

SUPPLEMENTARY INTERPRETATION FOR APPLICANTS AND CB AUDITORS

SEAFOOD PROCESSING STANDARD ISSUE 5.0 February 1, 2019

This interpretation is to be applied to the Seafood Processing Standard Requirements cited below for all ongoing Seafood Processing Standard (SPS) Version 5.0 Audits

In SPS 5.0 the Global Aquaculture Alliance modified some clause requirements as the language was not clear. Also, the Finished Product Testing Requirements from previous SPS versions to include addition of Florfenicol for farmed species, established baseline action levels for drug residue testing of farmed species, and addition of testing requirements for wild species. Under evaluation of audits conducted to date, and capabilities of ISO 17025 accredited laboratories worldwide, this interpretation document provides additional guidance regarding testing requirements to SPS 5.0 ANNEX 4 and aligns GAA-BAP Action Levels in SPS 5.0 with those cited in SPS 5.1.

Various clauses in SPS 5.0 have been updated in SPS 5.1 to provide accuracy and clarity to the scope of the SPS standard. Certification Body Auditors are hereby informed by way of this interpretation to audit SPS 5.0 clauses identified below using the revised clauses in SPS 5.1.

Section 2	Section 3	Section 5	Section 6	Section 9	Appendix
2.2.4	3.2.12	5.2.4	6.1.1	9.1.4	A2-2.4.1
2.8.1	3.2.15	5.2.6	6.1.5	9.3.1	A2 – 2.5
2.8.1.3	3.3.1	5.2.8		9.5.2	A3 – 3.2
2.9.2	3.4.1	5.2.9			A4 (see below)
2.9.5	3.5.2	5.3.5			
2.16.2	3.6.3	5.4.2			
	3.8.1	5.4.3			
	3.11.4	5.5.1			
	3.13.1	5.5.2			
		5.6.1			
		5.6.3			
		5.7.4			
		5.8.2			
		5.8.4			

ANNEX 4 – Table II

Required Finished Product Testing – Microbiological Criteria Applicable to both aquaculture (farmed) and wild-caught (fisheries) products

Acceptable Test Methods*	Microbiological Criteria	Species / Form	GAA-BAP Action Levels**	Reference (see ref. listings below)
BAM, AOAC	Escherichia coli	Finfish and crustaceans (<i>all forms</i>), and <i>processed***/cooked</i> 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)	1, 2
	Escherichia coli	<i>Shell stock, fresh-shucked thawed and frozen shellfish, shellfish frozen on half shell</i>	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)	1, 2, 3
	Staphylococcus aureus	Finfish/crustaceans (<i>all forms</i>)	Using only 1 of 2 possible tests methods: Reject if positive for either Staphylococcal enterotoxin ^(c) , or a level equal to or greater than 1×10^4 bacteria per g (MPN) ^(d)	3
	Salmonella sp.	Finfish/crustaceans/molluscan shellfish (<i>all forms</i>)	Reject if presence is detected in 25 grams	2, 3, 4
	Listeria monocytogenes	Finfish/crustaceans/molluscan shellfish (<i>cooked and raw, ready to eat products only</i>)	Reject if presence is detected in 25 grams	3, 4

^(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) US FDA. 2017. Bacteriological Analytical Manual, Chapter 13B Staphylococcal Enterotoxins Detection Methods

^(d) US FDA. 2016. Bacteriological Analytical Manual, Chapter 12 Staphylococcus aureus or; AOAC International. 1995. Official Methods of Analysis, 16th ed., sec. 987.09

* Other published methods of a sensitivity equal to or more sensitive than the stated method may also be used depending on the method and levels used in the countries of destination, provided such methods are published, and approved by the USFDA, USDA, EU, CFIA or other national regulatory bodies, and verifiable documented evidence of their approval provided.

** GAA-BAP Action Levels – at or above these levels an action is initiated by the Standard Program Management and oversight.

*** For the purposes of this 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.

ANNEX 4 – Table III
Required Finished Product Testing for Aquaculture (Farmed) Products

Acceptable Tests*	Chemical Residue - Aquaculture Drug	GAA-BAP Action Level** (µg/kg, ppb)	Limits	Reference	
HPLC/MS	Chloramphenicol	0.3	no residue permitted	3, 5	
	<u>Nitrofurans Metabolites</u>	1.0	no residue permitted	3, 5	
	Furazolidone				
	Furaltadone				
	Nitrofurantoin				
	Nitrofurazone				
	<u>Fluoroquinolones</u>	1.0	no residue permitted	3, 6	
	Sarafloxacin				
	Ciprofloxacin				
	Enrofloxacin				
	<u>Triphenylmethane Dyes</u>	0.5	no residue permitted	6	
	Sum of Malachite Green & Leuco-malachite Green				
	Sum of Gentian Violet & Leucogentian violet				
	<u>Quinolones</u>				
	Flumequine	5.0	no residue permitted	6, 7	
	Oxolinic acid	5.0			
Sulfonamide (parent drug)	10.0	no residue permitted in unapproved species ^(a)	7		
Oxytetracycline	10.0	no residue permitted in unapproved species ^(b)	7, 8		
Tetracycline	10.0	no residue permitted in unapproved species ^(b)	7, 8		
Florfenicol	10.0	no residue permitted in unapproved species ^(b)	3, 9		

^(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 depending on the method and levels used in the countries of destination, provided such methods are published, and approved by the USFDA, USDA, EU, CFIA or other national regulatory bodies, and verifiable documented evidence of their approval provided.

** GAA-BAP Action Levels – at or above these levels an action is initiated by the Standard Program Management and oversight. Levels stated are designated as minimum levels of testing laboratory method sensitivity for Annex 4 Table III. BAP recognizes that not all countries/regions may have laboratories with accredited scope to the sensitivity stated in GAA-BAP Action Levels. All efforts should be made to locate labs capable of achieving these sensitivity levels

(LODs, LORs, LOQs). CBs are asked to contact BAP Program Integrity for consideration where this has not been, or cannot be, achieved.

ANNEX 4 – Table IV

Required Finished Product Testing for Wild-Harvested Species

Acceptable Test Methods*	Toxin	GAA-BAP Action Level**	Limits	Reference
HPLC	Methyl Mercury ^(a)	0.5ppm ^(b)	0.5 ppm	3, 10, 13
Fluorometric HPLC	Histamine (scombrototoxin) ^(c)	50 ppm ^(d)	50 ppm	3, 11, 12

^(a) Mercury testing only required for species known to contain very high levels of mercury (i.e. more than 0.5 ppm), which includes king mackerel, orange roughy, shark, swordfish, tilefish, bigeye tuna, marlin, and Spanish Mackerel (see reference 13).

^(b) LOQ based on 0.5g analytical portion (see reference 10)

^(c) Only required for families of Scombridae, Scombresocidae, Clupeidae, Coryphaenidae and Pomatomidae (see Table 3-2 of reference 3 for full list)

^(d) LOQ based on 10 ML sample unit (see reference 12)

* Other published methods of a sensitivity equal to or more sensitive than the stated method may also be used depending on the method and levels used in the countries of destination, provided such methods are published, and approved by the USFDA, USDA, EU, CFIA or other national regulatory bodies, and verifiable documented evidence of their approval provided.

**GAA-BAP Action Levels – at or above these levels an action is initiated by Standard Program Management and oversight.