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CFIA Microbiology Audit Readiness Checklist & EMP Planning Worksheet

This checklist and worksheet help QA and operations leaders quickly assess how ready their microbiology program is for a CFIA food safety audit—without turning it into a weeks-long project.

Use it in a leadership meeting to:

- Score each pillar of your program by line or site
- Capture specific gaps, owners, and deadlines
- Prioritize where to invest time and budget before CFIA does its own review

There is no obligation or engagement required, but if you want external perspective after you've completed it, you can optionally book a no-pressure review call to walk through your results and next steps.

How to Use This Tool

- For each section, rate yourself 0–2 for each item:
  - 0 = Not in place
  - 1 = Partially in place / inconsistent
  - 2 = Clearly in place and documented
- Add comments, owners, and due dates where relevant.
- At the end, total scores and highlight the top 3 priorities for action.

Section 1 – PCP & Microbiology Alignment

Goal: Show a clear, logical link between biological hazards, preventive controls, and microbiology verification.

Checklist (0–2 each):

- Our PCP identifies biological hazards by product family and process step, not just in generic terms.
- For each significant hazard, we have named preventive controls (e.g., thermal steps, formulation, sanitation, zoning, suppliers).
- For each preventive control, we can point to specific microbiology verification activities (EMP, product tests, water, ingredients).
- Testing frequencies and sample sizes are risk-based and documented—not inherited without rationale.

Notes / Gaps / Owners:

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Section 2 – Environmental Monitoring Program (EMP) Design

Goal: Have an EMP that reflects real pathogen risk and would withstand CFIA questions.

Checklist (0–2 each):

- We have a zoned EMP (e.g., zones 1–4) with a documented site list and map.
- Sites include high-risk areas: drains, transitions, under/behind equipment, and post-lethality areas where applicable.
- Target organisms and indicators (e.g., Listeria spp., Enterobacteriaceae) are chosen and justified in writing.
- Sampling frequencies are documented and tied to risk and history (not just "weekly because we always have").
- There is a written escalation plan for positives (expanded swabbing, investigation, sanitation, potential design changes).

Notes / Gaps / Owners:

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Optional next step: Once you've completed this section, you may find it useful to discuss your EMP map, site list, and escalation rules in a short, no-obligation call with a lab partner who understands CFIA expectations. This often surfaces simple changes that significantly strengthen audit-readiness.

Section 3 – Product, Water, and Ingredient Testing

Goal: Show that your verification testing is aligned with risk and regulatory expectations.

Checklist (0–2 each):

- For high-risk or RTE products, we have documented sampling plans (lot definition, units tested, target organisms, criteria).
- We have written procedures for what happens when results are out of spec (holds, rework, destruction, communication).
- Water and ice testing programs are in place, with frequencies and criteria that reflect their use (e.g., direct contact with RTE product).
- Ingredient/supplier verification is risk-based: high-risk materials that bypass kill steps have appropriate micro specifications and verification.

Notes / Gaps / Owners:

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Section 4 – Methods, Laboratories, and Data Integrity

Goal: Be confident your test results are scientifically credible and defendable.

Checklist (0–2 each):

- We know which methods are used for our critical tests and can show they are recognized or properly validated.
- Our primary labs (internal or external) operate under robust quality systems; for critical tests, ISO 17025 accreditation is documented.
- Sample collection, transport, storage, and chain-of-custody procedures are written and followed consistently.
- We have access to relevant QC / proficiency testing evidence for key methods, and we review it at least annually.

Notes / Gaps / Owners:

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Optional no-pressure call: If you aren't certain whether your current methods and lab setup are sufficient for CFIA expectations, a short review call can help identify any high-risk gaps without any commitment to change providers.

Section 5 – Validation and Special Studies

Goal: Demonstrate that high-risk products and processes have been properly validated.

Checklist (0–2 each):

- For low-moisture products, we have kill-step validation files that define target organisms, log-reduction goals, and process parameters.
- For LACF/canned products (if applicable), we have thermal process and commercial sterility validation properly documented.
- For refrigerated RTE products, we have microbial challenge studies or equivalent data to support shelf life and claims.
- For products relying on pH/Aw or other hurdles, we have validation data and specifications that show the hurdle system works across variability.
- Validation files are organized and easy to retrieve, not scattered across departments or systems.

Notes / Gaps / Owners:

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Section 6 – Documentation, Trending, and CAPA

Goal: Prove control over time, not just on a single day.

Checklist (0–2 each):

- We maintain an index of key micro documentation (PCP sections, EMP, sampling plans, validation, lab agreements, recent results).
- We produce regular trend reports (e.g., monthly/quarterly) for EMP and key product tests.
- Trend reviews are part of management meetings, with defined action limits and triggers for deeper investigation.
- CAPA documentation includes root-cause analysis, specific actions, and effectiveness checks—not just "clean and retest."

Notes / Gaps / Owners:

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Consider a review call: If trends or CAPAs reveal recurring issues, a brief, non-binding call focused on one or two patterns can help distinguish between "noise" and genuine system weaknesses that CFIA might question.

Section 7 – People, Training, and Incident Playbooks

Goal: Ensure the right people are ready to act and explain your program under pressure.

Checklist (0–2 each):

- Named owners exist for EMP design, PCP verification, validation oversight, and audit/incident response.
- Staff who collect samples or interpret results have documented training and competency assessments.
- We have a written 24–72-hour incident playbook for CFIA positives or suspected contamination, including decision trees for holds and expanded testing.
- We have run at least one mock audit or tabletop exercise in the last 12–18 months to rehearse roles and responses.

Notes / Gaps / Owners:

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Section 8 – Scoring and Priority Planning

1. Scoring

For each section, total your 0–2 scores:

- Section 1 – PCP & Micro Alignment: ___ / 8
- Section 2 – EMP Design: ___ / 10
- Section 3 – Product/Water/Ingredient Testing: ___ / 8
- Section 4 – Methods & Labs: ___ / 8
- Section 5 – Validation & Special Studies: ___ / 10

- Section 6 – Documentation, Trending & CAPA: ___ / 8
- Section 7 – People & Incident Playbooks: ___ / 8

Overall score: ___ / 60

You do not need a "perfect" score. The value comes from seeing where risk and effort cluster.

2. Priority Matrix

Pick your top 3–5 gaps that:

- Have high risk if CFIA challenges them
- Would be costly or complex to fix under time pressure
- Require cross-functional decisions (QA, operations, engineering, regulatory)

List them here:

1.
2.
3.
4.
5.

Turning This Worksheet Into Action

This checklist is designed to stand on its own. You can use it entirely internally to:

- Prepare for upcoming CFIA audits
- Justify micro-related investments to leadership
- Align plant QA and operations on where to focus next

If you want an external perspective after you've completed it, a simple, no-obligation next step is:

Book a CFIA Microbiology Audit-Readiness Review Call

- *Walk through your scores and top gaps with an ISO 17025-accredited food microbiology partner*
- *Pressure-test your EMP design, validation files, and method/lab choices against current CFIA expectations*
- *Leave with a short, prioritized action plan you can execute with or without external help*

There is no commitment to move testing or validation projects. The goal of the call is to help you de-risk your next CFIA audit and give you a clearer, science-based narrative about how your plant manages microbiological hazards.