



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Inspection Modernization

OPTIMIZING CONFIDENCE IN FOOD SAFETY

Improved Food Inspection Model

Proposed Draft

RDIMS # 3349307



Canada

**Improved Food Inspection Model:
Proposed Draft**

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The following document describes the proposed details of the Canadian Food Inspection Agency's (CFIA) improved food inspection model. While this model was developed for food, representatives from the Agency's plant and animal health programs provided input with the intent that common components may be adapted. The model remains under development and will be revised following an intensive process of review and consultation with all internal and external stakeholders.

1.0 Licensing/registration

Regulated parties that are subject to the legislation administered and/or enforced by the Canadian Food Inspection Agency (CFIA) would need to be identified for licensing/registration if they

- import or export food, or
- operate as manufacturers or processors of food products destined for interprovincial trade.

Single licence

A single licence will be issued to individual facilities and importers to carry out their operations. Additional licences are not required for each activity or product (e.g. importing and manufacturing, meat and fish).

1.1 Requirements

Regulated parties that import or export food or that operate as manufacturers or processors of food products destined for interprovincial trade would have to

- a) submit an application for a license that includes the following information:

General

- legal name
- operating name
- physical location in Canada/ mailing address/ billing address
- responsible party email/ telephone contact information
- business status (e.g. seasonal)

Activities information

- interprovincial trade
- importer
- exporter

Product(s) and process information

- product (e.g. fish, cheese, meat, vegetables)

- product type (e.g. ready-to-eat, raw, preserved)
 - processes (e.g. canning, pasteurization, freezing, drying, packing)
 - volume of product (small, medium, large)
- b) provide a statement indicating management's commitment to meeting regulatory requirements
 - c) develop, document and maintain a preventative control plan, suitable to their activities and operations, to meet food safety and regulatory requirements
 - d) demonstrate that key personnel within the food business have successfully completed safe food handling training or have demonstrated experience in safe food handling practices and other appropriate training (e.g. good importing practices)
 - e) notify the CFIA of confirmed food safety non-compliance in the marketplace

Once licensed/registered, a regulated party would be responsible for updating changes to their business information (e.g. QA manager, new activities, products and processes).

Exceptions might be considered (see section 1.6: Exceptions to licensing).

1.2 Rationale for licensing/registration

For food safety and regulatory compliance, the CFIA needs to know who is doing what with food.

Information submitted by industry would allow the CFIA to develop a profile of regulated parties, their activities and, more broadly, a knowledge base about a particular food sector. This information would help the CFIA to determine the initial inherent risk associated with the regulated party's operations, which in turn would allow the CFIA to determine the conditions of the licensing/registration and the initial level of oversight.

1.3 Issuing, refusing and amending a license

1.3.1 Process for issuing a license

The regulated party would be required to submit a licensing application to the CFIA.

A regulated party would also be required to apply for a new license if the ownership of the food business (legally responsible party) were to change.

Step 1: Preliminary review

The CFIA would confirm that the application was accurate and complete.

Step 2: Assignment of risk category for determination of pre-licensing/registration inspection

The CFIA would assign a licence category based on risk. Food businesses and importers would be categorized into three Categories (1, 2, 3) by considering relevant information (risk factors) submitted.

Step 3: Issuance of license

Additional verification activities, such as an on-site visit, may be required before a licence would be issued to a Category 1 food business. For processors and importers not considered high-risk, licenses would be issued based on the information submitted. When a license is issued, the licensee would be provided with the appropriate links to the Department of Justice website so that they could review CFIA-administered legislation and regulations that apply to their operations.

Step 4: Inspection for high-risk processors and importers

For high-risk processors and importers, inspection could include

- a document review of the product and/or process controls in the preventative control plan (see section 4.2.5: Process and Product Controls)
- an on-site inspection visit focused on plant layout and product flow, as applicable, to verify the operating environment.

1.3.2 Conditions for refusing a license

The CFIA would not issue a license if the applicant

- were unable to meet regulatory requirements,
- did not have a physical location in Canada,
- had submitted an incomplete or inaccurate application,
- had falsified or forged documents or records, or
- had outstanding penalties or fees.

1.3.2.1 Appealing the refusal of a license

When a license application is refused, the applicant would have the right to appeal the decision.

The regulated party would be provided with an opportunity to demonstrate that they are capable of meeting the requirements. If the regulated party cannot provide facts to support their licensing application, the decision to refuse a license would be upheld.

1.3.3 Amending a license

A regulated party would be required to apply for an amendment to their license when there is

- a change in legal name or operating name,
- a change to the physical structure, or

- a change to the activities, processes or product type.

The preventative control plan would need to be updated to reflect any changes. The CFIA would follow up, where appropriate.

1.4 Suspension and cancellation of a license

The proposed criteria for suspending a license are as follows:

- The regulated party has committed deceptive practices to obtain the licence, such as providing false information to inspectors.
- The regulated party has repeatedly failed to address and/or correct food safety issues.
- The regulated party has not addressed repeated fraudulent activities (e.g. product substitutions).
- The regulated party has outstanding penalties.
- The regulated party prevents the inspector from carrying out his or her regulated duties.

In some instances, it might be necessary to cancel a regulated party's license.

The proposed criteria for cancelling a license are as follows:

- The regulated party has an outstanding suspension that cannot be resolved.
- The regulated party continued to operate while their license was suspended.
- The regulated party has committed repeated serious/critical violations.

1.4.1 Process for suspending a license

Step 1: Initiation

- a) The inspector would identify an issue and gather facts to support a suspension.
- b) The inspector would inform management of the recommendation to suspend.

Step 2: Review

- a) Management would review the file and possibly seek expert advice within the CFIA for consistent application of the suspension criteria.
- b) CFIA would meet with the regulated party to discuss findings, explain the process, and give the regulated party an opportunity to respond to the issue(s).
- c) CFIA would render a decision. If the decision were to suspend, the process would continue to Step 3.

Step 3: Communication of decision

- a) If the decision were to suspend, the regulated party would receive a written notice of suspension.
- b) The regulated party could appeal the suspension within a prescribed time frame.

Step 4: Appeal

- a) Once an appeal was requested, the CFIA would arrange a hearing with the regulated party to allow the presentation of facts and information which may amend the decision. If required, the regulated party would submit a plan for re-establishing compliance. Requests for an extension may be considered.
- b) The decision to suspend would either be upheld or repealed.
- c) As part of the transparency initiative, suspensions may be posted on the CFIA's external website.

Step 5: Follow-up

- The inspector would follow up to determine whether the issues indicated in the suspension were addressed within an agreed upon time frame.
- If the issues were addressed, the inspector would report his or her findings and close the file. The suspension would be removed.
- If the issues were not resolved, the process would move to that described in section 1.4.2: Process for cancelling a license.

1.4.2 Process for cancelling a license

Step 1: Initiation

- a) The inspector would identify that, while under suspension, the regulated party had not taken corrective actions within the prescribed time frame.
- b) The CFIA would review the file for a decision on maintaining the suspension or moving to a cancellation procedure.
- c) The regulated party would be notified of the decision, in writing.

Step 2: Review

- a) The CFIA would review the file and seek expert advice from within the CFIA to ensure that the cancellation criteria were applied consistently.
- b) The CFIA and the regulated party would meet to discuss findings, explain the process, and give the regulated party an opportunity to respond to the issue(s).
- c) The CFIA would render a decision. If the decision were to cancel the license, the process would proceed to that described in Step 3.

Step 3: Communication of decision

- a) If the decision were to cancel, the regulated party would receive a written notice of cancellation.

- b) The regulated party could appeal the cancellation within a prescribed time frame.

Step 4: Appeal

- a) Once an appeal was requested, the CFIA would arrange a hearing with the regulated party to allow the presentation of facts and information which may amend the decision. Requests for an extension may be considered.
- b) The decision to cancel would either be upheld or repealed.
- c) As part of the transparency initiative, cancellations may be posted on the CFIA's external website.

1.5 Period of validity

A license would be subject to renewal annually unless

- the CFIA takes compliance action (suspension or cancellation)
- the licensee voluntarily relinquishes the license to the CFIA

If a licensee's food business is a seasonal operation, the license would remain valid provided the CFIA is notified of when the licensee's operations begin and end. These notifications would permit the CFIA to plan appropriate inspection activities.

1.6 Exceptions to licensing

There are no exceptions to licensing under the current definition of the parties that require a license. The CFIA might consider exceptions for regulated parties inspected by a recognized, competent authority.

2.0 Exemptions

An exemption is a temporary authorization issued by the CFIA that would allow a regulated party to conduct an activity that is not otherwise permitted by legislation. Exemptions would not be issued where there are potential food safety impacts.

2.1 Requirements for exemptions

To obtain an exemption, a regulated party would need to provide the following information:

- a) product name (scientific name, if applicable)
- b) product type and description of product
- c) reason for the exemption, such as
 - research or experimental use
 - exhibition (not for further sale)
 - test market of new products that do not otherwise comply with applicable regulatory standards
 - exemption from regulatory requirements (non-food safety: packaging, labelling, grade, composition)
- d) total quantity or volume of product to be included in the exemption
- e) whether there would be single or multiple entry of shipment(s)
- f) end use, including a description of any processing steps or mitigation measures, as required
- g) final destination in Canada
- h) anticipated arrival date of product and province or point of entry
- i) time period requested
- j) country of origin and/or country of export, as required

Import shipments would need to be accompanied by a copy of the exemption or the original exemption.

2.2 Rationale for issuing exemptions

Exemptions would provide industry with the flexibility to meet specified needs (e.g. test markets, research) while allowing the CFIA to maintain a level of assurance that there are no adverse effects on food safety. The regulatory requirements would need to be reviewed for potential amendments, however, in situations in which exemptions were repeatedly issued to a regulated party.

2.3 Issuing, amending, suspending or cancelling an exemption

Exemptions would be issued by the appropriate delegated or designated decision-making authority.

2.3.1 Issuing an exemption

- a) The applicant would apply for an exemption; the CFIA would then verify that the application is complete and that an exemption is required.
- b) The CFIA would set the conditions that the exemption holder must meet.
- c) If approved, the CFIA would issue an exemption. If denied, the CFIA would notify the applicant of the reasons, in writing.

2.3.2 Amending an exemption

In order to amend the conditions of an exemption, the regulated party would submit an amendment request to the CFIA and surrender the original exemption to the nearest CFIA office. The request for amendment would identify the reason for the amendment.

The request for amendment would follow the same process as for a new exemption.

The CFIA would reserve the right to amend, cancel or suspend an exemption at any time, if circumstances change.

2.4 Period of validity

Exemptions would be valid for the period of time indicated (one year or less) and would not be automatically renewed.

2.5 Verification of exemptions

The CFIA would conduct verification of exemptions in response to complaints.

An investigation of a complaint and the process of verifying compliance could include the following inspection activities:

- a) Data associated with the regulated party would be retrieved from the CFIA's information systems to determine whether the exemption holder had met the conditions prescribed in the exemption.
- b) If required, the regulated party's records would be verified on-site to confirm that conditions were met.
- c) If non-compliance were detected, the appropriate compliance or enforcement action would be determined.

Once the exemption had expired, the CFIA may follow up to verify that products were no longer being imported or distributed.

3.0 Level of CFIA oversight

Risks posed by biological, chemical and physical hazards must be managed or eliminated during food production and processing. Regulated parties would be required to use preventative control plans to identify hazards and implement effective controls to reduce the inherent risk of a product. The level of CFIA oversight will be determined by residual risk remaining (after regulated party’s effective controls and compliance).

There will be three levels of oversight

- enhanced
- normal
- reduced

The level of oversight for importers would also depend on the CFIA’s level of confidence in the exporting country’s food safety systems. Oversight for food imported from countries with a food safety system that is comparable to that in Canada would be as above. The level of oversight could change—or alternate inspection strategies such as targeted product surveys could be used—for food imported from countries that do not have a comparable food safety system.

3.1 Verification frequencies

The frequency of oversight would be determined by

- the number of establishments in each level of oversight,
- the CFIA’s available resources,
- the CFIA’s priorities,
- third-party results, if applicable, and
- the regulated party’s compliance history (see Table 1).

Table 1: Summary of the proposed level of oversight in response to a regulated party’s compliance history.

Compliance History	Oversight
No corrective action requests (CAR) at last inspection	Move one category down
No CARs, but “other” regulatory non-compliance	Unchanged
Serious CARs	Move one category up
Critical CAR	Immediate compliance and enforcement action; move to enhanced oversight

3.2 Triggers

Inspections could be planned or initiated by the following triggers:

- targeted surveillance
- complaint/illness investigation
- a request from the regulated party (for import, export, domestic)
- information received from a third party, another government department or an international trading partner
- the results of an inspection process or sampling

3.3 Workplan

Workplans would be developed annually, and would be based on

- a review of inspection data,
- surveillance information, and
- environmental scanning information.

Workplans would outline

- the frequency of inspections for each level of oversight (enhanced, normal, reduced),
- priorities for verifying the eight elements of the preventative control plan (see Section 4.2: Preventative control plans),
- targeted surveillance plans (imports, product, environmental, other regulatory requirements), and
- system assessment review plans.

4.0 Inspection process

This Inspection process section outlines the CFIA's proposed procedures to verify the effectiveness of the regulated party's controls in providing safe and compliant food.

Inspection procedures include plan and records review, visual verification and interviews with regulated party staff. The inspector would assess all deviations, their relationships and impact on food safety and compliance. This process would involve critical thinking, problem solving and root-cause analysis.

Three key steps would be used consistently in the Inspection process (see Section 4.1: Steps of Inspection).

4.1 Steps of Inspection



Step 1: Preparation for inspection

Proposed activities

- a) Identify that a regulated party/facility requires Inspection based on national workplans or triggers
- b) Review the regulated party's file, including
 - previous non-compliance actions (e.g. detentions, CARs)
 - complaints, sampling results and other enforcement issues or actions
- c) Determine the scope of the Inspection process by
 - identifying specific elements to be verified based on national priorities and a review of the regulated party's file, which should focus on the most significant issues
 - focusing the scope of the initial inspection process on the food safety controls (e.g. sanitation, product and process control) outlined in the preventative control plan
 - determining whether verification will be announced or unannounced
- d) Gather inspection documents and tools, sampling equipment, safety equipment, and applicable supplies.

Step 2: Conducting verification

Proposed activities

- a) Opening meeting
 - introductions
 - explain verification process to be used, discuss date and time of the closing meeting
 - confirm whether there are any changes to the plant, products, personnel or company profile and revise profile if needed
 - verify whether there are any changes to the preventative control plan and modify scope if needed
 - update the regulated party on any changes to the inspection process and/or relevant regulations
 - review any outstanding compliance issues
 - confirm bio-security and safety requirements for the regulated party's facility
- b) Performing verification
 - Always begin verification at the finished product and progress towards incoming product and ingredients.
 - Conduct an initial verification (walk-through) of the facility to identify any conditions that may pose a food safety risk. Modify the scope of the verification process, if needed.
 - Use a combination of visual verification, document reviews and staff interviews to collect facts and assess specific elements of the preventative control plan.
 - Verify how effectively corrective actions have addressed previous non-compliance (see Table 2).
 - Conduct additional activities, as necessary, such as environmental sampling or product sampling.
 - Systematically record all information that pertains to the verification process.
 - Immediately initiate action to control the affected products and inform the facility/operator if critical non-compliance is identified and not appropriately controlled.
- c) Determining compliance
 - for the element(s) being assessed, analyse all the information collected to determine whether there are any potential impacts on food safety or regulatory requirements
 - determine whether non-compliance is critical, serious, other, or an opportunity for improvement (OFI; see Table 3)

Prepare a verification report and all necessary documentation based on the above analysis and the level of non-compliance.

Table 2: Summary of proposed actions in response to possible levels of non-compliance

Potential scenario	Proposed action
The corrective action plan is documented, has been implemented and has effectively addressed the non-compliance	No further action
The corrective action plan is not documented but non-compliance was effectively addressed	Company to update preventative control plan Any recurrence will trigger a critical CAR
The corrective action plan is documented but did not effectively address non-compliance	Becomes a critical CAR with associated actions
No documentation and non-compliance was not addressed	Becomes a critical CAR with associated actions

Table 3: Summary of the degrees of non-compliance

Type	Description	Proposed action
Critical	Immediate impact on food safety or repeated “serious” non-compliance	Take control of product and issue CAR A root-cause analysis will be required
Serious	Potential impact on food safety or repeated “other” non-compliance	Issue CAR A root-cause analysis may be required
Other	Non-compliance with regulatory requirements that are not related to food safety.	Request correction; follow-up at next scheduled verification
Opportunity for improvement (OFI)	No impact on food safety or regulatory violation	For discussion with the regulated party and/or education of the regulated party

Note: Other enforcement actions may be taken as required and appropriate

Step 3: Communication of verification results

Proposed activities

- a) Closing meeting
 - discuss overall findings of the assessment
 - provide a copy and explanation of the verification report and associated documents.
 - explain next steps and expectations
 - obtain management commitment to document and implement corrective action for any CARs issued

4.2 Preventative control plans

As a condition of obtaining and maintaining a license, regulated parties that import or export food or that operate as manufacturers or processors of food products destined for interprovincial trade would need to develop, document, implement, verify, validate, and maintain a preventative control plan, suitable to their activities and operations. Implementing effective preventative controls would contribute to the production or preparation of safe food and compliant product.

The preventative control plan would provide the regulated party with a framework to assess how effectively their ongoing activities produce safe and compliant food.

The preventative control plan would need to address the following eight elements, as appropriate (noting that, for example, importers that do not have a facility would not include the elements that address physical structure and maintenance):

- physical structure and maintenance
- equipment design and maintenance
- employee hygiene and training
- sanitation and pest control
- product/process control
- transportation and storage
- traceability and recall
- company verification processes

For each element, the plan would need to include the

- expected outcome
- designated person responsible
- procedures, such as

- control activities
- monitoring activities
- corrective actions
- monitoring frequency
- records and document control
- verification

In addition to food safety, all other regulatory requirements for food need to be included in the preventative control plan. This may include other concerns such as zoonotics, veterinary drugs or medications in feed for food animals.

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4.2.1 Physical structure and maintenance

Proposed outcome

The design and layout of food establishments prevents cross-contamination between and during operations and facilitates effective maintenance and sanitation.

Proposed standard

Facilities would need to be constructed and maintained to

- minimize contamination, including appropriate product and people flow
- facilitate appropriate maintenance, cleaning and disinfection
- minimize microbial growth and product spoilage through appropriate temperature controls
- control humidity and minimize airborne contamination
- prevent pest access and harbourage

Proposed verification approach

- 1) Confirm that the preventative control plan addresses the standard for this element.
 - If there are issues that do not fully meet the standard, assess whether the regulated party's procedures can effectively address the issue. For example, if the plant design does not meet standards for reducing contamination, the procedures in place should mitigate the risk.
- 2) Review records to identify and observe any deviations and corrective actions taken.
 - Review a representative cross-section of the records.
 - Based on this review, determine the impact of any deviations noted and whether these deviations are administrative or have potential to impact on food safety.
 - Determine whether the corrective action has dealt with the deviation or there is an underlying, systemic problem.
 - If there is a systemic problem that has potential to impact food safety, gather facts to substantiate that the regulated party understands the problem and has ensured that controls are effective.
 - Possibly conduct a root-cause analysis to analyze systemic problems.
- 3) Conduct a visual verification to assess the effectiveness of the plan.
 - Focus on any deviations identified in the records review to determine if corrective actions are effective.

- Note other deviations not captured in the records and assess potential impacts on food safety.
 - Determine if procedures have been followed but have failed to address the deviation. Facts need to be gathered to substantiate that the regulated party understands the problem and has validated that controls are effective.
 - Inspect outside including harbourage, water pooling, other possible areas of contamination
 - Inspect inside including physical structure and layout, conditions of floors, walls and ceilings, temperatures, lighting, ventilation, people and product flow.
- 4) Interview staff, if needed, to confirm observations and investigate discrepancies.
- Staff interviews should confirm that employees
 - understand the risks associated with their responsibilities
 - understand how actions mitigate the risks
 - understand the procedures and their impacts
 - have received the appropriate training
 - understand actions to be taken when problems arise
 - understand the importance of accurate records

4.2.2 Equipment design and maintenance

Proposed outcome

Equipment, utensils and containers are effective for their intended purpose and are designed, constructed, installed and maintained in a manner that prevents product contamination.

Proposed standard

Equipment, utensils and containers would have to be

- adequately and appropriately designed, constructed, installed and maintained (including calibration) such that they do not become sources of contamination for food products and are effective for their intended purpose
- easily cleaned, disinfected, and accessible for servicing and inspection or easily disassembled for those purposes, as required
- constructed of non-toxic materials

Proposed verification approach

- 1) Confirm that the preventative control plan addresses the standard for this element.
 - If there are issues that do not fully meet the standard, assess the effectiveness of the regulated party's procedures. For example, equipment cleaning specifications should be validated for effectiveness.
- 2) Review records to verify that the equipment is maintained and calibrated according to the plan and note any deviations and corrective actions taken.
 - Verify that the regulated party has validated any new equipment to confirm it is effective for its intended use.
 - Review a representative cross-section of the records.
 - Based on this review, determine the impact of any deviations noted and whether these deviations are administrative in nature or have potential to impact on food safety.
 - Determine whether the corrective action has dealt with the deviation or there is an underlying systemic problem.
 - If there is a systemic problem that has potential to impact food safety, gather facts to substantiate that the regulated party understands the problem and has ensured that controls are effective.
 - Possibly conduct a root-cause analysis to analyze systemic problems.
- 3) Conduct a visual verification to assess the effectiveness of the plan.

- Focus on any deviations identified in the records review to determine if corrective actions are effective.
 - Note other deviations not captured in the records (e.g. rust on equipment), assess potential impacts on food safety and determine whether procedures are adequate.
 - Determine if procedures have been followed but have failed to address the deviation. Facts need to be gathered to substantiate that the regulated party understands the problem and has validated that controls are effective.
 - Inspect equipment maintenance, such as signs of deterioration (e.g. rust, leaking oil).
 - Check that equipment functions properly—it is able to maintain proper temperatures, has appropriate pressure, net quantity, glass and metal detection—and is appropriately calibrated.
 - Note equipment location and whether it is accessible for maintenance and cleaning.
- 4) Interview staff, if needed, to confirm observations and investigate discrepancies
- Staff interviews should confirm that employees
 - understand the risks associated with their responsibilities
 - understand how actions mitigate the risks
 - understand the procedures and their impacts
 - have received the appropriate training
 - understand actions to be taken when problems arise
 - understand the importance of accurate records

4.2.3 Employee hygiene and training

Proposed outcome

All persons handling food adhere to sound hygiene practices so as to not contaminate food or transmit illness. All staff are adequately trained and supervised to ensure safe and compliant food.

Proposed standard

Employees would have to

- maintain an appropriate degree of personal cleanliness
- behave and operate in an appropriate manner (includes appropriate protective clothing)
- receive appropriate training for the operations they perform
- follow effective bio-security practices

Visitors would have to

- adhere to the company's bio-security and hygiene practices

Proposed verification approach

- 1) Confirm that the preventative control plan addresses the standard for this element.
 - If there are issues that do not fully meet the standard, assess the effectiveness of industry's procedures to meet the standard. For example, training provided in-house rather than by an outside provider will meet the requirements of the preventative control plan if the training is deemed adequate.
- 2) Review records to verify that appropriate employee training has been completed.
 - Review a representative cross-section of the records.
 - Based on this review, determine the impact of any deviations noted and whether these deviations are administrative or have potential to impact on food safety.
 - Determine whether the corrective action has dealt with the deviation or there is an underlying, systemic problem.
 - If there is a systemic problem that has potential to impact food safety, gather facts to substantiate that the regulated party understands the problem and has ensured that controls are effective.
 - Possibly conduct a root-cause analysis to analyze systemic problems.

- Confirm that there are appropriate records, including training program records (e.g. technical training, health and hygiene) and any other records related to this element (e.g. visitor's bio-security log).
- 3) Conduct a visual verification to confirm that employee practices adhere to the plan (e.g. hand washing, protective clothing, hair nets).
- Focus on any deviations identified in the records review to determine if corrective actions are effective.
 - Note other deviations not captured in the records and assess potential impacts on food safety. For example, if visitors are observed in processing rooms without appropriate attire, assess whether there is a potential impact on food safety.
 - If procedures have been followed but have failed to adequately address the deviation, gather facts to substantiate that the regulated party understands the problem and has validated that controls are effective.
- 4) Interview staff, if needed, to confirm observations and investigate discrepancies.
- Staff interviews should confirm that employees
 - understand the risks associated with their responsibilities
 - understand how actions mitigate the risks
 - understand the procedures and their impacts
 - have received the appropriate training

4.2.4 Sanitation and pest control

Proposed outcome

Prevent contamination, control hazards and facilitate hygienic production of food through effective sanitation and pest control.

Proposed standard

Cleaning and disinfection would have to

- ensure that all parts of the establishment are appropriately clean
- be continually and effectively monitored for suitability and effectiveness

Pest control would have to

- prevent the entry of pests into the facility (including detection and elimination of pest infestation on the site or in the facility)

Proposed verification approach

- 1) Confirm that the preventative control plan addresses the standard for this element.
- 2) Review sanitation and pest control records, including environmental sampling, and observe any deviations and corrective actions taken.
 - Review a representative cross-section of the records.
 - Based on this review, determine the impact of any deviations noted and whether these deviations are administrative or have potential to impact on food safety.
 - Determine whether the corrective action has dealt with the deviation or there is an underlying systemic problem.
 - If there is a systemic problem that has potential to impact food safety, gather facts to substantiate that the regulated party understands the problem and has ensured that controls are effective.
 - Possibly conduct a root-cause analysis to analyze systemic problems.
- 3) Conduct a visual verification to assess the effectiveness of the plan.
 - Focus on any deviations identified in the records review to determine if corrective actions are effective.
 - Note other deviations not captured in the records, and assess factors that affect or have the potential to affect food safety. For example, if problems are noted with sanitation in the facility—such as product build-up—assess whether there is potential for impact on food safety.

- If procedures have been followed but have failed to adequately address the deviation, gather facts to substantiate that the regulated party understands the problem and has validated that controls are effective.
- Check that surfaces, overhanging structures and equipment are visibly clean.
- Observe cleaning and disinfection process and note any concerns (e.g. equipment contaminated by spray from floor).

4) Interview staff to confirm observations and investigate discrepancies.

- Staff interviews should confirm that employees
 - understand the risks associated with their responsibilities
 - understand how actions mitigate the risks
 - understand the procedures and their impacts
 - have received the appropriate training
 - understand actions to be taken when problems arise
 - understand the importance of accurate records

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4.2.5 Process and product controls

Proposed outcome

Process and product controls ensure the production of safe food that is in compliance with applicable regulations.

Proposed standard

Process controls would be based on hazard analysis and critical control points (HACCP) principles and would

- identify potential hazards
- identify steps critical to food safety or regulatory compliance
- implement effective control procedures at each of those steps
- monitor control procedures to ensure continuing effectiveness
- document deviations and corrective actions
- review control procedures periodically and when operations change

Product controls would focus on achieving regulatory compliance and would

- identify regulatory requirements that must be met
- identify steps to achieve compliance
- implement effective control procedures at those steps
- monitor control procedures to ensure continuing effectiveness
- document deviations and corrective actions
- review control procedures periodically and when operations change

Importers would establish, implement and maintain procedures for ensuring offshore processors meet both product and process control standards.

Exporters would establish, implement and maintain procedures for ensuring exported products meet importing country requirements. The CFIA will notify importing countries (the receiving country) of Canadian food products that they have received that have been found to be non-compliant for food safety.

Proposed verification approach

Process controls

- 1) Confirm that the preventative control plan addresses the standard for this element.

- 2) Review records to verify that process controls are implemented according to the plan and observe any deviations and corrective actions taken.
 - Review a representative cross-section of the records.
 - Based on this review, determine the impact of any deviations noted and whether these deviations are administrative (e.g. records missing a signature) or have potential to impact on food safety.
 - Determine whether the corrective action has dealt with the deviation or there is an underlying, systemic problem.
 - If there is a systemic problem that has potential to impact on food safety, begin to identify products that may have been affected and gather information for a health risk assessment. Control any affected product at the facility.
 - Possibly conduct a root-cause analysis following corrective action to ensure that the problem doesn't reoccur.
 - Confirm that there are appropriate records, including product or environmental sampling records impacting on food safety, processing records, import records impacting on food safety (e.g. proof of process validity).
- 3) Conduct a visual verification to assess the implementation of the plan.
 - Focus on any deviations identified in the records review to determine if corrective actions are effective.
 - Note other deviations not captured in the records, and assess potential impacts on food safety (e.g. the diversion valve on the pasteurizer was not tested at the start of operation).
 - Determine whether food safety was impacted and, if so, initiate compliance action.
 - If not, determine the cause of the non-compliance.
 - Note any deviations, whether procedures are being adhered to and any corrective actions taken.
 - Bring in additional expertise, if needed, to evaluate complex operations and equipment such as pasteurization, low acid canning, container integrity, time/temperature processes, and process deviation controls.
- 4) Interview staff to confirm observations and investigate discrepancies.
 - Staff interviews should confirm that employees
 - understand the risks associated with their responsibilities
 - understand how actions mitigate the risks
 - understand the procedures and their impacts
 - have received the appropriate training
 - understand actions to be taken when problems arise
 - understand the importance of accurate records

Product controls (domestic, import and export)

- 1) Confirm that the preventative control plan addresses the standard for this element.
- 2) Review records to observe any deviations and corrective actions taken.
 - Review a representative cross-section of the records.
 - Based on this review, determine the impact of any deviations noted and whether these deviations are administrative or have potential to impact on food safety (e.g. net quantity deviation should be addressed with recalibration of equipment or, for imported products, resolving issue with supplier).
 - If the non-compliance results in marketplace deception or misrepresented product, take appropriate compliance action (e.g. relabelling, repacking, importer alert).
 - Confirm that there are appropriate records, including incoming product and ingredient records, recipes, records of analysis, calibration records, supplier quality assurance certificates, foreign country certificate, etc.
- 3) Conduct a visual verification to assess the effectiveness of the plan (e.g. label verification, net quantity, grades).
 - Focus on any deviations identified in the records review to determine if corrective actions are effective.
 - Note other deviations not captured in the records, and assess factors that affect or have the potential to affect regulatory compliance (e.g. determine the cause of improper labelling—deception or procedural failure).
 - If the non-compliance results in marketplace deception or misrepresented product, take appropriate compliance action (e.g. relabelling, repacking).
- 4) Interview staff to confirm observations and investigate discrepancies.
 - Staff interviews should confirm that employees
 - understand the procedures and their impacts
 - have received the appropriate training
 - understand actions to be taken when problems arise
 - understand the importance of accurate records

4.2.6 Transportation and storage

Proposed outcome

Food is protected from potential sources of contamination and any damage that is likely to render the food unsuitable for consumption. Growth of pathogenic or spoilage micro-organisms are controlled.

Proposed standard

Transportation and storage would

- protect food from contamination or damage
- control growth of micro-organisms (refrigeration, freezing)
- be suitable for its purpose, maintained and clean

Proposed verification approach

- 1) Confirm that the preventative control plan addresses the standard for this element.
- 2) Review records to identify and observe any deviations and corrective actions taken (e.g. tanker cleaning records, temperature charts).
- 3) Interview staff to confirm observations and investigate discrepancies.
 - Staff interviews should confirm that employees
 - understand the procedures and their impacts
 - understand actions to be taken when problems arise
 - understand the importance of accurate records

4.2.7 Traceability/recall

Proposed outcome

Non-compliant food products are effectively controlled from entering the marketplace and/or retrieved if they have been distributed.

Proposed standard

Traceability and recall procedures would ensure that

- food is properly identified, including incoming and outgoing ingredients
- food products can be rapidly removed from the marketplace
- the CFIA is notified of any unsafe food products in the marketplace
- recalled product is properly controlled and prevented from re-entering the marketplace

Proposed verification approach

- 1) Confirm that the preventative control plan addresses the standard for this element.
- 2) Review records to observe any deviations and corrective actions taken.
 - Review mock recall records that demonstrate the effectiveness of the traceability and recall programs (request a mock recall if none has been done as per the written plan).
- 3) Visually verify that the traceability system matches the records (e.g. proper coding is used, production code).
- 4) Interview staff to confirm observations and investigate discrepancies.

4.2.8 Regulated party's verification processes

Proposed outcome

To validate that the preventative control plan continues to be suitable, adequate and effective.

Proposed standard

Verification would

- confirm that preventative control measures achieve their specified purpose and are adjusted as required
- initiate a preventative control plan update if there is any change that impacts food safety and regulatory compliance

Proposed verification approach

- 1) Confirm that the preventative control plan addresses the standard for this element.
- 2) Review records to ensure that the regulated party's verifications are implemented according to the plan and observe any deviations and corrective actions taken, including the initial validation and subsequent verifications (e.g. environmental testing, product testing).
 - Based on this review, determine the impact of any deviations noted and whether these deviations are administrative or have potential to impact on food safety.
 - Determine whether the corrective action has dealt with the deviation or there is an underlying systemic problem.
 - If there is a systemic problem that has potential to impact on food safety, begin to identify products that may have been affected and gather information for a health risk assessment. Control any affected product at the facility.
 - Analyze systemic problems using a root-cause analysis to ensure that the problem doesn't reoccur.
- 3) Conduct a visual verification
 - Focus on any deviations identified in the records review to determine if changes made to the preventative control plan have been implemented.
 - Note other deviations not captured in the records, and assess factors that can affect or have the potential to affect food safety.
 - If the non-compliance results in unsafe product, take appropriate compliance action.
- 4) Interview staff to confirm observations and investigate discrepancies

- Focus on confirming what actions are taken when the verification process reveals trends of non-compliance.
- Assess whether the preventative control plan has incorporated the analysis of the verification results.

4.3 Third-party verification

The realities of the food supply chain have led the industry to develop and implement third-party certification schemes. These third-party verifications could be taken into account by the CFIA for consideration, including adjusting the level of oversight, provided that the verifications address requirements.¹

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¹ The CFIA would have to develop consistent guidelines for recognizing third-party service delivery providers.

5.0 Imports

All requirements would apply equally to domestic processors and importers. As importers do not process food, they would have to ensure that they import safe and compliant food products by having preventative control plans to address the risks. This section provides further details related to importing.

5.1 Licensing and exempting

All importers must hold a valid licence/registration in order to import food into Canada.

5.2 Preventative control plans

Food products entering Canada must meet all regulatory requirements for safety, nutrition, composition, labelling, packaging and quality, as applicable. Further diligence is required at the importer level to meet Canadian requirements and prevent the introduction of animal and plant diseases and pests

Importers do not have direct control over food production and would therefore need to develop other strategies to address risks. Mitigation strategies that the importer could use include

- selecting suppliers that are regulated by a foreign country competent authority and are identified on a list of eligible exporters;
- selecting suppliers that are subject to third-party audits by internationally-recognized accreditation or certification;
- selecting and verifying suppliers that are using a HACCP-based system or preventative control plan in their production;
- selecting suppliers that conduct regular sampling and testing and provide certificates of analysis; or
- using accredited or recognized sampling and testing laboratories to do their own testing at the time of importation.

Importers would need to include elements of the preventative control plan that apply to their operation. For example, importers without facilities would not be expected to address physical structure and maintenance. However, all importers would, at a minimum, need to include the following elements in their preventative control plans:

- product control
- traceability and recall
- company verification process

It is important that accurate records be maintained so that product can be tracked and the CFIA can be notified when non-compliant product is found. This information is

necessary to determine further strategies for preventing entry of non-compliant product (e.g. importer alert, foreign country notification, de-listing).

5.3 Inspection

The CFIA would review importer records to verify they have the proper controls in place and that their controls are effective. The CFIA would use product surveillance as a tool to determine the level of compliance for products entering Canada.

When notified by an importer of non-compliant product, the CFIA would take steps appropriate to the nature and severity of the issue to prevent further product from entering the country until corrective action is taken at the source. The CFIA would notify all known importers of the affected product through an import alert and the competent authority in the exporting country.

When importation of a product from a previously non-compliant foreign supplier resumes, the importer would be required to hold and test the product using an accredited laboratory until acceptable results are obtained from five consecutive shipments. Acceptable sampling techniques must be used and records of analysis maintained.

Depending on the nature and severity of non-compliance, the CFIA may review technical arrangements or other bilateral agreements to determine whether amendments are required.

5.4 Surveillance

Surveillance is a key activity when

- food is prepared outside the country where requirements or competent authority oversight is not comparable, or
- on-site verification of the processing controls cannot be conducted by the CFIA.

To inspect importers, the CFIA would use product surveillance as a tool to identify gaps and trends, to determine sector performance, or to provide baseline information such as the level of chemical contaminants in certain foods. Analysis of this type of information would provide a mechanism for continuous improvement through activities such as adjusting risk profiles, changing standards or requirements, and planning work.

6.0 Exports

All of the requirements of the model apply to exporters. Exporters are responsible for exporting safe and compliant food products that meet all foreign regulatory requirements. This section provides further details related to exporting.

6.1 Preventative control plans

Food products exported from Canada must meet all foreign regulatory requirements.

In addition to their domestic preventative control plan, exporters would require export controls that address any foreign regulatory requirements (e.g. labelling requirements). At a minimum, all exporters would need to include the following information in their export control plan:

- importing country requirements and standards;
- additional testing or treatment requirements;
- product identification, segregation, and traceability requirements; and
- records required for exports.

6.2 Inspection

Following the process for inspection described in section 4.0, the CFIA would verify how effectively the exporter's preventative controls ensure safe and compliant food that meets the exporting country's certification requirements.

6.3 Issuance of export certificates

Export certificates would be issued based on the exporter's compliance with their export controls, and could be issued without further lot-by-lot product inspection. Clearly, this approach would only be used if it were accepted by the importing country. The CFIA would continue to negotiate with its trading partners to promote this concept. If required by the foreign country, the CFIA could conduct product inspection of exported lots.

If notified by an exporter that non-compliant product had been exported, the CFIA would take appropriate steps to recover and control the non-compliant product. Trading partners would be alerted of this non-compliance using established protocols. The exporter should adjust their preventative controls to address this non-compliance.

7.0 Compliance and enforcement

7.1 Compliance options

Once non-compliance is identified, the CFIA would determine the most appropriate response; CFIA officials would examine each case individually. The CFIA's *Compliance and Enforcement Policy* would be used as a basis for all compliance and enforcement decisions.

The level, type and extent of response to non-compliance would depend on a range of factors including

- circumstances under which non-compliance is identified, such as
 - detection by the CFIA during inspection
 - notification of non-compliance by a foreign country competent authority
 - outbreak of a foodborne illness
 - notification from a regulated party
 - notification by a third party
 - complaint
- potential impact or potential for harm
 - the degree to which non-compliance could impact on food safety, public health or consumer protection
 - the type of the non-compliance (e.g. critical, serious, other)
- intent of the regulated party
 - the extent to which the regulated party has exercised due diligence
 - whether non-compliance was intentional, accidental or negligent
- regulated party's demonstrated performance
 - history of complaints
 - history of non-compliance
 - level of commitment by management

Specific responses could be directed at the product and/or the regulated party. Increasingly stringent compliance and/or enforcement actions could be considered, depending on the severity of non-compliance.

Range of possible responses

- issue corrective action request
- issue letter of non-compliance
- seize and detain product
- restrict or stop operations
- forfeiture of product or thing
- dispose of product
- condemn product
- issue import alert
- refuse entry
- issue order to remove from Canada
- refuse to certify
- recall product
- communicate with foreign government competent authority
- suspend or cancel license
- amend, suspend or cancel exemption
- administer monetary penalty
- publish non-compliance
- prosecute

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8.0 System Performance

To validate the food inspection program for continuous improvement, the CFIA would conduct environmental scans, review inspection and surveillance data, and complete trend analysis on an annual basis. The objective of validation would be to

- assess overall effectiveness of the food inspection system
- assess program integrity to ensure that inspection program is delivered consistently, effectively and efficiently
- identify gaps and trends
- create accountability and provide feedback to support continuous improvement.

The results of validation would be used to review program effectiveness, adjust workplans and make improvements to program design and delivery.

Measuring performance is a collective CFIA responsibility. The validation process will be delivered jointly by Operations, Policy and Programs and Science Branches.

8.1 Effectiveness of the food inspection system: program effectiveness

Product sampling is an important tool to determine program effectiveness. This could include baseline sampling or targeted sampling to:

- confirm a system is effective,
- establish a baseline,
- identify trends, and
- verify compliance.

8.2 Integrity of the food inspection program: consistency and quality

In order to assess the consistency and quality of the inspection program, there would be planned oversight and review of the delivery of the inspection program. This includes

- reviewing documentation for completeness and accuracy to identify issues such as training needs, updates required for policies, procedures, and clarity of instructions
- conducting on-site review to evaluate delivery of inspection activities, with attention to
 - national consistency
 - the level of understanding of responsibilities
 - appropriate identification of non-compliance

- taking appropriate action in cases of non-compliance, including root-cause analysis
- identifying issues that require correction
- directing any issues identified through the process to the accountable party for response and correction

8.2.1 Levels of review

To assess overall consistency and quality of the inspection program, an annual workplan would be developed that would identify reviews to be conducted. This would create accountability and provide feedback to support continuous improvement.

8.2.2 Proposed process for reviews

- a) Identify scope of review.
- b) Request a cross-section (e.g. domestic, import, export) of documents for review that relate to previous inspections.
 - focus on non-compliance actions (e.g. detentions, CARs)
- c) Select criteria to be included in the review from Table 4, while ensuring that all criteria were covered over a five-year period.
- d) Complete a summary report of findings. Any findings that could be addressed locally would have to be discussed with the inspector and supervisor. Findings that need to be addressed at higher levels would be forwarded to the appropriate contacts to allow them to take action and to identify common issues and trends.
- e) Additional expertise, if needed, would be brought in to evaluate complex operations and equipment such as container integrity, time/temperature processes, and process deviation controls.

Table 4: Summary of proposed steps involved in the validation process under the draft modernized inspection model

Step	Details of review
Licensing review	
1. Preparation Inspector authorization	<ul style="list-style-type: none"> • the inspector has the appropriate designation to conduct the activity • the person conducting the inspection has a valid CFIA badge and ID card that is legible, valid, has the correct name, etc.
Inspector training	<ul style="list-style-type: none"> • the inspector has successfully completed the required training
Reference and inspection documents and tools	<ul style="list-style-type: none"> • the inspector has the appropriate documents, tools and supplies for the inspection
2. Inspection Issuing license	<ul style="list-style-type: none"> • a review of the preventive control plan is completed, if required, that focuses on plant layout and product flow • a correct licensing decision is made, as determined by the results of the review
3. Communication of verification results Issuing license	<ul style="list-style-type: none"> • the license is issued or notice of refusal is issued within the timeframe outlined
On-site review	
1. Preparation Inspector authorization	<ul style="list-style-type: none"> • the inspector has the appropriate designation to conduct the activity. • the person conducting the activity has a valid CFIA badge and ID card that is legible, valid, has the correct name, etc.
Inspector training	<ul style="list-style-type: none"> • the inspector has successfully completed the required training
Reference and inspection documents and tools	<ul style="list-style-type: none"> • the inspector has the appropriate documents, tools and supplies for the inspection
Determine scope	<ul style="list-style-type: none"> • the regulated party that requires verification is identified appropriately from the workplan or triggers • the regulated party file is reviewed and scope is appropriately identified
2. Conducting verification Opening meeting Performing verification	<ul style="list-style-type: none"> • an opening meeting is conducted appropriately and scope is adjusted, if required
	<ul style="list-style-type: none"> • initial on-site assessment of the general conditions is conducted and scope adjusted if required—taking into account any previous CARs • visual verification, record review and staff interviews are used appropriately to collect facts • non-compliance is appropriately identified and potential impacts are assessed

Step	Details of review
	<ul style="list-style-type: none"> • inspector assesses whether the regulated party's corrective actions were effective; if not, takes the appropriate compliance action
Product and environmental sampling	<ul style="list-style-type: none"> • samples are collected, identified, handled, stored, packaged, tagged and shipped appropriately
Determining level of compliance	<ul style="list-style-type: none"> • the appropriate level of compliance is assigned and supported by facts, and recorded appropriately
3. Communication of verification results Closing meeting	<ul style="list-style-type: none"> • results are communicated in a clear, concise, factual and timely manner. Questions are addressed • a CAR for critical and serious non-compliance is issued and discussed • any other regulatory non-compliance is discussed • management commitment is obtained or, if not, a proper note is included in the report
Document review	
Final report	<ul style="list-style-type: none"> • the inspection report provides the regulated party with an accurate summary of the verification and includes any CARs • the inspection report conveys the results in a clear, concise, factual, complete, and accurate manner • a CAR is issued for critical and serious non-compliance
Export certificates	<ul style="list-style-type: none"> • export certificate is complete and accurate • decision to issue certificate is appropriate
Sample reports	<ul style="list-style-type: none"> • sample submission form is complete and accurate • sample integrity is maintained
Other forms	<ul style="list-style-type: none"> • documents are complete and accurate, such as <ul style="list-style-type: none"> ○ letters of non-compliance ○ detention documentation