Fisheries and Oceans Canada Pêches et Océans Canada

Aquatic Biotechnology & Genomics Research and Development Strategy

Shaping the Future

Aquatic Bitechnology Program

Canada

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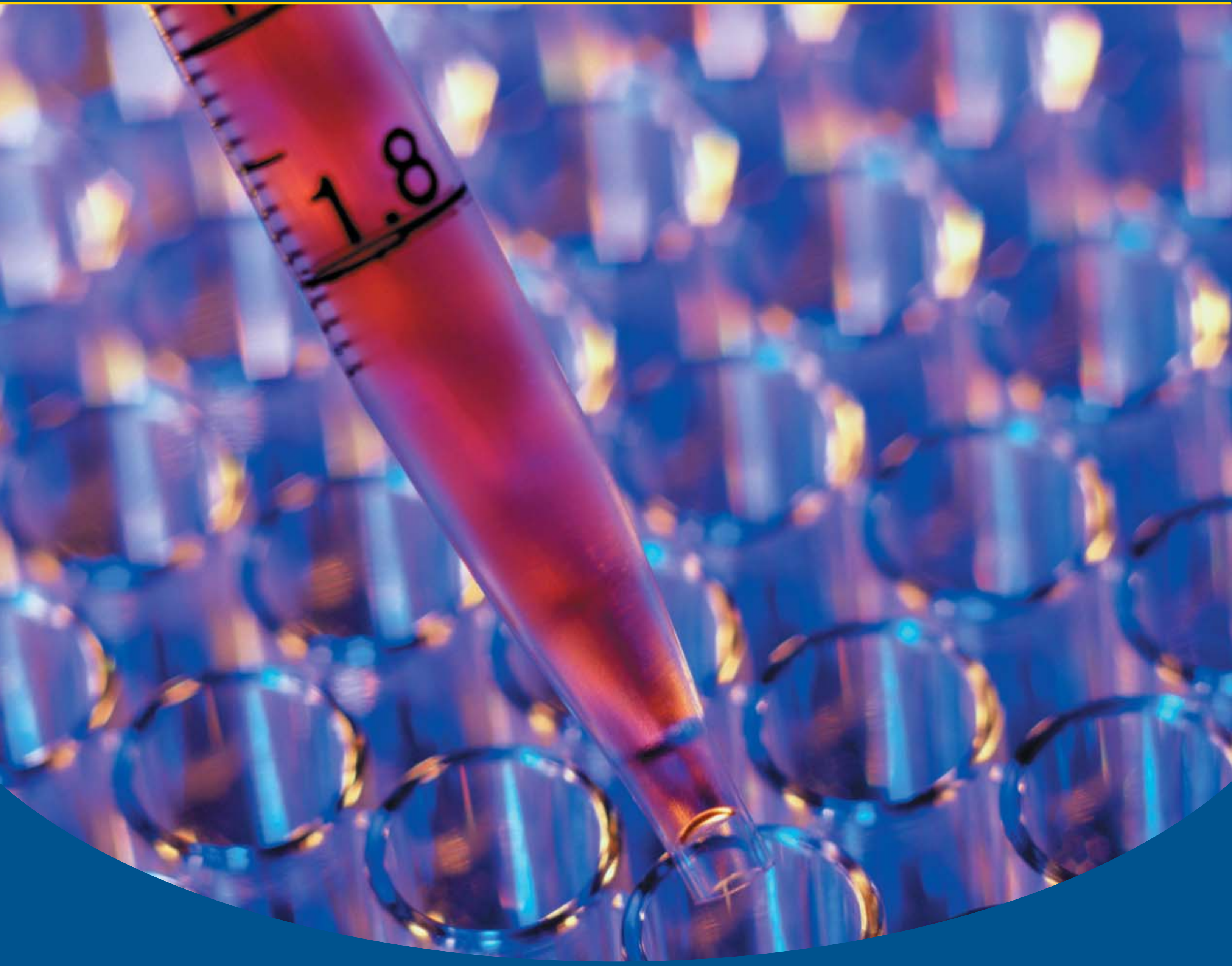


Introduction

Fisheries and Oceans Canada (DFO) is linking innovative biotechnology and genomics science with higher level policy making and on-the-ground fishery and aquatic ecosystem management decisions.

The development and application of biotechnology and genomics tools to enhance sustainable resource management and environmental conservation and protection is increasing in Canada and around the world. Advances and application developments in biotechnology and genomics present the possibility for lower-cost biotechnology applications with advantages, such as greater sensitivity, accuracy, faster results and increased efficiency, over more traditional technologies. DFO is part of this biotechnology and genomics wave with innovative science across the country supporting our mandate.

As biotechnology and genomics tools and information are increasingly incorporated into DFO research and development activities, an integrative approach to identifying opportunities for sharing expertise, coordinating efforts and increasing efficiencies within DFO's biotechnology and genomics R&D activities was taken.

DFO's Aquatic Biotechnology Program has been in place since the late 1980s, with the majority of our developments occurring within the last 10 years. With targeted start-up funding, DFO has strategically developed expertise and capabilities in biotechnology and genomics. DFO researchers and key partners have developed new biotechnology techniques that support policy and management decisions to enhance the ecological sustainability of the wild fishery, aquaculture and oceans ecosystems. Our success has been a result of being able to quickly apply our research through effective partnerships, deploying products and tools to enable clients in other government agencies, and the private and public sectors to adopt and benefit from the application of new technologies, while keeping the research aligned with departmental priorities.

DFO's Mandate and Aquatic Biotechnology

Key departmental priorities, as outlined in the 2005-2010 Strategic Plan: *Our Waters, Our Future*, can be supported by biotechnology and genomics research, development and innovations. The Department's strategic plan clearly states that sustainable development is a priority. An underlying premise of sustainable development is that a strong sustainable economy is a product of a healthy natural environment and healthy society. Habitat destruction, loss of biodiversity, and land and sea-based pollution all have a negative impact on our culture, society and economy. Properly managed, our natural resources and aquatic environment will be sustained for future generations, and provide the basis for growth and co-existence of current and emerging aquatic resource users.

Biotechnology **is a powerful "enabling technology" with applications in many sectors and holding much promise for the future. It is a term that covers a broad spectrum of scientific applications. The Canadian Environmental Protection Act defines biotechnology as "the application of science and engineering in the direct and indirect use of living organisms or parts or products of living organisms in their natural or modified forms."**

Aquatic biotechnology **involves the application of science and engineering for the direct or indirect use of aquatic organisms or parts or products of living aquatic organisms in their natural or modified forms. It includes genomics, a discipline that aims to decipher and understand the entire genetic information content of plants, animal/fish organisms, and micro organism. It is fundamental to all biological and biotech research.**

Components of aquatic biotechnology include aquaculture biotechnology (e.g., fish health and broodstock optimization); aquatic bioprocessing (e.g., obtaining valuable compounds from marine organisms); and aquatic bioremediation (e.g., use of microorganisms to degrade toxic chemicals in the aquatic environment).

Biotechnology and genomic tools and products contribute to the three inter-related DFO priority outcomes:

1. ***Healthy and Productive Aquatic Ecosystems –*** Refers to the sustainable development and integrated management of resources in or around Canada's aquatic environment through oceans and fish habitat management, and the critical science activities that support these two programs.

2. ***Sustainable Fisheries and Aquaculture –*** Refers to an integrated fisheries and aquaculture program that is credible, science-based, affordable and effective, and contributes to sustained wealth for Canadians.

3. ***Safe and Accessible Waterways –*** is about providing access to Canadian waterways, and ensuring the overall safety and integrity of Canada's marine infrastructure for the benefit of all Canadians.

DFO Strategic Outcomes

Sustainable Fisheries and Aquaculture (SFA)	Healthy and Productive Aquatic Ecosystem (HAPAE)	Healthy and Productive Aquatic Ecosystem (HAPAE)
↑	**Healthy and Productive** State of Aquatic Ecosystems Impacts of Human Activities Safety, Security and Sovereignty	↑
Status of the Fishery Resources	Impacts of development activities	Products & services for navigation
Species at Risk	State of ecosystems and integrated management	Mapping the Ocean Floor (UNCLOS)
Aquatic Invasive Species	Roles of Oceans in Global Climate	Impacts of Climate Variability & Change
Aquaculture Production	**Genomics and Biotechnology**	
Aquaculture-Environment Interactions	Aquatic Animal Health	

DFO Science Renewal

In 2004, DFO embarked on a review of all science activities in order to identify and match all science activities to the three key departmental and government priorities, review commitments and capacity in order to balance advice needs with ability to deliver the advice, and to finalize and implement a long-term plan to ensure relevance and sustainability of the Science Program.

DFO's Science Sector must also be responsive to internal drivers, such as the increase in demand for science advice, products, and services. These requests are increasingly complex, requiring integrative approaches and ecosystem considerations. Additionally, the scientific information, products, services and advice needs to be flexible and responsive to rapidly emerging departmental and federal priorities. However, there is an acknowledgement that the scientific capacity and resources required to meet these ever increasing demands are not available.

In response to these drivers, Science Renewal aims to produce a vibrant aquatic science program based on excellence that supports and informs DFO and Government needs and best serves Canadians. The framework to deliver on this objective is to ensure that DFO science is relevant, and responsive to priorities; effective, through a modern and effective science functions; affordable; and valued.

To support DFO priorities, 13 clusters of science activities have been identified, including Biotechnology and Genomics (see figure, above). These clusters have been identified as key program areas that support national Science Sector priorities through research, monitoring, providing science advice, products and services, data management, and science management. Many of the core clusters have been identified as Centres of Expertise, a new management and coordination approach to streamline science service delivery and national coordination, thereby increasing efficiency and effectiveness.

Standard biotechnology tools are now used throughout the Department with the more specialized developmental work concentrated in biotechnology centres across the country, resulting in the development of core capacity and expertise. DFO is continually increasing its capacity in terms of highly skilled personnel, and specialized equipment and facilities in order to develop and deploy leading-edge biotechnology and genomics tools. In part, the success that DFO has had in integrating and deploying biotechnology and genomics tools and information is due to the development of strong and vibrant partnerships with researchers in other government departments, academia and industry, as appropriate. This has enabled DFO researchers and DFO Science to capitalize on third party resources to deliver better and stronger programs, to meet its mandate and key priority objectives more efficiently, to foster and support world-class scientific and technological innovation, to train new scientific personnel, and to develop and maintain a national and international reputation for scientific excellence in aquatic biotechnology and genomics research.

Partnering with Canadians

DFO scientists take on research in support of issues that matter to our stakeholders. We work closely with the aquatic resource managers, users and conservation groups and identify priorities based on the needs of these communities. Biotechnology research also provides information that support Canada's national and international commitments in aquatic animal health, stock management and assessment of risks associated with biotechnology-derived products.

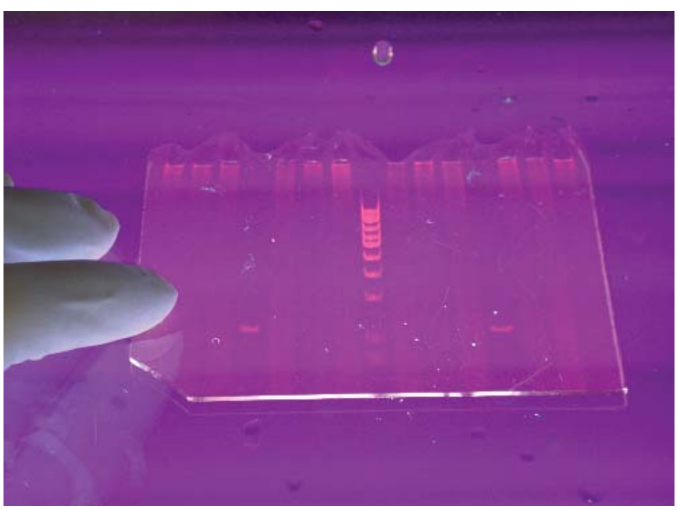
The multi-faceted nature of fisheries, aquaculture, and management of aquatic ecosystems, and the interdisciplinary nature of biotechnology requires, and benefits from, strong partnerships and effective stakeholder relations. DFO works with a diverse range of stakeholder groups and individuals including: local communities; fishery biologists; enforcement personnel; international scientists; international research and regulatory organizations; international governments; aboriginal groups with fishing and resource rights; commercial aquaculture and wild fishery organizations; companies; and, provincial and territorial counterparts with shared resource management responsibilities. DFO has partnerships with governments and research institutes in the United States, Norway, France, the United Kingdom, Sweden, Japan, Korea, and Germany.

Moving Forward – Aquatic Biotechnology and Genomics Research and Development Strategy: Shaping the Future

Despite progress made possible through start-up funding, the incremental costs associated with ongoing research and its application are challenging the Department to regularly seek additional funds to meet the increasing capacity needs and maximize the application of these tools for sustainable development. As enabling technologies that are inherently multidisciplinary, biotechnology and genomics may have applications and information to support the aims of many of the other science clusters, including Aquatic Animal Health, Aquatic Invasive Species, Species at Risk, Aquaculture Production, etc.

To build on success to date, and chart a clear path forward, DFO has developed the following Aquatic Biotechnology and Genomics R&D Strategy to support DFO's departmental and national obligations over the next number of years. This Strategy is the product of input from DFO's scientists, the National Biotechnology Coordinators, biotechnology regulators, and managers.

This strategy was intended to capture the wide range of science initiatives either underway or proposed within DFO. The biotechnology and genomics R&D opportunities and priorities have been mapped out over a variety of timeframes, allowing for the actions and outcomes to build on one another, thus permitting the integration of experiences, and outputs from previous activities.



By increasing the awareness and understanding of the multiple benefits derived from the application of biotechnology tools, senior government officials will be better able to make informed policy decisions and invest in areas where science gaps remain. Risk assessments and critical decisions need to be made at all levels, reinforcing the need for an integrated approach.

The Strategy also outlines the inherent multidisciplinary aspect of biotechnology and genomics, and provides examples of applications of these enabling technologies to many of DFO's mandated science advice and activities. The opportunities for biotechnology and genomics research and development to provide new and precise tools and information to help meet the Department's mandate will continue to be explored as the science and technology matures. Science Renewal involves linking the science program to Departmental and federal strategic outcomes and priorities within a new Departmental reporting structure. Biotechnology and genomics tools and applications can add value, efficiencies and improve effectiveness in meeting core mandated science advice and information needs.

Priority Research Themes

Four priority research themes form the Strategy's key elements and include goals, objectives and actions designed to shape DFO's biotechnology agenda for the next four years. It is expected that this Strategy will continuously evolve in dynamic response to departmental priorities.

1. Biotechnology and Aquatic Resource Profiling
2. Biotechnology and Aquatic Animal Health
3. Biotechnology and Aquatic Ecosystem Health
4. Regulatory Science for Aquatic Animals with Novel Traits

Vision for 2015

The following Strategy proposes a vision of where we want to be in 2015 and a roadmap to get there.

To have in place by 2015:

> *A successful, innovative, dynamic biotechnology and genomics program to enhance the sustainability of our aquatic resources and the ecological health of our aquatic ecosystems, that is characterized by strong partnerships and stakeholder involvement; innovative research programs; the application of effective biotechnology and genomics tools and products; and funding to maintain required expertise.*

The successful implementation of this Strategy will depend on leadership, commitment, creativity and expertise of DFO's management, scientists, external stakeholders, resource managers and decision-makers across the country.

Issues, Trends, Drivers and Opportunities

Developments at the national and international scale shape DFO's priorities. For instance, we know that competing resource demands; human population growth; climate and environmental change; scientific and technological advances; international responsibilities and obligations; shifting economic paradigms; traditional funding of high value/high visibility species; and, societal demands are a just a few of the drivers shaping DFO's agenda. We are faced with the challenge of understanding the complex interrelationship between these and other variables, in order to target our science, and inform policy choices, ultimately ensuring the long-term viability of the aquatic resources, and health of aquatic ecosystems for which we are responsible.

Public expectations for government action on these issues are high. The department is facing pressure from industry and communities, to increase investment in science and apply efficient and effective tools to better comprehend and manage aquatic resources. The public also sees a role for government to help in capitalizing on the potential of biotechnology to increase jobs and economic growth in Canada. This is especially true for coastal and rural Canadians.

DFO is responding by, as part of a department-wide science renewal, expanding its Aquatic Biotechnology and Genomics R&D Program. It has been proven that the speed, sensitivity and accuracy of using biotechnology and genomics tools provides many advantages in addition to more traditional methods of, for example, species identification, contaminated site remediation, and disease diagnosis.

Key Trends

Canada stands to gain from aquatic biotechnology and genomics innovation as these tools directly and indirectly support aquatic resource management and ecosystem integrity. To put this into context:

- In 2004, Fish and seafood was the largest single export food commodity, by value, in Canada. We are the fifth largest seafood exporter in the world.
- The quantity of fish and seafood products exported increased in 2005 with more than 703,000 tonnes of Canadian fish and seafood products exported worldwide, valued at $4.3 billion – up 2.6 per cent compared to 2004.
- The United States remains Canada's largest export destination, with 62 percent of its seafood products, valued at $2.7 billion sold to the U.S. market. Japan ranked second with Canadian imports valued at more than $471 million. China and Hong Kong followed at $383 million.
- In 2004, aquaculture products were worth nearly $527 million in Canada. The value of aquaculture exports exceeded $425 million in 2004. For some valuable species of salmon, aquaculture production far exceeds wild harvest.[3]
- Resource availability is a concern, and the passage of the *Species at Risk Act* has focused attention on threatened and endangered species. The impact of bycatch of threatened or endangered species, habitat and the economies of coastal communities are all of DFO concern.

4.1 Canadian Biotechnology Trends and Activities

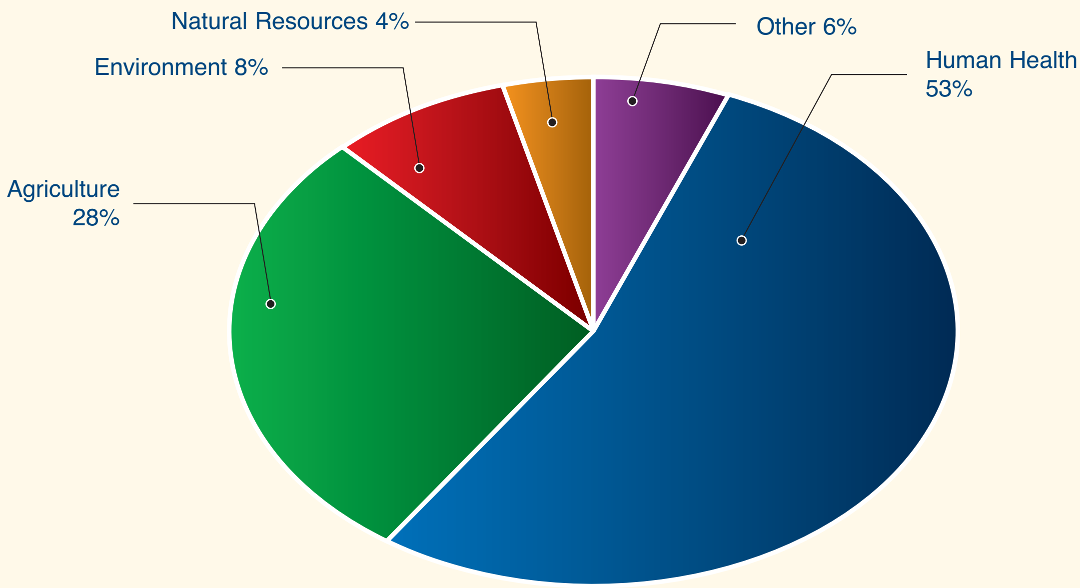
The National Context

The rapid pace of biotechnology discoveries continues to accelerate with some viewing its potential analogous to the impact of information and communication technologies. According to *Canadian Trends in Biotechnology*, Second Edition 2005:

- In fiscal year 2003-04, Canada's federal science and technology (S&T) expenditures on biotechnology totalled $746 million, which represented 8% of all federal S&T expenditures. Close to 95% of the federal S&T spending on biotechnology was dedicated to R&D activities.
- Most federally funded biotechnology S&T activities were conducted outside the federal government.
- The number of product/processes that reached the market almost doubled between 1999 and 2003.
- As of 2003, firms had at least 17,000 products and processes under development and on the market.
- Biotechnology is spread across the country: Ontario, Quebec and B.C. account for well over half of all revenues generated by biotechnology companies.

[3] Vista October 2005.p.3

Biotechnology Companies By Sector – 2004



*Other: Aquaculture, Bioinformatics
*Source: Statistics Canada

From 1997 to 2003, biotechnology revenues more than quadrupled, from $813 million to $3.8 billion. Over that entire period, more than half of biotechnology revenues were received by companies in the human health sector. As noted earlier, this figure could change if the national and federal focus were to be expanded to include a greater emphasis on natural resources and the environment, in recognition of the correlation between a healthy population, environment and economic growth.

The Canadian Biotechnology Strategy: A Federal Initiative

The federal government plays a major role as an innovator, commercializer and regulator of biotechnology products with provinces and territories valuable partners. DFO has been a partner at the federal level in the implementation of the Canadian Biotechnology Strategy (CBS) since its inception in 1998.

The CBS provides a framework to guide national biotechnology activities. The CBS is led by Industry Canada in partnership with a number of federal departments, agencies, and research institutes such as Environment Canada (EC), Canadian Food Inspection Agency (CFIA), Natural Resources Canada (NRCan), Health Canada (HC), National Research Council (NRC), Agriculture and Agrifood Canada (AAFC), DFO and others.

The CBS vision is: "*to enhance the quality of life of Canadians in terms of health, safety, the environment and social and economic development by positioning Canada as a responsible world leader in biotechnology*". The CBS is comprised of three pillars: Innovation, Regulation and Public Outreach. This strategy outlines DFO's role in all three of these pillars, and highlights both DFO's future role and direction in supporting these pillars, and some current accomplishments.

4.2 The International Context

One of the priorities of the federal government is to place Canada as a world leader in biotechnology. According to Organization for Economic Cooperation and Development (OECD) data for the year 2000, the number of dedicated biotechnology firms per million inhabitants is highest in Sweden, Switzerland and Canada. We also rank second in the proportion of total publicly funded R&D investments that is devoted to biotechnology. Denmark, Canada and New Zealand invest more than 10% of their total publicly funded R&D budgets in biotechnology. [5]

Internationally, in 2003 nearly 89% of all biotechnology R&D expenditures were in the human health sector, with 6% of biotechnology R&D in the agriculture and food processing sectors. Biotechnology investment in the natural resource and environment sector is minimal, despite the untapped potential for benefits to Canadians. DFO can be instrumental in changing this trend.

The strong link between natural resource-based economic development in Canada, and economic growth, along with the direct and indirect impact of the quality of the natural environment on human health and environment are two reasons why a shift in R&D investments is necessary. Canada can become a global leader in the development, application and transfer of innovative aquatic biotechnology techniques and products. Doing so will not only benefit the international community with the uptake of products that will ultimately foster a more sustainable global fishery, but also Canadian industry and coastal communities, and consumers.

International Fisheries and Oceans Management

Global production from capture fisheries and aquaculture supplied about 101 million tonnes of food fish in 2002. [6]

International fisheries and oceans management issues are complex. Uncertainty arises from many factors including cumulative impacts, climate change, an increase in the number of people using ocean resources, the variety of ocean activities, as well as international markets and socio-economic pressure.

For many years, a major challenge for the management of the international fishery has been the quest to establish appropriate fishing quotas in light of the high level of uncertainty and complexity.

With the development of genetic tools to "genetically fingerprint" fish as individuals and populations, new information can be generated that enables the attribution of fish stocks that straddle international boundaries to country of origin. This additional information can be used by the Department, and the international community, to develop and propose quotas that are more reflective of migratory patterns and the need to maintain the health of fish stocks. Through the development of sensitive, accurate and rapid tests that provide valuable information to fisheries and oceans managers, Canada is contributing to the international knowledge and tool base for addressing the challenge of managing international fisheries, thereby supporting and contributing to our responsibilities under the United Nations Convention on the Law of the Sea (UNCLOS), International Council for the Exploration of the Sea (ICES), the Pacific Salmon Commission, North Pacific Anadromous Fisheries Commission, and, the North Atlantic Fisheries Organization.

Aquaculture in the World

Worldwide, aquaculture is the fastest-growing sector in agri-food, with fish accounting for more than 40% of revenues. The United Nations' Food and Agriculture Organization (FAO) reports total aquaculture production was 39 million tonnes in 2002, and predicts total aquaculture fish production will exceed 130 million tonnes per year by 2030.

Under the Department's 2005-2010 Strategic Plan, DFO will "seek opportunities to create the conditions for the development of an environmentally sustainable, internationally competitive aquaculture industry in Canada." Biotechnology and genomics innovations will continue to contribute to the industry's growth and success through development and application of tools, including those for regulatory and production support.

In support of sustainable aquaculture, DFO's biotechnology and genomics research is investigating and evaluating methods to mitigate the interactions between wild and domesticated strains. Through the development of accurate and efficient methods that allow for aquaculture strains to be distinguished from wild populations, assessment of the impact of interactions can be made, as well as allowing for the tracing of aquaculture products. In addition, the application of sensitive and specific techniques for detecting aquatic animal pathogens will provide information on disease transmission. The tools and results from these studies can then be used to inform aquaculture management decisions.

[5] Canadian Trends in Biotechnology 2nd ed. Government of Canada. 2005

[6] FAO. World Review of Fisheries and Aquaculture. The State of World Fisheries and Aquaculture.

Biotechnology and genomics tools have applications to support the development of robust aquaculture broodstock, both for species that have been used extensively in aquaculture and for new aquaculture species. For example, DFO scientists, in collaboration with academic partners are developing two elite cod broodstocks, one in New Brunswick and one in Newfoundland and Labrador, both based on local stocks of cod, using traditional and biotechnology and genomics tools and information. The genetic information anticipated to be generated from this project will be used to direct the selective breeding to prevent inbreeding and to select for fast growing and/or disease resistant families for use in aquaculture.

Aquatic Ecosystem Health

There is now growing international acceptance for ecosystem-based integrated management practices to protect our aquatic resources. Ecosystem health information can be informed by the development and use of standardized indicators, which can then be used as part of the risk management decision process. The application of outcomes from biotechnology and genomics research provide the means to monitor aquatic ecosystem health using biomarkers – multiple biomolecular signatures that when examined together present a unique pattern of molecular change in an organism and identify an exposure or response to a specific environmental stressor. Furthermore, advances in biotechnology will provide novel means monitor and address the remediation of existing contaminated sites (e.g., bioremediation strategies).

The Aquatic Biotechnology and Genomics R&D Strategy

Dhe following Strategy elaborates on the four themes and includes goals, objectives and actions designed to shape DFO's biotechnology and genomics. It is expected that the strategy will continuously evolve in response to departmental priorities, but that the broad themes and objectives capture key opportunities and activities that biotechnology and genomics applications and information can address, as it relates to DFO's mandate, strategic objectives and Science Sector's Renewal.

As biotechnology and genomics are enabling technologies and therefore multidisciplinary in nature, there are opportunities for the results from each of the research themes' activities and objectives to be incorporated and built on in other research themes. By mapping out the strategic direction and opportunities for biotechnology and genomics R&D, it is anticipated that new collaborations and partnerships can be identified, additional opportunities to transfer knowledge, expertise and applications will be realized, and efficiencies identified and implemented.

Theme #1: Biotechnology and Aquatic Resource Profiling

This research theme encompasses all activities related to understanding the genetic make-up of our aquatic resources. Biotechnology and genomics in this area include studying the genome of aquatic species, studying the population structure of these species and studying the genetics behind interactions between aquatic species and their environment (other species and environmental conditions).

Aquatic resource profiling directly supports sustainable fisheries, sustainable aquaculture, protection of biodiversity and recovery of species at risk. The goal is to optimize the productivity of the aquatic environment (from wild capture and aquaculture) while maintaining environmental health and biodiversity.

By charting each species, population by population, scientists can better assess which populations can support fisheries and how to prevent the loss of genetic diversity in designing breeding programs.

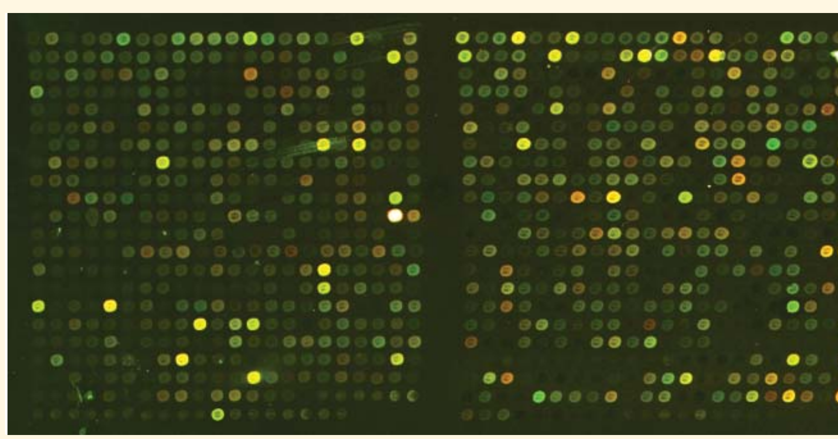
Endangered populations can also be identified and protected to ensure the genetic variability of each survives and thrives. Collated data on both endangered populations is housed in genomic libraries where the information is used to establish a clear understanding of population dynamics.

On the enforcement side, the development of forensic DNA capability in DFO has expanded the scope of enforcement actions while reducing expenditures associated with prosecutions for illegal harvest or sale of fish and shellfish.

Goal: By 2015, to have developed biotechnology tools for genetic profiling of aquatic species and facilitated their widespread application in Canada and abroad, contributing to the sustainable use of aquatic resources.

Objectives:

1. Identify genetic markers to improve species, strain and stock identification for fisheries management and to allow for the protection and enhancement of biodiversity and aquatic fish habitat, including species at risk.
2. Improve biotechnology knowledge base for enhanced sustainability of aquaculture production: increase strain development and enhance biotechnology tools for identification and control of aquaculture species.
3. Enhance and apply research on population genetics and genomics to identify and monitor response of aquatic organisms due to environmental factors.



Objective #1. Identify genetic markers to improve species identification for fisheries management and to allow for the protection and enhancement of biodiversity and aquatic fish habitat.

Action #1: Develop genetic markers for commercially important fisheries species to integrate into sustainable fisheries management practices.

- There is an increased demand for the "real-time" management of fisheries through stock identification techniques using genetic information derived from non-lethal sampling. This information and the speed at which it can be collected helps fishery managers decide if and when the fishery should open. This enables managers to avoid the harvest of populations of conservation concern, including endangered stocks.
- The US/Canada Coded Wire Tagging (CWT) program is expensive, slow and effectively tags only a fraction of the fish (hatchery only) caught in fisheries or recovered from the spawning grounds. Genetic markers, however, allow identification of different populations or groups whenever they become a conservation or management priority, replacing the need to tag the group years in advance of fishery analysis. This is of particular interest when the fisheries occur along migration routes used by mixed stock groupings.

Did You Know That...

DFO is using genomic tools such as mitochondrial DNA (mtDNA) and nuclear DNA (nDNA) to identify stocks of beluga whales. The tools are used to estimate the proportion of beluga belonging to different stocks in an aboriginal mixed-stock fisheries and establish maximum harvest limits that reflect the sustainable harvest of each stock. Management actions are taken to enforce area closures when the DNA indicates that the area is frequented by a stock at a lower abundance level.

Did You Know That...

Due to its commercial viability and ease of tracking, salmon have become one of the most studied aquatic species in Canada and globally. Large, genetic baseline datasets for Pacific salmon, developed by DFO scientists, are used for the most intensive genetic management of fisheries on a real-time basis in the world. Over 10,000 chinook, sockeye and coho salmon samples are analyzed each year to manage fishery openings, enabling Canada to maximize catch under the US/Canada Pacific Salmon Treaty (PST) allocations while maintaining strict harvest limits on stocks of conservation concern. For example, real-time genetic management of the 2003 and 2004 north coast troll fishery on chinook salmon enabled the PST quota to be achieved for the first time since 1994 without overharvesting west coast Vancouver Island populations of conservation concern, resulting in increased annual revenue to the fisheries of over $3 million dollars.

- For estimating population abundance, conventional mark and recapture techniques cannot be used for some species (e.g. rockfish die if brought to the surface for tagging). However, using genetic markers individuals can be genetically "marked" by creating a genetic profile from a non-destructive tissue sample (e.g., samples taken using a barbless hook) and then re-identified during the recapture process, either through resampling with barbless hooks or during a commercial or recreational fishery.
- Similarly, estimation of several cetacean population abundance is very difficult using conventional techniques as they occur over a wide geographical range, have clumped distribution and spend much time under water. Skin samples taken from various whale species including narwhal, beluga and bowhead are taken by aboriginal hunters via non-lethal sample harpoons. As well as being used for stock identification, these samples could be used to estimate the population number by mark and recapture estimation.

Action #2: Develop genetic markers for species of interest to Habitat Management including vulnerable species such as those listed by the Committee on the Status of Endangered Wildlife in Canada (COSEWIC) for protection under the Species at Risk Act (SARA) or under the Convention on the International Trade of Endangered Species (CITES).

- DFO has developed tools that help the Department fulfill its responsibilities under the Species at Risk Act (SARA). Genetic methods are applied to identify population units deserving of designation (as vulnerable, threatened or endangered) according to COSEWIC.
- These methods are also used in developing a captive breeding program for Atlantic salmon; determining the establishment of Marine Protected Areas for marine organisms; and to investigate the effects of population bottlenecks and extensive transplantation on genetic diversity in salmon.

Did You Know That...

Using genetic profiling tools, DFO scientists have been able to distinguish the 'inner' yelloweye rockfish population resident in the Strait of Georgia and Queen Charlotte Sound from an outer coastal population that extends from Oregon to Alaska. The genetic isolation and reduced abundance of the inner yelloweye rockfish population have been documented in a status report on the species for COSEWIC.

Action #3: Enhance the use of forensic species identification for enforcement of fisheries and for the implementation of traceability requirements in other regulations.

- This action will build on the work done under Actions #1 and #2.
- The same genetic information that will support improved management decisions can also be used to increase the certainty and strength of the evidence base for prosecutions for the illegal harvest and sale of aquatic organisms.
- DFO also needs to enhance its ability to meet its CITES obligation to issue "non-detriment" permits for export of cultured product while ensuring that illegally harvested wild product is not laundered through the culture operations. This is required to ensure certainty for exporters of our products.

Action #4: Expand the scope of genetics and genomics databases for species under DFO management and those aquatic species managed through international agreements.

- Information derived from DFO's genetics and genomics databases is used to manage domestic and international fisheries to enable harvest of abundant populations (species) while protecting "listed" populations and species of concern (e.g., species listed as endangered or threatened under the *Species at Risk Act*).

Did You Know That...

Molecular markers are being used to determine the population structure of redfish (Sebastes sp.) in the Northwest Atlantic. This information is particularly important given the transborder nature of these stocks. The use of microsatellite markers has highlighted the important role of hybridization that occurs between redfish species S. fasciatus, S. mentella, and S. marinus in the Gulf of St. Lawrence and Laurentian Channel. Population genetic structure and genetic diversity of these marine species are being determined, and the analysis of archived otoliths is providing key information on the distribution of these species as well as their recruitment history.

Objective #2. Improve biotechnology knowledge base for enhanced sustainable aquaculture production: increase strain development and enhance biotechnology tools for identification and control of aquaculture fish.

Action #1: Develop genetic markers to distinguish aquaculture strains from wild populations in order to assess their interactions.

- Genetic markers can be used for the accurate identification of escaped domesticated fish in the wild environment and to monitor their ecological and reproductive interactions with wild populations.
- Being able to identify aquaculture fish also enables the branding and tracing of aquaculture products, which is increasingly important as consumers demand more information and assurance on the source of seafood products.

Action #2: Incorporate genetic markers into pedigree identification of aquatic species and estimate the genetic merit in selective breeding programs.

- The identification of individuals to a family within a breeding program can be accomplished with genetic markers. This eliminates the need for rearing individual families in separate tanks and then applying tags for identification. The elimination of individual tanks saves hatchery costs and improves the estimation of “genetic merit” in breeding programs.
- Selective breeding may be revolutionized in near future by incorporating molecular markers into the identification of fish with superior performance traits, such as growth and survival, while they are still juveniles.
- Atlantic salmon aquaculture industries on both coasts rely on North American and European domesticated strains, respectively, with importation of new genetic material severely limited because of disease and ecological concerns. Productivity of both groups of fish will require constant improvement by selective breeding in order for the industries to remain competitive in the world market.

Did You Know That...

Molecular markers are being used to study mollusc species such as giant scallop, soft shell clam, and blue mussels, in order to provide information to the aquaculture industry on the origin of collected spat, to help optimize production and to evaluate potential impacts of aquaculture practices on wild populations.

Did You Know That...

The development of Y-chromosome DNA markers associated with male sexual development have simplified the methods for production and maintenance of monosex salmon strains which have important benefits for production and conservation in aquaculture. For chinook salmon, monosex technology has been critical for the survival of the entire industry for more than 20 years; more recently, with Y-marker technology greatly simplifying the development of all-female monosex strains.

Action #3: Develop methods of reproductive control.

- Various methods of reproductive control have and are continuing to be developed to avoid inter-breeding between aquaculture and wild fish populations that may have a negative impact on the wild fish. The effects of the reproductive control methods on the growth and survival of aquaculture strains will determine the feasibility of their implementation in aquaculture. Biotechnology and genomics tools can be used in the development and evaluation of reproductive control methods.
- Reproductive containment of cultured shellfish strains will become more important as more invertebrate species are cultured. Shellfish culture tends to be co-located with wild populations in the aquatic environment, increasing the opportunity and likelihood of reproductive interactions between cultured and wild populations.
- Research is also ongoing to evaluate the effectiveness of sterilization of male and female salmonids to prevent the breeding of escaped farmed salmon with wild salmon stocks.

Objective #3. Enhance and apply research on population genetics and genomics to identify and monitor responses of aquatic organisms to environmental factors.

Action #1: Develop laboratory and bioinformatics capability for the application of cDNA microarrays and other genomics tools to detect physiological responses of aquatic organisms to environmental factors.

- Genomic and molecular biology technologies such as qPCR, Bacterial Artificial Chromosome (BAC) and Expressed Sequence Tag (EST) library screening and sequencing, and microarray analysis are being developed in-house and through partnership with large national and international collaborative efforts.
- DFO has begun to use these tools to determine the basis for altered behaviour and development (e.g., altered migration, reproduction and growth) and reduced survival due to environmental disruption. This information is becoming increasingly important for regulatory and management decisions in order to ensure sustainable use of aquatic resources. For example, applying DNA marker technology has allowed detection of endocrine disruption effects on salmon gonadal development caused by municipal and industrial effluents.
- Specialized genomics techniques include those that determine gene expression (i.e., when genes are ‘turned on’). Examples include quantitative PCR (qPCR), RNA isolation, microarray analysis, large-scale genome sequencing, genome-wide identification of important genes (QTLs), proteomics, metabolomics (the characterization of the metabolites in an organism), meta-genomics and analysis of genomes via bacterial artificial chromosome technology.

Theme #2: Biotechnology and Aquatic Animal Health

DFO contributes to the viability of our international seafood trade through the development and application of biotechnology tools to manage and protect aquatic animal health thereby enabling the Department to meet it's dual role in aquatic animal health: (1) to protect our aquatic ecosystems and (2) to meet the ever changing international standards, through the new National Aquatic Animal Health Program (NAAHP).

To control disease and its spread in aquatic animals, DFO scientists work with epidemiologists and veterinarians, deploying lab tests in commercial aquaculture settings and surveying wild stocks for diseases of concern. Quarantine and disease control measures are applied to aquaculture in order to preserve stocks and export trade. Diagnostic development, validation and application for reportable diseases is now administered through the new National Aquatic Animal Health Program (NAAHP), which involves the Canadian Food Inspection Agency (CFIA) and DFO.

These measures generate the knowledge to make recommendations in the management and control of significant aquatic animal diseases in Canada including economically important diseases like Infectious Salmon Anaemia (ISA) and Infectious Hematopoietic Necrosis (IHN) and the pathogen *Haplosporidium nelsoni* (MSX disease of oysters).

The health of aquatic animals is critical as Canada exports approximately $4.3 billion worth of seafood products each year. To protect this trade Canada must meet international standards set by organizations such as the World Organization for Animal Health (Office International des Epizooties, or OIE), which sets standards for controlling diseases of international trade importance.

Our research helps set international standards for diagnostic tests – including the development and validation of new molecular assays. The application of molecular tools also demonstrates that organisms once believed to be pathogens of international concern are in fact innocuous (benign) host-specific parasites. DFO research into the development of DNA vaccines and how fish respond to these treatments provides additional health management tools to the Canadian aquaculture industry. Enhancing health through vaccination and other husbandry activities minimizes any risk that cultured aquatic animals will serve as a source of infection for susceptible wild species.

The major advantage of molecular tools is their specificity and sensitivity as applied to understanding diseases, disease progressions, host /carriers, and opportunities for mitigation and prevention.

Goal: By 2015, to have developed and applied leading edge biotechnology-based techniques to detect, monitor and minimize the impact of pathogens on aquatic animals and apply this information to assess and improve the health of aquatic animals.

Objectives:

1. Develop, validate and employ molecular techniques to detect and identify endemic and exotic pathogens.
2. Incorporate molecular techniques in studies on epidemiology and transmission of aquatic pathogens for disease management.
3. Apply biotechnology-based techniques for the treatment and prevention of aquatic animal diseases.
4. Integrate biotechnology and other technologies in assessing the impact of disease in aquatic animals through risk analysis.

Objective #1. Develop, validate and employ molecular techniques to detect and identify endemic and exotic pathogens.

Action #1: Develop, validate and apply reliable gene-based tests for parasites and pathogens.

- The detection of aquatic animal pathogens remains a priority for DFO and the seafood sector as a whole. Molecular techniques provide sensitive and pathogen- specific tools to meet these obligations.

- Currently, validated molecular tests are not available for most pathogens of concern, and biotechnology is therefore under-utilised in aquatic animal health. There is a need to develop, validate and apply this technology to investigate aquatic animal diseases.
- The development and application of molecular techniques in Canada is necessary for the implementation of a national surveillance program. Surveillance is internationally required to demonstrate freedom from diseases of economic and ecological concern.
- Licences required for product export may be issued only if health certification is based on sensitive and specific diagnostic techniques. Certification confirms that the product is free of disease agents that may be harmful to the protection and conservation of fish, and therefore, facilitates trade and the activities of the aquaculture industry.

Action #2: Identify and characterize emerging pathogens of economic and ecological concern.

- As aquaculture techniques are developed for commercially valuable native species, previously unknown diseases are likely to be encountered. Identifying the disease agents and understanding their biology and pathogenesis will be facilitated by the application of biotechnology.
- The application of molecular techniques will significantly decrease the time required to identify emerging pathogens, to evaluate their dispersal in the environment and to determine the disease status of different geographical zones. This information will contribute to the prevention and/or control of emerging pathogens economic and ecological concern.

Did You Know That...

DFO scientists identified a "universal non-metazoan" polymerase chain reaction assay that selectively amplifies a segment of the non-metazoan Small Subunit rDNA gene. This assay was validated as a powerful tool for obtaining molecular information on pathogens that have not been isolated from metazoan host tissue. Thus, solving the dilemma of identifying the DNA of protistan pathogens that cannot be obtained free of host DNA, which is usually amplified by the application of conventional universal primers.

Action #3: Establish standard quality assurance and quality control methods and take steps to facilitate their general use.

- Successful application of molecular diagnostic techniques depends on the reliability of the results. Strict applications of prescribed procedures in a quality assurance and quality control (QA/QC) laboratory setting will ensure this reliability.
- Validation of novel molecular techniques will assure that the assays can be reliably reproduced in all certified QA/QC laboratories.
- The strength of our seafood exports will be enhanced if Canada maintains the level of expertise that is required to meet the ever changing international standards that reflect the emergence of new technologies of disease control and surveillance.

Did You Know That...

DFO scientists use polymerase chain reaction-based (PCR) test to differentiate between MSX and SSO infections in oysters during the outbreak in Nova Scotia. The differentiation allowed the control measures to be concentrated on areas affected by the more pathogenic MSX infections and limited the economic impacts of culture operation closures. As a result of the Canadian diagnostic experience, the Office international des epizooties (OIE) has declared the PCR confirmation as the international standard for the diagnosis of MSX and SSO infections in oysters. Canada, through its extensive research, has gained international recognition as a world leader in molecular diagnostic techniques.

Objective #2. Incorporate molecular techniques in studies on epidemiology and transmission of aquatic pathogens for disease management.

Action #1: Use high resolution genetic typing techniques to characterize economically significant pathogens.

- To enhance our understanding of pathogenesis, the development and application of molecular tools to detect pathogens *in situ*, and thus characterize pathogen dissemination within and between hosts is needed.
- Understanding the genetic types or strains of a particular aquatic pathogen that exists throughout geographic zones over extended periods of time is essential in determining epidemiological inferences.
- The characterization of specific strains of disease agents supports the implementation of appropriate responses (e.g., virulent vs. avirulent strains of some viruses require different control measures).
- The establishment of epidemiologically-robust molecular-based pathogen surveys of wild and cultured stocks of aquatic animals will serve to identify trends in the health of these populations and to identify new potentially harmful pathogens. The detection of sub-clinically infected animals allows for the application of preventative control measures to limit disease outbreaks.
- Genetic typing, combined with phylogenetic analyses, provides information on pathogen evolution, which can be used to develop sensitive molecular assays that can be applied to understanding pathogen dispersal and mode of transmission. The ability to track pathogens that undergo differentiation and transmission through unexpected routes, such as host reproductive products or intermediate host(s), will allow for the application of measures to prevent disease transmission.

Action #2: Develop and implement an accessible aquatic pathogen genetic strain database.

- A database documenting the genetic variability among strains of a particular disease agent will facilitate fish health management decisions on the movement of infected fish stocks as well as provide epidemiological information detailing transmission events and disease sources.
- Information on the expression of genes within a host exposed to selected pathogens, generated through the use of microarrays, add to our understanding of the genetic and physiological impact of the pathogen on the host. Through the collection and comparison of this type of data, additional information on the similarities and differences in host-pathogen responses and the impact on gene regulation can be generated.

Objective #3. Apply biotechnology-based techniques for the treatment and prevention of aquatic animal diseases.

Action #1: Develop biotechnology-based therapies for aquaculture and hatchery aquatic animals.

- Infectious diseases are a major constraint to the development and success of aquaculture in Canada and negatively impact stock enhancement programs. The development of prophylaxes against economically significant pathogens will greatly benefit the survival of aquatic animals in culture facilities. Biotechnology and genomics tools can be applied to the development of new therapies against aquatic pathogens to not only benefit aquaculture, but also reduce the spread of pathogens to wild stocks. In addition, using molecular techniques to develop and evaluate fish responses to new therapies against aquatic pathogens of concern will speed up the development phase of these prophylaxis treatments.
- DNA vaccines are proven to be effective against some virus pathogens of finfish and overcome many of the problems encountered with conventional vaccines such as safety, cost and storage. Considerable basic genomics research is still required to identify the appropriate genetic elements of most known parasitic, bacterial and viral pathogens.
- Conventional vaccination of cultured finfish involves intraperitoneal injection or immersion delivery, whereas current technology requires the intramuscular delivery of DNA vaccines. Research is necessary to explore alternative delivery methods for DNA vaccines and ideally, to integrate the delivery of conventional and DNA vaccines.
- DNA vaccines and other new therapies such as heat shock protein-based recombinant vaccines will be explored as new therapies for hatchery reared animals.

Action #2: Use biotechnology to understand the host immune response to natural infections and follow vaccination against specific pathogens.

- The presence of infection is a necessary, but not unique prerequisite for disease. The ability of an aquatic animal to defend itself against the effects of infection will determine the outcome of infection. Basic research is required to better understand how aquatic animals respond to infection and to vaccination. Biotechnology can provide molecular markers of exposure and fish response to infection. Knowledge of the defense mechanisms of aquatic animals will enable the development of “host response” molecular diagnostic techniques. The combined ability to diagnose infection and host response to infection will permit a more thorough assessment of the health of wild and cultured species.
- Significant progress has been made elucidating many of the genes relevant to the salmonid immune system and these gene sequences provide new tools for studying the teleost immune system response to pathogens and vaccines.
- By collaborating nationally and internationally through the Genome Canada projects on aquatic organisms such as the Genomics Research on Atlantic Salmon Project (GRASP) or the Consortium for Genomics Research on all Salmonid Projects, and by using technologies such as qRT-PCR and microarray analysis, DFO laboratories will investigate expression changes of important cytokine and immune response genes during natural infections or following immune stimulation due to vaccination. New markers may also be identified and differential responses to pathogen variants are expected.

Objective #4. Integrate biotechnology and other technologies in assessing the impact of disease in aquatic animals by risk analysis.

Action #1: Work closely with CFIA to develop a formal risk-analysis process for established and emerging pathogens and diseases of aquatic animals.

- Biotechnology will provide pathogen and host response data of sufficient resolution that together with conventional tools, will substantiate the foundation of risk analysis. The risk analysis approach may be useful in establishing priority pathogen/host/disease combinations for policy development or research.

Theme #3: Biotechnology and Aquatic Ecosystem Health

DFO's mandate is to conserve, protect and enhance aquatic ecosystem health. Healthy and productive aquatic ecosystems are not only home to an enormous number of species, but also the basis for a thriving resource industry. Effective conservation and protection of this valuable resource remains a challenge with so much to learn about the living organisms in aquatic environments, their life-cycles and broader ecosystem structure and functions.

While we are a long way from fully understanding ecosystem dynamics, recent advances in biotechnology enable us to assess and in certain cases, mitigate the impact of anthropogenic and environmental stressors. For example, changes in community structure and function can be monitored using new techniques in meta-genomics and novel bioremediation techniques such as biostimulation, and bioaugmentation can be used to treat contaminated sites.

DFO has a history of monitoring contaminated sites in aquatic environments. With increased concern over the negative impact of contaminants on the ecosystem including fish habitat and human health, the Department takes a proactive approach to site remediation. In this regard, habitat restoration is now a recognized component of the Oceans Action Plan.

Healthy ecosystems are the basis for biodiversity, healthy communities and development. Environmental health assessments are an essential component of integrated management initiatives including protection, conservation, mitigation and/or restoration. Biotechnology and genomics tools can generate information about populations, individuals, physiological and metabolic responses to alterations, all of which can provide discrete information that can be integrated into models and approaches for evaluating ecosystem integrity.

Goal: By 2015, to develop and apply biotechnology and genomics tools to enable assessment, mitigation and restoration of aquatic ecosystems.

Objectives:

1. Develop and apply genomic indicators to detect and monitor environmental stress in aquatic ecosystems.
2. Develop genomic tools to understand biological processes for mediating natural recovery in contaminated sites, and for development of bio-remediation technologies for mitigation.
3. Develop sensitive tools based on genetic methods to detect and monitor invasive species and assess potential impacts.
4. Improve measures of ecosystem health using meta-genomics and other biotechnology and genomics tools.

Objective #1. Develop and apply genomic indicators to detect and monitor environmental stress in aquatic ecosystems.

Action #1: Evaluate biological stress indicators, using biotechnology and genomics tools, for key species and ecosystem components within various aquatic ecosystems

- Ecosystem components may respond different to the same environmental stress, resulting in the need to develop and implement tools that can detect environmental stress within different organisms representing different ecosystem components, including microbial populations and sensitive species.

- Changes in fitness and genetic alterations in fish can been used as indicators for environmental stress. For example, genetic markers have been identified that are tightly genetically linked to the sex determination locus in salmon, thereby allowing for unambiguous determination of genetic sex independent of the developmental state of the gonad. These genetic markers provide a valuable tool for sensitizing assays identifying endocrine disruption effects, like gonadal sex reversal, which have been linked to exposure to effluents in the environment. Evaluation and further development of sensitive tools like these allow researchers to quickly and sensitively monitor the effects of changes in the environment and provides valuable information for evaluating ecosystem integrity, and making recommendations for changes in human-based activities.

Action #2: Develop and apply biotechnology and genomics tools to detect environmental alterations.

- The application of genomics to identify changes in the genetic structure of living organisms and the way in which they function provides a unique tool for the delineation of impacted zones and as a means to monitor contaminant degradation potential and/or habitat recovery.
- Gene expression profiling distinguishes altered physiological pathways in fish in response to environmental changes, and may provide an “early warning” system for detecting pollution, stress, habitat degradation, etc., in the aquatic environment.
- Genomics capability allows for the investigation into the effects of alterations in the environment on the physiological, metabolic, protein and gene expression within aquatic organisms. From this information, potential end point indicators can be identified through the evaluation of reference sites or laboratory studies that focus on the impact of habitat degradation, pollution, climate change, etc on the organism.

Objective #2. Develop genomic tools to understand biological processes mediating natural recovery in contaminated sites, and further develop bio-remediation technologies for mitigation.

Action #1: Develop genomic tools to characterize biological processes thatremediate contaminated sites.

- Develop genomic assays to identify, isolate and characterize microorganisms responsible for the biodegradation and biotransformation of contaminants.

Action #2: Develop biostimulation and bioaugmentation methods to promote the biodegradation and/or biotransformation of contaminants.

- Laboratory development and evaluation of potential bioremediation strategies for use in contaminated aquatic environments.
- Develop application methods for bioremediation strategies and protocols for monitoring treatment efficacy.
- Assess bioremediation strategies in field trials and publish guidance documents for technology transfer to internal (resource managers) and external (industry) clients.

Did You Know That...

The National Centre for Offshore Oil and Gas Environmental Research is developing new sensitive, cost-effective and rapid assays, based on recent advances in biotechnology for monitoring habitat recovery. A coupled application of analysis in meta-genomics and physical oceanography has improved our understanding of natural recovery and the feasibility of pro-active remediation procedures in contaminated harbours (e.g., Sydney Harbour). Bioremediation strategies developed by DFO have provided direct benefit to government emergency response agencies (e.g., Canadian Coast Guard) and private sector industries that offer advice and products for oil spill cleanup on a national and international scale.

Objective #3. Develop sensitive tools using genetic methods to detect and monitor invasive species and assess potential impacts.

Action #1: Develop tools for early detection of invasive aquatic species.

- Invasive species cost the Canadian economy billions of dollars annually and wreak havoc on aquatic ecosystems. There is international recognition that invasive species are a global environmental, economic and political issue warranting urgent attention.

Action #2: Develop tools to assess and mitigate pathogens and parasites associated with exotic species.

- Ballast water may contain exotic species, and associated pathogens and parasites, which may be difficult and time-consuming to identify using conventional techniques. Through biotechnology and genomics tools and information scientists can quickly and accurately assess which pathogens, parasites and exotic species are found in a sample.

Objective #4. Improve measures of ecosystem health using meta-genomics and other biotechnology and genomics tools

Action #1: Examine microorganism gene pools within aquatic ecosystems to monitor degradation or recovery (metagenomics).

- Microorganisms are essential for the basic metabolic processes controlling ecosystem function such as primary production, nutrient cycling, the biodegradation and biotransformation of contaminants. Advances in biotechnology and genomics will help us better understand their community structure and function.
- Studies on the application of meta-genomics (i.e., quantification of changes in genomic structure and expression in natural microbial populations as a means to identify changes in environmental conditions and/or ecosystem health), have been conducted in partnership with the Biotechnology Research Institute (BRI) of the National Research Council located in Montreal, Quebec.
- Metagenomics could be applied to study the impact of seawater netpens on the benthic microbial community. A progression of microbial populations within these communities has been observed, and metagenomics could be applied to track this progression and the rate and effect of changes in these microbial communities in response to the presence of aquaculture activities.
- Metagenomics could also be applied to identify the microbial communities that are currently found frozen in northern arctic sea-ice. This could help researchers understand whether these bacteria are still viable, whether there are pathogens present in these communities, and thus contribute to the knowledge and understanding of the historic microbial community within the arctic.

Action #2: Generate ecosystem integrity information, using biotechnology and genomics tools that can be integrated into aquatic ecosystem science management approaches.

- Biotechnology and genomics tools can provide information that helps to identify changes in biodiversity, and in some cases, can reveal linkages between ecosystem health and the health and biodiversity of species.
- Linkages between biodiversity changes and ecosystem integrity can be very complex, and although the information generated through biotechnology and genomics tools can greatly enhance our understanding, ecosystem science and ecosystem management approaches will continue to require additional biological and ecosystem science information as well as refinement. Ultimately, the aim is to be able to detect and interpret linkages, which can contribute to informing management decisions, setting ecosystem objectives, and supporting actions to restore or enhance ecosystem health.

Action #3: Develop and apply the expertise to enable the evaluation of the biological significance and compatibility of genomics, proteomics and metabolic profiling data, and the integration of this data into ecosystem integrity models.

- As genomics, proteomics and metabolic profiling tools and techniques become more sophisticated and are increasingly integrated into research, the quantity of data that is produced rapidly increases. A critical function that will have to be addressed will be both the standardization, evaluation and handling of data from specific, related experiments, as well as addressing questions on how to evaluate and integrate information from multiple sources and experiments.
- Biotechnology and genomics tools can provide information on changes in environments (e.g., population structure), and responses to environmental changes (e.g., gene expression changes), but do not immediately indicate that an impact has occurred. In order to asses impacts, the genomics information will need to be integrated into existing in-house DFO knowledge and understanding of ecosystems and aquatic organism biology, and placed in context of the normal variance seen for ecosystems and organisms.
- Through the further development, understanding and application of biotechnology tools, more refined estimates and interpretations of ecosystem impacts, habitat recovery and overall ecosystem integrity can be incorporated into scientific advice given to support DFO's activities to conserve, protect and enhance aquatic ecosystems.

Theme #4: Regulatory Science for Aquatic Animals with Novel Traits

DFO is responsible for the regulation of aquatic organisms with novel traits under the New Substances Notification Regulations (Organisms). In support of this regulatory responsibility, DFO undertakes a research program which involves the development and assessment of aquatic animals with novel traits, including transgenic fish. The majority of this research takes place in the Centre for Aquaculture and Environmental Research (CAER) in British Columbia, with other projects at the Pacific Biological Station in Nanaimo, British Columbia, and Bedford Institute of Oceanography in Halifax, Nova Scotia.

Included in the scope of organisms addressed under this theme are aquatic animals that express a trait (or traits) that is new to the organism, is no longer expressed in the organism, or is expressed outside the normal range of expression for that trait in that organism. In order to obtain factual information on performance characteristics, fitness parameters and food safety characteristics of aquatic animals with novel traits, DFO has developed non-commercial salmon strains with novel traits using conventional approaches such as selective breeding and modern biotechnology. This information is important in order to assess potential impacts that escaped fish with novel traits might have on wild populations. The transgenic strains are also used by other federal regulatory departments and agencies (e.g. Health Canada and the Canadian Food Inspection Agency) in support of biotechnology regulatory responsibilities.

Our program has identified regulatory science issues that must be addressed in the design of DFO's regulations including the interactions with wild fish; data requirement hurdles such as sample size uncertainty; lab scale uncertainty; the scope of "novelty"; the effectiveness of containment approaches; and what information is needed in order to complete a risk assessment.

Goal: By 2015, to undertake research to provide sufficient understanding to be able to assess the use of aquatic novel living organisms and to allow effective regulation.

Objectives:

1. Enable risk assessment science through the identification, development and evaluation of appropriate novel aquatic animal models.
2. Conduct studies in support of risk assessment methodology and the design and implementation of regulations.

3. Develop and evaluate the efficacy of preventative and mitigative measures to prevent interaction between wild and novel aquatic animal strains (containment strategies).
4. Assess potential ecosystem impacts of transgenic aquatic animals.

Objective #1: Enable risk assessment science through the identification, development and evaluation of appropriate novel aquatic animal models.

Action #1: Identify domesticated and invasive aquatic animal species and strains with potential threats to Canadian ecosystems.

- Aquatic animal strains that differ phenotypically or genetically from those found in a specific ecosystem being considered have the potential to have short or long term effects on conspecifics and other members of the ecosystem. Examples include strains of Canadian aquaculture species that have been selectively bred to possess characteristics not found in nature; fish which have been enhanced in mass scale in hatcheries; foreign introduced species; and invasive "stowaway" species.

Action #2: Develop and maintain contained transgenic strains of aquatic animals to inform regulatory development.

- It is difficult to evaluate novel aquatic animals through modelling and theoretical assessments due to the complex unpredictability of phenotypes arising from many genetic modifications. Thus, assessments are best performed on actual transgenic organisms. In Canada transgenic aquatic animals are being developed for commercial use, but such animals are not available for risk assessment research by the federal government.

- The synthesis of similar public domain strains for use by DFO, other government departments, and other national and international researchers is critical to allow development of empirical risk assessment information in support of emerging regulations. Information derived from this collaborative and public domain approach greatly enhances the knowledge base for DFO scientists and regulators on transgenic organisms, keeps DFO in contact with the latest developments in the field and creates access to a network of collaborative expertise.

Action #3: Evaluate environmental parameters required for growth, survival and overwintering of common R&D aquatic animals, particularly those that are not native to Canada

- Aquatic animals are increasingly being used as models for research and development purposes, due to the rapid growth and short life-span for common R&D aquatic organisms like zebrafish and medaka. The generation of knowledge of the ranges and tolerances to environmental parameters required for growth, survival and overwintering in Canada will provide regulators with scientific information that can be incorporated into the design and implementation of regulatory approaches for the oversight of R&D activities involving novel aquatic animals.

Objective #2: To conduct studies in support of risk assessment methodology development and the design and implementation of regulations for novel aquatic organisms.

Action #1: Evaluate specific phenotypes of various strains of novel and domesticated aquatic animals in order to better determine key parameters that influence environmental risk.

- Physiology provides the link between genotype and phenotype and behaviour, and thus can provide a critical insight into processes that are affected by transgenesis and domestication. Experiments are needed to measure key survival fitness characteristics (such as risk taking behaviour, growth and energy metabolism, reproductive performance) and reproductive fitness characteristics (spawning success, fertility, fecundity, gamete quality) of transgenic and domesticated salmon. The results of these studies will provide knowledge to help in the assessment of possible risks to wild salmon should the transgenic salmon escape to natural environments, and to identify key parameters to investigate in newly developed aquatic animals.
- Assessments of behaviour, physiology and genetics of wild, domesticated and transgenic strains provide baseline data and knowledge that are used to develop the optimum approaches needed for risk assessments.
- Similar phenotypes can arise through the application of selective breeding or modern biotechnology, including recombinant DNA techniques. Detailed comparisons of domesticated and transgenic strains are required to determine the nature of genotypic changes resulting from traditional selective breeding techniques or recombinant DNA techniques, respectively. Empirical studies of genotype/phenotype relationships can help provide clarity for the definition of a regulatory trigger.

Action #2: Evaluate ecosystem impacts and fitness of transgenic aquatic animals using model systems, prior to their release.

- The main objectives of risk assessments of transgenic fish are: 1) to evaluate the phenotype of the animal compared to nontransgenic animals to estimate the potential impacts the former may cause on ecosystems; and 2) evaluate the relative fitness of transgenic organisms to determine if they can effectively compete in nature and persist through subsequent generations. To undertake these assessments, knowledge of factors affecting the ability of the novel organisms to survive to maturation and their ability to reproduce are critical to assess the overall lifetime fitness.
- Many factors continue to be evaluated to assess survival and reproductive performance, invasiveness, and potential ecosystem effects (e.g., resource utilization or habitat degradation), using simple laboratory apparatus (e.g., swim tunnels, disease challenge facilities, behaviour chambers, nutrition tanks, etc.)
- Comparisons of behaviour (predation avoidance, competitive growth, spawning success) are underway for nontransgenic and transgenic fish either raised in tanks or semi-natural environments. However, there is much uncertainty in the conduct of empirical research of transgenic aquatic animals because the way an organism interacts with its environment profoundly affects survival and reproductive fitness. While such information provides the foundation for planning more detailed investigations, more complex experimental habitats are urgently required to undertake such studies under conditions that simulate natural conditions more realistically.
- Information from the semi-natural environments developed to date indicates that much more complicated interactions among fish of different genotypes occur, and that pleiotropic phenotypic traits are extremely complicated to evaluate due to genotype by environment interactions, because different data is generated depending on the experimental conditions employed. These observations suggest that risk assessments based on data generated in simple laboratory apparatus may have very little practical use for assessments of risk to the natural environment.
- Pleiotrophic effects in fish are known to be significant. Therefore, the process by which a novel aquatic animal has been developed may influence other traits and phenotypic expression, particularly when the method uses modern biotechnology. In order to design and implement appropriate and effective regulations, information on the effect of the method (or process) used to develop the novel aquatic animal is needed.

Objective #3: Develop and evaluate the efficacy of preventative and mitigative measures to prevent interaction between wild and novel strains (containment strategies).

Action #1: Develop and evaluate biological containment methods.

- Biological containment options for finfish and shellfish have been identified and developed as methods to limit the impact of these novel aquatic animals on aquatic ecosystems, by preventing interbreeding with wild strains. The evaluation of the efficacy of biological containment is required to determine its appropriateness as a containment method.
- Triploidy (pressure shock induced within all-female strains) is currently the most achievable method of inducing sterility in finfish and shellfish on a large scale. DFO now has a large series of experiments underway to test the efficacy of this approach for containment of finfish.
- Previous DFO research has shown that triploidy may not provide sufficient containment for some situations (e.g. use of transgenic strains). Thus, biological containment strategies including those involving transgenic techniques, that provide a higher level of containment are desirable, but have not yet been fully developed. These techniques require further development and efficacy assessment which may in turn require the development of model strains.

Action #2: Evaluate physical containment methods for tetraploid shellfish broodstock.

- Physical containment strategies are required for preventing environmental release and interactions with wild populations of fertile tetraploid shellfish broodstock that are used to produce triploid shellfish. Potential challenges for physical containment exist due to the lifecycle and lifestages of shellfish. Therefore, scientists need to evaluate the efficacy of various physical containment methods in order to inform the development of appropriate standards and approaches for effectively containing these fertile aquatic animals.

Action #3: Evaluate mitigative strategies for limiting and/or preventing interactions between wild and novel aquatic animals.

- The development and evaluation of mitigative strategies is important as an backup approach to preventing interactions between wild and novel aquatic animals. One such approach is to develop conditional expression systems that can control survival and reproduction of escaped individuals in nature.

Objective #4: Assess potential ecosystem impacts of transgenic aquatic animals

Action #1: Generate knowledge to enable the evaluation of potential ecosystem impacts resulting from intentional mass introductions of novel aquatic animals into various environments

- Potential ecosystem impacts from mass introductions (e.g., triploid shellfish) will depend, among other factors, on the type of introduced novel aquatic animal, it's novel trait, the ecosystem it is introduced into, including the presence of conspecifics or competitors, the lifecycle of the introduced organism, adjacent ecosystems, and the current environmental conditions. These factors and their interactions will require an ecosystem approach, integrating information generated from various studies.
- Determination of potential ecosystem impacts is necessary for evaluation of likely short and long term impacts resulting from mass introductions of novel aquatic organisms both on the ecosystem into which it is intended to be introduced, and adjacent ecosystems.

Action #2: Evaluate potential ecosystem impacts resulting from unintentional releases of novel aquatic animals into various environments

- The potential ecosystem impacts that may result from an unintentional release of novel aquatic animals, particularly novel fertile aquatic animals, will need to be evaluated and the information generated from these studies incorporated into regulatory considerations. Potential impacts of an unintentional release of novel aquatic animals will likely be influenced by the scale of the unintentional release. The development and evaluation of models that take into account the scale of unintentional release in addition to factors that would be used to estimate potential ecosystem impacts of an intentional introduction, can inform estimates of potential ecosystem impacts from unintentional releases.

Action #3: Evaluate ecosystem factors that may influence competitive ability of novel aquatic animals.

- Ecosystem factors, such as the size and complexity of a habitat, the type and availability of food resources, population density and the potential for migration within the ecosystem, are thought to influence the competitive ability of aquatic animals. By evaluating the significance and complexity of such ecosystem factors, scientists will be able to identify which factors are likely to effect predictions of behaviour and survival of novel aquatic animals in an ecosystem, which are important for risk assessment models.

Action #4: Generate knowledge to better understand the nature of ecosystems that may be most affected by novel aquatic animals

- The generation of baseline data (e.g., species diversity, food resources, and habitat availability) on the different ecosystems that may be impacted, particularly from the introduction of anadromous novel aquatic animals (e.g., salmon), is required to further develop the knowledge base upon which assessments can be made.

Conclusions – Charting a Path Forward

The realization of the goals and objectives outlined in this strategy will require significant support. Investment will be required to support the research and development activities, the increased capacity and expertise to carry out the R&D activities, and a proactive approach to succession planning for senior scientists. Senior management support will remain a critical component to help foster a coordinated approach that integrates regional and national needs. Further investments are also anticipated in order 1) to meet the incremental costs that are associated with ongoing research and equipment requirements to enable the development of innovative biotechnology applications for internal use and for technology transfer to appropriate end-users, 2) to generate research information in support of DFO's mandate and regulatory responsibilities, and 3) to allow for effective partnering and collaborations with external scientists.

In order to move from this strategy for aquatic biotechnology and genomics to an action plan for research and development activities, a number of steps must be undertaken including increased engagement of researchers, scientists and scientific advisors within DFO in order to further explore opportunities for incorporating biotechnology and genomics tools and applications to support goals such as sustainable fisheries and aquaculture, aquatic ecosystem health, protecting and managing aquatic natural resources and biodiversity. Although standard biotechnology tools are now used throughout the Department, with the more specialized developmental work concentrated in biotechnology centres across the country, the stabilization of existing expertise and development of additional and new expertise, through enhanced partnerships and collaborations within DFO, will be necessary in order to achieve these goals. Enhanced partnerships will also help to identify opportunities for the incorporation of biotechnology and genomics in delivering core mandate Science Sector services. This will help to keep the Strategy current and responsive to departmental pressures, Science Sector goals and approaches, and the goals and objectives of the Canadian Biotechnology Strategy.

It is important to build on the success that has been realized to date. One of the key successes has been in integrating and deploying biotechnology and genomics tools and information through the development of strong and vibrant partnerships with researchers in other government departments, academia and industry, as appropriate. This has enabled DFO researchers and DFO Science to capitalize on third party resources to deliver better and stronger programs, meet its mandate and key priority objectives more efficiently, foster and support world-class scientific and technological innovation, train new scientific personnel, and develop and maintain a national and international reputation for scientific excellence in aquatic biotechnology and genomics research. As we move forward to realizing the goals and objectives in this Strategy, there will continue to be a concerted effort to identify and maximize external partnerships and collaborations in order to best place and utilize DFO resources and expertise.

Through fostering an active, internationally respected and innovative R&D program for aquatic biotechnology and genomics, DFO can help to shape the development of expertise in aquatic biotechnology within Canada, can better influence the research agenda and support for academic research in aquatic biotechnology and genomics, as well as be an international leader in the field. This Strategy articulates a collective vision of where biotechnology and genomics research and development can best be incorporated in a value-added, innovative, efficient and effective manner, into DFO Science activities and services to help position the Department in delivery of its mandate and achieving the three strategic priority objectives of safe and accessible waterways, sustainable fisheries and aquaculture, and healthy and productive aquatic ecosystems.