PRACTICAL, REGULATORY & TECHNICAL REFERENCE

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PURPOSE

This guide is intended to support seafood industry stakeholders, including processors, harvesters, exporters, and quality assurance/food safety staff, by clarifying which species and products require testing, what hazards should be monitored, which parts of the product should be sampled, how often testing should occur, how to prepare and ship samples, where to send them, and how to interpret results. The guidance is aligned with Canadian regulatory frameworks (Canadian Food Inspection Agency (CFIA) and Health Canada) as well as international best practices.

SCOPE

Covers biological (microbiological) and chemical (marine biotoxin, additives) hazards. It is applicable to raw, live, frozen, fillet or meat portions, organ products such as tomalley or hepatopancreas, and processed ready-to-eat (RTE) seafood.

DISCLAIMER

This guide summarises current Canadian and international standards as of 2026. It is intended for informational purposes only. Operators must verify specific export market/buyer requirements, keep up with regulatory updates, and integrate testing into their Preventive Control Plan (PCP) under the Safe Food for Canadians Regulations (SFCR).

1. HAZARDS & TESTING OVERVIEW

1.1 HAZARD CATEGORIES

Microbiological hazards

- *Listeria monocytogenes* (especially in RTE), *Salmonella* spp., *Vibrio* spp. (*V. parahaemolyticus*, *V. vulnificus*, *V. cholerae*), *Escherichia coli* (including O157:H7), *Staphylococcus aureus*, yeasts/molds, and general spoilage indicators (Total Aerobic Count, psychrotrophs). Biological hazards also include parasites.
    - » **Parasites:** nematodes (e.g., *Anisakis* spp. and *Pseudoterranova* spp.), cestodes (e.g., *Diphyllobothrium* spp.) and trematodes (e.g., *Clonorchis* spp., and *Opisthorchis* spp.) especially in raw/undercooked fish. Routine laboratory testing for parasites is uncommon; control is primarily achieved through visual inspection and removal, validated freezing or cooking treatments, and supplier verification.

Chemical

- Heavy metals such as Mercury (Hg), Cadmium (Cd), Lead (Pb) and Arsenic (As), histamine (especially in scombroid-type fish such as tuna & mackerel), veterinary drug residues (aquaculture), and legacy contaminants (PCBs, dioxins) as applicable. Chemical hazards also include marine biotoxins.
    - » **Marine biotoxins:** Paralytic Shellfish Poisoning (PSP; saxitoxins), Diarrhetic Shellfish Poisoning (DSP; okadaic acid, dinophysistoxins-DTX1, DTX2, DTX3, and Pectenotoxins- PTX1–11), and Amnesic Shellfish Poisoning (ASP; domoic acid).

1.2 KEY MESSAGE

Product and environmental testing must be **risk-based**. Not all species/products require every test; the required panel depends on species or species group (e.g., bivalve shellfish, crustaceans, scombroid fish, large predatory fish), product form (live, whole, fillet/meat, organ/tomalley, processed RTE), processing method, target market (domestic or export with specific requirements), and risk factors (harvest area history, handling/chilling, process controls). Proper sampling, sample preparation, accredited lab methods, and documented results/trending are critical for regulatory compliance and brand protection.

2. CHEMICAL CONTAMINANTS, MARINE BIOTOXINS & ADDITIVES

Table 2.1: Chemical Contaminants and Marine Biotoxins in Fish and Seafood.

Sources

Appendix 3: Canadian Guidelines for Chemical Contaminants and Toxins in Fish and Fish Products

Species / Product Group	Key Chemical / Toxin Tests	Canadian Action Level / Limit	Part to Sample
All fish products (except Swordfish, Shark, Fresh/Frozen Tuna, Escolar, Orange Roughy and Marlin)	Mercury	0.5 ppm (except high-mercury species)	Edible portion / fillet
High-mercury fish (Swordfish, Shark, Fresh/Frozen Tuna, Escolar, Orange Roughy, Marlin)	Mercury	1.0 ppm	Edible portion / fillet
Fish Protein Concentrate	Arsenic (As)	3.5 ppm	Product as sold
Fish Protein Concentrate	Lead (Pb)	0.5 ppm	Product as sold
Fish Protein Concentrate	Fluoride (F)	150 ppm	Product as sold
All Fish Products	2,3,7,8-TCDD (Dioxin)	20 ppt	Product as sold
All Fish Products	DDT	5 ppm	Product as sold
All Fish Products	PCB	2 ppm	Product as sold
All Fish Products	Other agricultural chemicals or their derivatives	0.1 ppm	Product as sold
Dried Cod	Piperonyl butoxide	1.0 ppm	Product as sold
Enzyme-ripened products e.g., anchovies, anchovy paste, fish sauce	Histamine	20 mg/100 g	Edible portion / fillet
All other scombroid products, e.g., canned, fresh, frozen tuna, mackerel, mahi-mahi	Histamine	10 mg/100 g	Edible portion / fillet

Molluscan Shellfish (Clams, Oysters, Scallops, Mussels, Whelks)	Saxitoxins (PSP)	80 µg/100 g	Edible portion (pooled drained meats, 100 g from 5 sub-samples)
	Domoic Acid (ASP)	20 µg/g	Edible portion (pooled drained meats, 100 g from 5 sub-samples)
	DTX-1 & Okadaic Acid (DSP)	0.2 µg/g	Edible portion (pooled drained meats, 100 g from 5 sub-samples)
	Pectenotoxins (PTX-1,2,3,4,6,11)	0.2 µg/g	Edible portion (pooled drained meats, 100 g from 5 sub-samples)
Crustaceans (Lobster, Crab)	PSP (Saxitoxins) in tomalley	80 µg/100 g	Tomalley / hepatopancreas
All fish and fish products (except marine mammal meat)	Nitrites	15 ppm	Product as sold
All fish and fish products	Nitrates	15 ppm	Product as sold
Clams (raw and canned)	Sulphites	10 ppm	Product as sold
Shrimp (raw, cooked and canned)	Phosphates	1.60 %	Product as sold
Scallops (raw)	Phosphates	1.47 %	Product as sold
Fish fillets	Phosphates	1.37 %	Product as sold
Crab (raw and cooked)	Phosphates	1.70 %	Product as sold
Lobster (raw and cooked)	Phosphates	1.47 %	Product as sold
Surf clams (raw and cooked)	Phosphates	1.00 %	Product as sold

Table 2.1

Notes

- Scombroid-prone fish require lot-level histamine testing.
- For additives that are intentionally added, refer to the Lists of permitted food additives – Health Canada Lists of permitted food additives – Health Canada.
- Mercury: All crustaceans should be monitored for mercury in edible meat; levels above 0.5 ppm are non-compliant.
- PSP (Saxitoxins): Required for lobster and crab tomalley; mandatory for some export markets. Not applicable to shrimp meat.
- Sample the relevant part for the hazard: e.g., shucked meat for biotoxins, edible tissue for metals.

3. MICROBIOLOGICAL GUIDELINES

Table 3.1: Microbiological Guidelines for Fish and Seafood Products (End Product).

Sources

CFIA Bacteriological Guidelines for Fish and Fish Products (End Product)
Microbial Guidelines for Ready-to-Eat Foods – Health Canada

Test Organism / Parameter	Product Type	Sample Units	Limit / Acceptance	Notes / Interpretation
Escherichia coli	Raw bivalve molluscs (mussels, oysters, scallops)	5	Acceptable: 1 Sample ≤230/100g; Unsatisfactory; if any sample >330/100g or 1 or more samples >330/100g	Unsatisfactory if ≥2 samples exceed 230 /100 g or any sample exceeds 330 /100 g Routine hygiene indicator for raw products
Escherichia coli	Cooked / RTE seafood	5	Acceptable: 1 Sample ≤4 CFU/g Unsatisfactory; if any sample >40 CFU/g or 1 or more samples >40 CFU/g	Unsatisfactory if ≥2 samples exceed 4 CFU/g or any sample exceeds 40 CFU/g Process control check
Escherichia coli	All other types	5	Acceptable: 2 Samples ≤4 CFU/g Unsatisfactory; if any sample >40 CFU/g or 1 or more samples >40 CFU/g	Unsatisfactory if ≥3 samples exceed 4 CFU/g or any sample exceeds 40 CFU/g
Coagulase-positive *Staphylococcus aureus*	All types	5	Acceptable: 1 sample ≤1000 CFU/g Unsatisfactory; if any sample >10,000 CFU/g or 1 or more samples >10,000CFU/g	Unsatisfactory if ≥2 samples exceed 1000 CFU/g or any sample exceeds 10,000 CFU/g hygiene/process control indicator
Salmonella spp.	All types	5	Absent in each 25 g (or pooled 125 g)	Any detection is unsatisfactory, required for safety verification
Vibrio cholerae	Cooked / RTE seafood	5	Absent in each 25 g (or pooled 125 g)	Any detection is unsatisfactory, required for safety verification
Vibrio parahaemolyticus	Live oysters	5	Acceptable: ≤ 100/g Unacceptable: any sample >100/g	Unsatisfactory if any sample exceeds 100 CFU/g, required for safety verification
Listeria monocytogenes	RTE seafood	5	Category 1: absent in 125 g; Category 2A: ≤100 CFU/g; Category 2B: ≤100 CFU/g; growth will not occur throughout the stated shelf-life (that is, increase not exceeding 0.5 log CFU/g throughout the stated shelf-life)	Pathogen unsatisfactory if detected / exceeds limits, applies to Category 1 only Category 2A and 2B: unsatisfactory if any sample is >100 CFU/g.

Aerobic Colony Count	RTE seafood	-	Unsatisfactory ≥ 10^5 CFU/g	High levels indicate poor handling, post-processing temperature abuse, inadequate cooking, storage, or sanitation
Total *Coliforms*	RTE seafood	-	Unsatisfactory ≥10^3 CFU/g	Indicate inadequate processing or post-processing contamination.
Yeast and mould	Smoked, dried, fermented, salted, vacuum-packed	-	No defined regulatory limit available	May cause spoilage (off-odours, flavours, colours); some intentionally added for flavour
Listeria spp. (environmental swabs)	RTE processing areas	Risk-based; both food-contact surfaces (FCS) and non-food contact surfaces (non-FCS); zone-based sampling required	FCS: Non-detect; Non-FCS: trend monitoring. Any positive Listeria environmental result (FCS or non-FCS) requires a corrective action plan	Environmental hygiene check

Table 3.1

Notes

Listeria spp. (environmental swabs): Environmental monitoring programs for *Listeria* spp. should be developed and implemented in accordance with Health Canada's Policy on *Listeria monocytogenes* in ready-to-eat foods.

RTE CATEGORIES & VALIDATION

- Category 1: RTE foods which support the growth of L. monocytogenes under reasonable foreseeable conditions of distribution, storage and use throughout the stated shelf-life; detection is unsatisfactory.
- Category 2A: RTE foods in which the growth of L. monocytogenes may be limited to levels not exceeding 100 CFU/g under reasonable foreseeable conditions of distribution, storage and use throughout the stated shelf-life.

This includes RTE foods that:

1. Are known to occasionally contain low levels of *L. monocytogenes* and their processing does not involve heat-treatment (based on validation), and
2. Refrigerated foods with a stated shelf-life of ≤5 days.

- Category 2B: RTE foods in which the growth of *L. monocytogenes* will not occur under reasonable foreseeable conditions of distribution, storage and use throughout the stated shelf-life or RTE foods that do not support the growth of *L. monocytogenes* throughout the stated shelf-life. Category 2B RTE manufacturers should regularly monitor the physico-chemical parameters of the food such as pH and a_w, formulation etc. (if not frozen) to demonstrate that it continues to meet the criteria that justify its categorization as a Category 2B food.
  In cases where validation was conducted for categorization, the manufacturer should have documentation of adequate validation studies substantiation that *L. monocytogenes* cannot grow throughout the stated shelf-life.

RTE PHYSICO-CHEMICAL CRITERIA FOR 2B CLASSIFICATION (NO VALIDATION NEEDED IF THESE APPLY):

- pH < 4.4 at any aw (water activity)
- a_w < 0.92 (regardless of pH)
- combination of pH < 5.0 AND a_w < 0.94
- Product is frozen until consumption (product must be labelled "keep frozen" on the package).
- Other RTE foods in which *L. monocytogenes* does not increase in numbers by more than 0.5 log CFU/g throughout the stated shelf-life based on validation.

VALIDATION REQUIREMENTS

- If RTE products have a longer shelf-life (>5 days), partial kill steps, or use anti-*Listeria* additives/treatments, supporting validation data must demonstrate limited growth (<0.5 log CFU/g) to classify as 2B or 2A.

4. SAMPLING & LABORATORY SUBMISSION

4.1 HOW TO COLLECT SAMPLES

- **Representative sampling:** Randomly select units across the lot, harvest day or production batch that are representative of the entire lot and production conditions and meet the sample size requirements of the lab; avoid bias. Follow documented sampling plan in your PCP.
- **Define "lot":** production run, shipment, or batch with same source/process/harvest date.
- **Matrix / sample part:** use edible portion (muscle/fillet) for chemical/heavy metal tests; for shellfish toxins, use whole shucked tissue or specified organ; for microbiology, typically edible meat/flesh unless specified otherwise.
- **Use compound/composite samples** where methods allow (e.g., multiple fish pooled for histamine testing; multiple shellfish units for biotoxin testing) - confirm with lab.
- **Avoid cross-contamination:** use aseptic techniques, wear disposable gloves, use sterile bags (e.g., Whirl-Pak), sanitized utensils, clean sampling surfaces, change gloves between lots/units.
- **Document sampling:** record product name, lot/harvest number, matrix, number of units sampled, date/time of collection, sampler name, temperature at time of sampling.
- **Retention sample:** Keep retention samples frozen at −18 °C or lower (or as per internal procedure) as an archive until all laboratory results have been reviewed and confirmed. Re-testing is needed when:
  - » Laboratory results are inconclusive or invalid or there is a justified reason to question the result (e.g., suspected sampling or analytical error).
  - » Investigation is required for suspected contamination, non-compliance, or quality deviation.
  - » Follow-up testing is requested by a regulatory authority (e.g., CFIA) or internal quality assurance team.

4.2 PREPARING SAMPLES FOR LABORATORY SUBMISSION

- **Pre-check with laboratory:** Contact the accredited laboratory to confirm sample size, matrix, composite rules, analytical method, acceptable packaging and temperature requirements, receiving hours, sample acceptance criteria, and shipping instructions.
- **Materials needed:** Sterile food-grade bags, disposable knives/utensils, gloves, labels, waterproof marker, insulated cooler/box, ice packs or dry ice (as applicable), absorbent material, chain-of-custody form. Example sources: laboratory and food-sampling suppliers (Neogen – Sample Collection Solutions).
- **Collection & packaging:** Remove non-edible parts as required (e.g., guts, shell), homogenize if required for composite, Place the labelled, weighed sample into a sterile bag or container. Avoid using metal containers for heavy-metal testing due to the risk of contamination.

- **Labeling & documentation:** Include product name, matrix (e.g., fillet, tomalley, whole shellfish), lot/harvest date, collector name, sample ID, temperature at sampling. Use chain-of-custody form and place in waterproof pouch within shipping container.
- **Sealing & shipping:** Seal sample bags securely, place inside secondary container with absorbent material, then into the insulated shipping box. For official regulatory samples (e.g., CFIA seafood sampling) apply approved seals or include CFIA supervision. Ship same day or overnight.
- **Retention & traceability:** Maintain records linking sample to lot, retain results and archive sample if needed.

5. SAMPLING FREQUENCY & PCP INTEGRATION

- **Frequency planning:** Testing frequency must be defined in your Preventive Control Plan under the SFCR and based on a risk assessment considering your product, process, supplier/source, historical results, and target market.
- **Key influencing factors:** Product type (ready-to-eat vs. raw), processing method, harvest area conditions (for shellfish), historical results, supplier performance, export or buyer requirements, and production volume/ frequency.

5.1 ENVIRONMENTAL SAMPLING FREQUENCY - *LISTERIA*

Table 5.1 below presents recommended FCS testing frequencies when preparing the highest risk Category 1 RTE food.

FCS testing frequency per production line according to the relative risk level for the highest risk Category 1 RTE foods: smoked seafood and cooked ready to eat crustaceans.

Production volume	No antimicrobial agent or post-lethality treatment	Antimicrobial agent	Post-lethality treatment	Antimicrobial agent and post-lethality treatment
Very small	Once per month	Once every 2 months	Once every 2 months	Once every 3 months
Small	Twice per month	Once per month	Once per month	Once every 2 months
Medium	3 times per month	3 times every 2 months	3 times every 2 months	Once per month
Large	4 times per month	Twice per month	Twice per month	Once per month

Table 5.1

Table 5.2 presents recommended FCS testing frequencies for RTE foods not covered by Table 5.1

FCS testing frequency per production line according to the relative risk level (RRL) for RTE foods not covered by Table 5.1.

RTE risk category	No antimicrobial agent or post-lethality treatment	Antimicrobial agent	Post-lethality treatment	Antimicrobial agent and post-lethality treatment
Category 1	Once per month	Once every 2 months	Once every 2 months	Once every 3 months
Category 2A	Once every 3 months	Once every 6 months	Once every 6 months	Once per year
Category 2B	Once every 6 months	N/A	Once per year	N/A

Table 5.2

Table 5.3 presents recommended finished product testing frequencies.

Product sampling frequency according to the relative risk level (RRL).

RTE risk category	No antimicrobial agent or post-lethality treatment	Antimicrobial agent	Post-lethality treatment	Antimicrobial agent and post-lethality treatment
Category 1	Once per month	Once every 6 weeks	Once every 6 weeks	Once every 2 months
Category 2A	Once every 2 months	Once every 3 months	Once every 3 months	Once every 6 months
Category 2B	Once every 6 months	N/A	Once per year	N/A

Table 5.3

Source for Table 5.1, 5.2 & 5.3: Control measures for ***Listeria monocytogenes*** in ready-to-eat foods

Document rationale: Record your frequency plan and the justification for the chosen frequency (based on risk) in the PCP. Increase testing if there are new risks e.g., non-conforming results, changes in environmental factors, new suppliers, new species, new export markets, etc.

6. WHERE TO SEND SAMPLES / LABORATORY SELECTION

- Use accredited laboratories (ISO/IEC 17025 or equivalent) that have validated methods for your species/matrix/hazard.
- Confirm the lab's scope: species covered, matrix (fillet, whole shell, organ), test method, turnaround time, cost, reporting format (must deliver results with units, method reference, accreditation).
- For export markets, ensure the lab is recognised by the destination country or meets buyer requirements (i.e., export certificate, method equivalency, chain of custody).

7. HANDLING NON-CONFORMING RESULTS

If a test result is out-of-spec:

1. Immediately segregate the lot or batch. Do not ship until a decision is made.
2. Investigate root causes: supplier variation, harvest area change, process/temperature control lapse, lab or sampling error.
3. Apply corrective actions: On a case-by-case basis, determine appropriate measures based on the identified root cause. Examples may include cleaning and sanitizing equipment, reviewing harvest or handling conditions, adjusting processing or chilling, or retraining staff.
4. Retest as appropriate: Only perform re-testing when justified, based on risk assessment or identified reason. Examples include inconclusive, invalid, suspected sampling or analytical error, or verification of corrective actions in a subsequent lot. Re-testing should **not** be done automatically for every out-of-spec result; valid, confirmed results from accredited laboratories generally **do not require re-testing** unless there is reason to doubt the initial result.
5. Document all actions in your PCP record.
6. If results exceed regulatory thresholds (e.g., maximum metals or toxins), consider recall or notification per regulatory obligations.
7. Review sampling plan/frequency and increase if necessary.

8. EXPORT & MARKET-SPECIFIC CONSIDERATIONS

- Many export markets (USA, EU, Asia) have additional or different requirements (e.g., metal limits, sampling plans, documentation). Always verify buyer/export country standards.
- For shellfish: The Canadian Shellfish Sanitation Program (CSSP) harvest area classification is critical. Areas must meet CFIA criteria for water/biotoxin/microbiological safety.
- Ensure chain of custody, lab accreditation, certificate of analysis, export documentation are in place.
- Some markets require specific tests (e.g., Japan requires testing for PSP toxins in lobster tomalley), even if these tests are not required domestically.
- Labelling and traceability are also export issues: The SFCR requires one-step-back and one-step-forward traceability, lot code, origin, etc.

9. KEY TAKE-AWAY

Seafood testing is not just a regulatory checkpoint; it is a core part of risk management, product quality assurance, and brand protection. Align your sampling and testing program with your product profile (species, form, process, market) to focus on the right hazards at the right points in your supply chain. Document everything: sampling plans, lot definitions, lab certificates, corrective actions, and trending data to build assurance for both domestic and export markets.

10. REFERENCES

- Appendix 3: Canadian Guidelines for Chemical Contaminants and Toxins in Fish and Fish Products
- Canadian Shellfish Sanitation Program
- CFIA Bacteriological Guidelines for Fish and Fish Products (End Product)
- Control measures for Listeria monocytogenes in ready-to-eat foods
- Health Canada — Maximum Levels for Chemical Contaminants in Foods
- ISO/IEC 17025:2017 – Testing and Calibration Laboratories Competence Requirements
- Lists of permitted food additives – Health Canada
- Microbial Guidelines for Ready-to-Eat Foods – Health Canada
- Perennia Food and Agriculture Inc.: Sampling Seafood for Microbiological Analysis (Fact Sheet – Dec 2022)
- Policy on *Listeria monocytogenes* in ready-to-eat foods
- Public Health Ontario Laboratory Guide – Public Health Ontario
- Requirements and guidance by food commodity: Fish – Canadian Food Inspection Agency
- Safe Food for Canadians Regulations (SOR/2018-108)