

Government
Microbiological
Testing
Programs 4

How does the CCA ensure that ready-to-eat (RTE) fish of the order Siluriformes products are free of *Listeria monocytogenes*, *Salmonella*, or other pathogens of public health concern through sampling and other verification activities?

NOTE: RTE products are products that are edible without further preparation.

NOTE: Please submit annually (by May 18th) your updated microbiological sampling and testing program, previous year's test results, and reactions to positive results. Provide all supporting documentation that you use to verify the elimination of *Listeria monocytogenes*, *Salmonella*, or other pathogens of public health concern in RTE products.

Government
Microbiological
Testing
Programs 5

How does the CCA ensure that thermally processed/commercially sterile fish of the order Siluriformes products are free of microorganisms capable of growing in non-refrigerated conditions in storage and distribution (over 50°F or 10°C) through sampling and other verification activities?

NOTE: Thermally processed or commercially sterile product is a shelf-stable product that has had an application of heat, irradiation, high-pressure, or other processes or ingredients, applied alone or in combination, that causes the product to become free of microorganisms capable of growing at non-refrigerated temperatures.

NOTE: A process schedule contains all required factors applied to make a thermally processed/commercially sterile product shelf stable.

NOTE: A process authority can be a person or organization that has expert knowledge of the requirements to produce a thermally processed/commercially sterile product.

NOTE: Please submit prior to production for export to the US updated processing schedules for each certified establishment's product that is developed by a processing authority.

Government
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Programs 6

How does the CCA ensure control over government sampled fish of the order Siluriformes until the test results are received for microbiological or economic adulteration verification testing?

Government
Microbiological
Testing
Programs 7

How does the CCA ensure that fish of the order Siluriformes sampled and found to be positive for an adulterant (e.g., *Listeria monocytogenes* or *Salmonella* in RTE fish of the order Siluriformes product) is not retested to negate the previous result?

Component 5 Government Chemical Residues Testing Programs

The following questions are required and will be used to determine the equivalence with FSIS standards pertaining to chemical residue testing programs. The inspection system must have a chemical residue control program, which includes sampling for chemical residues identified by the CCA or by FSIS as potential contaminants.

Government Chemical Residues Testing Programs 1 How does the CCA ensure the implementation and maintenance of a national chemical residue control program that prevents and controls all specific compounds of concern both domestically and in the US?

NOTE: Please submit annually (by May 18th) your updated residue control program, previous year's residue test results, and reactions to residue findings.

Government Chemical Residues Testing Programs 2 How does the CCA ensure chemical independence of one production lot from another during government testing of fish of the order Siluriformes?

Government Chemical Residues Testing Programs 3 How does the CCA ensure chemical independence of one production lot from another during government testing of fish of the order Siluriformes?

NOTE: This information is important because FSIS can use it to conduct a recall of fish of the order Siluriformes in the event that there is a detection of non-compliance in fish of the order Siluriformes from your country.

Government Chemical Residues Testing Programs 4 How does the CCA ensure control over government sampled fish of the order Siluriformes until test results are received for chemical residue verification testing?

Component 6 Government Microbiological Testing Programs

The following questions are required and will be used to determine the equivalence with FSIS standards pertaining to any government testing programs the CCA maintains. Under this section, countries should capture all food safety controls (including sampling and other verification activities) that address *Salmonella*, *Listeria monocytogenes*, and other pathogens of public health concern.

Government Microbiological Testing Programs 1 How does the CCA ensure the implementation and maintenance of its fish of the order Siluriformes food safety inspection system's microbiological sampling program?

Government Microbiological Testing Programs 2 How does the CCA ensure that the inspection system's microbiological sampling program includes supportable sample collection procedures, frequencies, and test methods?

NOTE: Please include the sample collection requirements and controls that ensure the sample integrity, reliability, and chain of custody.

Government Microbiological Testing Programs 3 How does the CCA ensure the reduction of *Salmonella* in raw fish of the order Siluriformes products through sampling and other verification activities?

NOTE: Please submit annually (by May 18th) your updated microbiological sampling and testing program, previous year's test results, and reactions to positive results.



Component 3 Government Sanitation

The following questions are required and will be used to determine the equivalence with FSIS standards pertaining to sanitation. The inspection system must require that each certified establishment operate in a manner to prevent insanitary conditions, and develop, implement, and maintain written standard operating procedures for sanitation.

- Government Sanitation 1** How does the CCA ensure that fish of the order Siluriformes for use as human food are not grown or farmed under conditions that would cause them to be inedible?
- Government Sanitation 2** How does the CCA ensure (for cause) samples of feed, fish of the order Siluriformes, or pond water are collected for the purpose of verifying that they are being raised under sanitary conditions?
- Government Sanitation 3** How does the CCA ensure that fish of the order Siluriformes are transported under sanitary conditions from ponds to the certified establishment?
- Government Sanitation 4** How does the CCA ensure producers exercise controls to separate fish of the order Siluriformes that have died other than by slaughter?
- Government Sanitation 5** How does the CCA ensure that each certified establishment operates in a sanitary manner?
- Government Sanitation 6** How does the CCA ensure that certified establishment's construction, facilities, and equipment prevent the contamination or adulteration of fish of the order Siluriformes products designated for export to the US?
- Government Sanitation 7** How does the CCA ensure that each certified establishment develops, implements, and maintains daily pre-operational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of fish of the order Siluriformes products?

Component 4 Government HACCP System

The following question is required and will be used to determine the equivalence with FSIS standards pertaining to HACCP. The inspection system must require that each certified establishment develop, implement, and maintain a HACCP plan. A sufficient HACCP plan will achieve the food safety objective of preventing and controlling, biological, chemical, and physical hazards in products shipped to the US.

- Government HACCP System 1** How does the CCA ensure the implementation and maintenance of a fish of the order Siluriformes products food safety inspection system that prevents and controls identified food safety hazards?

- Government Oversight 11 How does the CCA ensure that laboratories testing chemical residues for fish of the order Siluriformes products for export to the US comply with the general criteria for testing laboratories provided in International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025?
- Government Oversight 12 How does the CCA ensure that methods of analysis (including both sampling and testing procedures) used for food safety testing have been scientifically validated or have been approved and adopted by a recognized international organization?
- Government Oversight 13 How does the CCA ensure that internal quality control procedures for laboratories are established, effective, and followed?

Component 2 Government Statutory Authority and Food Safety and Other Consumer Protection Regulations
The following questions are required and will be used to determine the equivalence with FSIS standards.

Government Statutory Authority and Food Safety 1 How does the CCA ensure that government inspection personnel perform continuous inspection at certified establishments during all hours of operation while fish of the order Siluriformes are slaughtered for example beheading and eviscerating?

Government Statutory Authority and Food Safety 2 How does the CCA ensure government inspection occurs at least once per shift at certified establishments while fish of the order Siluriformes are processed, for example filleting and breading?

Government Statutory Authority and Food Safety 3 How does the CCA ensure that a representative of the government inspection system makes periodic supervisory visits to each certified establishment?

Government Statutory Authority and Food Safety 4 How does the CCA ensure that the food safety inspection system provides for complete separation of certified from non-certified establishments?

NOTE: Any fish of the order Siluriformes products intended to be exported to the US cannot be produced in an establishment (or part of an establishment) that was not certified as eligible to export to the US.

NOTE: If a certified establishment also produces fish of the order Siluriformes products not intended for export to the US, the products not intended for export to the US must be produced separately by either time or space.

Government Statutory Authority and Food Safety 5 How does the CCA ensure control over condemned fish of the order Siluriformes, which can include portions of inspected fish of the order Siluriformes, and inedible material until destroyed or otherwise denatured?

NOTE: A condemned fish of the order Siluriformes or inedible material is any fish of the order Siluriformes, part of a fish of the order Siluriformes carcass, or fish of the order Siluriformes-based product that is determined not fit to be eaten by humans.

NOTE: The denaturing of fish of the order Siluriformes products is to add a chemical substance, e.g. charcoal or dye, to ensure that the product cannot be used for human food.



Government
Oversight 3

How does the CCA ensure that the same set of laws, regulations, and policies are applied consistently to all certified establishments that manufacture fish of the order Siluriformes are eligible to export to the US?

NOTE: A certified establishment is an establishment that the CCA determines as meeting US requirements and, therefore, eligible to export fish of the order Siluriformes products to the US.

NOTE: A de-certified establishment is an establishment that the CCA determines as not meeting US requirements and, therefore, not eligible to export fish of the order Siluriformes products to the US.

NOTE: Countries are required to notify FSIS when there are changes in the eligibility of certified establishments, and must confirm with FSIS at least annually (by May 18th) all certified establishments eligible to export to the US.

Government
Oversight 4

How does the CCA ensure that source product from fish of the order Siluriformes used in processing operations originates only from certified establishments in eligible countries?

NOTE: An eligible country is a country that the US has already determined to have an equivalent meat, poultry, or egg products inspection system.

Government
Oversight 5

How does the CCA ensure that US import requirements are communicated to certified establishments as import requirements are issued?

Government
Oversight 6

How does the CCA ensure that an ongoing staffing plan provides continuous government inspection for the production of safe, wholesome, and accurately labeled fish of the order Siluriformes products in certified establishments?

Government
Oversight 7

How does the CCA ensure that government inspection personnel assigned to certified establishments exporting fish of the order Siluriformes products to the US are employees of and paid by the government?

NOTE: Criteria for government inspection include the following:

- Government Inspector – inspector employed directly by the government on a permanent or intermittent basis, and who is authorized to perform all aspects of inspection.
- Licensee (Limited Government Inspector) – inspector employed under individual contract by the government to perform inspection.
- Contract employee (Private Contractor) – operator employed by a third party organization contracted to conduct inspection activities on behalf of the government. Operator is under the direct supervision of a government inspector; however, without government supervision in place, this class of operator would fail to meet FSIS government inspection criteria.
- Government authorized establishment employee – operator performing sorting and assessment activities under the direct supervision of a government inspector. Also refers to an operator directed to perform activities not specifically related to inspection.

NOTE: In items b, c, and d, the final inspection and disposition must be made by a government inspector based upon issues identified by non-government personnel.

Government
Oversight 8

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

Government
Oversight 9

How does the CCA ensure that specialized, ongoing training on the US import requirements is provided to government inspection personnel assigned to certified establishments?

NOTE: Examples of types of training include food safety, sanitation requirements, sample collection procedures, and compliance verification.

Government
Oversight 10

How does the CCA ensure that adequate administrative and technical support is available to certified establishments and laboratories performing food safety testing?

that submitted paper SRT responses, the CCA will be provided an opportunity to verify a paper copy of the English translated SRT responses entered into PHIS. Note that by not communicating the SRT responses in English and by using a paper copy rather than PHIS for inputting SRT information by the CCA, the equivalence review process could be delayed by weeks and possibly months. Importantly, regardless of how the CCA manages the SRT, FSIS relies upon the PHIS English version of the SRT responses when making equivalence decisions. Countries are encouraged to gain access to PHIS in order to ensure completeness of documentation of the SRT.

FSIS, using food safety objective-based criteria, will then review the SRT responses and associated supporting documentation to determine whether the country's food safety inspection system is equivalent. After FSIS completes its review, FSIS will send to the CCA any clarification questions, and make the English translated SRT responses and supporting documentation available for review in PHIS (or send a paper version if paper was previously provided). Through this process, the CCA will have the opportunity to verify that the translated responses and supporting documentation are accurate, and, if applicable, provide clarification to FSIS's questions.

On-going Equivalence Verification

After equivalence is granted, on an annual basis no later than May 18, the CCA must either (1) update its SRT responses, or (2) communicate to FSIS that the CCA has verified its SRT responses as recorded in PHIS (e.g., by reviewing the SRT electronically in PHIS or by hard copy of the version of SRT responses FSIS has entered for the CCA) are accurate and complete. Updates to its SRT are expected whenever the CCA makes changes to its food safety inspection system, whether the change is a result of the country's changes or the US implements new policies that may impact the design of the CCA's food safety inspection system for products exported to the US.

In addition, the CCA must provide the following on an annual basis no later than May 18th if applicable for the eligible product(s):

1. An up-to-date list of all certified establishments eligible to export to the US.
2. An updated government residue control program, including the previous year's residue test results and reactions to residue findings.
3. An updated microbiological sampling and testing program, including the previous year's test results and reactions to *Salmonella* results in raw fish of the order Siluriformes and *Listeria monocytogenes*, *Salmonella*, or other pathogens of public health concern in ready-to-eat (RTE) fish of the order Siluriformes.

Component 1 Government Oversight

The following questions are required and will be used to determine the equivalence with FSIS standards pertaining to government oversight and authority. In summary, the FSIS criteria for this section includes identifying the CCA's authority, laws, and regulations governing the inspection system for fish of the order Siluriformes for certified establishments who will be exporting to the US, and the staffing requirements and procedures.

Government Oversight 1 How does the CCA ensure that the laws and regulations governing fish of the order Siluriformes inspection are enforced?

NOTE: The CCA is a country's national government authority who is responsible for ensuring the safety of the food supply.

NOTE: Please identify the name of the CCA, and attach an organizational chart.

Government Oversight 2 How does the CCA ensure that all fish of the order Siluriformes products for export to the US are certified, and not adulterated and properly labeled and packaged (not misbranded)?

NOTE: Please define adulterated product as it relates to fish of the order Siluriformes.

2016 – Siluriformes Self Reporting Tool - Version 4 (Note: This model SRT is not to be filled out)

Equivalence is a prerequisite for trade for the United States (US) Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS). Equivalence is the process of determining whether a country's food safety inspection system achieves FSIS's appropriate level of protection for public health as applied domestically in the US. Additionally, the country's food safety inspection system is to provide standards equivalent to FSIS to ensure other non-food safety requirements (such as accurate labeling, and assurance that fish of the order Siluriformes products are not economically adulterated) are met. This means that the country is not required to develop and implement the same procedures that the US does, but rather the country must objectively demonstrate how it meets the US level of protection. In order to determine whether a country's food safety inspection system is equivalent, FSIS assesses information collected through a questionnaire called the self-reporting tool (SRT). The SRT is designed for countries that want to export fish of the order Siluriformes products to the US. The SRT provides an organized means for the country's government to demonstrate that its inspection system achieves an equivalent level of protection. The SRT is arranged into six (6) components:

1. Government Oversight (e.g., Organization and Administration)
2. Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)
3. Government Sanitation
4. Government Hazard Analysis and Critical Control Point (HACCP) System
5. Government Chemical Residues Testing Programs
6. Government Microbiological Testing Programs

The questions under these six components are called component questions. The country's central competent authority (CCA) is expected to answer all component questions in the SRT in order for an effective determination of equivalence. The CCA is the country's national government authority that is responsible for ensuring the safety and truthful labeling of the food supply.

The CCA should provide complete responses to SRT questions. Complete responses include a short narrative, accompanied by supporting documentation, to characterize how a country's food safety inspection system is implemented. Responses should include references to where in the supporting documentation the answer to the question is found. For example, answers should include the page number, section number, or chapter from the relevant supporting documentation. The CCA will need to submit to FSIS the completed SRT with all applicable programs and supporting documentation. Types of supporting documentation the CCA should include about the government inspection system are as follows:

- a. food safety and inspection laws and legislation
- b. regulations, policies, standards, decisions, annexes, and decrees
- c. inspection procedures, manuals, and directives
- d. control programs
- e. inspection training programs
- f. mechanisms for documenting compliance/noncompliance
- g. enforcement and compliance programs

Food safety objective-based criteria are the standards that FSIS uses to determine whether the country's food safety inspection system is equivalent. The component questions are the food safety objective-based criteria that FSIS uses to determine equivalence in the form of a question.

Submission of the SRT

To submit the SRT with all applicable programs and supporting documentation, the CCA can either use the Microsoft Word version of the SRT or upload the information into the web-based Public Health Information System (PHIS). The benefits for using PHIS to submit the information include an expedited SRT review, transparency, and security. To ensure an expedited review of a submitted SRT, particularly an SRT submitted in PHIS, FSIS encourages countries to submit SRT responses and supporting documentation in English. If the CCA submits SRT responses and supporting documentation in a language other than English, FSIS will send the documentation for translation into English, and place the translated English responses into the SRT. FSIS maintains all countries SRT responses and submitted supporting documentation in PHIS. Through PHIS the CCA will have the opportunity to verify that the translated responses are accurately captured by FSIS in PHIS. For countries



United States
Department of
Agriculture

Food Safety
And Inspection
Service

Myanmar - Plants Eligible to Export Meat (Siluriformes only) to the United States
April 14, 2016

In accordance with the FSIS rule published on December 2, 2015 (80 FR, 75590), the following country has submitted documentation to FSIS showing that they have laws or other legal measures in place that provide authority to regulate the growing and processing of Siluriformes fish for human food, and that will ensure compliance with the Food and Drug Administration's regulatory requirements in 21 CFR part 123, Fish and Fishery Products. In addition, the country has put forward the following establishments as eligible to export Siluriformes fish and fish products to the United States. FSIS will update the list of establishments as new information is received.

By the end of the 18-month transitional period, September 1, 2017, foreign countries seeking to continue exporting such product to the United States must submit adequate documentation showing the equivalence of their Siluriformes inspection systems with that of the United States.

EstForgnNBR	Establishment Name	Date Listed	Date Delisted	Date Relisted
DOF001USMZ	Myeik Zenith Industrial Co., Ltd	3/1/2016		
DOF002USGWI	Ghani Win International Ltd	3/1/2016		
DOF003USYTG	YadanarTheingi Cold Store (EO)	3/1/2016		
DOF004USTB	Twin Brothers Seafood Cold Storage	3/1/2016		
DOF005USSM	Shwe Myanmar Cold Store	3/1/2016		
DOF006USMY	May Yu Marine Products Co., Ltd	3/1/2016		
DOF007USMM	Mega Marine Frozen Sea Food Cold Store	3/1/2016		
DOF008USSN	ShweNgar Processing and Cold Store Plant	3/1/2016		
DOF009USGFC	Golden Flower Cold Store	3/1/2016		
DOF010USATP	Annawar Trade Park Marine Products Co., Ltd	3/1/2016		
DOF011USHHK	HlaingHtateKaung Co., Ltd	3/1/2016		
DOF012USMZN	Min Zar Ni Co., Ltd	3/1/2016		
DOF013USGS	Golden Sea Processing Plant & Cold Store	3/1/2016		
DOF014USMKF	Myanmar King Fish Ltd	3/1/2016		
DOF015USHNL	Htun Nay Linn Cold Store	3/1/2016		
DOF016USUIC	Universal Cold Store	3/1/2016		
DOF017USSKB	Shwe Kaba Maung Maung Cold Store	3/1/2016		
DOF018USYTI	Yadanar Theingi Industrial Co., Ltd	3/1/2016		
DOF019USGOT	Gallant Ocean Trading Co., Ltd	3/1/2016		
DOF020USMMH	Myint Myat Hein Co., Ltd	3/1/2016		
DOF021USOP	Ocean Pacific Cold Storage Processing and Ice Plant	3/1/2016		
DOF022USF2	Fisheries And Marine Products 2000 Limited	3/1/2016		
DOF023USMSL	MSL Industries Company Limited	3/1/2016		