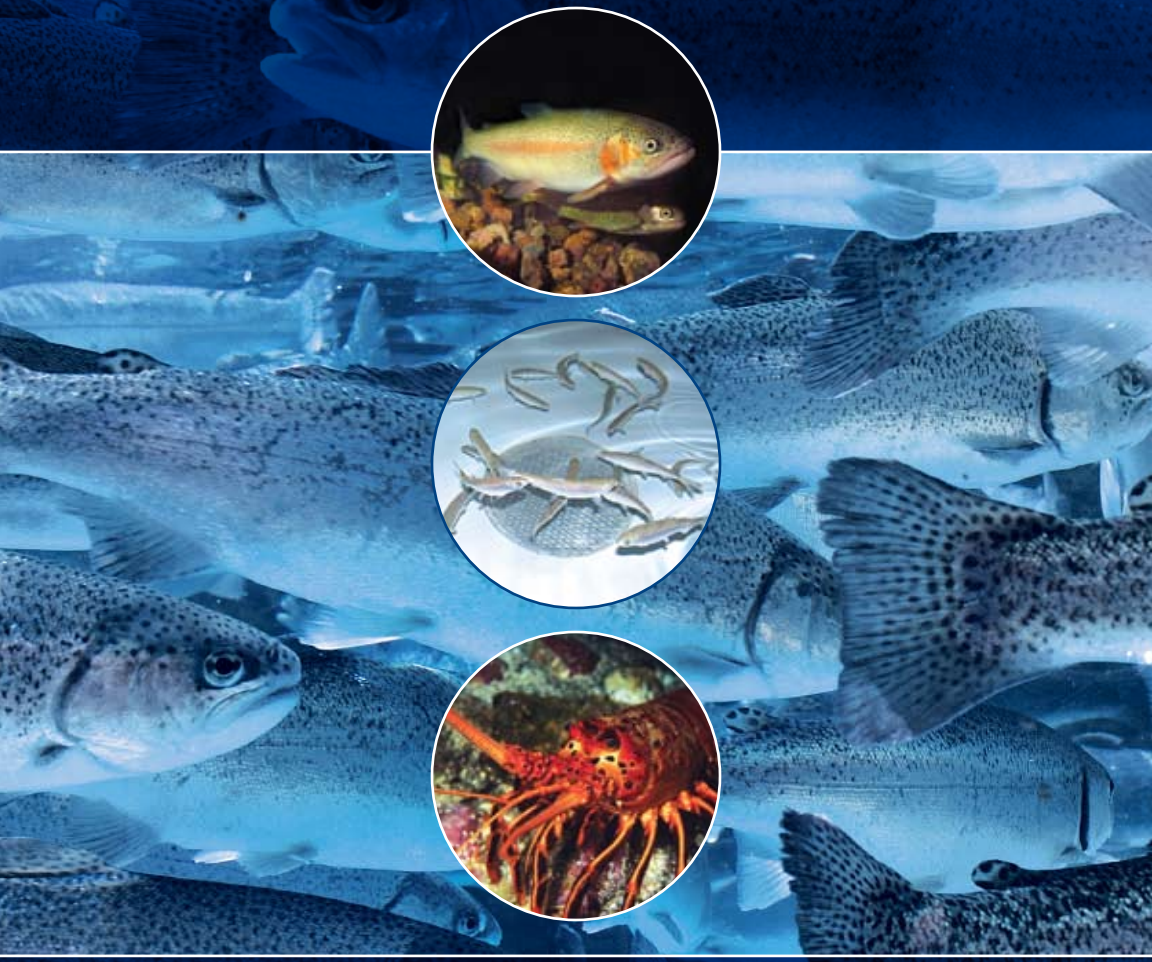
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

CONTAINMENT STANDARDS

for Facilities Handling Aquatic Animal Pathogens

First Edition



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The development of these standards has been an ongoing process and the Canadian Food Inspection Agency (CFIA) is grateful to those who were involved in the preliminary phases of this project. The current version of the standard was developed by the Office of Biohazard Containment and Safety (OBCS) and reviewed by a group of individuals/ organizations that have been involved in this process from the inception. The OBCS would like to acknowledge the advice, expertise and input provided by these individuals and organizations.

Aquatic Animal Health Division (AAHD), Canadian Food Inspection Agency

Canadian Council on Animal Care (CCAC)

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Public Health Agency of Canada (PHAC)

Veterinary Biologics Section (VBS), Canadian Food Inspection Agency

The OBCS would also like to take this opportunity to thank all of the individuals and organizations that participated in and provided comments throughout the public consultation process.

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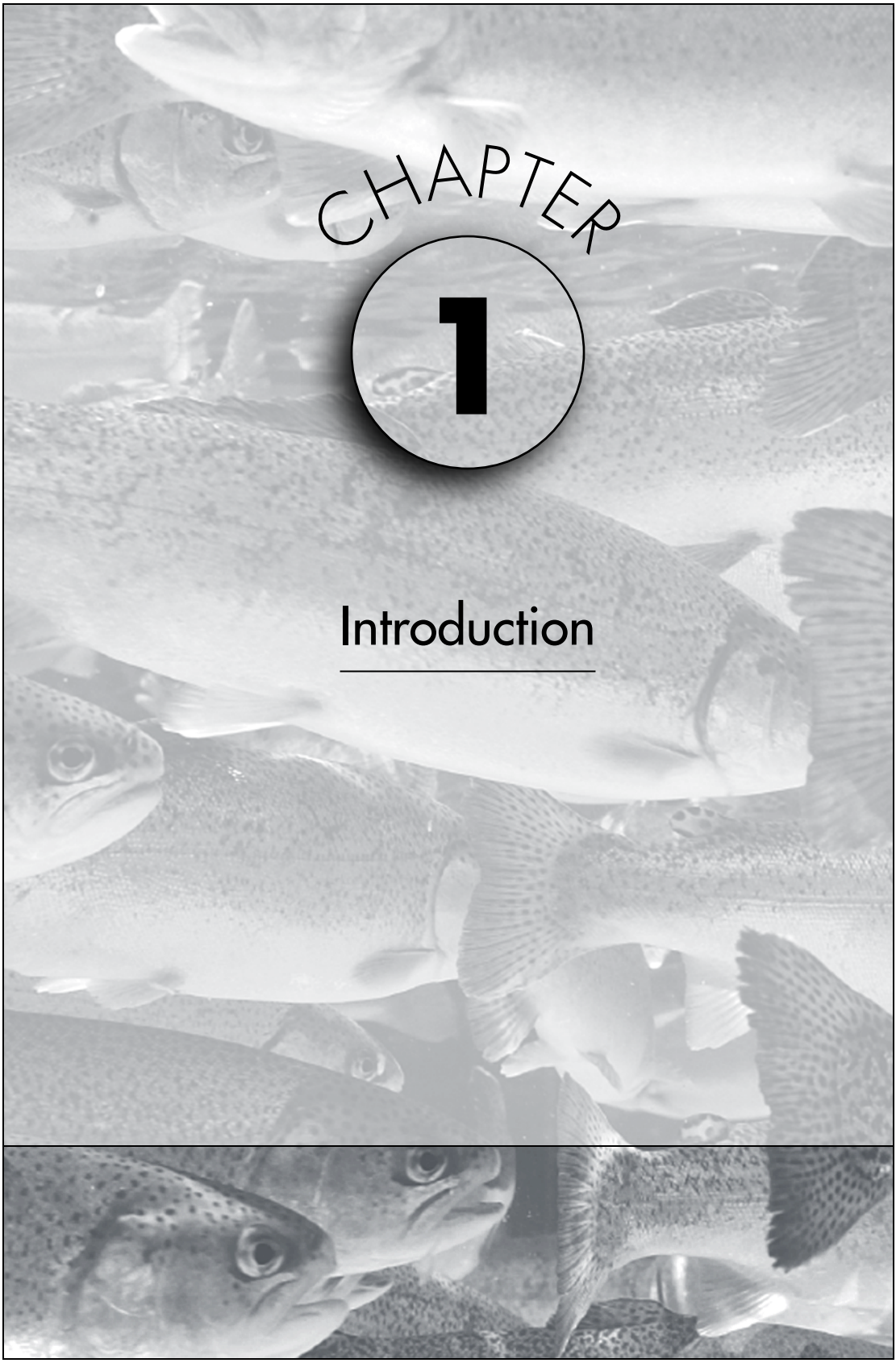
Abbreviations

AAHD	Aquatic Animal Health Division
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
AQCx	Aquatic Containment Level 1, 2 or 3
BSC	Biological Safety Cabinet
BSO	Biosafety Officer
CCAC	Canadian Council on Animal Care
CFIA	Canadian Food Inspection Agency
CSA	Canadian Standards Association
DFO	Fisheries and Oceans Canada
ERP	Emergency Response Plan
HEPA	High Efficiency Particulate Air
HVAC	Heating, Ventilation, and Air Conditioning
MSDS	Material Safety Data Sheet
NAAHP	National Aquatic Animal Health Program
NSF	National Sanitation Foundation
OBCS	Office of Biohazard Containment and Safety
PPE	Personal Protective Equipment
PHAC	Public Health Agency of Canada
SOP	Standard Operating Procedure
VBS	Veterinary Biologics Section



CHAPTER

1

Introduction

1.1 Scope

This document applies to **facilities**[1] importing **aquatic animal pathogens**, aquatic animal product(s) and by-product(s) or other substances that may carry an aquatic animal pathogen or part thereof. The document sets forth the minimum physical and operational requirements for facilities **importing** and subsequently working with aquatic animal pathogens or infectious materials. These facilities may include private, government, university establishments, research **laboratories**, vaccine production and vaccine testing facilities. While the *Containment Standards for Facilities Handling Aquatic Animal Pathogens* are mandatory for facilities importing aquatic pathogens, they also provide general guidance on the design and operating requirements for any aquatic animal containment facility.

This document will be used by Canadian Food Inspection Agency (CFIA) staff responsible for overseeing the importation of aquatic animal pathogens and for the certification of facilities in which imported aquatic animal pathogens are handled and stored. All persons wishing to import aquatic animal pathogens and related infectious materials for ***in vitro*** or ***in vivo*** work must comply with these standards along with any import requirements established by the CFIA and, where applicable, by the Public Health Agency of Canada (PHAC).

This document also serves as a resource for:

- researchers working with microorganisms for vaccine development, production and testing related to aquatic animal disease;
- researchers conducting **pathogenicity**/epidemiological investigations for laboratories that routinely handle **aquatic animals** for disease screening and diagnostics;
- commercial, academic, private and government facilities (e.g., zoos, aquariums, universities, Fisheries and Oceans Canada) working with aquatic animals that carry, or that originate from facilities, zones or countries known to be exposed to, pathogens presenting unknown or unacceptable risks to aquatic resources in the environment surrounding the holding facility.

[1] See the Glossary for the definition of the bolded terms in the text.

Compliance with the requirements related to the importation of aquatic animal pathogens and the physical and operational requirements described in these standards will help to prevent the inadvertent release of economically and environmentally significant aquatic animal pathogens.

1.2 Background

Agriculture and Agri-Food Canada's *Containment Standards for Veterinary Facilities*, 1st Edition[2], 1996, is a document that sets out standards to be applied by those who design, build, operate, or work in facilities in which animal pathogens are handled. The *Laboratory Biosafety Guidelines*, 3rd Edition[3], published in 2004 by the Public Health Agency of Canada, provides similar guidance for laboratories in which human pathogens are handled. Until now, facilities carrying out aquatic animal diagnostic, research, vaccine production and vaccine testing activities were required to comply with the current version of the *Containment Standards for Veterinary Facilities*. However, those containment standards are not applicable in all cases to work involving aquatic animal pathogens.

Although only a few aquatic animal pathogens are considered to be **zoonotic**, some are considered opportunistic and therefore may pose a low direct risk to personnel. Many aquatic animal pathogens pose a significant risk of introduction and spread of infectious diseases to vulnerable aquatic animal populations in Canada. As a result, it is important that personnel working with aquatic animal pathogens and the facilities housing these organisms take steps to prevent the accidental release of potentially harmful pathogens into the aquatic environment. The containment level that is required depends on the biology of the specific pathogens involved and the impact that a release of the pathogens might have on the Canadian environment.

Until 2005, the management of aquatic animal health was regulated by Fisheries and Oceans Canada (DFO) under the *Fisheries Act*. However, the *Fisheries Act* and associated Regulations were limited in scope and not specifically designed for the management of aquatic animal diseases, leaving Canada vulnerable to impacts on wild and cultured aquatic resources. With the development and implementation of the National Aquatic Animal

[2] Refer to http://www.inspection.gc.ca/english/sci/lab/convet/convete.shtml for the *Containment Standards for Veterinary Facilities*, Agriculture and Agri-Food Canada, 1st Edition, 1996.

[3] Refer to http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/index.html for the *Laboratory Biosafety Guidelines*, Public Health Agency of Canada, 3rd Edition, 2004.

Health Program (NAAHP) in Canada, the CFIA is now the lead agency responsible for health management of aquatic resources in Canada. The *Containment Standards for Facilities Handling Aquatic Animal Pathogens* have been developed to reflect this change in regulatory authority and the corresponding requirements pertaining to the importation of aquatic animal pathogens under the *Health of Animals Act* and associated Regulations.

1.3 Regulatory Authorities

The *Health of Animals Act* and associated Regulations give the CFIA the legislative authority to control the importation of pathogens that may cause disease in animals. The CFIA has established the conditions under which imported animal pathogens are to be handled and stored. The CFIA's Office of Biohazard Containment and Safety (OBCS), in collaboration with the CFIA's Aquatic Animal Health Division (AAHD), has taken a lead role in the development and administration of the *Containment Standards for Facilities Handling Aquatic Animal Pathogens*. Import permits issued by the OBCS are required for the importation of all aquatic animal pathogens into Canada. For work involving zoonotic aquatic animal pathogens, the PHAC's *Laboratory Biosafety Guidelines* must also be followed and an import permit may be required by the PHAC under the *Human Pathogens Importation Regulations*.

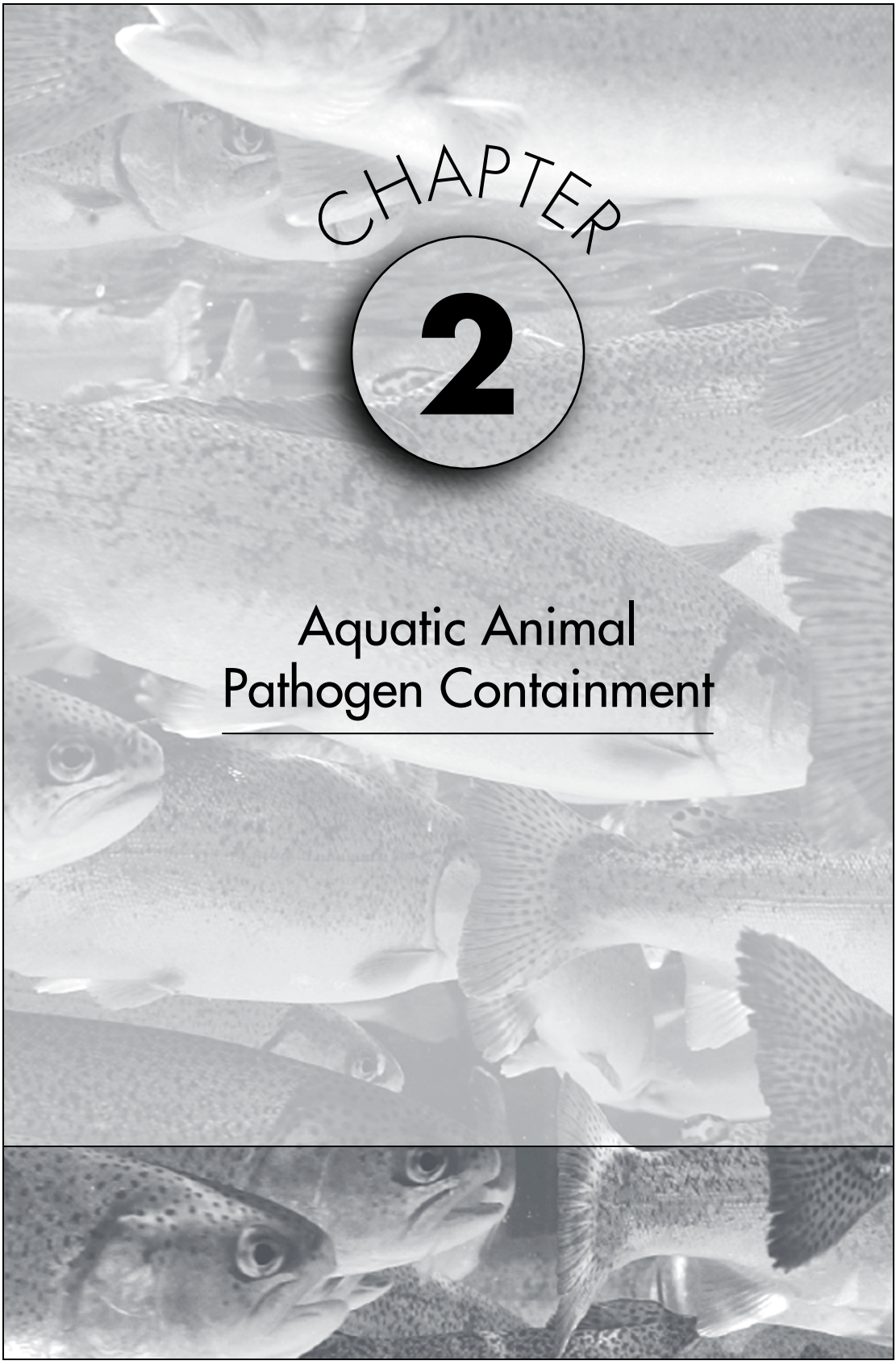
With the development of specific containment standards for aquatic animal facilities, all facilities importing aquatic animal pathogens, infected aquatic animals or parts thereof are now required to comply with the new standards. In some instances, facilities will be required to upgrade or renovate to meet the new standards, and therefore a transition period will be part of the implementation plan. Facilities wishing to begin or to continue activities that fall within the scope of these standards must comply with the physical requirements and the operational practices described in this document.

Additional requirements apply to work conducted with **veterinary biologics**, including fish vaccines and *in vitro* diagnostic test kits for the detection of fish pathogens. The CFIA's Veterinary Biologics Section (VBS) is responsible for regulating veterinary biologics in Canada under the *Health of Animals Act* and associated Regulations[4]. Written authorization must be obtained from VBS prior to the introduction of a new aquatic animal pathogen into

[4] Refer to http://laws.justice.gc.ca/en/H-3.3/C.R.C.-c.296/index.html for *Health of Animals Regulations*

veterinary biologics production, testing, research and development facilities. A *Permit to Release Veterinary Biologics* must be obtained from VBS prior to the release of an unlicensed or an experimental veterinary biologic outside the **containment zone**. For specific information about the regulatory requirements for veterinary biologics, please contact VBS.

For any work that involves aquatic animal pathogens that may be transmitted via the airborne route or pathogens that affect aquatic mammals, additional containment requirements may be required and will be assessed on a case-by-case basis by the CFIA.



CHAPTER

2

Aquatic Animal Pathogen Containment

CHAPTER 2 – AQUATIC ANIMAL PATHOGEN CONTAINMENT

2.1 Risk Factors and Challenges

The *Containment Standards for Facilities Handling Aquatic Animal Pathogens* are needed to ensure that aquatic animal pathogens are securely contained and safely handled for experimental or commercial development purposes.

The required containment level and the stringency of operational practices are based on an evaluation of the **hazards** and risks posed by the aquatic animal pathogens, the proposed activities involving the pathogens, and mitigating measures. In the case of **live aquatic animal holding facilities** (also referred to as *in vivo* facilities), consideration is given to the facility's physical characteristics and also to the pathogen itself in determining the containment level required.

When aquatic animal pathogens are handled in live aquatic animal holding facilities, treatment of **liquid effluent** from animal holding units is a key requirement for preventing the inadvertent release of pathogens into the environment. In live aquatic animal holding facilities, water is the transport mechanism and the tanks represent the **primary containment** devices. Tanks must be contained to reduce the risk of spillage. Aeration should be slowed or stopped before the removal of covers to prevent the aerosolization of pathogens. In these facilities, potentially contaminated water is discharged from flow-through and recirculation-based aquatic animal holding systems. Other sources of waste water include:

- wash water discharge collected in the floor drains;
- waste water from tank and boot cleaning;
- spillage from equipment (nets, transport tanks and pails, plumbing equipment, etc.);
- regularly scheduled maintenance of animal holding units (flushing/removal of sludge from drains and pipes, debris from animal holding units, etc.);
- experimental procedures (retrieving healthy carriers, collecting moribund and dead animals, discharge of contaminated water, tissue waste from necropsies, etc.).

Contaminated or potentially contaminated liquid effluent and solid/semi-solid wastes from both laboratories and live aquatic animal holding facilities must be prevented from entering local **watersheds**. Exposure of susceptible aquatic species to untreated or inadequately treated liquid effluent is a hazard that must be taken seriously.

Water introduces many biological challenges that may alter the effectiveness of **decontamination** in live aquatic animal holding facilities. Mechanical filtration of water, also called de-bulking, is useful as a first stage of liquid effluent treatment; however, a secondary treatment such as chemical, heat, gas, ozonation, irradiation, UV or other method of treatment is also necessary to ensure effective decontamination. Given the large volumes of water involved, decontamination of waste water requires the appropriate contact time to ensure effective inactivation of infectious agents. The contact time may vary greatly depending on factors including but not limited to the level of organic loading, the method of treatment, and the resistance of the pathogens to the chosen method of decontamination. Physical and chemical factors, such as **water type**, suspended solids and chemical characteristics, also influence the effectiveness of any given decontamination method. Processes for sediment decontamination must also be considered and implemented.

Spread or movement of aquatic animal pathogens can also occur via **fomites** such as clothing, boots, hands, netting material, transport containers and equipment. In addition, the handling and management of live animals can facilitate the spread of aquatic animal pathogens. Some examples include the movement of infected animals between holding units, ineffective decontamination of multi-use equipment, maintenance of floor drains and plumbing and feeding of animals. Protocols must be developed and followed to reduce the transfer of pathogens by personnel through animal handling and/or transport, as well as to ensure appropriate decontamination of equipment and solid and liquid wastes.

It has been documented that some aquatic animal pathogens can be transmitted via the airborne route[5]. In laboratory situations the likelihood of aerosol generation and transmission is increased due to the processes used. This risk can be mitigated through the use of primary containment

[5] Bishop, T. M., A. Smalls, G. A. Wooster and P. R. Bowser. 2003. *Aerobiological (airborne) Dissemination of the Fish Pathogen Ichthyopthirius multifiliis and the Implications in Fish Health Management*. The World Aquaculture Society.

devices, such as **biological safety cabinets** (BSCs), and through the provision of inward directional airflow in facilities. Additional containment requirements may be required for any work that involves aquatic animal pathogens that may be transmitted via the airborne route or for pathogens that affect aquatic mammals. These projects will be assessed on a case-by-case basis by the CFIA.

2.2 Risk Assessment

Biosafety risk assessments must take into account the **risk group (RG)** of a pathogen as well as the containment level of the facility where the pathogen will be handled. Classification of pathogens according to a risk group (e.g., RG1-RG4) is an internationally accepted practice in the biosafety field and is used to categorize the relative hazard associated with a particular pathogen. The containment requirements for particular microorganisms, activities or animal species are often project-specific, necessitating the modification of containment conditions. In these instances, containment requirements will be developed or existing requirements will be adjusted based on an assessment of various hazards and risk mitigation factors, including the following:

- the current physical and operational attributes of the facilities in which the proposed work will be done;
- the geographic location of the facility;
- the proximity of actual and potential hosts or carriers of the pathogen;
- the pathogen host range;
- the existence of significant organism biotypes or strains within Canada;
- the behaviour of the pathogen in the environment;
- the **virulence** of the pathogen;
- the mode of transmission or spread (e.g. water-borne, direct or indirect, airborne);
- the potential for local or long-distance spread;
- the persistence of the organism in the environment (survivability in salt or fresh water, water temperature, etc.);

- the availability of pathogen risk information;
- the nature of the proposed work (*in vitro*, *in vivo* or **large scale** (LS) *in vitro*);
- the potential capacity to control or eradicate the pathogen if it is released;
- the health status of experimental animals entering the facility;
- the potential for economic or environmental impacts from the release of the pathogen;
- the **biosecurity** related risks (e.g., the potential for theft and misuse).

Based on a review of the above, the CFIA will determine the appropriate containment level for mitigating the risk of pathogen escape and establishment in Canada.

In the planning stages for live aquatic animal holding facilities, consideration must be given to the proximity of the facility to receiving water bodies due to the potential risk of effluent treatment failure, which could result in the release of pathogens into the environment.

2.3 Containment Levels

Facilities handling aquatic animal pathogens must be constructed and operated to ensure the appropriate containment level for the anticipated work. Consideration is given to the pathogen itself, as well as to the procedures used to manipulate infectious materials and animals, and the volume of the biological material that will be handled.

In order to provide a framework ensuring appropriate aquatic animal pathogen containment in Canada, a containment classification system has been developed that is similar to the systems used for human, plant, and terrestrial animal pathogens. The classification system for aquatic animal pathogens consists of three levels: AQC1, AQC2 and AQC3, with associated *in vitro* and *in vivo* requirements for AQC2 and AQC3. At this time, there are no pathogens requiring AQC4; however, the decision to designate a pathogen as requiring level AQC4 will be made on a case-by-case basis.

Physical requirement descriptions are provided in Chapter 3 for AQC2 and AQC3. Operational requirement descriptions are provided in Chapter 4 for AQC1, AQC2 and AQC3. The following brief descriptions explain the major features of each containment level.

2.3.1 Aquatic Containment Level 1 (AQC1)

Although the physical requirements for AQC1 facilities are not formally described in this document, AQC1 corresponds to the physical and operating conditions which characterize any well-run laboratory or aquatic animal holding facility working with pathogens that may be present in the aquatic environment but that are not considered a risk to aquatic animals or to the aquatic environment. An AQC1 facility follows basic biosafety and biosecurity protocols related to personnel, animals (if present) and laboratory practices (use of laboratory coats, hand washing stations, standard biohazard waste sites and disposal, good microbiological techniques, appropriate decontamination procedures, sanitary carcass disposal, **standard operating procedures** (SOPs), etc.).

2.3.2 Aquatic Containment Level 2 (AQC2)

In AQC2 *in vitro* facilities, containment is achieved through facility design, operational procedures and the use of specialized equipment. An autoclave or other proven technology must be available to treat solid waste and waste water. Containment is achieved primarily through operational practices including training in biosafety and containment precautions, limiting access to authorized personnel, use of protective clothing, effective sanitation and housekeeping, and the use of good microbiological laboratory practices. All AQC1 physical and operational requirements also apply to this containment level.

For AQC2 *in vivo* work, certain enhancements are required in order to address the unique risks associated with the transmission of aquatic animal pathogens in water, such as the connection of drains and associated piping to an effluent treatment system.

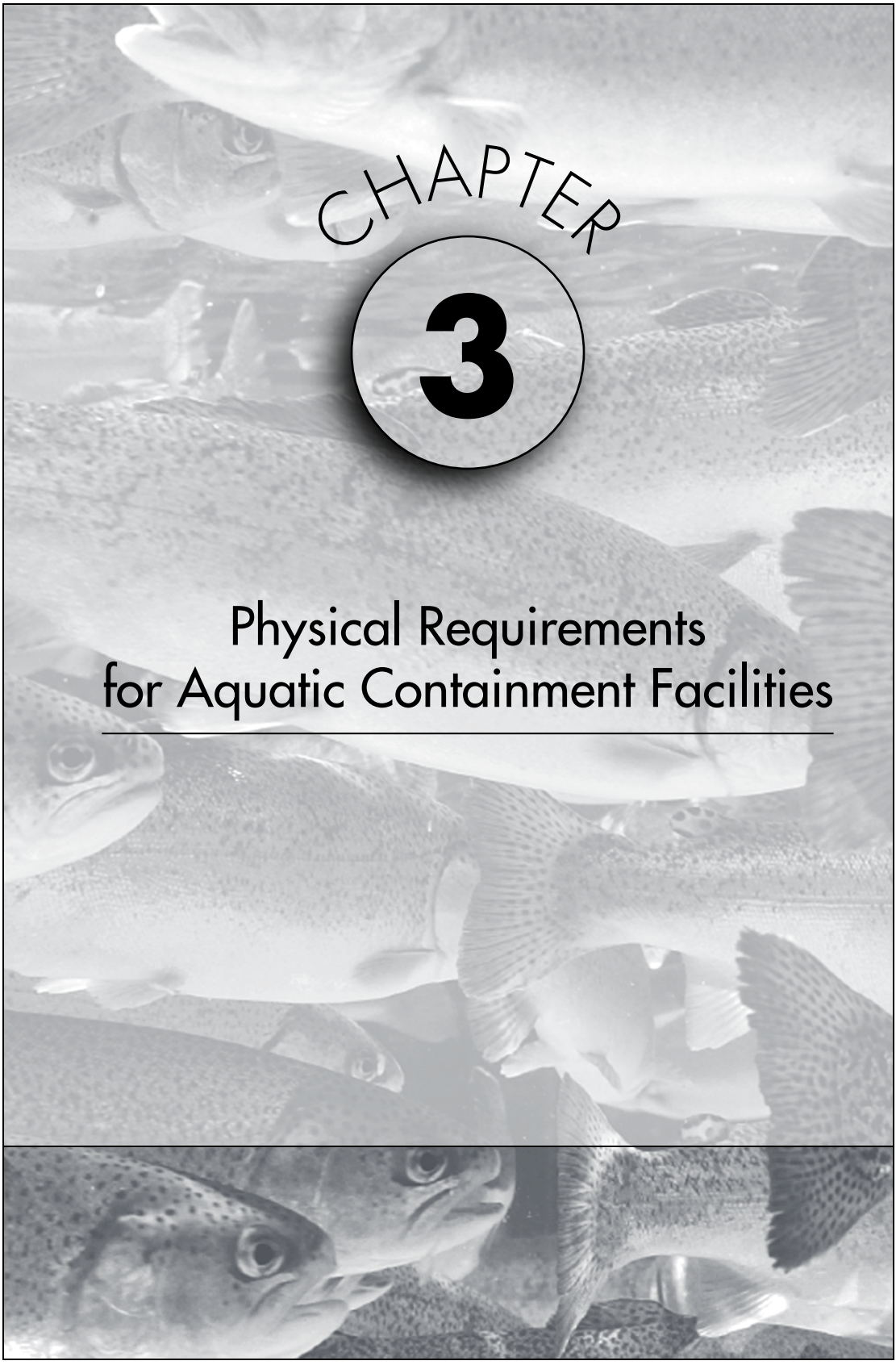
2.3.3 Aquatic Containment Level 3 (AQC3)

AQC3 *in vitro* containment is achieved through highly specialized facilities, stringent operational procedures and the use of specialized equipment. This type of containment is achieved primarily through physical requirements including inward directional airflow and controlled access systems.

For AQC3 *in vivo* work, certain enhancements are required in order to address the unique risks associated with the transmission of aquatic animal pathogens in water and containment is achieved through additional physical requirements and operational practices. Washing or showering upon exit may be required based on a **local risk assessment**. There may be additional heating, ventilation and air conditioning (HVAC) requirements for large scale or *in vivo* facilities handling pathogens transmissible via the airborne route.

2.3.4 Containment Level for Large Scale Work With Aquatic Animal Pathogens

Enhancement of the containment standards may be required for large scale *in vitro* work with aquatic animal pathogens. The applicable physical and operational containment requirements depend on the specific pathogen, the volume of pathogen involved, the frequency of activities, and the processes used. Therefore, the containment requirements for handling a large volume of aquatic pathogens will be determined on a case-by-case basis. For specific requirements related to the containment and safe handling of a large volume of microorganisms for research purposes, the OBCS should be contacted. For regulatory requirements pertaining to the manufacturing and testing of vaccines or diagnostic tests for aquatic animals, the VBS should be contacted.



CHAPTER

3

Physical Requirements for Aquatic Containment Facilities

CHAPTER 3 – PHYSICAL REQUIREMENTS FOR AQUATIC CONTAINMENT FACILITIES

This section describes the physical requirements for the containment of aquatic animal pathogens. When working with various aquatic animal pathogens, the facility must be capable of containing the pathogen(s) requiring the highest level of containment. New facilities must be constructed to meet applicable building codes and other relevant legislated or regulatory requirements.

In addition to the requirements and recommendations set out in this chapter, the design of the live animal holding facility must also comply with and meet the physiological, husbandry and welfare requirements for the animal species under investigation as specified by the Canadian Council on Animal Care (CCAC)[6].

3.1 Primary Containment

Primary containment devices, such as BSCs and centrifuges with sealed rotors, are used in conjunction with good microbiological techniques to reduce or eliminate potential exposure to infectious agents within a containment zone. In a live aquatic animal holding facility, the primary containment devices are the live animal holding tanks or possibly the tank room.

3.2 Secondary Containment

The design of the entire facility, along with operational practices, provides **secondary containment** to prevent or reduce potential exposure outside the containment zone. The selection, design and installation of casework, surface finishes, and air handling systems, along with the use of appropriate sealants, are factors that determine how well a facility can contain aquatic animal pathogens. Dedicated and trained staff who follow documented procedures and effectively utilize primary containment devices are an essential complement to proper facility design and construction.

[6] *Refer to* the *Guidelines on: The Care and Use of Fish in Research, Teaching and Testing.* Canadian Council on Animal Care (CCAC), 2005.

3.3 Risk Mitigation

Where feasible, risk mitigation measures should be applied within containment facilities, to further reduce the risk of aquatic animal pathogen release and thereby effectively reduce the physical containment requirements needed for a particular pathogen. These measures may include providing adequate separation between infected and non-infected aquatic animals, and rendering all infectious material non-viable at the end of experiments. Risks from aquatic animal pathogens can also be mitigated by locating new containment facilities in areas where susceptible aquatic species are not present.

3.4 Design Considerations for New Facilities

Facility design needs to address issues specific to aquatic animal pathogens in order to enhance the overall performance and operation of a containment laboratory or live aquatic animal holding facility. Designers, owners and operators should consider:

- Facility location – The site selection process for a containment facility should include an assessment of local aquatic programs as well as the local environment. The risks to aquaculture and the environment, including the impact of possible pathogen releases, should be considered before any work is begun with a particular aquatic animal pathogen. In areas prone to natural disasters, buildings and support systems for containment facilities should meet more stringent building code requirements.
- Energy conservation – If energy conservation measures are envisaged (e.g., through the use of building automation controls, night air-change set-back (reductions), heat recovery and air recirculation), these measures must not compromise the level of containment provided by the facility.
- Containment facilities require frequent wash downs of surfaces and these surfaces need to be resistant to chemical attack, absorption, and the effects of salt water in some cases. The use of epoxy bench-top surfaces or other non-absorbent solid surfaces is required.

- To facilitate decontamination and maintenance, systems such as liquid effluent treatment systems and HEPA filter housings must be located as close to the containment perimeter as possible, and consideration must be given to installing valves to isolate sections of plumbing and ductwork. Appropriately sized screens or filters may be used to collect some of the sediment and organic material before it enters the liquid effluent treatment system.
- New facilities require storage space for supporting operations, cleaning equipment, spill management, emergency safety response tools and equipment. The provision of dedicated equipment, storage areas and paperwork workstations inside the containment zone should be considered to minimize traffic into and out of the containment facility.
- Air handling systems should be designed to accommodate the additional moisture that is generated in live aquatic animal holding facilities and that auxiliary localized dehumidifiers may be required.
- Inward directional airflow – Some standards (i.e., ANSI/ AIHA Z-9.5-2003) recommend or require the use of inward directional airflow for new laboratory construction. Although it is advisable for all new and existing facilities to have inward directional airflow, this is a requirement for AQC2 *in vivo* and AQC3 facilities but only a recommendation for AQC2 *in vitro* facilities.
- Circuit breakers and shut-off valves should be located outside the containment perimeter to facilitate maintenance.
- Liquid effluent treatment systems must be designed with convenient sampling ports allowing for the collection of samples of treated effluent to monitor decontamination efficacy.
- Animal delivery systems must be taken into consideration to ensure proper containment in the live animal holding facilities and disinfection of the transport mechanism (i.e., container or vehicle) used.

3.5 Physical Containment Requirements

The following tables describe the physical containment requirements for AQC2 and AQC3 *in vitro* and *in vivo* (also called live animal holding) facilities and large scale facilities.

The following symbols are used:

● **Required**

○ **Recommended**

The absence of a symbol in the tables indicates that an item is either not required or not applicable. Where ● or ○ are followed by the suffix "LS", the item applies only to large scale facilities. Where the suffix "LS" is not present, the item applies to all facilities (live animal holding, *in vitro*, and large scale facilities). In the instances where the item does not apply to an *in vitro* facility, this will be specified in the text.

3.5.1 Structure, Location and Access

3.5.1	Structure, Location and Access	AQC2	AQC3
1	Containment zone to be separated from public areas and offices by lockable doors.	●	●
2	Dedicated paperwork stations within the containment zone to be located away from aquatic animal holding areas.	●	●
3	Support facilities for waste disposal, feed, storage, aquatic animal handling, equipment cleaning, and outer garment storage (boots, accessories, etc.) to be located within the containment zone.	●	●
4	A dedicated area or necropsy room for experimental activities such as animal necropsy, tissue manipulations and surgical preparation to be provided within the containment zone. [Not required for *in vitro* work.]	●	●
5	Access limited to authorized personnel.	●	●
6	Restricted access to the containment zone is to be ensured through a controlled access system (e.g., electronic access card, code or equivalent).		●
7	Signage to be installed on entry doors to the containment zone indicating containment level, contact information, and entry requirements.	●	●
8	Entry to containment zone to be provided via an **anteroom**. [Not required for AQC2 *in vitro* work.]	●	●

3.5.1	Structure, Location and Access *(continued)*	AQC2	AQC3
9	Anteroom doors not to be opened simultaneously (interlocking doors, audible or visual alarms, or protocols are acceptable).		●
10	Interlocked doors, if present, to have manual overrides for emergency exit.		●
11	Entry to containment zone must have clothing change area designed to separate personal clothing from dedicated facility clothing for the zone (i.e., "clean" change area separated from "dirty" change area) in keeping with specific Personal Protective Equipment (PPE) requirements.	●	●
12	Exit from facility should be provided with a walk-through shower on the containment barrier (i.e., between "clean" and "dirty" change rooms).		○
13	Size of door openings designed to allow passage of all anticipated equipment.	●	●
14	Live aquatic animal entry to the holding facility to be provided in a manner that prevents breach of containment. [Not required for *in vitro* work.]	●	●

3.5.2 Surface Finishes and Casework

3.5.2	Surface (i.e., floors, walls, ceilings, sealants) Finishes and Casework	AQC2	AQC3
1	Doors, frames, casework and bench-tops and all material supporting animal holding units (i.e., tanks and equivalent structures) to be non-absorbent (wood surfaces are not permitted).	●	●
2	Surfaces to be scratch, stain, moisture, chemical and heat resistant in accordance with facility function.	●	●
3	Surfaces to provide impact resistance in accordance with facility function. [Only a recommendation for AQC2 *in vitro* work.]	●	●
4	Surfaces to be continuous and compatible with adjacent and overlapping materials (i.e., to maintain adhesion and a continuous perimeter). [Only a recommendation for AQC2 *in vitro* work.]	●	●
5	Interior coatings to be cleanable and resistant to chemicals, as well as to repeated disinfection in accordance with function (e.g., will withstand disinfection or fumigation).	●	●
6	Continuity of seal to be maintained between the floor and wall (a continuous cove floor finish up the wall is recommended). [Only a recommendation for AQC2 *in vitro* work.]	●	●

3.5.2	Surface (i.e., floors, walls, ceilings, sealants) Finishes and Casework *(continued)*	AQC2	AQC3
7	Floors to be slip-resistant.	●	●
8	Bench-tops designed to contain spills of materials (e.g., with **marine edges** and drip stops, trays or other equivalent strategy). [Only a recommendation for AQC3 *in vitro* work.]	○	●
9	Backsplashes, if installed tight to wall, to be sealed at wall-bench junction. [Only a recommendation for AQC2 *in vitro* work.]	●	●
10	All animal holding units to be provided with covers or equivalent strategies to prevent splashing transfer between tanks and reduce room humidity.	●	●

3.5.3 Containment Perimeter

3.5.3	Containment Perimeter	AQC2	AQC3
1	Autoclave or other validated and acceptable means of waste decontamination to be located within the containment zone. If not available in the containment zone, then strict waste control procedures must be implemented for the transport of waste in leak-proof and impact-resistant containers to a suitable autoclave within the facility or off site to a certified waste disposal facility.	●	
2	Dedicated double-door barrier autoclave is to be located on the containment perimeter; equipped with interlocking doors (recommended) or audible or visual alarms, to prevent the simultaneous opening of both doors. Body of autoclave should be located outside the containment zone for ease of maintenance.		●
3	Autoclave condensate drain to have a closed connection; an open connection is allowable if located within the containment barrier.		●
4	Autoclave to be equipped with a cycle log recorder to record time, temperature, and pressure.	●	●
5	Waste decontamination processes (heat, chemical, etc.) must be equipped with an appropriate monitoring and recording system in order to capture critical operational parameters such as date, cycle number, time, temperature, chemical concentration and pressure.	●	●

3.5.3	Containment Perimeter *(continued)*	AQC2	AQC3
6	Water decontamination processes (chlorine, ultra violet, heat, ozone injection, etc.) must be equipped with a monitoring and log recording system to record critical operational parameters. [Not applicable to *in vitro* work.]	●	●
7	Dedicated equipment for euthanasia to be provided within the containment zone. [Not applicable to *in vitro* work.]	●	●
8	Containment zone to be proofed against entry or exit of vermin and insects.	●	●
9	Within each separate live animal holding room, a combination of sealed surfaces and appropriate drainage must be provided to retain the largest single volume of contaminated liquids present within the containment zone. [Not applicable to *in vitro* work.]	●	●
10	All penetrations of the containment perimeter, including all conduits and wiring, to be sealed with non-shrinking sealant. [Not required for AQC2 *in vitro* work.]	●	●

3.5.4 Heating, Ventilation and Air Conditioning (HVAC)

Processes carried out in laboratories and live aquatic animal holding facilities may increase the risk of aerosol transmission of aquatic animal pathogens. This risk can be mitigated through the use of BSCs and through the provision of inward directional airflow. There are standards that recommend or require the use of inward directional airflow for new laboratory constructions. Other reasons for maintaining inward directional airflow include control of odours from animals, proper ventilation for chemical use (e.g., during decontamination), humidity control, compliance with CCAC requirements, and prevention of cross-contamination.

3.5.4	Heating, Ventilation and Air Conditioning (HVAC)	AQC2	AQC3
1	Provide appropriate ventilation for use of chemicals (e.g., during large vessel decontamination).	●	●
2	Inward directional airflow to be provided at the containment perimeter such that air will flow towards area of higher containment. [Only a recommendation for AQC2 *in vitro* work.]	●	●
3	Visual pressure differential monitoring devices to be provided at entry to containment area.	● LS	●
4	Alarm (visual or audible) to be provided within the containment area and outside the containment area (i.e., to warn others and maintenance personnel) to signal air handling systems failure.	● LS	●
5	Supply air system to be interlocked (i.e., fans, dampers, electrical) with exhaust air system, to prevent sustained laboratory positive pressurization.	● LS	●

The requirements for air quality, supply and exhaust air, and air recirculation within a containment zone for a veterinary biologics manufacturing and testing facility depend on the specific pathogen(s), procedures performed, and design and construction of the facility. Therefore, HVAC requirements for veterinary biologics manufacturing and testing facilities will be determined on a case-by-case basis. Some of these requirements include HEPA filtration of supply and exhaust air as well as sealed and dedicated supply and exhaust ductwork. For more details on these requirements, VBS must be contacted.

3.5.5 Facility Services

Facility services include all plumbing, electrical, gas, oil and safety equipment, etc., related to the operation of the facility. All such systems must be installed in a manner that does not compromise the containment required for the aquatic animal pathogens to be handled in the facility.

3.5.5	Facility Services	AQC2	AQC3
1	Hooks or lockers to be provided for clothing and personal protective equipment at facility entry/exit; street and facility clothing areas must remain separated.	●	●
2	Hand washing sinks to be located near the point of exit (either near the exit from the facility and/or on the dirty side of the anteroom).	●	●
3	Hand washing sinks to be provided with "hands free" capability.	○	●
4	Foot bath to be provided on the dirty side of the anteroom. [Not required for *in vitro* work.]	●	●
5	Appropriate primary containment devices to be available (e.g., BSCs), as required, to minimize potential contamination of the containment zone.	●	●

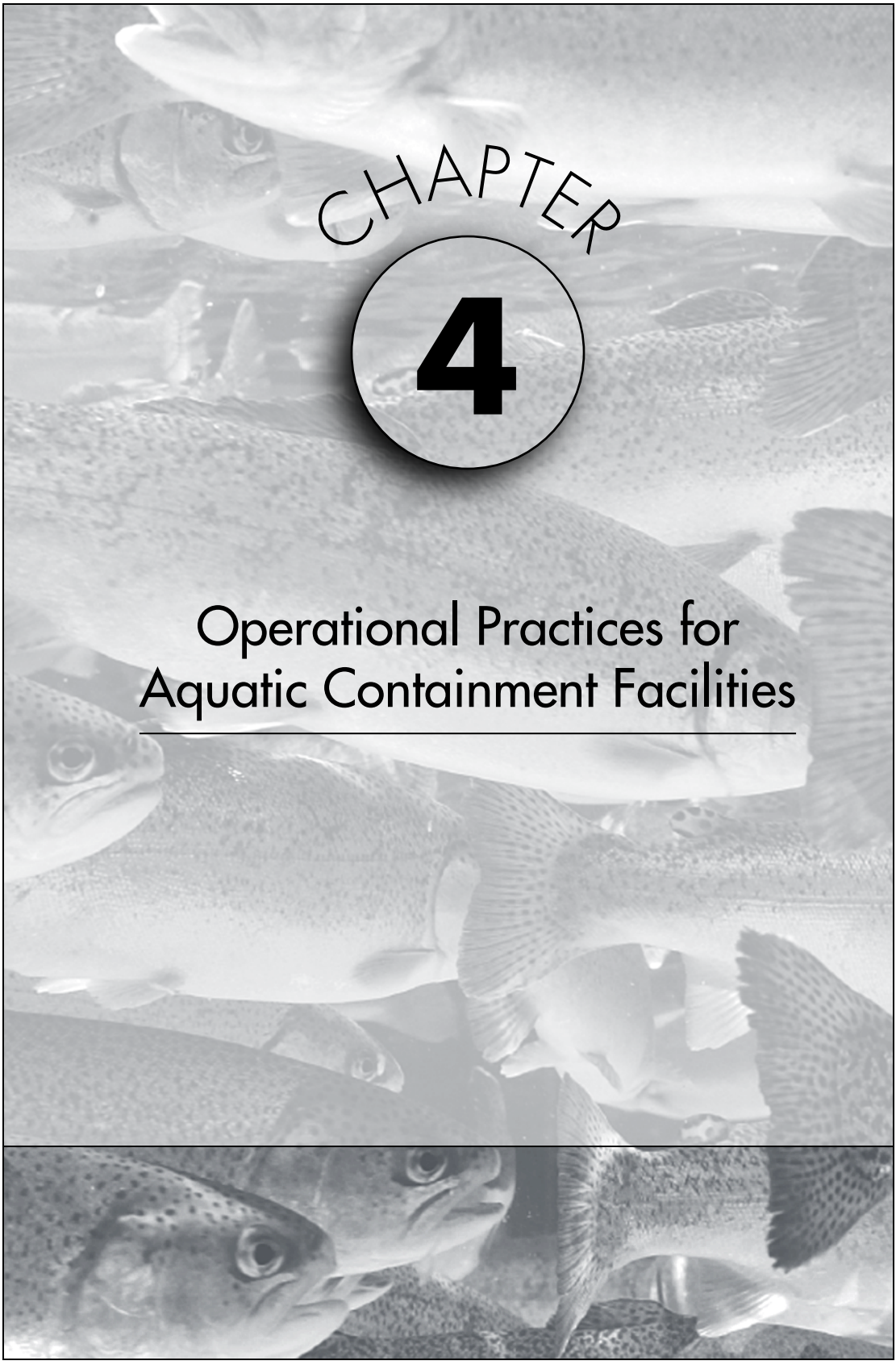
3.5.5	Facility Services *(continued)*	AQC2	AQC3
6	Class I and II BSCs to be tested in situ in accordance with NSF/ANSI 49-2008.	●	●
7	Emergency eyewash facilities to be provided in the containment zone in accordance with facility activities and applicable regulations (i.e. ANSI Z358.1-2004).	●	●
8	Emergency shower equipment to be provided in the containment zone in accordance with facility activities and applicable regulations (i.e., ANSI Z358.1-2004).	●	●
9	Communication system to be provided between laboratories and/or live animal holding facility zones and outside containment zone. [Not required for AQC2 *in vitro* work.]	○	●
10	Systems (e.g., fax, computer) to electronically transfer information and data to be provided (note: paperwork may be removed from the live animal holding zone after decontamination).		●
11	Water quality monitoring equipment (such as pH meters and temperature controls) to be located outside the containment zone or be subject to decontamination prior to removal from containment zone.	●	●
12	Water supply services to be provided with **backflow prevention** in accordance with CAN/CSA-B64.10-07/B64.10-07, and isolation valve to be located in close proximity to the containment perimeter. [Not required for AQC2 *in vitro* work.]	●	●

3.5.5	Facility Services *(continued)*	AQC2	AQC3
13	Drains and associated piping to be separated from zones of lower levels of containment. [Not required for AQC2 *in vitro* work.]	●	●
14	Drainage traps to be provided to required deep seal depth in accordance with air pressure differentials.		●
15	A backup system to be provided to supply air or oxygen to animals inside the facility in case of power supply failure. [Not applicable to *in vitro* facilities.]	●	●
16	Electrical outlets to be installed well above floor level, sealed to be water tight, and covered. [Not required for *in vitro* work.]	●	●
17	Power system circuit breakers to be located outside containment perimeter. [Not required for AQC2 *in vitro* work.]	●	●
18	Alarm system to be provided to indicate failures (excessive water levels, failure of backflows, etc.). [Not applicable to *in vitro* work.]	●	●
19	Life-safety systems, lighting, BSCs and other critical equipment to be supported by emergency power.	●	●

3.5.6 Liquid Effluent Treatment for Live Animal Holding Facilities

3.5.6	Liquid Effluent Treatment	AQC2/AQC3 *in vivo*
1	Drains from live animal holding tanks, sinks, sumps, showers, or drainage in contact with contaminated materials to be connected to an effluent treatment system.	●
2	Drains and associated piping leading to liquid effluent treatment system (including associated vent lines) to be tested in accordance with the *National Plumbing Code of Canada*, section 3.6 (1995).	●
3	Drains connected to effluent treatment systems to be sloped towards the decontamination system to ensure gravity flow; consideration should be given to installing valves to isolate sections for decontamination.	●
4	The effluent treatment system (e.g., piping, valves, tank) to be heat and chemical resistant consistent with use.	●
5	A backup effluent decontamination system or holding system must be in place to prevent discharge of untreated or partially treated effluent.	●
6	Effluent treatment systems that are not completely closed and contained must be housed in a room designed to the same containment level as the highest level of containment of the laboratory being serviced.	●

3.5.6	Liquid Effluent Treatment *(continued)*	AQC2/AQC3 *in vivo*
7	The following provisions apply to the room housing a completely closed and contained liquid effluent treatment system: • Doors must be kept locked at all times. • Doors must have appropriate signage. • Room must accommodate the volume capacity of the effluent treatment system. • Floor surfaces must be sealed. • Floor drains must be sealed or re-routed to the effluent treatment system.	●
8	Alarm system to be provided to indicate failure of effluent treatment system.	●
9	Exposed facility service piping with stand-offs to allow access for maintenance and cleaning.	●
10	Water supply shut-off valves and other controls to be located outside the containment zone.	●
11	Systems must be in place to ensure that in the event of effluent system failure, water supply lockout to tanks is activated before spill retention capacity is reached.	●
12	All effluent drainage pipes must be labelled for ease of accurate identification.	●
13	All effluent drainage pipes should be accessible for regular inspection for any leaks, repair and maintenance.	○
14	The effluent system must be equipped with a sludge/sediment removal/collection system.	●



CHAPTER

4

Operational Practices for Aquatic Containment Facilities

CHAPTER 4 – OPERATIONAL PRACTICES FOR AQUATIC CONTAINMENT FACILITIES

Work with aquatic animals presents a variety of special hazards including exposure to physical hazards (e.g., noise, extreme temperatures) and chemical hazards (e.g., cleaning agents, disinfectant chemicals). In addition, allergic conditions may result from handling aquatic animals and their tissues, or chemicals used in the facilities. Personnel should be familiar with and have access to **Material Safety Data Sheets** (MSDS) for all chemicals used, and employees should be aware of potential allergies that could be aggravated by working with live aquatic animals and/or their tissues. Although few aquatic animal pathogens are recognized as being zoonotic, care must be taken when working with any aquatic animal or aquatic animal pathogen, particularly those that have not been studied extensively.

Following are the general operational practices for work carried out in research and diagnostic laboratories as well as live animal holding facilities. Facilities are required to comply with the operational practices corresponding to the assigned physical containment level of their facility. The operational practices outlined in sections 4.1 through 4.3 are cumulative. Section 4.4 outlines the requirements that *in vivo* facilities must comply with in addition to those described in the previous sections.

4.1 AQC1 Practices

The following general practices are required when working with aquatic animal pathogens in an AQC1 facility.

4.1.1 Access

Access to laboratory and support areas is limited to authorized personnel.

4.1.2 Documentation

4.1.2.1 A **Biosafety Manual** that covers basic safety and general laboratory operations relating to biosafety and biosecurity protocols must be available to all staff in the facility.

4.1.2.2 A basic Emergency Response Plan (ERP) must be available that describes emergency procedures in the event of accidents, fires, spills, power loss, and other situations. Plans must cover emergency egress procedures, corrective actions and notification of key personnel.

4.1.3 Training

Personnel must be trained in, and follow, the SOPs for the area. Personnel must demonstrate that they know and understand the required precautions; training must be documented; and refresher and retraining programs must be implemented as appropriate.

4.1.4 Personal Protective Equipment

4.1.4.1 Appropriate protective clothing, properly fastened, must be worn by all personnel, as well as by visitors, trainees and others, when working in the facility.

4.1.4.2 Laboratory clothing must not be worn in non-laboratory areas; laboratory clothing must be stored separately from street clothing.

4.1.4.3 Gloves must be worn to avoid inadvertent contamination of samples and work areas; gloves are to be removed when leaving the laboratory and decontaminated prior to disposal.

4.1.4.4 Only completely enclosed (toes and heels) footwear with low heels must be worn in containment areas.

4.1.5 Work Practices

4.1.5.1 Comply with all conditions specified on Permits to Import, if applicable.

4.1.5.2 Render all organisms and contaminated waste non-viable prior to disposal.

4.1.5.3 Doors to laboratories must remain shut (this does not apply to an open area within a laboratory).

4.1.5.4 Eating, chewing gum, drinking, smoking, storing of food and utensils, storing of personal belongings, applying cosmetics, and inserting or removing contact lenses is not to occur in the laboratory or containment zone. The wearing of contact lenses is recommended only when other forms of corrective eyewear are not suitable.

4.1.5.5 Long hair is to be tied back or restrained so that it cannot come into contact with hands, specimens, containers or equipment.

4.1.5.6 Hands must be washed after removing gloves and before leaving the containment zone.

4.1.5.7 All handling procedures must be designed and carried out to minimize the creation of aerosols.

4.1.5.8 All contaminated materials and equipment must be decontaminated prior to disposal or cleaning for reuse.

4.1.5.9 Good microbiological laboratory practices intended to prevent the release of 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 to be kept clean and tidy).

4.1.5.10 Contaminated work surfaces must be decontaminated with an appropriate disinfectant.

4.1.5.11 Leak-proof containers are to be used for the transport of pathogenic materials within facilities (e.g., between laboratories in the same facility).

4.1.5.12 Traffic flow patterns from clean to dirty areas must be established and adhered to (i.e., movement from least to most contaminated areas).

4.1.5.13 Oral pipetting of any substance is prohibited in containment areas.

4.1.5.14 The use of needles, syringes and other sharp objects should be limited to where necessary.

4.1.5.15 Open wounds, cuts, scratches and grazes should be covered with waterproof dressings.

4.1.5.16 All spills, accidents and overt or potential exposures to infectious materials must be reported immediately to the laboratory supervisor; written records of such incidents must be kept.

4.1.5.17 An effective rodent and insect control program must be maintained.

4.2 AQC2 Practices

The following section describes the minimum operational practices for AQC2 facilities; they must be applied in addition to the practices specified for AQC1 facilities that handle aquatic pathogens.

4.2.1 Access

4.2.1.1 Entry must be limited to facility staff, maintenance staff and personnel with the appropriate training. Visitors and any untrained personnel must be escorted by trained staff in order to work in the containment facility.

4.2.2 Documentation

4.2.2.1 A documented Biosafety Manual must be available for all staff and adhered to; it must be reviewed and updated regularly. This manual must include a brief description of the containment zones and how they operate as well as the containment facility SOPs describing the entire chain of events from receipt of infectious material (e.g., samples, specimens and animals) to decontamination and disposal. Topics covered in SOPs should include staff training, document archiving, entry/exit, spill clean-up, air handling/biosafety cabinet failure, effluent treatment, fire, animal escape and other emergencies, waste treatment, biohazard storage and disposal, etc.

4.2.2.2 Entry/exit protocols for persons, animals, equipment, samples, waste, hazardous components, etc., must be written, and followed; general protocols must be supplemented with protocols specific to each project in progress.

4.2.2.3 An ERP must be available that describes emergency procedures, including those for accidents, fires, chemical spills, air handling failure, BSC failure, power loss and containment loss. Plans must cover emergency entry/exit procedures, corrective actions and notification of key personnel and appropriate regulatory authorities.

4.2.2.4 In the event of life-threatening emergencies, human health and safety are a priority; exit SOPs must be established whereby routine procedures may be bypassed; a reporting area must be identified where further steps are to be taken (e.g., disinfecting footwear, showering) prior to contact with the surrounding environment and aquatic resources.

4.2.2.5 Procedures must be in place for the decontamination of exposed surfaces following splashing or spillage of contaminated water or debris in laboratory and live animal holding areas. Procedures must include prevention of release of contaminated materials into drainage systems unless linked to a decontamination system.

4.2.2.6 An assessment of hazards for the proposed activities is to be provided. Mitigation and management strategies for the hazards identified are to be incorporated into operational and physical requirements where applicable.

4.2.2.7 The Laboratory Director or the Director's designate(s) is responsible for:

- aquatic animal pathogens that enter, are held within, or leave the containment zone;
- compliance with all regulatory requirements;
- provision of employee training;
- maintenance of SOPs and the Biosafety Manual;
- compliance with SOPs and the Biosafety Manual;
- determining who is authorized to work in the facility.

4.2.2.8 Records of activities carried out in the facility shall be kept for three years, including records of all building and equipment maintenance, inspection reports prepared by the internal **Biosafety Officer** (BSO), shipments received, dates of import, CFIA Permits to Import, associated imported aquatic pathogen material, associated organisms detected, decontamination of packaging materials and transfer of aquatic animal pathogens to other facilities where authorized by a CFIA inspector. Records shall also be kept of all movement of aquatic animal pathogens into or out of containment.

4.2.2.9 Appropriate signage indicating the nature of the aquatic animal pathogens being used (i.e., type and containment level) must be posted on the entry door to each laboratory. If there are special provisions for entry, the relevant information must be included on the sign; the contact information of the laboratory supervisor or other responsible person(s) must be listed.

4.2.2.10 A BSO or biosafety representative with the authority to oversee biosafety and biosecurity practices must be designated for the containment facility; a biological safety committee may be used to assist the safety program.

4.2.2.11 All spills, accidents and overt or potential exposures to infectious materials, as well as containment failures (e.g. pump-failure and backflow), must be reported immediately to the laboratory supervisor, the BSO, and the appropriate regulatory authorities; written records of such incidents must be maintained for five years.

4.2.3 Training

4.2.3.1 Personnel must receive training on the potential hazards associated with the work involved and the precautions required to prevent exposure to infectious substances and potential zoonotic agents; training records must be signed by both employee and supervisor.

4.2.3.2 All persons (e.g., maintenance staff) entering the containment zone must receive training in the operational procedures for entry and exit; trainees must be accompanied by a trained staff member.

4.2.3.3 Employees working in the containment zone must have general knowledge of the physical operation and design of the facility (filtration and decontamination systems, alarm systems, etc.).

4.2.4 Personal Protective Equipment

4.2.4.1 Persons entering the containment zone must have access to and wear appropriate dedicated protective gear such as gloves, lab coats, boots, coveralls, respirator, and eye protection when required.

4.2.4.2 Personnel must remove all clothing dedicated to the containment zone before exiting. Contaminated clothing must be autoclaved prior to laundering (unless laundering facilities are located within the containment perimeter and have been proven to be effective in decontamination). Some activities and/or projects may require more thorough entry and/or exit procedures.

4.2.5 Work Practices

4.2.5.1 Personnel may not bring unnecessary personal belongings (e.g., hats, coats, purses) into the containment zone.

4.2.5.2 Containment zone doors on the perimeter are to be kept closed as required by facility design.

4.2.5.3 Persons entering the containment zone should bring all materials they will need with them in order to minimize movement into and out of containment.

4.2.5.4 To facilitate minor repairs that do not require a skilled tradesperson, a basic tool kit should always be available inside the containment zone.

4.2.5.5 Prior to removal from the containment zone, all contaminated liquid and solid waste (gloves, pipettes, culture media, sample material, etc.) must be decontaminated or procedures must be in place for transporting waste securely to the decontamination area.

4.2.5.6 Autoclaves and other decontamination processes are to be verified to ensure appropriate operation and validated using representative loads with appropriate biological indicators.

4.2.5.7 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 and impact resistant containers labelled appropriately.

4.2.5.8 Leak-proof containers are to be used for the transport of infectious materials within facilities (e.g., between laboratories in the same facility). Infectious materials to be transported from the facility must be done in accordance and compliance with the appropriate regulatory authority (e.g., *Transportation of Dangerous Goods Regulations*).

4.2.5.9 Periodic inspections of the containment zone must be made by facility staff to check for inward directional airflow (if applicable), faults and deterioration (e.g., deteriorated door seals); corrective action must be taken and records kept for three years.

4.2.5.10 Primary containment devices (i.e., BSCs) must be used for procedures that may produce aerosols and that involve high concentrations or large volumes of aquatic animal pathogens.

4.3 AQC3 Practices

All operational practices for AQC1 and AQC2 facilities apply to AQC3 facilities. The following section describes the additional minimum operational practices required in AQC3 facilities.

4.3.1 Access

4.3.1.1 Entry to the containment zone must be restricted to authorized laboratory staff, maintenance staff, and others on official business. Access to specific areas within the containment zone may be granted on an "as needed" basis only.

4.3.2 Documentation

4.3.2.1 The Laboratory/Facility Director or designate is responsible for the Biosafety Manual which includes procedures specific to the operation of the facility. It must be kept current, and employees must certify that they have understood and agree to abide by relevant SOPs. The Biosafety Manual must include policies and procedures for the following:

- Training;
- Entry and exit of personnel (including visitors) and materials;
- Handling of infectious material (i.e., transport within containment, storage, shipping, and receiving);

- Decontamination and waste disposal;
- Emergency procedures such as spill response, BSC failure/power failure;
- Incident and accident reporting;
- Use and maintenance of equipment;
- Housekeeping and facility maintenance;
- Medical surveillance if applicable.

4.3.2.2 The above SOPs are to be supplemented with SOPs specific to the nature of the work being conducted and to each project or activity, as appropriate.

4.3.2.3 A log book of all people entering and leaving the facility must be maintained and kept for three years.

4.3.2.4 Inspection reports prepared by the internal BSO must be maintained as well as medical surveillance documentation if applicable.

4.3.3 Training

4.3.3.1 Personnel working in the containment zone must possess knowledge of the physical operation and design of the facility (e.g., containment perimeter, air pressure gradients between zones, directional airflow patterns, and the alarm signals for effluent systems).

4.3.3.2 Personnel must demonstrate proficiency in appropriate practices (SOPs) and techniques.

4.3.4 Personal Protective Equipment

4.3.4.1 Persons entering the containment zone must wear appropriate dedicated protective gear such as gloves, lab coats, scrubs, boots, boot covers, coveralls, respirators, and eye protection when required.

4.3.5 Work Practices

4.3.5.1 Personnel entering a containment zone must bring all materials they will need with them; if something has been forgotten, established traffic patterns must still be adhered to (i.e., either telephone for someone to bring it in, or exit using proper protocols).

4.3.5.2 If aerosol exposure presents a risk, protocols must be in place to determine whether showering is required on exit from the containment zone.

4.3.5.3 A visual confirmation of inward directional airflow, using a smoke pencil or other visual aid held at the critical doors on the containment perimeter, is to be done regularly by trained staff to verify that inward directional airflow is in accordance with facility design.

4.3.5.4 Routine cleaning must be done by personnel who use the containment zone, or by other personnel specifically trained for this task, in order to minimize the number of people in containment.

4.3.5.5 The containment zone must be kept locked at all times.

4.3.5.6 Water seals must be maintained in drainage traps (i.e., through regular sink/shower/floor drain usage and/or by sufficiently frequent filling of traps in areas that are not being used).

4.3.5.7 Materials that cannot be autoclaved out of the containment zone must be decontaminated using another technology that has been proven effective prior to removal from zone.

4.4 *In Vivo* Additional Practices

All operational practices for AQC1, AQC2, and AQC3 provided in the previous sections are applicable to *in vivo* facilities. The following additional practices are required when working with aquatic animal pathogens *in vivo* (i.e., in a live animal holding facility) at any level unless otherwise specified.

4.4.1 Access

There are no additional access requirements from the previous sections for *in vivo* work.

4.4.2 Documentation

4.4.2.1 Additional procedures must be in place for aquatic animal care (procurement, handling, transport vehicles, isolation/quarantine, etc.) and effluent treatment use, maintenance and **validation**.

4.4.2.2 Procedures must be in place for receiving infected aquatic animals or potentially infected aquatic animals to ensure that the carrying reservoir (e.g., tank truck) is appropriately decontaminated prior to departure from the containment facility, or disposed of in a sterile manner (boxes, coolers, etc).

4.4.2.3 ERPs must include procedures for effluent treatment system failure.

4.4.3 Training

4.4.3.1 Personnel must receive training on the potential hazards associated with work involving live animal holding facility equipment and the additional precautions to minimize aerosolization associated with splashes and spills from tanks.

4.4.4 Personal Protective Equipment

4.4.4.1 Persons entering the containment zone must wear appropriate dedicated protective gear such as gloves, lab coats, scrubs, boots, boot covers, impermeable gear, coveralls, respirators, head covers and eye protection when required. Full coverage and dedicated PPE must be worn in AQC3 *in vivo* facilities.

4.4.4.2 Gloves must be worn when handling dead or live animals and parts of animals. Gloves must be resistant enough to prevent penetration by spines, teeth, etc., and to prevent exposure to infectious materials.

4.4.4.3 When heavy-duty gloves are required for handling live aquatic animals, they must be dedicated to individual tanks.

4.4.5 Work Practices

4.4.5.1 Waste from animal holding tanks (feed, water and debris from animal transport containers, floor catchments, clothing, nets, animal tissues, etc.) must be decontaminated prior to removal from the containment zone.

4.4.5.2 Foot baths must be used prior to exit. For foot baths to be effective, organic matter must be removed before use and disinfectant must be changed regularly. A log of the disinfectant used and maintenance of the footbath must be kept near the foot bath.

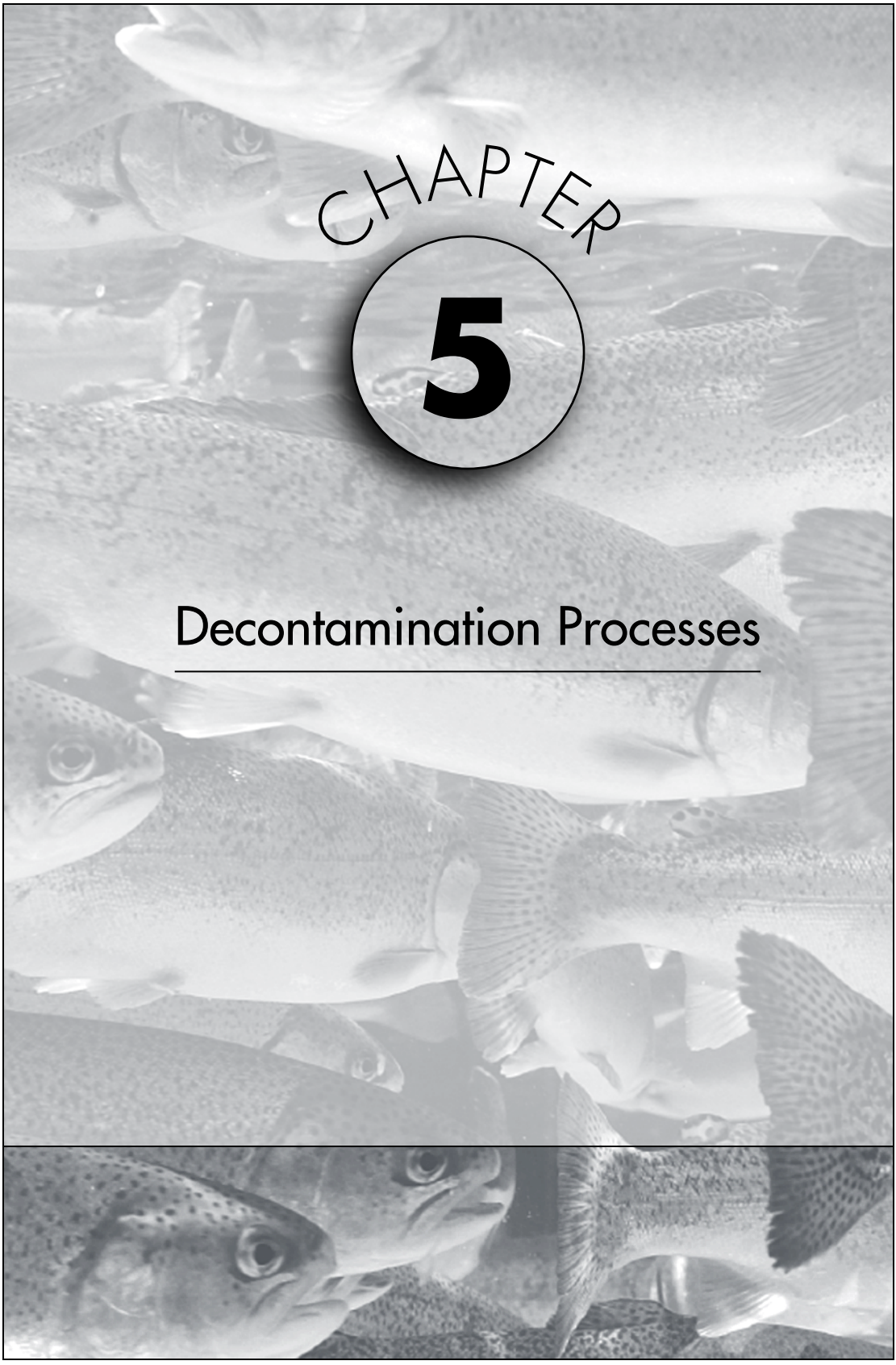
4.4.5.3 Animal holding units must be covered or other approved strategies used in order to prevent the spread of infectious agents between tanks and among units (specific requirements may be further prescribed by a local risk assessment).

4.4.5.4 Animal handling equipment and specialized accessories such as anaesthetic baths or surgical tables must be dedicated to each tank or to a series of tanks containing aquatic animals of identical origin or treatment.

4.4.5.5 Animal holding units must be designed to prevent animal escape.

4.4.5.6 Tanks for collection or retention of untreated effluent should be inspected at regular intervals for cracks or damage.

4.4.5.7 Sludge/sediment should be safely collected and stored within the containment zone until properly decontaminated and disposed of.



CHAPTER

5

Decontamination Processes

CHAPTER 5 – DECONTAMINATION PROCESSES

Decontamination processes used for all contaminated or potentially contaminated materials must be in place. All decontamination and waste management procedures must be in accordance with applicable federal, provincial and municipal regulations. It is the facility's responsibility to ensure that the decontamination method used is effective against the microorganisms handled under the conditions present at that facility. Decontamination parameters, such as time, temperature and chemical concentration, must be clearly defined and must be effective against the microorganisms of concern. Validation of the selected decontamination process must be submitted to the OBCS for review. The decontamination process must also be monitored regularly to ensure its efficacy. Clear and strict procedures must be in place to support daily decontamination and monitoring.

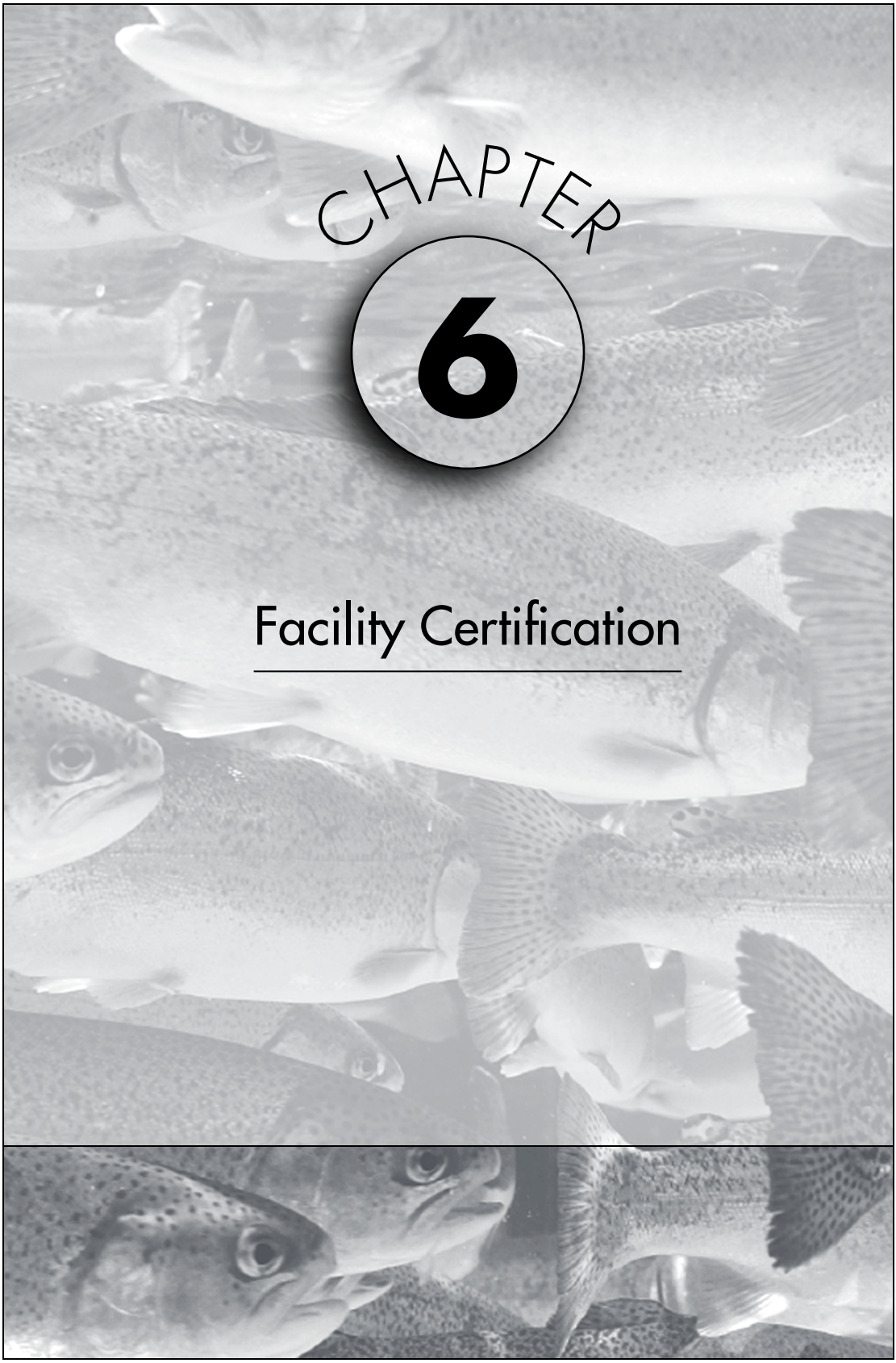
One of the most critical challenges when dealing with live aquatic animal containment is the volume of water that needs to be decontaminated. Ensuring that the microorganisms are effectively inactivated prior to discharging the waste into the environment is crucial. In order to prevent the discharge of untreated waste, a redundant effluent treatment system or holding system must be in place. In addition, the decontamination system must be equipped with alarms to detect a failure and with sampling ports to verify successful decontamination. Decontaminated liquid waste released from the effluent treatment system must meet all applicable regulations (bylaws pertaining to temperature, chemical/metal content, suspended solids, oil/grease, biochemical oxygen demand, etc.). Since decontamination technologies and testing protocols are constantly evolving, it is not possible to prescribe one or more specific protocols at present. Until these technologies are validated, each proposal will be evaluated on a case-by-case basis.

Live aquatic animal containment facilities pose additional challenges for effective decontamination of liquid effluent since the method of decontamination may render treated products detrimental to aquatic resources. For example, when chemical residues (e.g., chlorine and ozone) are not neutralized prior to release they can generate noxious fumes and water-borne residues or by-products (e.g., bromine in salt water) that can be harmful to aquatic animals and humans if inhaled, absorbed or ingested. Other types of treatment, such as heat, may require post-treatment cooling of the decontaminated waste before discharge into municipal drains or waterways.

The waste treatment area or facility must be designed to the same aquatic containment level as the containment zone unless it is a completely closed and contained system. If these areas are separated, all contaminated materials transferred between the two areas must be contained. This applies to off-site waste disposal as well as waste treatment carried out in a separate area of a larger facility.

The *Manual of Diagnostic Tests for Aquatic Animals* published by the World Organisation for Animal Health (OIE – Office International des Épizooties)[7] provides disinfection guidelines for finfish, mollusc and crustacean aquaculture operations. Additional measures may be required based on a local risk assessment. Although not specifically aimed at containment waste decontamination, the principles and physical/chemical processes described in the manual may be applicable to the design of a waste treatment system.

[7] Refer to OIE website: http://www.oie.int/eng/normes/fmanual/A_summry.htm



CHAPTER

6

Facility Certification

Where appropriate, CFIA inspectors will conduct site visits and certify that facilities comply with these standards, thereby ensuring that they are constructed and operated in a manner that adequately contains aquatic animal pathogens.

6.1 Certification

Facilities handling aquatic animal pathogens should refer to Chapters 3 and 4 of these standards to ensure that their physical containment and operational practices are adequate to contain the pathogens that will be handled. In order to receive a Permit to Import, AQC2 and AQC3 facilities must be certified by the CFIA. Facilities importing pathogens and planning work that requires AQC2 *in vitro* containment may be required to complete a detailed certification checklist, whereas AQC2 *in vivo* facilities may be inspected by the CFIA. Facilities importing pathogens and planning work that requires AQC3 will undergo an inspection by CFIA inspectors. If a facility is not granted certification or its certification is revoked for any reason, the deficiencies must be corrected before the facility can be certified or recertified.

The critical containment components to be verified during certification of AQC2 *in vivo* and AQC3 facilities are outlined in section 6.3. All of these components are to be verified as part of the commissioning process for a new facility (some may not apply to AQC2 *in vivo*). Certification and recertification records must be retained for three years and they must be available for review by a CFIA inspector, who may elect to re-verify some or all of the components. All as-built drawings and specifications of AQC2 *in vivo* and AQC3 facilities must be submitted for review. The Biosafety Manual must also be submitted for review before work can be carried out with aquatic pathogens at the facility to be certified. Personnel training must be completed and documented. Users must understand containment principles and proposed procedures.

6.2 Recertification

Recertification of AQC2 *in vivo* and AQC3 facilities must be done annually. Before **program changes** are implemented, operational procedures must be submitted to the CFIA for review and approval. Program changes include those related to the nature of the work or the procedures employed that could increase the risk of pathogen release from the facility.

6.3 Verification and Performance Testing of AQC2 *in vivo* and AQC3 Facilities

6.3.1 Room Integrity

Room integrity must be verified visually for cracks and also with a smoke pencil, or other visual aid, to confirm the integrity of all penetrations and seals on the containment perimeter (includes service penetrations and seals around doors, windows, autoclaves and dunk tanks). Floors, walls, and ceilings as well as wall/floor and wall/ceiling joints must be visually inspected for cracks, chips or wear.

6.3.2 Communication Devices

Communication and electronic data transfer systems (e.g., computer, telephone, facsimile) must be tested to ensure that they operate as specified. Communication should be maintained with minimum interruption during a power outage.

6.3.3 Door Interlocks

Interlocked doors and emergency overrides must be tested to ensure that doors cannot be opened simultaneously and that emergency egress overrides the interlocks.

6.3.4 Access Control and Security Devices

Access control and security devices (e.g., key, proximity card, keypad, biometric reader) on all entry points to the facility must be verified to ensure that they operate as intended.

6.3.5 Inward Directional Airflow

Inward directional airflow must be visually demonstrated at all critical doors (e.g., by holding a smoke pencil, or other visual aid, at each door leading to an adjacent area).

6.3.6 Autoclaves and Decontamination Systems

Autoclaves and other decontamination systems (dunk tanks, fumigation chambers, etc.) must be verified to ensure operation as specified and microbiologically tested using representative loads. A description of the different types of loads to be run and a short description of the load test procedure (laundry, solid waste, liquid waste, etc.) must be provided.

Biological indicators or an internal load temperature probe must be used to confirm that treatment parameters have been achieved. References pertaining to the maintenance and efficacy of decontamination systems and disinfectants must be kept for three years.

6.3.7 Backflow Preventers

Water supply backflow preventers must be tested in accordance with CAN/CSA -B64.10-07/B64.10.1-07: *Selection and Installation of Backflow Preventers/ Maintenance and Field Testing of Backflow Preventers* (2007). Backflow prevention for other services (e.g., gases) must be verified to ensure that the system will operate as specified.

6.3.8 Emergency Generator

Emergency electrical generators must be tested under appropriate load conditions to ensure systems will operate as specified. Verification that all critical systems are on emergency power (including, but not limited to, controls, fans, security, critical equipment, phones, effluent treatment, etc.) must be provided.

6.3.9 Liquid Effluent Treatment

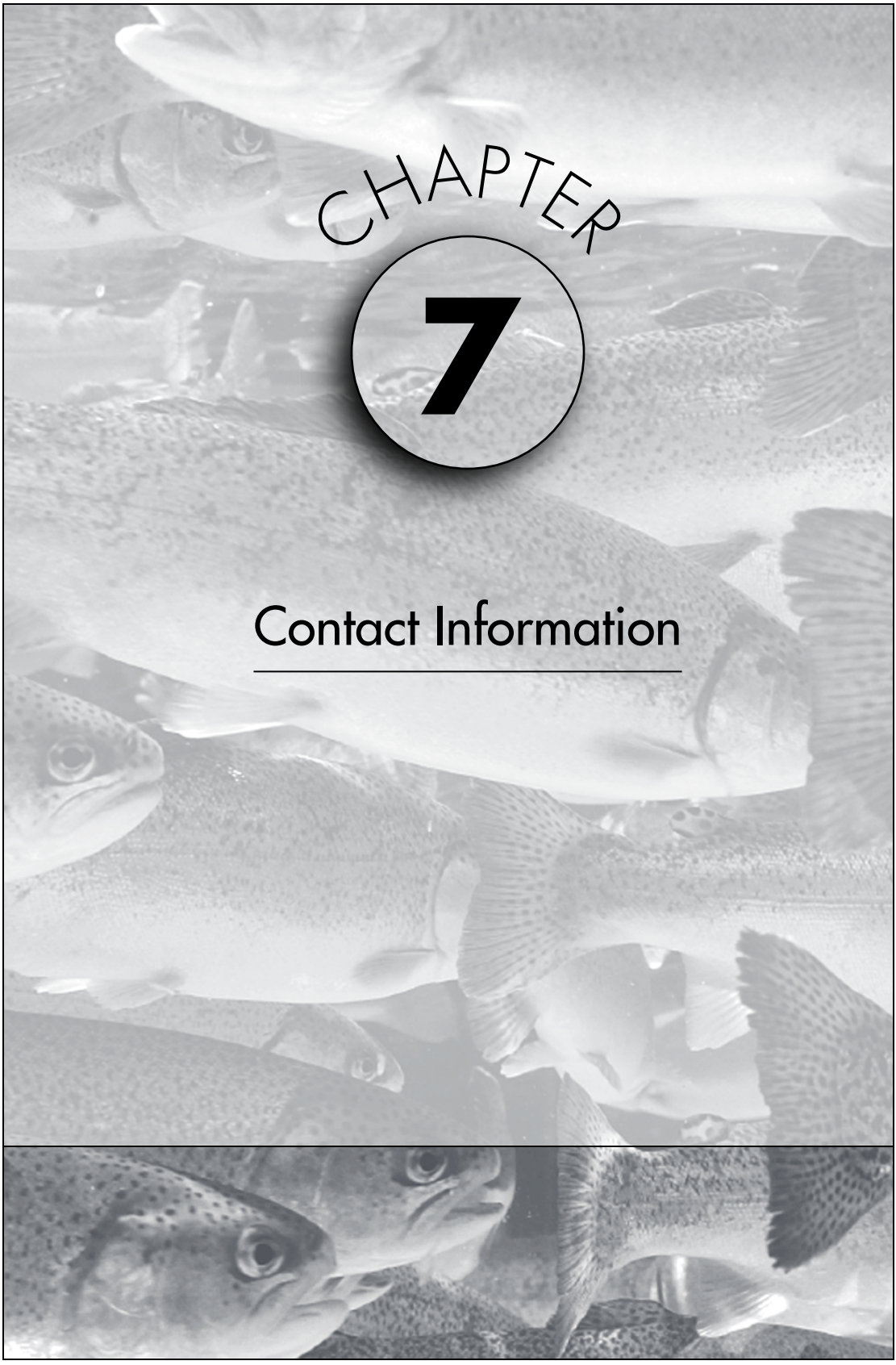
Effluent treatment systems must be verified for operation as specified and microbiologically tested using representative loads. A description of the different types of loads to be run and a short description of the load test procedure must be provided. The system and run criteria are to be validated by a microbiological challenge. Drains and associated piping leading to liquid effluent treatment systems (including associated vent lines) are to be tested in accordance with the *National Plumbing Code of Canada*, section 3.6 (1995).

6.3.10 Biological Safety Cabinets

Testing and certification of BSCs must be performed in accordance with NSF/ANSI 49-2008. Interlocks (i.e., Class II Type B2 BSC internal cabinet supply fan and exhaust fan) are to be tested in accordance with the applicable NSF standard.

6.3.11 Biosafety Manual

The Biosafety Manual, which may consist of a collection of SOPs, is a critical part of the certification documentation. SOPs must be updated on a regular basis and all changes must be submitted to the CFIA.



CHAPTER

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Contact Information

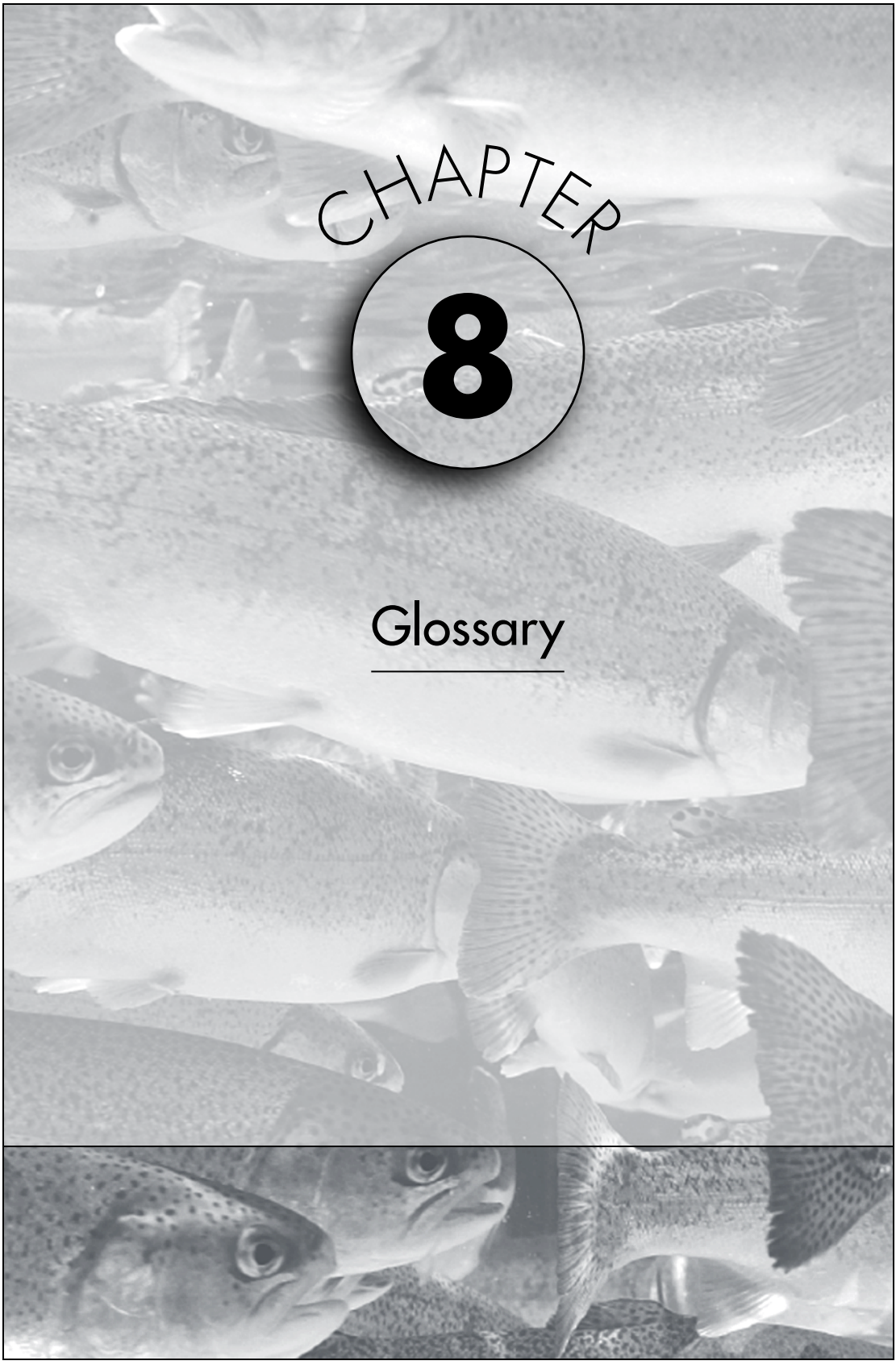
CHAPTER 7 – CONTACT INFORMATION

For information regarding the *Containment Standards for Facilities Handling Aquatic Animal Pathogens*, please contact:

Office of Biohazard Containment and Safety
Canadian Food Inspection Agency
59 Camelot Drive
Ottawa Ontario
K1A 0Y9
Tel: 613-221-7068
Fax: 613-228-6129
http://www.inspection.gc.ca/english/sci/bio/bioe.shtml

Aquatic Animal Health Division
Canadian Food Inspection Agency
8 Colonnade Road
Ottawa Ontario
K1A 0Y9
http://www.inspection.gc.ca/english/anima/aqua/aquae.shtml

Veterinary Biologics Section
Canadian Food Inspection Agency
8 Colonnade Road
Ottawa Ontario
K1A 0Y9
Tel: 613-221-7566
Fax: 613-228-6612
http://www.inspection.gc.ca/english/anima/vetbio/vbpbve.shtml



CHAPTER

8

Glossary

CHAPTER 8 – GLOSSARY

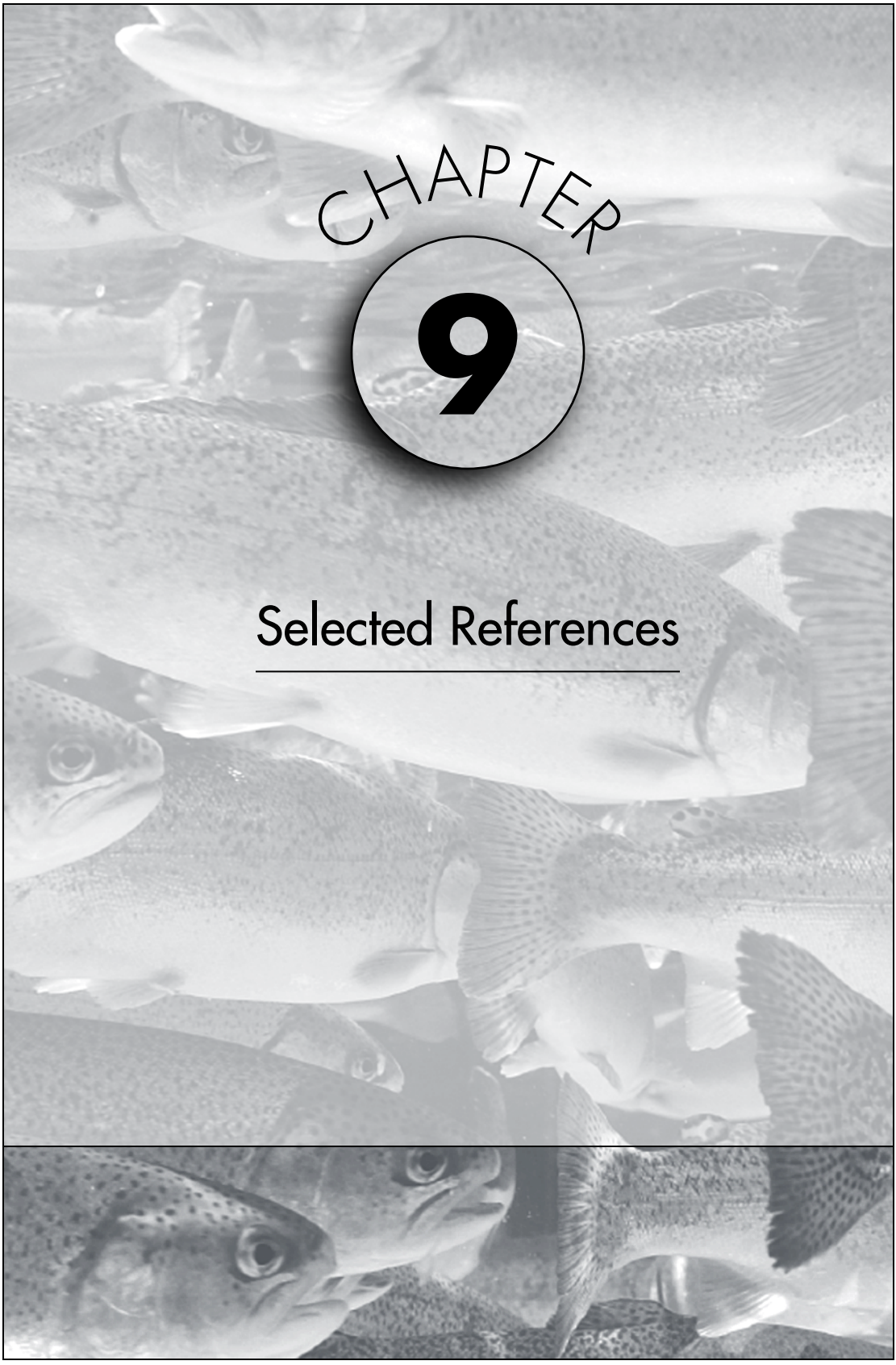
Anteroom	Entry room which leads into a containment zone.
Aquatic animals	In the context of this document, aquatic animals are defined as finfish, molluscs, and crustaceans.
Aquatic animal pathogen (also referred to as pathogen)	A microorganism or parasite that can cause disease in an aquatic animal.
Backflow prevention	System that protects water supplies from contamination. Many types of backflow devices also have ports so that they can be tested or examined for proper function.
Biological safety cabinet (BSC)	A primary containment device that provides protection from airborne contaminants for personnel, the environment and the product (in some models).
Biosafety	The containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins as well as their accidental release.
Biosafety Manual	A collection of SOPs and all other documentation pertaining to the specific biosafety and biosecurity aspects of a given facility.
Biosafety officer	A person who is trained and assigned to oversee biological safety and biosecurity at a given facility.
Biosecurity	Institutional and personnel security measures to prevent the loss, theft, misuse, diversion or intentional release of pathogens.

Containment zone	A contiguous physical area within a physical structure that meets specified containment requirements.
Decontamination	The process of rendering biological material non-viable, i.e., specific pathogen(s), gametes, nucleic acid, or other biological materials including cloning vector(s). The process is also applied non-specifically to all liquid and/or solid waste. Decontamination may be accomplished through the application of a chemical treatment, heat, heat and pressure, irradiation, biological degradation, and other means.
Facilities	Aquatic animal holding areas or buildings such as research and diagnostic laboratories (government, commercial, university or private) as well as commercial operations involved in producing or developing vaccines or other biologics.
Fomite	An object that does not cause disease itself but which can spread infection by being contaminated with pathogens.
Hazard	A source of risk that could potentially cause adverse effects. A hazard produces risk only if an exposure pathway exists and if exposure creates the possibility of adverse consequences.
Importing	The activity of acquiring aquatic animal pathogens, aquatic animal product(s) and by-product(s) or other substances that may carry an aquatic animal pathogen or part thereof into Canada from another country.

In vitro	Research where the experiment is performed in a laboratory environment or outside a living organism.
In vivo	Activities that involve the use of whole living animals in scientific experiments.
Laboratory	For the purposes of this document, a laboratory is an area within a facility or the facility itself that handles aquatic animal pathogens for *in vitro* or *in vivo* research, maintains aquatic animal pathogens or aquatic animal gametes in storage, or conducts diagnostic work on tissues (fresh, frozen, preserved).
Large scale	Volumes of microbial cultures in excess of the volume typically required for identification and characterization of microorganisms, diagnosis of infectious diseases, and pathogenicity or vaccine studies with a small number of animals within containment.
Liquid effluent	The liquid waste produced by a containment facility which must be decontaminated prior to release.
Live aquatic animal holding facility	Facility that undertakes research or diagnostic work involving live aquatic animals.
Local Risk Assessment	A site-specific risk analysis that identifies the potential risk factors (i.e., nature of the work, personnel, environment, protocols and equipment used) associated with the use of an organism for a specific laboratory or facility project.
Marine edges	Surfaces that have raised edges to help prevent liquid from dripping or spilling onto the floor.

Material Safety Data Sheet (MSDS)	A form containing data regarding the properties of a particular substance (chemical or biological) intended to provide workers and emergency personnel with procedures for handling or working with that substance in a safe manner. MSDSs include information such as physical data, health effects, storage, disposal, protective equipment, and spill handling procedures.
Pathogenicity	The ability of an organism to enter a host and produce pathological changes generally associated with a particular disease.
Primary containment	Ensures the protection of personnel and the immediate laboratory from exposure to infectious agents and is provided by both good microbiological techniques and the use of appropriate safety equipment. In general, primary containment provides a physical barrier between the worker and/or the work environment and the hazardous material. Examples: BSCs, glove box, fume hood, animal containment caging, centrifuge safety cups, PPE (lab coat, gloves, respiratory protection, positive pressure suits, etc.).
Program change	A change in a certified facility that relates to the nature of work or the procedures. Examples: pathogen list changes, program intent change, location of work change.
Risk group	Internationally accepted term used for the inherent risks of a pathogen that are based on factors such as severity of disease caused, routes of infection, virulence and infectivity; it also takes into account the existence of effective therapies, possibilities for immunization, presence of vectors, quantity of agent and whether the agent is indigenous to Canada, possible effects on other species, or possible economic environmental effects.

Secondary containment	The protection of the environment external to the work environment from exposure to infectious materials (protects people/ environment outside the immediate work area). Examples: facility design and construction, good operational practices.
Standard Operating Procedures (SOPs)	Documents that describe the procedures used for a specific task, such as entry and exit of personnel into containment, liquid effluent waste decontamination and sample reception.
Validation	A process that verifies that the specific parameters of the particular decontamination process have been met.
Veterinary biologics	Veterinary biologics are vaccines, antibody products, and diagnostic tests which are used in prevention, treatment or diagnosis of infectious diseases of animals, including infectious diseases of aquatic animals.
Virulence	The degree or ability of a pathogenic organism to cause disease.
Watersheds	A high area of land where rain collects, some of it flowing down to supply rivers, lakes, etc., at lower levels.
Water type	In the context of this document, refers to salt or fresh water.
Zoonotic (defining Zoonosis)	Any disease or infection which is transmissible from animals to humans.



CHAPTER

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