FACILITY GUIDANCE FOR SPS 5.0 ANNEX 4 PRODUCT TESTING

Applicable to

SEAFOOD PROCESSING STANDARD (SPS) – all current versions

This guidance is to be applied to Annex 4 Sampling and Testing Verification Requirements for all ongoing Seafood Processing Standard (SPS) audits. It is intended to help clarify the requirements of SPS Finished Product testing. **Facilities are recommended to share this guidance and all Reference Documents (Section 1. Below) with laboratories conducting tests to Annex 4.**

Sections

1. Reference Documents (current versions are found on the BAP website: https://www.bapcertification.org/Standards)

a) Seafood Processing Standard
b) Supplementary Interpretation for Applicants and Auditors
c) Sampling & Testing Requirements – SPS Farmed
d) Sampling & Testing Requirements – SPS Wild

2. Description of Annex 4 – Sampling and Testing Verification Requirements

Annex 4 of SPS establishes facility testing requirements for Finished Product Testing. There are four different conditions in which sampling may occur:

i) During the Audit – collection by auditor (A4 1.0)
ii) During the Audit – collection by 3rd party samplers (A4 2.0)
iii) Once Certified – Ongoing Monitoring, collection by facility (A4 3.1-3.4)
iv) Once Certified – Ongoing Monitoring, collection by 3rd party samplers (A4 3.5-3.9)

For detailed information on these conditions, refer to the individual sections in SPS (Reference 1.a). Briefly these are described below:

i) & ii) During the audit: Facilities shall provide the CB-assigned auditor and/or 3rd party sampler a complete copy of the facility full current product inventory sheet prior to sampling. Auditors or samplers shall select the lots to sample, arrange and supervise the collection, labeling, and shipment to a qualified 3rd party lab. Facilities may be asked to help collect the samples and bring packaged product to the designated sample collection area.

iii) Collection by facility: Facilities shall randomly collect the required number of samples per species based on the guidance in references cited at 1.c & 1.d, label them, and ship them to a qualified 3rd party lab.

iv) Collection by 3rd party: Facilities shall provide a BAP or CB designated 3rd party sampler a full current product inventory sheet at short notice (1-2 days) upon request. Samplers shall arrive at the facility, select the lots to sample, arrange and supervise the collection, labeling, and shipment to a qualified 3rd party lab. Facilities may be asked to help collect the samples and bring packaged product to the designated sample collection area.

3. Collection of samples

3.1 Aquaculture Products

The number of samples of aquaculture products are based on volume of production per species for the last calendar year:

Table 1. Volume (total production) for last calendar year of individual species and sample collection size per species

Volume (MT) per species	Number of Samples per Species
0-1,000	4
1,001-3,000	8
>3000	12

Individual samples shall consist of single lots of 750g of product. Samples should be taken from separate lots across various product forms currently available in the current product inventory provided by the facility. Samples should target product that appears to be in a high-risk category. Examples include RTE product and product where traceability appears suspect (e.g. temporary packaging, not labeled properly, no traceability). Individual samples shall be individually packaged and labeled. For additional information see Reference 1.c.

3.2 Wild-Caught Products

A total of twelve (12) samples shall be collected from across a maximum of 3 different species from separate lots as follows:

Table 2. Sample collection sizes for wild-caught species based on the numbers of species present at the time of sampling.

Number of Species Present	Number of Species to Sample	Number of Samples per Species	Number of Primary Product Forms per Species
> 3	3	4	1
2	2	6	2
1	1	12	3

Product forms should be of high-risk material including RTE and Histamine and Mercury susceptible species. Individual samples shall be individual packaged and labeled. For more information see Reference 1.d.

4. Laboratory Selection

Facilities need to ensure that the selected laboratories meet the following requirements:

- Accredited to ISO 17025 or equivalent standards.
- Be able to test for all parameters listed in Annex 4.
- Meet sensitivities (e.g. LODs, LORs, LOQs) equal to or more sensitive than the specified GAA-BAP Action Levels stated in Annex 4 of SPS 5.1 (or current version).
  NOTE All efforts should be made to locate labs capable of achieving these sensitivity levels (LODs, LORs, LOQs); however, BAP recognizes this is not always possible. Facilities and CBs are asked to contact BAP Program Integrity for consideration where this cannot be achieved.

For additional information see reference 1.b.

5. Sending Samples to the Laboratory

Unless otherwise instructed by GAA, auditors, or 3rd party samplers, facilities are responsible for packaging samples according to laboratory instructions for delivery to the laboratories. Facilities shall cover the costs for materials and shipping/delivery.

6. Compositing of Samples by the Laboratory

6.1 Aquaculture Products

All compositing shall be done at the laboratory. The following criteria shall be followed:

a) Composites shall consist of 1-4 separate samples (sampled from separate lots). No more than 4 samples can composited together.
b) Drug residue testing can combine different primary product forms. Note: Laboratories may advise that marinated product should not be composited with other primary product forms.
c) Microbiological testing must consist of the same primary product forms.
d) Before samples are composited, an individual portion of each sample must be retained to test in the event a substance is detected in its composite. When compositing, labs should use only the amounts necessary to complete the initial tests using the composited sample for both microbiological and drug residue testing.
e) When a composite test results in a detection or failure the retained samples from individual samples (lots) comprising that composite must be tested individually for the specific parameter detected to determine the contaminated lot(s). **BAP Office and the CB must be notified immediately regarding any failure in Finished Product Verification testing**, regardless if the test purpose was for the audit or Plant Ongoing Monitoring. No re-testing or substitution of samples is permitted.

6.2 Wild Products

All compositing shall be done at the laboratory. The following criteria shall be followed:

a) Composites shall consist of up to 4 separate samples (sampled from separate lots).
b) Microbiological testing must consist of the same primary product forms.
c) Environmental contaminant/toxin testing must also consist of same primary product forms.
d) When compositing, labs should follow the same process as in 5.1.d).

7. Testing by the Laboratory

7.1 Aquaculture Products

a) For required parameter testing and limits see Annex 4 in reference 1.a and reference 1.b
b) The initial (composite) number of drug residue and microbiological tests per species is based on Table 3 located on the last page of this guidance document.
c) Microbiological tests
i. *E.coli* – each *E.coli* test requires a 5 sub-sample analysis (whether composite or individual breakout testing). Reports must reflect this testing.

Example: *E. coli* composite test = initial composite of 4 samples, showing the 5 replicate results

Reported *E. coli* results:

E. coli Result 1	< 3	MPN/g
E. coli Result 2	< 3	MPN/g
E. coli Result 3	3.6	MPN/g
E. coli Result 4	3.6	MPN/g
E. coli Result 5	< 3	MPN/g

ii. For Staph, Salmonella and L. monocytogenes, no 5 sub-sample replicates are required.

d) Composites that have no detection are considered passing results for all samples in the composite.
e) Composites testing above stated GAA-BAP Action Levels (see reference 1.b) require testing for all individual samples (lots) comprised in that composite for the specific parameter detected. The contaminated lot(s) shall be identified, and results stated in the laboratory report.
f) Composites showing detection levels that are below the stated GAA-BAP Action Levels may or may not require breakout testing. In this case laboratories may use Reference 1.c for guidance, or contact BAP Program Integrity at programintegrity@bapcertification.org.
g) See Table 3 next page for laboratory testing examples of aquaculture product.

7.2 Wild Products

a) For required tests to be conducted please see Annex 4 in reference 1.a
b) Laboratories shall conduct 3 sets of microbiological tests for each set of 12 samples submitted.
c) Laboratories shall conduct 1 Methyl Mercury test on each susceptible species present.
d) Laboratories shall conduct 1 Histamine test on each susceptible species present.
e) 7.1 e) applies
f) Composites showing detection levels that are below the stated GAA-BAP Action Levels may or may not require breakout testing. In this case laboratories may use Reference 1.d for guidance, or contact BAP Program Integrity at programintegrity@bapcertification.org.

8. Notification of Results

Laboratory results must always be issued by the laboratory directly to the CB and GAA-BAP. Facilities must ensure this is strictly communicated to the laboratories when samples are sent. Failure to adhere to this may invalidate testing results.

Passing results send to: bapcert@gaalliance.org

Detections and failed results send to: programintegrity@bapcertification.org

Table 3. Residue and microbiological test enumerations for aquaculture products based on the number of samples submitted per species.

Number of Samples per Species	Number of Residue Tests per Species	Number of Microbiological Tests per Species	
		Number of Primary Product Forms Present per Species	
		1	≥ 2
4	1	1	Equal to the number of primary product forms present in samples (minimum = 2)
8	2	2	
12	2	2	
	Maximum number of samples in a composite = 4	Maximum number of samples in a composite = 4	
	Composites may contain mixed primary product forms	Composites must contain the same primary product form - no mixing of primary product forms.	

Example 1: The lab receives 12 samples of aquaculture product from 1 primary product form (raw frozen).

Drug residue testing:
2 composite tests, each composite consisting of 4 individual samples of product.

Microbiological testing:
2 composite tests, each consisting of 4 samples.
Verify that *E. coli* testing consists of 5 subsamples.

Example 2: The lab receives 8 samples of aquaculture product consisting of 3 primary product forms (raw frozen and/or block, cooked, breaded).

Drug residue testing:
2 composite tests, each composite consisting of 4 samples of product in any combination.

Microbiological testing:
3 composite tests (3 primary product forms present) of up to 4 samples in each composite. Each composite consisting of the same primary product form. Cooked product considered ready to Eat (RTE) shall be tested for Listeria. Verify that *E. coli* testing consists of 5 subsamples.