

Aquaculture/Farm Raised Products
Supplementary Sampling and Laboratory Testing Instructions
(Issue 2.0 – 16-January-2021)

Seafood Processing Standard (SPS)
(Current Issue)

Use in conjunction with SPS ANNEX 4 – Sampling and Testing Verification Requirement

1.0 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

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.

Example 1 – Primary Product Forms:

A seafood processing facility produces the following product forms of *L. vannamei*: cooked, breaded, raw ready to eat, marinated, and 3 forms of peeled and/or deveined for a total of 7 products:

- The number of primary product forms to be sampled = 5, (Cooked, breaded, raw ready-to-eat, marinated, and raw).
- When sampling, primary product forms are based on a per species basis. So, If the facility above was also producing raw *P. monodon* in frozen block and IQF, that would be 5 primary product forms for *L. vannamei* and 1 for *P. monodon*.

2.0 Sampling Instructions

2.1 Number of Samples

- a. The number of samples to collect per species is based on annual production volumes of each BAP certifiable species produced at the processing facility according to Table 1 below.

Table 1. Volume (total production in MT) 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

Example 2 – Number of samples per species:

A processing facility previous year's production record states the following:

L. vannamei – 3,500 MT

P. monodon – 1,200 MT

O. niloticus – 800 MT

On the day of sampling, the following 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 fillet, breaded frozen fillet

Total number of samples to take from various lots in the inventory = 24 as follows:

- *L. vannamei* = 12 samples randomly selected between raw, breaded and cooked primary product forms. In this instance, raw frozen IQF and raw frozen block are considered a single primary product form.
- *P. monodon* = 8 samples randomly collected between raw production lots.
- *O. niloticus* = 4 samples randomly selected between fillet and breaded production lots.

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

<u><i>L. vannamei</i></u>	<u># Samples</u>	<u><i>P. monodon</i></u>	<u># Samples</u>	<u><i>O. niloticus</i></u>	<u># Samples</u>
Raw frozen IQF	2	Raw frozen IQF	4	Raw frozen fillet	2
Raw frozen block	3	Raw frozen block	4	Breaded frozen	2
Breaded frozen	4	Total	8	Total	4
Cooked frozen	3				
Total	12				

total primary product forms = 3

primary product forms = 1

primary product forms = 2

2.2 Sample Collection Requirements

a. Compositing of samples is to be conducted by a qualified third-party laboratory and not the sampler.
b. Collect up to twelve samples (750 grams each) as described above from among the primary product forms of finished products that are in the active inventory from various lots available at the processing plant at the time of the audit.
c. In cases where a processing plant 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 products), additional samples will have to be collected from higher- risk or higher-volume production lots to reach the required number of samples.
d. For Seafood Processing Plants that also process wild-caught species, please refer to PI - Interpretation Guidelines - Sampling & Testing Requirement - Wild - Issue 2.0. Additional samples shall be collected for wild-caught species under separate instructions. These instructions in this document are for aquaculture/farm raised products only.
e. Aseptic sampling protocols shall be followed at all times.
f. Sampling shall be conducted in accordance with SPS ANNEX 4, sections A4_1.0-3.0 and Table I.
g. Samplers shall organize and obtain equipment necessary to conduct the sampling: thermo- cool boxes, sterile polyethylene bags (confirm with the assigned 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).
h. DO NOT USE permanent markers that may contain prohibited dyes utilized in aquaculture (example black Sharpie markers) to identify the alphanumeric codes on sample bags.
i. Samplers shall organize the traceability/chain of custody information related to samples that will be collected and document these details.
j. Samplers shall inform the lab of the expected date and time for delivery of samples – especially if it is out of normal business hours for the lab, so that they can make arrangement to store the samples accordingly.
k. Samples shall be packaged in an outer package containing only individual samples from a single species.

3.0 Laboratory Testing Instructions

- a. Testing laboratories must be accredited to ISO 17025.
- b. Compositing of samples is allowed given the following conditions:
 - i. Compositing is to be conducted by a qualified third-party laboratory and not by the sampler.

- ii. Before compositing is done, samples shall 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.
 - iii. No more than 4 samples can be combined into a single composite.
 - iv. No compositing between aquaculture (farm raised) products and wild-caught fishery products is allowed.
 - v. Compositing across primary product forms is acceptable for drug residue testing ONLY. Mixing primary product forms is NOT allowed for microbiological tests.
- c. Testing shall be in accordance with SPS ANNEX 4 Tables I, II, III.
- d. Laboratories shall determine the number of tests based on the number of samples received per species according to Table 2 (below). MT is provided as a reference only for laboratories as they will be unaware of plant volumes.

NOTE: Shellfish shall be tested for microbiological parameters only (SPS Annex 4 Table I). Drug residue testing is not required on shellfish.

Table 2. Residue and microbiological test enumerations based on metric tonnage (MT) and number of samples submitted per species.

Volume (MT) per Species	Number of Samples per Species	Number of Drug Residue Tests per Species	Number of Microbiological Tests per Species	
			Number of Primary Product Forms Present per Species	
			1	≥ 2
0-1,000	4	1	1	Equal to the number of primary product forms present in samples (minimum = 2)
1,001-3,000	8	2	2	
>3000	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 3 – Laboratory testing enumerations for aquaculture species:

The testing laboratory receives 24 individual samples for product testing as indicated in example 2 above:

<u><i>L. vannamei</i></u>	# Samples	<u><i>P. monodon</i></u>	# Samples	<u><i>O. niloticus</i></u>	# Samples
Raw frozen IQF	2	Raw frozen IQF	4	Raw frozen fillet	2
Raw frozen block	3	Raw frozen block	4	Breaded frozen	2
Breaded frozen	4	Total	8	Total	4
Cooked frozen	3				
Total	12				

Microbiological and Drug Residue Testing can be determined as follows:

Microbiological Testing:

- *L. vannamei*: 12 samples total and 3 primary product forms. Number of microbiological tests required = 3 (Table 2). Composite up to 4 individual samples per composite by primary product form. Raw frozen IQF and raw frozen block are considered a single primary product form and can be composited together.

Examples of acceptable composites:

Composite 1: two samples (lots) each of raw frozen IQF and raw frozen block

Composite 2: four samples breaded frozen

Composite 3: three samples cooked frozen

- *P. monodon*: 8 samples total and 1 primary product form. Number of microbiological tests required = 2. Composite 4 individual samples per composite in any combination. Note that since all samples are raw primary product forms the 8 samples can be composited into 2 composites of 4 samples each without restrictions.
- *O. niloticus*: 4 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: two lots of raw frozen fillet

Composite 2: two lots of breaded frozen

Drug Residue Testing:

- *L. vannamei*: 12 samples total. Number of drug residue tests required = 2 (Table 2). Composite 4 individual samples per composite in any combination. When possible, laboratories may try to separate raw with cooked samples in compositing; however, mixing across primary product forms is acceptable for drug residue testing. Note that in this case a maximum of 8 samples could be combined into 2 composites (2 composites containing 4 samples each), leaving 4 samples untested for drug residues.
- *P. monodon*: 8 samples total. Number of drug residue tests required = 2. Composite 4 individual samples per composite in any combination.
- *O. niloticus*: 4 samples total. Number of drug residue tests required = 1. Composite 4 individual samples into 1 composite.

4.0 Detections

4.1 Microbiological Detections

A detection on a composite requires breakout testing (of individual samples) only if the result exceeds GAA-BAP Action Levels (SPS ANNEX 4 Table II). *E. coli* and Staphylococcus results showing detections but not exceeding GAA-BAP Action Levels are to be reported as detections and not failures for that composite.

4.2 Drug Residue Detections

A drug residue detection on a composite that is proportionately capable of exceeding GAA-BAP Action Levels specified in SPS ANNEX 4 Table III shall 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. Table 4 provides BAP guidelines for laboratories to use for breakout testing when a composite

detection is obtained. NOTE: Table 4 is to be used as a guideline only and may not be applicable at very low Action Levels (i.e. table values may be below the sensitivity capability of the testing equipment).

In the event that breakout testing is conducted, ONLY THE SAMPLES IN THE COMPOSITE PRODUCING THE DETECTION SHALL BE RETESTED (USING THE RESERVE PORTIONS), AND ONLY FOR THOSE PARAMETER(S) THAT RESULTED IN A POSITIVE DETECTION.

Table 4. BAP Guidelines for determining whether a drug residue composite detection should be broken out into individual samples for retesting.

Samples per composite	GAA-BAP Action Level (µg/kg or ppb)				
	0.3	0.5	1.0	5.0	10.0
	Breakout Value (µg/kg or ppb)				
2	0.18	0.30	0.60	3.00	6.0
3	0.12	0.20	0.40	2.00	4.0
4	0.09	0.15	0.30	1.50	3.0

Example 4 – Determination of breakout testing for a composite detection:

The testing laboratory conducts drug residue tests per SPS ANNEX 4 on a composite consisting of 3 individual samples. Results indicate a positive detection for Chloramphenicol at a 0.15 µg/kg. Per SPS ANNEX 4, the GAA-BAP Action Level for Chloramphenicol is listed as 0.3 µg/kg or ppb. Using the guideline in Table 4, any value ≥ 0.12 µg/kg would initiate breakout of the composite, and the 4 samples that comprise the composite must be retested individually for Chloramphenicol.

5.0 Failures

5.1 Microbiological Test Failures

- Individual samples testing above the GAA-BAP Action Levels in SPS ANNEX 4 Table II are considered a Failed Test Result.
- Any composite testing above GAA-BAP Action Levels for *Staphylococcus aureus*, *Salmonella* sp., or *Listeria monocytogenes* stated in SPS ANNEX 4 Table II, requires immediate notification by the testing laboratory to the overseeing Certification Body and GAA-BAP. All potential violative sample production lots shall be identified within the notification. Once the notification has been established, the laboratory shall proceed with confirmatory testing on individual samples comprised in the composite of detection for the Microbiological Criteria detected to determine the violative sample production lot(s).

5.2 Drug Residue Failures

- A Drug Residue Detection on an individual sample testing above the “GAA-BAP Action Level” value listed in SPS ANNEX 4 Table III is considered a Failed Test Result.
- A Drug Residue Detection that is above the Testing Laboratory’s LOQ, but below the “GAA-BAP Action Level” value listed in SPS ANNEX 4 Table III is considered a “Detection”.

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