

Discussion Paper: Proposal for a Fish Food Safety Regulation under the *Food Safety and Quality Act, 2001*

Ministry of Agriculture,
Food and Rural Affairs

Ministère de l'Agriculture, de
l'Alimentation et des Affaires rurales



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Executive Summary

The Ministry of Agriculture, Food and Rural Affairs (OMAFRA) is seeking input on a proposal to modernize the food safety regulation of fish processors that are not federally registered.

The ministry provides oversight of fish processors that distribute products only within the province under R.R.O. 1990, Reg. 456 - Quality Control (Regulation 456) made pursuant to the *Fish Inspection Act*.

The proposal (subject to approval) is to replace Ontario's current *Fish Inspection Act* and Regulation 456 with a new regulation under the *Food Safety and Quality Act, 2001*.

The proposed regulatory changes would:

1. Set out who the regulation applies to, and focus on:
 - Fish and fish products
 - Businesses processing fish or fish products for distribution
2. Have different requirements, based on risk:
 - Require registration of processors conducting lower-risk processing but distributing significant amounts of fish or fish products
 - Require registration and licensing of processors conducting higher-risk processing of fish or fish products for distribution, and of licensed meat plants under Ontario Regulation 31/05 Meat (Meat Regulation) processing fish or fish products.

This discussion paper outlines the province's proposal to regulate the processing of fish and fish products and poses questions for your consideration. The ministry seeks your input before the regulatory proposal is finalized. Should the decision be made to proceed with one or all elements of the proposal, the comments received will be considered during final preparations.

Comments and Feedback

Your responses to the questions posed, and any other feedback must be received by October 3, 2016 and may be submitted either to the ministry contact information identified below or through the Ontario Regulatory Registry at:

www.ontariocanada.com/registry/

**Proposal for a Fish Food Safety Regulation under the
*Food Safety and Quality Act, 2001***

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Electronic versions of this document and legislation referenced in this document may be found on the Regulatory Registry or on the Ontario Ministry of Agriculture, Food and Rural Affairs' website at:

www.ontario.ca/fishinspection

Introduction

The Ontario commercial fish food industry is comprised of: freshwater commercial fishing, aquaculture and processing. Ontario's freshwater catch accounts for 53 per cent of the total value of commercial freshwater fisheries in Canada, making it one of the largest freshwater fisheries in the world. Aquaculture in Ontario includes the breeding, rearing and harvesting of fish in lakes, ponds and rivers, usually in cages or contained areas. While commercial freshwater fishing and aquaculture in Ontario provides for 11 per cent of fish used in processing in the province, 89 per cent of processed fish rely on imported fresh and frozen fish.

The fish processing sector is an important contributor to Ontario's agri-food economy. The average annual total revenue from processed fish in Ontario between 2010 and 2012 in both provincial and federal plants was approximately \$283 million. Fish processors conduct activities such as eviscerating, cutting, filleting, breading, freezing, pre-cooking, pickling, smoking, and packaging of fish for human consumption.

There are approximately 170 fish processors in Ontario. Of these, 69 are federally-registered fish processors that may sell products outside of the province and are subject to the federal *Fish Inspection Act*, with oversight provided by the Canadian Food Inspection Agency (CFIA).

About 100 fish processors sell products only within Ontario and are currently subject to the Ontario's *Fish Inspection Act*, administered by the Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA). Provincial fish processors account for about 15 per cent of fish processed and consumed in Ontario annually. It is estimated that about 80 per cent of the fish processed by provincial processors is derived from imported fish.

Fish processors in the province may also be also inspected by Public Health Units under the *Health Protection and Promotion Act*, administered by the Ministry of Health and Long-Term Care (MOHLTC).

Why Consider Changes Now?

The ministry is proposing changes to support the growth and development of a strong fish processing industry in Ontario. Strengthening the food safety standards would give consumers confidence in the quality and safety of Ontario's fish and fish

products. With clear food safety standards, Ontario's fish processors can better brand their business and seize new market opportunities.

Changing Industry

Ontario's *Fish Inspection Act* establishes basic construction, operational and processing requirements; however, it does not adequately address modern food safety standards and current industry practices. When it was enacted over 60 years ago, more of the fish marketed in Ontario was harvested from Ontario commercial fisheries and most fish received lower-risk processing (e.g., eviscerating, cleaning, filleting, icing). The sources and processing of fish have changed and expanded over time as a significant quantity of fish processed in Ontario is now imported.

Fish and fish product handling and processing activities are conducted in a wide range of operations. Fish is processed on land, but also on boats. The preparation of fish products takes place not only at fish processing facilities, but also at restaurants, grocery stores and bakeries. Food businesses are evolving, processing fish alongside other food products such as meat. In addition, the processes used at many operations are more complex, and commonly include higher-risk activities such as pickling, smoking and preparing ready-to-eat products.

Expected Outcomes

Enhanced Food Safety

Consumers expect food to be safe. Ontario is the only province in Canada with a significant provincial fish processing industry that does not license its fish processors and have clear risk-based requirements. A modern inspection program, including enhanced food safety requirements and appropriate enforcement tools, could strengthen consumer confidence in the safety and quality of fish from Ontario's processors.

Modern Risk-Based Regulation

There are provisions in Regulation 456 that are prescriptive and do not allow Ontario fish processors to address food safety risks in a flexible way, acknowledging that there are many ways to achieve the desired outcome. An outcome-based regulation would reduce unnecessary burden and establish requirements that are appropriate for the level of risk. At the same time, requirements that are no longer

relevant would not be included in the proposed regulation. It is the ministry's intent to focus on areas of higher-risk.

Support Competitiveness

With the changes, duplicative regulatory oversight would be eliminated and the scope of the proposed regulation would be more clearly defined. Requirements would be appropriate for the potential risks and would enable business innovation.

Proposed Regulatory Changes

The ministry is proposing to focus the scope of the regulation on fish and fish products (where fish products would be defined as a food product containing more than 25 per cent fish by weight or a ready-to-eat raw fish product), and regulate only those facilities that process fish and fish products for distribution to other businesses. Fish processors under the regulation would either require registration (if conducting lower-risk fish processing activities and distributing a significant amount of fish or fish products), or require registration and licensing (if conducting higher-risk fish processing activities for distribution).

1. Set Out Who the Regulation Applies To

The scope of Ontario's *Fish Inspection Act* is very broad and overlaps with other provincial legislation, including Ontario Regulation 562 - Food Premises (Food Premises Regulation) under the *Health Protection and Promotion Act*. The ministry is proposing to focus the scope of the provincial fish regulation by clearly setting out which businesses should be regulated. The proposed regulation would not apply to federally registered fish processors, businesses processing only food products containing small amounts of fish, and any business that only sells directly to the consumer, regardless of the process used. However, due to the risks of processing both meat and fish or fish products in the same facility, any provincially licensed meat plant processing fish or fish products will be required to be registered and licensed.

This would reduce potential duplication of oversight from other ministries or levels of government so that regulatory requirements are appropriate for the risk.

Distinguish Between Fish Products and Other Food Products

Many food processors prepare products containing fish. The proposal would clearly narrow the scope of the *Food Safety and Quality Act, 2001* regulation by distinguishing between fish products and other food products.

Generally, food products that contain small amounts of various ingredients are not regulated under commodity-specific regulations. For example, in Ontario, foods that contain meat, such as pasta sauce with meat, pepperoni pizza and chicken soup at a food premises are regulated through the Food Premises Regulation under the *Health Protection and Promotion Act*, and not in the commodity-specific meat regulation, Ontario Regulation 31/05 Meat (Meat Regulation) under the *Food Safety and Quality Act, 2001*.

For the purposes of the proposed fish regulation, products containing more than 25 per cent fish by weight, such as gravlax, breaded fish sticks, pickled herring, etc., would be considered fish products, and would be subject to the proposed regulation. Products containing 25 per cent fish or less by weight, such as salads, stews and pizza with anchovies, would not be considered fish products, and not be subject to the proposed provincial fish regulation.

Despite this proposed 25 per cent threshold for defining a fish product, a ready-to-eat raw fish product (e.g., sushi) could be included due to its higher level of risk.

Example

A bakery receives filleted white fish, cooks it and uses it as an ingredient to prepare fish pies. According to the bakery's recipe, the white fish accounts for 15 per cent of the weight of the product. The bakery does not use or process fish for any other products.

Based on the information in this example, this business would be outside of the scope of this proposed regulation. While the pie contains fish, it would be considered a food product and would not be subject to the proposed fish regulation. The business would instead be inspected by the local Public Health Unit for compliance with the Food Premises Regulation under the *Health Protection and Promotion Act*.

Questions for Consideration

Is the 25 per cent fish content by weight threshold an appropriate way to distinguish fish products from other food products containing fish? What other threshold(s) could be used and why do you think any suggested threshold would be preferable to the proposed threshold?

Are there any other products that should be considered fish products and should come under the provincial regulation, despite the 25 per cent content by weight threshold? Why?

Focus the Regulation on Businesses Processing Products for Distribution

It is proposed that the provincial fish regulation would only apply to businesses that process fish and distribute the fish products to other businesses. This would include distribution to other food processors, grocery stores, restaurants and caterers, etc.

If a business processes fish and sells all fish and fish products directly to consumers, it would not be subject to the proposed regulation, regardless of the type of processing performed or the fish content of the products. Most sales made directly to consumers take place in grocery stores or at food service premises like restaurants. Local Public Health Units are responsible for enforcing the Food Premises Regulation of the *Health Protection and Promotion Act* at these premises.

Example

A restaurant smokes fish on site and serves the fish in meals to customers. The restaurant also prepares fish for take-out. All sales from the restaurant are made directly to consumers.

Based on the information in the example, the restaurant would be outside of the proposed scope of this regulation but would be inspected by the local Public Health Unit for compliance with the Food Premises Regulation under the *Health Protection and Promotion Act*.

Question for Consideration

Are there any circumstances that should require businesses that only sell directly to consumers (e.g., restaurant or grocery store) to be included in the proposed regulations? Why?

2. Requirements Based on Risk

Requirements for fish processors should align with the risk associated with the different processing activities and with the volume of products being distributed. The proposed requirements for fish processors would build on the foundation established in the current regulation and could include a requirement for registration, additional good manufacturing practices and plant design improvements. To address more complex, higher-risk fish processing activities it is proposed that the facility be licensed and that additional procedures and written programs be required.

When determining risk, both likelihood and impact must be considered. The type of processing activity can affect the likelihood of a food safety incident occurring. Processing activities can be grouped into lower-risk and higher-risk categories. Distribution of products can increase the impact of a food safety incident as products are distributed to customers throughout the province. Generally, the greater the volume of products distributed, the greater potential impact on the public, should a food safety incident occur.

Lower-risk processing activities are usually simple processes like eviscerating, cleaning, filleting and cutting.

Higher-risk processing activities generally require multiple steps and are complex, including: canning, fermenting, pickling, smoking, and any other secondary process resulting in a ready-to-eat fish product. “Ready-to-eat” means the product is edible without additional preparation to achieve food safety, e.g., sushi.

Questions for Consideration

Are the types of activities listed as lower-risk appropriate? Are there other processes that should be included?

Are the activities included in the list of higher-risk processing activities appropriate? Are there others that should be included?

Does the proposed meaning of “ready-to-eat” make sense?
“Ready-to-eat” means the product is edible without additional preparation to achieve food safety, e.g., sushi.

Registration for Fish Processing Facilities

Under the proposal, if a processor conducts only lower-risk activities, like cleaning and filleting fish, and distributes products to another business, then the processor would require registration with the ministry or be required to provide information to OMAFRA. For example, registered fish processors may eviscerate, clean and cut the fish into steaks, then distribute the product to grocery stores. Once registered, certain requirements of the proposed regulation would need to be met (see Appendix B).

Exception to the Registration Requirement

Greater product distribution can increase the impact of a food safety incident. Therefore, food safety risk is considered low if a small volume of fish or fish products from lower-risk activities are distributed.

It is proposed that a business could be excluded from the proposed regulation if only lower-risk activities are performed and less than 25,000 kg of fish and fish products are distributed (e.g., sold to other businesses like restaurants) annually. These types of businesses would be under the inspection of the local Public Health Unit for compliance with the Food Premises Regulation under the *Health Protection and Promotion Act*.

The proposed exception to the registration requirement is similar to the provincial meat inspection regulation where if a meat plant produces a small amount of lower-

risk meat products, it is exempt from the requirements of the meat regulation. This supports small business competitiveness without compromising food safety.

Registration Requirements

The proposed requirements for a processor who is required to provide information to the ministry would build on those in the current regulation under Ontario's *Fish Inspection Act*. Requirements would be outcome-based to provide processors with flexibility in meeting the requirements (refer to *Appendix A – Overview of Current vs. Proposed Requirements*)

There would be additional requirements regarding the following:

- Identification to the ministry and providing:
 - Facility location
 - Information such as the types of processing performed
 - Records of the volume of products distributed and received
- Facility and personnel requirements:
 - Location and site design, and approvals for new plants
 - Drainage and a back-flow prevention device for the plant's plumbing, etc.
 - Ensuring plant has potable water and ice, which could include testing
 - Food handler training
- Program requirements:
 - Control of hazards
 - Record keeping

Example

A fish processor receives fish, cuts them and then repackages the fish. Some fish is sold directly to consumers, but the majority of fish is distributed to grocery stores and restaurants. The processor is not a licensed meat plant. The processor estimates that the business sells over 70,000 kg of fish per year, with 70 per cent of its sales (~ 49,000 kg) distributed to other businesses.

Based on the information in the example, this business would be under the proposed regulation. The processes used are not considered higher-risk; however, the operator distributes 49,000 kg to grocery stores and restaurants. To be excluded from registration, the business needs to fall below the proposed distribution limit of 25,000 kg annually.

Questions for Consideration

Is the limit of 25,000 kg annually an appropriate way to exclude businesses from the regulation? If not, why?

Taking into consideration the possible changes discussed, would you be significantly impacted if your business requires registration?

Licensing of Higher-risk Processing Facilities

The ministry is proposing greater oversight of businesses that distribute products derived from higher-risk activities. Processes such as fermenting, pickling and smoking provide an increased risk for introduction and growth of bacteria and other pathogens that can cause foodborne illness. This risk is increased by the fact that most of these processes lead to ready-to-eat products, consumed without any cooking to destroy any harmful pathogens.

Under the proposed changes, higher-risk processes would be defined as the following: canning, fermenting, pickling, smoking, and any other secondary process resulting in a ready-to-eat fish product where “ready-to-eat” means the product is edible without additional preparation to achieve food safety, e.g., sushi.

Licensing Requirements

It is proposed that businesses conducting higher-risk activities and distributing products to other businesses, regardless of quantity, would require a licence from the ministry to operate. The licensing requirement would be in addition to registering their business with the ministry. A licence would be issued or renewed when processors meet the regulatory requirements for both registration and licensing.

To cover the administrative costs of licensing and licence renewal, a fee would likely be charged. It is proposed that licences would require renewal every three years, which is the same as the licensing requirement under the Meat Regulation.

The current Ontario *Fish Inspection Act* is out-dated. A modernized regulation would establish programs to address the risks associated with common processes such as hot and cold smoking, canning and fermenting of ready-to-eat fish products (See *Appendix B – Detailed of Proposed Requirements*).

The ministry proposes that processors conducting higher-risk processes as defined above, identify, document, and monitor risks by:

- preparing their own written programs for maintenance, sanitation, and pest control;
- establishing and following process controls and keeping records for higher-risk processes; and
- developing a recall plan that is tested periodically (e.g., performing mock recalls).

Example

A fish processor receives fresh fish then prepares smoked, salted fish. The processor sells most of the prepared products directly to consumers through a retail store on site. The processor also sells a small amount of the fish or fish products to a few nearby restaurants.

Based on the information in the example, the business would require licensing. In this case, the business uses a higher-risk process (smoking), and not all products are sold directly to consumers. If a business prepares fish products using a higher-risk activity and distributes any fish products to other businesses, then the business would be subject to the proposed regulation with specific requirements for those processes.

Questions for Consideration

Do you currently have written food safety programs and/or process controls?

What changes would have the most impact on you? Why?

Provincially Licensed Meat Plants Processing Fish

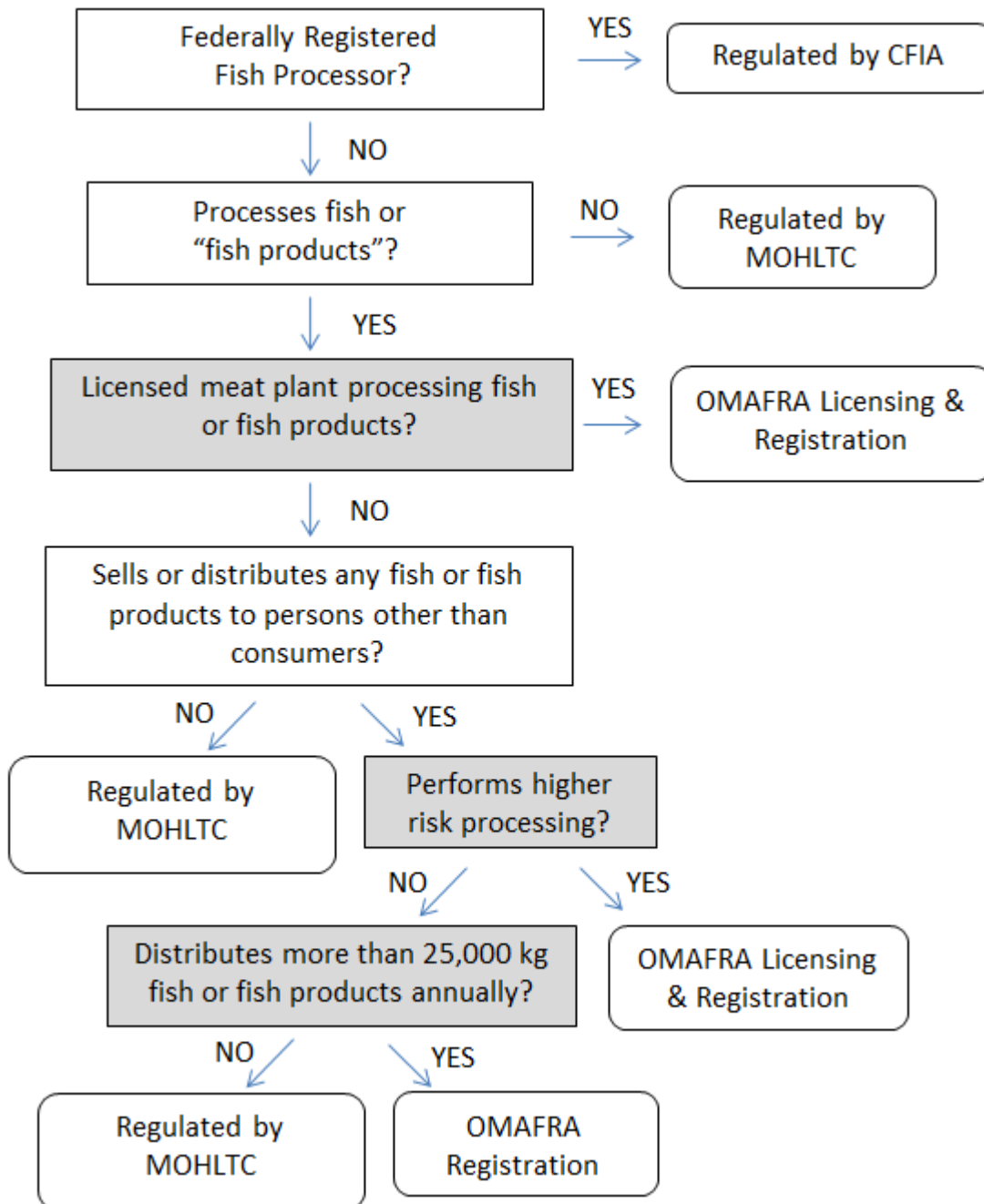
Businesses that carry on licensed activities such as processing meat and meat products under the Meat Regulation are required to be licensed as a meat plant. Some licensed meat plants also process fish or fish products. Because of the risks associated with processing meat at a facility processing fish or fish products, it is proposed that any licensed meat plant that also processes fish or fish products would require registration and licensing under the provincial fish regulation.

As part of this regulatory review process, the ministry is exploring options for efficient renewal of licences and delivery of inspection programs at facilities handling both meat and fish and fish products.

Question for Consideration

Should all provincially licensed meat plants processing fish or fish products also be licensed and registered as fish processors? Why or why not?

Chart 1 - Would my business be registered or registered & licensed under the proposed changes?



Other Changes

Modern Compliance Framework

Modern compliance approaches aim to respond with the tool that is proportionate to the severity of the issue. The *Food Safety and Quality Act, 2001* provides for a range of compliance tools and processes, including oral and written compliance orders and suspension or removal of licensing for more severe infractions.

Removal of Outdated Provisions

Provisions in the current regulation that are outdated or no longer relevant would not be included in the new regulation, for example, requirements for the coding of cans of fish. In other cases, product standards for specific fish products (e.g., breaded fish and scallops, shrimp cocktail) would not be included as processors are required to follow the same fish product standards found in the federal *Food and Drugs Act* and regulation.

Appendix A – Overview of Current vs. Proposed Requirements

Current Requirements	Proposed Requirements
<div data-bbox="123 1209 573 1276"> All facilities </div> <div data-bbox="123 1283 573 1686"> <ul style="list-style-type: none"> - Facility design, operation and equipment - Personal hygiene - Potable water and ice - Safe handling and processing of fish - Sanitation, maintenance and pest control requirements </div>	<div data-bbox="1049 373 1482 783"> <div data-bbox="1049 373 1482 472"> Licensing and Registration </div> <div data-bbox="1049 478 1482 783"> <p>Higher-risk activities (e.g. canning, fermenting, pickling, smoking, and any other secondary process resulting in a ready-to-eat fish product) and distribution; and licensed meat plants processing fish</p> </div> </div> <div data-bbox="1049 789 1482 1102"> <ul style="list-style-type: none"> - Licensing - Written programs for sanitation, maintenance and pest control - Process controls for higher-risk fish products - Recall plan </div> <div data-bbox="610 852 1032 1102"> <div data-bbox="610 852 1032 919"> Registration </div> <div data-bbox="610 926 1032 1102"> <p>Lower-risk processing activities (e.g. evisceration, cleaning, filleting and cutting) and significant* distribution</p> </div> </div> <div data-bbox="610 1115 1482 1276"> <ul style="list-style-type: none"> - Registration - Food handler training - Recordkeeping </div> <div data-bbox="610 1283 1482 1686"> <p>Current requirements would be modified to be more flexible and outcome-based while strengthening food safety standards. Most prescriptive requirements would be removed.</p> <ul style="list-style-type: none"> - Facility design, operation and equipment - Personal hygiene - Potable water and ice - Safe handling and processing of fish - Sanitation, maintenance, and pest control </div>

*Where significant distribution is more than 25,000 kg of fish products annually

Appendix B – Details of Proposed Requirements

Area	Proposed Requirements	Registered Facilities	Licensed Facilities
Registration	<ul style="list-style-type: none"> • Provide basic information such as facility location, types of processing and records of volume of products distributed and received 	Required	Required
Licensing	<ul style="list-style-type: none"> • Submit process control protocols • Possible fee 		Required
Facility design, operation and equipment	<ul style="list-style-type: none"> • Location, site design and approvals for new plants • The facility location allows for hygienic operation • Does not provide harbourage for pests or other contaminants 	Required	Required
	<ul style="list-style-type: none"> • Design the facility interior in a condition that permits adequate sanitation, and allows for hygienic handling of all products • Able to maintain the facility to ensure safe food product • Require drainage and a back-flow prevention device 	Required	Required
	<ul style="list-style-type: none"> • Materials used are safe and easily cleanable • Adequate hand washing and storage facilities 	Required	Required
Personal hygiene and food handler handling	<ul style="list-style-type: none"> • Employees follow hygiene and requirements • Train employees on personal hygiene and safe 	Required	Required

Area	Proposed Requirements	Registered Facilities	Licensed Facilities
	food handling		
Potable water and ice	<ul style="list-style-type: none"> • Use only potable water, ice, and steam • Require sampling tap • Show that standards for potable water/ice have been met (could include testing) 	Required	Required
Safe handling and processing of fish	<ul style="list-style-type: none"> • Appropriate temperatures are maintained • Employees follow safe handling requirements • Ensure products are received and shipped at appropriate temperatures and in clean vehicles 	Required	Required
Sanitation requirements	<ul style="list-style-type: none"> • Label, use and store chemicals in a way that will prevent contamination of food 	Required	Required
	<ul style="list-style-type: none"> • Conduct cleaning and sanitizing activities for all equipment, utensils, and areas of the facility that may impact food safety 	Required	Required
	<ul style="list-style-type: none"> • Develop written programs that identify: <ul style="list-style-type: none"> - areas, equipment and utensils to be cleaned and sanitized; - the designated person(s) responsible for the cleaning and sanitizing; - the chemicals and/or cleaning products (including concentrations and 		Required

Area	Proposed Requirements	Registered Facilities	Licensed Facilities
	contact times) and process to be used; - the cleaning and sanitizing processes to be used; - the frequency of cleaning and sanitizing; and - records of inspection and monitoring.		
	<ul style="list-style-type: none"> • Monitor effectiveness and keep records 		Required
Maintenance requirements	<ul style="list-style-type: none"> • Conduct preventative maintenance activities on all equipment and devices that may impact food safety 	Required	Required
	<ul style="list-style-type: none"> • Develop written procedures that include schedules and methods 		Required
	<ul style="list-style-type: none"> • Monitor effectiveness and keep records 		Required
Pest control requirements	<ul style="list-style-type: none"> • Implement pest control strategies to prevent the entrance and harbourage of pests within the facility 	Required	Required
	<ul style="list-style-type: none"> • Develop written programs that identify: <ul style="list-style-type: none"> - the responsible pest control operator; - strategies used for pest control; - the procedures and methods to be used; - the frequency of application; and - records of inspection and monitoring 		Required

Area	Proposed Requirements	Registered Facilities	Licensed Facilities
	<ul style="list-style-type: none"> • Monitor effectiveness and keep records 		Required
Process controls for higher-risk fish products	<ul style="list-style-type: none"> • Maintain a current written recipe for each prepared fish product at the plant and follow the recipe • Identify, document, and monitor hazards • Develop written program to show the processes used • Develop and implement control procedures to identify, quantify, eliminate, minimize or control hazards in a process that are critical to ensuring that the fish product is safe • Critical Control Points recorded 		Required
Recall plan	<ul style="list-style-type: none"> • Keep records of raw materials received (e.g., fish, ingredients, packaging etc.) and finished product distribution • Written program • Tested periodically 		Required

Appendix C – Questions for Consideration and Additional Comments

Please detach and return the completed questions below.

Contact Information *(optional)*

Name:

Business Name:

Address:

Email and/or phone number:

Please check all that apply. Are you a:

- ☐ Non-federally registered fish processor
- ☐ Federally-registered fish processor
- ☐ Licensed commercial fishery
- ☐ Provincially licensed meat plant

Other: _____

Clarifying Who the Regulation Applies To

Is the 25 per cent fish content by weight threshold an appropriate way to distinguish fish products from other food products containing fish? What other threshold(s) could be used and why do you think any suggested threshold would be preferable to the proposed threshold?

Are there any other products that should be considered fish products and should come under the provincial regulation, despite the 25 per cent content by weight threshold? Why?

Are there any circumstances that should require businesses that only sell directly to consumers (e.g., restaurant or grocery store) to be included in the proposed regulations? Why?

Requirements Based on Risk

Are the types of activities listed as lower-risk appropriate? Are there other processes that should be included?

Are the activities included in the list of higher-risk processing activities appropriate? Are there others that should be included?

Does the proposed meaning of “ready-to-eat” make sense?
“Ready-to-eat” means the product is edible without additional preparation to achieve food safety, e.g., sushi.

Is the limit of 25,000 kg annually an appropriate way to exclude businesses from the regulation? If not, why?

Taking into consideration the possible changes discussed, would you be significantly impacted if your business requires registration?

Do you currently have written food safety programs and/or process controls?

What changes would have the most impact on you? Why?

Should all provincially licensed meat plants processing fish or fish products also be licensed and registered as fish processors? Why or why not?

Additional Comments