SEAFOOD TESTING GUIDE

Bivalve Shellfish (clams, mussels, oysters, scallops)

PRACTICAL, REGULATORY & TECHNICAL REFERENCE

PURPOSE

This guide is intended to support seafood industry stakeholders, including processors, harvesters, exporters, and quality assurance/food safety staff, by clarifying which bivalve 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. This guidance aligns with Canadian regulations (Canadian Food Inspection Agency (CFIA) and Health Canada) and international best practices.

SCOPE

Covers biological (microbiological) and chemical (marine biotoxin, additives) hazards. Applicable to live, raw whole, shucked meat, and processed ready-to-eat (RTE) products.

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* (a concern for RTE products), *Salmonella* spp., *Vibrio* spp. (*V. parahaemolyticus*, *V. vulnificus*, *V. cholerae*), *E. coli* (including O157:H7), *Staphylococcus aureus*, yeasts/molds, Total Aerobic Count (TAC), coliforms. Biological hazards also include parasites.
- **Parasites:** Not considered a routine hazard for bivalve shellfish.

Chemical

- Heavy metals (Hg - mercury, Cd - cadmium, Pb - lead, As - arsenic), veterinary drug residues, legacy contaminants (polychlorinated biphenyls (PCBs), dioxins).

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**. Required tests depend on **species** (clams, mussels, oysters, scallops), product form (live, raw whole, shucked meat, RTE), processing method, target market, and risk factors (harvest area, handling, process controls). Proper sampling, use of accredited laboratories, and documented results are critical for compliance and brand protection.

2. CHEMICAL CONTAMINANTS, MARINE BIOTOXINS & ADDITIVES

Table 2.1: Chemical Contaminants and Marine Biotoxins & Additives in bivalves

Sources

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

Hazard / Analyte	Canadian action level / limit (from CFIA Appendix 3)	Part to sample
PSP	80 µg / 100 g	Edible portion - pooled drained meats: 100 g composite from 5 sub-samples (follow CFIA pooling rules)
ASP	20 µg / g	Edible portion - pooled drained meats (100 g from 5 sub-samples)
DSP (DTX-1 & Okadaic acid), Pectenotoxins (PTX-1, 2, 3, 4, 6, 11)	0.2 µg / g	Edible portion - pooled drained meats (100 g from 5 sub-samples)
Mercury (Hg)	0.5 ppm (general fish/seafood action level)	Edible portion / shucked meat
Nitrites / Nitrates	15 ppm	Product as sold (processed products)
Sulphites	10 ppm (clams - raw & canned)	Product as sold (processed products)
Phosphates	1.47% (Scallops (raw) 1.00% (surf clams - raw and cooked)	Product as sold (processed products)

Table 2.1

Notes:

- Sample the relevant part for the hazard: e.g., shucked meat for biotoxins, edible tissue for metals.
- For additives that are intentionally added, refer to the Lists of permitted food additives – Health Canada Lists of permitted food additives – Health Canada.

3. MICROBIOLOGICAL GUIDELINES

Table 3.1: Microbiological Guidelines for bivalves

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	Cooked or ready-to-eat	5	acceptable: 1 Sample ≤4 CFU/g Unsatisfactory; if any sample >40 CFU/g or 1 or more samples >40 CFU/g	Routine hygiene indicator for raw products Unsatisfactory if ≥2 samples exceed 4 CFU/g or any sample exceeds 40 CFU/g
Escherichia coli	Raw bivalves	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 /100g or any sample exceeds >330 /100g Routine hygiene indicator for raw products
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 >10,000 CFU/g	Hygiene/process control indicator: Unsatisfactory if ≥2 samples exceed 1000 CFU/g or any sample exceeds 10,000 CFU/g
Salmonella spp.	Raw & RTE	5	Absent in each 25 g (or in 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
Vibrio cholerae	Cooked / RTE shellfish (if applicable)	5	Absent in each 25 g (or pooled 125 g)	Any detection is unsatisfactory, required for safety verification
Listeria monocytogenes	Bivalves processed for raw consumption and sold as RTE	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 shellfish	-	Unsatisfactory ≥ 105 CFU/g	High levels indicate poor handling, post-processing temperature abuse, inadequate cooking, storage, or sanitation

Total *Coliforms*	RTE shellfish	-	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, All positive swabs FCS or NFCS require 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, and 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

- Randomly select units across the lot/batch that are representative of the entire lot and production conditions and meet the sample size requirements of the lab; avoid bias.
- Define lot: production run, shipment, or batch with same source/harvest date.
- Sample parts: shucked edible meat for microbiology and biotoxins; whole pooled meat if required.
- Avoid cross-contamination: use aseptic techniques, sterile bags, gloves, sanitized utensils, clean surfaces.
- Document product name, lot, sample units, date/time, sampler, temperature.
- 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

- Confirm with lab: 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.
- Use sterile food-grade bags, disposable utensils, insulated cooler, ice/dry ice, absorbent material, chain-of-custody forms. Example sources: laboratory and food-sampling suppliers (Neogen – Sample Collection Solutions).
- Label with product, matrix, lot, collector, sample ID, temperature.
- Seal, place in secondary container with absorbent material, ship same day/overnight.
- Maintain chain-of-custody; retain archive sample.

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).
- Confirm lab scope: species, matrix, method, turnaround, reporting format.
- Ensure lab is recognized for export or meets buyer requirements (export certificate, 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

- Verify buyer/export country limits and documentation requirements.
- Ensure Canadian Shellfish Sanitation Program (CSSP) harvest area compliance.
- Maintain traceability, lab certificates, and proper labelling.

9. KEY TAKE-AWAY

Risk-based testing ensures safety, quality, and regulatory compliance. Testing should be aligned with species, product form, processing method, and target market. Sampling, lot identification, laboratory results, corrective actions, and trends must be properly documented.

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)