Annex 1 – Seafood Processing Standard 6.0 Finished Product Testing Operational Guidance

Issue 1.0

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Global Seafood Alliance Guidance

Table of Contents

Introduction

The purpose of Annex I is to provide operational guidance to the certification bodies, auditors and facilities that are required to conduct finished product testing. The Seafood Processing Standard (SPS) has identified three categories of risk to determine if finished product testing is required. The categories are low, elevated, and high risk. Finished product testing is required for all facilities that fall under the elevated and high-risk categories.

The following information is contained in Annex 1

- Defining risk status
- Sample selection
- Auditor required documentation
- Sample compositing requirements
- What type of testing shall be conducted
- Laboratory and methodology requirements

How to use Annex I

- Refer to section 1.0 Risk Status that provides the definitions and criteria for each of the risk categories.
- Determine if finished product testing is required based on the criteria in section 1.0
- If the assessment determines that the facility falls within the elevated or high-risk categories, proceed to Section 2.0 Instructions for Facilities and Auditors.
- Low risk assessments that fall outside of elevated or high-risk categories are exempt from product testing.

1.0 Risk Status:

1.1 Elevated Risk Status

Facilities will be initially designated under the Elevated Risk status if they fall under any of the criteria in 1.1.1-1.1.4 below.

1.1.1 New facilities applying for certification located in regions of high production and antimicrobial use, or in countries with high numbers of US FDA refusals or equivalent regulatory enforcement actions. Specifically, new facilities applying to the GSA Program located in China, Egypt, India, Indonesia, Mexico, Thailand, or Vietnam.

1.1.2 New facilities applying for SPS certification that have been listed on the US FDA Refusal List (or international equivalent) for microbiological pathogens, banned chemical residues, or histamine within the past 12 months prior to applying.

1.1.3 SPS certified facilities (or renewal in process) receiving non-conformities under local, federal, or national agency inspection refusal for microbiological pathogens, banned chemical residues, or histamine. When this occurs during a certification cycle, the facility shall be required to notify their certification body and GSA within 48 hours of the notification of the non-conformity, along with a written explanation of the non-conformity. Additionally, within 14 days, the facility shall provide a detailed corrective action plan that includes a root cause analysis. GSA will review the findings and determine if a supplementary Targeted Audit[1] that includes assessment of corrective actions and Finished Product Testing as described herein. In addition, the facility shall be required to undergo Finished Product Testing during their next recertification audit.

1.1.4 A facility that does not meet GSA Action levels specified in the Finished Product Testing Tables 2, 3, and 4 during a finished product testing event in either a targeted or certification audit may be required to undergo an additional 1-day Targeted Audit that includes assessment of corrective actions and finished product testing as described herein. In addition, the facility shall be required to undergo Finished Product Testing during their next recertification audit.

1.2 High Risk Status

A facility that fails 3 Finished Product Testing events is considered High Risk and subject to suspension from the SPS Program.

1.3 Low Risk Status

Facilities designated as Low Risk are those that fall outside designation criteria 1.1 and 1.2. Facilities that have successfully passed Finished Product Testing requirements under 1.1 will be moved to Low Risk Status and exempt from product testing during all recertification audits as long as Low Risk Status designation is maintained.

2.0 Instructions for Facilities and Auditors

2.1 All Finished Product Testing under the SPS shall be under the supervision of an assigned auditor. Plant ongoing monitoring is encouraged but no longer required under SPS Finished Product Testing.

2.2 At the beginning of an audit, facilities shall present to the auditor a full inventory of all products in storage. Auditors shall use this list to select lots for sampling, and for assessing potential discrepancies between inventory sheets and identification codes on packaging in storage. No product in storage can be excluded from the inventory list. This includes products destined for local distribution. Sampling lots should be selected by the auditor based on potential risk factors observed by auditors.

2.3 The auditor has a role during the annual audit to arrange for the selection and collection of samples to be sent to a qualified third-party laboratory for testing. Plants are responsible for all testing costs related to certification. SPS sampling requirements do not override legal sampling and testing obligations.

[1] See GSA Supplemental Audit Policy for requirements. Unless otherwise agreed upon between GSA and certification body, a Targeted Audit under Finished Product Testing is expected to be no more than 1-day which includes report writing.

2.4 Selection of Samples

2.4.1 The auditor shall select 8 samples total for aquaculture, and/or 8 samples total for wild-harvested products, depending on the scope of certification (aquaculture only, wild only, or both). See FPT Table 1 below for guidance

FPT Table 1: General Requirements for Finished Product Testing

Facility Scope	Test Category	Number of Tests	Composite Description	Facility Classification
Aquaculture and wild-harvested	Microbiological	1 set of tests (Table 2) as applicable for each primary product form sampled. *** Minimum 2 microbiological tests across the 8 samples submitted*	1-4 samples per composite depending on the number of samples per primary product form	All processors and re-processors
Aquaculture	Drug Residues, Histamines	2 sets of tests (Table 3) across 8 samples submitted	4 samples per composite	All processors and re-processors
Wild-harvested	Histamines	1 histamine test for each susceptible species sampled (Table 4)	Up to 4 samples per composite	All processors and re-processors

**Primary product forms are defined on page 14.

2.4.2 Species: If more than 1 species is present within the scope of the audit, the auditor shall select 4 samples from 2 different species under consideration of food safety risk factors. Aquaculture related risk factors may include species that require formulated feeds versus unfed species (e.g., antimicrobials are typically more associated with fed species; example: fed *Litopenaeus vannamei* versus unfed *Penaeus monodon*), or species whose health records indicate recent antimicrobial treatments. Wild species related risk factors include species whose finished products may contain histamines.

2.4.3 Product forms: Product forms shall also be selected based on food safety risk factors. Ready To Eat products are considered high risk and should be selected if present. If 2 or more product forms are present the auditor should select at least 2 different product forms for sampling.

2.4.4 Production lots: The auditor should select from across as many different production lot codes present at time of sampling within protocols stated in 2.4.1- 2.4.3. If production lots are segregated into exported versus local destinations, at least 1 lot of locally designated product should be sampled.

2.4.5 Sample size shall be 750g per sample.

2.4.6 Aseptic sampling protocols shall be always followed.

2.5 Auditor Documentation

2.5.1 Auditors shall supply documentation associated with the samples collected, to include:

- A copy of the plant inventory sheet in use on the day samples are collected, against which the selection of samples was made (supply as an Excel or Word file, or as a legible scanned file or photo)
- List of samples collected, facility and laboratory details (as an Excel file), detailing the following:
- Facility name and GSA Facility number
- Third-party laboratory name and contact details
- Sampling date and times
- Species (scientific name)
- Primary Product Form description (per sample)
- Alphanumeric Sample Code assigned by auditor – as written on sample bags (per sample)
- Production lot ID or date code (per sample)
- Description of product, including product specifications such as size or count, supplier code, etc. (per sample)
- Photos of each sample collected, showing the assigned alphanumeric code and any other tracking information visible on the bag (per sample).
- A description of how the samples were packed and shipped shall be provided to GSA.

2.6 Compositing and Testing

2.6.1 Compositing of samples is to be done at the Third-party Laboratory. General requirements for compositing and testing are described in FPT Table 1. Requirements for microbiological

parameters for all scopes are listed in FPT Table 2. Requirements for drug residues under the aquaculture scope are provided in FPT Table 3. Requirements for toxins under the wild-harvested scope are provided in FPT Table 4.

2.6.2 Once testing has been completed, the laboratory shall forward an original copy of the analytical results directly to the CB, with a copy to the facility. Results shall be documented in the certification records, and the CB shall supply GSA with copies of the test results.

FPT Table 2: Microbiological Testing Criteria (Aquaculture and Wild)

Intended Use Category	Microbiological Criteria	Species /Forms	GSA Action Level**
Raw and Ready to Eat	Generic *Escherichia coli*	Finfish, crustaceans, and mollusks /all forms fresh and frozen	Less than or equal to 40 CFU/g
Raw and Ready to Eat	*Staphylococcus aureus*	Finfish/crustaceans /all forms fresh and frozen	Reject if positive for either Staphylococcal enterotoxin), or a level equal to or greater than 1 x 10^4 bacteria per g (MPN)
Ready to Eat Only	Salmonella sp.	Finfish/crustaceans/molluscan shellfish / all forms fresh and frozen	Reject if presence is detected in 25 grams
Ready to Eat Only	*Listeria monocytogenes*	Finfish/crustaceans/molluscan shellfish /all forms fresh and frozen	Reject if presence is detected in 25 grams
Ready to Eat Only	*Vibrio parahaemolyticus* or Vibrio spp.	Molluscan shellfish e.g., oysters, clams, mussels either shucked, or in shell, post-harvest processed, frozen or unfrozen	Reject if presence is detected or greater than or equal to 30 bacteria per gram (MPN) in 25 grams

FPT Table 3: Required Chemical Residue Testing for Aquaculture Finished Products

Acceptable Test Methods*	Banned Chemical Residue - Aquaculture Drug	GSA Action Level** Greater than or equal to (µg/kg or ppb)	Limits
Test methods based on ELISA (screening) Chromatography-Mass Spectrometry Published ELISA screening methods may be permitted. In the event of residue detection, confirmation shall be conducted by standard methods: Chromatography-MS/MS, GC, HPLC	Chloramphenicol	0.3	no residue permitted
	Nitrofuran Metabolites	1.0	no residue permitted
	Furazolidone		
	Furaltadone		
	Nitrofurantoin		
	Nitrofurazone		
	Fluoroquinolones	1.0	no residue permitted
	Sarafloxacin		
	Ciprofloxacin		
	Enrofloxacin		
	Triphenylmethane Dyes	0.5	no residue permitted
	Sum of Malachite Green & Leuco-malachite Green		
	Sum of Gentian Violet & Leucogentian Violet		
	Quinolones		no residue permitted
	Flumequine	5.0	
	Oxolinic acid	5.0	

Specified residue levels of Sulfadiazine, Sulfamethazine, Oxytetracycline, Tetracycline, and Florfenicol may be permissible in some countries

Acceptable Test Methods	Chemical Residue - Aquaculture Drugs that are allowed in some countries for some species	GSA Action Level *Greater than or equal to (ug/kg or ppb)	Limits
Published rapid ELISA screening methods may be permitted. In the event of residue detection, confirmation shall be conducted by standard methods: Chromatography-MS/MS, GC, HPLC	Sulfonamide (parent drug)	10.0	no residue permitted in unapproved species
	Oxytetracycline	10.0	no residue permitted in unapproved species
	Tetracycline	10.0	no residue permitted in unapproved species
	Florfenicol	10.0	no residue permitted in unapproved species

FPT Table 4: Required Finished Product Testing for Wild and Aquaculture Fish Species that are associated with Scombrotoxin (Histamine)			
Examples of Acceptable Test Methods*	**Toxin**	**GSA Action Level***	**Limits**
HPLC/Colorimetric Assay, Enzymatic Assay	Histamine (Scombrotoxin)	50 ppm	50 ppm

* Published methods shall meet or exceed the sensitivity stated in FPT Table 4 .

FPT Table 5: Fish Species of Potential Scombrotoxin (Histamine)			
Market Names	Latin Names	Market Names	Latin Names
ALEWIFE OR RIVER HERRING	*Alosa pseudoharengus*	**MACKEREL, CHUB**	*Scomber spp.*
AMBERJACK	*Seriola spp.*	**MACKEREL, JACK**	*Trachurus spp.*
AMBERJACK OR YELLOWTAIL	*Seriola lalandi*	**MACKEREL, SPANISH**	*Scomberomorus spp.*
AMBERJACK OR YELLOWTAIL, AQUACULTURED	*Seriola lalandi*	**MACKEREL, NARROW-BARRED SPANISH**	*Scomberomorus commerson*
ANCHOVY	*Anchoa spp.*	**MACKEREL, SPANISH OR KING**	*Scomberomorus cavalla*
	Anchoviella spp.	**MAHI-MAHI**	*Coryphaena spp.*
	Cetengraulis mysticetus	**MAHI-MAHI, AQUACULTURED**	*Coryphaena spp.*
	Engraulis spp.	**MARLIN**	*Makaira spp.*
	Stolephorus spp.		*Tetrapturus spp.*
BLUEFISH	*Pomatomus saltatrix*	**MENHADEN**	*Brevoortia spp.*
BONITO	*Cybiosarda elegans*		*Ethmidium maculatum*
	Gymnosarda unicolor	**PILCHARD OR SARDINE**	*Sardina pilchardus*
	Orcynopsis unicolor		*Sardinops spp.*
	Sarda spp.	**SAILFISH**	*Istiophorus platypterus*
ESCOLAR OR OILFISH	*Lepidocybium flavobrunneum*	**SARDINE**	*Harengula spp.*
	Ruvettus pretiosus		*Sardinella spp.*
	Lepidocybium flavobrunneum	**SAURY**	*Cololabis saira*
HERRING	*Etrumeus teres*		*Scomberesox saurus*
	Harengula thrissina		*Trachurus spp.*
	Ilisha spp.	**SCAD OR HORSE MACKEREL**	*Trachurus trachurus*
	Opisthopterus tardoore	**SHAD**	*Alosa spp.*
	Pellona ditchela	**SHAD, GIZZARD**	*Dorosoma spp.*
	Alosa spp.		*Nematalosa vlaminghi*
HERRING OR SEA HERRING OR SILD	*Clupea spp.*	**SHAD, HILSA**	*Tenualosa ilisha*
HERRING, THREAD	*Opisthonema spp.*	**SPEARFISH**	*Tetrapturus spp.*
HORSE MACKEREL OR SCAD	*Trachurus trachurus*	**SPRAT OR BRISTLING**	*Sprattus spp.*
JACK	*Caranx spp.*	**TREVALLY**	*Caranx spp.*
	C. ignobilis	**TUNA (SMALL)**	*Allothunnus fallai*
	C.melampygus		*Auxis spp.*
	C.latus		*Euthynnus spp.*
	C. lugubris		*Katsuwonus pelamis*
	C. ruber		*Thunnus tonggol*
	Carangoides bartholomaei	**TUNA (LARGE)**	*Thunnus alalunga*
	Oligoplites saurus		*Thunnus albacares*
	Selene spp.		*Thunnus atlanticus*
	Seriola rivoliana		*Thunnus maccoyii*
	Urapsis secunda		*Thunnus obesus*
JACK OR BLUE RUNNER	*Caranx crysos*		*Thunnus thynnus*
JACK OR CREVALLE	*Alectis indicus*	**TUNA, AQUACULTURED**	*Thunnus spp.*
JACK OR RAINBOW RUNNER	*Elagatis bipinnulata*	**WAHOO**	*Acanthocybium solandri*
JACK OR ROOSTERFISH	*Nematistius pectoralis*	**YELLOW TAIL OR AMBERJACK**	*Seriola lalandi*
KAHAWAI	*Arripis spp.*	**YELLOWTAIL AMBERJACK, AQUACULTURED**	*Seriola lalandi*
MACKEREL	*Gasterochisma melampus*	**MACKEREL**	*Scrombus scrombus*
	Grammatorcynus spp.		
	Rastrelliger kanagurta		

Laboratory Testing and Methodology Requirements

- Product testing shall be conducted at an accredited ISO/IEC17025 3rd party laboratory OR
- The laboratory shall be operating under the principles of ISO/IEC17025 and participate in an accredited proficiency testing program OR
- The laboratory shall be operating under Good Laboratory Practices (GLPs) and participate in an accredited proficiency testing program.
- Methods shall be published, performance tested methods, such as AOAC, AOAC RI, NordVal AFNOR, Health Canada, and recognized by USFDA (BAM), EU, CFIA or other national regulatory bodies.
- Validation of the approved matrices for the methods used shall be suitable for products undergoing testing.
- The methodology applied for chemical residue testing shall meet the GSA action levels stated in FPT Table 3. The Levels stated are designated as minimum levels of method sensitivity for the chemical residues listed in Tables 3 and 4.
- GSA recognizes that not all countries/regions may have laboratories with accredited scope to the sensitivity stated in GSA Action Levels. All efforts should be made to locate labs capable of achieving these sensitivity levels (LODs, LORs, LOQs). *CBs are asked to contact GSA Program Integrity for consideration where this has not been, or cannot be, achieved.*

Suggested Further Reading

Canadian Food and Inspection Agency Bacteriological Guidelines For Fish and Fish Products- Standards and Methods Manual [Online] // Govenment of Canada. - https://inspection.canada.ca/food-safety-for-industry/food-safety-standards-guidelines/bacteriological-guidelines/eng/1558757049068/1558757132060.

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United States Food & Drug Agency Data Dashboard- Import Refusals [Online]. - www.datadashboard.fda.gov/ora/cd/imprefusals.htm.

United States Food and Drug Adminstration Fish and Fisheries Products Hazards and Controls Guidance [Online]. - June 22 . - www.fda.gov/media/80637/download.

United States Food and Drug Agency FDA and EPA Safety Levels in Regulations and Guidance -Table A5-1 [Online] // Fish and Fisheries Products Hazards and Controls Guidance. - June 2021. - www.FDA.gov/media/80400/download.

Definitions

AFNOR- Association française de normalisation

AOAC – Association of Official Analytical Chemists

BAM – Bacteriological Analytical Manual

CFIA- Canadian Food Inspection Agency

IQF – Individually Quick Frozen

LOQ – Limit of Quantification. A laboratory analyzing substances for which an LOQ is stated must utilize an approved method that has a minimum performance level in keeping with the LOQ.

Microbiological Criteria – Criteria defining the acceptability of a product, a batch of foodstuffs or a process based on the absence, presence or number of micro- organisms and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.

MPN – Most Probable Number

MRPL – Minimum Required Performance Limits – minimum limits for analytical methods used for the detection of banned substances. MRPLs are set by the EU for substances that are banned/not allowed to be used. And have set this limit for the analytical method used for substances for which no safe permitted limit has been established.

NordVal- NorVal International

ppb – parts per billion (µg/kg)

ppm – parts per million (µg/g)

Primary Product Forms - As referred to in the SPS – "Primary Product Form" examples are:

- Fresh
- Raw ready-to-eat (e.g. sashimi, sushi)
- Raw frozen
- Raw breaded
- Cooked breaded
- Cooked
- Dumpling
- Smoked - cold
- Smoked - hot
- Pickled
- Dried
- Canned
- Salted
- Marinated
- Modified Atmosphere

Raw frozen product forms – for the purpose of this definition, include all raw IQF or block frozen products expected to have the same hazards (e.g. microbiological). Examples include: deveined, peeled and deveined, whole, de-headed, butterfly tail on.

Residue analysis – involves both screening and confirmatory methods for identifying residues include Gas Chromatography (GC), High Performance Liquid Chromatography (HPLC) and Liquid Chromatography with Mass Spectrometry (LCMS/MS), ELISA (enzyme-linked Immunoassay) screening.