Chapter 9 • Fish health management

Introduction

My Terms of Reference direct me, among other things, to consider the policies and practices of the Department of Fisheries and Oceans (DFO), to investigate and make independent findings of fact on the causes of the decline of the sockeye salmon fishery, including the impact of disease, and to develop recommendations for improving this fishery's future sustainability. "Fish health" is not explicitly named in the Terms of Reference, and early in this Inquiry I had not identified it as a distinct theme, although "diseases, viruses, bacteria, and parasites" were identified in my Interim Report as topics to be explored.[1] Issues of fish health and fish health management emerged from several different hearing topics as important themes for my consideration, especially in laying a foundation for recommendations to improve the future sustainability of Fraser River sockeye.

This chapter addresses fish health management of wild and cultured salmon. As I learned in the Commission's hearings on disease, most of the work on fish health – both scientific research and management practices – is directed at cultured fish. Although some research has been done on the health of wild fish, much of what is known or suspected about the health of wild salmon, including sockeye, comes from research on cultured salmon. Similarly, fish health management efforts have focused on cultured rather than wild fish.

The transfer of diseases and pathogens between farmed and wild salmon was a concern of many participants in this Inquiry and a common theme in public submissions. These concerns escalated during the fall of 2011 when two non-government laboratories reported positive test results for infectious salmon anemia (ISA) virus – a disease known in Atlantic salmon – in wild Pacific salmon off the BC coast. These reports were circulated in local and international media. They prompted further document disclosure from Canada, revealing testing for ISAv in Pacific salmon by DFO scientists in 2003–4 and more recently. I reopened the Commission's hearings

in December 2011 to hear evidence about tests for ISAv conducted on wild Pacific salmon, including Fraser River sockeye, and Canada's management responses to these tests. Later in this chapter, I review the evidence I heard about ISAv as a case study of how DFO addresses fish health management issues. I discuss ISAv as a potential cause of the decline in Volume 2 of this Report.

In Chapter 8, Salmon farm management, I summarized concerns about fish health expressed in public submissions. In short they are as follows:

- Diseases and pathogens may be transferred from farmed fish to wild fish.
- Farmed fish pose a risk of introducing new or exotic pathogens.
- Government agencies are not transparent with information about fish health.
- Non-government scientists and the public lack access to scientific data that could be used to evaluate or challenge the work of government or industry scientists.
- DFO or the Canadian Food Inspection Agency (CFIA) has "covered up" evidence of ISAv in BC salmon.
- Science and laboratory testing for fish diseases in commercially valuable fish has been inappropriately politicized.

One public submission also raised concerns about the spread of diseases from hatchery salmon to wild salmon.

In this chapter, I begin by discussing the regulatory regime for fish health management in Canada, including the international context for Canada's fish disease–reporting obligations, and I identify the main programs and organizational responsibilities. Following that background, I review the evidence on fish health management in wild salmon (including assessments or surveillance plans to assess fish health), farmed salmon (including management options to reduce the risk of disease or pathogen transfer to wild sockeye salmon), and enhancement facilities (including issues about availability or lack of information). I then set out the evidence from the hearings on ISAv, including test results and management responses to those tests. Finally, based on the evidence discussed, I make findings to support the recommendations set out in Volume 3 of this Report.

The regulatory regime for fish health management

Within Canada, the regulatory regime for fish health management flows from the *Health of Animals Act* and the *Fisheries Act*.[2] The *Health of Animals Act* addresses reportable diseases that are significant to Canada's trade relations. The *Fisheries Act* regime includes regulations to control, monitor, and report the presence of disease in aquaculture facilities and regulations dealing with interprovincial transfers of fish. These Acts and regulations operate within the context of Canada's international reporting obligations described below.

International context

Canada is one of 28 member states of the Office International des Épizooties (OIE, also known as the World Organisation for Animal Health). The OIE addresses animal health globally by publishing standards on animal health, animal welfare, and food safety. It also collects, analyzes, and disseminates animal health information. Standards related to aquatic animal health can be found in the OIE's Aquatic Animal Health Code (OIE Aquatic Code).[3] As a member, Canada is obliged to report outbreaks of OIE–listed diseases.[4]

OIE-listed diseases

The OIE lists the following finfish diseases as reportable, which means that member countries must report confirmed cases to the OIE: epizootic hematopoietic necrosis, epizootic ulcerative syndrome (red-spot disease), gyrodactylosis, infectious hematopoietic necrosis (IHN), infectious salmon anemia (ISA), koi herpes virus disease, red sea bream iridoviral disease, spring viremia of carp, and viral hemorrhagic septicemia (VHS).[5] Dr. Michael Kent, author of Technical Report 1, Infectious Diseases, noted that IHN poses a high risk to Fraser River sockeye and that VHS poses a low risk.[6] (See further discussion of Dr. Kent's report in Volume 2 of this Report.) Dr. Kent did not identify any of the other OIE-listed diseases as being relevant to sockeye salmon. However, following his testimony, ISA emerged as a topic of concern for sockeye salmon in British Columbia (see case study of ISAv below).

Reference laboratories

The OIE has set up a system of reference laboratories:

> OIE Reference Laboratories are designated to pursue all the scientific and technical problems relating to a named disease or specific topic. The Expert, responsible to the OIE and its Members with regard to these issues, should be a leading and active researcher helping the Reference Laboratory to provide scientific and technical assistance and expert advice on topics linked to surveillance and control of the disease for which the Reference Laboratory is responsible. Reference Laboratories may also provide scientific and technical training for personnel from Members, and coordinate scientific and technical studies in collaboration with other laboratories or organizations, including through OIE Laboratory Twinning.[7]

OIE reference laboratories are different from a member country's national reference laboratories, although many OIE reference labs are located within their host countries' government laboratory systems. Countries with the capacity may set up their own system of national laboratories, which they use to conduct diagnostic tests on OIE-listed diseases. Dr. Peter Wright, national manager of DFO's National Aquatic Animal Health Laboratory System (NAAHLS), described the difference between OIE reference laboratories and national reference laboratories as follows:

> It's quite normal for any country like Canada, the U.S., anywhere in the U.K., that you do have your own national laboratory system, whether it's for aquatic animals or terrestrial animals, and within those – the infrastructure of those lab systems you will designate a national reference laboratory for specific diseases or groups of diseases.
>
> The OIE designation is just that, an OIE designation. It has really no implications for the host country, itself. The idea is that with the OIE you have different regions around the world and they try and put a reference laboratory into each of the individual regions and they're there to provide support to those member countries of the OIE that may not have the laboratory or veterinary infrastructure to conduct investigations for the diseases that those reference labs are responsible for.[8]

Diagnostic testing for OIE-listed diseases

The OIE distinguishes between "suspected" and "confirmed" cases of aquatic animal diseases.[9] The definitions are disease dependent. For example, the definitions of suspected and confirmed cases of ISA appear later in this chapter. Both suspected and confirmed cases may be reported to the OIE; however, Canada's practice is to report only confirmed cases of reportable diseases.[10]

The OIE publishes recommended diagnostic tests for aquatic animal diseases in the OIE Aquatic Code.[11] However, the OIE does not dictate what tests a country must use for listed diseases. A country may use whatever tests it wants so long as the test is validated as comparable to the ones recommended by the OIE.[12] The OIE has developed validation templates for countries to use for both screening and confirmatory diagnostic tests.[13] Validation includes ensuring that the test is repeatable, and that it works in the field (by testing on reference animals that are known to have or not to have the disease in question, or sometimes by using models to simulate what the test should detect).[14]

Canada has a test method agreement with the OIE, which sets out how Canada approaches diagnostics on behalf of the OIE.[15] For example, Canada does not use the OIE-recommended tests for ISAv; it uses a test that it has validated as comparable.[16] (For more on ISAv testing, see the ISAv case study below.)

The OIE Aquatic Code also contains a chapter on aquatic animal health surveillance, which provides guidance to member countries on how to set up surveillance systems to demonstrate freedom from disease.[17]

The *Health of Animals Act* and related regulations

CFIA, under the minister of agriculture and agri-food, administers the *Health of Animals Act*, which was amended to include aquatic animals, like salmon, in December 2010.[18] Under this Act, "disease" includes "(a) a reportable disease and any other disease that may affect an animal or

that may be transmitted by an animal to a person, and (b) the causative agent of any such disease."[19] Reportable diseases are "diseases that are of significant importance to animal health and to the Canadian economy."[20] Reportable diseases are set out in the *Reportable Diseases Regulations*. Aquatic animal diseases were added to these regulations in January 2011.[21] The *Reportable Diseases Regulations* list several salmon diseases including IHN, VHS, infectious pancreatic necrosis (IPN), and ISA,[22] but not all the OIE-listed aquatic diseases. Immediately notifiable diseases are "serious diseases of concern to animal health and to the Canadian economy."[23] They are listed in the *Health of Animals Regulations*.[24] Although some of these are fish diseases to which Fraser River sockeye may be susceptible, none was the focus of evidence before me.

The definition of "disease" under the *Health of Animals Act* is broad enough to include non-reportable disease, but the provisions of the Act do not describe a role for CFIA in relation to non-reportable diseases. CFIA's role depends on a disease being reportable: "Until an incident affecting aquatic animals is linked to a Reportable or Immediately Notifiable disease, the completion of the disease outbreak investigation resides with DFO and/or provincial / territorial authorities."[25]

The *Health of Animals Act* places an obligation on persons who own or have the "possession, care or control of an animal" to notify a veterinary inspector designated under the *Canadian Food Inspection Agency Act* "of the presence of a reportable disease or toxic substance, or any fact indicating its presence, in or around the animal, immediately after the person becomes aware of the presence or fact."[26] It also prohibits concealing the existence of a reportable disease or toxic substance among animals.[27]

Although mandatory reporting is new in the aquatic world, Dr. Kim Klotins, acting national manager, Disease Control Contingency Planning, CFIA, explained that mandatory reporting has been in place in Canada for terrestrial animals since the inception of the *Health of Animals Act*.[28] To advise Canadians about their obligations for reporting aquatic animal diseases, in January 2011, Dr. Klotins drafted and distributed directives to "Canadians who own or work with aquatic animals" and to "veterinarians and aquatic animal health specialists."[29] She sent the directives to DFO, colleges and universities, and others across Canada who work with aquatic animals.[30]

Dr. Klotins explained what it means to have a "suspicion" of a reportable disease sufficient to trigger the reporting requirements under the *Health of Animals Act*, and what CFIA was doing to educate people about what is suspicious:

> It means that they have some information or some idea that the disease may be present in the fish that they own – they possess, own, care or have control of. Some fact. And it could be whatever fact they think gives them the suspicion that the disease is there.
> …
> I guess what we're also planning to do, and we've started to do, is to provide some information to all who are obligated to notify about the, you know, information about the various diseases, or reportable diseases.
>
> We have a couple of the Q and A fact sheets up on the external website. The rest are in the process of being approved. And we have pictures that are going with those diseases. We let them know where we think they occur in Canada right now, and we give probably the most common clinical signs and who they can contact if they suspect [an animal] has disease.[31]

Dr. Klotins said that someone in a laboratory might become suspicious when they receive a request to test samples for a reportable disease. She said CFIA prefers to be notified sooner rather than later, "so that we can start investigating whether there is some basis to the suspicion. And if, for example, if it occurs in cultured animals, perhaps we can initiate an inspection and go visit the site, take a look at the animals, see if we need to collect more samples that can be submitted to the NAAHLS laboratories."[32] (The National Aquatic Animal Health Laboratory System is discussed below.)

Facilities such as salmon farms, enhancement facilities, or even research laboratories may be inspected by a CFIA inspector or officer "for the purpose of detecting diseases or toxic substances or ensuring compliance with [the *Health of Animals Act*] and the regulations."[33] Further, the *Health of Animals Act* gives CFIA inspectors or officers the power to seize animals or things in prescribed situations where the inspector believes an offence has been committed.[34] No

person shall "obstruct or hinder" an inspector or officer performing duties or functions under the Act, and persons in charge of places entered by an inspector or officer shall provide "reasonable assistance" and relevant information.[35] So when CFIA requests that samples be provided in relation to a reportable disease, co-operation is expected. The Act does provide for compensation to be paid for animals destroyed or injured, based on the market value of the animal minus any value of its carcass.[36]

Section 14 of the *Health of Animals Act* allows the minister of agriculture and agri-food to make regulations prohibiting the importation of any animal or other thing into Canada "for the purpose of preventing a disease or toxic substance from being introduced into or spread within Canada."[37] Part XVI of the *Health of Animals Regulations* pertains to aquatic animals. Any finfish listed in Schedule III (which includes Atlantic salmon and all species of Pacific salmon) "may be inspected, segregated and tested for any disease listed in the schedule to the *Reportable Diseases Regulations*; and (b) disease eradication programs may be instituted for preventing the spread of any disease listed in the schedule to the *Reportable Diseases Regulations*."[38] Section 191 requires a person to obtain an import permit before bringing into Canada any of the aquatic animals listed in Schedule III, including germplasm (eggs or sperm). Section 199 prohibits movement of an aquatic animal (including germplasm) from a province infected with a disease to an area free of that disease, except in accordance with a permit issued under section 160.[39]

The *Fisheries Act* and related regulations

As described in Chapter 3, Legal framework, DFO administers a number of regulations under the *Fisheries Act*, two of which address issues of fish health: the *Pacific Aquaculture Regulations* (PAR),[40] discussed in Chapter 8, Salmon farm management, and the *Fish Health Protection Regulations* (FHPR).[41]

The PAR apply to both salmon farms and enhancement facilities.[42] Under the PAR, the minister has the authority to make conditions of licence related to fish health, including the following:

> (f) the measures that must be taken to control and monitor the presence of pathogens and pest in the aquaculture facility;
> (g) the measures that must be taken to monitor the presence of pathogens and pests in wild fish in the waters that may be affected by the operations of the aquaculture facility;
> …
> (m) the notice that must be given to the Minister before
> (i) a substance is used to treat fish for pathogens or pests;
> (ii) fish are transferred to the aquaculture facility, or
> (iii) fish are harvested;
> …
> (o) the records that must be kept in relation to
> …
> (iii) any diagnosis or treatment of a fish pathogen or pest present in the aquaculture facility, including the extent to which the pathogen or pest affects the fish in the facility,
> (iv) any substance used to treat fish for pathogens or pests, including the quantity used and the date and method of its administration,
> (v) the number and species of fish that die prior to harvest, and the cause of death,
> …
> (ix) the data collected in the monitoring of the environmental impact of the aquaculture facility's operations.[43]

Under the PAR regime for aquaculture in British Columbia, routine transfers of cultured fish within the same "salmonid transfer zone" within the province are dealt with under conditions of licence.[44] Other introductions and transfers, such as those between salmonid zones identified in Appendix III of the conditions of licence for salmon farms, require permits issued by DFO under the FHPR but reviewed by the Introductions and Transfers Committee established under the National Code on Introductions and Transfers of Aquatic Organisms (see below).[45]

The FHPR allows a local fish health officer (who is defined as "a person approved as a local fish health officer in charge of the administration and enforcement of these Regulations"[46]) to issue interprovincial carrying permits for cultured and

wild fish as long as the person applying for the permit has obtained a certificate that fish are free of diseases listed in the schedules to the Regulations, or as long as the local fish health officer is satisfied that any such diseases listed on the certificate will not be harmful to the conservation and protection of fish in that province.[47] A "certificate" may be obtained from a fish health official (who is defined as "a person approved to inspect fish and fish sources for the purposes of these Regulations").[48] The FHPR apply to all species of Pacific salmon and Atlantic salmon. The diseases (or their causative agents) listed in the schedules are: VHS, IHN, IPN, whirling disease, ceratomyxosis, furunculosis, and enteric redmouth disease.

Stephen Stephen, director, Biotechnology and Aquatic Animal Health Science Branch, DFO, Ottawa, testified that the FHPR were "developed many years ago and to deal with the import of salmonids, any species in the family *Salmonidae*, so Arctic char, whitefish, trout, salmon, both Pacific and Atlantic," into Canada from international locations and between provinces within Canada.[49] In December 2011, Canada amended the FHPR to remove a duplication of regulatory authority between DFO and CFIA (under the *Health of Animals Regulations*, discussed above). Mr. Stephen said the definition of "import" under the FHPR has been amended to mean import "from one province to another instead of from outside the country into Canada."[50] He explained that, "with the world coming into more awareness of aquatic animal diseases in trade, it was seen as a real necessity for Canada to have a broader capacity to deal with diseases of finfish beyond just salmon."[51] Canada has developed that broader capacity under the lead of CFIA, focusing on international issues of safe trade and working under the auspices of the National Aquatic Animal Health Program (NAAHP), discussed below.[52]

As explained above, because CFIA takes the lead only on reportable aquatic diseases under the *Health of Animals Act* regime, DFO is responsible under its conservation mandate to deal with any fish diseases that arise in Fraser River sockeye that are not listed under the regulations as reportable or immediately notifiable. (See chapters 3, Legal framework, and 4, DFO overview, for further details on DFO's conservation mandate.)

National Code on Introductions and Transfers of Aquatic Organisms

An "introduction" of an aquatic organism is "the intentional or accidental transportation and release of the organism into an environment outside its present range (ICES 1988)."[53] A "transfer" is "the shipment of individuals of a species or population of an aquatic organism from one location and its release to another within its present (geographic) range (ICES 1988)."[54]

As of the Commission's hearings on aquaculture in August 2011, DFO's Introductions and Transfers Committee reviewed applications for fish transfers that are not addressed under conditions of licence. The committee reports its operations to the director general of the Aquaculture Management Directorate (AMD) at DFO.[55] Trevor Swerdfager, former director general, AMD, said that the system is national in structure, though there are nuances in different provinces.[56]

The committee's review of applications includes a risk assessment that considers ecological, disease, and genetic factors.[57] The committee may identify potential mitigation requirements (for example, egg disinfection, treatment of effluent, quarantine holding) in its recommendations, and these may form conditions of licence.[58]

Dr. Kyle Garver, research scientist (virology), DFO, testified that the Introductions and Transfers Committee oversees and monitors the movement of (cultured enhanced) fish between different watersheds to ensure diseases are not being spread from one to another.[59] Dr. Peter McKenzie, veterinarian and fish health manager for the salmon-farming company Mainstream Canada, testified that the introductions and transfer process has been in place for years, controls any introduction in British Columbia, and is a collaborative effort between the federal and provincial governments.[60]

National Aquatic Animal Health Program

CFIA and DFO co-deliver the NAAHP, which began in 2005. CFIA describes it as follows:

> The Canadian Food Inspection Agency's (CFIA) National Aquatic Animal Health Pro-

gram (NAAHP) is a science-based regulatory program. It addresses aquatic animal diseases of finfish, molluscs and crustaceans.

The program is consistent with international standards set by the World Organisation for Animal Health (OIE).

The program regulates aquatic animal health as per the *Health of Animals Act* and Regulations.

The NAAHP is co-delivered by the CFIA and Fisheries and Oceans Canada (DFO). The CFIA is the lead federal authority and is responsible for the administration and enforcement. DFO provides the laboratory and research expertise through the National Aquatic Animal Laboratory System.

The Program is being implemented using a phased approach. Mandatory disease notification comes into effect immediately upon publication of the regulations in Canada Gazette, Part II. One year following that date, the requirements for import permits will be brought into force. Movement controls within Canada will likely come into force two years later.[61]

During the ISAv hearings, Dr. Klotins described the NAAHP as a partnership of CFIA and DFO.[62] The partnership proceeds according to a memorandum of understanding, which describes the partners' roles:

> The NAAHP will be co-delivered with CFIA providing the overall program direction under the authority of the *Health of Animals Act* and the field operations capability for the aquaculture industry. DFO will perform the surveillance and monitoring activities for the wild stock, deliver and oversee the diagnostic and research and development support responsibilities.[63]

Dr. Klotins described the work of CFIA under NAAHP as being "to design and implement the National Aquatic Animal Health Program, and the program consists of import controls, disease controls within the country, expert health certification, and with support from risk assessment and surveillance."[64] Mr. Stephen described DFO's work under the program:

> DFO … has the responsibility under the program for the diagnostic research, the diagnostic testing, and providing scientific advice on diagnostic activities under the scope of the program. The program was funded in 2005 by the Federal Government and it was a partnership envisioned because of DFO's decade-old knowledge and experience in testing for aquatic animal diseases paired up with CFIA's regulatory authorities under the *Health of Animals Act* and *Regulations*. And our Moncton laboratory is one of three key laboratories doing the diagnostic work, and each laboratory is designated based on the type of diseases as a national reference laboratory.[65]

Mr. Stephen said the DFO laboratories within the national reference laboratory system are the Gulf Fisheries Centre (DFO Moncton), the Pacific Biological Station (PBS) in Nanaimo, the Freshwater Institute in Winnipeg, and the biocontainment laboratory in Charlottetown.[66] Dr. Wright said that these labs are called the National Aquatic Animal Health Laboratory System (NAAHLS), and they use harmonized testing platforms.[67]

Before NAAHLS staff may conduct diagnostic testing on behalf of CFIA, the president of CFIA must designate them as analysts under section 32 of the *Health of Animals Act* and subsection 13(3) of the *Canadian Food Inspection Agency Act*.[68] Under that same power of designation, CFIA may designate non-government laboratories to conduct diagnostic work for CFIA, provided they prove to CFIA that they use testing protocols validated according to the "Validation Pathway for NAAHLS Diagnostic Test Methods, Dossier Template."[69]

CFIA mandate and policies related to NAAHP

CFIA's mission is to safeguard "food, animals and plants, which enhance the health and well-being of Canada's people, environment and economy."[70] With respect to aquatic animals, Dr. Klotins testified that the mandate of CFIA is "actually to facilitate safe trade of aquatic animals. It's not to protect the interests, but it's to facilitate safe trade by working on negotiations for technical market access."[71] She used the example of ISAv to make her point:

> So if, let's say, we do find ISA[v] in B.C. and all of a sudden markets are closed, our role is then to try to renegotiate or negotiate market access to those countries. Now, what it will be is a matter of they'll let us know what the requirements are. We'll let them know what we can do and whether we can meet that market access. If we can't meet it, then there will be no trade basically.[72]

CFIA has developed a number of policies or plans under the NAAHP, some of which are still in draft form. In relation to mandatory reporting of diseases, CFIA has developed the Mandatory Notification and Suspect Phase Disease Response Policy for the National Aquatic Animal Health Program to describe the mandatory notification policy and to determine when to initiate the "suspect" phase of disease response (the phase that begins when CFIA is notified of a reportable aquatic animal disease[73]).[74] Figure 1.9.1 depicts the phases of disease response in relation to cultured animals.

Also in relation to cultured fish, CFIA has developed the Procedure for Receipt and Evaluation of Mandatory Notifications for the National Aquatic Animal Health Program that describes the "procedure for CFIA staff to follow when receiving and processing notifications concerning reportable, immediately notifiable, and emerging diseases."[75]

The (draft) Aquatic Animal Health Functional Plan (Functional Plan) "is intended for CFIA staff members who are responsible for responding to aquatic animal disease incidents."[76] The Functional Plan sets out the CFIA process for responding to emergencies, and in particular outlines the responses to be taken in the case of disease outbreak, detection, or suspicion in cultured or wild aquatic animals. Dr. Klotins explained that (as of December 2011) CFIA was also in the process of developing hazard-specific plans for reportable diseases.[77]

For wild fish, the Functional Plan sets out a flow chart showing the response process (see Figure 1.9.2). Both CFIA and DFO have roles in relation to wild aquatic animals. When CFIA initiates an investigation based on disease outbreak, detection, or suspicion, one of its primary concerns is chain of custody. Dr. Wright said that establishing a chain of custody of fish samples ensures that "CFIA knows where they came from, how they were collected, how they were preserved, how they were shipped, and when they were received in the lab, and that chain of custody goes all the way through every lab procedure that's done, all the way to the point where the report of analysis is issued."[78] Unless CFIA is notified sufficiently early, the agency will not be able to establish a chain of custody to confirm the presence of a disease.

Steps taken by CFIA and others to investigate reports of ISAv in wild Pacific salmon are discussed in the case study at the end of this chapter.

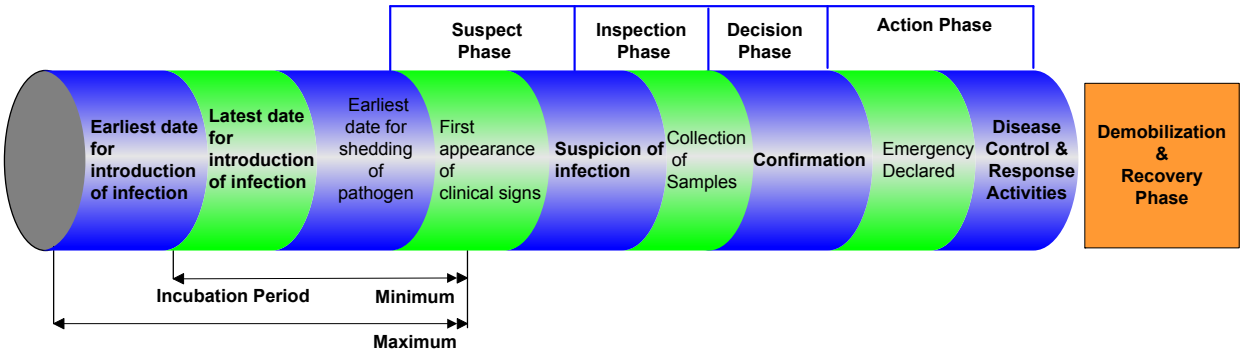

Figure 1.9.1 Aquatic animal health disease response phases for cultured fish

Source: Exhibit 2105, p. 157.

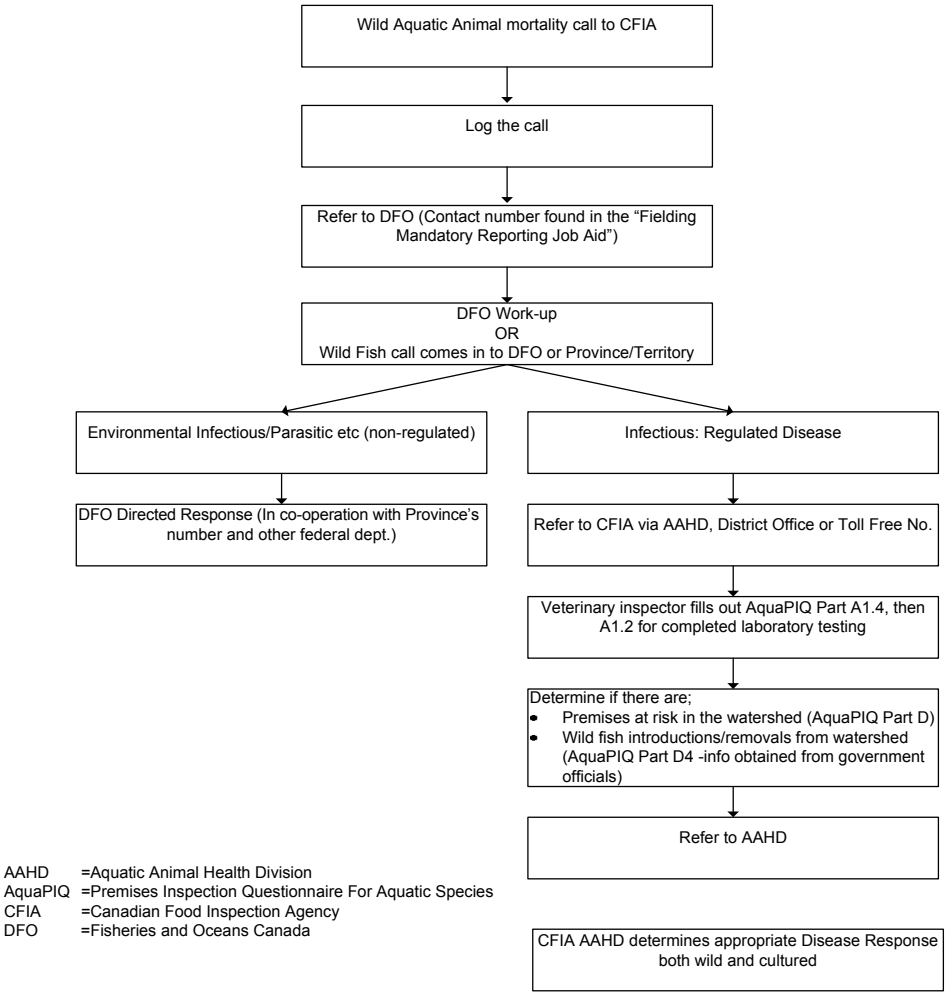

Figure 1.9.2 Flow diagram illustrating the disease-response process for wild aquatic animals

Source: Reproduced from Exhibit 2105, p. 193.

Fish health management in wild salmon

Dr. Garver told me, "It is very difficult to mitigate disease in wild populations … it is hard to eliminate [a] pathogen from a population. But you can track it." He said that sometimes diseases in wild populations can be confined to a certain watershed "by eliminating movement of fish from one watershed to another," though he gave no examples of how this could be accomplished or whether it was possible with a migrating species such as sockeye salmon.[79] In general, I heard little evidence on what could be done to manage fish health in Fraser River sockeye. Instead, management efforts are targeted at farmed salmon or hatchery salmon, as discussed in the sections below.

Similarly, little research has been done on fish health in wild fish stocks; most of the research is in captive stocks.[80] Dr. Kent testified that studies of infectious diseases, parasites, viruses, and bacteria at a population level in wild salmon have "been very minimal." Investigating disease and chronic infections at a population level requires repeated sampling from the same population, which poses a problem with salmon because they are difficult to track in the ocean. Also, many populations of salmon are protected, so there are a limited number of samples available.[81]

Dr. Kent identified another factor that makes it difficult to carry out fish health surveillance work: when a fish in the ocean dies, it disappears. Dead

wild fish drop to the bottom of the ocean, never to be seen again. Dr. Kent testified that, even if a devastating viral disease swept through a wild population killing large numbers of fish, scientists might not be able to detect it.[82]

Dr. Stewart Johnson, head, Aquatic Animal Health Section, Science, DFO Pacific Region (see description below), testified that it is difficult to relate laboratory studies to wild populations. For example, most studies focus on a single pathogen whereas most wild fish carry multiple pathogens.[83] Dr. Johnson said, "I cannot think of any papers off the top of my head where they've actually studied multiple infections in fish."[84] Further, it is "extremely difficult" to maintain sockeye in a laboratory.[85] Dr. Johnson did say that much can be learned generally about sockeye stress responses from research done on other salmonid species, but that "we would need to do these particular studies on sockeye salmon to actually set the limits of their tolerance."[86]

Dr. Laura Richards, regional director, Science, DFO Pacific Region, testified that the department is aware of the "gap" in research with respect to wild fish health and is looking for opportunities to address this gap.[87] She said that DFO's science research priorities are directed by its clients:

> I'd have to say that our priorities for research are very much weighted by the need for us to provide advice. So in the context of working on fish disease, we are working together, and one of our major clients in terms of the provision of science advice is the Canadian Food Inspection Agency, who are the leaders in our National Aquatic Animal Health Program. And so we, you know, given that obviously we have limited resources to spend on things like research, we do look for direction and we work with them to identify priorities.
>
> We also work with our clients or others in the Department, including those in Fisheries Management and those responsible for Aquaculture Management to help us identify the priorities.[88]

Dr. Richards did not agree with the proposition that there is a "serious" deficiency in fish health information for wild fish, but she said, "[T]here is a lack of evidence on this and a large number of other topics." By way of explanation, she said that DFO Science attempts to do research with respect to the questions of the day; now that disease questions have been raised, DFO Science is trying to address them.[89] Dr. Kent said that during his 11 years at DFO there was a "frustration" among scientists "in that they'll be working on a project and it does not come to completion or significant progress because of pressure from political reasons" and that resources are redirected to the "disease of the day that has become popularized in the media."[90] He said that is why work was not continued on *Parvicapsula*,[91] a disease he rated as high risk to Fraser River sockeye.[92] That work was supplanted by work on sea lice.

Dr. Richards said it was not the case that DFO has done no studies in the last decade related to disease transmission from salmon farms to wild fish, but she had difficulty identifying anything other than sea lice work of recent years and work related to water circulation and pathogen dispersion started in 2010 or 2011 by Dr. Garver.[93] When faced with the proposition that the only reason DFO has not seen evidence of disease transmission from farmed to wild salmon is that DFO has never studied this topic, Dr. Richards said, "I don't think that's a fair statement." Yet she went on to say, "[W]e would have done the studies if we had thought that we had seen any evidence that [disease transfer to wild stocks] was a possibility."[94]

Dr. Richards did say that survey and monitoring work on wild fish "is important and is part of the function that government would carry out."[95] To that end, DFO began assessing the health of Fraser River sockeye in 2010, and in the fall of 2011, CFIA began to develop a surveillance plan for monitoring wild Pacific salmon for the reportable diseases (or their disease agents) ISA, IHN, and IPN. These initiatives are discussed below.

Roles and responsibilities

Both DFO and CFIA have roles and responsibilities in relation to the health of wild fish. As discussed above, under the NAAHP and depicted in Figure 1.9.2, once a regulated (or reportable) disease is suspected in wild fish, CFIA assumes responsibility for conducting an investigation to confirm whether that disease exists. It determines an appropriate disease response in order

to satisfy the concerns of trade partners who purchase wild Canadian seafood. (See also ISAv case study, below.)

Also, as discussed above, DFO has a role under the NAAHP to perform surveillance and monitoring activities and diagnostic research and development.[96] During the ISAv hearings, Nellie Gagné, molecular biology scientist and laboratory supervisor, Molecular Biology Unit, DFO Moncton, testified about how a DFO diagnostic laboratory determines what viruses to test for in wild fish:

> There's a list of viruses or diseases that are regulated in the sense that we look for them because they are of a concern for import and export, for example, so the decisions for the virus tests that we have to do, doesn't rely solely on my shoulders. It's based on, like I said, import / export, presence of viruses or absence of viruses in other regions, zones or other countries, so it's a more complex question to answer that just there.[97]

In addition, as discussed above, DFO's conservation mandate includes addressing those diseases that do not fall within the NAAHP regulatory program. This would include diseases that are not reportable, or research into the detection of novel or emerging diseases or those not previously known to exist in Fraser River sockeye.

DFO Pacific Region's Science Branch contains an Aquatic Animal Health Section (sometimes called the Fish Health Group) under the Salmon and Freshwater Ecosystems Division.[98] Dr. Johnson heads the Aquatic Animal Health Section. He reports to the division manager, Mark Saunders, who reports to the Pacific regional director of Science, Dr. Richards. The Aquatic Animal Health Section has approximately 25 staff (research scientists, aquatic science biologists and technicians, and one veterinarian).[99] Dr. Johnson testified that the Fish Health Group's main role is to "provide science-based advice for managers. And so we have to be somewhat responsible to questions which are posed to managers, and that can have an impact on, you know, longer term research programs."[100] In response to a question about whether scientists have any ability to decide for themselves what to work on, Dr. Johnson said the following:

> I think that both the senior managers, as well as fish managers, do listen to the Science staff when they do propose new areas of up-and-coming importance for disease studies. And most Science staff have other projects which may or may not be funded by DFO which is usually more along the lines of things which they are personally interested in, as well. So the overall – although the overall goal of Science is to provide science-based advice to senior management, there is lots of opportunity to work on other things and lots of opportunity to obtain funding from other groups and other agencies such as NSERC [National Sciences and Engineering Research Council] to do other projects.[101]

The Salmon and Freshwater Ecosystems Division also includes a Molecular Genetics Section (sometimes called Salmon Genetics) headed by Dr. Kristina Miller. This section consists of approximately 30 staff (research scientists, aquatic science biologists, and technicians).[102] Dr. Miller has used molecular genetics techniques to study disease in salmon, as described below and in Volume 2 of this Report.

Sockeye health assessment in the Strait of Georgia

After the poor return of Fraser River sockeye in 2009, DFO developed a three-year program to survey sockeye salmon health. Dr. Johnson described the program as follows:

> We basically came up with a program to approach sockeye salmon health more from an overall health perspective rather than simply doing more surveys for disease. So the goal of this program is to integrate with our fisheries biologists, fisheries ecologists, the disease staff, Dr. Miller's group [Molecular Genetics Section], to come up with an overall assessment of health status of Fraser River sockeye starting in the lake, throughout their period of migration through the Strait of Georgia. So we received three years of funding. The first field season was in 2010 and that year we also received some support [from] Marine Harvest [Canada, a salmon-farming company operating in the province] for some of

> the ship time, and some work from the Salmon Foundation, Dr. Riddell's group.
>
> So in each of these years, we have done large-scale surveys of sockeye salmon throughout the Strait of Georgia at up to 70 to 80 different sites ranging from the mouth of the Fraser River right to through Johnstone Strait. We've also collected fish in 2010 at the mouth of Chilko Lake where we take advantage of the fact that there's a counting fence that we can actually obtain samples. And this year in 2011 we also added sampling of fish in the lower river, just immediately before they leave the strait.
>
> And on these fish they're receiving a complete health assessment. [In] 2011 we've included things such as water chemistry … [and] toxic phytoplankton sampling with associated surveys … Dr. Garver is doing the virology work and we're using recognized and validated diagnostic tests, as well as a lot of histopathology[.][103]

The sockeye health assessment occurs under a broader salmon survey, funded under the Program for Aquaculture Regulatory Research (PARR), which is described in Chapter 8, Salmon farm management. The goals of the survey are as follows:

> To conduct a 3 year program to address the following questions for wild juvenile salmon of Fraser River origin:
>
> - Which species of sea lice are found on juvenile salmonids and how abundant are they?
> - When and where do juvenile salmon become infected with sea lice and how does the level of infection change over time?
> - What role/s if any do farmed salmon play in the infection of juvenile wild salmon with sea lice?
> - What role/s do wild host (salmonid and non-salmonid species) play in the infection of juvenile wild salmonids?[104]

The work is being conducted in partnership with Marine Harvest Canada and the Pacific Salmon Foundation.[105] In 2010, the program sampled fish in the Strait of Georgia and Johnstone Strait. Approximately 1,000 sockeye were collected in 2010. Those samples were processed for histology, virology (for IHN, VHS, and ISA), and bacteriology (for bacterial kidney disease [BKD]), as well as sea lice and molecular diagnostics.[106] The results of the testing with respect to ISAv are discussed in the case study at the end of this chapter.

Draft CFIA surveillance plan for ISA, IHN, and IPN viruses

In the fall of 2011, CFIA developed a draft plan called "Surveillance Plan for ISAV, IPNV, and IHNV in Anadromous Salmonids in British Columbia" (draft surveillance plan).[107] Under the *Health of Animals Act* and the NAAHP, "[t]here [have] always been plans to put in surveillance programs for all … the commodities," Dr. Klotins noted.[108] She explained that, while these plans were in the works, the time frame for developing a surveillance program for the health of Pacific salmon was moved up in the fall of 2011 in response to presumptive positive test results for ISAv in Pacific salmon from non-NAAHLS laboratories.[109] She said CFIA prepared the draft surveillance plan in part to satisfy Canada's trading partners – to provide them with information about the "health status of finfish in B.C." and to demonstrate to them that BC fish are free from disease.[110] In explaining why a health surveillance program for wild fish was not in place sooner, Dr. Klotins said this:

> It hadn't been done up until this point because we needed to secure the resourcing to move ahead with the surveillance program, and in addition we had to work with industry to find out basically what was being done on the cultured side, identify the gaps, and then identify what we needed to do on the wild side. It was already in progress. It's just this event happened to push things forward because our countries [that we trade with] are starting to ask for our claims of disease freedom, and our supporting information for those claims.[111]

At the time of the ISAv hearings in December 2011, CFIA had put the draft surveillance plan through internal review and had received comments on it from DFO. CFIA intended to start a broader consultation on the draft plan in January 2012 and begin implementing the plan "towards the late Spring in 2012."[112] Dr. Klotins expected the

plan to undergo several more revisions before it was ready to implement.[113]

The draft surveillance plan's goal is "to effectively determine the absence or presence of three diseases of significance in both cultured and wild marine anadromous fish populations off the west coast of Canada," the three diseases being ISA, IPN, and IHN, all of which are reportable diseases.[114] CFIA intends the evidence garnered through surveillance to "[p]rovide support for the protection of aquatic resources," "[s]upport international trade negotiations," and "[s]upport the risk-based compartmentalization program."[115]

A briefing note to the minister of agriculture and agri-food describes the surveillance plan in part as follows:

> Surveillance for cultured and wild species will be conducted differently and evaluated separately, given that industry has already put in place a surveillance program for cultured species. The CFIA's preliminary review of this industry-led testing program shows that there has been a significant amount of testing for viral disease, including ISAV, in cultured fish over the last 10 years. It is proposed that the CFIA play an oversight role for the surveillance of cultured species, given the existing surveillance industry program.
>
> For wild species, more work will be required. Based on the recommendation of the draft surveillance plan, about 3850 fish samples per year for the two first consecutive years would be collected. After this initial effort, it is recommended to continue collecting but at a reduced level. To be noted, this is the first instance of CFIA-led active surveillance effort for finfish in B.C. since the creation of the National Aquatic Animal Health Program. However, DFO has undertaken some surveillance initiatives in wild fish in the past.
>
> The total cost to CFIA for this work is about $350,000 over two years, which covers the operational requirements, except for the testing, which is the responsibility of DFO's NAAHLS. After this period, there will be significantly lower ongoing costs that will need to be determined based upon the implementation of the surveillance plan and the findings. These costs will be covered internally by reallocation. DFO will be responsible to cover the costs related to the testing under the surveillance plan.[116]

Other exploratory research on Fraser River sockeye health

Dr. Miller and the Molecular Genetics Section at DFO have used molecular techniques and functional genomics to study fish diseases. Her approach involves looking at the pathogen loads in fish and then comparing them to the degree of host response at a genetic level. Her method provides a way to "rank which, among the various pathogens, [that salmon] carry might be causing harm."[117] It is a novel approach. The microarray data that she has for over 3,000 fish enable her to do retrospective genomics. When new data (such as discovery of a new virus) become available for a fish sample, they can be compared to the microarray data already on file for that fish sample.[118] Dr. Miller testified that she believes "we can add a layer to our knowledge of fish disease and wild fish by using the genomic, and by using the microarray data that we already have."[119]

Dr. Miller testified twice before me, during the disease hearings in August 2011 and during the ISAv hearings in December 2011. Both times, she indicated there is resistance from the Aquatic Animal Health Section to her genomics work. During the disease hearings she commented about working with her colleagues in the Fish Health Group in relation to the mortality-related signature (MRS) she has identified (see discussion of the MRS in Volume 2). She said that the Fish Health Group was "not comfortable in continuing on or paying a lot of attention to this until we actually had a virus … [T]here was a lot of reluctance to take any action based on a genomic signature, because people don't understand what is a genomic signature, and how well can you actually predict a mechanism from one."[120] Dr. Miller said that in July 2011, the Fish Health Group was uncomfortable approaching the salmon-farming industry for samples to test for the parvovirus which had, by that time, been identified in many of the MRS-positive fish.[121] However, in July 2011, Andrew Thomson, director, Aquaculture Management Directorate, Pacific Region, approached the farms, and they agreed to have their fish tested.[122] In December 2011, Dr. Miller testified that, shortly after she testified in August, she and Mary Ellen Walling, executive director of the B.C. Salmon Farmers Association, disagreed on when

and how Atlantic salmon would be tested, with the result being that Dr. Miller no longer had an agreement with the salmon-farming industry to obtain Atlantic salmon samples to test for parvovirus.[123]

During the ISAv hearings, Dr. Miller remarked that there is a difference in "philosophical approach" between her laboratory and the Fish Health Group: "Their approach is to make sure [a disease is] not there. My approach is to ask if there's any way that it is there."[124] She further testified that, in her view, research on disease in wild BC salmon needs to go further than the viruses currently known to exist, and needs to be explored using alternative methods.

She said that she is working in an area of fish diseases that can generate a lot of data relatively quickly and in a novel way. It can take managers by surprise:

> We can run 30 pathogens in 200 fish in a day, quantitatively. And so there's a lot of power in the level of information one can get very quickly, and I'm learning that for managers, having new information all the time is not necessarily a good thing because they don't have time to adapt to that.[125]

During the ISAv hearings, Dr. Miller reported that she had recently (as of December 2011) identified the piscine reovirus, the virus that is thought to cause heart and skeletal muscle inflammation (HSMI), in wild migrating sockeye salmon.* She had also identified it in farmed chinook salmon.[126] Dr. Are Nylund, a professor in fish health diseases from the University of Bergen, Norway, testified that HSMI is a significant disease of concern for fish farms in Norway, causing significant losses and morbidity and reducing the quality of the fish.[127] Although Dr. Miller noted that her finding was still "research in progress,"[128] it serves to emphasize her point that DFO researchers do not know the scope of what diseases and pathogens are carried by wild salmon like sockeye. They need to be open to new techniques that can explore this question and not place all their focus on regulated diseases.

Fish health management at salmon farms

As discussed further in Volume 2 of this Report, Dr. Kent testified about how salmon farms could impact wild fish such as Fraser River sockeye by introducing new exotic diseases to wild fish or by making endemic diseases worse by amplifying the pathogens.[129] The densities of fish held in net pens "would play a [negative] role in directly transmitted diseases," although other factors about salmon farms are more positive, such as the opportunity to vaccinate and remove sick and dead fish from the net pens.[130] Dr. Kent said that, during a disease outbreak, it would be reasonable to assume that the numbers of pathogens in and around salmon farm net pens are increased. However, whether this would increase exposure and infection in wild fish is still "an important question that has to be answered for most diseases."[131]

All the researchers of Technical Report 5, Salmon Farms (Dr. Lawrence Dill, Dr. Donald Noakes, Dr. Brendan Connors, and Dr. Josh Korman), agreed that, if fish farms are point sources of diseases, then pathogens should be discoverable on farms, and therefore record keeping and fish health management procedures are the key to guard against transferring pathogens to wild fish.[132] All four researchers also agreed that "if managed properly" aquaculture and wild fish can coexist.[133] However, I am not sure that the four had a common understanding of what constitutes "proper management."

In addition, each witness who testified on a panel addressing fish health management issues during the aquaculture hearings in August 2011 – Dr. Gary Marty, fish pathologist at BC's Animal Health Centre; Dr. Mark Sheppard, lead veterinarian in DFO's Aquaculture Environmental Operations (AEO); Dr. McKenzie; and Mr. Swerdfager – agreed that the risk posed to wild salmon from disease at salmon farms is manageable with "appropriate care and attention."[134] Again, I am not sure that the four had a common understanding of what constitutes "appropriate care and attention."

* On April 23, 2012, I received an application from one participant in this Inquiry, the Aquaculture Coalition, to reopen hearings to receive evidence on the epidemiology and impacts of piscine reovirus and HSMI in salmon in British Columbia. I dismissed that application in a ruling released May 16, 2012.

No regulation dictates how much or how little disease is allowed in a population of farmed fish,[135] and conditions of licence do not prohibit the presence of pathogens on salmon farms.[136] Further, no special rules or regulations with respect to fish health apply to salmon farms on the migratory pathway of wild salmon.[137]

Mr. Gavin Last, assistant director of the province's Policy and Industry Competitiveness Branch (responsible for aquaculture program administration), confirmed there has never been a year when there were not disease and pathogens present on BC fish farms. As under the current federal regulations, he was not aware of anything in the previous provincial licensing regime that could prevent diseases from occurring on fish farms.[138]

The Wild Salmon Policy recognizes that salmon farms pose risks to wild salmon, including the chance of disease and parasite transfer. It says these risks are addressed through Fish Health Management Plans (FHMPs, discussed below), improved cage structures, and proper farm siting.[139]

Federal conditions of licence and approach to fish health on salmon farms

The 2010 federal conditions of licence for salmon farms set out the measures, notices, records, and reports that licence holders must employ related to fish health at sections 5–9, and 14, and appendices IV, V, VI, VII, and VIII.[140]

DFO has developed a draft "Approach to Fish Health"[141] to guide the Fish Health Management Program for salmon farms. It does not "put forward a fish health approach for all organisms in the sea."[142] DFO's draft "Approach to Fish Health" sets out its approach to managing fish health at salmon farm facilities as follows:

- Keeping fish healthy by minimizing disease and spread of disease within and between sites through adequate hygiene and disinfection procedures, biosecurity measures, minimal fish handling, adequate escape prevention measures, use of vaccines, disease screening of broodstock and cultured fish prior to transport / harvest, and treatment of pests and pathogens as directed by a licensed aquatic animal health veterinarian.
- Monitoring fish health by routine visual assessments to observe unusual behaviour, lesions, or other signs of disease, and routine sampling and examination "upon the instructions of the operator or Veterinarian / fish heath professional or at the direction of Fish Health Management."
- Responding appropriately to different types of fish health events (FHEs)*:
  - Non-disease-related mortality events should result in implementation of a response plan involving mitigation measures of physical factors.
  - A disease requiring treatment – but which does not pose an emergency or serious concern of outbreak – requires a fish health report.
  - An endemic disease of serious concern for a potential outbreak must be immediately reported as a fish health emergency.
  - A non-endemic disease of serious concern for a potential outbreak must immediately be reported to CFIA and DFO.
- Recording and reporting fish health data. Regular record keeping at a farm should include "chronological records of disease history and management, patterns of morbidity and mortality, actions taken to prevent, control and treat disease, movements of fish within facility, and health risk factors specific to the site or the affected group of fish." Licence holders must report fish health data to DFO on a regular basis as set out in conditions of licence, as well as making reports on an emergency basis of outbreaks of a significant disease.
- Developing and using Fish Health Management Plans that identify the types of actions and procedures that licence holders must use at a facility, as set out in Appendix V of the conditions of licence.[143]

* An FHE "is defined as an active disease occurrence or a suspected infectious event on a farm that triggers: 1) veterinary involvement and 2) an action, such as: lab diagnosis, recommendations / report, husbandry change, prescription medication, further investigation, etc. where such action is intended to reduce or mitigate risk associated with that event" (Exhibit 1560, p. 5).

Roles and responsibilities

Although DFO has the main regulatory role for salmon farms in British Columbia, it does not have the only role in relation to fish health. DFO's Aquaculture Environmental Operations staff conduct audits and monitoring of fish health data from salmon farms; the salmon-farming companies all employ veterinarians to look after the health care of their fish; the province has a diagnostic laboratory which both industry and DFO's fish health audit program hire to perform diagnostic tests on cultured fish; and CFIA investigates notifications of reportable and immediately notifiable diseases. These various roles are discussed below.

DFO's AEO biologists and veterinarians

AEO staff include biologists and veterinarians who assess aquaculture projects, conduct audits, and monitor fish health.[144] A Fish Health Unit, responsible for sea lice and fish health monitoring, is located within AEO and headed by the lead veterinarian, Dr. Sheppard.[145] Dr. Sheppard came to DFO after three years as the aquatic animal health veterinarian with the province, overseeing the former provincial Fish Health Program.[146] He testified that his work with the provincial program has largely been carried over into his work with DFO.[147]

DFO's Fish Health Surveillance Program for salmon farms, conducted by AEO staff, is discussed further below.

Salmon farm company veterinarians

The role of a fish health veterinarian is to work with the farmers to ensure their stocks are healthy and that appropriate husbandry is being provided for the fish, and to examine any ill fish to determine the appropriate action.[148] Dr. McKenzie, veterinarian and fish health manager for Mainstream Canada,[149] explained his function as a company veterinarian. He described the role of a fish farm veterinarian as being quite broad, including "everything from egg to plate, as we say." He said he manages all areas of fish health within the company, which includes the company's genetics program, monitoring brood fish, maintaining eggs and juvenile fish in top physical health, and monitoring, controlling, and managing disease throughout the production cycle in both fresh- and saltwater.[150]

Dr. McKenzie said that company veterinarians try to manage salmon farms on an area basis: "[W]e always have to manage disease in a very holistic perspective," and must be "conscious of diseases that are found in the wild stocks." He said his team looks at interactions in the environment, migratory pathways, and any changes in the environment which may affect the company's production strategies. The team is in close communication with other farms in the area, he said, which allows it to better understand any changes happening in the environment.[151] Further, Dr. McKenzie said he relies on others, such as Dr. Marty, to provide information about the fish on his company's farms to add to his own clinical on-site experience.[152]

The veterinary profession in British Columbia is governed by a code of ethics and conduct.[153] Sometimes salmon farm veterinarians are faced with treating farmed fish in situations that are not medically necessary. Dr. McKenzie testified that, in his view, some of the management responses imposed by government are not needed for the health of fish on the farm. Rather, they are intended to serve the interest of healthy wild stocks. He described what he called a "conflict for me," when treatment for sea lice is administered to farmed fish as a precaution for wild fish, even when "lice levels are incredibly low on farms," and the treatment is not medically necessary. He also spoke about the IHN outbreak on salmon farms in 2003, during which he recommended culling farmed salmon because of a risk to wild salmon. The cull was "very contrary to the business model of the company," given that mortalities on the farm were not that high, but his advice was accepted by the company.[154]

Provincial diagnostic laboratory

The Animal Health Centre (BC Lab) in Abbotsford is a fee-for-service provincial veterinarian diagnostic laboratory for all species of animals. Dr. Marty said he is "specifically charged to work with fish" and is responsible for any "final case send off" on any fish analyzed by the laboratory.[155] He explained that he has the ability to provide a diagnosis and prepare a report based on observing tissue under a microscope, whereas Dr. Sheppard and Dr. McKenzie are

trained to read his report and interpret the results along with their clinical findings.[156]

The BC Lab receives samples of farmed fish from official government audit or monitoring programs (see discussion below) and directly from fish farmers, either when tests are requested by veterinarians because of specific health concerns, or when a farm does a health screen of fish prior to transferring them.[157] Technicians conduct bacteriology and PCR (polymerase chain reaction) tests as requested, and Dr. Marty himself does the histopathology (the study of disease at the cellular level). Dr. Marty brings "all these different diagnostic modalities" together in a single case report, which includes background information, and will often provide a diagnosis. These reports go either to the veterinarian in the field (such as Dr. McKenzie) or to the regulatory veterinarian (Dr. Sheppard).[158] These veterinarians use Dr. Marty's results to assess whether diseases exist in the field.[159]

Dr. Marty testified that part of his role as a pathologist is to provide information to his clients. As an example of this, he explained that, given the public interest and concern about the potential for ISA to come into British Columbia, in cases where he sees symptoms that have been associated with ISA infection, he will include a standard comment, which says "sinusoidal congestion ... is a classic lesion associated with ISAV." He notes that he follows this with a clause "'but ISAV has not been' – 'never been identified in British Columbia.'" He said this is simply a statement of fact to provide clients with information.[160]

Canadian Food Inspection Agency

As described above, CFIA becomes involved in fish health management issues at a salmon farm if there is an outbreak, detection, or suspicion of a reportable disease, such as ISA or IHN. When a disease is in the "suspect phase" depicted in Figure 1.9.1 (above), CFIA inspectors will determine whether inspection of the premises is necessary. In the inspection phase, CFIA inspectors will attempt to determine the health status of the premises; implement any movement controls or make quarantine orders; send samples of fish to laboratories for diagnostic testing; complete a CFIA report called an AquaPiQ; and discuss the expected response and timelines with the salmon farm operator. During the "decision phase," CFIA will consider whether to implement emergency response measures. Then, in the "action phase," CFIA will implement any emergency responses. Emergency responses might include biosecurity, movement control, evaluating the market value of the animals in question, destroying infected animals, disposing of carcasses, cleaning and disinfection, vaccination or treatment of animals, epidemiology and tracing, or surveillance and diagnostics.[161]

Fish Health Management Plans

Fish Health Management Plans set out processes for managing diseases and pathogens on salmon farms, but they do not prohibit diseases.[162] Susan Farlinger, regional director general, DFO Pacific Region, testified that despite FHMPs, diseases still occur in the salmon farms.[163] FHMPs "set out a strategy or application to deal with fish health problems when they arise in order to control or eradicate them."[164] Ms. Farlinger said the FHMPs for aquaculture finfish focus on three things: "human health and health of the fish that are growing in the pen and, thirdly, the path of the environment in which they operate."[165] In contrast, she said FHMPs for enhancement facilities (discussed below) focus less on human health; "the focus is more on the impact, on potential impact on wild stocks, either genetically or from a biodiversity perspective."[166]

In 2003, FHMPs became a condition of licence under the provincial regulatory regime for aquaculture.[167] At the time of the hearings on salmon farms in August and September 2011, Mr. Swerdfager told me that DFO also intends FHMPs to become a condition of federal salmon farm licences, beginning in December 2011. He said FHMPs were not made a condition of licence during the first year of the federal regulatory program because, in December 2010, the templates for the federal FHMP were not complete. He said part of Dr. Sheppard's work is to design the structure and content of the required FHMPs.[168]

Dr. Sheppard testified that FHMPs can be broken down into two components: fundamental guiding principles and standard operating procedures. An example of a principle might be "collection of your carcasses on a regular and routine basis." The standard operating procedure for how that is done

might vary from site to site within a company, and those procedures could be reviewed and revised by the company on a regular basis. The conditions of licence require salmon farmers to submit any revisions to the standard operating procedures to DFO annually. Although companies may revise their standard operating procedures, they are not able to change the fundamental principles of the FHMP.[169] As of August 2011, Dr. Sheppard was in the process of updating the required elements and templates used under the prior provincial regime,[170] after which companies will have to update their previous FHMPs to comply with the new federal templates.

Providing an industry perspective, Dr. McKenzie testified that the FHMP is "sort of the Bible for our production system" in that it dictates "how we do business to ensure that our fish are kept in optimum fish health." He said it is his job as a company veterinarian to ensure that the FHMP is accurate, up to date with evolving science and emerging concerns, and fully implemented.[171] His company uses its FHMP as a "guidance document" for his team's management of day-to-day activities.[172]

Fish health monitoring

In chapters 7, Enforcement, and 8, Salmon farm management, I discussed monitoring, compliance, and enforcement in relation to salmon farms. In this section, I discuss monitoring and compliance activities that relate specifically to fish health issues. Since the federal program is premised on the previous provincial program, I begin with a discussion of the latter. Under both the previous provincial and the current federal program, BC coastal waters have been divided for the purposes of monitoring and reporting into "fish health zones" and "sub-zones" that are "loosely based on watersheds" and "follow natural geographical divisions of the aquaculture industry."[173] Figure 1.9.3 depicts these fish health management zones.

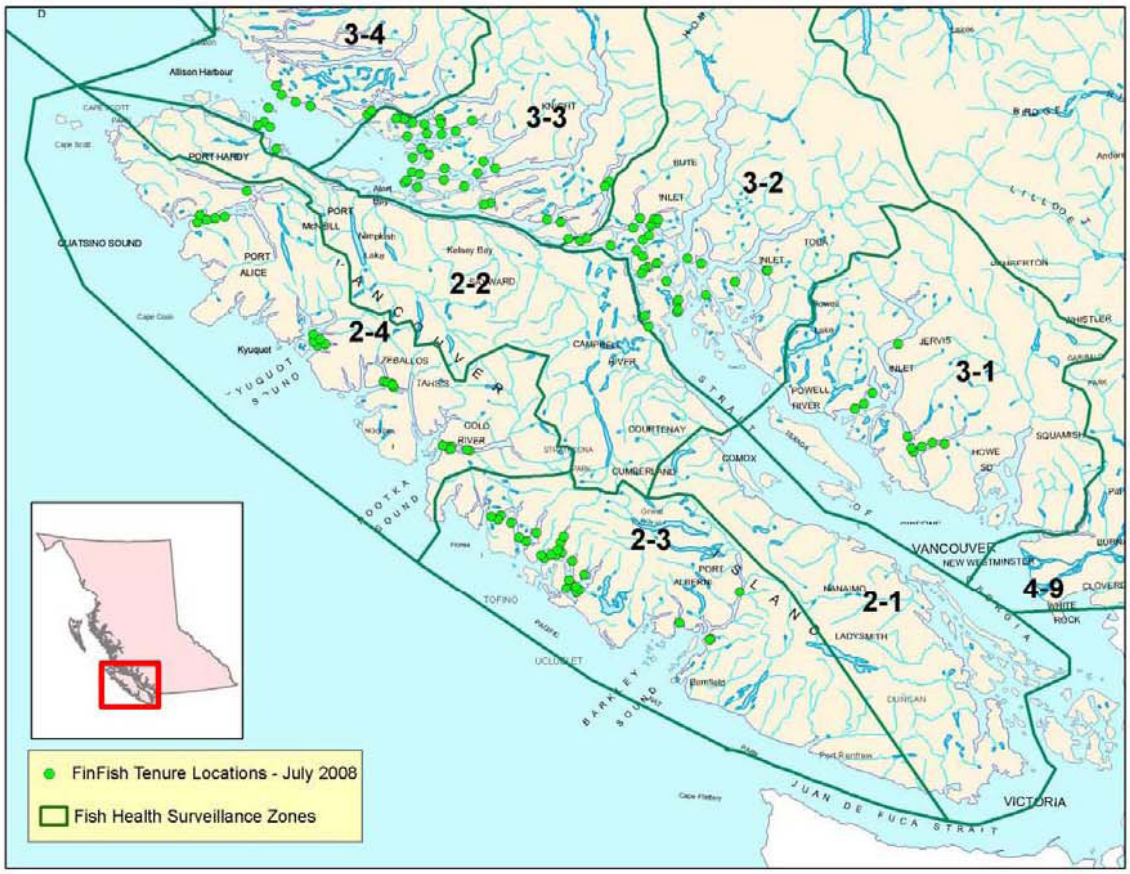

Figure 1.9.3 Fish health management zones

Source: Exhibit 1594, Appendix VI, p. 31.

Previous provincial fish health audit and surveillance program

The province implemented a salmon health management program in the early 2000s. It comprised "on-farm health management plans [that is, the FHMPs], mandatory monitoring and reporting of disease events, and a BC MAL [BC Ministry of Agriculture and Lands*] audit of industry-reported information."[174]

On-site monitoring and reporting was a requirement of FHMPs under the provincial regime.[175] All commercial salmon aquaculture facilities, in both fresh and saltwater, reported "site-specific information" to the industry database of the B.C. Salmon Farmers Association (BCSFA) on a monthly basis, including all mortality, causes of mortality, and FHEs.[176] The BCSFA then submitted quarterly reports of these data to BCMAL.

BCMAL posted the quarterly reports of fish health data as well as its annual Fish Health Reports on the provincial Animal Health Branch's website. BCMAL also required fish farms to conduct sea lice assessments on active Atlantic salmon farms "on a monthly basis and report the monthly data (in an aggregated form) from each sub-zone."[177]

At the request of BCMAL, in 2006, the Centre for Coastal Health, a private non-profit research organization, conducted a review of the BC Fish Health Audit and Surveillance Program (FHASP).[178] The review praised the program:

> The data collected as part of the BC FHASP exceed international standards to demonstrate freedom of disease and the level of fish health monitoring in BC is more comprehensive than in other parts of Canada and other salmon producing regions of the world. Maintenance of the current program, with minor adjustments, will go a long way towards maintaining Canada's international reputation for disease freedom and control.[179]

Dr. Craig Stephen, director of the Centre for Coastal Health and professor in the Faculty of Veterinary Medicine, University of Calgary, testified that the program covered a "significant number of animals. We look at some of our ongoing screening for endemic problems or food safety issues that might be done federally[;] this is a larger sample size than you'll see in a lot of other ongoing monitoring programs."[180]

During the transition from provincial to federal regulation, there was a period of approximately one year when the provincial government had stopped auditing self-reported fish health data and the DFO's licences and program had not yet come into effect. During this period, the Centre for Aquatic Health Sciences, a non-profit society based in Campbell River, conducted audits of the fish farms and posted this information on its website.[181]

Federal fish health surveillance program for salmon farms

As described in Chapter 8, Salmon farm management, the federal monitoring regime for salmon farms is based on industry self-reporting and government audits. The self-reported information is set out in Chapter 8; the audit and surveillance function related to fish health is described here.

Dr. Sheppard testified that, at the beginning of each calendar quarter, 30 farms are selected for audit. He said DFO's goal is to visit active farms 150 to 160 times each year: 120 farms for a fish health audit and surveillance, and about 40 for a sea lice audit.[182] Audits include collection of samples for diagnostic work.

AEO staff use a standard checklist for their audits: the DFO health management and mortality management plan inspection.[183] They use the checklist to ask farm managers a series of questions, look through records, and conduct a walkabout of the farm.[184] Dr. Sheppard said that DFO's fish health technicians also have "several other field sheets" on which "we document much of the same information which comes back with the actual fish tissues and is incorporated into the fish health database." He said that is the information that is largely used "in conjunction with all other bits of evidence from the pathologist and the laboratory results to help make our [farm level] diagnosis."[185] (See the discussion of diagnoses below.)

* Although BCMAL is no longer a current ministry, I use this acronym for consistency with documents and testimonial evidence. See discussion of BC ministries in Chapter 8, Salmon farm management.

Dr. Sheppard testified that the "Audit and Surveillance Program is very precautionary in following the requirements and expectations of the international community, the World Organisation for Animal Health, the OIE."[186]

Dr. Marty testified about the testing performed on audit fish at the BC Lab. He said that all fish collected by the audit staff are tested, but "sometimes we'll pool fish up to five fish per pool, for the test, and that's an international standard." Dr. Marty said he tests for the endemic diseases VHS and IHN, and the exotic diseases IPN and ISA. He also tests for *Piscirickettsia salmonis* bacteria, which is sometimes found in fish in British Columbia.[187]

Dr. Marty said the number of fish required for testing depends on the goal for the study. For example, he said, to certify to OIE standards that a specific lot of fish is disease-free:

> [W]e always ran 150 … The audit program is quite different … the goal of that program is to audit the fish health events that are reported by industry. So we are not attempting to certify any individual farm free from disease.
> …
> [W]e get about 150 fish a quarter[;] our epidemiologists tell us that we can actually add those up, and because it's a randomized sample, we're sampling fish that are the most likely to be diseased, so at the end of the quarter we have 150 fish, [and] if they are all free of, say, ISA, we can then state with a level of confidence that we have 95 percent confidence that the prevalence of ISAV in our population, our British Columbia fish, is less than two percent.[188]

Disease diagnoses on fish farms

Disease diagnoses can be made at the level of an individual fish (such as what Dr. Marty does when he makes a diagnosis based on laboratory reports and histology of specific fish), or a farm level. Dr. McKenzie testified to farm-level diagnoses made by a company veterinarian. He said that every time a veterinarian investigates a problem, he or she looks at the history of conditions that might have created a probability of disease, the behaviour of the fish and any changes in behaviour or in mortality, the appearance of the fish themselves including necropsies,* and any laboratory information. Then, the veterinarian makes a "differential diagnosis"; that is, he or she uses the information gathered to knock unlikely diagnoses off the list. Dr. McKenzie stressed that "[i]t's not a single test" informing a diagnosis.[189]

Dr. Sheppard described the process for making a "farm level diagnosis" as a government regulator:

> We need to compile all of the information collected not only from the farm, the interviews with the staff, the information on the field sheets, all these different tools we use in terms of, if you'll allow me, evidence, right through to what Dr. Marty will present as his diagnosis on a cellular level and a tissue level and an individual fish level, we use all that as tools and we compile all that in an epidemiological approach to look at all the factors to determine not what is the diagnosis in that individual fish, in other words, a lab result or a histopathology result, but what is the diagnosis at the farm level, at the population level, where the audit was conducted.
> …
> So as an example, we may collect 10 fresh carcasses at a farm. One of them may have indications of pathology as described by Dr. Marty. Then my job would be to look at, is that relevant to the main population when the mortality rate is low, there have been no treatments required, no fish health events, the attending veterinarian is very aware of what's going on and is taking no action. So I would tend to not call that a disease-level problem at that farm. I would consider it one fish, one sample, it's a lab result.[190]

Dr. Sheppard said that it "can occur quite regularly" that one or two individual fish might be found to have a disease, but there are no diagnoses of disease at a farm level. Those cases are listed as "open" diagnoses on a farm level. The Supplemental Appendices to the 2009 Annual Report of the BC Fish Health Program explain how and why the provincial veterinarian (then Dr. Sheppard) would come to an "open" diagnosis at the population level:[191]

* A necropsy is an examination of the dead (Transcript, Dr. Gary Marty, August 31, 2011, p. 16).

> **Open diagnosis**: The information collected and observations made during an audit are often inconsistent with the results of laboratory tests, or the test results of the samples submitted reflect a mixed etiolology [*sic*], or no pathogen observed. Often insufficient evidence exists to suggest population involvement of a specific disease (i.e. there is a low mortality rate and few silvers [freshly dead fish] are available). In these cases, one must conclude that either the cause of death remains unknown or the mortality observed is incidental and not sufficient to assign a farm-wide disease diagnosis.[192]

Dr. Sheppard said that, as soon as the AEO Fish Health Unit makes a finding, it is communicated to the attending veterinarian to ensure that any known issues are addressed.[193] In the case of an open farm-level diagnosis, it does not mean that there is no disease on the farm, only that there is no "consistent disease across the farm." "We would call it an open diagnosis because we are unable to conclude why those fish, the silvers that we collected that day, may have ended up in the dead pile."[194] Also, the presence of indigenous pathogens in a fish does not mean that the fish died of that disease. As an example, Dr. Sheppard said that many people in the courtroom where he was testifying likely had the bacteria *Staphylococcus* on their skin, yet they did not have flesh-eating disease.[195] Further, Dr. McKenzie explained that "there is a natural background disease level that we will see, and just like any salmonid species in the same waterway, we would see at some level those diseases: whether it's an outbreak, no; presence of a pathogen, yes."[196]

Concern surfaced during the hearings about the diagnoses done at a farm level. More specifically, the authors of technical reports 5A, 5B, 5C, and 5D, Salmon Farms, relied on data in BCMAL's fish health databases as the basis for their conclusions about the impact of disease and pathogens from salmon farms on the health of Fraser River sockeye, possibly assuming that an "open" diagnosis meant that no disease was present on a particular farm. Dr. Korman, author of Technical Report 5A, Salmon Farms and Sockeye Information, the project that summarized the data provided by the province, Canada, and the BCSFA for use by the other Technical Report 5 authors, testified that his analysis proceeded on the basis of farm-level data, not individual fish.[197] With reference to the farm-level diagnoses spreadsheet from the BCMAL fish health audits,[198] Dr. Korman testified that the "open" farm diagnoses comprise over 50 percent – even as much as 60 percent – of all audits.[199] In Dr. Korman's analysis, he treated farms with an open diagnosis as if they were healthy farms.[200] Dr. Korman agreed with a suggestion from one participant's counsel that, if up to 60 percent of the farm diagnoses are "open," then it would be "statistically valuable" to know "if there was a rise in one or more symptoms over time," and that such a rise in symptoms would suggest further inquiry was needed.[201]

Egg importation

Dr. McKenzie described the steps that a fish farm company formerly had to go through if it wanted to import salmon eggs into Canada from another country. I understand that the regulatory regime has changed as of December 2011, with amendments to the FHPR and consequent movement of responsibility for international imports from DFO to CFIA under the *Health of Animals Act* (see discussion above). Still, the process described by Dr. McKenzie was the state of play at the time of the hearings about salmon farms in August 2011 and describes past egg importations to salmon-farming operations in the province.

Dr. McKenzie testified that a company would make an application to import eggs to DFO. The Introductions and Transfers Committee (discussed above) and the local fish health officer would ensure that the applicant was able to meet the criteria under the FHPR (as they were then), such as obtaining eggs from a quarantine facility. DFO would provide an import contract to the company, laying out the conditions of testing, quarantine, release, and communications with DFO. The company would put the eggs into quarantine where they would undergo a series of tests, usually once per month. After a DFO-approved laboratory provided satisfactory test results to DFO, DFO would release the eggs from quarantine, but the company would still keep them in separate facilities. The fish grown from the eggs would then be tested and tracked as an individual group, even in saltwater.[202] Dr. McKenzie said that, in

particular, ISA was listed as a disease that companies were required to test for on their import contracts. He said that the company he works for, Mainstream Canada, tests for ISA six or seven times prior to release, using PCR methods. It has never found ISA in that testing.[203]

Mr. Swerdfager testified about DFO's system for reviewing egg import applications: "[T]he system is not just simply a rubber stamp." He said that, although DFO has not had cause to refuse imports of eggs to British Columbia, it has done so in Nova Scotia.[204] Mr. Swerdfager also noted that egg importation is "not an area where there's a lot of activity."[205]

Dr. Kent characterized DFO's program for egg importation as a "very rigorous program."[206] He said an "eggs only" policy "dramatically" reduces the opportunity for the introduction of an exotic pathogen into the province.[207] More specifically, the importation and quarantine programs used in British Columbia have reduced the risk of importing exotic diseases through egg transfer.[208] Dr. Kent agreed with the opinion of Dr. Larry Hammell, expressed in a report that Dr. Hammell prepared for the BCSFA:

> Three important aspects of the egg importation reduce the probability of pathogen introduction from low to extremely low. These are 1) taking eggs from FHPR approved sources, 2) restricting movement of live animals to the eyed egg stage, and 3) post-transfer quarantine with extensive diagnostic testing requirements. These actions are directed toward identifying stock that could be infected with an exotic pathogen and containing that infection if it occurred. It appears to be successful at least to the point of not identifying any exotic pathogens through the process to that stage of release from quarantine.[209]

A document in evidence written by Alexandra Morton, executive director of Raincoast Research Society, expresses concerns that egg importations have proceeded despite concerns both within and outside DFO over the potential to import exotic diseases.[210] While I accept such concerns exist, the evidence before me from Dr. McKenzie, Mr. Swerdfager, and Dr. Kent indicates that DFO has taken appropriate steps to deal with them.

Management options to reduce risks to wild salmon

Witnesses discussed several different options for reducing risks of disease and pathogen transfer from salmon farms to Fraser River sockeye, ranging from good fish husbandry practices to keep farmed fish healthy to closed containment systems that prevent sharing of water between wild and farmed fish. Central to this discussion is the concept of "biosecurity."

Dr. Dill, author of Technical Report 5D, Dill Salmon Farms Investigation (see discussion in Volume 2), told me that biosecurity refers to the measures taken to prevent "the movement of disease from farm to farm" whether steps are taken at a local, regional, or international level.[211] Dr. McKenzie said that "biosecurity is a paramount piece in fish health management in all aspects, whether it be in hatcheries or in fish farms."[212]

Dr. Christine MacWilliams, veterinarian in DFO's Aquatic Animal Health Section, described the "principles of biosecurity" in relation to captive fish:

> [T]here … [are] three main tenets and one is that you want to keep pathogens out of your facility, one is if they do happen to get in, then you want to prevent them from spreading, and the third is the efforts that you … [make] to keep your population as healthy as possible and reduce their susceptibility to the pathogens having a deleterious effect.[213]

Dr. Garver told me that biosecurity is "one of the first and foremost things that you implement … if you know what the disease agent is and how to prevent it, and to eliminate its spread," but that "it's really hard without a specific pathogen to recommend methods to eliminate it without knowing the biology behind each pathogen."[214] And Dr. Johnson told me that the risk posed to Fraser River sockeye from captive fish is related to the biosecurity of a particular facility.[215]

Ms. Morton said the concept of biosecurity on a fish farm is confusing given that "the reason that they use the nets is so that millions of gallons of water will pass through the farm from inside to the outside."[216] Catherine Stewart, salmon-farming campaign manager, Living Oceans Society, agreed with Ms. Morton, saying: "You can't secure, biologically, an open net pen that relies on tidal flushing and the free flow of water. There's no securing possible."[217]

Disease control options

Dr. McKenzie described different measures taken by salmon farmers to ensure that stock in their pens remain healthy throughout their lives:

- Control broodstock to "start off with good, healthy stocks," including having a genetics program.
- Produce eggs in "a manner that is sanitary" and adheres to strict biosecurity standards.
- Maintain a good rearing environment and a good nutritional environment for fish.
- Use dip vaccines when the fish are 3 grams to help them fight off disease.
- Disinfect water coming into the hatchery.
- Take biosecurity very seriously "to ensure we're not moving high risk people, equipment, animals, into and between hatcheries."
- Monitor fish on a daily basis. Early detection and constant monitoring is key.
- Treat or cull fish as necessary.
- Use injectable vaccines on every fish prior to release to saltwater.
- Test the fish for optimal smoltification before moving them to saltwater.
- Once in saltwater, make daily observation and monitoring, including daily necropsies.
- Investigate any issues and involve veterinarians for treatment.
- Do regular health screening for health issues that might not be visible.[218]

Dr. McKenzie said the above elements of good fish husbandry are set out in a company's FHMP.[219]

In 2009, the Salmon Aquaculture Dialogue, a multi-stakeholder, multi-national group initiated by the World Wildlife Fund, commissioned a report on salmon diseases.[220] That report set out "basic categories of methods for disease control" as shown in Table 1.9.1. Mia Parker, an industry representative formerly with Grieg Seafood BC Ltd., said these categories of actions are listed in "order of severity" and that the bottom five (including "no action") are part of daily practice on a salmon farm.[221] In respect of the "test and slaughter" category, Ms. Parker said that in British Columbia, if a pathogen is found that cannot be treated and should result in the culling of those animals, then the entire cohort is culled, not just the animals that tested positive.[222]

Table 1.9.1 Methods of disease control, by category

Category	Explanation and comments
Mass slaughter	All individuals in a population at risk that were potentially exposed to the disease are killed and disposed of
Test and slaughter	Only fish that test positive for the presence of the disease or pathogen are killed and destroyed. As most tests for fish disease require the fish to be killed to achieve a diagnosis, this is typically not an alternative under commercial farming conditions
Quarantine or isolation	Exposed and/or infected individuals are separated from other susceptible individuals in a manner that prevents transmission of a pathogen. Open netpen systems or closed pens that do not have capacity to treat water are not conducive to this intervention
Mass treatment	All infected or exposed individuals are treated with a drug or chemical to kill the pathogen and reduce it to a level where it cannot be sustained and cause harm in individuals and populations.
Mass vaccination	Vaccines are used to bolster the immune system, allowing it to combat the infection. This action is best used in groups not yet exposed to a pathogen due to the time delay between vaccination and a protective immune response
Environmental management	Changing features that stress fish and increase their susceptibility (water oxygen, water temperature, crowding, nutrition etc) or facilitate exposure to the pathogen (poor hygiene and biosecurity etc) in a manner to reduce exposure or susceptibility to infection
Education	Providing information to allow for appropriate assessment of the significance of a disease (and thus need to act), the best way to treat and/or best way to prevent a disease
Surveillance	Monitoring a population until such time as a specific threshold of diseases signals the need to intervene
No action taken	

Source: Reproduced from Exhibit 1561, p. 41.

Ms. Stewart expressed concern that rapid response in terms of "mass treatment" is not possible when treatment comes in the form of medicated feed, because feed needs to be ordered, milled, and then shipped to the farms, which are often in remote locations.[223]

Sea lice treatment

There are two species of sea lice that infect salmon (both farmed and wild) in the coastal waters of the province: *Lepeophtheirus salmonis* (the "salmon louse" or "*Leps*"), and *Caligus clemensi* (the "herring louse" or "*Caligus*"). In Volume 2, I discuss sea lice as a possible cause of the decline. In this section I review the evidence that I heard about sea lice treatment. As noted above, farmed fish are treated for sea lice normally as a preventive measure for the protection of wild salmon, not because treatment is medically necessary for the farmed fish.[224]

"SLICE" is the trade name of the only in-feed therapeutant that is used to treat fish for sea lice in British Columbia.[225] The active ingredient in SLICE is emamectin benzoate.[226] The treatment of farmed salmon for sea lice is done only on a prescription written by a veterinarian; SLICE treatments are not mandated by regulation.[227] In around 2003, BCMAL set a "three motile-lice trigger" level for SLICE treatment.[228] When the trigger level was reached, other species-specific management actions were triggered. Assessments had to be increased to twice per month, and, if the trigger was reached during the outmigration of wild juvenile salmon (March 1 to June 30), a farm would have to implement further actions as outlined in its lice management strategy.[229]

According to BCMAL, initial assessments conducted in the period 2003–5 showed that farmed Pacific salmon harbour very few lice. Therefore, BCMAL did not require fish farms cultivating species of Pacific salmon to "routinely count and report lice abundance; however, producers continue to visually monitor the Pacific salmon for sea lice at opportune times."[230]

Dr. Sheppard explained the three motile-lice trigger for SLICE treatment as follows:

> The trigger level of three motile lice per fish in the out-migration period was initiated, that trigger, I think, around the period of 2004, and it was largely based on the precautionary principle in looking at the scientific information from other regions that were having effects by a pathogenic strain of this *Lepeoptheirus salmonis*, Atlantic salmon louse, or Atlantic Ocean louse. And so the Province of British Columbia adopted that same level, which would be comparable to what was seen as a trigger level in Norway and in Europe.[231]

Sometimes SLICE is applied below the three motile-lice trigger if, for example, fish are going to be harvested, precluding a later treatment of SLICE due to the withdrawal periods necessary (for human health reasons) before harvest. In those cases, SLICE is applied earlier to ensure that lice levels are kept low during the outmigration of smolts.[232]

Dr. Sonja Saksida, executive director of the Centre for Aquatic Health Sciences and a private veterinarian who works for salmon farmers, told me that farms in the province treat for sea lice much less frequently than in other jurisdictions; there are BC farms that never have to treat because they never reach the trigger point. She said that most farms that do treat for sea lice do not treat more than twice in a production season (which is equivalent to once per year).[233] Dr. Saksida also testified that she treats for *Leps* on farms at "far lower thresholds than I would believe that the fish are actually experiencing stress" but that, on the few occasions when she has treated for *Caligus*, "it is because I believe that the fish were actually – that it might be a welfare issue."[234]

Michael Price, biologist, Raincoast Conservation Foundation, testified that "SLICE does not appear to be very effective at reducing *Caligus*" (the species of louse predominantly found on Fraser River sockeye – see Volume 2) but that fallowing salmon farms is effective, "specifically on the juvenile sockeye migration route."[235] However, Dr. Saksida said that finding *Caligus* on farms is "a rare occurrence" but when it happens, SLICE "is an effective treatment for *Caligus*."[236]

Dr. Simon Jones, research scientist, Aquatic Animal Health Section, Science, DFO Pacific Region, testified that "the development of resistance to the widely-used therapeutic [SLICE] is an obvious consequence" – that where stringent triggers or thresholds are used for the application of SLICE, resistance can develop as a result of

overuse. He said, "[I]t is a [phenomenon] that is not uncommon in biology, that under selective pressure that you can see the rise of resistant strains."[237] Similarly, Dr. Craig Orr, executive director, Watershed Watch Salmon Society, said that there is no question that SLICE is effective for lice on this coast but that he has concerns about how quickly resistance could develop.[238] He favours the use of chemical therapeutants as an "emergency interim measure" only. In his view, to continue to treat sea lice, "you have to probably be removing these salmon farms from the migration routes of these juvenile fish if you want to have sustainable long-lasting benefits."[239]

Dr. Saksida testified that there are no signs of resistance to SLICE in British Columbia. She said sea lice are "still very susceptible to SLICE."[240] Dr. Noakes, author of Technical Report 5C, Noakes Salmon Farms Investigation, said that, in his view, the risk of lice on salmon farms developing resistance to SLICE is minimized by the fact that, each year, returning migrating wild salmon recruit lice from a large population of lice in the North Pacific and then transfer those lice to fish farms as they pass by on their home migration. He also said that efforts to reduce the possibility of SLICE resistance could be achieved by relaxing the trigger for treatment, and only treating at times when it will protect the outmigrating juvenile salmon.[241]

Some witnesses identified additional options for managing sea lice levels on fish farms. Dr. Jones said that "enhanced management actions for sea lice" could include "monitoring and surveillance of the farm population, appropriate siting and stocking activities and harvesting activities, in other words, being coordinated. It would include treatment where practical or harvest where appropriate."[242] Dr. Orr talked about methods that have been used in the Broughton Archipelago:

> [A]ge class management, [whole] bay management, you know, coordinated treatment of farms, early treatment of farms, that's been the biggest benefit for the Broughton. All the farmers are treating in December which has been a real big benefit for the wild fish, you can reduce the numbers of lice. You can reduce the impacts and infestations on wild fish. But we don't yet know whether that's enough to counterbalance the population of impacts we've seen in those fish. Those studies haven't been done.[243]

Closed containment systems

Some participants in this Inquiry suggested a transition from net-pen salmon farming to closed containment aquaculture as a means of addressing some of their concerns about open-net pen aquaculture. Dr. Dill said that, although improvements in fish husbandry can reduce risks to wild salmon, the only thing that can eliminate risks is to "get them out of the same common water."[244] The province has said that "[t]he development of closed containment aquaculture as an alternative to conventional net pens aligns with the Ministry's goals for the development of an aquaculture sector that is economically, environmentally and socially sustainable."[245]

DFO describes "closed containment" aquaculture as follows:

> Closed-containment is a term used to describe a range of technologies that attempt to restrict and control interactions between farmed fish and the external aquatic environment with the goal of minimizing impacts and creating greater control over factors in aquaculture production. Closed-containment introduces a range of new complexities, including CO_2 build up, waste management, siting and installation and energy requirements.[246]

DFO's work related to closed containment falls under the director of innovation and sector strategies, under the Aquaculture Management Directorate (AMD) at national headquarters, with support from DFO Science.

In 2008, DFO's Canadian Science Advisory Secretariat (CSAS) reviewed six papers, which in turn reviewed over 40 closed containment systems around the world, finding that none was "producing exclusively adult Atlantic salmon and that many previous attempts to do so had failed."[247] Reasons for previous failures included "mechanical breakdown, poor fish performance, management failure, declines in market price and inadequate financing."[248] CSAS recommended further work, including work on rearing Atlantic

salmon in fresh / brackish water, water quality parameters, the animal welfare aspects of rearing salmon at high densities, disease risk assessments and quantitative monitoring, and environmental impacts associated with net-pen aquaculture and closed containment alternatives.[249]

Other recent reviews of closed containment technology include a 2008 study for the Coastal Alliance for Aquaculture Reform, the David Suzuki Foundation, and the Georgia Strait Alliance called *Global Assessment of Closed System Aquaculture* and a May 2010 report by the Save Our Salmon Marine Conservation Council called *Technologies for Viable Salmon Aquaculture – An Examination of Land-Based Closed Containment Aquaculture*. Neither of these reports is in evidence before me, but other exhibits suggest they either advocate for closed containment aquaculture or conclude that there are no technological barriers to closed containment aquaculture.[250]

In September 2010, DFO's AMD published *Feasibility Study of Closed-Containment Options for the British Columbia Aquaculture Industry* with the goal of using "financial analysis tools to respond to the CSAS report" described above.[251] The report compared a conventional net pen with a closed containment, land-based "recirculating aquaculture system" (RAS).[252] The report found as follows:

> Overall, the analysis showed that RAS technology is marginally viable from a financial perspective, but that it presents a higher level of risk compared to net-pen systems. However, these findings still need to be assessed – and their assumptions validated – in a real-life scenario. Potential next steps could include a pilot scale or demonstration system capable of producing salmon at commercially viable levels (e.g., one module scalable to financially feasible levels) to demonstrate the technical and financial feasibility of closed-containment salmon rearing under real world conditions.[253]

Marine Harvest Canada, in collaboration with Coastal Alliance for Aquaculture Reform (CAAR), has commenced work on a pilot project to test the feasibility of RAS technology. Witnesses from both Marine Harvest and CAAR spoke about this project. Clare Backman, a representative from Marine Harvest, said that the company is working on a pilot project for a closed containment fish farm – using RAS technology that it has developed for its hatcheries. Mr. Backman described the main benefits of closed containment to his company:

> You maintain the quality and the control over the environment of the water in which fish are living in terms of chemical makeup of the water, freedom from pathogens. And so those elements are beneficial to the grower. We can be sure that we're not going to be losing our product due to changes in the environment.[254]

Mr. Backman said the pilot project will document all the costs and look for cost efficiencies. Preliminary work "showed us that the likelihood of it being economically profitable at this time was slim," but he said it was still "worthwhile to take what we know now to the next level and actually determine where improvements could be made to bring in greater efficiencies and see what level within our entire range of growth options ... where it would fit into the mix."[255] He gave his view that at this point in time the risks do not justify the cost of moving to closed containment in a short period of time.[256]

Ms. Stewart said that often the cost of waste disposal associated with net pens does not get considered in the evaluation of closed containment because companies are "able to externalize that cost into our ocean waters."[257] She said it is important to "compare the value of those ecosystem services that are currently being provided at no cost to the industry, so that we're looking at apples to apples and there's a more level playing field when factoring in the actual operating costs."[258] Mr. Backman responded by saying that there are currently costs associated with monitoring and fallowing of current net-pen technology that are internalized by a company. He said the "Conservation Strategies Fund" report that will evaluate the pilot project is intended to capture all these things.[259] Ms. Parker provided an example of costs internalized by the industry: under the former provincial waste regulations for salmon farms, companies had to pay annual waste management fees depending on the amount of waste discharged.[260] Mr. Backman said this "went into the hundreds of thousands of dollars every year" for all Marine Harvest sites.[261]

Fish health management at salmon enhancement facilities

Salmon enhancement or production facilities are described in Chapter 6, Habitat management. In brief, these facilities include hatcheries, spawning channels, and other improvements; there are 23 major federal (DFO) enhancement facilities, 21 community hatcheries operated as part of the Community Economic Development Program (CEDP), and about 350 public involvement projects (PIPs) which are supported by 18 DFO community advisors.[262] There are also provincial trout hatcheries operated under the Freshwater Fisheries Society of BC (FFSBC).

During the hearings on the marine environment, Dr. Richard Beamish, retired research scientist, Salmon and Freshwater Ecosystems, PBS, testified that disease can occur in hatcheries and many cases may not be reported or investigated because hatchery fish do not exhibit clinical signs of disease (or hatchery staff may not recognize the clinical signs of disease).[263] During the hearings on disease, two expert witnesses, Dr. Craig Stephen and Dr. Christine MacWilliams, gave further testimony about the potential for disease transfer from fish enhancement facilities to wild Fraser River sockeye. Dr. Stephen is the author of the Commission's Technical Report 1A, Enhancement Facility Diseases.[264] Dr. MacWilliams is a fish health veterinarian in the Aquatic Animal Health section and the veterinarian responsible for DFO's Salmonid Enhancement Program (SEP).

Federal conditions of licence in respect of fish health

Under the *Pacific Aquaculture Regulations,* DFO issued licences to salmon enhancement facilities on July 1, 2011. These licences contain general conditions of licence. The entirety of the fish health conditions is as follows:

3. Fish Health
3.1 The fish cultivated in the enhancement facility must be given the care and attention consistent with their biological requirements.
3.1 If there is a fish health problem, it must be investigated by the licence holder or designate. The project may seek advice / assistance from the FHV* directly if the licence holder or designate is not available.
3.3 All reasonable efforts shall be made at the enhancement facility to keep complete and accurate records of fish health and inventory in the enhancement facility, using Appendix III (attached) to capture the relevant information.
3.4 Major mortality events shall be reported within 24 hours to the FHV. Where the licence holder or designate is unavailable, the project shall contact the FHV directly.
3.5 Where fish must be destroyed, the licence holder shall seek the directions of the FHV.[265]

In addition, the general conditions say that fish shall be released only if "no disease outbreak is apparent in the stock and losses in the stock have been low during the entire rearing period; and the stock is not currently being treated for a disease, nor has it had an antibiotic treatment during rearing."[266] There is no prohibition against releasing diseased fish, only that losses must be "low." There are minimal data-reporting requirements; licensees need only make "reasonable efforts" to record fish health information. There are no self-monitoring requirements. Further, there is no formal government auditing program.

As of July 2011, there was no requirement under the conditions of licence for salmon enhancement facilities to have a Fish Health Management Plan; see discussion above. However, as discussed below, some facilities do have FHMPs.

Roles and responsibilities

Dr. MacWilliams, as the fish health veterinarian assigned to SEP, has responsibility to oversee fish health issues in all the enhancement facilities under that program. She explained that the major DFO

* FHV refers to the fish health veterinarian who is a licensed veterinarian in British Columbia and on staff at DFO. As of the time of hearings in August 2011, the FHV was Dr. Christine MacWilliams.

facilities have professional "fish culturists" on site who are responsible for the FHMPs and operations at a given hatchery in concert with their managers and with Dr. MacWilliams.[267] The community facilities have "fish culture staff" who do the daily husbandry and care, and an assigned community advisor who is a DFO staff person who can provide "advice and technical support" and be a liaison to Dr. MacWilliams.[268]

Management practices and operating procedures

According to Dr. Stephen, when dealing with disease at fish production facilities, there is "no management standard against which to work."[269] As Dr. Stephen described in Technical Report 1A, Enhancement Facility Diseases, a management standard is important for knowing what is reasonable in terms of risk assessment:

> We know of no legal fish health standard that establishes an acceptable level of fish pathogen risk for enhancement operations except for legislation dealing with the exclusion of foreign or exotic disease from Canada. A single standard for acceptable exposure cannot currently be defined as the capacity for individuals and populations to cope with a disease is context specific and would be affected by things such as the pathogen, host species, life stage, habitat quality, water temperature and many other factors.[270]

Dr. Stephen recommended that DFO set a health management target or standard for acceptable risk.[271]

In oral testimony and in his report, Dr. Stephen noted a number of deficiencies relating to disease in terms of standard practices and record keeping at fish production facilities. For example, there was a lack of consistency in record keeping at the hatcheries, "particularly when we got to some of the community and public involvement programs where we were getting handwritten records."[272] For provincial facilities, Dr. Stephen said that the biggest challenge in writing his report was that he was only able to get some "anecdotal evidence about release patterns," though he reported that the province did say that it does not "release their fish into sockeye-bearing lakes or take their brood stock from lakes with sockeye salmon, so that would suggest there would be a lower opportunity for exposure [of sockeye to diseased hatchery fish]."[273] He recommended improvements to auditing and oversight of fish health, especially in terms of assessing risk to wild fish.[274]

Dr. MacWilliams testified that "the level of screening [of enhancement facilities] is, in my opinion, … sufficient. We … probably [do] not miss any disease outbreaks." She said that, under the SEP, DFO screens for BKD in watersheds where it knows the bacteria is present. For IHN virus, DFO does annual screening of sockeye broodstock. She further said DFO has a number of management practices in place to limit the risk of disease, such as "compartmentalization" of stocks among multiple sites and the use of virus-free water sources. However, she admitted that only some pre-release screening of fish for disease is done and this screening is done only at major DFO facilities.[275]

Each of DFO's major facilities, as well as the CEDP and PIP facilities, takes steps to treat infectious diseases. Facilities with FHMPs follow these plans for drug and chemical treatments of fish. However, treatment records exist in a variety of non-standardized formats. The application and reporting of chemical and pharmaceutical treatments vary from facility to facility, and treatment records are not always accompanied by a diagnosis.[276]

Technical Report 1A, Enhancement Facility Diseases, reviewed FHMPs for DFO facilities and reported that they contain generic and specific biosecurity and management principles.[277] Pre-release risk assessment information is not consistent across DFO facilities. For example, some DFO facilities do not require any formal pre-release risk assessment, and facilities with formal pre-release operating procedures require varying degrees of assessment.[278] FHMPs contain operating procedures relevant to a fish health event or potential disease outbreak, including procedures for sample collections and quarantines. Specific procedures for the collection and counting of dead fish, disinfection of equipment, and disposal of dead fish vary by hatchery, but overall there are similar biosecurity principles. DFO applies the principles of the *Alaska Sockeye Culture Manual* for IHN control. DFO no longer does routine broodstock screening for this disease because of the lack of historical correlation between

screening outcomes and subsequent diseases. It does population screening by testing 60 fish and, if IHN is found to be prevalent (level not specified), it will do additional egg disinfection.[279]

CEDP and PIP operating procedures vary in scope and completeness.[280] FFSBC's standard operating procedures include health risk assessments of fish releases for fish that are known to have been exposed to a pathogen, that have been treated with a drug or chemical or are affected by an unknown cause of death or illness, or that require a permit for transport.[281]

Technical Report 1A summarizes the main issues found by Dr. Stephen relating to FHMPs:

> All major DFO and FFSBC hatcheries have Fish Health Management Plans that are intended to support the goal of not releasing fish with known infections. The Plans have not been audited. There are inadequate resources to allow fish health professionals to visit enhancement facilities to help adapt Fish Health Management Plans to local conditions, audit their practices and develop ongoing disease prevention programs. The Plans vary in detail and in their adaptation to local conditions. There is little opportunity to apply Fish Health Management Plans to spawning channels and it did not appear that the Community Economic Development Program or Public Involvement Project hatcheries have comprehensive fish health management plans.[282]

When asked about FHMPs at the hearings, Dr. Stephen appeared to be of the view that FHMPs for enhancement facilities were just template documents.[283] These FHMPs did not bolster his confidence that the plans were being met; there was no definite evidence that measures were actually being taken to reduce risks to wild fish.[284]

Dr. MacWilliams said all the DFO major facilities have FHMPs as a condition of licence, though that is not apparent from the licences issued in July 2011.[285] FHMPs include biosecurity practices and standard operating procedures. Community production facilities have a "small booklet with biostandards for culture rearing"; they have also been given a copy of the template for the FHMPs, and "we've done a couple of workshops on writing SOPs or standard operating procedures for the CEDPs to encourage them to start writing down their own procedures of what they do in developing their own set of SOPs for operations."[286]

With respect to the three tenets of biosecurity (described above in the section on salmon farms), Dr. MacWilliams said the following are specific measures used by DFO:[287]

- choosing broodstock;
- disinfecting eggs;
- practising daily surveillance;
- using mortality or morbidity rate thresholds for contacting fish health professionals;
- separating broodstock from incubation;
- optimizing nutrition;
- limiting handling; and
- controlling densities.

Release of diseased fish

In his report, Dr. Stephen documented cases where fish with known or suspected infections were released from fish production facilities into fish-bearing waters. In none of these cases was there evidence of post-release monitoring of surrounding wild fish.[288] Dr. MacWilliams agreed that DFO enhancement hatcheries periodically release fish that are known to be carrying pathogens, specifically, BKD.[289] DFO treats BKD in the hatchery population with antibiotics and does pre-release screening to determine the population-level prevalence of the disease. If that level is deemed "too high," they cull the fish; if not, they release them, recognizing that a zero-tolerance level does not work for endemic pathogens.[290] Dr. MacWilliams did not say what degree of population-level prevalence for BKD is acceptable. However, a 2010 memorandum from Dr. MacWilliams to staff at the Snootli Creek Hatchery notes that "[t]he high prevalence of BKD in this stock is a bit overwhelming. I'm glad these progeny will all be promptly released to reduce the horizontal transmission of this pathogen during prolonged rearing."[291] In testimony, Dr. MacWilliams explained that "low positives" of the pathogen levels are considered suitable for

fry release, but that moderate-to-high positive pathogen levels ordinarily result in destruction of the fish.[292]

Dr. MacWilliams described other circumstances where diseased fish may be released. Fish may be released from enhancement facilities with other "normal skin or gill parasites that are also endemic pathogens, ubiquitous in wild circumstances." Some of these pathogens are cured by the entry into saltwater, and so in her view, although there is a risk that they will be passed to other freshwater stocks as they are migrating to the sea, this risk will decline in the estuary and beyond. Finally, the other situation where disease-positive enhanced fish may be released to the wild is when these fish are reared in open-net pens where the "rule of thumb is normally that if [there is] any sign of mortality, regardless of what the cause is, we let them go."[293]

Case study: infectious salmon anemia virus

During the hearings on disease in August 2011, Dr. MacWilliams and Dr. Kent testified that ISAv had never been identified in wild or farmed BC salmon.[294] However, as noted in the introduction to this chapter, during the fall of 2011 two non-government laboratories reported positive test results for ISAv in wild Pacific salmon off the BC coast. I reopened the Commission's hearings to hear evidence about tests for ISAv conducted on wild Pacific salmon and Canada's responses to those tests. I discuss that evidence here as a case study of how Canada responds to potential health threats to Fraser River sockeye salmon.

I did not set out to investigate ISAv as a case study; it is a topic that emerged in the public realm during the course of this Inquiry. It engaged the Terms of Reference of this Inquiry, in particular my investigation into disease as a cause of the decline, the policies and practices of DFO, and the future sustainability of the Fraser River sockeye fishery. Although I would not have chosen to focus so much attention on one particular disease (without evidence that it is responsible for the decline in Fraser River sockeye), the hearings on ISAv provided me with a valuable understanding of how fish health issues are addressed in Canada and the state of readiness of programs and policies to deal with disease, particularly in wild Pacific salmon.

The ISAv case study is a story about how DFO and CFIA, its partner under the NAAHP, have investigated the presence or absence of ISA in BC waters. The telling of this story was prompted by laboratories at the Atlantic Veterinary College (AVC) under the supervision of Dr. Frederick Kibenge, and the University of Bergen in Norway, under the supervision of Dr. Are Nylund, which reported presumptive positive tests for ISAv in wild BC salmon. These reports led to a CFIA investigation and further testing (to confirm results) by the DFO laboratory in Moncton, under the supervision of Ms. Gagné. CFIA interpreted test results against the backdrop of years of negative test results for farmed salmon in British Columbia, conducted by the BC Lab in Abbotsford under the supervision of Dr. Marty. CFIA ultimately reported that there is no evidence of ISAv in British Columbia. The AVC and Norway tests also led to DFO's disclosure to this Inquiry of ISAv test results – including presumptive positive results – it obtained in 2003 and 2004, under the supervision of Dr. Molly Kibenge (whose first name I will continue to use to distinguish her from her husband, Dr. Frederick Kibenge), and more recent tests conducted on historical sockeye samples during the fall of 2011, under the supervision of Dr. Kristina Miller. DFO also produced results of negative ISAv tests in sockeye salmon conducted under the supervision of Dr. Kyle Garver in 2010 and 2011.

Because the various tests were conducted by different researchers, using different methods, and reaching different results, testing methodologies became an issue during the ISAv hearings. I also heard evidence about the accuracy of DFO's communications, the focus and purpose of DFO's research in this area, and the adequacy of information-sharing with non-DFO researchers.

In the sections below, I discuss ISAv, testing methods and their limitations, methods used and results obtained by the various researchers mentioned above, and the management responses to the presumptive positive tests for ISAv.

What is ISAv?

Dr. Kibenge, who heads the OIE reference laboratory for ISA located at the AVC in Prince Edward Island, described ISAv as follows:

> ISAV is Infectious Salmon Anaemia virus, and that's a virus for fish. It infects farmed Atlantic salmon and … it is called the Infectious Salmon Anaemia, or ISA. The virus structure of this virus is similar to influenza viruses and they are both grouped together in the same virus family. The family is called Orthomyxoviridae …
>
> I think right now Infectious Salmon Anaemia virus is probably the only known [example of] what are characterized [as] Orthomyxo virus that affects fish …
>
> ISA virus is – it causes communicable disease in farmed Atlantic salmon, but it has also been found in various species of wild fish.[295]

There is a difference between the detection of the ISA virus and the actual disease; a fish may be able to carry the virus without actually coming down with the disease. Dr. Nylund, head of the fish disease group at the University of Bergen (Norway) and a leading world ISA expert, explained that "usually you will only find disease development in Atlantic salmon" – not the other salmonid species, though they may carry the virus.[296] Dr. Kibenge said ISA lesions, symptomatic of ISA, "have only been documented in Atlantic salmon."[297] Tests on Pacific salmon (steelhead trout, chum, chinook, and coho) showed that these Pacific salmon species "are quite resistant to ISAV relative to Atlantic salmon"; however, the potential for ISAv to adapt to Pacific salmon "should not be ignored."[298]

ISAv is spread through water and may also be spread through vectors such as sea lice (*Leps* in particular).[299] Transgenerational transmission (from parent to offspring) may also be possible.[300]

The ISA virus is an RNA virus that has a genetic sequence composed of eight segments (called segment 1, segment 2, segment 3, etc.). Each segment is composed of nucleotides and ranges in size from roughly 970 nucleotide to 2,300 nucleotide bases.[301] There are two known major genotypes: the European and the North American. The European genotype has been subdivided into several clades.[302]

The European genotype of ISAv was first detected in Norwegian salmon farms in the mid-1980s.[303] ISA was later detected in New Brunswick salmon farms in 1996,[304] and since then both the European and North American genotypes of the virus have been detected in Atlantic Canada salmon farms.[305] Dr. Kibenge testified that a survey published in 2002 documented ISAv in wild Atlantic salmon in Canada "on a few occasions," but "the report that keeps coming back is that these [wild] fish have virus without communicable disease."[306]

Dr. Nylund explained that scientists think the European and North American strains of ISAv diverged from one another over a hundred years ago.[307] As set out below in the section describing results of recent ISAv testing on Pacific salmon, Dr. Miller has obtained presumptive positive test results for ISAv in Pacific salmon samples collected as long ago as 1986. She said that the level of divergence in segment 7 of her samples, as well as the fact that she detected viral genetic material as far back as 1986, suggests that ISAv (or an ISAv-like virus) might have existed in Pacific salmon for more than 25 years.[308]

Dr. Nylund also explained that there are avirulent (non-virulent) and virulent forms of ISAv. Avirulent forms can mutate into virulent forms:

> [I]f you look at evolutionary biology, in a fish farm where you have a large population density, many hosts, if you have mutation it has the opportunity to spread and multiply. In a wild population, which is very small, few individuals, such a mutation will be very fast lost in a wild population, while in a farm population it can multiply for several – yeah, for years, actually, depending on how the farms are run.[309]

In 2007, ISA was detected in Atlantic salmon farms in Chile. Dr. Kibenge, who was involved in detecting that outbreak, said it was called the "Chilean ISA crisis … it destroyed about 75 percent of their production."[310] ISA virus isolated from farmed Atlantic salmon in Chile in 2008 belonged to the European genotype and was "in a clade with exclusively Norwegian ISA viruses, where one of these isolates was obtained from a Norwegian brood stock population."[311] The 2008 study, in which Dr. Nylund was one of the co-authors, concluded

that "Norway export[s] large amounts of Atlantic salmon embryos every year to Chile; hence, the best explanation for the Norwegian ISA virus in Chile is transmission via these embryos, i.e. vertical or transgenerational transmission."[312]

Test methods and protocols

Anyone who attended the ISAv hearings became conversant in the language of the molecular diagnostic tests used to screen for and diagnose viral diseases such as ISA. In order to set out the evidence, it is necessary to explain a few terms and concepts related to testing methods.

Common screening tests for ISAv use a molecular method called RT-PCR, or reverse transcriptase polymerase chain reaction.[313] The purpose, as I understand it, is to find within a sample of tissue from the host organism, RNA genetic material specific to the ISA virus – and then replicate (or amplify) it into a quantity that can be detected. In order to be amplified using the PCR method, RNA must first be converted into DNA using a process called reverse transcription – the RT part of RT-PCR.[314] Laboratories may also test for RNA quality prior to running RT-PCR tests. This may be accomplished by testing for the quality of a reference gene from the host organism.[315]

After the RT step, the amplification of DNA in a sample happens with the assistance of highly specific genetic primers, which are designed to amplify a known sequence of DNA from within the sample, if such a sequence is in fact present. Ms. Gagné described the methods as follows:

> In this case we're working with RNA viruses, so we need to start by extracting the RNA from, in this case, a fish tissue. And if the RNA of the virus is present in there, mixed with the RNA of the fish, where we'd try to detect it with the PCR assay.
>
> So the assay requires primers. Primers are short custom-made segments of DNA that will anneal [bind to target genetic material] if there's a match with the DNA in your mixture. If the virus is in the mixture with the DNA of the fish, we would get a match, and the PCR process will amplify that segment between the two primers that you have put in your mixture.
>
> The probe is in between those primers. The probe is linked with a reporter or fluorescent molecule. So when the PCR process goes on, if there was a match with the primers first, the PCR process amplifies what's in between those primers, so it creates a sequence, a short fragment of DNA, and the probe will be released, and what the real time RT-PCR [assay] detects is the fluorescence from a probe.
>
> …
>
> In the conventional RT-PCR, there is no probe. We amplify what's – the primers will anneal to a matched sequence, and the polymerase reaction will amplify what's between those primers, the primer is included. So there is no probe. But at the end of the process we will put the product in a gel, and if there was sufficient target [viral genetic material] to start with in the material [sample], we will see the amplification product on the gel after electrophoresis.
>
> With the real-time assay it's different because you have the probe, you don't need to use a gel, you just rely on the fluorescence produced by the probe.[316]

The amplification of DNA occurs over a series of replication cycles in which one copy is replicated into two, two copies into four, four copies into eight, and so on. After the targeted DNA sequence is amplified, its presence must be detected, using either a "real-time" or a "conventional" technique.

If a real-time assay is being used, when sufficient probes are released, the fluorescence can be detected with a machine, indicating a positive test for the virus.[317] The "Ct" value refers to the number of cycles run before the fluorescence is detected. In general, although there is some variability between laboratories, the lower the Ct value, the greater the number of virus particles detected in the sample. (A difference of three Ct values is approximately the equivalent of a tenfold difference in the amount of genetic material detected in the sample.)[318] If a conventional assay is being used, the amplification procedure will be stopped after a certain number of cycles and the product of the amplification will then be run on

a polyacrylamide gel with electrophoresis. If the target genetic product is detected, it will produce a visible band on the gel; the bigger the band, the greater the number of copies produced from the original sample.[319]

If ISAv is detected by PCR, the next steps are usually to try to sequence the PCR product to compare it to known genetic sequences of the virus, and to try to culture the virus.

Dr. Miller described genetic sequencing as "an ultimate validation that what you're picking up by PCR is a real product and it's the product that you're expecting to be picking up."[320] The method of checking one's sequence against known ISA viral sequences is called "blasting." The sequence from the test is sent to a large database of known sequences and blasted against those known sequences to look for matches. The result is a list of best matches showing the percent homology or divergence of the sample sequence to known sequences.[321]

Cell culture is a process whereby scientists attempt to grow a virus on a cell line that has been developed for that purpose. If successful, it provides good evidence of the virus. However, the method is not always successful. Not all strains of ISAv can be cultured;[322] infections that show up as Ct values over 30 in a real-time PCR test usually cannot be cultured;[323] and ISAv can only very rarely be cultured from wild fish.[324] Indeed, Dr. Miller mentioned that it originally took "something like eight years to culture [ISAv] out of Norway."[325] Similarly, Dr. Kibenge said that during the Chilean ISA crisis in 2007–10, it was very difficult to use cell culture as a diagnostic method, so the principal method used during that outbreak was real-time RT-PCR.[326]

Limitations, sensitivity, and reproducibility of RT-PCR methods

Dr. Kibenge, Dr. Nylund, Ms. Gagné, and Dr. Miller collectively identified several limitations of RT-PCR testing for ISAv, particularly in applying current testing methods to Pacific salmon such as sockeye:

1 Tests may not be repeatable for light infections (detectable at high Ct values, over 35) using some assays.[327]
2 Different assays may have different relative sensitivities to different genotypes and/or different variants of the ISA virus.[328] For example, in Dr. Miller's testing, she found the "Snow segment 8" assay (described below) to be the least sensitive for picking up ISA-like virus in Pacific salmon; she also found that she gets "a lot more positives from segment 7" such as the test developed by Plarre (described below).[329] Dr. Miller commented that the use of multiple assays has advantages:

> If you don't know that your assay picks up whatever variant is here, it's sort of meaningless. In my view, if you really wanted to do this properly, you would look at more than one segment of a virus to make sure that ... you weren't picking up false negatives.[330]

3 Most RT-PCR tests for ISAv have been designed to target the most conserved regions of the genome in segments 7 and 8 and they are designed to detect known strains of ISAv.[331] Their ability to detect novel strains is unknown.
4 Current tests for ISAv have been developed based on viral infections in Atlantic salmon, not Pacific salmon. As Dr. Kibenge explained, in Atlantic salmon "we know the best tissue to take, which has the most amount of virus," but for "sockeye salmon and other wild fish in B.C., we really don't have a very good idea of the disposition of this virus in the tissues. We don't know which is the best tissue to take, at what time, and what's the amount of virus that is likely to be in this fish."[332]
5 There is substantial difference in the repeatability of RT-PCR test results among different laboratories.[333] Dr. Nylund said there could be several different reasons for this, including the assay and the interpretation of results.[334]
6 Diagnostic sensitivity of certain assays might be influenced by the thermocycler machines and software used in real-time RT-PCR to detect fluorescence.[335] In a study by Dr. Kibenge, looking at 12 different laboratories, seven laboratories which use Stratagene real-time machines with the associated MXPro software reported "consistently very high Ct values" and in some cases false negatives for known ISAv positive samples, compared to the LightCycler system by Roche and systems by ABI.[336]

The Stratagene systems produced results approximately three to seven Ct values higher than the other machines. According to Dr. Kibenge, this means "if you're using that machine, you are most likely to miss positive samples that have low virus amounts."[337] Ms. Gagné, whose laboratory uses the Stratagene system, said she thought Dr. Kibenge's results in this study were "just pointing to a coincidence, not a problem with the machine probably."[338]

7 The length of the nucleotide sequence amplified by different assays (the "amplicon") can influence the sensitivity of the test. "The smaller the target, the more sensitive the test."[339] Dr. Nylund recommends using an assay targeting around 60 nucleotides "because that is as sensitive as you can get when you have two primers and a probe."[340] DFO Moncton's Aquatic Animal Health Section Diagnostic Laboratory's manual on "Primers and Probes Design and Usage" recommends an "amplicon size of 50–150" for Taqman (a trade name brand of commercial primers and probes) probe assays.[341] The length of the probe part of the assay is also important, and can be as short at 13 nucleotides,[342] or even as short as seven or eight bases, though it is usually in the 21–25 base range.[343]

Confirming presumptive positives and use of validated tests

Dr. Nylund described the specificity of most RT-PCR tests as being very good:

> [I]f you're using an ordinary real-time PCR, I would say that the chances for picking up something else is very, very small. So I would say that an ordinary real-time PCR would be picking up ISA virus, but only the known ISA virus. So the chances of getting a false negative is larger than getting a false positive.[344]

Still, any diagnostic screening test carries a possibility of false positive or false negative results. One possible source of false positives is from contamination. Sources of possible contamination include the presence in the laboratory of PCR products and plasmids that have multiplied the target gene, or fish highly infected with ISAv.[345] Another potential source of contamination is positive controls.[346] Contamination can be avoided through practices such as physical separation of activities[347] (e.g., different rooms or work spaces for taking samples from fish, performing RNA and DNA extractions, mixing assays, and performing the reaction),[348] using positive controls that contain an artificial insert so they can be distinguished from ISAv in the sample (in the event of contamination),[349] bleaching surfaces regularly, taking a systematic approach to controlling contamination,[350] and running several blanks alongside your samples to check for cross-contamination.[351]

A false negative might result from sample degradation (hence negative results are reported as "inconclusive" when the samples are degraded)[352] or, as noted above, from using tests that are not ideal for detecting the strain targeted. Also as noted above, a low virus infection, where there are fewer copies of ISA RNA in the sample, may also be harder to detect, resulting in false negatives.

The OIE Aquatic Code[353] requires confirmatory steps before diagnosing a disease. The OIE Aquatic Code defines a "suspect case" and a "confirmed case" of ISA as follows:

> **7.1. Definition of suspect case**
>
> ISA or infection with ISAV would be suspected if at least one of the following criteria is met
>
> i) Clinical signs consistent with ISA or pathological changes consistent with ISA (Section 4.2) whether or not the pathological changes are associated with clinical signs of disease;
> ii) Isolation and identification of ISAV in cell culture from a single sample (targeted or routine) from any fish on the farm, as described in Section 4.3.1.2.1;
> iii) Evidence for the presence of ISAV from two independent laboratory tests such as RT-PCR (Section 4.3.1.2.3) and IFAT* on tissue imprints (Section 4.3.1.1.2);
> iv) Detection of antibodies to ISAV.

* IFAT stands for indirect fluorescent antibody test.

7.2 Definition of confirmed case

The following criteria in i) should be met for confirmation of ISA. The criteria given in ii) and iii) should be met for the confirmation of ISAV infection.

i) Mortality, clinical signs and pathological changes consistent with ISA (Section 4.2), and detection of ISAV in tissue preparations by means of specific antibodies against ISAV (IFAT on tissue imprints [Section 4.3.1.1.2] or fixed sections as described in Section 4.3.1.1.3) in addition to either:
   a) Isolation and identification of ISAV in cell culture from at least one sample from any fish on the farm, as described in Section 4.3.1.2.1 or
   b) Detection of ISAV by RT-PCR by the methods described in Section 4.3.1.2.3;
ii) Isolation and identification of ISAV in cell culture from at least two independent samples (targeted or routine) from any fish on the farm tested on separate occasions as described in Section 4.3.1.2.1;
iii) Isolation and identification of ISAV in cell culture from at least one sample from any fish on the farm with corroborating evidence of ISAV in tissue preparations using either RT-PCR (Section 4.3.1.2.3) or IFAT (Sections 4.3.1.1.2 and 4.3.1.1.3).[354]

The OIE Aquatic Code, section 4.3.1.2.3, recommends the following real-time RT-PCR methods for screening suspect cases and for confirmatory testing: segment 7 and segment 8 tests by Snow and others (2006);[355] and a segment 7 test by Plarre and others (2005).[356] Dr. Kibenge testified that the Snow segment 8 test is probably the most commonly used primer probe set for ISAv around the world.[357]

As noted above in this chapter, the NAAHLS does not use one of the OIE-recommended tests for ISAv; its laboratories use a test that the DFO Moncton laboratory has developed and validated as comparable.[358] Ms. Gagné said, "[W]e use an assay that looks a bit like the Snow 2006 paper" targeting segment 8.[359] Dr. Wright testified that the test, developed by Ms. Gagné, has been validated as acceptable to both the OIE and Canada for ISAv testing.[360] Dr. Wright said that any testing done on behalf of Canada under the NAAHP does not necessarily have to be done using Ms. Gagné's test, but does need to be done using a validated test and in a laboratory approved by CFIA.[361] As of the time of the ISAv hearings (December 2011), no tests or laboratories other than DFO NAAHLS had been approved by CFIA.[362] Dr. Wright noted that for most other tests or laboratories the validation information is not available – the tests have not been validated with reference animals and analyzed for their diagnostic performance.[363] Dr. Wright was not able to comment on whether the BC Lab in Abbotsford uses a validated test; some validation work may have been done but may not be in the form required for CFIA approval.[364]

Both Ms. Gagné and Dr. Wright testified about the need to adapt and modify assays for RT-PCR tests as new information becomes available or new strains of virus are identified. Ms. Gagné said, "[I]t's written in our documents that we adapt, we evolve," but she saw no indication that the DFO Moncton assay was not working.[365] Dr. Wright said he did not know as of December 2011 whether Canada would have to update its test based on a possible new variant of Pacific ISAv.[366]

Methods and results of ISAv tests on wild Pacific and BC farmed salmon

Different laboratories use different testing "protocols" for their PCR screening tests. Protocols set out such things as the number of cycles per test, the length of the genetic sequence amplified by the assay, whether multiple assays are used, and whether a pre-amplification step is used prior to running a real-time PCR.* As noted above, the methods used can affect the ability of the test to detect ISAv. During the ISAv hearings, I had the benefit of hearing directly from Dr. Kibenge, Dr. Nylund, Ms. Gagné, and Dr. Miller about their methods and results. I also heard direct evidence

* For examples, Ms. Gagné's protocol is at Exhibit 2047; Dr. Miller's protocol is at Exhibits 2076 and 2041; the BC Lab's protocol is at Exhibits 2048 and 2049.

from Dr. Marty of the BC Lab during the hearings about salmon farms in August 2011. In addition, I received indirect and documentary evidence about tests performed by these individuals, as well as by Dr. Molly Kibenge and Dr. Garver. I discuss each set of results, along with whatever information is in evidence on the test methods in the sections below.

Dr. Molly Kibenge, Pacific Biological Station (DFO), 2003–4

In 2003–4, Dr. Molly Kibenge conducted post-doctoral research at DFO's PBS under the supervision of Dr. Simon Jones.[367] Dr. Jones described her work as being "to survey wild Pacific salmon for viruses, for IHN virus, VHS virus and for ISA virus and our expectation was that we would not see evidence of ISA."[368] Dr. Molly Kibenge obtained positive PCR results for ISAv using the methods described by Devold and others (2000),[369] which is an OIE-recommended test for conventional RT-PCR.[370] An abstract she prepared for a draft paper describing her results reads as follows:

> Juvenile Chinook (*Oncorhynchus tshawytscha*), chum (*O. Keta*), coho (*O. Kisutch*), pink (*O. Gorbushcha*), and sockeye salmon (*O. Nerka*) from the West Coast of Vancouver Island, Southeast Alaska, and the Bering Sea were surveyed between August 2002 and April 2003 for infectious salmon anaemia virus (ISAV). Spawning sockeye from the Cultus Lake and Kokanee from Lois Lake, BC population was also sampled. Pooled or individual tissues were tested by RT-PCR, nucleotide sequencing and virus isolation. ISAV segment 8 was amplified from 34 of 121 (28%) Chinook and 15 of 88 (17%) pink salmon caught off the west Coast Vancouver Island and southeast Alaska. ISAV segment 8 was also amplified from all 64 spawning sockeye and one cultured Atlantic salmon. The 220bp [base pair] RT-PCR products were 94% to 98% homologous with Canadian ISAV isolates and 92% to 93% with European ISAV isolates. A product of 377 bp was obtained with Segment 7 ORF1 products were obtained in 5 chinook fish and the nucleotide sequence corresponded to ISAV segment 7 ORF2 products and was 95.7% identical to NBISA01 control isolate (Canadian isolate) and 99.7% identity to an ISAV isolate 810/9/99 from Norway. ISAV segments 2, 6 and full opening frame for segment 8 were not amplified nor was ISAv isolated onto SHK or CHSE and ASK-2 cells [i.e., cell culture was not successful]. These results lead us to conclude that an asymptomatic form of ISA occurs among some species of wild Pacific salmon in the north Pacific.[371]

Dr. Frederick Kibenge testified that there was "clearly a positive amplification of ISA virus in those samples."[372] However, he also said that for Cultus Lake sockeye the product obtained was not a match for ISAv.[373] Indeed, in an email from Dr. Molly Kibenge to Dr. Jones, she says that "the sockeye clone sequences show homology to short sequences of human, mouse, rat, and zebrafish clones."[374] Dr. Jones said this indicated that the PCR results for the Cultus Lake fish were false positives.[375]

Dr. Jones said that, in October 2003, they decided to get another opinion on Dr. Molly Kibenge's results, so they sent 20 blind samples of chinook salmon (10 that were positive in Dr. Molly Kibenge's results, and 10 that were negative) to the laboratory of Dr. Frederick Kibenge at the AVC.[376] Dr. Frederick Kibenge was able to confirm that six samples were positive; however, three of these were in Dr. Molly Kibenge's negative samples and three were in her positive samples. Dr. Jones said that he, Dr. Molly Kibenge, Dr. Dorothy Kieser, and Dr. Garth Traxler decided to send samples to Ms. Gagné's laboratory at DFO Moncton for further testing.[377]

Ms. Gagné testified that, in 2004, she received 93 samples from Dr. Molly Kibenge and tested them for ISAv using the same primers and kits that Dr. Molly Kibenge had used, with "minor differences at some points." Ms. Gagné was unable to find positives in the samples. Further, Ms. Gagné testified that in the fall of 2011, she re-tested backup tissues she had kept from Dr. Molly Kibenge's samples, using the validated real-time RT-PCR assay developed at DFO Moncton, as well as the Snow segment 8 primers. All those tests were negative.[378]

Dr. Jones testified that shortly after Ms. Gagné tested the samples in 2004, Dr. Molly Kibenge left PBS and went back to AVC.[379]

Dr. Gary Marty, Animal Health Centre (BC Lab), 2003–11

During the hearing on salmon farms in August 2011, Dr. Marty testified that his laboratory has tested between 600 and 800 farmed fish every year since 2003 with a "highly sensitive and specific PCR test" for ISAv. All those tests have been negative. He said, "[T]hat [result] gives me a great deal of confidence that we don't have ISAV in British Columbia."[380]

In a May 2011 email from Dr. Marty to Dr. Klotins at CFIA (and similarly in an email from Dr. Marty to Karia Kaukinen, molecular biology technician in Dr. Miller's laboratory at PBS), Dr. Marty explained that from 2006 to October 2009, the BC Lab used a conventional PCR "designed by our microbiologist … to target the RNA Polymerase (PB1) gene."[381] Since then, the laboratory has used a "Real-time Assay for ISA which targets the matrix protein gene. This test was designed by a masters student that we had working here about 4 years ago."[382] Dr. Marty's email went on to note that, although the conventional test may have missed detecting some strains, he concluded that the more recent real-time test should pick up all strains – at least as well as tests recommended in the OIE Aquatic Code.[383] In the email to Ms. Kaukinen, Dr. Marty wrote that the positive control used for his lab's testing is the Canadian (North American) strain of ISAv (i.e., the strain found in New Brunswick), though he said the primers and probes are designed to pick up all known strains.[384] Other documentary evidence describing the province's real-time ISAv assay indicates the test targets a 74 base pair region of segment 8, and is run for 40 cycles. The test was designed, adapted, and validated by BCMAL staff.[385]

Ms. Gagné testified that, in May 2011, Dr. Klotins asked her to review the primers used by the BC Lab. She did so and found some possible "mismatches with some rarely detected strains of ISA," but she did not see "any huge problems" with the primers.[386]

Exhibit 2079 is a spreadsheet showing the BC Lab's ISAv testing from January to November 2011. The document shows re-testing of all samples tested at the BC Lab (from both the DFO's audit program and fish submitted to the BC Lab directly from industry) for the 2011 calendar year; it shows the results of original testing with the BC Lab's protocol, and retesting with all the OIE-recommended PCR assays. Three samples (out of several hundred) "reacted with" one primer set or another, but, since repeat testing was negative, the document lists all samples as negative for ISAv.

Dr. Kyle Garver, Pacific Biological Station (DFO), 2010–11

As noted above in the section discussing the sockeye health assessment in the Strait of Georgia, Dr. Garver's laboratory at PBS conducted tests for ISAv on Fraser River sockeye collected during the summers of 2010 and 2011. Documentary evidence before me indicates that he used the DFO Moncton assay and protocol to test for ISAv.[387] Dr. Garver's laboratory tested tissue from 637 anterior kidneys in 2010; all results were negative. As of November 9, 2011, his lab had tested tissue from 232 gills sampled in 2011; all results were negative.[388]

Ms. Gagné testified that Dr. Garver's laboratory passed a proficiency test for coming within the NAAHLS for diagnostic testing.[389] Documentary evidence (emails exchanged between Dr. Garver's and Ms. Gagné's laboratories concerning the proficiency of Dr. Garver's laboratory in using the validated assay) indicates that Dr. Garver's laboratory uses the MxPro software – the software used with the Stratagene thermocycler machines.[390]

Dr. Frederick Kibenge, Atlantic Veterinary College, fall 2011

Dr. Kibenge said he runs 45 cycles on a Roche LightCycler machine. He uses the Snow and others (2006) test (described above), which targets a region of 104 bases (or nucleotides) on segment 8.[391] He also uses a real-time RT-PCR test targeting segment 6 for genotyping samples that have tested positive using the Snow and others (2006) test.[392] Dr. Kibenge relies on the person submitting samples to provide information about the species and provenance of the fish.[393]

During the fall of 2011, Dr. Kibenge tested four sample sets of Pacific salmon for ISAv. The first sample set came from Dr. Richard Routledge, a professor at Simon Fraser University (SFU). It comprised tissues from 48 sockeye salmon smolts from Rivers Inlet (SFU samples).[394] Dr. Kibenge found

"samples #26 and #36 tested positive for ISAV of the European genotype. All the submitted material for samples #26 and #36 was used up in this testing, and no further testing (e.g., virus isolation and DNA sequencing) was attempted." The Ct values for the segment 8 test were 29.82 for sample #26 and 30.86 for sample #36. The segment 6 Ct values were, respectively, 32.7 and 33.21.[395] Dr. Kibenge also attempted, unsuccessfully, to culture ISAv from these 48 samples.[396]

The other three sample sets were provided to him by Alexandra Morton.[397] The second sample set consisted of tissues from 20 fish collected in the Harrison River near Weaver Creek (Harrison River samples).[398] Three of these fish – one coho heart, one chum gill, and one chinook gill – tested positive with the segment 8 test (with the respective Ct values of 33.61, 33.77, and 32.99).[399] Only the coho heart had a positive segment 6 test (Ct 33.06). Dr. Kibenge attempted to culture virus from the three samples with Ct values. The results were all negative.[400]

The third sample set consisted of sockeye smolts from Okisollo Channel and herring from the south side of Malcolm Island. All these samples tested negative for ISAv.[401] The fourth sample set consisted of sockeye, coho, and pink salmon from the Harrison River. All these samples also tested negative.[402]

Dr. Kibenge testified that he does not report a positive result until he has "ruled out all possible causes of contamination" so that "by the time we put [out] a result, we are confident that [it] is a true positive result."[403] He said he was "confident that the results we got were not as a result of cross-contamination."[404]

Dr. Nylund commented that he thought Dr. Kibenge's results on the first sample set were correct and reliable:

> [W]hen you look at Kibenge's results from fish 26 and 36, he gets different Ct values on the different assays. The difference between those Ct values suggests that his findings are correct, because you find exactly the difference you would expect with the two assays he's been using. So, to be honest, I think that Kibenge's results on this are correct.
>
> Unfortunately the material that I look at [discussed below] were so degenerated and so destroyed that it was impossible to reproduce any results at all, but we got one positive. But I – since it's only one we – positive and it was not possible to repeat, I wouldn't put too much into that. But I think that Kibenge's results are reliable, …[405]

In contrast, Ms. Gagné testified that because of the high level of degradation in samples that she had seen, "even samples that came directly from Kibenge's lab and that were tested in his lab and reported as PCR positive, … it is hard to imagine that if there [were] traces of ISA viral genome in there, that it has survived due to that degradation."[406] She said the positive results from Dr. Kibenge's lab "were produced quickly without the proper time to verify them, confirm them." Also, "just a few precautions to confirm things properly before making a detection like that public would have been a better route."[407] (In fairness, I note that it was not Dr. Kibenge who made his results public.)

Dr. Are Nylund, University of Bergen, fall 2011

Dr. Nylund runs his screening tests on an ABI 7500 machine using two different assays, a segment 8 test (Snow and others 2006, described above), and a segment 7 test of 84 base pairs (Plarre and others 2005, test described above).[408]

In the fall of 2011, Dr. Nylund tested four sets of samples of Pacific salmon for ISAv.[409] All samples were submitted to him by Ms. Morton. The first set of samples contained tissues from the same 48 sockeye salmon smolts as in Dr. Kibenge's first sample set. However, Dr. Nylund tested gill tissues while Dr. Kibenge tested heart tissues.[410]

On this first sample set, Dr. Nylund initially found no positive results.[411] However, because Dr. Nylund knew Dr. Kibenge had positive results for fish #26 and #36, he reran four additional replicas of his tests for those two samples. He obtained one positive result (Ct 36.3 for fish #36 for segment 7). He performed a new extraction of RNA from the remaining gill tissues of samples #26 and #36 and ran five additional replicas, all of which were negative.[412] Dr. Nylund commented in his report that he may not have obtained the same results as Dr. Kibenge "as a result of tissue tropism for ISA virus in *O. nerka* [sockeye], or a combined result of tissue tropism and poor quality of the RNA in the gill tissues sent to us. To my knowledge nothing is known about

the susceptibility of *O. nerka* to ISA viruses, and the tissue distribution of the virus in this species is unknown."[413]

The second sample set consisted of 16 salmon hearts and gills and five herring hearts collected in British Columbia. All samples tested negative for ISAv.[414]

The third sample set consisted of heart and gill tissues from 24 salmonids; the species and location of the samples were not identified in the evidence. Dr. Nylund obtained positive results for segment 7 in one sample of gill tissue. That result was repeatable with Ct values of 34.5 and 35.4. He also obtained one positive result for segment 7 in heart tissue. That result was not repeatable and had a Ct value of 35.5.[415] In his report, Dr. Nylund made the following comment:

> None of the samples were positive when using the Uni-ISAV8 assay. As can bee [*sic*] seen from the positive controls both assay have the same sensitivity for detection of ISA virus RNA from European ISA viruses. This fact raises the question: *What are we detecting with the ISA7 Assay?* Based on my experience with both assays a reasonable answer to this question is that we are not detecting any of the known ISA viruses from Europe (or from eastern North America). A more exact answer requires that we are able to sequence the RNA that is target by the ISAV7 assay. [Emphasis in original.][416]

The fourth sample set comprised gill tissues from several salmonids collected in British Columbia. None tested positive for ISAv, though Dr. Nylund also tested for IHNv and VHSv and found several samples positive for IHNv.[417]

As for whether his positive ISAv results could have resulted from contamination, Dr. Nylund said this:

> I had no sign of contamination. I mean, we have a specially designed lab for this kind of work, and I have also been running just as many negative controls as positive tissues. And it was only these tissues that came up positive. But of course I was not able to sequence any ISA virus from these samples. So I was not able to verify that this was actually ISA virus I was picking out. But you know that the assays that we are using, the real time assay we're using are very specific, so they should only be picking out ISA virus, and maybe not all ISA virus, but most of the ISA viruses that we know.[418]

Nellie Gagné, Gulf Fisheries Centre (DFO), fall 2011

Ms. Gagné runs 40 cycles on a Stratagene machine using a primer probe set developed in-house at DFO, which targets 169 bases on segment 8.[419] Her protocol is CFIA's approved, validated protocol for diagnostic ISAv testing in Canada.

Exhibit 2038 is a chart that Ms. Gagné said was an accurate summary of the testing conducted at DFO Moncton.[420] In relation to Rivers Inlet sockeye, the laboratory tested tissues from the same 48 fish tested by Dr. Kibenge and Dr. Nylund. Ms. Gagné's laboratory had the carcasses, which contained some gill tissue, and extracts of kidney homogenate. (At one point Dr. Miller had the kidneys for these fish, as she was going to test them for parvovirus. She turned the kidneys into homogenate, but her test was interrupted by CFIA seeking the tissue from her for ISAv testing.[421]) CFIA inspectors also collected from SFU and sent to the DFO Moncton laboratory 299 fish that had been sampled at the same time as the original 48 fish.[422] They also collected and sent to DFO Moncton samples (61 smolts) held at the University of British Columbia (UBC) that were collected around the same place and time as the SFU samples.[423] Finally, DFO Moncton also obtained the 20 heart and gill homogenates from AVC, corresponding to the second sample set tested by Dr. Kibenge.[424]

None of the tests on the carcasses and gill tissues from the 48 smolts from Rivers Inlet "showed positive results for ISAV by qRT-PCR (samples tested in duplicate)." However, "the reference gene test results indicated compromising RNA degradation on all samples tested, hence the inconclusive result."[425] The laboratory tests on the kidney extracts from the same fish were similarly negative, and "the reference gene test results indicated compromising RNA degradation on all samples tested, hence the inconclusive result."[426]

Of the 299 additional fish from SFU, 297 hearts and 157 gills were tested for ISAv. None tested positive. The reference gene test for sample quality on 84 samples indicated "compromising RNA

degradation (hence the inconclusive result) and testing was halted at this point for that reason."[427]

Test results for the UBC samples are not in evidence.

For the gill and heart homogenates from Dr. Kibenge's second sample set, the DFO Moncton laboratory first tested one heart sample and found it to be negative. Again, owing to sample degradation the result was called inconclusive.[428] When DFO Moncton tested the remaining homogenates it obtained one weak positive result (Ct 37.79) in one of the duplicate samples.[429] Ms. Gagné testified that normally she would not report this as a positive result. After several attempts, the positive result was not reproducible so she determined it was a false positive.[430] Ms. Gagné explained that "there are occasional signals produced that are just fluorescence from the probe, and that's the reason why you should have always your duplicate well showing a result, because a single signal like that could just be non-specific fluorescence."[431]

Ms. Gagné testified that her laboratory attempted to do cell culture from the samples described above and was not successful.[432]

Ms. Gagné explained why her lab would, and did, interpret all the test results as "inconclusive":

> We reported them as inconclusive based on our policy. Samples are tested additionally for the quality of the RNA tissue, and in this case all samples submitted show extensive to total degradation of RNA. So for that reason we would not reject a positive result if we had found one, we would have investigated and followed our own policies, but in the case of negative results, because of the possible degradation of any material in there, we have to declare the samples inconclusive.[433]

Ms. Gagné explicitly adopted as accurate a description of the samples found in an email from Anne Veniot, section head of the Aquatic Animal Health Group in Moncton, to Dr. Stewart Johnson (copied to both Ms. Gagné and Dr. Wright) which said: "Absolutely every sample we received showed signs of degradation … much more than what allows for conclusive testing."[434] Ms. Gagné told me that news releases saying the negative testing was "conclusive" must have contained qualifying statements in the supporting material.[435]

As Dr. Wright explained in an email to Dr. Johnson, a test might be "negative" from an analytical perspective (i.e., the test was performed and gave a negative result), but from a diagnostic perspective it must be qualified or reported as inconclusive because of the degradation of the test material.[436] In testimony, Dr. Wright initially confirmed that "the interpretation of the screening tests that we've done should be considered inconclusive because of the degradation of those samples."[437] However, later in his testimony, when confronted with a transcript of a news briefing held December 2, 2011, in which both he and Mr. Stephen called samples from the 48 Rivers Inlet sockeye "negative" rather than "inconclusive," he modified his answer:

> Okay. Subsequent to that email [from Anne Veniot, described above], there was [*sic*] discussions with Anne Veniot, who is the head of section at GFC [Gulf Fisheries Centre] and she agreed that she had answered too quickly and, in fact, based on the testing that was done, although there was degradation, it wasn't nearly as severe as the original samples that we received. So, in essence, what we're saying is the results for those kidney extracts for the 48 of the original are negative, negative analytically and we would interpret them as negative diagnostically.[438]

When referred to the same chart summarizing the laboratory tests performed at DFO Moncton to which Ms. Gagné testified (and said the "inconclusive" results were correct), Dr. Wright said there were several versions of this chart "and it was corrected for any discrepancies." Further, he said this was not a recent change in interpretation.[439] For his part, Mr. Stephen said, "On my understanding from the information I was provided … those samples were negative."[440]

Dr. Klotins said that it is CFIA's role to interpret Ms. Gagné's results; those results are just one factor in its investigation. She testified that CFIA viewed the results of the 48 kidney extracts as conclusively negative:

> [W]e take those test results and we interpret them, given what we know of the possibility of ISA being out there, the possibility that, you know, this is a susceptible species, other

> information about ISA. So basically we have an idea already of whether these results can be interpreted with any sort of meaning. As I mentioned to you before, that *not all the results were inconclusive, I need to repeat again that the 48 kidney samples were negative for sure*. And in terms of inconclusive on those 48 fish, inconclusive doesn't mean the samples were not negative, as they're not just sure if they could have been positive. [Emphasis added.][441]

Dr. Kibenge expressed concerns about Ms. Gagné's real-time RT-PCR methods, noting that she runs her machine only for 40 cycles, that she uses the Stratagene system that is associated with higher Ct values (so low infections may be missed if she cuts off the machine at 40 cycles), and that she uses a primer probe set with a long nucleotide sequence that may be less sensitive than the tests used by other researchers.[442] Ms. Gagné responded that her machine was set to work properly, that she runs only 40 cycles because experience has shown her that nothing usually shows up after that, and that she received the same results when testing samples with both the DFO-validated assay and the Snow and others (2006) segment 8 assay.[443]

Dr. Kristina Miller, Pacific Biological Station (DFO), fall 2011

Dr. Miller runs 45 cycles and uses a combination of assays targeting segment 8 (roughly 104 bases, 70 bases, and 60 bases) and segment 7 (Plarre and others 2005, described above).[444] She used two different machines and two different methods to conduct her tests. One of the methods she used, which differs from the methods used by the other witnesses, is run on a machine called a Fluidigm BioMark. She describes this machine as "high output." It allows her to amplify 96 different biomarkers on 96 samples all at once.[445] To do that, the volumes of samples used are very small, requiring a "pre-amplification" step at a very low primer concentration (1/20th of what is used in a typical assay). This pre-amplification step then allows her to pick up lower copy numbers of viruses more effectively (i.e., at lower Ct values).[446] She has also run samples on an ABI 7900 machine without a pre-amplification step.[447] The same positive samples run with the pre-amplification step on the Fluidigm system began fluorescing at a Ct value of approximately 25, whereas the samples without pre-amplification on the ABI 7900 system began fluorescing at a Ct value of approximately 35.[448]

Dr. Miller testified before me twice. The first time was on August 24 and 25, 2011, when she was called to give testimony about a mortality-related genomic signature (MRS) she had identified in Fraser River sockeye that may be linked to both a parvovirus and pre-spawn mortality in sockeye (see discussion in Volume 2). During the course of that testimony, Dr. Miller said that she had tested MRS-positive fish for ISAv.[449] When she appeared before me the second time, Dr. Miller explained why she went back to retest her samples:

> When I testified here before, I talked about running tests for various different known viruses, in association with our mortality related signature, and I had testified that we had tested for ISA and it was negative. And so when I heard about these initial potential positives results, I went back to what we had done previously, and looked at what assay we had used, and realized that we had used an assay to segment 6, which does not necessarily pick up all strains of ISA.
> …
> So I was concerned that, you know, we hadn't done enough due diligence to make sure that indeed our fish were negative. So I embarked to try to obtain the primers that Dr. Kibenge used, and [the primers] that our DFO validation assay [uses] as well. I was not able to obtain any of those primer probe sets [until mid-December 2011[450]], so we went to the published literature and we got the papers from Plarre, and from Snow and Christiansen paper that was a revision of a segment 8. We ordered five different TaqMan assay primer probe sets, and we started running those on our own fish that we had run on microarrays previously, because of course our question was do we see any indications of ISA in our fish, and do they have any association with our signature?[451]

Dr. Miller said that she attempted to get a positive control from within DFO but was not able to get one, and so she ran her assays without one. She said the one advantage of this is that there

was nothing in her laboratory to contaminate her assays: "So if we obtain a positive and are able to sequence a positive, it is a real sequence positive."[452] Dr. Miller did indeed find and sequence positive results from four of the five primer sets she used and matched the amplified product to ISAv. She obtained the most positive results using the assay from Plarre and others (2005) for segment 7. The products obtained with this assay were divergent from known ISA strains, but also 95 percent similar to known strains.[453] Some short sequence strands detected with a segment 8 assay were 100 percent similar to known Norwegian strains of ISA.[454] Dr. Kibenge commented that "the fact that [Dr. Miller's sequences] were obtained without any positive control and when we have blasted the GenBank, which has most of the published ISA virus sequences, I mean, I think that result is credible."[455] Dr. Miller compared the sequences she obtained to those that Dr. Molly Kibenge obtained, finding differences between the two sets of sequences.[456]

Dr. Miller initially tested gill and liver tissues from 160 Fraser River sockeye smolts collected in the years 2007–10. She found the greatest prevalence (number of samples infected) in liver tissues using the Plarre and others (2005) segment 7 test (18 percent), and when she combined all the assays she used, the prevalence of positive tests was 25 percent.[457] In gill tissue, Dr. Miller obtained an overall prevalence of 17 percent positive tests.[458]

Dr. Miller then tested liver tissues from adult Fraser River sockeye (and one subset of pink salmon[459]) from 1986, 1992, 1993, 1999, and 2001, finding positives in all groups, with a prevalence of 5 to 16 percent in different years.[460] She said, "[T]he patterns of PCR that we observed between the different primer sets were very similar to what we had seen now, where we see a lot of positives for ISA-7 and fewer positives for the ISA-8 primer sets."[461]

Dr. Miller had access to farmed chinook salmon from Creative Salmon, sampled in the winter of 2010. She tested livers and gills from those fish for ISAv. She found Ct values and prevalence (25 percent) similar to the tests she had performed on wild sockeye.[462] Dr. Miller noted that, in her positive tests of farmed chinook salmon, gill and liver tissues for the same fish did not necessarily both test positive.[463]

Dr. Nylund expressed concern about the pre-amplification step that Dr. Miller uses prior to running her samples in the Fluidigm BioMark machine. Although he admitted that he has no experience with that method,[464] he said that adding the primers to a sample in a pre-amplification step could introduce "artificial genome that could match part of the assay" in the real-time PCR part of the test, causing non-specific amplification.[465] Dr. Nylund further noted that parts of the sequences obtained by Dr. Miller were 100 percent identical to the primers she used, indicating that she may have been replicating primer, and in one sequence there was a "stop codon"* in a place where it should not be.[466]

Dr. Miller did not agree with Dr. Nylund's concern about non-specific amplification. She said, "[W]e didn't make this pre-amplification step up, by the way; this is something that was developed for use in the Fluidigm system."[467] She said that, in other testing she has done, she has run tests without a pre-amplification step on the ABI 7900 machine and with a pre-amplification step on the Fluidigm machine and obtained "highly corroborative results." She said, "I do not believe that pre amp is any issue in terms of getting false sequences."[468] Dr. Miller also noted that the concentrations of primers used in the pre-amplification stage were "1/20th of the concentration that anyone would use to amplify the product in a normal reaction."[469] Further, she said that once she obtained Ms. Gagné's primer, she tried to amplify PCR product from her samples using Ms. Gagné's primers on a conventional PCR, starting with the same pre-amplification step used in her previous tests. She was not able to obtain any positive results with Ms. Gagné's primers, despite pre-amplification.[470]

Dr. Miller acknowledged there was a stop codon in one of her sequences,[471] but counsel moved on to another question before she could offer further thoughts on why or how that might have occurred.

After Dr. Miller told her colleagues in the Aquatic Animal Health Section at PBS about her

* A stop codon is a nucleotide sequence that normally appears at the end of a coding sequence, not in the middle of a functional protein sequence (Are Nylund, Transcript, December 15, 2011, p. 100).

initial results from testing Fraser River sockeye, they decided to try to replicate her results:

> Initially we provided a set of positive and negative blind samples on to Dr. Kyle Garver, who is a virologist that I testified with previously. He's at the Pacific Biological Station, and he ran an assay – he ran basically the same assay that Nellie Gagné has run, the validation assay, and he also ran our ISA-7, the Plarre-7 primer sets that we use, and he – he ran it under two different conditions under their – using the protocol that is part of the validation protocol, and then also using the protocol that we use in our lab.
> …
> So he ran basically the validated assay that Nellie uses, and the ISA-7 Plarre assay and he was able – he was not able to pick up any positives using the DFO validated assay, but he did pick up a positive of ISA-7 using our assay with our pre-amplification.[472]

The one positive that Dr. Garver picked up was repeatable in all three replicates.[473]

Dr. Miller also sent 96 samples of liver tissues to Ms. Gagné's lab for testing with the DFO Moncton's validated assay. Ms. Gagné reported that all these samples tested negative with her assay.[474]

In addition to ISAv testing, Dr. Miller's laboratory has used functional genomics to gain information about the physiological condition of the fish in her laboratory. When Dr. Miller testified in August 2011, she described the microarray technology that allowed her to identify an MRS in Fraser River sockeye. She described it as a molecular tool that allows one to look at tens of thousands of genes in a tissue sample all at once to see which genes are turned on and which genes are turned off. Information about the physiological condition of the fish can be gained by looking at the functions of those genes.[475] Although it is a novel approach to studying disease, she has used it to look at a number of pathogens.[476] In November or December 2011, researchers in her laboratory applied these techniques to look for genes that are correlated with the Ct values she obtained for the ISA segment 7 test.[477] She described the results as follows:

> [B]asically what we found was that there was a very strong genomic response to fish that carried this ISAV-7 sequence. And if we did a functional analysis, we looked for what kinds of pathways were being stimulated in that functional response. We found that the very top hit was influenza infection.
>
> So this is an influenza virus, and that really speaks to the fact that these fish are responding in an influenza-like response to this virus.[478]

Dr. Miller went on to say that, although the populations of fish from which she sampled may not be suffering disease and mortality related to ISA, there is a biologically consistent, flu-like response in them to whatever it is she is detecting with the ISA segment 7 test.[479]

Management responses to presumptive positive ISAv test results

CFIA and DFO take no management actions in relation to negative results of ISAv tests. The sections below set out the evidence about steps taken by CFIA and DFO in response to reports of presumptive positive tests for ISAv.

Response to Dr. Molly Kibenge's results

Dr. Jones characterized Dr. Molly Kibenge's results from 2004 as being "some lab results that indicated the possibility of ISA." He said DFO knew the significance of those results:

> We were obviously aware of that, so we conducted, and we were aware of the significance of that, as well. This is not something we treated trivially. We conducted a lot of confirmatory tests, and there's – as a result of those tests, we found that we could not confirm the findings. And so as is the result of many things that we look at, we determined that that was a negative result and we carried on.[480]

As noted above, Dr. Jones was of the view that the positive results obtained by Dr. Molly Kibenge

in relation to 64 samples of Cultus Lake sockeye were false positives because the tests could not be repeated consistently by other laboratories. He did not initiate or suggest that further Cultus Lake sockeye be sampled and tested for ISAv, and he was (as of December 2011) unaware if anyone in the virology program at DFO had done so.[481] Dr. Jones also testified that he did not advise local First Nations, who would have assisted in the collection of those spawning Cultus Lake sockeye, about the ISAv results; nor did he advise the Cultus Recovery Team, because he saw no evidence of the disease ISA.[482] The circle of people within DFO who knew about Dr. Molly Kibenge's results in 2004 was small (see discussion below), and Dr. Jones said he could only speculate that no one initiated a surveillance program to see if she was right because it was "decided [that] this was not significant because of our determination that this was not a positive finding."[483]

Dr. Jones also testified that, based on "what we know now, there's a very good reason and a highly compelling reason to explore exactly what [the 2003–4] tests were finding." He said:

> Had Dr. Molly Kibenge stayed in the lab, this would have been an important part of the further research she would have conducted, is trying to understand why when we send samples to another laboratory that they come back negative, why is that? It would be a very important part of the research, to explore the inconsistencies in the tests that we were using."[484]

Dr. Jones testified that back in 2003–4, his colleague, Dr. Garth Traxler, a virologist, was aware of Dr. Molly Kibenge's results, as was the manager of DFO's diagnostic laboratory at PBS, Dr. Dorothy Kieser. He said that Dr. Garver was hired shortly after Dr. Molly Kibenge left and that he was also aware of her results.[485] (Dr. Johnson, the current head of the Animal Health Section, was not working at DFO until much more recently.[486]) Dr. Jones testified that, after Ms. Gagné was unable to reproduce Dr. Molly Kibenge's findings, he, Dr. Traxler, and Dr. Kieser decided that the findings "were not representative of ISA."[487] Dr. Jones said that it was not until mid-October 2011 that he discussed Dr. Molly Kibenge's earlier findings with his then superiors, "and it was obviously relevant that the documents be included [for disclosure to this Inquiry] at that point."[488]

Correspondence continued between Dr. Jones and Dr. Molly Kibenge until January 2006, in which they discussed the possibility of preparing the results of her work for publication.[489] Dr. Jones testified that he did not hear from Dr. Molly Kibenge again after January 2006 until November 2011, when she contacted him asking if she could publish the results, and he said "no."[490] Dr. Jones gave a number of reasons for refusing Dr. Molly Kibenge's request:

> The timing seemed to be more than just a coincidence, it was seemingly to take advantage of the events. And it was a surprise to me that when I received the manuscript it hadn't changed since the version that we'd seen in 2004. So it was – it did not mention, for example, the Nellie Gagné results, it didn't clarify the inconsistencies in which the PCR results had been obtained, the difficulty to demonstrate reproducibility, it didn't clarify the results, for example – or it did include, despite the weakness of the sockeye salmon, the Cultus sockeye salmon results, these were posed or presented as positive findings in the paper, and I – I had to judge this work based on my own experiences as a scientist and as an author of a lot of scientific papers, many of which are published in the peer-reviewed literature. I sit on an editorial board of an international journal in fish disease, and I understand what is necessary to maintain, or what are the high standards that are necessary to maintain in order to publish this kind of work, and I felt that this manuscript didn't come close to achieving those standards.[491]

Dr. Frederick Kibenge testified that it was he who asked Dr. Molly Kibenge to see if the paper could be published. He said that, when he encountered such a strong reaction from CFIA to his positive ISAv tests, he wanted to make the prior test information available to the agency, but his inclination was to first check with Dr. Molly Kibenge about the publication possibility: "When the information came back that it would not be published, then I thought that at least we could make this information aware to CFIA."[492]

Dr. Frederick Kibenge also noted the following in relation to the dismissal of Dr. Molly Kibenge's positive test results for ISAv in 2003–4:

> What people miss here is that this study was not only doing ISA, it was actually testing for three different viruses. The other two viruses, all the results were negative. But ISA was being done by the same person. So the negative results were quickly accepted. The positive results were considered contamination. If contamination is because of the activities in the lab, the person doing the work, and so on, I wouldn't expect that contamination to be virus-specific, or ISA-specific.[493]

Response to Dr. Frederick Kibenge's results

Dr. Kibenge made two notifications to report positive findings of ISAv in Pacific salmon to CFIA under the mandatory reporting regime of the *Health of Animals Act*. Those notifications relate to the SFU samples and the Harrison River samples.[494] He made two further notifications that he was testing for ISAv; as discussed above, those results were negative.[495]

For the first notification related to the SFU samples, Dr. Klotins testified that CFIA took several actions:

- It asked Dr. Kibenge for backup samples that CFIA could test; there were none.
- It started to trace back where the specimens came from, how they were collected, and whether there were related samples.
- It took measures to locate and issue quarantine orders on related samples and have them collected and shipped to DFO Moncton for ISAv testing.
- It identified that some samples from the same specimens went to Dr. Nylund's lab in Norway and requested information about those samples from Dr. Nylund.[496]

On the second notification, involving the Harrison River samples, CFIA took similar actions:

- It requested backup samples from Dr. Kibenge.
- It traced back the samples to determine where the fish came from, what condition they were in, and whether they exhibited any clinical signs.[497]

Dr. Klotins explained that CFIA knew from the start that confirming positive results in these notifications would be challenging if not impossible because of chain-of-custody concerns. Still, CFIA moved to take control of the samples:

> We basically knew right from the beginning we probably wouldn't be able to confirm the results [of positive tests for ISAv that had been conducted by non-government laboratories], but we wanted to get an idea of whether ISAV actually exists out there or not, and which is why we did some of the testing, corroborative testing.
> …
> [We knew from the beginning we couldn't confirm the results] because we had no oversight on the collection. So the CFIA, because our decisions are very important, can affect multiple stakeholders and partners, including international trade, and because these were wild fish, so it would affect the commercial fishing industry in particular, we need to be very sure that when we make decisions about calling an area or a particular population of fish positive that they truly are positive.
>
> So as part of that process, we provide oversight in the collection, the shipping, in the approved laboratories and so we can be sure of the results applied to those populations in terms of our decision-making[.][498]

Both Dr. Routledge and Ms. Morton have requested a return of their samples from CFIA.[499] At the time of the hearings in December 2011, Dr. Klotins said CFIA had not decided whether the samples would be returned.[500] She said that, if CFIA did not return the samples, this would not have a chilling effect on reporting suspicions of disease to CFIA because "to encourage reporting we do offer compensation for a number of things, including animals that are hurt or destroyed because of sampling," and that compensation could be made to a researcher if their animals were destroyed.[501] As noted above in this chapter, the compensation available under the *Health of Animals Act* is based on the market value of the animal in question minus the value of its carcass. It is difficult to imagine

this formula providing any compensation to Dr. Routledge for sockeye smolts collected in Rivers Inlet, or to Ms. Morton for the dead adult salmon she collected from the Harrison River.

On November 4, 2011, Dr. Klotins suggested to Dr. Con Kiley, acting director of CFIA's Aquatic Animal Health Division and spokesperson on the ISAv issue, that CFIA advise all labs in Canada and the US not to test any more samples of wild finfish from the Pacific Ocean for ISAv.[502] Dr. Klotins said she made this suggestion out of a concern for chain of custody and a preference to have CFIA oversight of testing, given that CFIA is "by legislation the final arbiter of fish health status in Canada." However, she said her suggestion was not acted upon.[503]

Also in response to the notifications from Dr. Kibenge, Dr. Klotins said that CFIA "started the investigation of why we couldn't corroborate results."[504] As early as October 19, 2011, CFIA had put together "[a] small team, which includes staff from the Aquatic Animal Health Division (AAHD), CFIA's Science Branch and DFO" to consider "the assessment of the laboratory at the Atlantic Veterinary College."[505] I heard evidence about the laboratory assessments conducted by CFIA. While the manner in which the laboratory assessments were conducted was controversial, it is not necessary for me to resolve that controversy. Other evidence I heard has led me to make a recommendation about the relationship between DFO and CFIA.

By October 25, 2011, CFIA had determined that it needed to "start discussing the potential requirements for surveillance activities and design" first within the agency and then including DFO.[506] CFIA's draft surveillance plan is discussed above in the section on fish health management in wild salmon.

An email written by the acting regional director of CFIA for the BC Mainland and Interior Region, on the day after Canada and British Columbia hosted a joint news conference and technical briefing on ISAv, stated the following:

> It is clear that we are turning the PR tide to our favour, – and this is because of the very successful performance of our spokes at the Tech Briefing yesterday, – you [Con Kiley], Stephen [Stephen], Peter [Wright], and Paul [Kitching] were a terrific team, indeed. Congratulations!
>
> One battle is won, now we have to nail the surveillance piece, and we will win the war, also.[507]

When this email was put to Dr. Klotins, she testified that "[w]e may get a little exuberant internally," but there is not a "particular viewpoint that we're following."[508] Similarly, Mr. Stephen spoke to DFO's perspective on the investigation, saying, "[W]e're not about disproving anything; we're about proving the facts."[509]

Dr. Klotins summarized the status of the CFIA investigations into both Dr. Kibenge's notifications and Dr. Miller's notification (see discussion below) as of the time of the hearings in December 2011:

> We've basically [done] all the work on the samples. The results have come back. We've interpreted them as negative at this point, and that was for the first notification. That included the samples from SFU. The same with the second notification from fish that were sampled in Weaver Creek, Harrison River, and we are still continuing our investigation with the two notifications that involved test results from Kristi Miller's lab.
>
> In terms of the samples from SFU, we're in the process of deciding to lift the quarantine orders and making a decision about returning – returning samples as requested by Dr. Routledge, and we're continuing our investigation with the Kristi Miller samples and we're also putting together a surveillance program.[510]

Dr. Kibenge testified that, in the fall of 2011, after he reported positive test results for ISAv to CFIA, he felt he was "attacked" by government (though he could "understand where the government is coming from") and that there had been a lot of pressure put on him and his university as a result. He gave his view, based on his past experience in reporting negative results, that he would not have faced similar scrutiny if he had reported negative results of an ISAv test.[511]

Response to Dr. Miller's results

During the week of November 14, 2011, Dr. Miller advised her superior (Mark Saunders) that her laboratory was conducting ISAv testing on her samples.[512] Two meetings ensued on November 18 and 24, 2011, described by Dr. Miller as follows:

> I had two meetings with our Fish Health Group, and the names of the people are listed there [on

Exhibit 2056: Karia Kaukinen, Mark Saunders, Mark Higgins, Kyle Garver, and Stewart Johnson], as well as Mark Saunders, who's the division manager. He called the meetings.

These were meetings to let them know what we were doing and what our results were, and on the November 18th meeting it was simply that first positive sequence that we – I had identified and the PCR results that we had. The second meeting we had more sequence information. Between the first and second meeting, Kyle Garver had taken 10 of our samples and done some testing as well, so he had some results to report.

At the end of the second meeting, because we had had the second segment of ISA that had been sequenced as positive, it was decided that we should contact Ottawa about this, and so Stephen Stephen in Ottawa was contacted, and there was another person in the NAAHP program, but I didn't get the name of that person, that was on the phone call, and we basically told them the results that we had.

There was an ensuing discussion about whether this was really ISA or simply an Orthomyxovirus of some other sort, and a discussion about how one defines an ISA virus compared to, you know, other Orthomyxoviruses ... So anyway, this is an ensuing discussion, but I believe it was decided that if it was the – by definition of the definition that CFIA uses, that it needs to be both cultured and culturable and it needs to validate with their validated primer set. If it doesn't meet those criteria ... then it's not classified as ISA ...

I don't think that Stephen Stephen, in Ottawa, was very pleased that we were doing this testing, because we are not the validated lab. You know, we're – and I tried to explain, you know, we're doing this in a research context, we're looking at a variety of different pathogens, ISA being one of them, and I fully agreed that anything that we get that's positive should be validated in one of their testing labs. But I – basically, there was the feeling that the labs that are not NAAHP labs should not be looking at disease ... There was the general feeling that we shouldn't be looking so closely at disease if we didn't – if we weren't one of the NAAHP labs and didn't understand the ramifications...

[W]e discussed the need to share results with Nellie Gagné's lab, but it was told to me that the decision on whether or not to share this with CFIA was Stephen Stephen's decision to make, not – not certainly mine....

One of the issues that had been brought up, and it had been brought up with Fish Health previously and it was brought up again in these discussions, is that if something is classified as being ISA that CFIA will come and basically take all the samples in the lab away, and as a way – as their way to control for disease spread.

I have a very large genomics program that relies on the very extensive sampling inventory that we have, and I was very concerned that that would be one threat if this was classified as ISA, that I could lose the samples that I rely on for my genomics program.[513]

Dr. Miller said that Mr. Stephen told her that there were "repercussions of new diseases on wild fish and their price and exchange between countries," and that she "should not be undertaking research on something if [she] didn't understand the ramifications of what the results could do."[514] She said no direct restrictions were placed on her research, and that "[n]obody said that I could not continue on with my research, but I think that there was the recognition that this needs to be something that's discussed in the department in the future."[515] She said she felt intimidated:

I personally took a level of intimidation at the idea of my samples perhaps being taken away. I don't know that he meant – you know, I mean, it was said to me by a number of different individuals over again, and of course I did read about what happened to Rick Routledge's samples in his freezer in his graduate students' program when CFIA took away all those samples and they weren't able to continue with the research that they were doing.

Of course, I look at my own program and I think I have a lot to lose here if CFIA decided to sweep in and take all my samples. I've got thousands of samples and a very big program in jeopardy, so whether Stephen Stephens [*sic*] meant that or not, I certainly have been very concerned about that.[516]

Further, Dr. Miller said it was "fairly recognized in the department that we weren't talking about ISA over email."[517] Dr. Miller also talked about her alienation in the department: "I'm pretty alienated in the department at the moment so the end result of all of this is I'm not included in any conversations about any of this so once I reported this information on the 24th, nobody in the department talked to me about disease or ISA after that."[518] She clarified that since November 24, she has had discussions with Ms. Gagné about testing samples, but that no one in a managerial position in DFO's Pacific Region is talking to her about ISA or DFO's approach or response to ISA issues.[519] Dr. Miller, along with others, received an email from Mr. Saunders on December 8, 2011, attaching a draft research and monitoring plan related to ISA and seeking input to be forwarded to Mr. Stephen.[520] Dr. Miller testified that, although she received this email, she was not involved in any conversations related to this proposal.[521]

Mr. Stephen testified that he told Dr. Miller "that coming with results from a research angle without proper confirmation of those results from a diagnostic perspective could have dire consequences."[522] Mr. Stephen further testified as follows:

> What I said is that perhaps until CFIA starts their investigation, we should defer further sampling, but I do not have any direct functional or direct authority over Dr. Miller. It was a suggestion, because recognizing trying to chase a number of different results if they're coming constantly, it makes it hard to follow up on an investigation. I did talk to Mark Saunders several times after that call and suggested that in advance or in preparation for CFIA's findings we should plan and have a strategic plan about what questions we have to answer based on Dr. Miller's finding, where we should go with further research, where funding could come from, those sort of things. And Mark Saunders has sent me an e-mail, I believe it was December 8th, relating to referencing that and in consultation with CFIA's plan for surveillance.[523]

Mr. Stephen explicitly did not agree with Dr. Miller's characterization that she should not be conducting ISA research because she did not understand the ramifications. He said he told her that "in the context of a reportable disease … research can tie into regulatory research as we are doing already within the scope of the NAAHP program," and that he spoke to her supervisor about bringing her research into the regulatory program.[524] Although Mr. Stephen does not have any direct functional or reporting authority over Dr. Miller, he does control a large component of her research budget.[525] He explicitly did not accept that his remarks could be interpreted as intimidation.[526]

Mr. Stephen also said he was "surprised that Dr. Miller had not come forward with her original findings – or her findings earlier, because she was obviously aware of an ongoing investigation, and that [it] was important to notify CFIA." He said that she "had not come forward to CFIA and properly notified them in an appropriate and timely manner."[527] After the call on November 24, Mr. Stephen said he called CFIA and told the agency of Dr. Miller's results, and left it with the agency to speak to her further.[528]

Dr. Miller testified that between November 24 and the date she testified (December 15, 2011), she was in contact with CFIA officials about her results.[529]

Dr. Klotins testified that CFIA was investigating Dr. Miller's results and subjecting her research methodology to the same scrutiny as for Dr. Kibenge's laboratory at the AVC.[530] That investigation might include an assessment of Dr. Miller's laboratory – that decision had not been made at the time of the hearing.[531] Dr. Klotins said: "It would be more an assessment of whether the PCR methodology is providing the information or the results that were presented" so that CFIA can identify areas "where the errors can occur."[532]

Communications and reporting of ISAv test results

Dr. Klotins and Mr. Stephen spoke about Canada's approach to reporting test results for fish diseases to the public. Dr. Klotins said that the CFIA does not report results right away to the public, "but we did notify our trading partners and we did notify [provincial] government[s] in Canada" after being informed of Dr. Kibenge's results.[533] Mr. Stephen said he has been working in regulatory reporting and surveillance for 20 years both at CFIA and DFO, and

that "[t]he Government of Canada does not routinely report presumptive or preliminary results until we can confirm those results."[534] Dr. Klotins said that, because the presumptive positives obtained by Dr. Kibenge could never be confirmed because of chain of custody issues, if the results had not been reported to the media by SFU in a news conference on October 17, 2011, "it is possible the Canadian public would not have known."[535]

In the fall of 2011, Canada made a number of different communications about ISAv tests, which are in evidence before me and are summarized below.

October 21, 2011	A CFIA Information Bulletin advised that CFIA in collaboration with DFO was investigating recent reports of ISA in wild sockeye in British Columbia. [Exhibit 2026]
October 24, 2011	The minister of fisheries and oceans and minister of agriculture and agri-food made a joint statement: "After initial investigations, we are concerned that proper protocols may not have been followed in the testing and reporting of these findings. CFIA and Fisheries and Oceans Canada are working to assess the results through scientifically sound and internationally recognized procedures, which must include additional testing to verify the presence or absence of ISA virus in these samples." The joint statement said that in the last two years DFO has tested over 500 wild and farmed salmon in British Columbia for ISA and that from 2003 to 2010, BCMAL has tested over 4,700 farmed salmon for ISA. All these samples were negative for the virus. [Exhibit 2028]
November 8, 2011	A Government of Canada news release stated, "Based on analysis conducted at the DFO national reference laboratory, there have been no confirmed cases of infectious salmon anaemia in wild or farmed salmon in BC. "DFO has tested all 48 samples received as part of the original investigation and the results are all negative for the virus. These results are consistent with the findings of an independent laboratory in Norway, which also tested samples associated with this investigation and provided a report to the CFIA." The news release went on to say that over 5,000 BC wild and farmed salmon have been tested by the province and DFO and "none have ever tested positive for the disease."[Exhibit 2029]
November 8, 2011	CFIA, DFO, and the Province of British Columbia held a joint news conference (which was also referred to by witnesses as a "technical briefing") to discuss the results of testing to that date. During the course of the briefing, both Mr. Stephen and Dr. Wright confirmed that DFO was calling the 48 kidney samples from the Rivers Inlet sockeye conclusively negative. Dr. Con Kiley from CFIA said that the one positive result that Dr. Nylund obtained from gill tissue of those same 48 fish is considered a negative by CFIA because it was not repeatable. Speakers included Dr. Con Kiley, director, National Aquatic Animal Health Program, CFIA; Mr. Stephen; Dr. Wright; and Dr. Paul Kitching, chief veterinarian officer for British Columbia. [Exhibit 2030]
November 9, 2011	The federal minister of fisheries and oceans (Keith Ashfield) and the provincial minister of agriculture (Don McRae) released a joint statement, referring to the discussion at the technical briefing the day before. Minister Ashfield said in part, "Because some have chosen to draw conclusions based on unconfirmed information, this has resulted in British Columbia's fishing industry and Canada's reputation being put at risk needlessly." He relied on the "over 5000 fresh, properly stored and processed salmon" tested by the province and DFO in the past to say there has never been a confirmed case of ISA in British Columbia. Minister McRae said in part, "Reckless allegations based on incomplete science can be devastating to these communities and unfair to the families that make a living from the sea. Since Premier Clark is currently on a trade mission to China, I have personally asked her to reassure our valued trading partners that now as always BC can be relied upon as a supplier of safe, sustainable seafood." [Exhibit 2089]

cont'd

November 9, 2011	CFIA issued an information bulletin stating there are no confirmed cases of ISA in British Columbia and repeating information from the November 8, 2011, news release. [Exhibit 2021]
November 10, 2011	CFIA and DFO held a technical briefing for provincial government and industry representatives to discuss "Who are we and what are we doing; Documents on the CFIA website; The CFIA reporting to the OIE; What's different from the normal suspected cases; Investigation to date; Market access issues; Surveillance going forward." [Exhibit 2138]
December 2, 2011	The federal minister of fisheries and oceans (Keith Ashfield) made a statement titled "Negative Infectious Salmon Anaemia Test Results in British Columbia Salmon." He said, "After Canada's reputation has needlessly been put at risk over the past several weeks because of speculation and unfounded science, additional in-depth, conclusive tests, using proper and internationally recognized procedures, are now complete and we can confirm that there has never been a confirmed case of ISA in BC salmon, wild or farmed." He again referred to the over 5,000 fish previously tested by provincial and federal officials. [Exhibit 2004]
December 2, 2011	CFIA released an information bulletin saying, "The Government of Canada in collaboration with the Province of British Columbia has completed testing all samples related to the suspected infectious salmon anaemia investigation in BC. Based on the final results, there are no confirmed cases of the disease in wild or farmed salmon in BC." [Exhibit 2090]
December 2, 2011	CFIA, DFO, and the province held a joint news conference / technical briefing describing test results that DFO Moncton performed on samples related to the first and second sample sets tested by Dr. Molly Kibenge. Speakers included Dr. Kiley, Mr. Stephen, Dr. Wright, and Dr. Kitching. [Exhibit 2032]

Witnesses, particularly Mr. Stephen and Mr. Wright, faced many questions during the hearings about the following:

- why Canada reported inconclusive results as negative results;
- why Canada reported Dr. Nylund's positive results as negative results;
- why Canada omitted any mention of Dr. Kibenge's presumptive positive from samples collected in the Harrison River in the October 24 joint statement of Minister Ashfield and Minister Ritz and during the November 8 news conference; and
- why Canada omitted any mention of Dr. Miller's results during the statements made and news conference held on December 2, 2011.

I discussed the evidence of witnesses about inconclusive results above in the section of this chapter setting out Ms. Gagné's laboratory results.

Specifically in relation to the November 9 joint statement of Minister Ashfield and Minister McRae, Mr. Stephen said he didn't know how a positive from Dr. Nylund was consistent with negatives from Canada.[536] Dr. Klotins said: "That would have been an assessment by the CFIA, an assessment of all the information we had gathered to date, an assessment of whether those findings were true positives or false positives, and also in terms of the negative testing, how confident we could feel in that."[537]

On the failure to mention the positive results in Dr. Kibenge's second sample set in the October 24 statement, Mr. Stephen said: "Because we do not report, as I mentioned earlier, preliminary results. The results have to be confirmed through our national reference laboratory, and my understanding as of this date there were none of those tests, and as of this date today, none of those tests have been confirmed from our national reference laboratory."[538] Similarly, concerning what was said at the November 8 news conference, Mr. Stephen testified before me as follows: "I'll repeat that I was aware of presumptive positive. We had not confirmed that [in the national] reference laboratory ... I'll repeat that we don't share presumptive positives in the normal course of business, no."[539]

In relation to why there was no mention in the December 2 statement of Dr. Miller's positive results, Mr. Stephen said this:

> We were aware of [Dr. Miller's results], but again, as I repeated earlier, those are only preliminary results.
> …
> Preliminary results are never released. We have to confirm them. We've gone and done tests for the first set of results Dr. Miller produced. We are now going to be producing – trying to confirm the preliminary findings of the second set. We may in fact at some time come across ISA in B.C., and we will report according to these to CFIA. But until such time, preliminary results will not be reported as positives and will not be made public.[540]

I note that none of the government communiqués discussed the results obtained by Dr. Molly Kibenge in 2003–4, or the presumptive positives found by Dr. Nylund in the third sample set he tested. Mr. Stephen did indicate that DFO is aware of multiple sets of presumptive positives, but reiterated that until confirmed those positives do not mean much:

> I don't know why people are calling it a crisis. As I've repeated multiple times in the last day and a half that we have not confirmed in any way, shape or form that ISA is actually in B.C. yet. There are presumptive positives, there are suspect positives of results from a number of different laboratories, but we have not been able to confirm, to provide enough information for CFIA to render a decision that ISA is in B.C.[541]

I also note that several of the communiqués referred to the tests performed at DFO Moncton as "proper and internationally recognized" procedures, presumably in contrast to procedures used by non-government laboratories. However, the evidence before me is that both Dr. Kibenge and Dr. Nylund's laboratories used internationally recognized tests recommended in the OIE Aquatic Manual. In contrast, both DFO Moncton and the BC Lab used in-house tests that are not – on the evidence before me – internationally recognized in the sense that they are used anywhere outside those specific laboratories. In DFO's case, the test has been validated according to an OIE validation protocol.

Findings

Wild Fraser River sockeye

From my review of evidence about the regulatory tools to address fish health management and the work under way to assess the health of Fraser River sockeye, I conclude that the Department of Fisheries and Oceans (DFO) needs to take a more proactive role in conducting research into the health of wild Fraser River sockeye. The health of wild salmon stocks needs to be DFO's number one priority in fish health matters. DFO's diagnostic work and surveys to support the Canadian Food Inspection Agency's (CFIA) goal of proving Canada's seafood products are safe for trade purposes should not overshadow the department's mandate for the conservation of marine resources.

DFO's conservation mandate includes the mandate to address fish diseases that may threaten wild salmon stocks. It extends beyond reportable diseases to non-reportable diseases, and to the discovery of new and emerging diseases. In my view, DFO should be proactively investigating the possibility of new diseases and developing management plans to address such diseases before they threaten the sustainability of wild stocks. I saw little evidence that DFO is doing this. Indeed, when Dr. Kristina Miller, head of Molecular Genetics, DFO, undertook research on the infectious salmon anemia (ISA) virus outside the "regulatory" National Aquatic Animal Health Program (NAAHP), the response of managers was to try to contain that research and bring it within the NAAHP. Also, I saw no evidence of a clear reporting structure or plan for dealing with emerging non-reportable diseases like heart and skeletal muscle inflammation (HSMI). I see great value in DFO encouraging innovation in its scientists outside the regulatory framework used by CFIA. Such innovation could provide information that may improve the regulatory framework.

The work started in 2010 by DFO under the Program for Aquaculture Regulatory Research (PARR) program, in partnership with

Marine Harvest Canada and the Pacific Salmon Foundation, to survey wild sockeye health appears to be limited to reportable diseases, sea lice, and bacterial kidney disease (BKD). Other diseases that may be of high risk to Fraser River sockeye, such as *Parvicapsula*, may not receive adequate consideration in that survey. As well, work conducted under PARR is, by definition, of short duration (see Chapter 8, Salmon farm management). And so this survey will only provide a snapshot of sockeye health, not trend data. Having said that, I note that work needs to begin somewhere and I am heartened to see DFO taking these first steps.

Overall, I am concerned that in letting its research agenda be influenced by trade concerns, DFO does not give the priority it should to the conservation and protection of wild salmon. DFO should not be a follower on issues of wild fish health; it should be a leader. Ensuring the health of wild stocks should be DFO's number one priority in conducting fish health work.

Managing risks to Fraser River sockeye from salmon farms

As Dr. Michael Kent, professor of microbiology and biomedical sciences, Oregon State University, told me, the focus of much fish health work has been on cultured fish, not wild fish. I also heard evidence from Dr. Laura Richards, regional director, Science, DFO Pacific Region, and others that little work has been done by DFO to investigate the effects of fish farms on Fraser River sockeye. This situation is of concern, especially since the Wild Salmon Policy recognizes the potential risk that salmon farms pose to wild salmon from the "chance of disease and parasite transfer"[542] and relies on mitigation measures to reduce the risk. Without research to assess the risks, no one can be confident that mitigation measures are effective in reducing them.

I do accept the evidence of Dr. Peter McKenzie, veterinarian and fish health manager, Mainstream Canada, that keeping farmed fish healthy is an important component of reducing the risk to wild sockeye. However, I am concerned that an overemphasis on the health of farmed fish, particularly at the population or farm level, may inadvertently mask risks posed to wild stocks. Dr. Mark Sheppard, head veterinarian, Aquaculture Environmental Operations, DFO, told me that, despite there being diseased individuals at fish farms, farms may never be diagnosed with a disease because that disease has not risen to a level at which it is a concern for the farmed fish population. Further, more than half the diagnoses of fresh silvers collected in the government auditing program are "open diagnoses," though the fish have obviously died of something. These factors may lead one to conclude erroneously that because farmed fish populations are not suffering, neither are Fraser River sockeye. However, it may be that some level of disease is tolerable in farmed fish populations. I accept the evidence of Dr. Stewart Johnson, head, Aquatic Animal Health, Salmon and Freshwater Ecosystems Division, DFO, that until tests are performed on wild sockeye, scientists will not know the responses of sockeye – at either an individual or population level – to diseases infecting farmed (predominantly Atlantic) salmon. These factors all lead me to the conclusion that the risks to wild sockeye salmon swimming by these farms have not been adequately assessed to date. Again, this relates to the health of wild salmon not being DFO's first priority for fish health management.

Not only did I hear about a lack of research on farmed–wild fish pathogen interaction, I also heard that, where disease concerns or conditions do arise in wild salmon, researchers face difficulties in obtaining samples of farmed salmon in order to test whether farms are the source of these conditions. One such example is in relation to the mortality-related genomic signature and parvovirus identified by Dr. Miller. Industry has resisted providing her with samples of farmed Atlantic salmon so that she can test them. Having mechanisms in place so that farmed salmon could be quickly tested as potential threats to Fraser River sockeye would appear to be in the best interests of DFO's conservation mandate.

Overall, as I discuss further in volumes 2 and 3 of this Report, I am concerned that the risk to Fraser River sockeye cannot be fully mitigated until those risks have been adequately researched and described. Until more is known about the effect of salmon farms on wild sockeye, precautions need to be taken, so that the promise of the Wild Salmon Policy – that risks are addressed – is upheld.

Managing risks to Fraser River sockeye from salmon enhancement facilities

I accept the evidence that disease can occur in hatcheries and that many cases may not be reported or investigated because there are no fish health standards that establish an acceptable level of fish pathogen risk, something that is key for risk assessment. I also conclude that there is a lack of standard practices and there are deficiencies in record keeping at enhancement facilities in relation to disease and fish health.

It may be that the licences implemented in July 2011 start the process of standardizing some of that information. However, given the lack of compulsory language and the relative lack of detail (compared to the requirements placed on salmon farms), something more is needed to assess the adequacy of fish health management practices at hatcheries.

Further, there is no auditing of Fish Health Management Plans (FHMPs) at major DFO and Freshwater Fisheries Society of BC (FFSBC) hatcheries. Community enhancement facilities do not have adequate access to fish health experts and there is a lack of oversight of these facilities regarding their fish health practices. I am also satisfied on the evidence that fish with known and suspected infections have been released from fish production facilities into fish-bearing waters.

The ISAv case study

From the evidence I heard on the limitations and sensitivity of various tests to detect ISAv, I conclude that *if* there is a novel or unknown strain of ISAv in Pacific salmon in British Columbia, none of the current tests may be ideal for detecting it, since they were all developed for Atlantic salmon, and for known genotypes of ISAv.

I accept the evidence of Dr. Frederick Kibenge, chair, Department of Pathology and Microbiology, Atlantic Veterinary College (AVC), that the RT-PCR assay and protocol for ISAv used by the DFO Moncton laboratory, which is the CFIA-approved assay and protocol, *may* not be as sensitive as other tests recommended by the OIE (World Organisation for Animal Health). Coordination between researchers and a review of the National Aquatic Animal Health Laboratory System (NAAHLS) testing protocols is in order. Dr. Miller's results using a variety of assays indicates that the use of multiple assays may be a better way to screen for ISAv in species of Pacific salmon where the disease is not commonly known or understood; however, I accept the evidence of Dr. Peter Wright, national manager, NAAHLS, DFO Moncton, that Dr. Miller's methods would need to be validated before being used in a diagnostic setting.

I do accept that the DFO Moncton's assay has been validated and may well do the job it was designed to do in detecting known ISAv strains common to Atlantic salmon. However, that does not mean it is a good test for ISAv in Pacific salmon, nor for testing potentially new strains of ISAv. The management preference within DFO to use only the one approved validated test – even in the context of pure research – might prohibit research that identifies a better way to test Pacific salmon like sockeye for diseases such as ISA.

As discussed further in Volume 2 of this Report, I cannot conclude on the evidence before me whether ISAv or an ISAv-like virus at present exists in Fraser River sockeye. The expert opinion is mixed, and there is clearly much more work to be done. Although functional genomics work stemming from Dr. Miller's laboratory indicates that positive tests for ISAv appear to be associated with a flu-like response, this work is at a very early stage. I cannot make any conclusions on the evidence about what effect this virus, if it exists, has on Fraser River sockeye.

Several aspects of the management response to the presumptive positive ISAv tests by Dr. Molly Kibenge, Dr. Frederick Kibenge, and Dr. Miller give me cause for concern. First, the only response to Dr. Molly Kibenge's work showing a significant prevalence of presumptive positives for ISAv appeared to be to have some of the samples retested, both by Dr. Frederick Kibenge at AVC and then by Nellie Gagné, molecular biology scientist and laboratory supervisor, Molecular Biology Unit, DFO Moncton. When Ms. Gagné's results came back negative, researchers at DFO who were aware of the results decided Dr. Molly Kibenge's results were false positives.

They did not implement any further testing of wild salmon in British Columbia. They did not continue an investigation into methodologies until they determined why different laboratories got different results. They concluded that the results must have been false positives.

Second, the response within DFO to Dr. Miller's results is especially puzzling to me. Mr. Stephen Stephen, director, Biotechnology and Aquatic Animal Health Sciences Branch, DFO, told me he suggested that she defer any further work and that her work should be brought into the regulatory program led by CFIA. This move, in my view, would diminish the value of her work. As I said above, if DFO restricts its research into fish health on wild salmon to meet the needs of one "client" (CFIA), it jeopardizes its ability to be innovative and risks failing in its mandate to conduct research that will further scientific knowledge about the health of wild sockeye salmon.

Finally, the public statements made in the fall of 2011 left the impression that all was well – that there was no reason to be concerned about ISAv in wild BC salmon. At a minimum, there was a strong case for further research before that conclusion could be drawn.

I discuss these findings and any related recommendations in Volume 3 of this Report.

Notes

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2 *Health of Animals Act,* SC 1990, c. 21; *Fisheries Act,* RSC 1985, c. F 14.
3 Exhibit 1676; Exhibit 2134.
4 PPR 20, pp. 102–3.
5 Exhibit 2092, p. 9.
6 Exhibit 1449, p. 19.
7 Exhibit 2011.
8 Peter Wright, Transcript, December 16, 2011, pp. 99–100.
9 Kim Klotins, Transcript, December 16, 2011, pp. 142–43; Exhibit 1676, pp. 11–12.
10 Kim Klotins, Transcript, December 19, 2011, pp. 7, 13.
11 Exhibit 1676.
12 Peter Wright, Transcript, December 16, 2011, pp. 102–3.
13 Exhibit 2117, p. 1.
14 Peter Wright, Transcript, December 16, 2011, pp. 138–39.
15 Peter Wright, Transcript, December 16, 2011, p. 97.
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17 Exhibit 2134.
18 *Health of Animals Act*, SC 1990, c. 21; Kim Klotins, Transcript, December 16, 2011, p. 130.
19 *Health of Animals Act*, SC 1990, c. 21, s. 2.
20 Exhibit 2128, p. 1.
21 *Reportable Diseases Regulations*, SOR/91 2.
22 *Reportable Diseases Regulations*, SOR/91 2, Schedule 2.
23 Exhibit 2128, p. 1.
24 *Health of Animals Regulations*, CRC, c. 296, Schedule VII.
25 Exhibit 2105, p. 9.
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29 Exhibit 2027; Exhibit 2103.
30 Kim Klotins, Transcript, December 16, 2011, p. 133.
31 Transcript, December 16, 2011, p. 90; see also Exhibit 2025.
32 Transcript, December 16, 2011, p. 91.
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34 *Health of Animals Act*, SC 1990, c. 21, s. 41(2).
35 *Health of Animals Act*, SC 1990, c. 21, s. 35.
36 *Health of Animals Act*, SC 1990, c. 21, s. 51.
37 *Health of Animals Act*, SC 1990, c. 21, s. 14.
38 *Health of Animals Regulations*, CRC, c. 296, s. 196.
39 *Health of Animals Regulations*, CRC, c. 296, s. 196.
40 *Pacific Aquaculture Regulations,* SOR/2010 270.
41 *Fish Health Protection Regulations*, CRC, c. 812.
42 *Pacific Aquaculture Regulations,* SOR/2010 270, s. 2.
43 *Pacific Aquaculture Regulations,* SOR/2010 270, ss. 4, 5.
44 Exhibit 1594.
45 Exhibit 1594, Appendix III, pp. 7–8.
46 *Fish Health Protection Regulations,* CRC, c. 812, s. 2.
47 *Fish Health Protection Regulations,* CRC, c. 812, ss. 4, 5.
48 *Fish Health Protection Regulations,* CRC, c. 812, ss. 2, 6.
49 Transcript, December 16, 2011, pp. 130–31.
50 Transcript, December 16, 2011, p. 131.
51 Transcript, December 16, 2011, p. 131.
52 Kim Klotins, Transcript, December 16, 2011, pp. 131–32.
53 PPR 20, Aquaculture, p. 81.
54 PPR 20, pp. 81–82.
55 Trevor Swerdfager, Transcript, August 31, 2011, pp. 32–33.
56 Transcript, August 31, 2011, p. 32.
57 PPR 20, pp. 83–84.
58 PPR 20, p. 84.
59 Transcript, August 25, 2011, pp. 58–59.
60 Peter McKenzie, Transcript, August 31, 2011, p. 30.
61 PPR 20, p. 54.
62 Transcript, December 16, 2011, pp. 136–37.
63 Exhibit 2127, p. 9.
64 Transcript, December 16, 2011, p. 85.
65 Transcript, December 16, 2011, p. 86.
66 Transcript, December 16, 2011, pp. 86–87.
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68 Peter Wright, Transcript, December 16, 2011, pp. 87–88; see also Exhibit 2022.
69 Exhibit 2073.
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78 Transcript, December 16, 2011, p. 97.
79 Transcript, August 25, 2011, pp. 32–33.
80 Michael Kent, Transcript, August 22, 2011, p. 10.

81 Michael Kent, Transcript, August 22, 2011, pp. 11–12; Stephen Stephen, Transcript, August 22, 2011, p. 15.
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83 Stewart Johnson, Transcript, August 22, 2011, pp. 12–13.
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87 Transcript, September 23, 2011, p. 5.
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91 Transcript, August 22, 2011, p. 36.
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95 Transcript, September 26, 2011, pp. 62–63.
96 Exhibit 2127, p. 9.
97 Transcript, December 15, 2011, p. 131.
98 Exhibit 1452.
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106 Exhibit 1461, pp. 9, 12.
107 Exhibit 2112.
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110 Transcript, December 19, 2011, pp. 8, 58, 60, 78.
111 Transcript, December 19, 2011, p. 78.
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113 Transcript, December 16, 2011, p. 121.
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115 Exhibit 2112, pp. 6–7.
116 Exhibit 2119, pp. 2–3.
117 Kristina Miller, Transcript, December 15, 2011, p. 135.
118 Kristina Miller, Transcript, December 15, 2011, p. 136.
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121 Transcript, August 25, 2011, pp. 12–13.
122 Kristina Miller, Transcript, August 25, 2011, p. 13.
123 Transcript, December 15, 2011, pp. 102–3.
124 Transcript, December 15, 2011, p. 140.
125 Transcript, December 15, 2011, p. 126.
126 Transcript, December 15, 2011, p. 113.
127 Transcript, December 15, 2011, p. 113.
128 Transcript, December 15, 2011, p. 113.
129 Transcript, August 23, 2011, pp. 42, 43, 46.
130 Michael Kent, Transcript, August 23, 2011, p. 42.
131 Transcript, August 23, 2011, p. 43.
132 Transcript, August 26, 2011, pp. 28–29.
133 Transcript, August 29, 2011, p. 101.
134 Transcript, August 31, 2011, p. 66.
135 Mark Sheppard, Transcript, August 31, 2011, p. 93.
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137 Mark Sheppard, Transcript, August 31, 2011, pp. 93–94.
138 Transcript, August 30, 2011, pp. 86–87.
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140 Exhibit 1594.
141 Exhibit 1611.
142 Trevor Swerdfager, Transcript, August 31, 2011, p. 24.
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144 PPR 20, pp. 48, 96.
145 PPR 20, p. 96.
146 Exhibit 1660, p. 1.
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156 Transcript, August 31, 2011, p. 16.
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159 Gary Marty, Transcript, August 31, 2011, p. 60.
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161 Exhibit 2105, pp. 158–74.
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163 Transcript, September 26, 2011, pp. 74–75.
164 Susan Farlinger, Transcript, September 26, 2011, p. 75.
165 Transcript, September 26, 2011, p. 42.
166 Susan Farlinger, Transcript, September 26, 2011, p. 43.
167 PPR 20, p. 33; Mark Sheppard, Transcript, August 31, 2011, p. 29.
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169 Mark Sheppard, Transcript, August 31, 2011, pp. 26–27.
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178 Exhibit 1668.
179 Exhibit 1668, p. 3.
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202 Peter McKenzie, Transcript, August 31, 2011, pp. 30–31.
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206 Transcript, August 23, 2011, p. 15.
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208 Michael Kent, Transcript, August 23, 2011, p. 23.
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271 Transcript, August 22, 2011, p. 80; Exhibit 1454, p. 105.
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274 Transcript, August 22, 2011, p. 80; Exhibit 1454, p. 103.
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283 Craig Stephen, Transcript, August 22, 2011, p. 81.
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285 Transcript, August 22, 2011, p. 77; see also Exhibit 1593.
286 Christine MacWilliams, Transcript, August 22, 2011, pp. 77–78.
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293 Christine MacWilliams, Transcript, August 22, 2011, pp. 48–49.
294 Transcript, August 22, 2011, pp. 21, 85.
295 Transcript, December 15, 2011, pp. 9–10.
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297 Transcript, December 16, 2011, p. 6.
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304 Frederick Kibenge, Transcript, December 16, 2011, p. 64; see also Exhibit 1676, s. 2.3.3.
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308 Transcript, December 15, 2011, pp. 78–79.
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477 Exhibit 2052.
478 Transcript, December 15, 2011, p. 49.
479 Transcript, December 15, 2011, p. 88.
480 Transcript, December 19, 2011, p. 73.
481 Transcript, December 19, 2011, pp. 57–58.
482 Transcript, December 19, 2011, p. 95.
483 Transcript, December 19, 2011, p. 74.
484 Transcript, December 19, 2011, p. 96.
485 Transcript, December 19, 2011, pp. 51–52.
486 Simon Jones, Transcript, December 19, 2011, p. 51.
487 Transcript, December 16, 2011, pp. 127–28.
488 Transcript, December 19, 2011, p. 51.
489 Exhibit 2115.
490 Transcript, December 19, 2011, p. 4.
491 Transcript, December 19, 2011, pp. 4–5.
492 Transcript, December 15, 2011, p. 92.
493 Transcript, December 16, 2011, p. 81.
494 Kim Klotins, Transcript, December 16, 2011, p. 95.
495 Exhibit 2107.
496 Transcript, December 16, 2011, p. 95.
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498 Transcript, December 16, 2011, p. 96.
499 Kim Klotins, Transcript, December 16, 2011, pp. 98–99.
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503 Transcript, December 16, 2011, pp. 91–92; see also Transcript, December 19, 2011, p. 48.
504 Transcript, December 16, 2011, p. 143.
505 Exhibit 2107-01, p. 1.
506 Exhibit 2107-05, p. 2.
507 Exhibit 2110, p. 1.
508 Transcript, December 16, 2011, p. 112.
509 Transcript, December 16, 2011, p. 113.
510 Transcript, December 16, 2011, pp. 143–44.
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512 Exhibit 2056.
513 Transcript, December 15, 2011, pp. 54–56.
514 Transcript, December 15, 2011, pp. 108, 127.
515 Transcript, December 15, 2011, pp. 108–9.
516 Transcript, December 15, 2011, pp. 126–27.
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518 Transcript, December 15, 2011, p. 109.
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520 Exhibit 2064; Exhibit 2065.
521 Transcript, December 15, 2011, p. 84.
522 Transcript, December 19, 2011, p. 67.
523 Transcript, December 16, 2011, p. 108.
524 Transcript, December 19, 2011, pp. 68–69; see also Transcript, December 16, 2011, p. 108.
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526 Transcript, December 19, 2011, p. 69.
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531 Kim Klotins, Transcript, December 19, 2011, p. 7.
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536 Transcript, December 19, 2011, p. 42.
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538 Transcript, December 19, 2011, p. 39.
539 Transcript, December 19, 2011, p. 44.
540 Transcript, December 19, 2011, p. 72.
541 Transcript, December 19, 2011, p. 101.
542 Exhibit 8, p. 31.