

The *Fisheries Act* and Fish & Ecosystem Health Management Activities

DRAFT Discussion Paper on the
Need for Greater Clarity of Governance
for Subsection 36(3) and Section 32 of the *Fisheries Act*

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Executive Summary

In the absence of regulatory tools, the current general prohibition against the deposit of deleterious substances found in Section 36 of the *Fisheries Act*, and the provisions of section 32 preventing destruction of fish are presenting issues with respect to the sound management of aquatic resources.

The situation is such that, where an activity may be duly authorized by one federal Act, the same activity can be in direct contravention of the *Fisheries Act* Subsection 36(3). In fact, this prohibition provides no leeway for the effective management of fish and ecosystem health, where there is a requirement to use products in the marine environment for disease control or eradication among wild and/or cultured populations, nor for the management of aquatic invasive species. There are a number of departments/agencies affected by the lack of cohesion between federal legislation, including: Fisheries and Oceans Canada (DFO), Environment Canada (EC), the Canadian Food Inspection Agency (CFIA), as well as a variety of sections within Health Canada - most notably the Pest Management Regulatory Agency (PMRA), and the Veterinary Drug Directorate (VDD). Similarly, the control of disease or aquatic invasive species may require destruction of fish, which would violate Section 32 of the *Fisheries Act*. While Section 32 is not as inflexible as Section 36, it presents a significant barrier to the effective management of disease and invasive species. Thus, in the interests of fish health and ecosystem health, this discussion paper includes consideration of federal responsibilities in Canadian marine environments for

aquaculture, aquatic animal health (for both wild and cultured populations), and aquatic invasive species.

Given the broad definition of “deleterious”, in the absence of further clarification of the application of Section 36 with regards to aquatic resource management activities, there is a risk that:

- Aquaculture operations could be found to be in contravention of the *Fisheries Act* through the regular course of doing business, even with requisite federal and provincial permits and approvals in place. Two broad aquaculture issues are of concern, including:
 - the release of various types of waste from aquaculture operations, and
 - the use of products designed to control pests and keep fish healthy.
- Similarly, the *Health of Animals Act (HAA)* enables various activities with respect to controlling and eradicating disease among wild and cultured aquatic populations, as an important component of meeting international trade standards. The authority granted under the *HAA* is likely to come into conflict with the Section 36 prohibition, as well as Section 32. The control of diseases is linked to ecological health of fish populations, and may be achieved through chemical or physical treatment to reduce incidence of a disease, to destroy infected animals, and/or to disinfect facilities.
- The control of Aquatic Invasive Species may require similar approaches to controlling harmful populations of species that are not native to Canada, in order to protect Canadian ecosystems.

Products used for maintaining aquatic animal health and controlling invasive species may be registered under authorities vested in the *Pest Control Products Act*, the *Food and Drug Act*, or other federal laws, each having varying degrees of environmental assessment requirements, but none of which meet the regulatory requirements of Section 36.

While these issues have been recognized as being problematic for at least twenty-four years, and were subject to intense scrutiny by the Commissioner for the Environment and Sustainable Development and the House of Commons Standing Committee on Environment and Sustainable Development in 1999, nothing has yet been done to resolve the problem. Legal advice dating from 1999 also called for the development of regulations under Section 36 in order to clarify the use of fish health products. The same issues that were highlighted in the 1995 authorization of the use of cypermethrin for control of sea lice for aquaculture purposes, have resurfaced once again with the recent authorization for the use of AlphaMax™ in June of 2009, fourteen years later. The only difference is the more critical nature of the need for access to fish health products for both wild and culture populations due to increasingly stringent international standards and market access issues as well as problems with the small number of registered aquatic animal health products becoming ineffective over time with prolonged use of the same product (in much the same way that humans must have access to greater varieties of antibiotics over time). There is also a higher degree of frustration on the part of industry and provincial governments over the lack of federal government action to address these important concerns. Basically, the problem is two-fold:

1. In the first place, the federal environmental assessment requirements differ from legislation to legislation, for example, “the *Canadian Environmental Protection Act, 1999 (CEPA 1999)*, the *Pest Control Products Act*, and the *Fisheries Act* “each have

different thresholds of acceptable risk”. The *Fisheries Act* has the most stringent requirements, being based on a “zero tolerance” approach whereby no deleterious substance may be deposited in waters frequented by fish unless under conditions authorized by Regulation. Neither of the current EA processes governing the registration of aquatic animal health products, whether under the *Food and Drug Act* (which makes use of *CEPA 1999* for its environmental assessment) or the *Pest Control Products Act*, meet the requirements of Section 36. This makes the whole process of environmental assessment awkward for federal departments/agencies involved and has caused conflict at times.

2. Secondly, registrations and approvals to use products granted under the *PCPA* or the *FDA* do not relieve the user of responsibilities under the *Fisheries Act*. Therefore, in relation to aquatic resource management activities taking place in an open marine environment, registration decisions made by Health Canada are meaningless in the current context of the *Fisheries Act* Section 36 Prohibition. In other words, regardless of any authority to use products granted under federal statutes, the use of the products, even when applied in accordance to specific labeling instructions and/or under the authority of a veterinarian, contravenes Section 36 of the *Fisheries Act* if the product is deleterious. It is important to note that many of these products are designed to be highly active at low concentrations, and almost all of them fall within the definition of “deleterious substances” contained in the *Fisheries Act*.

Developing a regulation under Section 36 would effectively address both of these issues of concern.

Potential economic implications of inaction are noteworthy. The costs of disease outbreaks are high. For example, 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. In 1999, the CFIA estimated that disease in Canadian aquaculture operations had financial impacts totaling approximately \$34 million (7 percent of cost of production valued at ~\$487 million). More recently, the Chilean aquaculture industry has recently been hit with an outbreak of Infectious Salmon Anemia (ISA) and is still experiencing the effects. First detected there in 2007, ISA has spread, forcing the closure of numerous salmon farms and processing factories. As many as 15,000 jobs have been lost, and in April 2009, industry leader Marine Harvest suffered a 64% decline in exports, whereas Cultivos Marinos Chiloé exports of salmon and trout fell by 42%, as compared to the same month in the previous year.

Experts agree that there is currently a serious lack of aquatic animal health products registered for use in Canada, and pharmaceutical companies have noted the uncertain regulatory environment as an added impediment to registering products in relation to Canada’s comparatively small market for their products. Having a product registered for use in Canada can cost from hundreds of thousands to millions of dollars and take several years, with no guarantee that in the end that an approval would be granted. The lack of regulatory certainty with regards to Section 36 of the *Fisheries Act* means that a company could go through Health Canada’s entire registration process (whether via the *Pest Control Products Act* or the *Food and Drug Act*), and yet the registration,

once obtained, might be useless as its application could be found to be in contravention of federal law.

There are two key issues of concern with respect to the inflexibility of Subsection 36(3): the production of aquaculture wastes, and the use of products for maintaining fish health and ecosystem health. For the purposes of this document, these issues are separated into two categories of activities, defined as follows:

- the production of *wastes from aquaculture*, including all types of wastes (ie. organic and other), which has implications for Section 36 of the *Fisheries Act*, and
- *aquatic resource management* including activities related to fish health for both wild and culture populations (ie. *Health of Animals Act* requirements and aquaculture fish health), and aquatic invasive species management, which have implications related to both Section 32 and Section 36 of the *Fisheries Act*.

A range of options, from status quo, policy only, regulatory development to legislative change, have been assessed using the following criteria to determine their potential to address key concerns: timeliness, regulatory transparency, cost, effectiveness, protection of human health, adherence to international standards/protocols, international precedence, operational pragmatism, policy cohesion with respect to other *Fisheries Act* requirements, and the ability to address both Section 36 and 32 requirements simultaneously. Status quo and policy only approaches are not considered to be viable options as they are not capable of addressing the concerns at hand. Recent Department of Justice legal advice has confirmed that Section 36 specifically requires the development of a regulation in order to address the General Prohibition. Legislative change is rejected as a viable approach due to the length of time required and the costs involved, as well as the fact that such changes are not warranted as regulatory tools can effectively solve the problems.

Thus, regulatory change is the minimum requirement to address Section 36 conditions for managing the deposit of deleterious substances, and, whether developed under the *Fisheries Act*, or another Act passed by the Governor In Council, the regulations must meet the strict requirements of Subsection 36(5). Note that there is a regulatory framework for aquaculture wastes being developed for the BC context as part of a separate exercise in response to a federal/provincial jurisdictional ruling on aquaculture management made by the BC Supreme Court, therefore the focus of this paper is on fish health and ecosystem health management. Within the regulatory framework, there are two design considerations:

I A decision needs to be made regarding whether to develop a set of one or more regulations to address the issues at hand, in particular:

- a. *One national regulation*: Whether to regulate all activities under one “Fish and Ecosystem Health Management Regulation” for all of Canada (ie. 1 Canada-wide regulation dealing with aquaculture, wild populations and aquatic invasive species, including Section 36 and 32 provisions) - this comprehensive approach would require the most work to be completed up front, involve the entire range of stakeholders in consultations, and would therefore take the longest to develop, but it would provide for maximum coherence in the regulatory framework. The delay could cause problems for aquaculture, particularly in Atlantic Canada where there are issues related to sea lice and immediate requirements for new treatment products;

- a. *Two national regulations:* To regulate aquaculture fish health management under one framework; and develop a separate regulation that would deal with requirements for “maintaining wild fish population health and ecosystem health” in Canada (ie. 2 Canada-wide regulations: one for aquaculture fish health issues and one for wild fish and ecosystem health management) - this option would facilitate a more rapid implementation of the pressing aquaculture regulatory regime in response to the sea lice crisis being faced in Atlantic Canada presently, and the broader wild fish population and ecosystem health issues would not be rushed to meet the needs of another marine sector. As well, it is anticipated that the stakeholders would be different for these issues, so consultation strategies would be unaffected and would benefit from additional time available for the NAAHP and AIS issues to be resolved. Nevertheless, it is clear that these issues of fish health (whether farmed or wild) and ecosystem health are inter-related and developing two separate regulations may lead to overlap/lack of clarity and may not be the best use of taxpayers resources;
- b. *Two national regulations with a phased-in approach for aquaculture:* To regulate aquaculture activities under a separate regulation starting in New Brunswick, but eventually moving to all of Canada (where the sea lice issue is most acute and public support for aquaculture is relatively high), and develop a separate regulation that would deal with requirements for “maintaining wild fish population health and ecosystem health” in Canada (as above) (ie. 2 Canada-wide regs with phase-in approach for aquaculture fish health management) - considerations with this approach are similar to option b, except that the ability to implement the regulatory change, along with required consultations, in time to address the sea lice crisis in New Brunswick is more realistic; or
- c. *Phased-in approach for a national regulation for all issues:* This option would include all provisions, as with option a., but would phase the regulation in over time. The current vision is to begin with the Province of BC, given that a new regulatory framework for aquaculture must be put in place by February 2010 anyway, followed by NB, where sea lice management is in crisis, and then move to nationwide implementation in a phased manner (ie. 1 reg with a phased-in approach for all fish and ecosystem health management issues, starting in BC and NB) - This option provides the most flexibility and pragmatism in meeting stakeholder consultation requirements, however, there would be some uncertainty with respect to the ability to achieve national consistency based on the likelihood of variances in stakeholder feedback and pressures to make the regulation meet regional needs as opposed to national needs. Costs involved in regulatory development could be spread out over time so the budget pressures for responsible departments would not be as intense as compared to the other options, however, due to potential for lack of cohesion/transparency, it may not be the best use of taxpayer resources.

Work involved in costing out the human and financial resource requirements for regulatory development, including consultations, drafting, etc is currently underway.

II Three potential regulatory options for “maintaining fish health and ecosystem health in Canada” are put forward in this discussion paper:

- a. *Regulation including detailed listing of substances and concentrations to be prescribed directly in the regulation* - based on the model of the Pulp and Paper Effluent Regulations and Metal Mining Effluent Regulations and requiring the development of lists of specific substances that would be allowed to be released, along with specific limits and conditions for their release (eg. concentration, frequency and method of use). This is the approach preferred by Environment Canada for dealing with point source pollution, however the situation of aquatic resource management is quite different. For example, it is difficult to envision a scenario where prescriptions for using fish health products could be written into a regulation. Generally, veterinarians are involved in writing prescriptions based on specific circumstances, including the species, the illness / pest, the environment surrounding, etc., and it would be impossible to prescribe these details in a regulation. In addition, there is no single control point for the release of waste substances related to aquatic resource management as there is with metal mining and pulp and paper (ie. there is no “pipe”). Thus, this regulatory approach is not seen to be effective in addressing the particular needs of aquatic resource management.
- b. *Regulation including detailed conditions to be prescribed directly in the regulations based on a combination of: i) biological measures of “concentrations” related to the potential to cause harm to fish and ii) thresholds governing the protection of the marine environment* - This option draws on guidance provided by regulations developed for Marine Protected Areas in terms of thresholds of acceptable impacts on the environment, and the use of LC-50 or other toxicological limits/concentrations for toxicity to fish as measures of “concentration” (as required under Subsection 36 (4)(a)). The biological measure (s) would need to ensure that releases from related activities would be “non-acutely lethal”, and may require additional conditions to be met. Environmental risk assessments (ERAs) would be required in advance of any approvals for products to be used in Canada, though existing ERA processes conducted as part of other legislative requirements (eg. *Pest Control Products Act*) would be used, where they exist. For other aspects, new ERA processes would be required. In addition, this regulatory option would require onsite and broader follow-up monitoring, to ensure that the environmental thresholds/conditions are not exceeded (eg. cumulative effects, sub-lethal/chronic effects, etc). Please see Annex 2: Marine Protected Areas, for more information on these regulations.
- c. *The basis for this regulation is the same as for Option b, above, but adds a Code of Practice containing principles that could be used to develop Best Management Practices (with BMPs - to be developed later, as needed) related to specific activities, such as application methods for certain products and the use of best available technology, etc.* This option would also involve the development of a regulation including detailed conditions to be prescribed directly in the regulations based on a combination of: i) biological measures of concentrations related to the potential to cause harm to fish and ii) thresholds governing the protection of the marine environment. Through reference in the Code of Practice, any BMPs would hold the strength of regulation, providing added flexibility and regulatory certainty over time. This option would require the same program provisions for any gaps in existing environmental assessment processes for approvals of new products for

Canada, and follow-up monitoring to ensure that thresholds are not exceeded.

Legal advice on the viability of either option b. or c. to address the Section 36 restrictions in particular, is still pending.

A new program to administer and enforce the regulations may be required, involving the need for new funding via a Memorandum to Cabinet (MC) and Treasury Board submission. Prior to undertaking these steps, a review of existing programs and initiatives would be undertaken to ensure no overlap, and existing MC processes would be accessed (eg. BC Aquaculture, AIS, NAAHP). Federal departments, primarily Environment Canada, would need to decide which federal agency or department would assume the responsibilities for administration and/or enforcement of any proposed new regulation for Section 36. The Canadian Food Inspection Agency (CFIA) would be responsible for administering and enforcing the destruction of diseased fish. A preliminary assessment of the above-mentioned regulatory options, as well as status quo, policy, and legislative approaches are provided in this document, along with a series of criteria used in the analysis.

In terms of **next steps** required to resolve the important issues highlighted above, they are proposed as follows:

1. a) In order to assess the validity of the proposed option, there is a need for in-depth analysis of options by relevant federal departments, with an important starting point being Environment Canada's willingness to consider these approaches, given their responsibilities for administering and enforcing Section 36. b) Simultaneously, a program/regulatory gap analysis must be undertaken in order to understand what areas of environmental impact assessment are already covered for the aquatic resource management issues in question.
2. Develop consensus among federal departments with respect to the development of options for moving forward, along with associated general timelines and funding approach (Environment Canada, Fisheries and Oceans Canada, Canadian Food Inspection Agency, Health Canada - Veterinary Drug Directorate and Pest Management Regulatory Agency, other?).
3. Refine the approach based on the above diagnostic process, assess stakeholder consultation requirements, and estimate potential costs both of action and inaction.
4. Based on the refined approach, develop a work plan for regulatory development and implementation, a consultation strategy, and develop a Memorandum to Cabinet to obtain necessary funding.

The Current Context for Interpretation, Administration and Enforcement of Section 36

Section 36 of the *Fisheries Act* contains a General Prohibition against the deposit of deleterious substances into waters frequented by fish, unless authorized by regulation. Specifically, subsection 36(3) of the *Fisheries Act* prohibits:

anyone from depositing or permitting the deposit of a deleterious substance of any type in water frequented by fish, or in any place under any conditions where the deleterious substance, or any other deleterious substance that results from the deposit of the deleterious substance, may enter such water

[Refer to Annex 1 for the full text].

Environment Canada (EC) administers and enforces pollution prevention and control provisions of Section 36 of the *Fisheries Act*. In general, Environment Canada determines compliance at the last point of control of the substance before it enters water frequented by fish, or, in any place under any conditions where a substance may enter such waters. Prioritization of the most pressing issues of concern, and the *Compliance and Enforcement Policy for the Habitat Protection and Pollution Prevention Provisions of the Fisheries Act - November 2001*, among other, guide enforcement-related decision-making.

Over the years, court decisions have confirmed a broad interpretation for the term ‘deleterious’. Following is the definition for ‘deleterious substance’ in the Act:

- 34(1)(a) any substance that, if added to any water, would degrade or alter or form part of a process of degradation or alteration of the quality of that water so that it is rendered or is likely to be rendered deleterious to fish or fish habitat or to the use by man of fish that frequent that water, or
- (b) any water that contains a substance in such quantity or concentration, or that has been so treated, processed or changed, by heat or other means, from a natural state that it would, if added to any other water, degrade or alter or form part of a process of degradation or alteration of the quality of that water so that it is rendered or is likely to be rendered deleterious to fish or fish habitat or to the use by man of fish that frequent that water, and without limiting the generality of the foregoing includes
- (c) any substance or class of substances prescribed pursuant to paragraph (2)(a),
- (d) any water that contains any substance or class of substances in a quantity or concentration that is equal to or in excess of a quantity or concentration prescribed in respect of that substance or class of substances pursuant to paragraph (2)(b), and
- (e) any water that has been subjected to a treatment, process or change prescribed pursuant to paragraph (2)(c).

EC clarifies that it is now clear that it is the deleterious character of the substance that is relevant, ie. It is not necessary for the Crown to establish actual deleterious effects on the fish that inhabit the receiving water or the deleterious character of that water. The deleterious character of a substance may be proven by:

- (i) evidence of fish kills in the proximity or under conditions that can be linked to a deposited substance;
- (ii) bioassay toxicity tests on the substance; and/or
- (iii) expert opinions concerning toxicity of the substance.

EC does currently provide advice to Responsible Authorities under the *Canadian Environmental Assessment Act* on ways to prevent the release of deleterious substances to fish bearing waters.

Need for Devising a New Federal Approach to the Management of Certain Section 36 Issues

Based on the general prohibition contained in Section 36 however, the provision of advice related to activities that may release deleterious substances into fish-bearing waters is problematic and could lead to officially induced error. While EC is careful in avoiding problems of officially induced error, the lack of regulations governing questions of health management is awkward for EC administration and enforcement. In addition, there is no regulatory context for allowing any releases of deleterious substances related to fish health or ecosystem health, nor for allowing activities leading to such releases to take place. Thus, the lack of an effective regulatory

framework under Section 36 opens EC up to legal risks in relation to failure to enforce and/or to judicial reviews. In order to mitigate risks, EC recommends the development and application of best management practices to avoid, and/or mitigate environmental impacts, in accordance with all applicable legislation. Yet there currently are no regulations allowing for the use of best management practices, or any other proactive measures, as a way to address the general prohibition against the deposit of deleterious substances. Thus, the current management regime could be characterized as prevention through compliance promotion activities and “end-of-pipe” enforcement based on complaints and departmental priorities based on risk.

In official legal advice dating from September 17, 1999, Department of Justice Legal Counsel for Health Canada, Fisheries and Oceans and Environment Canada recommended the creation of a regulation under subsection 36(5) of the *Fisheries Act* or under the *Pest Control Products Act* (PCPA), where authorized by the regulations-making power, in order to clarify the application of Section 36 for the use of registered pesticide products in Canada. The 1999 Report of the Commissioner of the Environment and Sustainable Development highlights what it calls “legal conflict” between the *Fisheries Act* and the *PCPA* with regards to the use of pesticides for aquaculture in open waters, and further explains that the Canadian Environmental Protection Act, the PCPA, and the Fisheries Act each have different thresholds of acceptable risk, wherein the Fisheries Act is based on a zero tolerance regime (refer to paragraphs 3.53 and 4.123 to 4.128). These issues were addressed in detail at the June 2, 1999 meeting of the House of Commons Standing Committee on Environment and Sustainable Development where responsible departments/agencies were instructed to resolve the inconsistencies in the legal framework related to the use of pesticide products and/or deleterious substances.

There are a number of federal departments/agencies for whom the implementation of mandated responsibilities is problematic given the current context of the Section 36 General Prohibition, including the Canadian Food Inspection Agency which has the responsibility to implement the National Aquatic Animal Health Program (key to maintaining market access for Canadian aquatic products), Fisheries and Oceans Canada which has the responsibilities for maintaining healthy marine ecosystems, protecting against aquatic invasive species and overseeing aquaculture management. Health Canada’s mandate is also encumbered by the lack of regulatory context for aquatic animal and ecosystem health management since various sections (such as the Pest Management Regulatory Agency - PMRA, Veterinary Drug Directorate - VDD, among other) provide the approvals necessary to use acceptable products in Canada, and yet their approvals are meaningless in the marine context when faced with the current Prohibition in Section 36 of the *Fisheries Act*. Health Canada’s approval processes are rigorous, lengthy and costly, yet a proponent could go through these processes, receive their required authorizations to apply a product, and ultimately be unable to proceed with a needed treatment. Problematic issues related to this kind of situation are further illustrated in the recent AlphaMax™ case study (refer to text box on page 12).

The sections below, elaborate further on the problems with the current *Fisheries Act* regime in relation to Sections 36 and 32, for federal responsibilities in Canadian marine environments related to: aquaculture, aquatic animal health (for both wild and cultured populations), and alien invasive species.

The Aquaculture Situation

Aquaculture - the farming of finfish, shellfish and plants - now provides for half of the world's seafood consumption. In 2007, total world aquaculture production was reported to be 66 million tonnes by quantity and \$101 billion by value. Canada is the world's 4th largest farmed salmon producer, having 6% of the global market share (top 3 are Norway 40%, Chile 26% and UK 8%). Export value of Canadian aquaculture totaled \$CAD 514M in 2007, with salmon making up 94% of the total, and mussels, 6%. The aquaculture sector employs about 16,000 people in year-round, relatively well-paying jobs, located primarily in rural and coastal areas. General concern for environmental impacts from aquaculture operations arise due to the exchange of substances between the aquaculture site and the surrounding aquatic environment. The open nature of marine aquaculture operations means that there is a direct exchange of substances between the aquaculture site and the natural environment, including two key issues:

1. outputs/waste production, and
2. inputs/applications of chemicals or other products.

Given the broad definition of "deleterious", in the absence of further clarification of the application of Section 36 with regards to aquaculture activities, there is a risk that aquaculture operations could be found to be in contravention of the *Fisheries Act* through the regular course of doing business, even with requisite federal and provincial permits and approvals in place.

a) Aquaculture Wastes

By the very nature of the activity of rearing fish, aquaculture results in the deposit of waste matter into water frequented by fish. A strict interpretation of Subsection 36(3) implies that an aquaculture operation could be found to be in contravention of the *Fisheries Act* by having just one feeding fish on a farm. This point was made by Justice Hinkson of the British Columbia Supreme Court in the case of *Morton et al.*, wherein he determined the following in reference to the introduction of fish into coastal waters via the licensed activity of fish farming:

fish introduced in this way leave waste matter in the water. The definition of "offal" in Catherine Soanes and Angus Stevenson, eds., *Concise Oxford English Dictionary*, 11th ed. (Oxford and New York: Oxford University Press, 2004) [*Concise OED*], includes "decaying or waste matter" along with "the entrails and internal organs of an animal used as food". Leaving this waste matter is thus directly contrary to S. 36(1)(b) of the federal *Fisheries Act*.

In other words, since a fish eats and produces waste as it grows, regardless of any other activity undertaken at an aquaculture site, there is an unintentional release of waste into the environment through the activity of rearing fish, which is a potential contravention of the *Fisheries Act*.

Aquaculture operators are expected to comply with all federal legislation and associated regulations, and much time and effort is put into obtaining necessary approvals and permits by the industry. In this context, due to the lack of clarity in the application of the general prohibition contained in Section 36, the aquaculture industry remains open to significant legal risk. Moreover, a new federal regulatory system for aquaculture in British Columbia is required to be put in place by February 10, 2010.

b) Aquaculture Use of Therapeutants for Treating Diseases and Pests

Just as farmers on land need access to veterinarians and pharmaceutical products to treat their animals, so do aquaculturists require access to specialized veterinary services and products to provide for healthy fish. Aquatic diseases are one of the key threats to the industry's livelihood, preying on its economic, social and environmental sustainability. To illustrate, the Chilean aquaculture industry has recently been hit with an outbreak of Infectious Salmon Anemia (ISA). First detected there in 2007, ISA has spread, forcing the closure of numerous salmon farms and

processing factories. As a result, as many as 15,000 jobs have been lost, and in April 2009, industry leader Marine Harvest suffered a 64% decline in exports, whereas Cultivos Marinos Chiloé exports of salmon and trout fell by 42%, as compared to the same month in the previous year. While there currently is no therapeutant in existence to treat ISA, this situation exemplifies the magnitude of the problem that the Canadian aquaculture industry could face, without appropriate access to registered therapeutants needed to control disease and pests in cultured fish. The top priority for addressing disease / pest issues in Canada is sea lice, followed by bacterial kidney disease, and other bacterial infections, which are treatable.

Canada's Regulatory Regime for Aquatic Animal Health Products, including environmental assessment requirements.

Canada's regulatory environment for therapeutants is rather complex, with the federal government providing the initial registration for any product to be able to enter the country (Provincial approvals may follow). There are two separate federal regulatory authorities and approval processes, depending on the nature of the product in question. Therapeutants considered as "drugs" are regulated by Veterinary Drug Directorate via the *Food and Drug Act (FDA)*, whereas those considered "pesticides" are regulated by the Pest Management Regulatory Agency under the *Pest Control Products Act (PCPA)*. Though both authorities fall within the auspices of Health Canada, the nature of the environmental assessment requirements necessary to obtain approval under these two Acts is significantly different. The *PCPA* is a modern piece of legislation that specifically provides for detailed environmental reviews prior to approval, whereas the *FDA*, an older legislation, relies on the *Canadian Environmental Protection Act, 1999 (CEPA 1999) New Substance Notification* requirements for its environmental reviews. Regardless of which legislation grants the approval for the registered use of a given therapeutant product, the fact remains that some of these products can be highly toxic to certain marine species, and they are applied in the marine environment, whether it be through a bath treatment (as with pesticide-type products) or via fish feed (as with drug-type products). The residue or unused portions of these products are directly entering waters frequented by fish and can therefore be considered to be in contravention of Section 36 of the *Fisheries Act*, regardless of the legal nature of the use of these products under either the *PCPA* or the *FDA* (in conjunction with *CEPA 1999*).

In fact, the need to resolve the contradiction within federal responsibilities with respect to the use of therapeutants in aquaculture is not a new issue. A 2001 report entitled *Regulatory Options: Fisheries Act (Section 36) and Aquaculture Pesticide Use* addressed the specific regulatory/legislative issue of the potential for the use of aquaculture pesticides registered under the *PCPA* to result in contravention of *Fisheries Act* Section 36(3) which prohibits the deposit of deleterious substances, and other reports mentioning this problem date as far back as 1985. The 2001 report analyzed a number of potential solutions but focused on options involving development of aquaculture pesticide regulations under the *Fisheries Act* Section 36(5) regulations, to permit the deposition of pesticides as per the *PCPA* registration conditions.

Aquatic Animal Health for Wild and Cultured Populations: Concerns Related to Section 36 and 32 of the *Fisheries Act*

The Canadian Food Inspection Agency (CFIA) of the Department of Agriculture and Agri-Food has been assigned the responsibility for aquatic animal health management, as per the *Health of Animals Act* and associated *Health of Animals Regulations (HAR)*. Canada's National Aquatic

Animal Health Program (NAAHP), a priority for the Canadian Council of Fisheries and Aquaculture Ministers, has been designed to implement this authority. The NAAHP manages both wild and farmed aquatic animal diseases that have been designated reportable or notifiable in Canada. The NAAHP relates to national and international trade certification responsibilities and standards which enable Canada to export seafood products. It also protects Canada's aquatic resources from introduction of exotic diseases, assisting the Department of Fisheries and Oceans (DFO) in meeting its conservation mandate.

The *HARs* are currently being amended to include aquatic animal diseases to enable the NAAHP to meet stated objectives. Included in the amended regulations will be the ability to "permit" the destruction of an aquatic animal affected or suspected of being affected with a communicable disease, or that has been in contact with an animal so affected or suspected of being affected. With the proposed amendments to the *HARs*, there are two sections of the Fisheries Act which could be in conflict with the need to protect aquatic animal health: Section 32 which prohibits the destruction of fish by means other than fishing, and Section 36 since there may be a need to use drugs, therapeutants, anesthetics, or disinfectants involved in controlling diseases (which may be considered as deleterious substances). In the case of Section 32, a Ministerial authorization can be granted on a case by case basis by the Minister of Fisheries and Oceans. Such authorizations are burdensome because each authorization triggers CEAA (unless done on an emergency basis), and inflicts a bureaucratic approval process on an already cumbersome system. Ministerial authorization can not be granted under Section 36.

If disease control issues as they relate to both farmed and wild fish populations can be resolved through managing the prohibition under Section 36, it is hoped that the Section 32 requirements could also be addressed within that resolution, reducing the need for case by case authorization.

Aquatic Invasive Species Management

Political sensitivities are becoming more delicate as the nature and magnitude of the threat of aquatic invasive species (AIS) grows in Canada. The increase in both the volume and speed of global trade, especially in the case of goods or vessels from countries with similar climates to Canada, has led to ever-higher risks of AIS entering Canada - risks that are further exacerbated by insufficient surveillance and enforcement. Allowing a species to spread may irreversibly alter the ecosystem, thereby threatening fishing, recreation, and hospitality industries. For example, AIS have already caused management issues in the shellfish aquaculture industry in Eastern Canada, with estimated costs to the growing and processing sectors being in the millions of dollars. The current regulatory framework under DFO's *Fisheries Act* is no longer comprehensive enough to adequately address issues pertaining to Aquatic Invasive Species such as eradication and rapid response. Federal intervention is required to meet international protection and prevent loss of aquatic resources and native biodiversity due to introduction or spread of those non-native invasive species. Canada's aim is to protect Canada's aquatic resources from introduction of exotic and invasive species; and prevent multi million dollars impacts to Canadian aquatic ecosystems, biodiversity and mostly its economy (both in terms of Canada's ability to trade commercial species and loss of biodiversity and ecosystem services). Without regulatory changes, Canada will appear to the international community as not having the ability to undertake its responsibilities under the Convention on Biological Diversity to adequately prevent AIS to establish and spread.

Efforts to resolve AIS problems are complicated and the solutions often involve trade-offs. There is a widespread lack of compliance with voluntary practices designed to limit the spread of AIS resulting from human activity. Although applicable legislation and regulations exist in some cases, there are no existing federal regulations that address the ability to control or manage aquatic invasive species. For instance, the *Fisheries Act* does not contain specific sections addressing the issue of AIS leading to a limited ability to prevent introduction and limited possibilities to respond rapidly to undertake eradication or control activities. Of concern here is that efforts to stem the spread of AIS may require, as with disease control approaches mentioned above, control or eradication via products that would conflict with the general prohibition under Section 36, as well as Section 32.

Criteria for Assessing Potential Options for Change

The goal of this discussion paper is to facilitate dialogue and decision-making with respect to how best to advance, from a federal perspective, with the management of the General Prohibition contained in Section 36 of the *Fisheries Act* as related to the issues described above. With this in mind, an analysis of general approaches and options is provided further below, using some key considerations/criteria as a basis for the assessment. Key considerations/criteria include:

1. Timeliness

Developing a solution to these issues is quite urgent. With respect to the aquaculture situation for example, there is a need to have a new waste management system to be put in place by February 10, 2010 in BC, and the need for alternate therapeutants to treat sea lice is also likely to bring these questions to the forefront of public attention by Spring 2010. Over the longer term, the need for disease control among Canada's aquatic resources is expected to increase along with related issues of increasing global population, food security and climate change.

2. Regulatory transparency/clarity - in the context of federal regulatory streamlining initiatives.

There is a need to ascertain whether the identified option can provide clear direction to stakeholders attempting to abide by regulatory requirements (transparency). Ensuring compatibility with federal priorities and regulatory streamlining initiatives is also essential. Furthermore, options must be assessed on their ability to provide legal certainty (for example reducing the potential for officially-induced error in the absence of clear regulations), and to meet federal legislative responsibilities.

3. Cost - fiscal prudence and cost efficiency for governments and industry

Both short and long-term costs which extend beyond those which are monetary are a fundamental consideration in determining a solution. Successful management of Canada's natural aquatic resource involves achieving cost-conscious balance between stock quality (health), environmental quality, and population levels. Any solution must take into consideration the link between what is done to obtain revenue today, and how this could affect future revenues.

4. Effectiveness - in relation to environmental protection requirements and remaining true to the spirit of the law.

Any solution must be flexible and able to accommodate changing environments including the need to maintain ecosystem resilience in order for natural systems to be able to adapt to changing ecological pressures. The preferred approach in any option would include a focus on avoidance

and mitigation against potential harmful effects or impacts, understanding that application of ecological principles lowers risks involved in managing natural resources and provides for greater long-term economic benefit to Canadians. In the context of the *Fisheries Act*, options must contribute to: the prevention of harm to fish and fish habitat; sustainable development; and, environmental and ecosystem protection including water quality and wildlife.

5. *Protection of human health - including water pollution and consumption of product, etc...*

There are two key manners in which the issues described above relate to human health risks: the release of deleterious substances contributes to water pollution and thus, impacts on human health related to exposure to deleterious substances found in marine environments; and the consumption or use of aquatic resources ("fish") can also pose significant risks to human health (eg. through the exposure to chemicals, toxins, antibiotics). On the other hand, human health risks also need to be considered in relation to the need to control pathogens, disease vectors. These issues will need to be balanced in the development of potential options.

6. *Adherence to international standards and protocols - Sustainable Development and the Precautionary Principle.*

International standards and protocols for aquatic natural resource management are becoming more stringent and more widespread in their application. The foundation of all international standards is the promotion of management systems for which the social, ecological and economic viability can persist indefinitely (sustainable development). Options must be in compliance with specific federal, international responsibilities and, in the absence of sound science, adherence to the precautionary principle must be considered in the development and implementation of a solution.

7. *International Precedence / harmonization with other countries.*

Drug and chemical regulations for use in aquatic ecosystems have been made in several nations and these will need to be reviewed for potential use as models in the development of solutions. In addition, several codes of practice have been established internationally to lay the groundwork for government action and decision-making related to effective aquatic ecosystem management (eg. Scotland, Norway). Further to a review, discussions with other countries will likely be required to gain confidence in any potential solution, enabling Canada to build on lessons learned from international jurisdictions.

8. *Operational pragmatism and opportunity to modernize management of aquatic ecosystems.*

Any adopted solutions must be operationally feasible and pragmatic. While certain solutions may hold theoretical appeal, they may simply not be workable in a real world context and need to be considered from that perspective. Solutions will have to ensure that aquatic resource development is not jeopardized by way of inadequate human and institutional capacity, and financial resources, for instance.

9. *Policy cohesion with respect to other Fisheries Act requirements.*

In attempting to resolve the Section 36 and 32 issues, it will be important to ensure that changes are in line with Fisheries and Oceans Canada policy directions and with other requirements of the Fisheries Act. For example, recognizing that substances for use in aquatic resource management

could pose threats to fish habitat, Section 35 of the Fisheries Act will need to be taken into consideration.

10. Ability to address Section 32 and Section 36 requirements concurrently.

While this paper focuses more on the Section 36 requirements given the broad application of the strict prohibition contained in Subsection 36(3) and the stringent requirements for regulatory development under Subsection 36(5), the need to surmount barriers to effective fish health and ecosystem health management found in Section 32 are not insignificant. The current regime calls for a *CEAA* review with each authorization by the Minister. Thus, any solution should be able to address both Section 32 and Section 36.

Note: Federal and provincial jurisdictional concordance must be considered at the stage of implementation but is not a criterion to be used in the assessment of potential solutions at this stage. Exclusive federal jurisdiction for management of fisheries in the marine environment is clear in the Canadian Constitution, and is implemented via the *Fisheries Act*. There remains some uncertainty for some aspects of aquaculture management, which has traditionally been a matter of joint management with Provinces and Territories. However, the federal role has recently been expanded in this area as a result of the British Columbia Supreme Court decision in the case of Morton *et al.* The division of legislative authority for aquaculture management between the federal Parliament and provincial legislatures dealing is currently under regulatory review in response to this decision. Also, federal-provincial-territorial agreements are in place to ensure cohesion among jurisdictions.

Analysis of Potential Approaches & Options

As with any question of developing a federal government approach to national issues management, there are four main approaches, ranging from status quo, policy development, regulatory options, and finally, legislative change. As demonstrated in the section below, the status quo and the policy approaches must be rejected outright given their inability to effectively address the problems at hand. Regulatory action is warranted based on the serious nature of the fish health and ecosystem health issues, and on the inefficiency of the current management regime which makes Canada a poor climate for business investment in fish health products and provides aquaculturists with little power to protect their investments. However, legislative change is not warranted as adequate regulatory tools are available. Each general approach may have a series of different scenarios or options, however, if a general approach is dismissed based on analytical criteria, elaboration of more detailed options is not provided. Further, while all criteria are used in the assessment, only the deciding factors are highlighted below. Also, given that waste management issues for aquaculture are being addressed as part of a separate exercise related to the BC situation, the regulatory options presented here focus in on the aquatic resource management issues related to fish health and ecosystem health.

1) Status Quo: This is not a viable approach. Under this scenario, federal/provincial governments and industry stakeholders would continue to manage within existing uncertainties and legal contradictions, as described above. Environment Canada's system of establishing priorities for enforcement activities would continue to be the only tool available for managing the gamut of potential Section 36 *Fisheries Act* contraventions and contradictions with other federal Acts. The status quo is perceived to be unworkable due to the inability for the federal government and industry stakeholders to carry on in such a

complicated regulatory environment. Under this scenario, industry business risks are too high. Federal departments would be open to legal risk, and given political sensitivities with respect to the protection of the marine environment, it is anticipated that requests for judicial review would be forthcoming. This “management through litigation” approach would be a very expensive way to deal with the issues at hand, and may tie the hand of government with respect to its ability to decide on a preferred approach.

2) Policy approach: This is not a viable approach. The *Fisheries Act* is very clear that regulations are the only manner in which the deposit of deleterious substances may be authorized. Furthermore, legal advice provided by the Department of Justice to Environment Canada and Fisheries and Oceans Canada, in both 2001, and more recently in 2009, has also clearly indicated that the only manner in which the deposit of deleterious substances can be authorized is via the development of regulations as per the specific conditions set out in Section 36(4):

- (4) No person contravenes subsection (3) by depositing or permitting the deposit in any water or place of:
 - (a) waste or pollutant of a type, in a quantity and under conditions authorized by regulations applicable to that water or place made by the Governor in Council under any Act other than this Act; or
 - (b) a deleterious substance of a class, in a quantity or concentration and under conditions authorized by or pursuant to regulations applicable to that water or place or to any work or undertaking or class thereof, made by the Governor in Council under subsection (5).

Legal advice has also indicated that, if a policy approach is taken with respect to the authorization of deposits under Section 36, there would be a high likelihood for requests for judicial review based on any related decision-making with respect to allowing any deposits. Given the strict regulatory requirements of Section 36, the policy approach is assessed in a similar manner to the Status Quo approach, and is not recommended for the same basic reasons (lack of transparency, a realistic assessment of operational pragmatism, potential costs of litigation and resultant potential for lack of flexibility in response, high business risk, etc). In addition, a policy approach would not address Section 32 concerns.

3) Regulatory Options: Regulatory change is viable. A regulatory approach to address aquatic resource management and Section 36 issues is consistent both with legal advice provided by the Department of Justice, and with previous recommendations made by consultants and federal agencies/departments over the last twenty-four years. In 1999, a report was prepared by DFO, EC, and PMRA recommending the development of Best Management Practice agreements with compliance monitoring to be undertaken jointly by EC and PMRA.

Guidance in the *Fisheries Act* with respect to the development of regulations for Section 36 are as follows:

- (5) The Governor in Council may make regulations for the purpose of paragraph (4)(b) prescribing:
 - (a) the deleterious substances or classes thereof authorized to be deposited notwithstanding subsection (3);
 - (b) the waters or places or classes thereof where any deleterious substances or classes

thereof referred to in paragraph (a) are authorized to be deposited;
 (c) the works or undertakings or classes thereof in the course or conduct of which any deleterious substances or classes thereof referred to in paragraph (a) are authorized to be deposited;
 (d) the quantities or concentrations of any deleterious substances or classes thereof referred to in paragraph (a) that are authorized to be deposited;
 (e) the conditions or circumstances under which and the requirements subject to which any deleterious substances or classes thereof referred to in paragraph (a) or any quantities or concentrations of those deleterious substances or classes thereof are authorized to be deposited in any waters or places or classes thereof referred to in paragraph (b) or in the course or conduct of any works or undertakings or classes thereof referred to in paragraph (c); and
 (f) the persons who may authorize the deposit of any deleterious substances or classes thereof in the absence of any other authority, and the conditions or circumstances under which and requirements subject to which those persons may grant the authorization.

Within this scope, there are three main regulatory options foreseen: a) a regulation including detailed conditions with quantities and concentrations of specific substances to be prescribed directly in the regulation, as per the Pulp and Paper Effluent Regulations (PPER) and the Metal Mining Effluent Regulations (MMER); b) a regulation including detailed conditions to be prescribed directly in the regulations based on a combination of: i) biological measures of “concentrations” related to the potential to cause harm to fish and ii) thresholds governing the protection of the marine environment; and c) a regulation using the same approach as for Option b, above, but adding a Code of Practice containing principles that could be used to develop Best Management Practices (with BMPs - to be developed later, as needed) related to specific activities, such as application methods for certain products and the use of best available technology, etc.

Any regulatory option could be designed in such a way as to address Section 32 requirements, as well as any requirement for “fishing” licenses for the purposes of disease management and aquatic invasive species management. In addition, any regulatory change would require the development of a comprehensive risk assessment to establish a point of reference for decision-making. This risk assessment would provide a baseline to help guide the regulatory development process in terms of design and approach. For aquaculture, this baseline risk assessment is currently underway (ie. the Framework for Aquaculture Environmental Management) and results are expected in fall of 2009. A description of each regulatory option is presented below.

- a. *Regulation including detailed conditions to be prescribed directly in the regulation* - This option is based on the model of the PPER and MMER and requires the development of lists of specific substances that would be allowed to be released, along with specific limits and conditions for their release (eg. concentration, frequency and method of use). This approach is consistent with legal opinion provided by EC-DLSU with respect to the requirements to meet the conditions for developing Section 36 Regulations. The development of these lists and conditions would require a significant amount of research, consultation and other work at the front-end, prior to being able to develop related regulations, and therefore timeliness is a factor with this option. EC estimates that it took approximately five years to develop the PPER and the MMER. Thus, it would be a long time before a resolution could be established and legal uncertainties and business risks could be addressed, leaving the complications of the status quo

situation in place for an extended period of time. Moreover, the situation of aquatic resource management is quite different from an industrial operation. For example, it is difficult to envision a scenario where prescriptions for using fish health products could be written into a regulation. Generally, veterinarians are involved in writing prescriptions based on specific circumstances, including the species, the illness / pest, the environment surrounding, etc., and it would be impossible to prescribe these details in a regulation. While the PPER/MMER approach would certainly remain true to the spirit of the law and provide for adequate controls to protect the environment, it is also seen as cumbersome, costly in its development phase, and inflexible in that it would limit the ability to respond to new situations as issues emerge since it would require a regulatory amendment in order to adapt to new realities. EC administers and enforces the PPER and the MMER. Both the PPER and the MMER relate to situations where there is a final control point before which the operator has control (eg. end of pipe). This may be difficult to apply in aquaculture which uses primarily open-net-pen technologies, and also in the case of aquatic invasive species and wild populations, as there is not usually a pipe or specific discharge. In summary, this regulatory approach would present major challenges for addressing the needs of aquatic resource management effectively.

- b. *Regulation including detailed conditions to be prescribed directly in the regulations based on a combination of: i) biological measures of “concentrations” related to the potential to cause harm to fish and ii) thresholds governing the protection of the marine environment* - This option draws on guidance provided by regulations developed for Marine Protected Areas in terms of thresholds of acceptable impacts on the environment, and the use of LC-50 or other toxicological limits/concentrations for toxicity to fish as measures of “concentration” (as required under Subsection 36 (4)(a)). The biological measure (s) would need to ensure that releases from related activities would be “non-acutely lethal”, and may require additional conditions to be met. Environmental risk assessments (ERAs) would be required in advance of any approvals for products to be used in Canada, though existing ERA processes conducted as part of other legislative requirements (eg. *Pest Control Products Act*) could be used, where they meet the conditions of Section 36, otherwise new ERA processes would be required. This regulatory option would require onsite and broader follow-up monitoring and enforcement, to ensure that the environmental thresholds/conditions are not exceeded (eg. cumulative effects, sub-lethal/chronic effects, etc). Based on a review of current regulations and management for aquatic animal health products, this approach would involve a first step of grouping substances into manageable “classes” that would include pesticides registered by the PMRA, drugs registered by the VDD that have undergone CEPA requirements, approved disinfectants and anaesthetics, and lampricides or similar products approved for the control of invasive species. Detailed conditions for the release of these classes of substances would then be established, and would be based both on biological measures to prevent harm to humans and non-target species, and on ecological measures to avoid environmental damage. DFO-DLSU has suggested that the MPA Regulations may offer some useful guidance in the

development of conditions, for aspects such as the setting of thresholds to determine the range of acceptable impacts based on cumulative effects on the environment. MPA Regulations prohibit particular activities for purposes of conservation and protection as stipulated in the *Oceans Act*, yet also provide a set of exceptions to allow for particular activities such as fishing (based on accordance with other regulations, or through the submission of an activity plan for carrying out scientific or educational activities). Despite exceptions, the Minister is not authorized to approve activities if the cumulative environmental effects, in combination with any past and current activities are likely to damage or destroy the habitat of living marine organisms in the area. These types of conditions could be used as a basis for the granting of permits to release deleterious substances under the proposed new regulation. Thus, this discussion papers puts forth the idea that it would be possible to develop specific conditions for the release of substances, in terms of allowable biological concentrations and allowable impacts, that would effectively remain true to the spirit of the law with respect to environmental conservation and protection, yet that would not require the development of detailed lists and limits for each substance. Based on the fact that the MPA Regulations took about five years to develop, it is estimated that building these conditions directly into the proposed Regulations would take at least three to four years and the status quo situation would prevail for sometime into the future.

- c. *The basis for this regulation is the same as for Option b, above, but adds a Code of Practice containing principles that could be used to develop Best Management Practices (with BMPs - to be developed later, as needed) related to specific activities, such as application methods for certain products and the use of best available technology, etc.* This option would involve the development of a regulation including detailed conditions to be prescribed directly in the regulations based on a combination of: i) biological measures of concentrations related to the potential to cause harm to fish and ii) thresholds governing the protection of the marine environment. The addition of a National Code of Practice containing important principles for effective, responsible management would provide added clarity and regulatory certainty for all stakeholders. The National Code of Practice would essentially provide guidelines for the development of Best Management Practices (BMPs), which could be developed at a later time. Thus, any BMPs would hold the strength of regulation, providing for additional flexibility and regulatory certainty over time. A code of practice is made up of a set of guiding principles consisting of broad statements about how management and other operational activities should be conducted, accompanied by best management practices designed to minimize adverse environmental impacts. It is reported that the most practical procedure is for a nation or industry to develop a general code of practice as a guideline for site-specific best management practice systems. As an example, under the auspices of the Food and Agriculture Organization of the United Nations (FAO), several producers, governments, international organizations, ENGOs, and others have developed codes of practice for aquaculture and most aquaculture codes reference FAO's "Code of Conduct for Responsible Fisheries". In most cases, a collection of BMPs are required, to be

selected based on site characteristics, and ecologically-responsible production systems. BMPs should be designed to be adaptable to new technologies and new knowledge. To illustrate, the National Code of Practice could include a number of principles such as pollution prevention, and lifecycle management of chemicals (consistent with recommendations made by Canada's Commissioner for Environment and Sustainable Development in 1999) and/or the use of best available technology along with appropriate training for the use of chemicals, whereas the BMPs could outline preferred application methods and technologies for a given substance along with specific dosages/concentrations for a given purpose, training programs and disposal methods, etc. As with b), this option would require the same program provisions for any gaps in existing environmental assessment processes for approvals of new products for Canada, and follow-up monitoring and enforcement to ensure that thresholds are not exceeded. This discussion paper is presenting the concept that the development of the BMPs could be done after the proposed regulation would be in place (based on a Code of Practice), allowing for a phased in approach to the development of the new regulatory context for Section 36. It is unclear at this time whether or not the BMPs would need to undergo the Gazette process, or if the Code of Practice could specify a lower level of interdepartmental/Ministerial approval based on relevant departmental mandates, provided that the BMPs would conform to the principles contained in the Code of Practice. This ability to phase in a comprehensive regulation (including the Code of Practice in the first phase, and the BMPs as subsequent phases) is expected to provide significant benefit in relation to timeliness factors for the issues discussed in this paper. Should the development of this type of regulation be made a federal government priority, it is possible that a general, first-phase regulation could be put in place by June 2010. Time required for developing BMPs would depend on the complexity of the issue at hand. (Please see Annex 3 for further background information).

Costs for implementation of the proposed regulation would be based on the proposed program/regulatory gap analysis. Option A would certainly be more costly at the development stage, but since it would not meet the needs of aquatic resource management anyway, it is somewhat irrelevant. Nevertheless, the existing PPER and MMER programs might be instructive in terms of estimating costs for programs to manage chemicals according to Section 36 requirements.

A new program to administer and enforce the regulations may be required, involving the need for new funding via a Memorandum to Cabinet (MC) and associated Treasury Board submission. An opportunity may exist to include some of these Section 36 considerations in an aquaculture MC being prepared for the BC context, in an MC on the aquatic invasive species issues, or other ongoing processes. There would need to be a decision made with respect to which federal agency or department would assume responsibilities for administration and/or enforcement of any proposed new regulation, or how those responsibilities might be shared.

4) Legislative Change: Legislative change is viable, but not warranted. This approach would include either making changes to the *Fisheries Act*, or developing new legislation

altogether, such as an *Aquaculture Act* (note that this would not directly address aquatic invasive species issues, nor wild populations of fish). Legislative change poses the absolute highest cost and greatest time requirements in order to reach a resolution. Furthermore, it would highlight profound political sensitivities with respect to protection of the marine environment, and would call into question the long-standing mandate of Environment Canada's enforcement program. In addition to these significant drawbacks, it is also perceived to be unnecessary since the *Fisheries Act* does provide the ability to regulate the deposit of deleterious substances via regulation.

Next Steps

1. a) In order to assess the validity of the proposed option, there is a need for in-depth analysis of options by relevant federal departments, with an important starting point being Environment Canada's willingness to consider these approaches, given their responsibilities for administering and enforcing Section 36. b) Simultaneously, a program/regulatory gap analysis must be undertaken in order to understand what areas of environmental impact assessment are already covered for the aquatic resource management issues in question.

2. Develop consensus among federal departments with respect to the development of options for moving forward, along with associated general timelines and funding approach (EC, DFO, CFIA, HC - VDD and PMRA, other?).

3. Refine the approach based on the above diagnostic process, assess stakeholder consultation requirements, and estimate potential costs both of action and inaction.

4. Based on the refined approach, develop a work plan for regulatory development and implementation, a consultation strategy, and develop a Memorandum to Cabinet to obtain necessary funding.

To complement these key next steps, there is a need for regulatory development according to Canada's federal requirements / Gazette process. Following is a draft timeline aiming toward implementation of regulatory changes by June of 2010 (Note that this timeline is ambitious and it may not be possible to meet these dates):

Timeframe for the Federal Regulatory Process for Fisheries Act Sections 32 and 36

#	Action / Milestone	Due Date	Notes
17	Regulations Published in <i>Canada Gazette Part II</i>	Jul 30, 2010	1-3 weeks after TB approves
16	Regulations Registered.	Jul 9, 2010	Within 3 days
15	TB meeting.	Jul 2, 2010	.
	Ministerial approval of Regulatory Package and submission of package to PCO/TB for placement on TB meeting agenda <i>Canada Gazette Part II</i>	Jun 11, 2010	Signed package must be submitted to PCO/TB 3 weeks before the TB meeting
14	Aquaculture management, Aquatic Invasives, Habitat, Aquatic animal health, and Policy work together to prepare final regulatory package and submit to Minister for approval to submit to PCO/TB for final approval and publication in <i>Canada Gazette Part II</i>	Jun 4, 2010	Depending on the nature and complexity of comments received and whether further drafting is necessary.
	Comment period ends	May 30, 2010	

13	Published in <i>Canada Gazette Part 1</i>	May 20, 2010	2 weeks after TB approval
11	TB meeting	May 6, 2010	Submission must be three weeks before meeting
10	Ministerial approval of Regulatory Package and submission to PCO/TB for placement on TB meeting agenda for consideration for <i>Canada Gazette Part 1</i>	Apr 15, 2010	Allow 3 weeks for Ministerial approval
9	Justice legal drafters return blue stamped regs for Part 1 of <i>Canada Gazette</i> and LRA submits Regulatory Package for Minister's signature demonstrating approval for submission to PCO/TB for consideration for prepublication in <i>Canada Gazette Part 1</i> (Blue Stamped Regs; RIAS, Communication Plan)	Mar 29, 2010	Must be received prior to DFO Ministerial approval- DOJ needs 3 months [Given the complexity, this will likely take longer than 3 months]
8	LRA submits Regulatory Package to Justice legal drafters for review (RIAS, Drafting instructions, Regulatory Communications Plan)	Jan 29, 2010	
7	Communications Plan; Regulatory Impact Assessment Statement, consultations; Meet with OGDs on wastewater reg development (EC), New Substances Notification amendments (HC)	Jan 20, 2010	[Warning: It is doubtful that this work could be completed within this timeframe. A RIAS includes a cost benefit analysis (CBA) and provides a summary of consultations that need to be done with interested and affected stakeholders (including provincial governments, aquaculture industry, ENGOs, commercial / recreational fishing sectors, aboriginal groups etc.)]
6	Finalize Triage Statement	Dec 6, 2009	30 days after initial submission
5	Comments on Triage from TBS	Nov 18, 2009	10 days after receipt
4	Draft Triage Statement to RAS (Regulatory Affairs Sector)	TBS; Department of Legal Services	
Unit (DLSU); Legislative and Regulatory Affairs (LRA)		Nov 6, 2009	
3	Complete drafting of Triage Statement using readily available information (not in-depth analysis)		
		Oct 30, 2009	
2	Begin work on Triage Statement.	Oct 26, 2009	Depending on the outcome, the regulatory proposal may 'skip' CGI but that is usually only for low impact and administrative amendments.
	Consultation with OGDs (CFIA, HC, EC)	Oct. 19, 2009	
	Internal DFO briefing to PIC, DMC, etc. Receive approval on initiative.		Oct. 13, 2009
	Depending on when we can get scheduled to brief up		
	Meet as a group to solidify consultation plan, budget, and timelines, followed by deck development (AMD), briefing, etc. Circulate brief to sectors for input.		Sep 28 - Oct. 9, 2009
	Work as a group to get organized with project work planning to brief up		
1	LRA advice and support work plan / timeline finalization	Sep 15, 2009	

Annex 1: Fisheries Act Section 36 Text

36. <http://laws.justice.gc.ca/fr/ShowDoc/cs/F-14/bo-ga:s_23::bo-ga:s_34/20090707/fr?page=5&isPrinting=false>

(1) No one shall

(a) throw overboard ballast, coal ashes, stones or other prejudicial or deleterious substances in any river, harbour or roadstead, or in any water where fishing is carried on;

(b) leave or deposit or cause to be thrown, left or deposited, on the shore, beach or bank of any water or on the beach between high and low water mark, remains or offal of fish or of marine animals; or

(c) leave decayed or decaying fish in any net or other fishing apparatus.

Disposal of remains, etc. <http://laws.justice.gc.ca/fr/ShowDoc/cs/F-14/bo-ga:s_23::bo-ga:s_34/20090707/fr?page=5&isPrinting=false>

(2) Remains or offal described in subsection (1) may be buried ashore, above high water mark.

Deposit of deleterious substance prohibited <http://laws.justice.gc.ca/fr/ShowDoc/cs/F-14/bo-ga:s_23::bo-ga:s_34/20090707/fr?page=5&isPrinting=false>

(3) Subject to subsection (4), no person shall deposit or permit the deposit of a deleterious substance of any type in water frequented by fish or in any place under any conditions where the deleterious substance or any other deleterious substance that results from the deposit of the deleterious substance may enter any such water.

Deposits authorized by regulation <http://laws.justice.gc.ca/fr/ShowDoc/cs/F-14/bo-ga:s_23::bo-ga:s_34/20090707/fr?page=5&isPrinting=false>

(4) No person contravenes subsection (3) by depositing or permitting the deposit in any water or place of

(a) waste or pollutant of a type, in a quantity and under conditions authorized by regulations applicable to that water or place made by the Governor in Council under any Act other than this Act; or

(b) a deleterious substance of a class, in a quantity or concentration and under conditions authorized by or pursuant to regulations applicable to that water or place or to any work or undertaking or class thereof, made by the Governor in Council under subsection (5).

Regulations for authorizing certain deposits <http://laws.justice.gc.ca/fr/ShowDoc/cs/F-14/bo-ga:s_23::bo-ga:s_34/20090707/fr?page=5&isPrinting=false>

(5) The Governor in Council may make regulations for the purpose of paragraph (4)(b) prescribing

(a) the deleterious substances or classes thereof authorized to be deposited notwithstanding subsection (3);

(b) the waters or places or classes thereof where any deleterious substances or classes thereof referred to in paragraph (a) are authorized to be deposited;

(c) the works or undertakings or classes thereof in the course or conduct of which any deleterious substances or classes thereof referred to in paragraph (a) are authorized to be deposited;

(d) the quantities or concentrations of any deleterious substances or classes thereof referred to in paragraph (a) that are authorized to be deposited;

(e) the conditions or circumstances under which and the requirements subject to which any

deleterious substances or classes thereof referred to in paragraph (a) or any quantities or concentrations of those deleterious substances or classes thereof are authorized to be deposited in any waters or places or classes thereof referred to in paragraph (b) or in the course or conduct of any works or undertakings or classes thereof referred to in paragraph (c); and
(f) the persons who may authorize the deposit of any deleterious substances or classes thereof in the absence of any other authority, and the conditions or circumstances under which and requirements subject to which those persons may grant the authorization.

Directions by the Minister <http://laws.justice.gc.ca/fr/ShowDoc/cs/F-14/bo-ga:s_23::bo-ga:s_34/20090707/fr?page=5&isPrinting=false>

(6) A person authorized to deposit a deleterious substance by or under regulations made pursuant to subsection (5) shall, when directed in writing by the Minister, notwithstanding any regulations made pursuant to paragraph (5)(e) or any conditions set out in an authorization made pursuant to paragraph (5)(f), conduct such sampling, analyses, tests, measurements or monitoring, install or operate such equipment or comply with such procedures, and report such information, as may be required by the Minister in order to determine whether the person is depositing the deleterious substance in the manner authorized.

R.S., c. F-14, s. 33; R.S., c. 17(1st Supp.), s. 3; 1976-77, c. 35, s. 7; 1984, c. 40, s. 29.

Minister may require plans and specifications <http://laws.justice.gc.ca/fr/ShowDoc/cs/F-14/bo-ga:s_23::bo-ga:s_34/20090707/fr?page=5&isPrinting=false>

Department of Justice. 2009. http://laws.justice.gc.ca/en/showdoc/cs/F-14/bo-ga:s_23/20090707/en#anchorbo-ga:s_23 <http://laws.justice.gc.ca/en/showdoc/cs/F-14/bo-ga:s_23/20090707/en>

Annex 2: Marine Protected Area Model

Marine Protected Area (MPA) Regulations have been developed under Section 35 of the *Oceans Act*. The regulations are designed to protect an area by first designating it and then creating prohibitions. The MPAs allow for some activity within the area either through an exception, e.g. Section 4 of Musquash Estuary Marine Protected Area Regulation:

EXCEPTIONS

4. The following activities may be carried out in the Area:

(a) the following fishing activities, namely,

- (i) fishing that is carried out in accordance with the *Aboriginal Communal Fishing Licences Regulations*,
- (ii) any of the following recreational fishing activities carried out in accordance with the *Atlantic Fishery Regulations, 1985* or the *Maritime Provinces Fishery Regulations*, namely,
 - (A) manually fishing for scallops or clams, and
 - (B) fishing for any other species by means of angling or a dip net, and
- (iii) any of the following commercial fishing activities carried out in accordance with the *Atlantic Fishery Regulations, 1985* or the *Maritime Provinces Fishery Regulations*, namely,
 - (A) in Zone 1, fishing for elvers or eels by means of a hand-deployed fyke net or dip net,
 - (B) in Zone 2A, 2B or 3, fishing for lobster by means of individual traps and for herring by means of a weir, beach seine, bar seine or drag seine,
 - (C) in Zone 3, fishing for scallops, and
 - (D) in any Zone, manually fishing for clams;

(b) in Zone 2A, 2B or 3, the recreational or commercial harvesting of dulse manually;

(c) the operation of a vessel in Zone 2A or 2B at a speed no greater than five knots or in Zone 3 at a speed no greater than eight knots;

(d) in Zone 2A, the construction of a boat launch, the maintenance, repair or removal of a wharf or boat launch or the maintenance of a navigation channel, for which approval or authorization is not required under the New Brunswick *Clean Water Act*, S.N.B. 1989, c. C-6.1, the *Navigable Waters Protection Act* or the *Fisheries Act*, as the case may be, or that is carried out in accordance with an approval or authorization required under any of those Acts; and

(e) any activity that is carried out for the purpose of public safety, national defence, national security or law enforcement or in response to an emergency.”

...or through the submission of an activity plan for carrying out scientific or educational activities. For e.g. Section 5 of Musquash Estuary Marine Protected Area Regulation:

ACTIVITY PLAN

5. Every person who proposes to carry out a scientific, educational, archaeological, commercial tourism or habitat restoration activity in the Area shall submit to the Minister for approval, not less than 60 days before the day on which the activity is proposed to begin, a plan that contains the following information and documents:

(a) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of a person who can be contacted in respect of the plan;

(b) a detailed description of the proposed activity that sets out

- (i) its purpose,
- (ii) the period or periods during which it is to be carried out,
- (iii) a map on which its location is identified,
- (iv) the types of data that are to be collected, if any, and the sampling protocols or other techniques to be used to collect the data,
- (v) the types of equipment, if any, that are to be used during the proposed activity, including those for gathering data and, if any of the equipment is to be anchored or moored in the Area, the methods by which the anchoring or mooring is to be conducted,
- (vi) the type and identity of every vessel that is to be used to carry out the proposed activity, and
- (vii) every substance, if any, that is to be deposited, discharged or dumped within the Area during the proposed activity;

(c) an assessment of the environmental effects that are likely to occur within the Area as a result of the proposed activity; and

(d) a list of every licence, permit, authorization or consent obtained or applied for in respect of the proposed activity.

The activity plan could be part of a code of practice in the case of S.36.3. Furthermore, Section 6 of the Musquash Regulations set out the approval process for the Minister to make a decision concerning cumulative environmental effects of the proposed activity, in combination with any other past and current activities carried out within the Area. Section 6 is as follows:

6.

(1) The Minister shall, within 30 days after the day on which a plan that is submitted in accordance with section 5 is received, approve the plan if the proposed activity is not likely to damage or destroy the habitat of a living marine organism in the Area and in the case of a habitat restoration activity, the proposed activity is to be carried out for the purpose of managing the Area.

(2) Despite subsection (1), the Minister shall not approve a plan if the cumulative environmental effects of the proposed activity, in combination with any other past and current activities carried out within the Area, are likely to damage or destroy the habitat of living marine organisms in the Area."

The above noted section provides the Minister with a "**threshold**" whereby an activity cannot be approved if cumulative environmental effects were to occur.

Another example is the *Basin Head Marine Protected Area* - (see Link <http://laws.justice.gc.ca/en/ShowFullDoc/cr/SOR-2005-293/20090820/en>)

Annex 3: Relevant Systems of Codes of Practice and Best Management Practices

Brief explanations of Codes of Practice and Best Management Practices are included here, followed by some example codes of practice from the FAO, a list of organizations with codes of practices, and an example of a BMP implemented within a regulation.

Codes of Practice / Conduct:

A code of practice is made up of a set of guiding principles consisting of broad statements about how management and other operational activities should be conducted. Codes of practice often include best management practices designed to minimize adverse environmental impacts. It is reported that the most practical procedure is for a nation or industry to develop a general code of practice as a guideline for site-specific best management practice systems.

Several producers, governments, international organizations, ENGOs, and others have developed codes of practice for aquaculture and most aquaculture codes reference the “Code of Conduct for Responsible Fisheries” prepared by the Food and Agriculture Organization of the United Nations. A list of organizations with codes of practices is exhibited in “Table 3”.

Best Management Practices (BMPs) / Standard Operating Plans:

BMPs are practices which typically support codes of conduct and are assumed to be the most effective practical methods of reducing environmental impact levels to those compatible with resource management and production goals. One study addressing effluent regulations, it was determined that the best option for environmental management was regulations including BMPs. Effective environmental management can sometimes be achieved with a single practice but in most cases, a collection of practices is required. Best practices are selected based on site characteristics, and ecologically responsible production systems as technology advances, and need to reflect new knowledge. Various components of waste management for flow-through systems have been known for some time, but how these components are organized together to form a BMP plan or Standard Operating Plan is critical. A BMP plan must be practical, make good financial sense, integrate into farm practices, and affect the desired result for end-of-pipe compliance.

Examples from the FAO Code of Conduct related to aquaculture:

The Food and Agriculture Organization of the United Nations developed a Code of Conduct for Responsible Fisheries including aquaculture. A relevant category and a couple of example codes are listed here.

Aquaculture Development

- Responsible aquaculture at the production level
 - States should promote effective farm and fish health management practices favoring hygienic measures and vaccines. Safe, effective and minimal use of therapeutants, hormones and drugs, antibiotics and other disease control chemicals should be ensured.
 - States should regulate the use of chemical inputs in aquaculture which are hazardous to human health and the environment.

- States should require that the disposal of wastes such as offal, sludge, dead or diseased fish, excess veterinary drugs and other hazardous chemical inputs does not constitute a hazard to human health and the environment.

List of organizations with codes of practice for aquaculture:

The table below was prepared by Claude E. Boyd in 2003 and published in the Journal of Aquaculture. It represents some organizations that have identified codes of conduct for aquaculture.

Table 3

Partial list of organizations that have prepared codes of conduct for aquaculture

Alabama Catfish producers	Global Aquaculture Alliance
Agro Eco Consultancy	Industrial Shrimp Action Network
Aquaculture Foundation of India	Irish Salmon Growers Association
Australia Aquaculture Forum	Malaysia Department of Fisheries
Australian Prawn Farmers Association	Marine Shrimp Farming Industry of Thailand
British Columbia Salmon Farmers' Association	Missouri Department of Natural Resources
British Trout Association	Naturland
Catfish Farmers of America	Ornamental Fish Industry (United Kingdom)
Coastal Resources Center (University of Rhode Island)	Shrimp Farming Industry of Belize
Florida Department of Agriculture and Consumer Services	Soil Association (United Kingdom)
Food and Agriculture Organization of the United Nations	

Description of a BMP implemented within a regulation using the US as an example:

Several BMPs have been prepared on global and local scales and can be used as support for regulatory and policy development. Often BMPs are voluntary but it has been reported that command and control regulations predominate in curbing environmental effects of aquaculture. In the following example, BMPs have been incorporated into a US regulation.

In 2004 the US Environmental Protection Agency established regulation on wastewater controls for fish farms. Rules have been established to ensure that facilities develop, maintain, and certify a Best Management Practice Plan that describes how the facility will meet the requirements of the regulation. These rules are required and applied in National Pollutant Discharge Elimination System permits under the US *Clean Water Act*. Other example requirements of the rule are that facilities must:

- Prevent discharge of drugs and pesticides that have been spilled and minimize discharges of excess feed.
- Report the use of experimental animal drugs or drugs that are not used in accordance with label requirements.
- Regularly maintain production and wastewater treatment systems.

It is expected that resulting improvements in water quality will create more opportunities for swimming and fishing and reduce stress on ecosystems in those waters.