Aquatic Animals – Biosecurity and Biotechnology

Effective Date:  March 2010

Applicable Legislation and Guidelines:

- Animals for Research Act
- Canadian Environmental Protection Act (CEPA 1999)
  - New Substances Notification Regulations
- Fisheries Act
  - Fish Health Protection Regulations
  - Ontario Fishery Regulations
- Food and Drug Act and Regulations
  - Novel Food Regulations
- Health of Animals Act
  - Health of Animals Regulations
  - Reportable Diseases Regulations
- Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade Act
  - Wild Animal and Plant Trade Regulations
- Species at Risk Act

Canadian Council on Animal Care (CCAC) Guidelines:

- The Care and Use of Fish in Research, Teaching and Testing (2005);
- Guide to the Care and Use of Experimental Animals
- Transgenic Animals (1997);
- Genetically-Engineered Animals (2nd draft, August 2008);
- Containment Standards for Facilities Handling Aquatic Animal Pathogens, CFIA (draft Oct. 2009)

Intent:  to promote awareness about federal acts and regulations concerning aquatic animals and containment standards, and compliance with prescribed requirements for human health, aquatic animal health and environmental protection;

to publicize University requirements for aquatic biosecurity, best practices and due diligence;

to identify appropriate guidelines for aquatic biotechnology including research with novel aquatic animals, novel feeds, novel pharmaceuticals, nutraceuticals and veterinary biologics for aquatic animals.

Scope:  all aquatic animals used for University research, teaching and testing.
Definitions:

**acclimation** a persisting physiological, biochemical or morphological change within an individual animal during its life as a result of a prolonged exposure to an environmental condition such as high or low temperature; generally the changes are reversible.

**aquaculture** the farming of fish, shellfish and aquatic plants in closed containment (e.g., net pens or cages) in fresh or salt water; the rearing processes generally enhance production, feeding, and protection from predators.

**aquatic biotechnology** involves the application of science and engineering for the direct and indirect use of aquatic organisms or parts or products of living aquatic organisms in their natural or modified forms. Components of aquatic biotechnology include aquaculture biotechnology (e.g., fish health and broodstock optimization), aquatic bio-processing (e.g., obtaining valuable compounds from marine organisms); aquatic bioremediation (e.g., the use of microorganisms to degrade toxic chemicals in aquatic environments). For the purposes of managing living aquatic animals, biotechnology consists primarily of observations and/or management of the genetic material of populations to maintain adequate levels of abundance and biodiversity.

**aquatic animals** means all life stages (including eggs and gametes) of fish, molluscs, crustaceans, and amphibians originating from aquaculture establishments or removed from the wild; may live in fresh water or sea water.

**aquatic organisms** includes all organisms (finfish, molluscs, crustaceans, echinoderms, and other invertebrates and their lifestages defined as “Fish” in the *Fisheries Act*, as well as marine and fresh water plants.

**biosecurity** the process of taking precautions to minimize the risk of introduction and spread of infectious organisms into or between populations.

**containment facility** a facility that has been specially modified to prevent the release of aquatic organisms to waters outside the facility (includes a quarantine facility with treated effluent). Some jurisdictions assign level of containment status to facilities based on defined standards.

**cultured fish** a fish listed in Schedule I of the *Fish Health Protection Regulations* that is propagated in an aquaculture facility, and includes the eggs of such fish.

**disease** a clinical or non-clinical infection with one or more of the etiological agents of fish diseases (see Part 1 Section 1.2 and Part 2 of the OIE Aquatic Animal Health Code, [http://www.oie.int/eng/normes/fcode/en_sommaire.htm](http://www.oie.int/eng/normes/fcode/en_sommaire.htm)).
disinfection  the application, after thorough cleaning, of procedures to destroy the infectious or parasitic agents of diseases of aquatic animals including zoonoses. The disinfectant of choice depends on microbiocidal efficacy, safety for aquatic animals and environmental considerations (e.g., 50 mg of iodine or chlorine per litre for one hour).

distress  a state of excessive stress in which the aquatic animal is unable to make the necessary adaptations to stressors.

fish  as defined in the Fisheries Act:  
(a) parts of fish,  
(b) shellfish, crustaceans, marine animals and any parts of shellfish, crustaceans or marine animals,  
(c) the eggs, sperm, spawn, larvae, spat and juvenile stages of fish, shellfish, crustaceans and marine animals;  
one or more individuals of one species.

fishes  individuals of more than one species.

fish with novel traits  any fish which has a characteristic of the aquatic animal that has been intentionally selected or introduced into a population of aquatic species through a specific genetic change. This includes fish derived through recombinant DNA techniques (e.g., transgenic or genetically engineered), traditional crossbreeding for a desired trait, or the importation of non-native fishes.

fomites  non-living objects that can carry disease organisms (e.g., nets, hand tools).

import  the movement of aquatic organisms across national or interprovincial boundaries.

introduced species  any species intentionally or accidentally transported and released by humans into an environment outside its present range, or into a facility with effluent access to open-water or into a flow-through system.

morbidity  visible manifestation of a diseased state.

mortality  loss of life; death.

novel trait  a new characteristic or attribute scientifically introduced into an aquatic animal.

noxious stimuli  those stimuli that are damaging or potentially damaging to normal tissue (e.g., mechanical pressure, extremes of temperature, chemicals).

pain  fish pain is a response to a noxious stimulus that results in a change in behavior or physiology; the same noxious stimulus would be painful to humans.
**Guidelines:**

**General**


2. The University’s Animal Care Policy and Procedures govern the review, approval and conduct of all aquatic animal research by University personnel whether conducted at the main campus, its regional campuses, research stations, other premises, or in the wild. They also govern the resolution of extraordinary matters related to aquatic animal ethics, welfare and reproductive management.
3. Investigators must anticipate potential risks associated with disease and zoonotic agents likely to be present in their fishes. Such risks must be identified in the Animal Utilization Protocol (AUP) submitted to the Animal Care Committee (ACC), and must be discussed with the Aquatic Animal Facility Manager. See the World Animal Health Information Database (WAHID): http://www.oie.int/wahis/public.php?page=home.

4. AUPs are required for fishes held live in a containment facility for research, teaching or testing, for fishes caught, sampled and released to the wild, for fishes caught in the wild and euthanized, and for all research in containment with transgenic fishes, novel feeds and novel veterinary biologics.

5. Permits are required pursuant to federal legislation as noted below (guideline statements 6, 7, 8, 9, 11). Permits are required for imports and exports of aquatic animals, introductions and transfers (releases), and if research activities might impact on a species at risk. The Director of Research Risk Management (519-824-4120 ext. 52048) will assist researchers with administrative requirements and with the preparation of prescribed applications to regulatory authorities. Copies of all permits must be forwarded to the Aquatic Facility Manager and to the Veterinary Director of Animal Facilities Management.


7. Canada’s National Code on Introductions and Transfers of Aquatic Organisms, http://www.dfo-mpo.gc.ca/science/enviro/ais-eae/code-eng.htm, fulfills international OIE obligations and is intended to protect aquatic ecosystems from impacts due to exotic and native species including pathogens and parasites. The Code outlines the information requirements and risk assessment procedures for intentional introductions and all transfers (releases) within Canada of live aquatic animals.

8. Research activities that may impact a species protected by the Species at Risk Act (SARA) will require a SARA permit. General information about species at risk is found at http://www.dfo-mpo.gc.ca/species-especes/home_e.asp, and instructions regarding SARA permit applications are available at http://www.sararegistry.gc.ca/sar/permit/permits_e.cfm. Species protected by the Species at Risk Act are listed at http://www.sararegistry.gc.ca/default_e.cfm. Also see http://www.dfo-mpo.gc.ca/species-especes/listing-eng.htm.

10. The *Ontario Fishery Regulations*, [http://laws.justice.gc.ca/en/ShowTdm/cr/SOR-89-93///en](http://laws.justice.gc.ca/en/ShowTdm/cr/SOR-89-93///en), restrict the release of live fish into open waters and prohibit the importation of baitfish (including crayfish and salamanders). Aquatic organisms released to provincial waters must be disease-free and must not have adverse affects on genetic characteristics or sizes of fish populations.


15. Pursuant to FHPR, University aquaculture facilities for Salmonidae (see Schedule I) must be inspected by Fisheries and Oceans Canada (DFO) Fish Health Officials at prescribed frequencies for FHPR pathogens (specified in Schedules II, III and IV). Fish specimens and samples are taken during inspections. Fish Health Certificates issued to the facility attest to the current FHPR pathogen status of the facility. Facility records must document all Salmonidae introductions and imports, losses, exports, disease histories and disease treatment programs. Facility records are subject to audits by Local Fish Health Officers, the Veterinary Director of Animal Facilities Management and by the Canadian Council of Animal Care (CCAC).
16. Schedule IV pathogens in the FHPR are notifiable to the Veterinary Director of Animal Facilities Management (519-824-4120, ext. 58856), to the Director of Animal Care Services (519-824-4120, ext. 54305), and to the DFO. The DFO Regional Administrative Authority for FHPR is:
   Ontario Ministry of Natural Resources,
   Fish and Wildlife Branch,
   300 Water Street,
   Peterborough ON K9J 8M5
   Telephone 705-755-1928

17. Aquaculture Facility Managers are responsible for notifying DFO Fish Health Officials about any change in status of their Fish Health Certificates so that the National Registry of Aquatic Animal Health may be up-dated. The Veterinary Director of Animal Facilities Management must be provided copies of all Fish Health Laboratory Reports and (new) Fish Health Certificates, and must be notified about compliance obligations (e.g., prescribed disease testing, facility inspection schedules, etc.).

Biosecurity

18. The Aquatic Animal Health Code from the World Organization for Animal Health (OIE) provides standards, guidelines and recommendations for the sanitary safety of international trade in aquatic animals; see http://www.oie.int/eng/normes/fcode/A_summary.htm. General information about aquatic disease prevention and control is discussed in Part I Section 4 of the Code. Recommendations applicable to specific diseases are presented in Part II.


20. Water quality parameters are species-specific. Guidelines for aquaculture are found at http://www.aquanic.org/publicat/usda_rac/efs/nrac/nrac170.pdf. Aquaculture facility water quality monitoring systems should be able to detect and react to changes in water quality before they become life-threatening.

21. Fishes must be acquired from hatcheries with defined health status and known genetic history. Fishes should be acclimated to laboratory conditions during an appropriate period of quarantine during which there is extraordinary health surveillance. The fish health monitoring program must be documented (e.g., water quality parameters, feed quality, disease agents, disease conditions, disease control measures, environmental and experimental stressors). The Aquatic Animal Health Code discusses surveillance, see http://www.oie.int/eng/normes/fcode/en_chapitre_3.3.1.htm. The OIE Manual of Diagnostic Tests for Aquatic Animals elaborates on health surveillance; see http://www.oie.int/eng/normes/fmanual/A_summary.htm.

22. Physical containment and operational practices for aquatic animal pathogens must comply with the Containment Standards for Veterinary Facilities, Agriculture and Agri-Food Canada, 1996,

23. Written standard operating procedures (SOPs) must be developed for experimental protocols, the care, feeding and maintenance of all fishes, for the cleaning and disinfection of tanks, rooms and equipment, for biosecurity and disease control procedures, and for personal hygiene practices. SOPs shall indicate that tanks must be disinfected before and after every experiment and that tools for use with aquatic animals must be disinfected before each use.

24. Basic physical and behavioral parameters indicative of well-being of fishes should be monitored daily and recorded. Perturbations of these parameters must be investigated; causes and stressors should be identified and corrected. Endpoints must be established for studies involving pain or distress and criteria for early euthanasia should be defined and documented (e.g., juveniles that are not likely to survive should be humanely euthanized as soon as their terminal conditions are identified). The Veterinary Director of Animal Facilities Management (ext. 58856) must be notified about abnormal aquatic animal behaviours.

25. Fishes should be handled only when necessary and the number of handling episodes should be minimized. Harm to mucus-skin barriers must be avoided or minimized.

26. Researchers should consult with the Aquatic Facility Manager about CFIA standards for effluent water treatment and monitoring. Water used for the transportation of aquatic animals should be appropriately treated after transport and/or before discharge in order to minimize the risks of transfers of pathogens.

27. Hazards may be transmitted from feed to aquatic animals by direct consumption and by contamination of the aquatic environment. All feed and feed ingredients should meet regulatory standards for feed safety. (See OIE Guidelines on the control of health hazards in aquatic animal feeds at [http://www.oie.int/eng/normes/fcode/en_chapitre_3.5.1.htm](http://www.oie.int/eng/normes/fcode/en_chapitre_3.5.1.htm).) Labeling should provide clear instructions about safe storage, handling and proper use. Aquatic animal care personnel must be cognizant about food-borne biological, chemical and physical hazards.

28. In general, fishes that have been kept in captive research environments must not be released into the wild. Adoptions are not permitted for biosecurity and compliance reasons, and releases of research aquaculture fish species for human consumption are not permitted. Methods for euthanasia must be approved by the Animal Care Committee (ACC). Carcass disposal must comply with provincial and municipal (local) regulations concerning biological materials. Consult the Director of Research Risk Management (ext. 52048) for advice and assistance.

29. All fish samples and specimens should be autoclaved, incinerated or otherwise sterilized before being discarded per the Ministry of Environment (MOE) guideline titled The Management of Biomedical Waste in Ontario, April 1994, [http://www.ene.gov.on.ca/envision/gp/425e.htm](http://www.ene.gov.on.ca/envision/gp/425e.htm). MOE Guidelines on microbiological testing of non-incineration biomedical waste treatment technologies are outlined at [http://www.ene.gov.on.ca/envision/gp/4321e.htm](http://www.ene.gov.on.ca/envision/gp/4321e.htm).
Biotechnology

30. Genetically modified fishes may have changes in anatomy and physiology as a result of their genetic alteration. Extraordinary health surveillance and record-keeping will be warranted.

31. Physical and/or biological containment strategies are required to prevent inadvertent releases of fish with novel traits and to protect natural aquatic ecosystems. Investigators must consult with the Aquatic Facility Manager and/or the Veterinary Director of Animal Facilities Management.

32. Information about due diligence in biotechnology research at the University is found at http://www.uoguelph.ca/research/forms_policies_procedures/biotechnology.shtml. Consult the Director of Research Risk Management (ext. 52048) for assistance with regulatory compliance and prescribed notifications to Environment Canada.

33. Genetically modified fishes and/or by-products must not be permitted to enter any food or feed chains. The New Substance Notification Regulations (Organisms) under the Canadian Environmental Protection Act (CEPA 1999) govern risk assessments and approvals of all experimental genetically engineered aquatic organisms by Environment Canada (EC) in conjunction with Health Canada (HC) and/or the Canadian Food Inspection Agency (CFIA), and/or the Department of Fisheries and Oceans (DFO). Information about Environment Canada’s New Substances Program is accessed at http://www.ec.gc.ca/substances/nsb/eng/home_e.shtml.

34. The principles of containment described in the Containment Standards for Veterinary Facilities, Agriculture and Agri-Food Canada, 1996, will apply to research involving genetically modified fish and aquatic animals with novel traits. Approaches to the containment of genetically engineered fishes include physical confinement, physicochemical (100% mortality) methods, and perhaps reproductive containment via transgenic technologies. Further information is described at http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T4D-4RH94RG-3&_user=1067211&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&acct=C000051237&version=1&_urlVersion=0&userid=1067211&md5=189cf89b7e71adb1fc4778228be781d.

35. Disposal of genetically engineered fish carcasses will require special arrangements. Consult the Director of Research Risk Management (ext. 52048) for assistance.

Additional Information

The Containment Standards for Facilities Handling Aquatic Animal Pathogens, CFIA, October 2009 (draft), are mandatory for facilities importing aquatic pathogens. This document is posted at http://www.inspection.gc.ca/english/sci/bio/anima/aqu/csfncie.shtml; it elaborates on the minimum standards for physical and operational requirements at aquatic animal containment facilities in Canada. Compliance with the standards is intended to prevent economic and environmental consequences from inadvertent releases of aquatic animal pathogens (both opportunistic pathogens and zoonotic pathogens). The containment prescribed depends upon the specific pathogen biology,
the pathogen’s Risk Group, and the impacts that any releases might have on aquatic environments in Canada. Operational due diligence must include personnel training, protocols for fomites and appropriate treatments of liquid and solid effluents.

Aquatic animal pathogen containment is categorized into three levels:
- *in vitro* containment: AQC1, AQC2, AQC3;
- *in vivo* containment: AQC2, AQC3.


Key containment features for AQC2 and AQC3 *in vivo* facilities, as recommended by the Aquatic Animal Health Division of CFIA, include:
- security system;
- anteroom with clothing change area;
- inward directional airflow;
- sealed surfaces in the containment zone;
- recording autoclave within the containment zone;
- liquid effluent treatment system with sludge /sediment collection/removal, and process monitoring;
- redundant liquid effluent treatment system or holding system;
- backflow preventers;
- water system failure alarm;
- essential power backup system (*e.g.*, generator) in the event of power failure.

As-built drawings and specifications for AQC2 and AQC3 *in vivo* facilities must be reviewed by CFIA. These facilities will be certified by CFIA and re-certified annually. An aquatic biosafety manual, SOPs, and an emergency response plan must also be developed. For assistance with aquatic pathogen containment, contact the Director of Research Risk Management (ext. 52048). More information is available from the CFIA Office of Biohazard Containment and Safety (OBCS) at 613-221-7068.

**The National Aquatic Animal Health Program**

Researchers should be aware that Canada’s aquatic animal health programs involve extensive regulatory activities by federal, territorial, provincial and municipal authorities. International and interprovincial exchanges of wild and cultivated aquatic species are managed by these levels of government to prevent the spread of serious infectious diseases.

The Canadian Food Inspection Agency (CFIA) and Fisheries and Oceans Canada (DFO) are mandated to develop Canada’s National Aquatic Animal Health Program (NAAHP) under the *Health of Animals Act*. The NAAHP protects Canada’s aquatic animal populations from introductions of reportable or notifiable diseases, advances laboratory diagnostic capabilities, performs aquatic disease surveillance and management initiatives, and conducts certification programs for imported and exported aquatic animals and products.

**New Substances**

The *Canadian Environmental Protection Act (CEPA 1999)* is the key authority to ensure that all new substances, including living organisms, introduced into Canada are assessed for their potential to harm human health, the environment and biodiversity. The *toxicity* of a new substance is under regulatory scrutiny; *i.e.*, capacities to cause injury to humans, animals, plants or to microorganisms; see http://www.ec.gc.ca/CEPARegistry/gene_info/fact_01.cfm.

Environment Canada is responsible for enforcing the *New Substances Notification Regulations (NSNR)* pursuant to CEPA whenever other Acts (*e.g.*, *Health of Animals Act, Health of Animals Regulations, Pesticide Products Act, and Pesticide Products Regulations*) do not address proposed uses of an imported or manufactured novel organism (product). The “regulatory roadmap” for new substances in Canada is found at http://www.ec.gc.ca/substances/nsb/pdf/roadmap_e.pdf. *NSNR (Organisms)* apply to aquatic animals. Proposed amendments to these regulations will likely remove research and development notification exemptions for novel aquatic organisms by the summer of 2010.

General information about the new substances program is available at http://www.ec.gc.ca/substances/nsb/eng/home_e.shtml.

Persons wanting to conduct research with, import, manufacture (*i.e.*, produce, develop or grow) or sell any novel aquatic plant, aquatic animal or aquatic microorganism are required to notify Environment Canada well in advance of the planned activity. Any organisms that do not appear on Canada’s Domestic Substances Lists (DSL) may be subject to NSNR; see http://www.ec.gc.ca/substances/nsb/eng/lists_e.shtml.

Since regulatory requirements concerning biotechnology research are evolving, University personnel must contact the Director of Research Risk Management (ext. 52048) for advice and assistance with NSNR compliance. See http://www.uoguelph.ca/research/policies/Adobe/New%20Substances%20Notifications%20Guidelines.pdf.

**Aquatic Pest Control Products**

References

http://www.oie.int/eng/normes/fcode/A_summry.htm

World Trade Organization, *Sanitary and Phytosanitary Measures*
www.wto.org/English/tratop_e/sps_e/sps_e.htm

Fisheries and Oceans Canada, *National Code on Introductions and Transfers of Aquatic Organisms*

Fisheries and Oceans Canada, *Manual of Compliance* (revised 2004),

*Guidelines for the Safety Assessment of Novel Foods, Volume I.*

CCME *Guidelines for the Treatment of Biomedical Waste in Canada*
http://www.ccme.ca/assets/pdf/pn_1060_e.pdf

Canadian Food Inspection Agency (CFIA) Import Program

Canadian Water Quality Guidelines
http://www.ec.gc.ca/cegg-rcqe/English/cegg/water/default.cfm

Import Permits for Live Terrestrial Animals