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Proceedings of the Expert Panel on National Containment Standards for Facilities Handling Aquatic Animal Pathogens

April 18, 2006
Ottawa, Ontario

Jake Rice
Chair

Nancy House
Editor

Canadian Science Advisory Secretariat
200 Kent Street
Ottawa, Ontario
K1A 0E6

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18 avril 2006
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SUMMARY

On April 18, 2006, experts on aquatic animal pathogen containment standards ('aquatic standards') from a variety of backgrounds participated in a workshop chaired by Dr. Jake Rice of Fisheries and Oceans Canada's (DFO) Canadian Science Advisory Secretariat (CSAS). The purpose of the workshop was to discuss a draft document '*National Aquatic Animal Pathogen Containment Guidelines for Laboratories and Live Holding Facilities*' written by DFO and CFIA.

With the implementation of the National Aquatic Animal Health Program (NAAHP), aquatic animal pathogen containment standards area key priority in order to reduce the risk of introducing exotic aquatic animal pathogens into Canada or spreading pathogens to parts of Canada where they do not currently exist. Invited experts were tasked with assessing whether the physical and operational requirements presented in the draft standards were accurate, supported by scientific data, represent global knowledge, and meet national requirements.

SOMMAIRE

Le 18 avril 2006, un éventail diversifié d'experts en normes de confinement des pathogènes des animaux aquatiques (ci-après « normes aquatiques ») a participé à un atelier présidé par M. Jake Rice, Ph.D., du Secrétariat canadien de consultation scientifique (SCCS), ministère des Pêches et des Océans du Canada (MPO). Le but de l'atelier était de discuter d'un document provisoire rédigé par le MPO et par l'ACIA et intitulé *Lignes directrices sur le confinement des agents pathogènes des animaux aquatiques à l'intention des laboratoires et des installations de garde en captivité*.

Avec la mise en œuvre du Programme national sur la santé des animaux aquatiques (PNSAA), les normes de confinement des pathogènes des animaux aquatiques constituent une priorité essentielle si l'on veut réduire le risque d'introduction de pathogènes des animaux aquatiques exotiques au Canada ou la propagation de pathogènes dans les régions canadiennes où ils sont encore absents. Les experts ont été invités à évaluer si les exigences physiques et opérationnelles présentées dans l'ébauche de normes étaient précises, soutenues par des données scientifiques, conformes aux connaissances globales et en harmonie avec les exigences nationales.

INTRODUCTION

There are currently no official containment standards for the handling of aquatic animal pathogens by laboratories or live holding facilities in Canada or elsewhere. Containment standards currently exist for veterinary facilities handling animal pathogens (red book), facilities handling plant pests, and laboratory biosafety guidelines (white book), but are all a poor fit for aquatic animals and aquatic animal pathogens. The Canadian Council on Animal Care (CCAC) has standards, which only apply to live holding or experimentation with live fish/animals. The proposed biocontainment standards are consistent with standard, but also include *in vitro* laboratory work. Australia has a short document that outlines the general requirements for the physical containment of fish and other aquatic organisms, but falls short of setting standards.

With funding in 2005 and the subsequent implementation of the National Aquatic Animal Health Programme (NAAHP) by the Canadian Food Inspection Agency (CFIA) and Fisheries and Oceans Canada (DFO), the need for such standards has become a key priority, particularly as the aquatic animal pathogen diagnostic and research activities increase across Canada with variable or negligible biosecurity guidance. Standards are necessary to reduce the risk of

INTRODUCTION

Actuellement, aucune norme de confinement officielle n'existe pour régir la manipulation des pathogènes des animaux aquatiques dans les laboratoires et les installations de garde en captivité au Canada et ailleurs dans le monde. Il existe toutefois des normes de confinement pour les installations vétérinaires où l'on manipule des pathogènes animaux (livre rouge) et les installations où l'on manipule des phytoravageurs ainsi que des lignes directrices sur la biosécurité dans les laboratoires (livre blanc), mais celles-ci conviennent toutes mal aux pathogènes des animaux aquatiques et aux animaux aquatiques eux-mêmes. Le Conseil canadien de protection des animaux (CCPA) a des normes qui ne s'appliquent qu'à la garde d'animaux en captivité ou aux expériences menées sur des animaux/poissons vivants. Les normes de bioconfinement proposées s'appliquent aux travaux standard et également aux travaux *in vitro*. Un court document australien décrit les conditions générales pour le confinement physique des poissons et d'autres organismes aquatiques, mais n'établi aucune norme à cet égard.

Avec le budget de 2005 et la mise en œuvre subséquente du Programme national sur la santé des animaux aquatiques (PNSAA) par l'Agence canadienne d'inspection des aliments (ACIA) et Pêches et Océans Canada (MPO), l'élaboration de telles normes devenait prioritaire, particulièrement du fait que le nombre d'activités de recherche et d'établissement de diagnostics sur les pathogènes des animaux aquatiques est en hausse au Canada et que les directives en matière

introducing exotic aquatic animal pathogens to Canada or the spread of pathogens to parts of Canada where they were previously unknown. Under NAAHP, DFO is responsible for providing the laboratory diagnostic and research component that underpins the program and aquatic animal pathogen containment standards (‘aquatic standards) will be useful in developing DFO National Aquatic Animal Health Laboratory System.

de biosécurité sont variables ou négligeables. Ces normes sont aussi nécessaires pour réduire le risque d’introduction de pathogènes des animaux aquatiques exotiques au Canada ou la propagation de pathogènes dans les régions canadiennes où ils sont encore absents. Dans le cadre du PNSAA, le MPO est responsable des activités d’établissement de diagnostics et des recherches en laboratoire qui soutiennent le programme. Les normes de confinement des pathogènes des animaux aquatiques (normes aquatiques) seront donc utiles pour l’élaboration du système de laboratoire national pour la santé des animaux aquatiques du MPO.

On April 18, 2006, experts in aquatic animal pathogen containment from a variety of backgrounds participated in a workshop to assess whether the physical and operational requirements presented in the draft standards were accurate, were supported by scientific data, represented global knowledge, and met national requirements. This peer review committee will help DFO and CFIA finalize and implement aquatic animal pathogen containment standards that are effective in preventing the escape or spread of pathogens into Canadian resources or waters.

Le 18 avril 2006, un éventail diversifié d’experts en confinement des pathogènes des animaux aquatiques ont participé à un atelier pour évaluer si les exigences physiques et opérationnelles présentées dans l’ébauche de normes étaient précises, soutenues par des données scientifiques, conformes aux connaissances globales et en harmonie avec les exigences nationales. Le comité d’examen par des pairs aidera le MPO et l’ACIA à compléter et à mettre en œuvre des normes sur le confinement des pathogènes des animaux aquatiques qui préviendront efficacement les échappées ou la propagation de tels pathogènes dans les ressources ou les eaux canadiennes.

These aquatic standards will apply to hosts and their pathogens, and to a broad range of facility categories including: all aquatic animal diagnostic laboratories and quarantine facilities

Les présentes normes aquatiques s’appliqueront aux hôtes et à leurs pathogènes ainsi qu’à un vaste éventail d’installations, y compris tous les laboratoires d’établissement de

that house aquatic animals or infectious materials that can affect aquatic animals; facilities that maintain live aquatic species and any facility (research laboratories, government and private establishments, universities, etc.) engaged in work involving pathogens and/or aquatic animal species or gametes that are considered a risk to aquatic animals.

diagnostics chez les animaux aquatiques et les installations de quarantaine qui hébergent des animaux aquatiques ou qui contiennent des substances infectieuses qui peuvent affecter les animaux aquatiques, ainsi que les installations dans lesquelles des animaux aquatiques sont gardés ainsi que toute installation (laboratoires de recherche, établissements gouvernementaux et privés, universités, etc.) et où ont lieu des travaux mettant en cause des pathogènes et/ou des animaux aquatiques ou des gamètes d'animaux aquatiques qui sont considérés comme étant à risque pour les animaux aquatiques.

The aquatic standards will be published as a CSAS Advisory document and posted on the CSAS website.

Les normes aquatiques seront publiées sous la forme d'un avis scientifique du SCCS et diffusées sur le site web du SCCS.

Input from the Expert Panel

1*. Who is the target audience and what are the potential applications of the aquatic animal pathogen standards?*

Discussion focused on potential applications of the standards and the target audience. The DFO-CFIA draft containment standards attempts to cover a range of aquatic animals and facility types (from high secure to low secure) and a broad range of projects or scenarios. These standards would apply to any aquatic organism, whether air breathing or not; however, if the aquatic animal is air breathing, such as marine mammals, this document plus the animal pathogen standards and the laboratory biosafety guidelines mentioned above would apply. In addition, it should be clear the aquatic standards do not supersede health or safety standards of the Canadian Council on Animal Care (CCAC) guidelines and quality assurance/quality control. The standards would be directed to research and/or diagnostic laboratories working with aquatic animal pathogens, but may be applicable for other uses.

Risk assessment and risk management should be expanded on in the introduction, since risk assessment will be routine in assessing work with aquatic pathogens.

Commentaires du groupe d'experts

1. *À qui s'adressent les normes sur les pathogènes des animaux aquatiques et quelles en sont les applications potentielles*?

La discussion se concentre sur les applications potentielles ainsi que sur les utilisateurs des normes. L'ébauche de normes de confinement du MPO et de l'ACIA tente de couvrir un éventail d'animaux aquatiques et de types d'installations (autant à haute qu'à faible sécurité) ainsi qu'une vaste gamme de projets ou de scénarios. Ces normes doivent s'appliquer à tous les organismes aquatiques, qu'ils respirent de l'air ou non; cependant, si l'animal aquatique respire de l'air (mammifère marin, etc.), le présent document s'appliquerait en plus des normes sur les pathogènes des animaux ainsi que des lignes directrices sur la biosécurité des laboratoires mentionnées ci-devant. En outre, il doit être mentionné clairement que les normes aquatiques ne remplacent pas les normes en matière de santé et de sécurité du Conseil canadien de protection des animaux (CCPA) ainsi que ses mesures de contrôle et d'assurance de la qualité. Les présentes normes visent les laboratoires de recherche et d'établissement de diagnostics où l'on travaille avec des pathogènes des animaux aquatiques, mais peuvent s'appliquer à d'autres fins.

L'évaluation ainsi que la gestion du risque doivent être mieux présentées dans l'introduction, puisque l'évaluation du risque sera une pratique courante dans l'évaluation des travaux mettant des pathogènes aquatiques en cause.

Introduction and Transfer Committees (ITCs)and Section 56 of the Fisheries (General) Regulations need to be developed further in order to ensure the purpose of the committees and the issuance of licences under Section 56 is clear to readers. ITCs and their operations are described in the National Code on Introductions and Transfers which was signed by the Canadian Council of Fisheries and Aquaculture Ministers (CCFAM). Any significant changes must go through the CCFAM process. Section 56 licences are governed by the Fishery (General) Regulations and as such amendments must follow the regulatory review process.

Les passages sur les comités des introductions et des transferts (CIT) ainsi que sur l'article 56 du *Règlement de pêche (dispositions générales)* doivent être améliorés afin que le but des comités et la délivrance des permis en vertu de l'article 56 soient clairs pour le lecteur. Les CIT ainsi que leurs activités sont décrits dans le *Code national sur l'introduction et le transfert d'organismes aquatiques*, lequel a été signé par le Conseil canadien des ministres des Pêches et de l'Aquaculture (CCMPA). Tout changement important doit être soumis au processus du CCMPA. Les permis délivrés en vertu de l'article 56 sont régis par le *Règlement de pêche (dispositions générales)* et, comme tel, tout changement doit être soumis au processus d'examen réglementaire.

2*. Is a new classification system needed to rank laboratories handling aquatic animal pathogens?*

2. *A-t-on besoin d'un nouveau système de classification pour classer les laboratoires qui manipulent des pathogènes des animaux aquatiques*?

The expert panel recommended a new classification system to rank levels of aquatic standards, since the classification levels 1, 2, 3, and 4 in the (terrestrial) animal pathogen standards do not meet the needs of the aquatic animal pathogen containment. Sterilised effluent is an extremely important component in the containment of aquatic animal pathogens. According to engineering experts at the workshop, tight standards are better than vague ones with gaps, since many containment facilities must be built to a specific standard for insurance purposes; however, laboratory facilities cannot be built to meet all foreseen situations. Therefore, standards should

Le groupe d'experts recommande un nouveau système de classification pour les niveaux des normes aquatiques, puisque les niveaux 1, 2, 3 et 4 utilisés dans les normes sur les pathogènes des animaux (terrestres) ne comblent pas les besoins concernant le confinement des pathogènes des animaux aquatiques. La stérilisation des effluents est un composant extrêmement important du confinement des pathogènes des animaux aquatiques. Selon les ingénieurs présents à l'atelier, des normes rigoureuses sont préférables à des normes vagues et incomplètes, puisque de nombreuses installations de confinement doivent être construites

meet a performance level, since they will be used to build new labs, but also retrofit existing labs.

selon des normes précises pour pouvoir être assurées; toutefois, les laboratoires ne peuvent être construits pour faire face à toutes les situations prévues. En conséquence, les normes doivent correspondre à un niveau de rendement, puisqu'elles seront utilisées au moment de la construction de nouveaux laboratoires, mais également au moment de la modernisation des laboratoires actuels.

3. *The words 'sterilisation', 'disinfection' and 'decontamination' have been used throughout the document. Which word or words best describes the purpose of the standards?*

3. *Les termes « stérilisation », « désinfection » et « décontamination » sont utilisés tout au long du document. Quel est le terme ou quels sont les termes qui décrivent le mieux le but visé par les normes*?

There was considerable discussion on the definitions of decontamination, disinfection, and sterilisation and which word was the most appropriate for the aquatic containment standards. In CFIA's red book on *Veterinary Facilities Handling Animal Pathogens*, decontamination is defined as disinfection (destruction of certain types of micro-organisms) and sterilisation (the complete destruction of all micro-organisms). Since the goal of the aquatic standards is similar to the red book, the term decontamination would be used throughout the text and replace disinfection and sterilisation, as appropriate.

On discute longuement des définitions des termes *décontamination*, *désinfection* et *stérilisation* et on tente d'établir quel terme est le plus approprié pour les normes de confinement aquatique. Dans le livre rouge de l'ACIA sur les installations vétérinaires qui manipulent des pathogènes d'animaux, le terme *décontamination* est défini comme étant la désinfection (destruction de certains types de microorganismes) et la stérilisation (la destruction complète de tous les microorganismes). Puisque le but des normes aquatiques est similaire à celui visé par le livre rouge, le terme *décontamination* devrait être utilisé dans le texte et devrait remplacer les termes *désinfection* et *stérilisation*, le cas échéant.

4. *Is the section on the physical requirements for containment facilities, including the checklist of physical features, sufficient and appropriate for the containment of aquatic animal pathogens?*

4. *Est-ce que la section sur les exigences physiques concernant les installations de confinement, y compris la liste de vérification des caractéristiques physiques, est suffisante et appropriée pour le confinement des pathogènes des*

animaux aquatiques?

This section should be verified that it agrees with the scope. Additional comments were made with regard to sections on Location, Personnel and Equipment Access, Aquatic Animal Access, Surface, Containment Perimeter, and Air Handling Systems on clarification and defining terms.

Il faut vérifier que cette section est conforme avec la portée. On formule aussi des commentaires sur les sections traitant de l'emplacement, du personnel et de l'accès à l'équipement, de l'accès aux animaux aquatiques, de la surface, du périmètre de confinement et des systèmes de traitement de l'air et on demande que l'on apporte des éclaircissements et que l'on définisse certains termes.

Due to time constraints and extensive discussion, only the first half of the aquatic standards was reviewed by workshop participants. It was agreed that Phil Byrne and Lisa Young would revise the balance of the document, with input from Nancy House as needed, taking into account the comments and advice given by the expert panel for the first half of the document.

En raison des contraintes de temps et de la longue discussion tenue, seule la première moitié des normes aquatiques est passée en revue par les participants à l'atelier. On décide que Phil Byrne et Lisa Young passeront en revue le reste du document, et que Nancy House participera au processus au besoin, en tenant compte des commentaires et des avis exprimés par le groupe d'experts sur la première moitié du document.

5. *Is a glossary necessary?*

5. *A-t-on besoin d'un glossaire*?

A glossary should be included at the end of the document to ensure the words used are clearly defined words for the reader. In addition, it is highly recommended that the glossary words or phrases are highlighted in key locations throughout the text.

Il convient d'inclure un glossaire à la fin du document pour faire en sorte que les termes utilisés sont clairement définis pour le lecteur. En outre, on recommande fortement que les termes ou expressions figurant dans le glossaire soient mis en évidence à des emplacements clés dans le texte.

Appendix 1: Discussion Document

Aquatic Animal Pathogen Containment Guidelines For Laboratories and Live Holding Facilities

Canadian Food Inspection Agency
And
Fisheries and Oceans Canada

December 2005

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1. INTRODUCTION

1.1 General

There is an increasing need for containment standards under which handling of aquatic animal pathogens for experimental or commercial development purposes can be safely undertaken. Such standards must be based on the evaluation of the risks posed by the aquatic animal pathogen(s) to resources in the surrounding environment, must be feasible, and must reduce any risks to those resources that are identified to an acceptable level.

Potential users of these containment standards are regulatory agencies responsible for protection of wild aquatic resources; researchers working with biologics of clinical significance for vaccine development, pathogenicity/epidemiological investigations; laboratories routinely handling aquatic animals for disease screening and diagnostics; as well as commercial, academic, private or government facility working on aquatic organisms carrying or originating from facilities, zones or countries known to be exposed to pathogens of unknown or unacceptable risk to aquatic resources in the environment surrounding the holding facility.

1.2 Background

Implementation of biocontainment standards applicable for terrestrial or air-breathing animals, for fish (finfish and shellfish) biocontainment facility is not always appropriate. The over-all principles are identical (*i.e*., prevention of viable infectious material from leaving designated containment zones), however many of the factors influencing the transmission of pathogens or movement of biological material differ between terrestrial and aquatic environments. Two important physical differences include the importance of aerosols (greater in terrestrial than in aquatic systems) and the primary mode of contaminant spread (air versus water). There are also a myriad of biological considerations that can increase or decrease the risk or consequence of loss of containment including environmental constraints on transmission of pathogens from warm water versus cold water host species, duration of viability of finfish and shellfish pathogens in terrestrial waste facilities and the increased number of carrier hosts for aquatic pathogens compared to those of terrestrial host species.

Terrestrial movement and aerosolization of aquatic animal pathogens likely occurs most frequently iatrogenically (human errors) *via* fomits (personnel clothing or hands, netting material, boots, transport containers, equipment, *etc*.). Therefore, although air handling systems within containment facilities can reduce the nominal risk of aerosol transmission, protocols involving personnel (entry and exit, changing footwear, handwashes, etc.), equipment movement and cleaning, animal handling and transport are of great importance in preventing breaches in the case of aquatic animal pathogen containment.

The primary medium of pathogen transmission in aquatic systems is water. In aquatic animal holding facilities, potentially contaminated waste effluent originates mostly from flow-through and recirculation animal holding systems. Other sources can include washing discharge collecting on the floor arising from floor, tank and boot cleaning and rinsing events, spillage from equipment (nets, transport tanks and pails, plumbing equipment, etc.), regular

maintenance of animal holding units (flushing/unplugging drains and pipes, removing debris from inside a water-filled animal holding unit, unplanned translocation of animals between units, *etc*.) and from experimental procedures (retrieving healthy carriers, collecting moribund and dead animals). Contaminated effluent and solid/semi-solid wastes have the potential of entering the local watershed facilitating the transmission of infectious material to indigenous species (*i.e*., fish, arthropods, birds, mammals, reptiles, amphibians and humans) that are susceptible to infection/carriage or to infection and subsequent disease.

Decontamination or sterilization, especially of large volumes of water, poses a logistic challenge compared to air decontamination using HEPA filtration (mechanically based), which can accommodate large volumes of air with relative ease. Mechanical filtration of waste water does not sufficiently cleanse, or sterilize, contaminated water. Decontamination or sterilization of waste water requires a certain degree of retention time (which varies with level of organic loading) in order to permit the sufficient contact time with chemical and/or mechanical processes or for heat & pressure to inactivate any infectious agents. Other differences exist whereby procedures for general biocontainment, decontamination/sterilization and personnel protection differ qualitatively &/or quantitatively between terrestrially-based and aquatic-based biocontainment systems. These are, however, relatively minor and are not covered here.

1.3 Scope

The emphasis in this document is to provide containment standards for pathogens affecting aquatic animals. These aquatic animal pathogen containment guidelines apply to both the hosts and their pathogens and to a broad range of facility categories including all aquatic animal diagnostic laboratories and quarantine premises, live holding facilities that contain non-indigenous aquatic species and all research laboratories engaged in work involving pathogens or engaged in work involving non-indigenous animal species or gametes that are considered a risk. The rare exceptions (where containment may not be required) include diagnostic facilities that receive only preserved specimens for examination and processing and quarantine facilities that work only with healthy indigenous animal species that are of no harm if they escape (both scenarios are highly unlikely).

The term ‘pathogen’ is used in its broadest sense and for these standards is used to conveniently refer to any viable infectious or transmissible agent regardless of its pathogenicity.

An important point regarding the expectations in these containment guidelines is that all waste water effluent and non-aqueous contaminated waste is expected to be rendered sterile (see 2.1.1 #4 in section 2).

All facilities in Canada including (but not restricted to) private, government, industry and academic entities are expected to comply with these guidelines if their activities fall within the scope. There will be a transition period to allow stakeholders to become familiar with these guidelines however there will be no grandfathering of past or current activities. Facilities wishing to begin or continue undertaking activities that are within the scope of these

guidelines will be required to become compliant with physical requirements, in addition to operational and administrative guidances outlined herein.

Aquatic animal diagnostic or research facilities handing pathogens affecting tetrapods (air breathing animals), must be compliant with the current version of *Containment Standards for Veterinary Facilities* (Canadian Food inspection Agency, 1996).

Where potential zoonotic pathogens are handled with any live aquatic animal, *The Laboratory Biosafety Guidelines* (Public Health Agency of Canada, 2004) must be followed, in addition to the *Aquatic Animal Pathogen Containment Guidelines For Laboratories and Live Holding Facilities* and Containment *Standards for Veterinary Facilities* as applicable.

Facilities conducting *in vitro* laboratory work with veterinary biologics[1] must follow the standards outlined in the *Containment Standards for Veterinary Facilities* (CSVF) (http://www.inspection.gc.ca/english/sci/lab/convet/convete.shtml). The veterinary biologics, including fish vaccines and *in vitro* diagnostic test kits for detection of fish pathogens, are regulated under the *Health of Animals Act and Regulations* (http://laws.justice.gc.ca/en/h-3.3/64369.html). The Veterinary Biologics Section of the Canadian Food Inspection Agency is responsible for regulation of veterinary biologics in Canada. The general requirements for manufacture, testing, importation, distribution and sale of veterinary biologics are stated in the *Health of Animals Regulations* Part XI, and explained on a series of guidelines and memoranda published by VBS (http://www.inspection.gc.ca/english/anima/vetbio/vbpbve.shtml). Once the regulatory requirements for new manufacturing and testing facilities and new veterinary biological products are met, a *Veterinary Biologics Establishment Licence* and a *Veterinary Biologics Product Licences* are issued with a validity period of up to two years. The manufacturing and testing facilities are inspected on a regular basis to ensure compliance with the Health of Animals Regulations and other conditions or restrictions specified by VBS.

Fisheries and Oceans (DFO) is responsible for assessing ecological risks posed by live aquatic animal transfers and setting conditions to mitigate those risks, as appropriate, under Sections 34-36 of the Fisheries Act. Transfer licenses for introductions and transfers are administered by the DFO regional office responsible for the receiving waters (http://intra.dfo-mpo.gc.ca/regions_e.htm) in New Brunswick, Prince Edward Island, Nova Scotia, Newfoundland, Québec (marine waters), and British Columbia. This responsibility is managed by the provinces and territorial governments for all other areas of Canada. Additional information is given in the National Code on Introductions and Transfers of Aquatic Organisms (http://www.dfo-mpo.gc.ca/science/aquaculture/code/prelim_e.htm).

[1] Veterinary biologics are helminthes, protozoan or micro-organisms, substances (or mixture of substances) derived from animals, helminthes, protozoan or micro-organisms, or a substance of synthetic origin that is manufactured, sold or used for restoring, correcting or modifying organic functions in animals or for diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in animals. Veterinary biologics include vaccines, bacterins, bacterin-toxoids, immunoglobulin products, diagnostics kits, and any veterinary biologic derived through biotechnology.

1.4 Licensing and Regulatory Authorities

The Health of Animals Act and its regulations give the CFIA the legislative authority to control the use of imported animal pathogens that pose a known or unknown risk to aquatic resources in the surrounding environment. This requires containment with sterilization of all effluent and waste, and disinfection of all materials that came into contact with the aquatic animals under containment. For an agent brought into Canada under an import permit which restricts its distribution, further approval must be obtained before transferring the agent to another location. Within the CFIA, the Biohazard Containment and Safety Unit administer these regulations. All of the above premises must receive approval for the required level of containment before any pathogen import permits (under The Health of Animal Act, CFIA) or fish import permits (Under section 56 of The Fisheries General Regulations of The Fisheries Act, DFO) are issued.

Written authorization must be obtained from VBS prior to introduction of a new aquatic pathogen into veterinary biologics production and testing facilities. A *Permit to Release Veterinary Biologics* must be obtained from VBS prior to release of an unlicensed veterinary biologic, including live and biotechnology-derived fish biologics, outside containment.

2. CONTAINMENT FOR LABORATORIES AND LIVE HOLDING FACILITIES

The physical containment and operational procedures for *in vitro* work in research and diagnostic laboratories and *in vivo* work in live holding facilities are described in the following sections.

Laboratories are those facilities that are handling aquatic animal pathogens for *in vitro* research, holding aquatic animal pathogens in storage, or performing diagnostic work on live aquatic animals, or tissues. Laboratories also include facilities that handle or store aquatic animal gametes that are deemed to pose a risk to surrounding aquatic resources. The laboratory zone serves as the primary containment barrier and is defined as an area of equal containment level, which may have multiple rooms and functions within a defined containment perimeter.

Live holding facilities are those handling aquatic animals for production purposes or undertaking *in vivo* research or diagnostics on live aquatic animals that also involve work with pathogens. Live holding facilities can also include facilities handling or storing viable aquatic animal pathogens or gametes, that pose a risk to surrounding aquatic resources. The primary containment facility is the live holding unit/tank, and the housing facility serves as the secondary containment barrier. Such a “live holding facility zone” is defined as *an area of containment that may have multiple rooms and functions within a defined containment perimeter*.

Furthermore, the design of the holding facility must permit adjustment of environmental controls to meet the physiological requirements of the species under investigation as specified by the Canadian Council for Animal care (CCAC) Guide to the Care and Use of Experimental Animals, 2004. It is the responsibility of the investigator to ensure that compliance to the CCAC Guide and other applicable guidelines is met (*e.g*., guides on the care and use of wildlife, fish and other animals).

Support facilities for waste disposal, feed, aquatic animal handling, necropsy, tissue preparation, equipment cleaning, and outer garments storage (e.g., boots, accessories, etc) must also be considered for containment within the facility. All serve as potential vectors of host organisms, or their pathogens. Containment conditions must ensure that no aquatic animals, gametes, tissues or pathogens deem to pose a high or unknown risk to surrounding aquatic resources is released into surrounding aquatic habitat.

2.1.1 Location

Key: ● mandatory
❍ recommended

2.1.1	Location	*In vivo*	*In vitro*
1	Separated from public areas by lockable door.	●	●
2	Surfaces, plumbing and holding containers laid out to ensure easy cleaning and decontamination of all surfaces.	●	●
3	Sterilization of all effluent and materials including feed transport and clothing coming in contact with aquatic animals, tissues or other materials within live holding facility.	●	
4	Dedicated clerical work stations permitted within the live holding facility away from aquatic animal holding areas.	●	
5	Anteroom to allow for equipment and clothing exchange and decontamination.	●	
6	Experimental areas (e.g., for necropsy, surgical procedures etc.) within live holding containment facility.	●	
7	Experimental areas to be located away from external building envelope walls.	❍	
8	Filtration barriers on all effluent water systems (HEPA-equivalent filtration of vent lines coming from plumbing fixtures that are upstream (*i.e.*, exposed to contaminated effluent venting) prior to treatment (sterilization).	❍	❍

2.1.2 Personnel and Equipment Access

2.1.2	Personnel and Equipment Access	*In vivo*	*In vitro*
1	Access limited to authorized personnel.	●	●
2	Room doors to have appropriate signage (i.e. biohazard sign, containment level, contact information, entry requirements).	●	●
3	Size of door openings to allow passage of all anticipated equipment.	●	●
4	Doors to the containment live holding facility lockable (does not apply to areas within containment facility).	●	
5	Doors to provide restricted access by a controlled access system (e.g., key card, locking hardware) or equivalent.	●	●
6	Electronic locking to be backed up with a physical key-lock system.	●	●
7	Entry to be provided via an anteroom with raised lips/barrier to contain all leakage. Anteroom is located within the restricted access area.	●	●
8	Anteroom door(s) located between clean and dirty change areas or live holding facility are not to be open simultaneously. Audible or visual alarms or equivalent protocols in place.	●	●
9	Entry to live holding facility zone to be provided with clothing change area designed to separate personal clothing from live holding facility clothing dedicated to that zone (i.e. "clean" change area separated from "dirty" change area).	●	

2.1.2	Personnel and Equipment Access	*In vivo*	*In vitro*
10	Controlled entrance/exit doors to have emergency manual overrides.	●	●
11	Exit from containment zone to be provided with a walk through boot, hand wash, or shower on the containment perimeter (i.e. between "dirty" and "clean" change rooms). This practice should be subjected to a local risk assessment.	●	

2.1.3 Aquatic Animal Access

2.1.3	Animal Access	*In vivo*	*In vitro*
1	Aquatic animal entry to housing facility zone to be provided via an anteroom	●	
2	Aquatic animal entry to housing facility zone to be provided via an anteroom with interlocking doors	❍	

2.1.4 Surface Finishes and Casework

2.1.4	Surface (i.e. floors, walls, ceilings, sealants) Finishes and Casework:	*In vivo*	*In vitro*
1	Doors, frames, casework and bench tops and all material on, within and supporting animal holding units (*i.e.*, tanks and equivalent structures) to be non-absorptive (no wood surfaces permitted) and have raised barriers to prevent leakage or spills.	●	●
2	Surfaces to be scratch, stain, moisture, chemical and heat resistant in accordance with laboratory or facility function.	●	●
3	Surfaces to provide impact resistance in accordance with laboratory or facility function.	●	●
4	Surfaces to be compatible with adjacent and overlapping materials (i.e. to maintain adhesion and a continuous perimeter); for walls and floors with welded seams, are acceptable.	●	●
5	Interior surfaces to minimize movement of vapours and liquids through perimeter membrane. Fumigation may also be used as an alternative.	●	●
6	Interior coatings to be gas and chemical resistant to withstand disinfection and fumigation.	●	●
7	Interior coating to be cleanable.	●	●
8	Continuity of seal to be maintained between the floor and wall (a continuous cove floor finish up the wall is recommended).	●	●
9	Floors to be slip-resistant.	●	●
10	Bench tops to have no open seams.	●	●
11	Bench tops to contain spills of materials (e.g. with marine edges and drip stops, trays or other equivalent strategy).	●	●
12	Benches, doors, drawers, door handles etc. to have rounded rims (no sharp edges) and corners.	●	●
13	Backsplashes, if installed tight to wall, to be sealed at wall-bench junction.	●	●

2.1.4	Surface (i.e. floors, walls, ceilings, sealants) Finishes and Casework:	*In vivo*	*In vitro*
14	Reagent shelving to be equipped with lip edges.	●	●
15	Drawers to be equipped with catches, i.e.; to prevent the drawer from being pulled out of the cabinet.	●	●
16	All animal holding units to be provided with covers to prevent splash transfer of water between tanks. Dip-net and related animal handling equipment to be dedicated to each tank or to each series of tanks containing aquatic animals of identical origin or treatment.	●	
17	Drawers to be equipped with catches, i.e.; to prevent the drawer from being pulled out of the cabinet.	●	●
18	Interior surfaces to be water and corrosion resistant.	●	●
19	Sealed volume capacity to be sufficient to retain spills and possible aquaria or tanks leaks.	●	●

2.1.5 Containment Perimeter

2.1.5	Containment Perimeter:	*In vivo*	*In vitro*
1	Autoclave or other acceptable means of decontamination to be located within the containment zone.	●	●
2	Autoclave to be equipped with a cycle log recorder or a digital electronic system to record time, temperature, and pressure.	●	●
3	Dedicated double-door barrier autoclave to be located on containment perimeter; body of autoclave to be located for ease of maintenance, preferably outside containment. Perimeter autoclave to be equipped with, interlocking doors, or audible or visual alarms to prevent both doors from opening simultaneously. This requirement is required for activities deem to represent a high risk to aquatic resources in surrounding environments	❍	
4	Appropriate measures must be taken to prevent unnecessary splashing from the holding units and procedures must be in place to decontaminate exposed surfaces when splashing or spillage does occur (without necessarily moving or removing animals).	●	
5	For materials that cannot be autoclaved (e.g. heat sensitive equipment, samples, film) other proven treatment technologies (e.g. incineration, chemical or gas decontamination, irradiation) to be provided at containment perimeter.	●	●
6	Facilities and equipment for euthanasia and tissue preparation for examination to be provided within the containment perimeter. No live aquatic animals or viable tissues to be removed from containment unless packaged appropriately (Transport of Dangerous Good regulations if applicable and other constraints imposed by inspection certification).	●	●
7	All conduit and wiring to be sealed with non-shrink sealant at containment perimeter.	●	●
8	Containment zone to be proofed against entry or exit of vermin or insects.	●	●
9	Containment exit of live holding room to be provided with an adequate	●	

2.1.5	Containment Perimeter:	*In vivo*	*In vitro*
	brim, high enough to contain water in the event of leaks or pump failure.		
10	Sealed standing pipes to be provided for all drains. All drainage to reservoirs for disinfection must be provided with a tilt, switch, or alarm system. Reservoir discharge must be neutralized or compliant with environmental release standards	●	●

2.1.6 Air Handling Systems[2]

2.1.6	Air Handling Systems:	*In vivo*	*In vitro*
1	Air exhaust systems and fume hoods must be available for air-spaces dealing with disinfectant and noxious gases for human safety purposes.	●	●
2	Inward directional air flow is highly recommended for the entire outer boundary of the containment zone as well as to maintain separation between different levels of containment within the containment zone. This will ensure that air flow is in direction of increased containment requirements, in order to hold aerosols of odours, moisture, chemical vapours, etc. within containment.	❍	❍

2.1.7 Live holding facility Services (*In vivo* only)

2.1.7	Live holding facility services (i.e. safety equipment, water, drains, gases and electricity):	*Checklist*
1	Hooks to be provided for live holding facility clothing at live holding facility exit; street and facility clothing areas to remain separate.	●
2	Footbaths to be provided.	●
3	Hand washing sinks to be located near the point of exit from the live holding facility or in the anteroom.	●
4	Emergency eyewash to be provided in accordance with facility activities and applicable regulations (i.e. ANSI Z358.1-1998).	●
5	Communication system to be provided between live holding facility areas and outside.	●
6	System (e.g. fax, computer) to electronically transfer information and data from live holding facility area to outside live holding facility zone to be provided (note: removing paperwork from the containment live holding facility may be carried out after appropriate decontamination).	●
7	Exposed live holding facility services piping with stand-offs to allow access for maintenance and cleaning.	●
8	Water supply control(s) to be located outside the live holding facility zone.	●

2 Aquatic animal pathogens are not typically spread by the aerosol route, therefore air handling requirements should be to a minimum unless prescribed following a risk assessment.

2.1.7	**Live holding facility services (i.e. safety equipment, water, drains, gases and electricity):**	***Checklist***
9	Supply water services to be provided with backflow prevention in accordance with CAN/CSA-B64.10-01/B64.10-01 ref and isolation valve to be located in close proximity to the containment perimeter.	●
10	Back flush cleaning of filters required for clean holding of live aquatic organisms.	●
11	Drains to be separated from other live holding facility zones (i.e., liquid effluent treatment system as appropriate).	●
12	Drains to be connected to an effluent decontamination system.	●
13	Drains connected to effluent treatment must be sloped towards the decontamination system to ensure gravity flow; consideration must be given to the installation of valves to isolate sections for decontamination; the effluent decontamination system (e.g., piping, valves, tank) to be heat and chemical resistant consistent with application.	●
14	Compressed gas cylinders (with the exception of fire extinguishers) to be located outside of the live holding facility zone.	●
15	Oxygen supply inside facility is required in case of electrical failure.	●
16	Supply conduit and wiring to be sealed at the containment perimeter.	●
17	Electrical outlets must be installed well above floor level, sealed and covered.	●
18	Power system circuit breakers to be located outside containment perimeter	●
19	Light ballasts and starters to be located outside containment perimeter	●
20	Power system circuit breakers to be located outside containment perimeter	●
21	Alarm system to be provided to indicate failure (e.g. excessive water levels; failure of effluent treatment system, backflows).	●
22	Hand washing sinks to be provided with "hands-free" capability	●
23	Biological Safety Cabinets (BSC) and/or other primary containment devices to be provided (e.g. where there is potential for production of aerosols, high or large volumes of infective material). Note that for certain procedures involving zoonotic agents the use of a BSC is mandatory.	❍
24	Emergency shower equipment to be provided in accordance with facility activities and applicable regulations (i.e. ANSI Z358.1-1998). This requirement is specific to facilities using hazardous chemicals only.	❍

2.2 Operational Procedures

Work with aquatic animals poses a variety of special hazards including exposure to physical hazards (e.g., noise, extreme temperatures) and chemical hazards (e.g., cleaning agents, disinfectant chemicals). Although rare, allergic conditions can result from handling aquatic animals, their tissues, or chemicals used in the facilities. Personnel must be familiar with, and have access to, Material Safety Data Sheets (MSDS) for all chemicals used, and be aware of any potential allergies that could be exacerbated working with live aquatic animals, their tissues and/or pathogens. Although zoonotic organisms from aquatic animals are rare, care must be taken when working with all pathogens, particularly those that have not been studied extensively. All training and reference material must be held outside containment facility and be signed off upon entry and exit from the containment perimeter.

Following are the general operational practices specific to working in any research and diagnostic laboratories or any live holding facility.

2.2	**Operational requirements**	***In vivo***	***In vitro***
1	Containment room doors must be kept locked as required by facility design.	●	●
2	A documented procedural manual must be available for all staff and its requirements followed; it must be reviewed and updated regularly.	●	●
3	There must be a biological safety officer (BSO) with appropriate authority to oversee safety and containment practices; a biological safety committee may be used to assist the safety program.	●	●
4	Personnel must receive training on the potential hazards associated with the work involved and the necessary precautions required to prevent exposure to noxious substances and potential zoonotic agents; personnel must show evidence that they understood the training provided, which must be documented and signed by both the employee and supervisor; retraining programs must also be implemented.	●	●
5	Employees working in the containment area must have general knowledge of the physical operation and design of the facility (e.g., plumbing layout; filtration and decontamination systems, alarm systems; and contact information for responsible managers).	●	●
6	Entry must be restricted to laboratory staff, maintenance staff and other persons on official business only, and who have completed the appropriate training.	●	●
7	All persons (including visitors, maintenance staff, etc.) entering the containment area must be trained in, and know how to follow, the operational protocols for the project in process; trainees must be accompanied by a trained staff member.	●	●
8	A health and medical surveillance program must be provided as appropriate (e.g., initial and periodic physicals, baseline titers, vaccinations).	●	●
9	Persons entering a containment facility must be well prepared and bring all materials they will need with them; if something has been forgotten, established traffic patterns must be adhered to (i.e. do not go back to get it; either phone for someone to bring it or exit via proper protocols).	●	●
10	Generally, traffic flow patterns from clean to dirty areas must be established and adhered to (i.e., movement from least to most contaminated areas).	●	●
11	Entry/exit protocols for persons, animals, equipment, samples, waste, hazardous components, etc., must be written, posted and followed; general protocols must be supplemented with protocols specific for each project in progress.	●	●
12	Smoke testing (i.e. with a smoke pencil, theatrical fog, or equivalent) must be done periodically by lab staff to verify correct airflow – for BSC and fume-hood within the containment perimeter.	●	●
13	Good microbiological laboratory practices intended to avoid the release of contained infectious agents must be employed (e.g. wearing protective clothing, washing hands, disinfecting work areas and decontamination of infectious tissue or waste before disposal; laboratories must be kept clean and tidy.	●	●
14	Procedures must be in place for receiving infected aquatic animals as	●	●

	appropriate to ensure that the carrying reservoir (e.g. tank truck) is appropriately disinfected prior to departure from the containment facility, or disposed of in a sterile manner (i.e., boxes, coolers, etc).		
15	Standard Operating Procedures (SOP's) for entry/exit, spill clean up, air handling/biosafety cabinet failure, effluent sterility, fire, animal escape and other emergencies must be written, validated, posted and followed. Records must demonstrate that all staff have read and have been trained (where deemed necessary) on these Sop's.	●	●
16	In the event of life-threatening emergencies, human health and safety are a priority; exit protocols must be established whereby routine procedures might be bypassed; a reporting area must be identified where further steps must be taken (e.g. disinfecting footwear, showering) prior to contact with the surrounding environment and aquatic resources.	●	●
17	All spills, accidents, overt or potential exposures to infectious materials, and losses of containment (e.g., pump-failure and back-flow) must be reported immediately to the laboratory supervisor; written records of such incidents must be maintained and the results of incident investigations used for preventing further incidents.	●	●
18	An effective rodent and insect control program must be maintained.	●	●
19	Where pathogen infectivity or water-borne chemicals pose a risk to staff, appropriate personal protective equipment (e.g. respirator, goggles, and gloves) must be provided and retained within the containment zone.	●	●
20	Gloves must be worn when handling infected fish. If disposable, these must be autoclaved or treated (along with all other disposable materials used) to ensure decontamination before removal from the containment zone.	●	●
21	Heavy duty gloves for handling aquatic animals which pose a physical (spines or teeth) or infectious hazard to personnel must be dedicated to individual tanks.	●	
22	Contaminated work surfaces must be decontaminated.	●	●
23	All contaminated materials must be decontaminated before disposal or cleaning for reuse.	●	●
24	Hands must be washed after removing gloves and before leaving the containment zone.	●	●
25	Water seals must be maintained in drainage traps (i.e. through regular sink/shower/floor drain usage and/or by filling traps in areas that are not being used).	●	●
26	Outer protective clothing must be autoclaved prior to laundering (unless laundering facilities are within the containment perimeter) or other method of decontamination proven to be effective against agent(s) of concern.	●	●
27	Tanks must be covered to prevent tank to tank spread infectious agents or gametes via splashes	●	
28	Tanks must be covered to prevent tank to tank spread infectious agents or gametes via splashes (unless demonstrated otherwise by a local risk assessment).	●	
29	Tanks must be covered (at least in part) with a see through material and/or be provided with a hinged (for opening) area on the top or side of the holding unit.	●	
30	Covers must be secured to prevent aquatic animal escape.	●	
31	All handling procedures must minimize the creation of aerosols.	●	●
32	All materials used within the containment perimeter must be disinfected	●	●

	before disposal or cleaning for reuse.		
33	Autoclave to be verified for operation as specified and to be microbiologically tested using representative loads with appropriate biological indicators.	●	●
34	Aquatic animal carcasses and tissues must be incinerated or processed using technology proven to effectively decontaminate all tissues; where such materials must be transported for decontamination outside the containment perimeter, this must be done using leak-proof containers labeled as “biohazardous material for decontaminated disposal only”.	●	●
35	Personnel must remove all clothing dedicated to the containment zone before exiting and ensure street clothing does not come into contact with that clothing. Foot baths and hand-washes must be used prior to exit. Wash-basin facilities must be provided for washing faces, arms, etc., that may have been exposed to splash contamination.	●	●

3. INSPECTION GUIDE AND CHECK LIST FOR CERTIFICATION AND RECERTIFIVATION OF LABORATORIES AND LIVE HOLDING FACILITIES

This form is required for any individuals who wish to undertake activities involving aquatic animals, animal &/or human pathogens (known or suspected or of unknown pathogenicity) and aquatic animals, or involving aquatic animal gametes. This form may be required to be re-submitted if there is any change to the proposed list of pathogens, animals, physical structure of the containment area, or with procedures/protocols or SOPs employed.

The containment capacity of each facility will differ. This will influence what risks will be deemed sufficiently low in order to permit projects of varying risks and complexities to take place. The risk associated with each proposal will depend on attributes identified in this document, notably the risk posed to the surrounding aquatic resources and to humans by the pathogens and animals that are proposed for use. Further documentation may be required, beyond what is in this form, for the certification to be acceptable for completion. An inspection of the premises, observation of operational procedures and/or in vivo or in vitro activities may also be deemed necessary prior to certification. Lastly, changes in facility design or procedures may be requested in order for the registering facility to be accredited for the activities specified.

Facility:	**Date:**

Summary of proposed activity categories (check all relevant)

Activities:	**YES**	**NO**
Live Aquatic animal		
Aquatic Animal Diagnostics		
Gametes		
Biologics		
In vitro pathogen culture		
Other (list)		
Describe in lay terms the proposed activities. Please include a general description of the facility and then outline containment-requiring activities areas.		
The registrant must demonstrate that there is an adequate management system (Quality Assurance system, Good Laboratory Practices, or equivalent) in place in which there is proper administrative coordination as well as for the containment work involving animal, gamete and pathogen-related activities. This aspect of the registration review is covered in each section below.		
Provide detailed floor plans in order to facilitate locating areas where: containment area(s) are located; where and schematically demonstrated how animal holding units are arranged; other experimental work areas; locations where storage and use of pathogen(s) takes place; effluent treatment locations and arrangement of equipment; waste collection and disposal; necropsy area(s); entry/exit point for personnel, animals and		

supplies; administrative areas within containment; *etc*. – these plans should be referred to in Protocols, SOPs and AUPs cited throughout this form. Please attach document to the form.		

Animals information

For each species or otherwise distinct population or stock of animals or gametes please complete the following.

Feature:	**YES**	**NO**
Scientific and common name(s) of aquatic animals proposed for use: *Please include any additional attributes necessary for proper identification of animals being used (i.e., genotype, family, population source, etc.)*		
Location in facility where the animals are housed:		
List the Animal Care protocol(s) for this animal:		
Non-indigenous or Exotic (not present locally)?		
Transgenic?		
Is there any known or possible risk to animals present in the facility or to the local environment if containment in breached?		
A risk analysis or literature review needs to be cited in order to validate the above response. Please provide complete citation information of material mentioned and attach copies of any referenced documentation if difficult to access. This information is required for all categories of animals being used for containment activity (*e.g*., indigenous, non-indigenous, transgenic, other).		
Any known risk to researchers and animal care workers? A risk analysis or literature review needs to be provided to validate the given answer.		
Please provide a list of animals present in the facility (or anticipated to arrive during the course of the containment activity) that are not identified in this form as being used for containment work:		
Are you aware of any risk the containment work poses to animals listed above?		
Please describe any concerns cited above:		

Animal Care & use

Feature:	**YES**	**NO**
Does an Animal Care Committee (ACC) oversee all live [vertebrate] animal activities at your facility?		
Does your ACC have CCAC-prescribed membership (please attach membership list including contact information and the ACC role for each member).		
Please list all relevant AUP's. You may be requested to submit copies of these documents later.		
Please attach copies of AUP's listed above, to this registration.		
Does your facility have CCAC accreditation?		
There should be Protocols and SOP's describing, or a Manual of Procedures, or equivalent documents that describe: Maintenance of housing & feeding requirements; Acclimation of newly arrived animals; Experimental work including but not restricted to pathogen challenges (preparation of pathogen/agent/vaccine etc. prior to use in vivo, challenge route(s), expected clinical signs of infection &/or disease, etc.); Daily monitoring of animals; Disposal of carcasses; Necropsy procedures; Storage of contaminated samples; *etc*. Please list all relevant SOP's, Protocols and Procedures. You may be requested to submit copies of these documents later.		
Identify location(s) in facility where pathogen-challenges of animals take place. Cite relevant Protocols and SOP's; you may be requested to submit copies of these documents later.		

Pathogens proposed for use

Feature:	**YES**	**NO**
Scientific name and relevant taxonomic information		
Zoonotic potential		
Host range:		
Identify location(s) in facility where pathogen is stored, cultured or maintained in vitro, and disposed. Cite relevant Protocols and SOP's; you may be requested to submit copies of these documents later.		
Source of pathogen(s) requested. Provide geographic coordinates of the pathogen's natural origin as well as the supplier/contact information (the pathogen may not have been supplied to you from its natural origin).		
Is pathogen present locally in region?		
Up-to-date documentation of all pathogens maintained at facility? Please list all microbial (viral, bacterial, prion, other), protozoal and parasitic agents stored within the facility; including animal and human and environmental agents and agents of no known or poorly characterized pathogenicity. Cite any relevant Protocols and SOP's in place to control, monitor and oversee these agents.		
Are any of the above listed agents not maintained within containment?		
Is there any known or possible risk to animals present in the facility (inside or outside of containment) or to the local environment if containment is breached? Please consider all animals present in the facility (or anticipated to arrive during the course of the containment activity) that are not listed above (i.e., include animals not being used for containment work).		

Physical and Operational Containment

Entry/Exit

Feature:	**YES**	**NO**
Double Doors		
Negative Pressure		
Clothing (lab coats, boots, gloves)		
Foot Bath		
Hand Bath		
Sign-In Book		
Records of all animals received, held and removed/euthanized/killed		
Signage - "Quarantine Containment area - Authorized Access Only"		
Contact Information (name, contact tel #s during/after hours)		
Access control(s)		
Locks		

Floor

Feature:	**YES**	**NO**
Plugged drainage or raised standing pipes to prevent leakage to non-controlled exits		
Traps for spilled water		
Disinfectant for trap-water		
Spill clean up kits and plan		
Sealed floor edges and cracks (non-porous floor material)		
Raised sills at door		

Walls/ceilings/fixtures on walls & ceilings

Feature:	**YES**	**NO**
Non-porous surface		
Secured windows		
Secured vents		
Secured duct and pipe inlets		
Wall and ceiling penetrations sealed		
Electrical outlets properly protected from moisture & grounded?		

Tanks/Pipes

Feature:	**YES**	**NO**
Materials which can be disinfected		
Structure not accessible to disinfection?		
Fixtures secure and sealed (no leakage)		
Piping that can be dismantled for cleaning		
Cleaning methods and schedule		

Water Flow & Effluent Treatment

Feature:	**YES**	**NO**
Provide detailed description of liquid effluent treatment. Include all relevant Protocols, SOP's and refer to floor plans and diagrams/photos where useful). Your description should consider (minimally) the following categories of information: Standing time in disinfection tank (minimum time); Type and concentration of effluent treatment chemicals (if any); Contact time of treatment (involving chemical, irradiation, heat and/or pressure, *etc*.); Method of neutralization (if required) of treatment chemical(s) and effluent discharge; Protocol in event of power failure – how is animal care, containment integrity and personnel safety maintained?		
Provide detailed description of how the efficacy of effluent treatment is monitored. Include all relevant Protocols, SOP's and refer to floor plans and diagrams/photos where useful). Your description should consider (minimally) the following categories of information: Frequency of monitoring for effluent sterility; Method(s) used to test effluent sterility (assay, molecular and/or other methods detailed); Records of treatment validation trials; Method of collection of effluent for testing/monitoring; Contingency plan for when testing/monitoring reveals a non-compliance including protocols for back-up effluent sterilization Procedure(s);		
Additional Protocols and SOPs involved in containment. Include all relevant Protocols, SOP's and refer to floor plans and diagrams/photos where useful). Your description should consider (minimally) the following categories of information: If any liquid effluent arising from within containment is treated differently than described above please elaborate here; Treatment of waste material (liquid and/or solid) arising from laboratory activities (gloves, pipettes, needles, syringes, blood tubes, packaging, cleaning tissues, *etc*.); Waste arising from specific activities (e.g., incidental run-off from floor/tank/boot washings, sink areas, net dips, animal transport containers/trolleys; *etc*.)		
Presence/absence of additional features:		
Water collected in reservoir		
Holding tank(s) total volume consistent with floor/drain holding capacity		
Back-up power available? How long and at what operational capacity?		
Water entry-exit alarms (tilt-switch, etc.)		
Disinfection alarms		
Back-up decontamination system		
Alarm on decontamination system		
Decontamination system on emergency power		

Solid waste and other material disposal methods

Feature:	YES	NO
Provide relevant protocol(s) & SOPs		
Disposable material disinfection		
Storage method(s) & location (note on floor plan)		
Removal method(s): note packaging procedures and contractor(s) involved (if applicable)		

Feeding Regime

Feature:	YES	NO
Feeding protocol(s) & SOP(s)? please provide		
Frequency of feeding		
Separation of feeding materials between tanks		
Disinfection of waste feed and holding materials prior to removal		

General Laboratory Practices: Documentation, Training, Safety, Protocols and Standard Operating Procedures

Feature:	YES	NO
Does your facility operate under a formal management system (e.g., GLP, QA, ISO/IEC, AAVLD, etc.)? If yes to the above, describe briefly what formal accreditation, auditing and review process you participate, in relation to the formal management system cited above.		
Management and laboratory activities:		
Provide relevant protocol(s) & SOPs		
Animal delivery receipt records (shipper, origin, number of animals, health on arrival, transfer license(s), other permits)		
Daily disinfection residues		
Mortality records (numbers, dates, tanks, gross observations)		
Laboratory examination specimen records (number, tank, method of preservation, shipping)		
Disposal records		
Spill/Cleanup records		

Site Manager's Signature: _____ Date: _____

Inspected by: _____ Date: _____

Reviewed by: _____ Date: _____

4. DECONTAMINATION AND STERILIZATION SYSTEMS

The objective is to ensure that no viable infectious agents that pose a known or unknown risk to aquatic or human health in the surrounding environment leave the containment facility. Since few disinfection procedures have been designed and assessed for efficacy against specific animal pathogens, it remains the responsibility of the facility to determine (by testing, or by reference to published research) to ensure that the treatment method is effective for the agent in question, under the conditions present at that facility. The proposed decontamination method must be validated for the agent(s) of concern.

It should be noted that aquatic animal containment facilities pose unique challenges for effective decontamination of effluent and solid materials. Variables inherent in salinity, organic loading, particle size of organic waste, feeding regimes and types, etc., all complicate or negate prescriptive disinfection measures. Likewise, disinfected products (solid or liquid) may be detrimental to surrounding aquatic resources if not neutralized prior to release from the containment facility. Back-up (chemical e.g. ozone, chlorine) of primary (most likely heat and pressure) decontamination system must be in place. Any decontamination system must also be on an alarm system in case of a failure. All laboratories, live holding and quarantine facilities must have their decontamination methods validated prior to introducing animals or pathogens of concern.

Pre-trials that assess the efficacy of effluent sterilization, as well as monitoring programs instituted during regular operations will involve testing of the pre- and post-treatment waste (effluent, solid wastes, etc.) for the presence of viable microbes. Any facility undertaking biocontainment work will be required to clearly demonstrate competence by way of well developed and clear protocols and Standard Operating Procedures, traceable training records of staff involved and all aspects related to maintaining containment integrity, and traceable records of mechanical attributes pertinent to maintaining containment integrity including waste treatment &/or packaging of contaminated material.

The design of a waste treatment regime must be such that access point(s) to post-treatment effluent is possible in order enable convenient retrieval of liquid effluent and/or items necessary for inspection of sterility. Easy aseptic retrieval is necessary for all types of waste that is being generated and treated (or packaged for treatment elsewhere within the facility or off-site), in order that claims of sterility or containment can be corroborated by inspectors as well as be assessed regularly by personnel. The effluent sample is processed for subsequent assay and/or molecular analysis using biosecure methods. Technologies and testing protocols are constantly
evolving, therefore assigning one or more specific protocols at this time is not possible. As tests become available and procedures validated, specific effluent testing requirements and protocols may become prescribed for specific containment scenarios. Until then, each submission will be evaluated on a case-by-case basis.

It should also be noted that chemical (e.g., chlorine and ozone) treatments can generate noxious fumes that are harmful if inhaled. Adequate venting is required for all such disinfection procedures. If outside tanks are used for treatment, these must be secured and

included within the containment perimeter. Other types of treatment, such heat, may require post-treatment cooling of the waste before discharge into municipal drains or waterways.

The World Organization for Animal Health (OIE – Office International des Épizooties) Manual of Diagnostic Tests for Aquatic Animals provides disinfection guidelines for finfish, mollusk and crustacean farms (OIE 2003; http://www.oie.int/eng/normes/fmanual/A_00014.htm). Although not specifically aimed at laboratory or containment facility decontamination, the principles and physical/ chemical processes described are applicable.

5. CERTIFICATION AND RECERTIFICATION OF LABORATORIES AND LIVE HOLDING FACILITIES

For the purposes of this document, "commissioning" (approval) is defined as the verification of the physical construction and performance of critical containment components. Commissioning of containment systems may be included as part of the overall commissioning processes normally undertaken to verify that the design meets applicable codes and standards and that it has been constructed in accordance with the design intent.

To ensure the physical requirements for the intended containment and use of the facility have been met, each laboratory and live holding facility undertaking work with aquatic animals and/or infectious agents that pose a high or unknown risk to aquatic resources in the surrounding environment must undergo an inspection in order to be commissioned. This requires verification and documentation of critical containment components. A complete set of blue prints, an understanding of the intended use and work to be performed, a list of equipment requirements, all system test results and an understanding of the intent of the systems operation are all part of the commissioning process.

The checklists (Section 3) provided must be used to ensure critical containment components are taken into account. For recertification, certain containment components must also be inspected. The nature and frequency of which depends on a variety of factors, for example, any visual leaks in the room perimeter and monitoring the efficacy of sterilization systems such as autoclaves can all be performed on a routine basis without disruption to the operation of the containment facility. Re-testing the integrity of the room perimeter and ductwork would be necessary after any structural changes. Re-testing of control systems for fail-safe operation would not be necessary unless the system underwent logic changes or upgrades. Detailed records of the commissioning process and test results must be maintained. Recertification is required for any of the following scenarios a) a facility is decertified and requires to be certified again, or b) an expiry date for the initial commissioning is reached, or c) for facility maintenance or upgrade purposes.

Operational protocols must also be established before work with infected materials, tissues, or animals can be carried out. Training of personnel is a critical aspect of this process and may involve initial work with non infectious material. Users must understand the containment systems and their operation in addition to scientific procedures.

Appendix 2: Meeting Agenda

NATIONAL AQUATIC ANIMAL PATHOGEN CONTAINMENT STANDARDS FOR LABORATORIES AND LIVE HOLDING FACILITIES

Aberdeen Room - Minto Suites Hotel Ottawa

April 18, 2006

PROPOSED AGENDA

Annexe 2 : Ordre du jour de la réunion

LIGNES DIRECTRICES SUR LE CONFINEMENT DES AGENTS PATHOGÈNES DES ANIMAUX AQUATIQUES À L'INTENTION DES LABORATOIRES ET DES INSTALLATIONS DE GARDE EN CAPTIVITÉ

Salle Aberdeen, hotel Minto Suites Ottawa

Le 18 avril 2006

ORDRE DU JOUR PROPOSÉ

9h00 - 9h30	**Welcome and Introductions Terms of Reference** Dr. Jake Rice, Chair Canadian Science Advisory Secretariat, DFO	**Mot de bienvenue et présentations Cadre de référence** Jake Rice, Ph.D., président Secrétariat canadien de consultation scientifique, MPO
9h30 – 10h00	**Summary of Draft Containment Standards** Dr. Phil Byrne Charlottetown Aquatic Animal Health Biosecurity Laboratory, DFO	**Sommaire de l'ébauche des normes de confinement** Phil Byrne, Ph.D. Laboratoire de biosécurité en santé animaux aquatiques de Charlottetow MPO
10h00 -10h 15	**Break**	**Pause**
10h15 – 12h00	**Discussions**	**Discussions**
12h00 – 1h00	**Lunch**	**Repas**
1h00 – 2h30	**Discussions**	**Discussions**
2h30 – 2h45	**Break**	**Pause**
2h45 - 5h00	**Discussions and Summary of Proposed Revisions**	**Discussions et résumé des changements proposés**

Appendix 3 : List of Participants Annexe 3 : Liste des participants

Last name/nom	First name/prénom	Affiliation	Affiliation	City/Prov/Country (ville/prov/pays)	Email/courriel	Attendance/ participation
Confirmed participants / participation confirmée						
Byrne	Phil	Aquatic Animal Health, DFO	Santé des animaux aquatiques, MPO	Charlottetown, PEI/ï-P.-É.	byrnep@dfo-mpo.gc.ca	Yes/oui
Cairns	Peter	Biosafety and Biosecurity, Canadian Food Inspection Agency	Biosécurité, Agence canadienne d'inspection des aliments	Winnipeg, Manitoba	pcairns@inspection.gc.ca	Yes/oui
Graham	Mary Louise	Public Health Agency of Canada	Agence canadienne de santé publique	Ottawa, Ontario		Yes/oui
House	Nancy	Aquatic Animal Health, DFO (Meeting logistics)	Santé des animaux aquatiques, MPO (logistique de la réunion)	Ottawa, Ontario	housen@dfo-mpo.gc.ca	Yes/oui
Kieser	Dorothee	Aquatic Animal Health, DFO Pacific Biological Station	Santé des animaux aquatiques, MPO Station biologique du Pacifique	Nanaimo, BC/C.-B.	kieserd@dfo-mpo.gc.ca	Yes/oui
Langevin	Paul	Merrick and Company	Merrick and Company	Ottawa, Ontario	Paul.Langevin@merrick.com	Yes/oui
Lee	Tim	Mechanical Engineer, Public Works and Government Services Canada (PWGSC)	Ingénieur mécanique, Travaux publics et services gouvernementaux Canada (TPSGC)	Edmonton, Alberta	tim.lee@pwgsc.gc.ca	No/non
McGladdery	Sharon	Aquatic Animal Health Division, CFIA	Division de la santé des animaux aquatiques, ACIA	Ottawa, Ontario	mcgladderys@inspection.gc.ca	Yes/oui
Rahey	Fred	Public Works and Government Services Canada (PWGSC)	Travaux publics et services gouvernementaux Canada (TPSGC)	Halifax, Nova Scotia/Nouvelle-Écosse	fred.rahey@pwgsc.gc.ca	Yes/oui
Uhland	Carl	Fish Pathology, U of Montreal	Pathologie des poissons, U. de Montréal	Montreal, Quebec/Montréal, Québec	Carl.F.Uhland@umontreal.ca	Yes/oui
Williams	Amy	Introduction & Transfer National Co-ordinator, Aquaculture Management Directorate, DFO	Coordonnateur national des introductions et des transferts, direction de la gestion de l'aquaculture, MPO	Ottawa, Ontario	macmillanli@dfo-mpo.gc.ca	Yes/oui
Wright	Peter	Aquatic Animal Health, DFO	Santé des animaux aquatiques, MPO	Winnipeg, Manitoba	wrightpe@dfo-mpo.gc.ca	Yes/oui
Young	Lisa	Canadian Food Inspection Agency	Agence canadienne d'inspection des aliments	Ottawa, Ontario	youngl@inspection.gc.ca	Yes/oui
Did not attend but provided comments by email / N'a pas participé mais a fourni des commentaires par courriel						
Winton	Jim	Western Fisheries Centre	Centre des pêches de l'ouest	Washington,USA/É.-U.	jim.winton@usgs.gov	No/non
Kreiberg[(1)]	Henrik	Aquatic Animal Husbandry, Aquaculture Division, DFO	Élevage des animaux aquatiques, division de l'aquaculture, MPO	Nanaimo, BC	kreibergh@dfo-mpo.gc.ca	No/non[(1)]