

**Department or Agency**

Fisheries and Oceans Canada

**Ministère ou organisme**

Pêches et Océans Canada

**Title of Proposal***Fish Pathogen and Pest Treatment Regulations***Titre du projet***Règlements de traitement de microbe pathogène et de parasite de poissons***Statutory Authority***Fisheries Act, section 36***Fondement législatif***Loi sur les pêches, articles 36 et 32***Submitted for Consideration for**

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Minister of Fisheries and Oceans  
Ministre des Pêches et des Océans

## REGULATORY IMPACT ANALYSIS STATEMENT RÉSUMÉ DE L'ÉTUDE D'IMPACT DE LA RÉGLEMENTATION

(This Statement is not part of the proposed Regulations.)

(Ce résumé ne fait pas partie du projet de règlement.)

### Executive Summary

#### Issue:

In the absence of regulatory provisions under the *Fisheries Act* (the *FA*) currently fish health management activities, which sometimes require the need to destroy or chemically treat (i.e. with drugs or pest control products) fish for pathogens and/or pest control are in contravention of section (s.) 36 and 32 of the *FA*. S.36 prohibits deposit of deleterious substances in waters bearing fish, in the absence of regulations. S. 32 prohibits the killing of fish by means other than fishing without Ministerial authorization or by regulations made under the Act. Pest control products and drugs used in fish pathogen and pest treatment are regulated under the federal *Pest Control Products Act* (PCPA) and the federal *Food and Drug Act* (F&DA) by Health Canada (HC). The sections of the *FA* render the use of federally approved/registered products, and activities in support of the federal priority to maintain healthy aquatic ecosystems, potentially illegal. Furthermore, implementation of the *Health of Animals Act* (HAA) by the Canadian Food Inspection Agency (CFIA) may also contravene these same two sections of the Act.

#### Description:

The proposed *Fish Pathogen and Pest Treatment Regulations* (the Regulations) would be made under s. 36 and s. 32 of the *FA* and would regulate the following methods of treatment:

- A. Non-chemical (i.e. mechanical) destruction to protect against the introduction, spread or establishment of fish pests or pathogens in farmed or wild fish.
  - For example (e.g.), destroying fish with harmful pathogens or pests through percussion stunning or electrofishing. (s.32)
- B. Chemical treatments for fish pests and pathogens in farmed or wild fish.
  - For e.g., drugs regulated under the F&DA for use in fish pathogen and pest treatment including medicated feed such as the use of SLICE® to combat sea lice. (s.36)
- C. Chemical destruction to protect against the introduction, spread or establishment of fish pests or pathogens in farmed or wild fish.
  - For e.g., pest control products regulated under the PCPA to destroy fish carrying pests or pathogens with reportable trade implications. (s.32 and s.36)

The proposed regulations would harmonize federal legislation and ensure that the conservation and protection of fish and fish habitat would be maintained.

Through the Canadian Environmental Protection Act (CEPA) or CEPA equivalent processes, all drugs and pest control products will have undergone an environmental risk assessment prior to deposit in water frequented by fish. Assessments would determine safe conditions for use to ensure no adverse impacts to fish outside the treatment area or fish habitat ensue.

The proposed regulations would also require a notification of planned treatment, emergency response planning, monitoring and mitigation measures, record keeping, and reporting on information related to fish pathogen and pest treatment. Information collected would guide in decision-making, assist with ongoing evaluation of risk assessments in changing environments, and provide a basis for compliance and enforcement planning.

These proposed regulations would complement and be separate from all provincial legislation and regulations including the Fish Toxicant Regulations. There is no intention or expectation for the need to make changes to existing legislation and regulations.

**Cost-benefit statement:**

The baseline for the cost-benefit analysis is the current situation in which the aquaculture industry continues to operate in potential contravention of the *FA*, where despite an approval for sale (F&DA) or a registration for use (PCPA), actual deposit of fish health products into fish bearing waters could be considered illegal.

In addition to controlling the deposit of fish health products for the protection of non-target fish and fish habitat, the proposed regulations would provide a mechanism to inform management decisions through environmental risk assessments, monitoring and mitigation, data collection and reporting for example. Through informed decision-making, it is expected that the proposed regulations would contribute to long-term sustainability of the aquaculture industry across Canada and would provide certainty about the Federal process for registration and use of fish pathogen and pest treatment products.

Expressing the importance of fish health management in the aquaculture industry can be understood in terms of statistics on the industry's impact as a whole, because aquaculture is not sustainable without the ability to manage fish health. In other words, without the ability to effectively treat for fish pathogens and pests, the entire industry could be at stake.

In 2007, the total aquaculture industry generated just over \$1.0 billion in Gross Domestic Product (GDP) in Canada with just over \$320 million in direct GDP and about \$685 million in spin-off impact. It created an estimated 14,500 full-time equivalent jobs, though the overall employment impact was higher because of the seasonality of some activities. Overall labour income is estimated at just over \$500 million.

For the Federal government, it is expected that the implementation of this regulation

would not incur significant additional costs. However, minor costs would be expected in the areas of administrative management and enforcement.

**Business and consumer impacts:**

The proposed regulations will help prevent the introduction or spread of serious pathogens and pests which is essential for the protection of, not only the aquaculture industry, but Canada's aquatic resources as a whole, and for maintaining the Canadian seafood industry's competitive access to international markets. Without the ability to manage fish pathogens and pests, Canadian trade benefits from the aquaculture sector and commercial fisheries dependant on specific wild populations and ecosystems, are at risk.

Consumer confidence in aquatic animals as a safe food source, public acceptance of the sustainable use of aquatic resources, and the international reputation of Canada for high quality aquatic products are all contingent upon having a healthy environment and healthy aquatic animals.

**Domestic and international coordination and cooperation:**

The responsible Ministry for the *FA* is Fisheries and Oceans Canada (DFO). However, Environment Canada (EC) and DFO have enforcement responsibilities under s.36 of the *FA*.

DFO is working, and would continue to work with other departments including EC, HC and the CFIA to evaluate the best possible approaches to address these regulations made under the *FA*. As necessary, DFO would collaborate with HC, EC, and CFIA to agree on interdepartmental protocols with respect to implementation of the proposed regulations, environmental conditions, and enforcement and compliance for fish pathogen and pest treatments.

## Issue

Diseases of fish species caused by parasites/pests and infectious pathogens have implications for Canada's ecosystem health. Conservation and protection mechanisms to maintain human, animal and marine ecosystem health management programs include the need to destroy or chemically treat - with drugs or pest control products - fish for pests and/or pathogens.

In Canada, fish pathogen and pest treatment products are regulated under legislation administered by Health Canada (HC). Drug products are regulated under the *Food and Drug Act* (F&DA) and pest control products are regulated under the *Pest Control Products Act* (PCPA). Through registration or approval processes, these products must comply with CEPA or a CEPA equivalent environmental protection process. Drugs fall under CEPA's New Substance Notification Regulations, and pest control products undergo a CEPA equivalent environmental risk assessment as per PCPA requirements.

However, in the absence of regulations under the *Fisheries Act* (FA) the deposit of fish pathogen and pest treatment products could be in contravention of section (s.) 36 and s. 32 of the FA. The two sections respectively prohibit the deposit of deleterious substances in waters bearing fish and the killing of fish by means other than fishing in the absence of regulations.

As well, the Canadian Food Inspection Agency (CFIA) is developing the National Aquatic Animal Health Program (NAAHP). Control measures for the NAAHP, a program to prevent the spread and introduction of aquatic animal diseases of concern to Canada, require treatment or destruction of fish pathogens and pests. In the absence of these proposed regulations, CFIA officials are not able to adequately control diseases and pests in fish.

## Objective

The Minister of Fisheries and Oceans proposes to introduce the Fish Pathogen and Pest Treatment Regulations applicable to fish pathogen and pest control methods across Canada. The proposed Regulations would harmonize DFO, HC, and CFIA legislation, and ensure that the conservation and protection of fish and fish habitat would be maintained.

## Description

The Fish Pathogen and Pest Treatment Regulations (the proposed Regulations) would regulate the following three methods of treatment:

- **Non-chemical destruction** such as through "electroshock-fishing" of pathogen infected fish or fish pests to protect against the introduction, spread or establishment of harmful pests and pathogens.
- **Chemical treatment** through drug administration by way of medicated feed or injection, or through pest control products by way of topical bath treatments applications, for fish carrying curable yet harmful diseases resulting from pests and pathogens; and,

- **Chemical destruction** of a fish pest or pathogen to reduce its spread once it is established, such as through the use of a pest control product application or drug administration.

In order to regulate fish pathogen and pest treatment products under s. 36 of the *FA*, treatment products must first be defined as “deleterious”. The following categories of substances would be identified:

- **Pest control products** as defined under the PCPA for fish pathogen and pest treatment
- **Drug products** regulated under the F&DA for fish pathogen and pest treatment

Under these proposed regulations the above categories of substances, when used to treat or destroy fish pathogens and pests would need to conform to the following conditions:

- a. The Responsible Minister is satisfied the deposit will not adversely affect non-target fish, fish habitat or man’s use of fish (for e.g. man’s ability to consume lobsters) outside the treatment area as determined through an environmental risk assessment conducted to the satisfaction of the Responsible Minister.
- b. The deposit conforms to any conditions of use that have been established as a result of the risk assessment including mitigation and environmental effects monitoring measures.
- c. The Responsible Minister is satisfied that an Emergency Response Plan (ERP) has been adequately prepared in the case of any incidents related to treatment, and that implementation of the ERP will aid in the identification of reasons for the incident, the extent of impact, and prevent adverse effects to non-target fish, fish habitat, or man’s use of fish.

Additionally, when the person (a provincial veterinarian, an aquaculture facility owner, CFIA or DFO officials) who deposits or orders the deposit of a prescribed substance through contracting or through the provision of veterinary prescriptions, expects to deposit such a substance they would be required to:

- Notify the Responsible Minister in writing; and,
- Provide follow-up reporting in a timely manner as specified by the Responsible Minister.

The notification would not be for authorization and could be in the form of an annual schedule of planned treatments or include short term notifications in the case of an emergency or the use of a new product. The intent of the notification would be to assist with enforcement planning to ensure that the administrators of these regulations can verify that the substances are being used in the appropriate, responsible manner. Information obtained through reporting would be used to evaluate the environmental risk assessments and to inform and improve decision making.

Reporting would include, for example:

- Actual quantity deposited of the prescribed substance;
- Dosage and method by which it was deposited;
- Results of the monitoring plans; and,
- All causes or perceived causes and outcomes of emergency response plan as applicable.

These proposed regulations would complement and be separate from all provincial legislation with respect to pest control product use for fish pathogen and pest treatment. They would also be

separate from the Fish Toxicant Regulations which are aimed at aquatic invasive species control. There is no intention or expectation for the need to make changes to existing legislation and regulations.

It is expected that the proposed regulations would:

- improve legislative harmony;
- ensure federal support to maintain DFO's mandate with respect to fish health; and,
- lessen environmental impacts through integrated fish health management planning, and record keeping of information on quantity and timing of deposit of products for reporting, and enforcement activities.

## Regulatory and non-regulatory options considered

Given the implications of the status quo, a number of options were examined for moving forward, considering: costs, timeliness, legal tenability, environmental protection, public transparency; and impact on investment climate:

1. *Policy approach* – A policy approach, such as an EC operational guidance to Enforcement staff and/or a formal commitment (MOU) between relevant departments, would be the least costly and most timely of potential solutions. DFO and EC are in fact, beginning discussions on a renewed MOU with respect to management of s. 36 by 2012. However, a policy approach would require that EC and DFO formally acknowledge that certain activities would be allowed despite being in contravention of the *FA*. It would therefore likely be considered legally untenable for departments to take this approach. Moreover, it would not provide for investor confidence and hence provide very little relief for industry.
2. *Legislative change* could be undertaken to reword s. 36 of the *FA* to be consistent with CEPA's risk management approach, or to make exemptions for decisions under other Acts where those decisions have considered environmental protection. Such legislative change, however, is unlikely to happen in the near future. As well, achieving these amendments to the *FA* is likely broader than the focus of this initiative.
3. *Regulatory change* – A regulation as provided for under s. 36 could be designed to improve environmental protection, and be consistent with other legislation such as the HAA, F&DA, and PCPA. It would support investor confidence providing a strong foundation for integrated fish health management in aquaculture and improved enforcement. It is also consistent with calls by the Standing Committee on Fisheries and Oceans, and the Office of the Commissioner for Environment and Sustainable Development dating back to 1999 for development of a regulation under s. 36. However, developing a regulation has costs (coordination, drafting, consultations) and brings controversy.

## Cost and Benefit Analysis

Overall, the economic impact of these proposed regulations is estimated to be neutral to slightly positive. The baseline scenario for the cost-benefit analysis is the current situation in which, despite federal approval for sale (F&DA) or federal registration for use (PCPA), the deposit of

pest treatment products are, under the most literary interpretation, rendered illegal by *FA* prohibitions.

Without the ability to manage fish pests and pathogens with a variety of registered/approved products, Canadian trade benefits from the aquaculture sector and commercial fisheries dependant on specific wild populations and ecosystems, are at risk. The proposed regulations would support the approval and use of a variety of products ensuring greater success in the prevention, introduction and spread of serious pest or pathogens which is essential for the protection of, not only the aquaculture industry, but Canada's aquatic resources as a whole. Further, it is imperative in order to sustain the Canadian seafood industry's competitive access to international markets.

Aquatic animals and their products are an important part of the economy of Canada, both directly as a source of food and trade, and also as a resource for recreational activities and ceremonials. The revenues obtained and the activities associated with fisheries resources contribute to the economy of many localities, particularly in rural and costal communities where alternative sources of economic activity and employment are limited.

Fish health management supports the value of aquaculture products which accounted for one-third of the total Canadian seafood value in 2006 as compared to one-quarter in 2005. In 2007, the contribution to the Canadian Gross Domestic Product (GDP) from the aquaculture industry alone was \$1.022 billion, with \$339.2 million in direct GDP. The total value of production from the Canadian aquaculture industry in 2007 was \$1.025 billion. The industry employs in excess of 2,100 people in direct, and indirect positions for a total of 14,700 full time employee (FTE) jobs in Canada with the vast majority in rural areas, particularly for the young, women and First Nations.

Canada exports \$4.6 billion worth of fish and seafood (live animals and products; commercial fisheries and aquaculture sources), with a net import of \$2.2 billion. In addition, recreational fisheries contribute an estimated \$7.5 billion to provincial and territorial economies. The value of the export trade, investments and purchase of goods generated by the ornamental fish industry is undocumented but can be estimated to be in the millions of dollars range, as well.

Sustaining economic activity directly linked to the proper management of healthy aquatic ecosystems includes building and maintaining consumer confidence in aquatic animals as a safe food source. Public acceptance of the sustainable use of aquatic resources, and the Canadian international reputation for high quality aquatic products are all contingent upon having a healthy environment and healthy aquatic animals. Canadians and consumers are requesting more and more quality products.

Potential environmental benefits and production savings related to improved fish health management for the aquaculture industry are difficult to quantify. In 1999 the CFIA estimated that disease in Canadian aquaculture operations had financial impacts totaling in excess of 7 percent of cost of production, i.e. \$34,090,000 of \$487 million. In the 1990s four waves of outbreaks of infectious haematopoietic necrosis virus (IHNV) hit the Province of British



Columbia (BC). The province estimated that the cost to BC salmon farmers was \$220 million over three years for that disease incident. Aquaculture disease impacts have also proved costly in New Brunswick (NB). From 1996-2001 Infectious Salmon Anemia (ISA) hit NB costing the industry and province an estimated \$28 million. Based on aquaculture industry data from 2009, losses of Atlantic Salmon related to sea lice in New Brunswick reached an estimated \$4M in direct losses to farming companies weekly. Industry in the province estimate that losses could be higher in 2010. Financial problems in aquaculture resulting from these types of disease events can lead to job losses, particularly impacting First Nations and women.

In terms of federal costs for regulatory implementation, it is expected that slight administrative costs and enforcement costs will be incurred. In terms of costs to provinces and industry, additional costs could be incurred for regulatory reporting and record keeping requirements. As a qualitative assessment, costs are estimated to be minimal. Benefits of the proposed regulations far exceed the costs.

## **RATIONALE**

The federal government has the goal to maintain healthy and productive aquatic ecosystems. Canada's oceans are integral to the historical, environmental, and cultural fabric of coastal communities, providing a strong and reliable resource base around which Canada's sense of nationhood grew. Diseases of fish caused by parasites/pests and infectious pathogens have implications for Canada's ecosystem health. Hence, managing aquatic diseases is an important objective in meeting the larger federal goal.

This proposal would provide for a harmonized and more effective, responsible, and enforceable regulatory environment in which to protect fish and fish habitat.

## **CONSULTATION**

Discussion on federal options to address the legislative issues surrounding fish pathogen and pest treatment began in the fall of 2009. An interdepartmental federal working group was formed with DFO, CFIA, EC and HC.

Key stakeholders have been engaged. Environmental Non-Governmental Organizations (ENGOS), the aquaculture industry, fishers, academia, provinces, Aboriginal representatives and First Nation groups were introduced to the regulatory initiative during consultations for the Pacific Aquaculture Regulations and the National Aquaculture Strategic Action Plan Initiative.

Regulatory updates and discussions took place during bi-weekly meetings with a multi-stakeholder National Working Group for Fish Health Management Tools in Aquaculture since November 2009. These meetings have involved the participation of the Canadian Veterinary Medical Association, the aquaculture industry associations, federal and provincial departments. Discussions have also taken place with other groups that represent key stakeholders such as the Inland Fisheries Committee consisting of several provinces, as well as with the Sustainable Aquaculture Program Industry Liaison Committee.

DFO also solicited comments from the public via the posting of a 15-day online consultation discussion document. A notification encouraging input was sent to broad groups of stakeholders across Canada including: the Veterinary Medical Associations; pest control product and drug manufacturers; ENGOs; aquaculture industry such as producers and processors, Aboriginal groups, First Nation groups, the commercial fishing industry, pharmaceuticals, Canadian Aquatic Animal Health Committee, pesticide users, and employees at DFO, CFIA, HC, and EC.

[Summary of consultations- Lee]

## **IMPLEMENTATION, ENFORCEMENT & SERVICE STANDARDS**

### Enforcement

EC is generally responsible for the enforcement of section 36, the provision prohibiting the deposit of deleterious substances into waters frequented by fish, unless authorized by regulations under the FA or other federal legislation. They are responsible for responding to spills, illegal deposit of deleterious substances, and enforcing regulations, for example the Metal Mining Effluent Regulations, the Pulp and Paper Effluent Regulations, and the Waste Water Effluent Regulations. EC's enforcement activities include: [Heather to send to Lee]

The Pest Management Regulatory Agency achieves compliance with the Pest Control Products Act requirements through compliance promotion programs, inspections, monitoring and surveillance, and investigations, in accordance with an established compliance program. Compliance promotion programs aim to educate, facilitate and promote compliance while monitoring programs assess the level of compliance of selected users, distributors and registrants of pest control products with specific terms and conditions of registration and re-evaluations and the provisions of the PCPA and regulations. Surveillance inspections are planned to target specific individuals or groups for follow-up on previous findings or concerns. Investigations are conducted in response to specific complaints or suspected violations. Enforcement response actions include:

- product detention,
- education (written and oral),
- administrative monetary penalties or warning under the Agriculture and Agri-Food Administrative Monetary Penalties Act (AMPA), and
- prosecutions under the PCPA.

Since the majority of the regulated community will comply with the law if they understand it and have the capacity to comply, many violations are dealt with and corrected using education as a means to address non-compliance situations and behaviour.

### Mechanisms to ensure compliance

EC would continue to be responsible for spill response and deposit of substances not included under these or other DFO regulations. PMRA would continue to be responsible for its PCPA

program. DFO would be responsible for receiving and verifying notification and reporting information and ensuring that those being regulated report on actual use. DFO anticipates doing this through examinations of sites, and fish health and financial records (s. 60, 61 of FA).

The mechanisms adopted to ensure compliance with these proposed regulations would include notification of deposit, conditions of use attached to product labels, record keeping, reporting, and monitoring data. Other mechanisms to ensure compliance would include inspections, warnings, with the ability to prosecute and prosecution. A detailed compliance and enforcement strategy is under development.

## PERFORMANCE MEASUREMENT AND EVALUATION PLAN (PMEP)

The proposed Regulations would reside under the Program Policy Branch, Aquaculture Management Directorate of DFO's Program Activity Architecture for 2010-11, and would contribute to the fulfillment of the departmental strategic outcome of "Sustainable Fisheries and Aquaculture."

In order to be able to assess the policy objectives of the regulations on a continuous basis, DFO is in the process of completing a performance measurement and reporting strategy. The strategy includes cost-effective indicators to measure the intended results of the regulations and mechanisms for timely reporting of results.

Evaluation of this regulatory initiative will be conducted in accordance with the *Policy on Evaluation* (2009) which requires that comprehensive evaluation coverage of all direct program spending be completed over a five-year cycle. The evaluation will take a *Value for Money* approach and examine issues of relevance and performance. The evaluation schedule of this regulation will be reflected in the Departmental Evaluation Plan updated annually.

The evaluation will review the program against the following outcomes:

- Availability of fish pathogen and pest control products for integrated fish health management;
- Accurate and timely reporting on fish pathogen and pest treatment products used; and,
- Records on compliance and enforcement incidents.

Achievement of these intermediate outcomes of the proposed Regulations is expected to support the ultimate outcome of safe seafood and competitive access of the Canadian seafood industry to international markets.

### Contact(s)

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