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

Issue 2.0

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Table of Contents

1.0 Introduction

The purpose of this guidance is to provide operational guidance to the certification bodies, auditors and facilities for Finished Product Testing module sampling and testing. The GSA Seafood Processing Standard (SPS) 6.0 has considered finished product testing through a risk-based approach by addressing: risks associated with the geographical regions of high antibiotic use, risks from facilities that are associated with non-conformities issued by regulatory bodies and risks from facilities that are listed on various refusal/detention/alert lists (US FDA or other international equivalent lists). Such instances are considered non-compliant with the requirements of SPS 6.0.

SPS 6.0 has identified three categories of risk statuses to determine if finished product sampling and testing is required by a facility and whether such facility must be audited to the Finished Product Testing module. The categories are Low Risk Status, Elevated Risk Status, and High Risk Status. Finished product testing is required for all facilities that fall under the Elevated and High Risk status. Such facilities must be audited to the Finished Product Testing (FPT) module during external third-party audits. Low risk facilities are exempt from finished product testing as well as from being audited to the FPT module.

2.0 How to use Annex I

Steps:

1. Refer to section 3.0 Risk Status Identification that provides definitions and criteria for each of the Risk Status categories and helps facilities, CBs and auditors to determine a facility's Risk Status.
2. Upon identification of Risk Status, the facility will determine actions needed for removal from a Risk Status. Instructions are provided so that facilities can implement those actions to achieve and maintain Low Risk Status.
3. If the Risk Status determination of a facility falls under Elevated or High Risk Status categories, then proceed to Section 4.0 Sample Selection – Instructions to understand documentation required, sample compositing, testing and laboratory & methodology requirements.

3.0 Risk Status Identification

3.1 Low Risk Status

3.1.1 Facilities designated as Low Risk Status are those that fall outside of the criteria detailed under sections 3.2 - 3.6. Facilities that have successfully passed Finished Product Testing requirements and other GSA requirements are designated Low Risk Status and exempt from finished product testing during third-party audits as long as Low Risk Status is maintained.

3.2 Elevated Risk Status

Facilities are designated Elevated Risk Status if they fall under any of the criteria from 3.2.1 - 3.2.4 below. Such facilities must be audited to the Finished Product Testing module and must keep testing finished products per FPT Module following this Annex during every SPS certification audit as long as the facility is in Elevated Risk Status.

3.2.1 New[1] facilities applying for SPS certification located in China, Egypt, India, Indonesia, Mexico, Thailand, or Vietnam.

3.2.2 New[1] or Recertifying[2] facilities applying for SPS certification that have been listed on the National/International Refusal/Alert/Detention Lists (e.g., Australia, Canada, Europe, Japan, USFDA , or other equivalents) for microbiological pathogens, banned chemical residues, or histamine within the past 12 months prior to audit start date.

3.2.3 New[1] or Recertifying[2] facilities that have received non-conformities during inspections/audits from local, federal, regional or national inspection agencies for microbiological pathogens, banned chemical residues, or histamine within the past 12 months prior to audit start date.

3.2.4 A facility already under Low Risk Status that does not meet GSA Action levels (i.e., test positive/a failed test) specified in the Finished Product Testing Tables 2, 3, and 4 during a finished product testing event[3].

3.3 Actions Needed for removal from Elevated Risk to Low Risk Status:

3.3.1 New[1] facilities located in China, Egypt, India, Indonesia, Mexico, Thailand, or Vietnam that comply with the all-other criteria and test negative during the initial SPS certification audit can move to Low Risk Status.

3.3.2 For facilities under Elevated Risk Status for 3.2.2 - 3.2.4, moving to Low Risk status requires the following.

3.3.2.a The facility and the CB must follow criteria stipulated in **Potential Non-conformances (PNCs) Independent of Audits (current issue).**

3.3.2.b The CB and GSA will review the findings and determine if a supplementary Targeted Audit[4] that includes assessment of corrective actions and Finished Product Testing as described herein are required.

3.3.2.c The facility must undergo Finished Product Testing during their next SPS certification audit with negative test results and be in full compliance with Finished Product Testing Module.

3.4 High Risk Status

Facilities are designated High Risk Status if they fall under the criteria 3.4.1 below. Such facilities must be audited to the Finished Product Testing module and must keep testing finished products per FPT Module following this Annex during every SPS certification audit as long as the facility is in High Risk Status.

[1] New Facilities – Any facility that has never been audited and certified to any version of the SPS.
[2] Recertifying Facilities – Any facility that has been audited and certified under the GSA Seafood Processing Standard (any version).
[3] Finished Product Testing Event – A testing event could be any testing conducted during the SPS audit (e.g. certification or targeted or supplemental) or by any regulatory body or those that are conducted by customers/buyers or the facility's own testing.
[4] 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.

3.4.1 A facility already in Elevated Risk Status and receives non-conformities specified under 3.2.2 – 3.2.4.

3.5 Actions Needed for removal from High Risk to Elevated Risk Status:

3.5.1 For facilities under High Risk Status, moving to Elevated Risk status requires the following:

3.5.1.a The facility and the CB must follow criteria stipulated in **Potential Non-conformances (PNCs) Independent of Audits (current issue).**

3.5.1.b The CB and GSA will review the findings and determine if a supplementary Targeted Audit[5] that includes assessment of corrective actions and Finished Product Testing as described herein are required.

3.5.1.c The facility must undergo Finished Product Testing during their next two (2) SPS certification audits with negative test results and be in full compliance with Finished Product Testing Module.

3.6 Suspension

3.6.1 A facility that receives three (3) non-conformities specified under 3.2.2 – 3.2.4, and/or 3.4.1 over a three-year period.

3.7 Actions Needed for removal from Suspension to High Risk Status:

3.7.1 For facilities under Suspension, moving to High Risk status requires the following:

3.7.1a The facility may reapply after 12-month suspension period and/or a remediation plan approved by GSA.

[5] 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.

4.0 Sampling Instructions and Testing

4.1.1 All Finished Product sampling must be conducted under the supervision of a third-party CB auditor (unless otherwise requested by GSA Program Integrity). The auditor must supervise the selection and collection of samples to be sent to an ISO 17025 accredited third-party laboratory for testing.

4.1.2 At the opening meeting or by the end of Day 1 of an audit, the auditor must obtain a full inventory of all finished products in storage, and the facility must readily provide this to the auditor. Auditors must use this inventory list to select finished product lots for sampling and testing. The auditor must assess any potential discrepancies including identification codes or traceability codes of products between those in the inventory list to those available physically in storage. No product in storage can be excluded from the finished product inventory list. This includes products designated for local distribution as well as for exports. Sampled finished product lots must be selected by the auditor based on potential risk factors observed viz., high risk (RTE) products, diversity in species, highest production, and primary product forms, etc.

4.1.3 Refer FPT Table 1A, B, C below for sample collection guidance. Primary Product Forms are defined in Section 8.

4.1.4 Species Selection: Refer to FPT Table 1A, B, C below for guidance on species selection. A total of eight (8) samples per source type/species category (aquaculture and/or wild) must be collected from across a maximum of 3 different species (per source type/species category – aquaculture and/or wild) from various finished product lots in the inventory. The number of samples per species depends on the number of species available in storage during the audit (refer to Table 1A, B, C). In the event that less than 3 species are present at the time of sampling, collect 8 samples total from the species that are present at the time of sampling (refer to Table 1A, B, C).

Consideration must be given to these 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 associated with high antimicrobial treatments due to disease likelihood. Wild species related risk factors include species whose finished products may contain histamines versus those that do not contain histamine. Species of higher production volumes may also present a relatively high risk, regardless of source.

4.1.5 Primary Product Forms Selection: Primary Product forms should also be selected based on food safety risk factors. Ready To Eat (RTE) products are considered high risk and should be selected if present. If 2 or more primary product forms are present the auditor must select at least 2 different primary product forms for sampling and one of which must be a high risk (RTE) primary product form, if applicable.

4.1.6 Production Lot Selection: The auditor should select from across as many different production lot codes present at the time of sampling with due consideration to the aspects stated in 4.1.4 and 4.1.5 above. If production lots are segregated into exported versus local destinations, at least 1 lot of locally designated products must be sampled. If a facility processes a majority of fresh chilled seafood, they might not have many different lots as the products are shipped as soon as they are produced. In such a situation the auditor must supervise collection of samples from each day and have the facility ship the samples to the laboratory on last day of the audit. In cases where a processing facility does not have the required number of different production lots in inventory for each species (which may occur in small plants or in plants that produce only fresh chilled products),

additional samples will have to be collected from higher-risk or higher-volume production lots to reach the required number of samples.

4.1.7 The standard sample size for aquaculture and wild species shall be 750g per sample. For aquaculture products only, the sample size should be 1000g for farmed species that are listed in FPT Table 5 of potential Scombrotoxin (Histamine) to accommodate microbiological, residue, and histamine testing portions.

4.1.8 Aseptic[6] sampling protocols must be always followed so as not to contaminate the samples and/or the products at the facility.

4.1.9 The facility must organize the finished product sampling activity and obtain equipment necessary to conduct the sampling: Styrofoam boxes, sterile polyethylene bags (confirm with the contracted laboratory concerning their standard procedures, as they may refuse the samples if improper packaging procedures are used), heat-sealing machines (normally available at the facility), and permanent markers (do not attempt to use stickers, as they may not stick properly to sample bags).

4.1.10 The facility MUST NOT USE permanent markers that may contain prohibited dyes utilized in aquaculture (e.g. black Sharpie markers) to identify the alphanumeric codes on sample bags.

4.1.11 The facility must gather the traceability/chain of custody information related to samples that will be collected and document these details. All samples must be labeled and documentation tracing the sample labels to their original lots must be recorded and provided to the auditor.

4.1.12 The facility must inform the laboratory of the below:

4.1.12.a The expected date and time for delivery of samples – especially if it is outside of normal business hours for the laboratory, so that they can make arrangement to receive and store the samples accordingly.

4.1.12.b The testing must be in accordance with FPT Tables 2, 3 & 4 and GSA Action Levels cited under must be adhered to and results must be reported to the CB & GSA accordingly.

4.1.13 The facility is responsible for all testing costs of collected finished product samples during the audits. SPS sampling requirements do not override legal and/or customer sampling and testing obligations of the facility.

4.1.14 Once testing has been completed, the facility must instruct the laboratory to submit an original copy of the analytical results directly to the CB, with a copy to the facility. The facility must provide these instructions (of sending the results directly to the CB) to the laboratory they work with as the results are generally sent to the party that pays for the testing. Results must be documented in the audit report (FPT Module), and the CB must supply GSA with copies of the test results within 1 week of receipt, via email to GSA Program Integrity[7].

4.1.15 The CB auditors must review the test results submitted by the laboratory and confirm compliance with SPS FPT criteria and work with the CB to update the audit report after final results are obtained (clauses FPT3 and FPT4).

[6] Aseptic Sampling Protocols – Aseptic sampling is a technique used to prevent contamination of food samples during collection samples employing a particular sampling method. Aseptic sampling involves the use of sterile sampling implements and containers.

[7] programintegrity@globalseafood.org

FPT Table 1A: Guidance for Finished Product Sample Collection – Aquaculture & Wild Caught – Microbiological Tests					
	Number of Samples				
Seafood Source	If 1 species processed & available	If 2 species processed & available	If 3 or more species processed & available	**Number of Tests to Perform[8]**	**Composite Sample Description[9]**
Aquaculture and Wild Caught Species	Take 8 samples of one species with due consideration for primary product forms of high-risk (RTE) products, high production volumes, and different production lots	Take 4 samples from each species with due consideration for primary product forms of high-risk (RTE) products, high production volumes, and different production lots	Take 3 samples of two species and 2 samples of the 3rd species with due consideration for primary product forms of high-risk (RTE) products, high production volumes, and different production lots	1 test per product form, per species	≤4 samples per composite **DO NOT COMPOSITE SAMPLES OF DIFFERENT SPECIES OR DIFFERENT PRIMARY PRODUCT FORMS.**

NOTE: Select samples from as many different production lots as practically feasible.

[8] Refer to examples below. Auditors may encounter different scenarios during the audit at the facilities. If in doubt, please reach out to your CB for guidance.
[9] Refer Figure 4.1 – Example of Compositing Samples

FPT Table 1B: Guidance for Finished Product Sample Collection – Aquaculture – Chemical Residue Tests					
	Number of Samples				
Seafood Source	If 1 species processed & available	If 2 species processed & available	If 3 or more species processed & available	**Number of Tests to Perform**	**Composite Sample Description[8]**
Aquaculture Species	Take 8 samples of one species with due consideration for high-risk products, high production volumes and different production lots.	Take 4 samples from each species with due consideration for high-risk products, high production volumes and different production lots.	Take 3 samples of two species and 2 samples of the 3rd species with due consideration for high-risk products, high production volumes and different production lots.	If 1 species: 2 sets of tests as per FPT Table 2 (4 samples in one composite) If 2 species: 1 set of tests as per FPT Table 2 per species (4 samples in one composite) If 3 species: 1 set of tests as per FPT Table 2 per species (3 samples in one composite each and 2 samples in one composite)	≤4 samples per composite. **DO NOT COMPOSITE DIFFERENT SPECIES TOGETHER.** ***DIFFERENT PRIMARY PRODUCT FORMS OF SAME SPECIES MAY BE COMPOSITED TOGETHER.***

NOTE: Select samples from as many different production lots as practically feasible.

FPT Table 1C: Guidance for Finished Product Sample Collection – Aquaculture & Wild Caught – Histamine Tests					
	Number of Samples				
Seafood Source	If 1 species processed & available	If 2 species processed & available	If 3 or more species processed & available	**Number of Tests to Perform**	**Composite Sample Description[8]**
Aquaculture and Wild Caught Species	Take 8 samples of one species with due consideration for high-risk products high production volumes and different production lots.	Take 4 samples from each species with due consideration for high-risk products high production volumes and different production lots.	Take 3 samples of two species and 2 samples of the 3rd species with due consideration for high-risk products, high production volumes and different production lots.	If 1 species: 2 sets of tests as per FPT Table 2 (4 samples per composite) If 2 species: 1 set of tests as per FPT Table 2, per species (4 samples in one composite) If 3 species: 1 set of tests as per FPT Table 2 per species (3 samples in one composite each and 2 samples in one composite)	≤4 samples per composite. **DO NOT COMPOSITE SAMPLES OF DIFFERENT SPECIES OR PRIMARY PRODUCT FORMS.**

NOTE: Select samples from as many different production lots as practically feasible.

4.2 Sample Documentation

Auditors must obtain the information below and submit the documentation to the CB and the CB must forward these onward to GSA.

- A copy of the 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 (as an Excel file)
- Facility name and GSA Facility number
- Third-party laboratory name, address and contact details
- Sampling date and times
- Species (Scientific/Latin 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, traceability 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.

4.3 Compositing Instructions

4.3.1 The facility is responsible for informing the lab about compositing samples correctly. This can be achieved either by ensuring the lab has a copy of, and ensuring conformance to, this guidance, and/or by providing detailed instructions to the lab based on the samples submitted.

4.3.2 The physical compositing of samples is to be done at the third-party laboratory by qualified personnel of the laboratory based on instructions from the facility.

4.3.3 Before compositing is done, samples must be split so there will be reserve portions of each sample available in case follow-up breakout testing for one or more parameters is required when the sample tests positive for any tested parameter.

4.3.4 No more than 4 samples can be combined into a single composite. No compositing between aquaculture (farm raised) products and wild-caught fishery products is allowed.

4.3.5 Compositing across primary product forms is acceptable for Chemical residue testing ONLY. Mixing primary product forms is NOT allowed for microbiological and histamine tests.

Example 1. Aquaculture Species

***Example 1 - Number of samples per species, primary product forms and production volumes*:**

A processing facility 's production records/inventory state the following:
L. vannamei – 3,500 MT

P. monodon – 950 MT

O. niloticus – 875 MT

Seriola lalandi – 525 MT

On the day of sampling, the following primary product forms are observed in inventory and storage:
White shrimp (*L. vannamei*) – raw frozen IQF, raw frozen block, breaded frozen, cooked frozen
Black tiger shrimp (*P. monodon*) – raw frozen IQF, raw frozen block
Nile tilapia (*O. niloticus*) – raw frozen fillets, breaded frozen fillets
Yellowtail (*Seriola lalandi*) – raw frozen fillets

Total number of samples to take from various production lots in the inventory = 8 as follows:

- *L. vannamei* = 3 samples randomly selected between raw, breaded and cooked primary product forms and different production lots. In this instance, raw frozen IQF and raw frozen block are considered a single primary product form.
- *P. monodon* = 0 samples as another crustacean species (*L. vannamei*) is being sampled which has an RTE primary product form and is high in production volume.
- *O. niloticus* = 2 samples randomly selected between fillet and breaded primary product forms and different production lots.
- *Seriola lalandi* = 3 samples randomly selected of raw frozen fillets from different production lots.

An acceptable sample collection for the above example is shown below:

Species	Number of Samples	Primary Product Forms	Rationale
L. vannamei	3	Raw frozen IQF – 1 sample Breaded frozen – 1 sample Cooked frozen – 1 sample	RTE – high risk product and high production volume
Seriola lalandi	3	Frozen Fillets – 3 samples from different production lots	Histamine
O. niloticus	2	Raw frozen fillet – 1 sample Breaded frozen fillet – 1 sample	A different species (finfish), breaded primary product form and high production volume
Total	**8**		

NOTE: Although *P. monodon* is high in production volumes compared to *O. niloticus* and *Seriola lalandi,* it is not selected for sampling as one shrimp species of high production and RTE primary product form has been selected.

Example 1 - Laboratory testing enumerations and compositing samples:

Microbiological and Chemical Residue Testing can be determined as follows:

Microbiological Testing per FPT Table 2:

- *L. vannamei:* 3 samples total and 3 primary product forms. Number of microbiological tests required = 3. Lots obtained are from different primary product forms and cannot be composited.

  Examples of acceptable composites:

  Composite 1: NO composite (1 sample per test) as only one sample of raw frozen IQF has been collected.

  Composite 2: NO composite (1 sample per test) as only one sample of breaded frozen has been collected.

  Composite 3: NO composite (1 sample per test) as only one sample of cooked frozen has been collected.

- *Seriola lalandi:* 3 samples total and 1 primary product form. Number of microbiological tests required = 1. Composite the 3 individual samples into one composite . Since all samples are raw primary product forms the 3 samples can be composited into 1 composite.

- *O. niloticus*: 2 samples total and 2 primary product forms. Number of microbiological tests required = 2. Lots obtained are from different primary product forms and cannot be composited.

  Examples of acceptable composites:

  Composite 1: NO composite (1 sample per test) as only one sample of raw frozen fillet has been collected.

  Composite 2: NO composite (1 sample per test) as only one sample of breaded frozen has been collected

Chemical Residue Testing per FPT Table 3:

- *L. vannamei:* 3 samples total. Number of Chemical residue tests required = 1. Composite 3 individual samples into one. When possible, laboratories may try to separate raw and cooked samples when compositing; however, mixing across primary product forms is acceptable for chemical residue testing. Note that in this case the 3 samples could be combined into 1 composite for testing for chemical residues.

- *Seriola lalandi:* 3 samples total. Number of chemical residue tests required = 1. Composite 3 individual samples into one composite test.

- *O. niloticus*: 2 samples total. Number of chemical residue tests required = 1. Composite 2 individual samples into one composite test.

Histamine Testing for Aquaculture Species per FPT Table 4:

As *Seriola lalandi* is a histamine susceptible species, the 3 samples collected must be subject to histamine

Lab	ABC Laboratory
Plant Name	Example Plant
Sampling Date	10-Oct-2025
Total Species	3

Sample details/information to Lab

ID Code (per sample)	LOT ID	Source	Species	Primary Product Form	Chemical Residue (FPT Table 3)	Micro (no Listeria) (FPT Table 2)	Listeria (FPT Table 2)	Histamine (FPT Table 4)
A1	Lot 101	Aquaculture	Litopenaeus vannamei	Frozen IQF	COMPOSITE 3 SAMPLES	TEST 1 SAMPLE		NO TEST
A2	Lot 102		Litopenaeus vannamei	Breaded Frozen		TEST 1 SAMPLE		
A3	Lot 103		Litopenaeus vannamei	Frozen Cooked		TEST 1 SAMPLE		
A4	Lot 104		O.niloticus	Raw Frozen Fillet	COMPOSITE 2 SAMPLES	TEST 1 SAMPLE		
A5	Lot 105		O.niloticus	Breaded Frozen Fillet		TEST 1 SAMPLE		
A6	Lot 106		Seriola lalandi	Raw Frozen Fillet	COMPOSITE 3 SAMPLES	COMPOSITE 3 SAMPLES		COMPOSITE 3 SAMPLES
A7	Lot 107		Seriola lalandi	Raw Frozen Fillet				
A8	Lot 108		Seriola lalandi	Raw Frozen Fillet				

testing as well. Note that an extra 250g might be needed per aquaculture histamine species sampled in order to ensure enough material is available for testing.

- *Seriola lalandi:* 3 samples total. Number of histamine tests required = 1. Composite 3 individual samples into one composite test.

Figure 4.1 - Example 1 Finished Product Testing Plan [10]

Example 2 - Wild-caught Species

Example 2 - *Number of samples per species, primary product forms and production volumes*:

A seafood processing facility provides an inventory list containing the following information concerning wild-caught species they process (Note: lot codes are required on inventory sheets for traceability purposes but have been omitted for this exercise):

King Mackerel, *Scomberomorus cavalla* – Frozen Fillets/Steaks, Cold Smoked, Hot Smoked – 356MT
Swordfish, *Xiphias gladius* – Frozen Fillets/ Steaks – 310MT
Sea Scallops, *Placopecten magellanicus* – Raw IQF – 155MT
Bay Scallops, *Argopecten irradians* – Raw IQF – 176MT
Albacore Tuna, *Thunnus alalunga* – Canned – 550MT
Yellowfin Tuna, *Thunnus albacares* – RTE Frozen Sushi, Frozen Steaks – 109MT

- Sample selection must consider Microbiological and Histamine food safety risks.
- Attempts should be made to sample different primary product forms between the species

[10] Figure 4.1 is only an example of possible sample compositing. Auditors may encounter different scenarios during the audit at the facilities. If in doubt, please reach out to your CB for guidance.

selected.

- Histamine samples include King Mackerel, Albacore Tuna, Yellowfin Tuna.
- The selections indicated in Solutions A or B would be considered acceptable:

Example 2 - Solution A

Species	Number of Samples	Primary Product Forms	Rationale
King Mackerel	3	Cold smoked – 1 sample Hot smoked – 1 sample Frozen fillets – 1 sample	Histamine, RTE – high risk product and high production
Yellowfin Tuna	3	RTE Frozen Sushi – 2 samples Frozen steaks – 1 sample	Histamine, RTE – high risk product
Albacore Tuna	2	Canned – 2 samples from different production lots	Histamine, High production
Total	**8**		

NOTE: Albacore Tuna for histamine ONLY.

Example 2 Solution A. Laboratory testing enumerations and compositing samples:

Microbiological Testing per FPT Table 2:

King Mackerel: 3 samples total and 3 primary product forms. Number of microbiological tests required = 3. Lots obtained are from different primary product forms and cannot be composited.

Examples of acceptable composites:

Composite 1: NO composite (1 sample per test) as only one sample of cold smoked has been collected.

Composite 2: NO composite (1 sample per test) as only one sample of hot smoked has been collected.

Composite 3: NO composite (1 sample per test) as only one sample of frozen fillets has been collected.

Yellowfin Tuna: 3 samples total and 2 primary product forms. Number of microbiological tests required = 2 – one per each primary product form. Composite 2 individual samples per composite of RTE Frozen Sushi into 1 composite. NO composite of frozen steaks (1 sample per test) as only one sample is collected.

Albacore Tuna: NO microbiological tests required.

Histamine Testing per FPT Table 4:

King Mackerel: 3 samples total and 3 primary product forms. Number of histamine tests required = 3 – one for each primary product form. Lots obtained are from different primary product forms and cannot be composited.

Yellowfin Tuna: 3 samples total and 2 primary product forms. Number of histamine tests required = 2 – one for each primary product form. Lots obtained are from different primary product forms and cannot be composited.

Albacore Tuna: 2 samples total and 1 primary product form. Number of histamine tests required = 1.

Example 2 - *Solution B*

Species	Number of Samples	Primary Product Forms	Rationale
King Mackerel	3	Cold smoked – 1 sample Hot smoked – 1 sample Frozen fillets – 1 sample	Histamine, RTE – high risk product and high production
Yellowfin Tuna	3	RTE Frozen Sushi – 2 samples Frozen steaks – 1 sample	Histamine, RTE – high risk product
Swordfish	2	Frozen Fillets/ Steaks – 2 samples	Histamine, High production
Total	**8**		

NOTE: Although Albacore Tuna is the highest produced product form it is not selected for microbiological testing as it is a canned product.

Example 2 Solution B. ***Laboratory testing enumerations and compositing samples:***

Microbiological Testing per FPT Table 2:

King Mackerel: 3 samples total and 3 primary product forms. Number of microbiological tests required = 3. Lots obtained are from different primary product forms and cannot be composited.

Examples of acceptable composites:

Composite 1: NO composite (1 sample per test) as only one sample of cold smoked has been collected.

Composite 2: NO composite (1 sample per test) as only one sample of hot smoked has been collected.

Composite 3: NO composite (1 sample per test) as only one sample of frozen fillets has been collected.

Yellowfin Tuna: 3 samples total and 2 primary product forms. Number of microbiological tests required = 2 – one per each primary product form. Composite 2 individual samples per composite of RTE Frozen Sushi into 1 composite. NO composite (1 sample per test) of frozen steaks as only one sample collected.

Swordfish: 2 samples total and 1 primary product form. Number of microbiological tests required = 1.

Histamine Testing per FPT Table 4:

King Mackerel: 3 samples total and 3 primary product forms. Number of histamine tests required = 3 – one for each primary product form. Lots obtained are from different primary product forms and cannot be composited.

Yellowfin Tuna: 3 samples total and 2 primary product forms out of which one sampled. Number of histamine tests required = 2 – one for each primary product form. Lots obtained are from different primary product forms and cannot be composited.

Swordfish: 2 samples total and 1 primary product form. Number of histamine tests required = 1 composite test of 2 samples. Lots obtained are from same primary product forms and can be composited.

Figure 4.2 - *Example 2 Solution B Finished Product Testing Plan example* [11]

Lab	ABC Laboratory
Plant Name	Example 2 Plant
Sampling Date	10-Oct-2025
Total Species	3

Sample details/information to Lab

ID Code (per sample)	LOT ID	Source	Species	Primary Product Form	Chemical Residue (FPT Table 3)	Micro (no Listeria) (FPT Table 2)	Listeria (FPT Table 2)	Histamine (FPT Table 4)
A1	Lot 101	Wild Caught	King Mackerel	Cold Smoked	NO TEST	TEST 1 SAMPLE		TEST 1 SAMPLE
A2	Lot 102		King Mackerel	Hot Smoked		TEST 1 SAMPLE		TEST 1 SAMPLE
A3	Lot 103		King Mackerel	Frozen Fillet		TEST 1 SAMPLE		TEST 1 SAMPLE
A4	Lot 104		Yellowfin Tuna	RTE Frozen Sushi		COMPOSITE 2 SAMPLES		COMPOSITE 2 SAMPLES
A5	Lot 105		Yellowfin Tuna	RTE Frozen Sushi				
A6	Lot 106		Yellowfin Tuna	Frozen Steak		TEST 1 SAMPLE		TEST 1 SAMPLE
A7	Lot 107		Swordfish	Frozen Fillet/Steak		COMPOSITE 2 SAMPLES		COMPOSITE 2 SAMPLES
A8	Lot 108		Swordfish	Frozen Fillet/Steak				

[11] Figure 4.2 is only an example of possible sample compositing. Auditors may encounter different scenarios during the audit at the facilities. If in doubt, please reach out to your CB for guidance.

FPT Table 2: Microbiological Testing Criteria (Aquaculture and Wild)			
Product Forms	**Microbiological Criteria**	**Species Category/Primary Product Forms**	**GSA Action Level****
Raw **and** Ready to Eat	*Escherichia coli*	Finfish and crustaceans (all forms), and processed*** or cooked molluscan shellfish	Out of 5 subsamples, reject if 3 or more subsamples exceed 4 per gram; 1 or more subsamples exceed 40 bacteria per gram (MPN) [(a)] **OR** Less than or equal to 40 CFU/g[12]
Raw **and** Ready to Eat	*Escherichia coli*	Shell stock, fresh-shucked thawed and frozen shellfish, shellfish frozen on half shell	Out of 5 subsamples, reject if 1 or more subsamples exceed 330 bacteria per 100g, or if 2 or more subsamples exceed 230 bacteria /100g (MPN) [(b)] **OR** Less than or equal to 230MPN/100g[13]
Raw **and** Ready to Eat	*Staphylococcus aureus*	Finfish and crustaceans – all forms of fresh and frozen	**Using only 1 of 2 possible tests methods:** Reject if positive for either Staphylococcal enterotoxin[(c)], **OR** a level equal to or greater than 1 x 10^4 bacteria per g (MPN) [(d)]
Ready to Eat **Only**	Salmonella spp.	Finfish, crustaceans and molluscan shellfish – all forms fresh and frozen	Reject if presence is detected in 25 grams
Ready to Eat **Only**	*Listeria monocytogenes*	Finfish, crustaceans and 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

(a) 3-tube MPN analysis acceptable for finfish, crustaceans, processed molluscan shellfish (BAM-4)
(b) 5-tube MPN analysis for raw and frozen forms of non-processed shellfish described (BAM-4)
(c) USFDA. Bacteriological Analytical Manual (Current Issue), Chapter 13B Staphylococcal Enterotoxins Detection Methods.
(d) USFDA. Bacteriological Analytical Manual (Current Issue), Chapter 12 Staphylococcus aureus or; AOAC International. 1995. Official Methods of Analysis, (Current Edition), method 987.09
** GSA Action Level – at or above these levels an action is initiated by the GSA. Published methods must meet or exceed the sensitivity stated in FPT Table 2.
*** For the purposes of these criteria, "processed" means any production process that could be applied to molluscan shellfish, and includes any combination of the following: Shucked, dried, smoked, marinated, salted, pickled, breaded, and cooked.

NOTE: Acceptable Test Methods – Use either BAM/AOAC. Other published methods of a sensitivity equal to or more sensitive than the stated method may also be used, provided such methods and levels used in the countries of destination, are published, and approved by the USFDA, USDA, EU or CFIA, or other national regulatory bodies, and verifiable documented evidence of their approval are provided.

[12] No subsamples are taken for this test.

NOTE: Molluscan Shellfish are tested for microbiological parameters ONLY per FPT Table 2. Chemical reside testing is NOT required.

NOTE: Canned/LACF seafood is tested for chemical/histamine residue ONLY per FPT Table 3 & 4. Microbiological testing is NOT required.

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

Acceptable Test Methods*	Banned Chemical Residue - Aquaculture Chemical	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	5.0	no residue permitted
	Flumequine		
	Oxolinic acid		

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

Acceptable Test Methods*	Chemical Residue - Aquaculture Chemicals 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: HPLC, -MS/MS Chromatography-Spectrometry/GC	Sulfonamide (parent Chemical)	10.0	no residue permitted in unapproved species[(a)]
	Oxytetracycline	10.0	no residue permitted in unapproved species[(b)]
	Tetracycline	10.0	no residue permitted in unapproved species[(b)]
	Florfenicol	10.0	no residue permitted in unapproved species[(b)]

(a) Specified residue levels of Sulfadiazine and Sulfadimethoxine may be permissible in some countries.
(b) Specified residue levels of Oxytetracycline, Tetracycline, and Florfenicol may be permissible in some countries.

* Other published methods of a sensitivity equal to or more sensitive than the stated method may also be used, provided such methods and levels used in the countries of destination, are published, and approved by the USFDA, USDA, EU or CFIA, or other national/international regulatory bodies, and verifiable documented evidence of their approval are provided to the CB and GSA.
** GSA Action Level – at or above these levels an action is initiated by the GSA. Levels stated are designated as minimum levels of testing for the laboratory method sensitivity for FPT Table 3. Levels stated are designated as minimum levels of testing laboratory method sensitivity for FPT Table 3.

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)	35 ppm	35 ppm

** GSA Action Level – at or above these levels an action is initiated by the GSA. Published methods must meet or exceed the sensitivity stated in FPT Table 4.

FPT Table 5. Fish Species of Potential Scombrotoxin (Histamine)[13]

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.*	**SWORDFISH**	*Xiphias gladius*
JACK **JACK OR BLUE RUNNER**	*C. ignobilis*	**TREVALLY**	*Caranx spp.*
	C.melampygus	**TUNA (SMALL)**	*Allothunnus fallai*
	C.latus		*Auxis spp.*
	C. lugubris		*Euthynnus spp.*
	C. ruber		*Katsuwonus pelamis*
	Carangoides bartholomaei		*Thunnus tonggol*
	Oligoplites saurus	**TUNA (LARGE)**	*Thunnus alalunga*
	Selene spp.		*Thunnus albacares*
	Seriola rivoliana		*Thunnus atlanticus*
	Urapsis secunda		*Thunnus maccoyii*
	Caranx crysos		*Thunnus obesus*
JACK OR CREVALLE	*Alectis indicus*		*Thunnus thynnus*
JACK OR RAINBOW RUNNER	*Elagatis bipinnulata*	**TUNA, AQUACULTURED**	*Thunnus spp.*
JACK OR ROOSTERFISH	*Nematistius pectoralis*	**WAHOO**	*Acanthocybium solandri*
KAHAWAI	*Arripis spp.*	**YELLOW TAIL OR AMBERJACK**	*Seriola lalandi*
MACKEREL	*Gasterochisma melampus*	**YELLOWTAIL AMBERJACK, AQUACULTURED**	*Seriola lalandi*
	Grammatorcynus spp.	**MACKEREL**	*Scrombus scrombus*
	Rastrelliger kanagurta		

[13] Not an exhaustive list.

5.0 Laboratory Testing and Methodology Requirements

5.1 The facility must ensure that the laboratory they contract adheres to the below.

5.1.1 Finished Product testing must be conducted at an accredited ISO 17025 third-party laboratory.

5.1.2 The methods used by the laboratory must 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.

5.1.3 Validation of the approved matrices[14] for the methods used must be suitable for products undergoing testing.

5.1.4 The methodology applied for chemical residue testing must 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 FPT Tables 3 and 4.

5.2 GSA recognizes that not all countries/regions may have laboratories with accredited scope to the sensitivity stated under GSA Action Levels. All efforts should be made to locate labs capable of achieving these sensitivity levels (LODs, LOQs, LORs). CBs must contact GSA Program Integrity for consideration where this has not been or cannot be achieved.

6.0 Detections and Results

6.1 Microbiological Detections

6.1.1 A detection on a composite requires breakout testing (of individual samples) only if the result exceeds GSA Action Levels (FPT Table 2). Individual samples testing above the GSA Action Levels in FPT Table 2 are considered a Failed Test Result.

6.1.2 E. coli and Staphylococcus results showing detections but not exceeding GSA Action Levels are to be reported as detections and not failures for that composite.

6.1.3 Any composite testing above GSA Action Levels for Staphylococcus aureus, Salmonella sp., or Listeria monocytogenes stated in FPT Table 2, requires immediate notification to the overseeing Certification Body and GSA, and the facility must inform the contracted laboratory of this requirement. All potential violative sample production lots must be identified within the notification and the laboratory should proceed with confirmatory testing on individual samples comprised in the composite for the Microbiological Criteria detected to determine the violative sample production lot(s). Original copies of test results for detections and failures must be sent to GSA Program Integrity from the laboratory.

6.2 Chemical Residue Detections

A chemical residue detection on a composite that is proportionately capable of exceeding GSA Action Levels specified in FPT Table 3 must be broken out into individual samples (using the reserve portions of the associated sample lots) for confirmatory testing to determine which sample production lot(s) may be adulterated. Chemical residue detection requires immediate notification

[14] To ensure method reliability, laboratories must perform matrix validation, a process demonstrating that an analytical method performs accurately, precisely, and consistently when applied to the specific product matrices being tested. This involves using representative matrices to prove the method's sensitivity, selectivity, and specificity, thereby confirming its fitness for its intended purpose and its ability to produce meaningful and reliable results for that specific product.

to the overseeing Certification Body and GSA. Original copies of test results for detections and failures must be sent to GSA Program Integrity from the laboratory.

6.3 If breakout testing is conducted either for microbiological or chemical residue detections, ONLY THE SAMPLES IN THE COMPOSITE PRODUCING THE DETECTION MUST BE RETESTED (USING THE RESERVE PORTIONS), AND ONLY FOR THOSE PARAMETER(s) THAT RESULTED IN A POSITIVE DETECTION.

6.4 Determination of breakout testing for a composite chemical residue detection:

Example: the laboratory conducts chemical residue tests on a composite consisting of 2 individual samples. Results indicate a positive detection for Chloramphenicol at a 0.15 µg/kg or ppb. Per FPT Table 3, the GSA Action Level for Chloramphenicol is listed as 0.3 µg/kg or ppb. As the detection observed is proportionally capable of exceeding GSA Action Limits, the 2 samples that comprise the composite must be retested individually for Chloramphenicol to determine the violative sample production lot(s). If one of the individual samples tested equal to or above 0.3 µg/kg it is deemed a failed test.

Proportions can be estimated by:

(detection concentration) x (# samples) ≥ Limit

Using the above example:

0.15 x 2 = 0.3 (which is ≥ 0.3 µg/kg GSA Action Level)

7.0 Suggested Further Reading[15]

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

Canadian Food Inspection Agency Canadian Food Inspection Agency Standards and Methods Manual (2013) Appendix 1A – CFIA Aquaculture Therapeutant Residue Monitoring. [Online]. - 2013. - https://epe.lac-bac.gc.ca/100/206/301/cfia-acia/2011-09-21/inspection.gc.ca/english/fssa/fispoi/man/samnem/app1ae.pdf

Codex Alimentarius Codex Standard for Canned Finfish [Report]: Food and Agriculture Organization of the United Nations. World Health Organization, 2016.

John DeBeer Jon W. Bell, Fred Nolte, et al Histamine Limits by Country: A Survey and Review [Journal]: Journal of Food Protection, 2021. - 9: Vol. 84. https://www.sciencedirect.com/science/article/pii/S0362028X22054606

Official Journal of the European Union Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs [Online]. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005R2073&from=EN

Official Journal of the European Union – Commission Decision of 13 March 2003 amending Decision 2002/657/EC as regards the setting of minimum required performance limits (MRPLs) for certain residues in food of animal origin [Online]. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003D0181&qid=1760545260429

Schar D., Klein, E.Y., Laxminarayan, Marius Gilbert & Thomas P. Van Boeckel Global Trends in antimicrobial use in aquaculture [Journal] / Scientific Reports. - [s.l.]: Scientific Reports, 2020. - 21878: Vol. 10. https://pmc.ncbi.nlm.nih.gov/articles/PMC7736322/pdf/41598_2020_Article_78849.pdf

T. Surya* B. Sivaraman, V. Alamelu, A. Priyatharshini, U. Arisekar and S. Sundhar, Rapid Methods for Histamine Detection in Fishery Products [Journal]. - [s.l.]: International Journal of Current Microbiology and Applied Sciences, 2019. - 22319-7706: Vol. Volume 8 Number 03. https://ijcmas.com/8-3-2019/T.%20Surya,%20et%20al.pdf

United States Department of Agriculture Food Safety and Inspection Service CLG-MRM1.08. Screening and Confirmation of Animal Chemical Residues by UHPLC-MS-MS. [Online]. https://www.fsis.usda.gov/sites/default/files/media_file/2020-09/CLG-MRM1.pdf

United States Food & Chemical Agency Data Dashboard- Import Refusals [Online]. https://datadashboard.fda.gov/oii/cd/imprefusals.htm

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

[15] Please check weblinks as they may have moved or changed by the respective owners of the websites.

United States Food and Chemical 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

United States Food and Chemical Administration Bacteriological Analytical Manual (BAM), BAM 4: Enumeration of Escherichia coli and the Coliform Bacteria – https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm064948.htm

Official Journal of European Union – COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R0037&qid=1760545643199

United States Department of Agriculture Food Safety and Inspection Service. CLG-FLOR1.04. Determination and Confirmation of Florfenicol. https://www.fsis.usda.gov/wps/wcm/connect/58ba54c7-2c8c-4742-bb4f-a45fe18a8887/CLG_FLOR_1_04.pdf?MOD=AJPERES

United States Food and Chemical Administration Elemental Analysis Manual for Food and Related Products 4.8. High Performance Liquid Chromatographic-Inductively Coupled Plasma-Mass Spectrometric Determination of Methylmercury and Total Mercury in Seafood. Version 1 (June 2008). https://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM479981.pdf

AOAC Official Method 977.13. Histamine in Seafood, Fluorometric Method. AOAC INTERNATIONAL. http://www.aoac.org/aoac_prod_imis/AOAC_Docs/OMA/977_13aoacmethod.pdf

Codex Alimentarius 2016. Standard for Canned Finfish. Codex Standard 119-1981. Food and Agriculture Organization of the United Nations. World Health Organization.

8.0 Acronyms and Definitions

AFNOR – Association Française de Normalisation – a French national standardization body provides internationally recognized testing method validation through its NF Validation program.

AOAC – Association of Official Analytical Chemists

AOAC RI – Association of Official Analytical Chemists Research Institute – is an affiliate of AOAC International and administers the Performance Tested Methods℠ (PTM) and Reviewed & Recognized℠ (R^2) certification programs including method validation services.

BAM – Bacteriological Analytical Manual

CFIA – Canadian Food Inspection Agency

IQF – Individually Quick Frozen

LOD – Limit of Detection – The lowest concentration that can be detected (but not necessarily quantified accurately).

LOQ – Limit of Quantification – It is the lowest concentration of an analyte (substance being measured) in a sample that can be quantitatively determined with acceptable precision and accuracy under stated experimental conditions. **Below the LOQ** – the analyte may still be detected, but the measurement is too uncertain for reliable quantification. **Above the LOQ** – the concentration can be reported with confidence, since the analytical method provides reproducible and accurate values. Always higher than LOD, since it requires a stronger confidence level and precision in measurement. LOQ is a technical capability (lowest concentration that can be reliably quantified with precision and accuracy).

LOR – Limit of Reporting – sometimes also called the Reporting Limit – it is the lowest concentration of an analyte that a laboratory will routinely report in test results, based on its validated method and quality assurance practices. LOR is a policy or reporting threshold (lowest concentration that the lab will officially state in the report to ensure results are meaningful for regulatory, client, or accreditation requirements). It may be equal to or higher than LOQ depending on the lab's procedures and agreements with the clients. For example: A pesticide method has an LOQ of 0.005mg/kg and the lab decides to set an LOR of 0.01mg/kg meaning anything below that will be reported as "<0.01mg/kg" (not detected above the reporting limit).

In short: LOD – "I can detect it's there"; LOQ – "I can measure it with confidence"; LOR – "This is the lowest value I will report".

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

MPN – Most Probable Number – is a statistical method used to estimate the concentration of viable microorganisms in a sample, especially when the organisms are present at low levels or difficult to count directly. In other words, MPN is an index of the number of microorganisms in a sample, obtained by inoculating multiple tubes of liquid growth medium at several dilutions and then statistically analyzing the pattern of positive (growth) and negative (no growth) results.

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 – NordVal International – is a Nordic validation and certification system for alternative microbiological test methods.

ppb – parts per billion (µg/kg)

ppm – parts per million (mg/kg)

Primary Product Forms – is the basic way a seafood is prepared for a particular intended use by the customer/consumer without any addition of secondary products like vegetables or meat or other seafood mixed into it. As referred to in the SPS – "Primary Product Form" examples are:

- Raw Fresh Chilled/Refrigerated
- Raw Frozen
- Raw Breaded
- Raw Marinated
- Raw Ready to Eat
- Cooked Ready to Eat
- Cold Smoked
- Hot Smoked
- Cured/Dried/Dehydrated/Pickled/Fermented
- Canned/LACF
- Canned/Refrigerated

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.

Finished Product Testing Event – A testing event could be any testing conducted during the SPS audit (e.g. certification or targeted supplemental) or by any regulatory body or those that are conducted by customers/buyers or the facility's own testing.