products tested for *Lm*, *Salmonella*, or STEC (relative to RTE beef products); RTE product that passed over food contact surfaces that have been tested for the presence of *Lm* and *Salmonella*; and livestock carcasses and parts subjected to both routine and suspect chemical residue testing for veterinary drugs, pesticides, and environmental contaminants.
- Describe the CCA's authority to recall adulterated or misbranded product. Identify whether recalls of

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adulterated or misbranded product are carried out by the CCA or the establishment, and identify whether the CCA maintains the authority and ability to take action if the recall is ineffective (e.g., product seizure). Describe whether recalls are carried out on adulterated or misbranded product in the distribution phase or in commerce. 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 U.S., 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 U.S. has determined have an equivalent meat, poultry, or egg products inspection system (i.e., eligible countries)?**

**NOTE:** A certified establishment is an establishment that the CCA determines as meeting U.S. requirements and, therefore, eligible to export meat, poultry, or egg products to the U.S.

**NOTE:** A de-certified establishment is an establishment that the CCA determines as not meeting U.S. requirements and, therefore, not eligible to export meat, poultry, or egg products to the U.S.

**NOTE:** Source is defined as materials that originate from a certified establishment in an eligible country.

To sufficiently respond to this question, the CCA must:

- Describe how and at what frequency government inspection personnel verify source materials originate from an establishment eligible to ship to the U.S. and located in a country eligible to ship meat, poultry, or egg products to the U.S.
  - Identify the source for shell eggs used to produce egg products for export to the U.S.
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 U.S.?**

**NOTE:** By May 18<sup>th</sup> of each year, the CCAs of countries wishing to maintain on-going equivalence and continue actively exporting meat, poultry, or egg products to the U.S. are required to provide FSIS an up-to-date list of all certified establishments used to produce or export products to the U.S. Therefore, if the production chain involves more than one establishment (e.g., beef is slaughtered at one establishment, further processed at a different establishment, packaged and labeled at yet another establishment, and then exported to the U.S. from a different establishment), each establishment in the production chain, including the storage facility from where the product is exported, must be listed on the certified establishment list. Furthermore, countries that are not eligible to export raw product directly to the U.S. (e.g., due to animal disease restrictions), but are eligible to use their own raw source materials for further processing are required to certify and list the establishments providing the raw source materials.

**NOTE:** FSIS requests that the CCA inform FSIS of any establishment delistment within 90 days.

- For more information on how to complete and submit an up-to-date list of all establishments used in the production of products eligible for export to the U.S., refer to [FSIS Guidance for a Suggested Reporting Table for the Certified Establishment List](#).

To sufficiently respond to this question, the CCA must:

- Describe how the CCA ensures that all certified establishments are held to the same laws, regulations, and policies.
- Identify the level of government directly responsible for ensuring that U.S. requirements are implemented at all certified establishments when producing product for export to the U.S., including how and at what frequency the CCA verifies that establishments meet U.S. requirements.
- Describe the processes that the CCA follows to certify establishments as meeting U.S. requirements, and to de-certify establishments that no longer meet U.S. requirements.

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- Describe how and at what frequency the CCA disseminates information regarding U.S. requirements from headquarters to government inspection personnel and certified establishments, including how the CCA communicates any changes to U.S. requirements in a timely manner. Further, describe how the CCA remains aware of FSIS requirements as they change over time.
- Identify whether U.S. requirements are translated into the country's official language.

5. **How does the CCA ensure that government inspection personnel assigned to certified establishments exporting meat, poultry, or egg products to the U.S. 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. When responding to this SRT question, use the terms and definitions below to identify the type of government inspection personnel used in your country's certified establishments when producing product for export to the U.S.

- 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 each and every livestock carcass, head, and viscera and poultry carcass and viscera<sup>1</sup>;
  - sanitation and HACCP verification activities in all meat and poultry establishments;
  - continuous inspection of egg products;
  - export verification activities; and
  - official government verification sample collection activities in meat, poultry, and egg product establishments.

**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 each and every livestock carcass, head, and viscera and poultry carcass and viscera;
  - sanitation and HACCP verification activities in all meat and poultry establishments;
  - continuous inspection of egg products;
  - export verification activities; and
  - official government verification sample collection activities in meat, poultry, and egg product establishments.

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 U.S. 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

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<sup>1</sup> Under modernized poultry inspection systems, similar to FSIS's New Poultry Inspection System (NPIS), the government inspector's visual inspection of each carcass also serves as the inspection of the viscera if the inspector's condemnation of a carcass also requires condemnation of the corresponding viscera. For countries that implement a modernized poultry inspection system, provide a response that describes the requirements and procedures of your modernized poultry inspection system under question 12.

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government inspector performs inspection activities (other than official government verification sample collection activities) without direct supervision from an on-site 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 each and every livestock carcass, head, and viscera and poultry carcass and viscera;
  - sanitation and HACCP verification activities in all meat and poultry establishments;
  - continuous inspection of egg products;
  - export verification activities; and
  - official government verification sample collection activities in meat, poultry, and egg product establishments.

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 U.S. continuously during slaughter operations and at least once per shift during processing 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 on-site government inspector continuously during slaughter operations and at least once per shift during processing operations.

To sufficiently respond to this question, the CCA must:

- Identify which inspection criterion or criteria above applies to the government inspection provided for meat, poultry, or egg products intended for export to the U.S.
    - For countries utilizing limited government inspectors or contracted 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 (i.e., government inspector is on premises during inspection activities continuously during slaughter operations and at least once per shift during processing operations) when producing product for export to the U.S.
  - Describe how all government inspection personnel or licensees are paid by the government. This may include direct or indirect payment by the government, such as payment through a third party.
  - Describe the conflict of interest controls in place to ensure that inspectors (government inspector, limited government inspector, or private contractor) 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 or poultry intended for export to the U.S.?**

**NOTE:** Processing operations include all non-slaughter activities, including but not limited to, boning, cutting, slicing, grinding, injecting, pumping, filleting, breaching, adding ingredients through other mechanical means, formulating, assembling, packaging, and labeling meat or poultry food products.

**NOTE:** In slaughter operations, FSIS requires continuous government inspection during slaughter activities to ensure that each and every livestock carcass, head, and viscera and each and every poultry carcass and viscera<sup>2</sup> are inspected.

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<sup>2</sup> See footnote 1

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**NOTE:** In processing operations (i.e., non-slaughter), FSIS typically requires that a government inspector 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 U.S., typically a government inspector must be present at least once during each production shift.

To sufficiently respond to this question, the CCA must:

- Describe how the CCA ensures that there will be enough qualified government inspectors to 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 and poultry products for export to the U.S., including during planned or unplanned government inspector absences.
7. **How does the CCA ensure that government inspection personnel have appropriate educational credentials, disciplinary backgrounds, and training to carry out their inspection tasks?**

To sufficiently respond to this question, the CCA must:

- Describe the minimum qualifications for government inspection personnel (e.g., educational credentials, training, and experience requirements), including whether official veterinarians in certified establishments are required to possess a Doctor of Veterinary Medicine or equivalent degree.
  - Describe how and at what frequency government inspection personnel are trained on U.S. import requirements, including how government inspectors in certified establishments are kept up to date on current FSIS requirements and policies.
  - Include a description of how government inspection personnel are evaluated on their knowledge of U.S. import requirements, including frequency of evaluations. Include documentation describing whether the training on U.S. import requirements includes animal welfare, ante-mortem inspection, post-mortem inspection, Sanitation Standard Operating Procedures (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 from non-certified establishments, control over condemned materials, official government sample collection practices, and enforcement of U.S. import requirements.
8. **How does the CCA ensure continuous government inspection during the processing of egg products designated for export to the U.S.?**

**NOTE:** Operations, or the processing of egg products, is defined in U.S. regulations as 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. In particular situations, continuous inspection is not required. The situations where continuous inspection is not required are the stabilization processing step and the heat treatment of dried egg whites. In these situations, the government inspector is required to be present at the beginning and end of these processing steps.

To sufficiently respond to this question, the CCA must:

- Describe how the CCA ensures that government inspection personnel are on the premises during operations, and conduct inspection activities (e.g., sanitation verification, review of monitoring records, and verification of time/temperature at critical points in the operation) during the processing of egg products intended for export to the U.S.
- Identify who (e.g., government inspector, limited government inspector, contracted employee) is providing

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continuous government inspection during the processing of egg products intended for export to the U.S.

9. **How does the CCA ensure adequate oversight of laboratories that perform analyses for official government sampling and testing programs for meat, poultry, or egg products that are exported to the U.S., including oversight to ensure that laboratories conducting official government analyses comply with the general quality assurance and control criteria provided in International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025?**

**NOTE:** The CCA must provide information for laboratories that perform analyses for the official government chemical residue and the official government microbiological sampling and testing programs.

To sufficiently respond to this question, the CCA must:

- Describe how the CCA ensures that every certified establishment that exports to the U.S. is included in official government chemical residue and microbiological sampling and testing programs.
- 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 destined for the U.S.
- Provide documentation demonstrating that laboratories are ISO 17025 accredited. If the laboratory is not ISO-accredited, please describe how laboratory management and technical requirements comply with ISO 17025.
- Identify whether laboratories conducting official government analyses are official government laboratories or third-party laboratories (e.g., international (foreign), private, or establishment laboratories). 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 17025.
- Provide documentation demonstrating that laboratory personnel are properly trained and proficient in the chemical residue and microbiological analyses performed (ISO 17025, Section 5.2).
- Describe how suitable facilities and equipment are verified, calibrated, and maintained in a manner consistent with international norms (e.g., EA04/10 or ALACC).
- Provide documentation describing the following procedures:
  - 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 17025, Section 5.4);
  - Internal quality control parameters, including positive and negative assay controls where appropriate, to assure the quality of the results for the analyses performed (ISO 17025, Section 5.9); 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 17025, Section 4.13).
- Provide scope of accreditation for methods, if applicable.
- 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 re-sampled or re-tested. Additionally, identify any circumstances where culture confirmation is not performed on screen positive results from samples collected as part of official government microbiological sampling.

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

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

To sufficiently respond to this question, the CCA must:

- Identify and describe the CCA’s laws and regulations requiring humane handling and humane slaughter of livestock and good commercial practices in poultry.
- 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 scald.

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

To sufficiently respond to this question, the CCA must:

- Identify and describe the CCA’s laws and regulations for ante-mortem inspection of livestock and poultry.
- Identify who (e.g., government veterinarian, government inspector, limited government inspector, contracted employee) is performing ante-mortem inspection of livestock and poultry in certified establishments, and how and at what frequency government inspection personnel verify ante-mortem requirements are met. Identify whether a government veterinarian oversees ante-mortem verification activities.
- Describe the ante-mortem disease conditions for livestock and poultry and identify which disease conditions are condemnable. Include how and at what frequency government inspection personnel verify the proper disposition of livestock and poultry identified with these conditions.
- Describe how and at what frequency government inspection personnel verify that dead, dying, diseased, or disabled animals are condemned and not used to manufacture meat and poultry products eligible for export to the U.S.

### 12. How does the CCA ensure that government inspection personnel perform post-mortem inspection of each and every livestock carcass, head, and viscera and each 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 inspectors working on the production line and performing post-mortem inspection procedures on each and every livestock carcass, head, and viscera and each and every poultry carcass and viscera<sup>3</sup>. The term “off-line” refers to government inspectors performing verification activities throughout the establishment (e.g., HACCP, sanitation, zero tolerance). Off-line government inspectors do not remain on the production line performing inspection activities throughout the day. Off-line government inspectors are also referenced in SRT question #22.

To sufficiently respond to this question, the CCA must:

- Identify and describe the CCA’s laws and regulations for post-mortem inspection of each and every livestock carcass, head, and viscera and each and every poultry carcass and viscera<sup>4</sup> at the time of slaughter. Furthermore, identify who (e.g., government inspector, limited government inspector, contracted 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 each

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<sup>3</sup> See footnote 1

<sup>4</sup> See footnote 1

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and every livestock carcass, head, and viscera and the point in the slaughter process where inspection personnel examine each carcass, head, and viscera. Include how on-line government inspection personnel perform post-mortem inspection activities to ensure that each and 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 (fecal, ingesta, or milk) on livestock carcasses, heads, or viscera.

- For poultry, describe how on-line government inspection personnel perform post-mortem inspection of each and every poultry carcass and viscera<sup>5</sup>. 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 contamination on poultry carcasses.
- For poultry, identify whether the CCA utilizes a modernized poultry slaughter inspection system (similar to FSIS's New Poultry Inspection System (NPIS)). If using a modernized poultry slaughter inspection system, describe how and at what frequency government inspection personnel verify that certified establishments conduct carcass and viscera sorting activities, dispose of carcasses and parts with condemnable conditions, and perform appropriate trimming and reprocessing tasks before carcasses are presented for government inspection.
- Describe the post-mortem disease conditions for livestock and poultry, and identify which disease conditions are condemnable. 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 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 inspection personnel?**

To sufficiently respond to this question, the CCA must:

- Describe how and at what frequency the CCA evaluates the performance of government inspection personnel in certified establishments, including who (level of government) conducts the performance reviews of government inspection personnel.
- Identify the inspection topics evaluated during these supervisory review visits. These visits should include reviews of the government inspectors' verification of the following: animal welfare, ante-mortem, post-mortem, Sanitation SOP and SPS, HACCP, labeling verification, export certification, import inspection to ensure source materials originate from certified establishments in eligible countries, separation from non-certified establishments, control over condemned materials, official government sample collection practices, and enforcement of U.S. import requirements. Supervisory reviews should also verify the frequency of government inspection in slaughter and processing operations.

### 14. **How does the CCA ensure complete separation of certified meat, poultry, or eggs products from non-certified meat, poultry, or egg products?**

**NOTE:** Any meat, poultry, or egg products intended to be exported to the U.S. cannot be produced in an establishment (or part of an establishment) that is not eligible to export to the U.S.

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

To sufficiently respond to this question, the CCA must:

- Describe how the CCA ensures that meat, poultry, or egg products intended for export to the U.S. are produced separately (by time or space) from products not intended for export to the U.S.

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<sup>5</sup> See footnote 1

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- Describe how and at what frequency government inspection personnel verify the separation of eligible meat, poultry, and egg products from ineligible products.

### 15. How does the CCA ensure that meat, poultry, and egg products intended for export to the U.S. meet U.S. labeling requirements?

**NOTE:** Labels can be submitted for FSIS approval electronically through [FSIS's Label Submission and Approval System](#) (LSAS), or 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 Compliance Guidance for Label Approval](#) and [Check List for Mandatory Features on a Label](#).

To sufficiently respond to this question, 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 accurate net weights and product formulation).
- Describe how and at what frequency government inspection personnel perform species verification activities, including species verification testing.

### 16. How does the CCA ensure that meat and poultry products designated for export to the U.S. are not restricted by the USDA Animal and Plant Health Inspection Service (APHIS)?

To sufficiently respond to this question, the CCA must:

- Identify and describe any APHIS disease restrictions for products that the country is currently exporting to the U.S. or intends to export to the U.S.
- 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.
- Describe how and at what frequency government inspection personnel verify that APHIS-restricted products are not shipped to the U.S.

### 17. How does the CCA ensure that all beef products are free of infectious materials associated with bovine spongiform encephalopathy (BSE), and all small ruminants (i.e., sheep and goats) are free of infectious materials associated with transmissible spongiform encephalopathy (TSE)?

To sufficiently respond to this question, the CCA must:

- Describe how the CCA defines specified risk materials (SRMs), and identify the 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, and 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.,

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charcoal or dye) to ensure that the products cannot be used for human food.

To sufficiently respond to this question, the CCA must:

- Identify and describe the CCA’s laws and regulations for identifying, handling, and controlling inedible material to ensure that it is not used to manufacture meat, poultry, or egg products destined for export to the U.S.
  - 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 an egg products food safety inspection system that prevents food safety hazards that can arise before, during, and after the intake of shell eggs for processing; and that only shell eggs determined to be fit for human food are used to produce processed egg products designated for export to the U.S.?**

**NOTE:** If the CCA requires egg product establishments to develop, implement and maintain a HACCP system, the CCA needs to answer question 25 also.

To sufficiently respond to this question, the CCA must:

- Describe how the CCA ensures that certified egg product establishments control hazards during egg product processing, including how and at what frequency government inspection personnel verify that hazards are controlled during the processing of egg products for export to the U.S.
- Identify the operating requirements and parameters for all egg product processing steps. Examples of egg product processing steps include, but are not limited to, candling and transfer-room, breaking room, freezing, defrosting, drying (i.e., spray process drying or albumen flake process drying), blending, packaging, heat treatment of dried egg whites, liquid egg cooling and holding, and pasteurization or heat-treatment of egg product to render it free of viable organisms including *Salmonella*.
- Define the minimum parameters (e.g., time and temperature requirements) for cooling, pasteurization, or other heat treatments to reduce and control food safety hazards for egg products intended for export to the U.S.
- Describe how the CCA evaluates and approves egg processing facilities and equipment, and any alternative thermal/heat handling processing criteria or processes.
- Describe the CCA’s requirements for evaluating shell eggs to determine if they are eligible for breaking (e.g., examining received shell eggs; washing, sanitizing, and drying shell eggs prior to breaking; and candling shell eggs), and identify which shell eggs are eligible for breaking for use in the production of egg products intended for export to the U.S.
- Describe how and at what frequency government inspection personnel verify that only eligible shell eggs are broken for use in the production of egg products intended for export to the U.S.

### **Component 3 Government Sanitation Verification**

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

To sufficiently respond to this question, the CCA must:

- Describe how and at what frequency the CCA verifies that Siluriformes fish intended for export to the U.S. 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., pre-harvest standards).
- Identify whether the CCA collects either routine or “for cause” official government samples of feed,

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Siluriformes fish, or source water to verify that Siluriformes fish are being raised under sanitary conditions. 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 U.S.

- 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 Siluriformes fish that have died from circumstances other than under the controlled circumstances of commercial fishing are separated from eligible Siluriformes fish and fish products?**

To sufficiently respond to this question, 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 sufficiently respond to this question, 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 matter, ingesta, and milk; and poultry carcasses by enteric pathogens and fecal matter.  
**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, heads, or viscera; or fecal material on poultry carcasses or viscera.

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### 23. How does the CCA ensure that the condition of certified establishments' construction, facilities, and equipment is adequate to prevent the contamination or adulteration of meat, poultry, or egg products designated for export to the U.S.?

To sufficiently respond to this question, the CCA must:

- Describe the CCA's requirements for certified establishments' construction, facilities, and equipment, including how and at what frequency government inspection personnel verify that conditions 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 enforcement actions the CCA takes when certified establishments do not comply with the requirements.
- Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions and preventive measures 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, and egg products designated for export to the U.S.?

To sufficiently respond to this question, the CCA must:

- Describe the CCA's requirements for daily sanitation procedures sufficient to prevent direct contamination or adulteration of product, including how and at what frequency government inspection personnel verify that certified establishments develop, implement, and maintain daily pre-operational and operational sanitation procedures.
- Identify who (e.g., government inspector, limited government inspector, contracted employee) is performing sanitation verification activities in certified establishments.
- Describe the CCA's sanitation recordkeeping requirements, 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.
- Describe the enforcement 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 and preventive measures 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 or poultry products for export to the U.S.?

**NOTE:** For countries that require HACCP for producing egg products, discuss food safety controls under this question.

**NOTE:** For countries using HACCP to address microbiological food safety hazards when producing thermally processed/commercially sterile (TP/CS) meat and poultry products, discuss food safety controls under this question.

To sufficiently respond to this question, the CCA must:

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- 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, prevent, and control hazards.
  - 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), for example, requiring certified establishments to incorporate into their HACCP plan a post-lethality treatment used to reduce or eliminate *Lm*.
- 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, monitor the performance of controls, and maintain records routinely. 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 perform initial validation to verify the adequacy of their HACCP systems in controlling the food safety hazards identified in the hazard analysis, including whether the CCA requires and verifies that certified establishments maintain both components of initial validation: in-plant implementation data, and scientific or technical support.
- Describe how the CCA requires and verifies that certified establishments perform ongoing verification activities (e.g., 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 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. 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 who (e.g., government inspector, limited government inspector, contracted 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 for export to the U.S. 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., preshipment review).
- 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 that is tested for STEC; RTE products tested for *Lm*, *Salmonella*, or STEC (relative to RTE beef products); RTE product that passed over food contact surfaces that have been tested for the presence of *Lm* and *Salmonella*; and livestock carcasses and parts subjected to both routine and suspect chemical residue testing for veterinary drugs, pesticides, and environmental contaminants.
- Describe how and at what frequency government inspection personnel perform HACCP verification activities

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in certified establishments (e.g., monitoring, verification, recordkeeping, corrective actions). Include the regulatory and enforcement actions government inspection personnel take 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 Control Program that prevents and controls all specific compounds of concern in the foreign country and in the U.S.?**

**NOTE:** The CCAs of countries wishing to maintain on-going equivalence and continue actively exporting meat or poultry products to the U.S. must submit an updated official government chemical residue sampling and testing program, the previous year's residue test results, and the actions taken in response to violative findings by May 18<sup>th</sup> of each year.

- For more information on how to submit annual Government Chemical Residue Control Program Plans and Residue Control Program Results, refer to [FSIS Guidance for Suggested Reporting Tables of the Government Chemical Residue Control Program](#).
- For an example of the information FSIS needs to evaluate foreign official National Residue Programs, refer to [Summary of FSIS Government Residue Control Program Frequencies](#).

To sufficiently respond to this question, the CCA must:

Describe how your country's official government chemical residue control program ensures that all chemical residues that are considered adulterants by the U.S. are not present in products that are exported to the U.S. Include the following:

- Describe the proposed number of samples for each production class and compound/analytical method.
  - Include the criteria used to determine the proposed sampling number (e.g., statistical basis, etc.).
  - Include the rationale or criteria used to determine whether a compound is included or removed from the testing program.
- Describe the process for reassessing the yearly official government chemical residue control program, including whether the new annual program is modified based on the previous year's findings.
- Provide the names of compounds analyzed for each production class or, if providing an analytical method, a list of compounds that are detected when using each method.
- For each compound tested or analysis method performed, include the type of tissue (e.g., muscle, liver, and kidney) analyzed.
- Describe the analytical methodology for screening and confirmation. For reference, current FSIS analytical methods can be found in the FSIS Chemistry Laboratory Guidebook ([FSIS CLG](#)).
- Include the established tolerance, action level, and detection limit used to take regulatory action (e.g., maximum residue limit (MRL)) for each chemical compound.
- Identify whether all official government chemical residue sampling is done by the CCA. 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 the CCA's requirements and controls for sample collection, including procedures used to ensure sample integrity and chain of custody (i.e., from sample collection in an establishment until receipt by the laboratory that conducts government chemical testing).
- 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.

Describe the previous year's official government chemical residue control program results. Include the following:

- The actual number of samples analyzed for each production class for each chemical compound.

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- The number of violative samples, specific violative chemical compound, and the violative levels for each sample (including tissue matrix).
- The corrective actions taken when a violative result was found. In addition, describe how the CCA notifies establishments when official government chemical test results are found violative.

### **Component 6 Government Microbiological Pathogen and Process Control Programs**

#### **27. How does the CCA ensure that a slaughter establishment's Microbiological Sampling and Testing Program for meat and poultry verifies process control using microbiological analyses for indicators of intestinal and fecal contamination?**

**NOTE:** The CCAs of countries wishing to maintain on-going equivalence and continue actively exporting meat or poultry products to the U.S. should provide indicator organism results for intestinal or fecal contamination if the official government sampling and testing program includes monitoring for indicator organisms. If applicable, submit your updated official government microbiological sampling and testing program for indicator organisms, the previous year's test results, and actions taken in response to positive results by May 18<sup>th</sup> of each year.

- For more information on how to submit annual Government Microbiological Sampling and Testing Program Plans and Microbiological Sampling and Testing Program Results, refer to [FSIS Guidance for Suggested Reporting Tables of the Government Microbiological Sampling and Testing Program](#).
- For an example of the information FSIS needs to evaluate foreign official Microbiological Sampling and Testing Programs, refer to [Summary of FSIS Government Microbiological Sampling Programs Frequencies](#).

To sufficiently respond to this question, the CCA must:

- Describe how the CCA requires and verifies process control in certified slaughter establishments, including microbiological sampling and testing programs for microbiological indicators of process control.
- Identify whether official government sampling for microbiological indicators of process control is done by the CCA. If official government sampling is performed by the establishment or third party contracted personnel, 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 chosen;
  - Frequency of sampling;
  - Points in the process where sampling will occur;
  - 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 ([FSIS 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 Communities (AOAC), Association Française de Normalisation (AFNOR), NordVal, Microval, or Spanish Association for Standardization and Certification (AENOR).
- Describe the CCA's requirements for maintaining 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 performance criteria are exceeded.
- Describe the enforcement actions or strategy the CCA takes when established microbiological criteria are not met, including how and at what frequency the CCA verifies that certified establishments take effective corrective actions.

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### 28. How does the CCA ensure the reduction of *Salmonella* in raw meat and poultry products, and *Campylobacter* in raw poultry products through sampling and other verification activities?

**NOTE:** The CCAs of countries wishing to maintain on-going equivalence and continue actively exporting meat or poultry products to the U.S. must submit an updated official Government Microbiological Sampling and Testing Program for *Salmonella* and *Campylobacter* in raw meat and poultry products, the previous year's test results, and actions taken in response to positive results by May 18<sup>th</sup> of each year.

- For more information on how to submit annual Government Microbiological Sampling and Testing Program Plans and Microbiological Sampling and Testing Program Results, refer to [FSIS Guidance for Suggested Reporting Tables of the Government Microbiological Sampling and Testing Program](#).
- For an example of the information FSIS needs to evaluate foreign official Microbiological Sampling and Testing Programs, refer to [Summary of FSIS Government Microbiological Sampling Programs Frequencies](#).

To sufficiently respond to this question, the CCA must:

- Describe how and at what frequency the CCA verifies that establishments reduce and control *Salmonella* in raw meat and poultry, and *Campylobacter* in raw poultry.
- Describe the CCA's requirements for poultry on-line reprocessing (OLR) and poultry off-line reprocessing (OFLR). Furthermore, if antimicrobial interventions are used during poultry reprocessing, describe the antimicrobial interventions used, and explain how the CCA ensures that these antimicrobial interventions are suitable for purpose, safe, and effective.
- 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 poultry, identify whether the CCA requires establishments to develop, implement, and maintain written procedures for chilling in their 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. In addition, 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 and Testing Program for *Salmonella* in raw meat and poultry, and for *Campylobacter* in raw poultry. Include the following:
  - Provide a written sampling plan with instructions for sample collection and testing. When describing the sampling program for *Salmonella* and *Campylobacter* in raw meat and/or poultry products, describe 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* and *Campylobacter* results, including how the CCA assesses on an ongoing basis whether certified establishments meet such performance standards for poultry: carcasses (young chicken and turkey), chicken parts, and comminuted poultry (from 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 raw meat: carcasses (cow/bull, steer/heifer, and swine) and raw ground beef.
- Identify whether official government sampling for *Salmonella* and/or *Campylobacter* in raw meat and poultry products is done by the CCA. If official government sampling is performed by the establishment or third party contracted personnel, 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*

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and *Campylobacter* conform to [FSIS MLG](#) methods or internationally recognized method standards (e.g., ISO methods).

**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, AFNOR, NordVal, Microval, AENOR.

- Describe the actions taken by the CCA when certified establishments fail to meet expected performance standard criteria, including follow-up government verification sampling and verification of corrective actions.
29. **How does the CCA ensure through sampling and other verification activities that raw beef products are free of STEC at the end of the production process?**

**NOTE:** The CCAs of countries wishing to maintain on-going equivalence and continue actively exporting beef products to the U.S. must submit an updated official Government Microbiological Sampling and Testing Program for STEC, the previous year's STEC test results, and actions taken in response to positive results by May 18<sup>th</sup> of each year.

- For more information on how to submit annual Government Microbiological Sampling and Testing Program Plans and Microbiological Sampling and Testing Program Results, refer to [FSIS Guidance for Suggested Reporting Tables of the Government Microbiological Sampling and Testing Program](#).
- For an example of the information FSIS needs to evaluate foreign official Microbiological Sampling and Testing Programs, refer to [Summary of FSIS Government Microbiological Sampling Programs Frequencies](#).

To sufficiently respond to this question, the CCA must:

- Identify whether the CCA considers STEC an adulterant in raw non-intact beef products (e.g., 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, heart meat, and product from advanced meat recovery systems (AMR)).
- 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 official government microbiological sampling and testing programs for (1) *Escherichia coli* (*E. coli*) O157:H7 and non-O157 STEC (O26, O45, O103, O111, O121, and O145) in beef manufacturing trimmings, and (2) *E. coli* O157:H7 in raw ground beef products and other raw ground beef components. Include the following:
  - Provide a written official government sampling plan with instructions for sample collection and testing. When describing the official government STEC sampling verification program, describe the following:
    - Frequency of sampling;
    - Points in the process where sampling will occur;
    - Sampling methodology;  
**NOTE:** For analyses of raw beef manufacturing trimmings 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 sampling for (1) *E. coli* O157:H7 and non-O157 STEC (O26, O45, O103, O111, O121, and O145) in beef manufacturing trimmings, and (2) *E. coli* O157:H7 in raw ground beef products and other raw ground beef components is done by the CCA. If official government sampling is performed by the establishment or third party contracted personnel, 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 *E. coli* O157:H7 or non-O157 STEC conform to [FSIS MLG](#) methods or internationally recognized method standards

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(e.g., ISO methods).

**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, AFNOR, NordVal, Microval, 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 lotting procedures are defined to establish microbiological independence of production lots so that if there is a positive sample result, all affected product can be identified.
- Describe how and what frequency government inspection personnel verify establishment sampling and testing programs for *E. coli* O157:H7 and non-O157 STEC in beef manufacturing trimmings and *E. coli* O157:H7 in raw ground beef products and other components.
- Describe the enforcement actions taken by the CCA when *E. coli* O157:H7 and non-O157 STEC positive test results are found through official government or establishment microbiological testing programs, including follow-up sampling, traceback procedures, and verification of corrective actions.
- Describe how and what frequency government inspection personnel verify that high-volume establishments (e.g., establishments that produce more than 50,000 pounds of beef trimmings daily) define, investigate, and respond to high event periods (i.e., periods of time in which slaughter establishments experience a high rate of positive results for STEC in production lots containing the same source materials).
- Identify any additional STEC controls required and verified by the CCA in establishments producing raw non-intact beef products, or raw beef products intended for raw non-intact use, for export to the U.S.

### 30. How does the CCA ensure through sampling and other verification activities that RTE meat and poultry products and all lots of pasteurized 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 Guide](#).

**NOTE:** The CCAs of countries wishing to maintain on-going equivalence and continue actively exporting meat, poultry, or egg products to the U.S. must submit an updated official Government Microbiological Sampling and Testing Program for *Lm*, *Salmonella*, and other pathogens of concern in RTE product, the previous year's residue test results, and actions taken in response to positive results by May 18<sup>th</sup> of each year.

- For more information on how to submit annual Government Microbiological Sampling and Testing Program Plans and Microbiological Sampling and Testing Program Results, refer to [FSIS Guidance for Suggested Reporting Tables of the Government Microbiological Sampling and Testing Program](#).
- For an example of the information FSIS needs to evaluate foreign official Microbiological Sampling and Testing Programs, refer to [Summary of FSIS Government Microbiological Sampling Programs Frequencies](#).

To sufficiently respond to this question, the CCA must:

- Identify whether the CCA considers RTE product containing *Lm*, *Salmonella*, or STEC (for 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 U.S.

**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

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injurious to health. Other pathogens are only a public health concern when multiplication occurs at levels that could lead to toxin formation (e.g., *Clostridium perfringens* (*C. perfringens*), and *Clostridium botulinum* (*C. botulinum*)).

For meat and poultry products:

- Describe the CCA's other non-sampling government verification activities for certified establishments producing RTE products, including the following:
  - Describe how and at what frequency government inspection personnel verify that certified establishments adopt *Listeria* control measures and institute testing for *Lm* or *Listeria* species as an indicator for *Lm* based on risk.
  - Describe how and at what frequency government inspection personnel review and verify certified establishment sampling and testing procedures and results.
  - 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 both post-lethality exposed RTE products and non-post-lethality exposed RTE products. 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*, *Salmonella*, and *E. coli* O157:H7 (for dry/semi-dry fermented beef sausages and cooked beef patties) in RTE products exported to the U.S. Include the following:
  - Provide a written sampling plan with instructions for sample collection and testing. When describing the sampling program for RTE products, food contact, and environmental (non-food contact) surfaces, describe 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 how the CCA ensures that both post-lethality exposed and non-post-lethality exposed (e.g., cook-in-bag) RTE meat and poultry products are included in its official government testing program.
  - 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 can be identified.
- Identify whether official government sampling for *Lm*, *Salmonella*, and STEC in RTE products is done by the CCA. If official government sampling is performed by the establishment or third-party contracted personnel, 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*, *Salmonella*, and STEC conform to [FSIS MLG](#) methods or internationally recognized method standards (e.g., ISO methods).

**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, AFNOR, NordVal, Microval, AENOR.
- Describe the enforcement actions taken by the CCA when insanitary conditions or contaminated products are

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identified in a certified establishment, including follow-up sampling and verification of corrective actions. Furthermore, in the event of a positive sample result for *Lm* or *Salmonella*, identify whether the CCA conducts follow-up sampling to test for the presence of *Lm* or *Salmonella* in product samples, and on food contact surfaces and environmental surfaces.

For egg products:

- Describe the official Government Microbiological Sampling and Testing Program for *Salmonella* in pasteurized liquid, frozen, and dried egg products in certified egg product establishments. In addition, identify whether the official Government Microbiological Sampling and Testing Program includes testing egg products for the presence of *Lm*. Include the following:
  - Provide a written sampling plan with instructions for sample collection and testing. When describing the sampling program for egg products, describe 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 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 can be identified.
- Identify whether official government sampling for *Salmonella* and *Lm* in pasteurized liquid, frozen, and dried egg products is done by the CCA. If official government sampling is performed by the establishment or third party contracted personnel, 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 (e.g., ISO methods).

**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, AFNOR, NordVal, Microval, AENOR.
- Describe the enforcement actions taken by the CCA when unacceptable results are found through official government or establishment microbiological testing programs, including verification of corrective actions.
- Describe whether the CCA requires certified egg product establishments to develop and implement *Salmonella* and *Lm* sampling programs for pasteurized liquid, frozen, and dried egg products. Describe how and at what frequency the CCA verifies establishment sampling and testing procedures and results.

**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 Guide](#).

To sufficiently respond to this question, the CCA must:

- 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, and sufficient reductions in *Lm* during lethality; the prevention of the growth of spore-forming bacteria (i.e., *C. perfringens* and *C. botulinum*)

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by maintaining critical operational parameters (low pH, relatively low water activity); and the prevention of the growth of *S. aureus* during the processing and 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 (i.e., *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 Guide](#).

To sufficiently respond to this question, 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 U.S.
- Describe how and at what frequency the CCA verifies that NRTE products are labeled with safe handling instructions and 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 U.S. labeling requirements for safe handling instructions and special handling statements, refer to [9 CFR 317.2\(k\) and \(l\)](#) (meat products) and [9 CFR 381.125\(a\) and \(b\)](#) (poultry products).

### 33. How does the CCA ensure that the processing of 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 U.S. (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 as providing an equivalent level of sanitary protection when producing TP/CS meat and poultry products for export to the U.S.

**NOTE:** FSIS recently consolidated its canning regulations for meat (9 CFR 318, Subpart G) and poultry (9 CFR 381, Subpart X) into one section in 9 CFR. These regulations are now located in 9 CFR 431. You may access the new Federal Register Notice and regulations, which became effective on July 30, 2018, online at this link: <https://www.govinfo.gov/content/pkg/FR-2018-05-31/pdf/2018-11300.pdf>.

**NOTE:** For countries using HACCP to address all food safety hazards during thermal processing/commercial sterilization, describe your country's food safety controls under question 25.

To sufficiently respond to this question, the CCA must:

- Describe how and at what frequency the CCA ensures that certified establishments producing TP/CS products for export to the U.S. 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. Include any strategies for reducing or eliminating these hazards.

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- 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  $\leq 1000$  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 U.S. 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 and closures are cleaned and examined prior to filling; stored and handled in a sanitary manner; and examined prior to closure (e.g., visual, teardown, or physical examination) by trained closure technicians;
  - Process schedules are developed by a processing authority prior to the processing of canned product for export to the U.S.;
  - 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, along with 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 standards for retorts- 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 (i.e., audit), 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;
  - Certified establishments maintain 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;

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- 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 U.S. is safe for human consumption and shelf-stable;
  - Finished product inspections are conducted to ensure that only normal appearing containers are exported to the U.S.; and
  - Direct supervisors of thermal processing operators and closure technicians possess knowledge and training specific to canning operations.
- Describe the enforcement actions taken by the CCA in response to processing deviations (i.e., deviation identified in process or through records review), 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 in PHIS for accuracy and completeness, including all English translated documents, as part of its annual update by May 18<sup>th</sup> of each year?**
- NOTE:** In the SRT response to this question, verify whether your country's current SRT responses and supporting documentation in PHIS are accurate and up-to-date, including whether translated documents were correctly translated into English. Countries unable to access PHIS can contact the FSIS Office of International Coordination through e-mail at [internationalcoordination@fsis.usda.gov](mailto:internationalcoordination@fsis.usda.gov) to obtain copies of English translated documents for review.
- 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.
35. **For countries requesting a reinstatement of equivalence, initial equivalence, or expansion of initial equivalence, identify the process category, product category and product group that your country intends to export to the U.S.**
- NOTE:** For more information, refer to FSIS Product Categorization guide (<https://www.fsis.usda.gov/wps/wcm/connect/abbf595d-7fc7-4170-b7be-37f812882388/Product-Categorization.pdf?MOD=AJPERES>).