

GREAT LAKES FISH HEALTH COMMITTEE

2011 Winter Meeting
Ann Arbor, Michigan
February 2-3, 2011

Minutes
(with attachments)

Submitted By:

Christina Haska
Great Lakes Fishery Commission

The data, results, and discussion herein are considered provisional; permission to cite the contents of this report must be requested from the authors or their agency.

GREAT LAKES FISHERY COMMISSION
2100 Commonwealth Blvd, Suite 100
Ann Arbor, Michigan 48105
Great Lakes Fish Health Committee

Table of Contents

List of Attendees	3
Meeting Agenda.....	4
Minutes	5
Welcome and Committee Business	5
Approval of Meeting Minutes.....	5
CLC/GLFC Update.....	5
Model Program Revisions	5
Overall Issues	5
Fish Diseases	5
Emerging Pathogens	6, 10
Emergency Pathogen Management.....	6
Restricted Pathogen Management	7
Releasing Fish.....	7
Inspections and Testing	7
Classification of Hatcheries.....	8
Risk Assessment	9
Agency Concerns.....	6, 9
Agency Updates	6, 8
Selection of New Vice-Chair.....	9
Fish Health Committee Roster	9
Review of Fish Health Pre-proposals	9
Webinar and Meeting Arrangements.....	9
Appendices.....	11
Gantt Chart.....	12
Model Program	13
Risk Assessment	28

List of Attendees

John Coll	U.S. Fish and Wildlife Service, Pennsylvania
John Dettmers	Great Lakes Fishery Commission
Christina Haska	Great Lakes Fishery Commission
Dave Insley	Ohio Department of Natural Resources
Roy Johannes	Minnesota Department of Natural Resources
Sue Marcquenski	Wisconsin Department of Natural Resources
Dave Meuninck	Indiana Department of Natural Resources
Andy Noyes	New York State Department of Environmental Conservation
Ken Phillips	U.S. Fish and Wildlife Service- Wisconsin
Ling Shen	Minnesota Department of Natural Resources
Gary Whelan	Michigan Department of Natural Resources
Greg Wright	Chippewa- Ottawa Resource Authority
Coja Yamashita	Pennsylvania Fish and Boat Commission

Great Lakes Fish Health Committee Meeting Draft Agenda
February 2-3, 2011
Weber's Inn, 3050 Jackson Ave., Ann Arbor, MI 48103
(734) 769-2500

Wednesday, February 2

- 8:00 am** **Welcome—Beth Wright**
 - 8:15 am** **Approval of Meeting Minutes—Beth Wright**
 - 8:30 am** **CLC/GLFC Update—John Dettmers**
 - 9:00-10:15 am** **Model Program (I): Discuss/Work on Issues —John Dettmers**
 - 10:15-10:30 am** **Break**
 - 10:30am-12:00 noon** **Model Program (II): Discuss/Work on Issues—John Dettmers**
 - 12:00 noon-1:30 pm** **Lunch (on own)**
 - 1:30 pm-2:00 pm** **Agency Updates (5-10 minutes each) - All**
 - 2:00 pm-3:30 pm** **Model Program (III): Discuss/Work on Issues—John Dettmers**
 - 3:30 pm-3:45 pm** **Break**
 - 3:45 pm-5:00 pm** **Model Program (IV): Discuss/Work on Issues—John Dettmers**
 - 5:00 pm- 5:30 pm** **Agency Updates (5-10 minutes each) - All**
- Adjourn for the Day**

Great Lakes Fish Health Committee Meeting Draft Agenda
February 2-3, 2011

Thursday, February 3

- 8:00 am-10:00 am** **Model Program (V): Discuss/Work on Issues—John Dettmers**
 - 10:00 am-10:15 am** **Break**
 - 10:15 am-11:30 am** **Model Program (VI): Discuss/Work on Remaining Issues—John Dettmers**
 - 11:30 am-1:00 pm** **Lunch (on own)**
 - 1:00 pm- 3:00 pm** **Model Program (VII): Discuss/Work on Remaining Issues—John Dettmers**
 - 3:00 pm- 3:15 pm** **Break**
 - 3:15 pm-3:45 pm** **Selection of new GLFHC vice-chair**
 - 3:45 pm – 5:00 pm** **Risk Assessment Discussion**
 - 5:00 pm-5:30 pm** **Meeting Wrap-up (review action items, next meeting details)**
- Adjourn**

Day 1: 2 February 2011

1. Welcome and Committee Business (K. Phillips)

Beth Wright has a new position with OMNR and can no longer be chair. Therefore, Ken is the new chair starting at this meeting and Ontario will have mixed representation on the committee.

2. Approval of Meeting Minutes (K. Phillips)

The minutes from the August 2010 meeting were approved by the committee.

3. CLC/GLFC Update (J. Dettmers)

The CLC has charged the committee with providing them a completed Model Program draft by October 2011. To accomplish this, a Gantt chart was created to outline when specific tasks should be done (see Appendix 1).

The EPA/SOLEC are creating indicators of pathogens for fish health. The committee may be sought for thoughts and feedback on their activities.

4. Model Program – Overall Issues (All)

The following edits reached consensus:

- Line 31: the text was changed to indicate that this document will not go hand-in-hand with the NAAHP.
- Line 54-55: this document is to guide whether or not to move fish which could have pathogens. As it is written here, it's too vague. Edits were made to reflect this.
- The definition for 'quarantine facility' was approved.
- A definition for 'wild broodstock population' was approved.
- A definition for 'secure water supply' was approved.
- The change to 'restricted fish pathogen' was approved.

The following edits will be addressed at a later time:

- OIE-specifics should be given for 'quarantine facility' at some point in the document.
- Determine if a definition for 'fish health inspection' is needed once that section is edited.

5. Model Program Edits: Fish Diseases (All)

The following edits reached consensus:

- Specify which VHS strains are Emergency pathogens.
- Include Asian tapeworm on the Emergency list.
- Include *Lymphosarcoma* on the Restricted list.

The following edits will be addressed at a later time:

- Sue will create a table showing which fish species are susceptible to which pathogens.
- Create criteria for moving a pathogen from the Emergency list to the Restricted list.

6. Model Program Edits: Emerging Pathogens (All)

The following edits reached consensus:

- A new definition and guidelines were created.

The following edits will be addressed at a later time:

- There needs to be clear guidance on the difference between Restricted and Emerging pathogens. Specifically, the management actions will need to be different to distinguish between the two. This will be gone into further depth in the Management section.

7. Agency Concerns I (L. Shen)

An EPA lab is using bacterial counts of discharge water as a parameter to make sure the effluent is being correctly treated. These numbers, however, fluctuate and they would like to use a different parameter (e.g., UV light level, ozone). The committee was asked for suggestions.

Chlorination is not an option because the water would then need to be de-chlorinated before discharging to the lake.

The hatchery could follow the guidelines of a quarantine facility and process the water in that recommended fashion.

Finally, if the water is too dirty, it may be best to filter it first and see if that helps with the results.

8. Model Program Edits: Emergency Pathogen Management (All)

The following edits reached consensus:

- Clarify how it is known whether or not imported fish are from an area enzootic for a pathogen (i.e., through collective knowledge, a literature review, and contact with the exporter).
- Remove Infectious Salmon Anemia (ISA) from the list of pathogens not vertically transmitted.
- Use the same criteria for testing of gametes as those for fish.
- The detection list was broken up to show what a facility has to do to prove freedom from a pathogen.

The following edits will be addressed at a later time:

- For detections, include page 21 of the old Model Program.
- Consider including the risk assessment in the Detection section.

9. Agency Updates I

Ohio DNR (D. Insley): The steelhead they received from Michigan have coldwater disease. The fish have been treated multiple times, but the mortalities are still higher than preferred. They lost about 10,000 fish total (20-30 fish/day). There have been no die-offs due to VHS. Castalia is still undergoing major renovations to cover 900 ft. of raceway. The facility that had burned down last year is being rebuilt. Changes are happening within the DNR administration; the top three positions are being replaced. Elmer Heyob is retiring in March.

Minnesota DNR (L. Shen): A decision was made to move the production line from French River hatchery to an inland hatchery to eliminate the VHS threat. The French River hatchery had never had clinical signs of BKD in the past, but recently one salmonid displayed symptoms and was tested positive. No other fish displayed any signs of disease.

U.S. Fish and Wildlife Service- Pennsylvania (J. Coll): The water at Allegheny will be turned on in May. Brook trout from New England will be the first to go in to the tanks. Surveys did not find any VHS this year. A few new projects are looking for EEDv and *Nucleospora* in the lower lakes.

Indiana DNR (D. Meuninck): There were a couple of cases during lot inspections that had high BKD, but the fish did not display any clinical signs. Steelhead broodstock have had a high survival rate, which may be due to a thiamine experiment. There are low populations in Lake Michigan, which may be because of quagga mussels or a donut-shaped phytoplankton bloom caused from the circulation pattern in the lake.

New York State DEC (A. Noyes): There was an increase in furunculosis in returning Chinook salmon. Fred Hanson accepted a new position so Andy is now solo in the lab. Phil Hubert is the new Fish Chief, replacing Jim Daley.

10. Model Program Edits: Restricted Pathogen Management (All)

The following edits reached consensus:

- Quarantine plans should be developed by each agency.

The following edits will be addressed at a later time:

- Andy will research a generic fish-stress protocol for inclusion.
- In the chart that Sue is making, include which pathogens are vertically transmitted.
- Need to clarify that moving pathogens not already present is discouraged.

Day 2: 3 February 2011

1. Model Program Edits: Releasing Fish (All)

The following edits will be addressed at a later time:

- This section needs to be rewritten by the writing subcommittee. Issues that need to be addressed include:
 - Criteria by which you can stock fish,
 - Groups that pathogens can be clustered in that have the same management,
 - Acceptable limits for stocking fish with a pathogen,
 - Transmission of the pathogen (intra v. intercellular),
 - Treatment of the pathogen, if available.

2. Model Program Edits: Inspections and Testing (All)

The following edits reached consensus:

- Acknowledge who will be doing the sample collection.
- Cite the 3 manuals in the earlier section for “representative sample”.
- Sample healthy fish along with those showing clinical signs of disease.

The following edits will be addressed at a later time:

- Gary will research a table to include numbers for sampling wild fish.

3. Model Program Edits: Classification of Hatcheries (All)

The following edits reached consensus:

- The definitions for Classes A, B, and C were reworded.
- To obtain a classification, the time was changed to 3 calendar years
- To maintain a classification, the fish must be obtained from a hatchery *or its equivalent*.
- Change the parasite acronyms to beginning with “S”.
- Remove ISA from the list of Exceptions for Gametes.
- Remove “for salmonid eggs only” from VHS.
- Add Whirling Disease to the Exceptions for Gametes.

The following edits will be addressed at a later time:

- Provide examples for each class and the classification notation.
- Sue will research *Y. ruckeri* to determine if it belong on the ‘Exceptions for Gametes’ list.
- Ken will write an alternative Classification section and have it reviewed by Dave Insley, Dave Meuninck, and Coja. It will then be brought before the committee.
- The classification of a depopulated and disinfected hatchery will be determined once the Hatchery Classification guidelines are complete. It will likely be a Class C.

4. Agency Updates II

Wisconsin DNR (S. Marcquenski): Al Kaas is the new Section Chief, and Dave Giebtbrock is the Production Manager. There is a vacant position to lead hatchery reconstruction and renovation, as well as a vacant veterinarian position. The latest issue is with brown trout having enlarged hearts.

Michigan DNR (G. Whelan): The Marquette hatchery has put in place some control measures for BKD. A UV array was installed with the open-water production fish, and this has reduced pathogen loads by nearly 99%. BKD is now reduced to zero by the culling of healthy fish and by the use of vaccinations. The Platt River hatchery has a confirmed whirling disease, but the origin is unknown. It has affected rainbow trout and Atlantic salmon. UV systems will be installed there this year. There was a large-scale fish kill in the Detroit and St. Clair River system. Gizzard shad likely had VHS, and it may travel to Lake Erie.

CORA (G. Wright): More ponds are needed for their walleye production, as well has a need to increase staff numbers.

USFWS- Wisconsin (K. Phillips): There was a small outbreak of furunculosis at the Iron River. Water has been diverted to minimize exposure to productions fish, although water temperatures are currently not favorable for furunculosis (it’s cold). The origin of the disease is unknown, and there currently is not a plan on what is needed to happen. The fish may just get destroyed.

USFWS- Pennsylvania (J. Coll): Eggs are coming from Vermont for the lake trout program.

5. Selection of a New Vice-Chair (All)

Nominations for a new vice-chair included Ling, Dave Insley, and Dave Meuninck. Insley and Meuninck had to decline the nomination, but everyone supported Ling. **Ling accepted the position of vice-chair.**

6. Fish Health Committee Roster (All)

Sue suggested the committee members' addresses be included in the roster. This information was collected and the roster will be updated to include this additional information.

7. Agency Concerns II (D. Insley)

Trout Unlimited has a Trout in Classroom program which introduces schoolchildren to fish production and stocking. The kids are given fertilized eggs to raise until the fish are of a stockable size, and then the fish are released into rivers or lakes. The concern is that these fish would not undergo any health testing before their release. There would be approximately 20-50 fish per program. Should this be a concern?

The overall consensus was that this program would be relatively harmless. This program is run throughout the country and has not caused any problems to-date, mainly because the fish are kept in closed systems. This program should be allowed to proceed in Ohio.

8. Review of Fish Health Pre-proposals (All)

The committee reviewed six pre-proposals that had been submitted to the GLFC for consideration of funding. Members reviewed and ranked each document and submitted recommendations back to the GLFC based on relevance to current fish health issues in the Great Lakes.

9. Model Program Edits: Risk Assessment (All)

A Risk Assessment had been written a few years ago by M. Faisal, G. Wright, N. Bruneau, and G. Whelan. With the revisions being done to the Model Program, it was brought up to the committee whether or not this should be included in the document.

Overall, the following concerns were made:

- More detail on the questions needs to be given and tailored depending on the perceived threat.
- It may be tough to gauge the usefulness of the document without running scenarios through it.
- Could it be put in a table format?
- The deadline for its inclusion in the Model Program would be by the August meeting. Greg, Gary, and Mohamad will prepare examples of how it works, as well as giving examples that each member can run through to see if similar results are reached.
- Because of the length of this document, it may be best to have as a stand-alone document that the Model Program can reference. Regardless, it needs to be completed this summer.

10. Webinar and Meeting Arrangements (All)

- A. Diane Elliott webinar dates
 - 1. FEBRUARY 28TH, time TBD
 - 2. MARCH 25th, time TBD
- B. Disinfection protocol for mass-marking trailers
 - 1. Will distribute, if problems/concerns, email Ken by Feb. 21
- C. Summer 2011 meeting details
 - 1. Dates: August 16-19
 - 2. Location: MIDNR to host, site TBD (northern MI)
- D. Winter 2012 meeting details
 - 1. Dates: 2-3 day meeting (potentially Feb. 8-9th)
 - 2. Location: Madison, WI

11. Model Program Edits: Emerging Pathogens (All)

Potential Actions were created for Emerging Pathogens because it is unknown how to proceed with these pathogens. These Actions also included possible management considerations.

The following pathogens were moved into this category: Asian tapeworm (moved from Emergency list); Nucleospora; EEDV; and Piscirickettsia-like organism (moved from Restricted list).

12. Adjourn

APPENDICES

Model Program DRAFT FEB 2011

Introduction

Fish disease management in the Great Lakes basin is a responsibility of those agencies that manage the fisheries resources. The Great Lakes Fish Health Committee, GLFHC, of the Great Lakes Fishery Commission (GLFC) developed a Model Program in 1980¹ to unify and coordinate the fish disease management efforts of the GLFC member agencies. The purpose of the Model Program is to assist efforts aimed at preventing introductions and spread of serious fish pathogens, classifying disease status at fish hatcheries, and establishing protocols for importation and risk assessments associated with fish pathogens. The Model Program is based on information known at the time of writing and will be revised as needed as new information becomes available and new pathogens are detected in the Great Lakes basin.

Each member agency is expected to work toward the management of fish diseases in the Great Lakes basin by:

- developing legislative authority and regulations to enable fish disease management and possible eradication of fish pathogens;
- minimizing the rearing and release of infected fish;
- preventing the release of clinically diseased fish;
- preventing the importation of fish infected with emergency pathogens into the Great Lakes basin;
- limiting the transfer within the Great Lakes basin of fish infected with restricted pathogens; and
- developing response plans, as needed and appropriate.

At the time of this most recent revision of the Model Program, both the Canadian and U.S. federal governments began to implement their respective NAAHPs: the National Aquatic Animal Health Program in Canada and the National Aquatic Animal Health Plan in the United States. The objective of the Canadian NAAHP is to protect the Canadian fish/seafood industries and activities that rely on aquatic resources against the introduction and spread of serious infectious fish diseases. The U.S. National Aquatic Animal Health Plan is being developed and will provide a framework for federal agencies to work together to protect aquatic resources. The Model Program does not replace or duplicate the components or obligations of member agencies to these federal NAAHPs, but rather should be viewed as a complimentary program directed specifically at the activities of member agencies such as the collection, rearing, release and transfers of hatchery and wild fish in the Great Lakes basin. Nothing in the Model Program shall derogate from the right of the member agencies to apply additional measures of inspection, quarantine, depopulation and pathogen eradication in efforts to prevent fish disease outbreaks.

All member agencies should anticipate that they could have detections of undesirable fish pathogens and appropriate response plans should be developed for timely and effective management actions to contain and, if possible, eliminate the detected pathogen. Response plans should include provisions on biosecurity, personnel needs, testing needs, necessary legislative authority for depopulation and disinfection if necessary, depopulation and disposal procedures, disinfection protocols, and communication needs for a coordinated response that may require state, provincial and federal governments, universities and/or private industry. The GLFHC may recommend steps to eradicate the pathogen from a hatchery and adjacent waters following the best science available in association with information provided in the Model Program.

Application

The recommendations of this Model Program apply to fish species that have the potential to harbor pathogens that could be transmitted to fish in the Great Lakes basin. In particular, this Model Program discusses movements of wild or hatchery-raised fish within/into the Great Lakes basin that are or could be infected with emergency or restricted pathogens.

Provided that all necessary biological containment measures are taken to avoid any dissemination of fish pathogens, the recommendations of this Model Program shall **not** apply to:

¹ In 1980 the committee was then called the Great Lakes Fish Disease Control Committee. It was renamed in 1994 to the Great Lakes Fish Health Committee.

- 53 a) Fish and water in transit through the Great Lakes basin that are not released from original shipping
 54 containers, and
 55 b) Specimens of fish for purposes of diagnostic services and related laboratory tests.
 56

57 Under this Model Program, member agencies signatory to *A Joint Strategic Plan for Management of Great Lakes*
 58 *Fisheries* are:

59 Chippewa Ottawa Resource Authority
 60 Fisheries and Oceans Canada
 61 Great Lakes Indian Fish and Wildlife Commission
 62 Illinois Department of Natural Resources
 63 Indiana Department of Natural Resources
 64 Michigan Department of Natural Resources
 65 Minnesota Department of Natural Resources
 66 New York State Department of Environmental Conservation
 67 Ohio Department of Natural Resources
 68 Ontario Ministry of Natural Resources
 69 Pennsylvania Fish and Boat Commission
 70 U.S. Fish and Wildlife Service
 71 Wisconsin Department of Natural Resources
 72

73 Pathogen Detection

74
 75 The most recent editions of the following three documents provide the basis for fish hatchery inspections and
 76 standard testing methods:

- 77 1) Suggested Procedures for the Detection and Identification of Certain Fish and Shellfish Pathogens,
 78 developed by the Fish Health Section (FHS) of the American Fisheries Society (Blue Book)²,
 79 2) Fish Health Protection Regulations Manual of Compliance (Miscellaneous Special Publication 31,
 80 Revised) of Fisheries and Oceans Canada³, and
 81 3) The World Organisation for Animal Health (OIE) Manual of Diagnostic Tests for Aquatic Animals⁴.
 82

83 More sensitive or definitive procedures may be used, but any departures from the basic procedures set forth by these
 84 manuals or updated versions of these manuals must be noted on reports. Efforts are encouraged to employ the most
 85 currently accepted methods for detection of pathogens not included in the manuals listed above.
 86

87 Risk Assessment

88
 89 The following risk assessment document may be referenced as appropriate to estimate the risks of introducing a
 90 pathogen into the Great Lakes basin:

- 91 • Import Risk Analysis for the Introduction of Non-Native Aquatic Animals in the Great Lakes
 92 Basin. Written by: M. Faisal, G. Wright, N. Bruneau, and G. Whelan. GLFC-FHC. **NEED**
 93 **APPROPRIATE REFERENCE**

94 This document provides information regarding risk communication, assessment, and management, as well as hazard
 95 identification. This step-by-step guide also offers recommendations for consideration by the decision-makers.
 96
 97

98 Amendment

99
 100 Model Program amendments may be proposed by the Council of Lake Committees (CLC) or by the GLFHC
 101 member agencies. Any proposed amendment shall be submitted to the GLFHC Chairperson in writing with a short
 102 explanation documenting the rationale for the request. The GLFHC Chairperson will seek consensus from member
 103 agencies; if the GLFHC endorses the amendment, the proposed amendment will be presented to the CLC for
 104 consideration, approval, and adoption.

² Available from American Fisheries Society www.fisheries.org

³ Available from www.dfo-mpo.gc.ca

⁴ Available from www.oie.int

105
106
107
108
109
110
111
112
113
114
115
116
117
118
119
120
121
122
123

Definitions

Definitions for some of the terms used in this document:

Clinical sign: visually apparent abnormalities in the body, organ, or behavior.

Disease: a condition that impairs normal functioning of the fish and may be manifested by distinct clinical signs.

Emergency fish pathogen: a fish pathogen that has not been confirmed to be present in the Great Lakes basin but is known to be able to cause epizootic events.

Emerging fish pathogen: a fish pathogen with uncertain geographic distribution, with limited information on life history strategy, and whose ability to cause disease and epizootic events within the Great Lakes basin may be unknown.

Enzootic: present at a locality over an extended period of time.

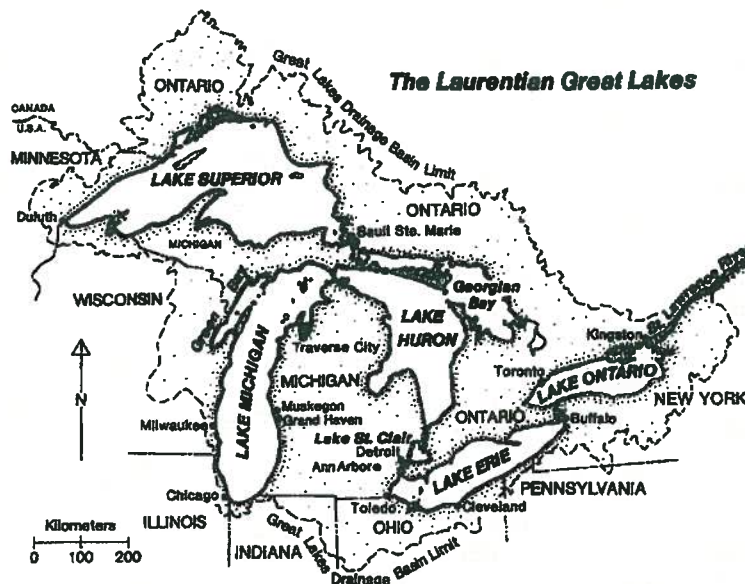
Epizootic event: an occurrence of disease affecting many fish of one or more species at the same time.

Fish: all life stages of fish, dead or alive.

Fish Health Inspection: testing of all fish on site in a hatchery within a calendar year.

Gametes: all sexual products of fish including sperm, unfertilized eggs and fertilized eggs.

Great Lakes Basin: the geographical area encompassing lakes Ontario (including the St. Lawrence River from Lake Ontario to the 45th parallel of latitude), Erie, Huron, St. Clair, Michigan, and Superior including their connected watersheds (Figure 1).



124
125
126
127
128
129
130
131
132
133
134
135
136
137
138
139

Figure 1. Great Lakes basin map from Taylor and Ferreri (1999).

Hatchery: any source facility that holds and rears fish.

Infection: the occurrence of a pathogen in a fish.

Intensity: estimation of the pathogen load.

Lot: fish of the same species, of the same age, that have always shared the same water supply, and that originated from a discrete spawning population.

Member agency: federal, provincial, tribal or state government fishery management or conservation agency that is signatory to *A Joint Strategic Plan for Management of Great Lakes Fisheries*⁵.

Non-secure water supply: water source that may contain fish or fish pathogens such as streams, lakes and unenclosed springs.

Pathogen: a micro- or macro-organism that is capable of causing a disease

Prevalence: percent of infected individuals within a population at a given time.

Quarantine facility: an isolated biosecure unit with disinfected effluent where fish are maintained until testing can occur.

⁵ For a list of member agencies see Application Section

- 140 **Rearing unit:** any hatchery container that is used to hold or raise fish, including a raceway, pond, or tank.
 141 **Restricted fish pathogen:** a fish pathogen that exists in one or more locations in the Great Lakes basin and is
 142 known to cause epizootic events, and for which the GLFC member agencies intend to restrict their spread,
 143 prevalence, and impacts.
 144 **Secure water supply:** a water supply that is free of fish and fish pathogens (or treated to remove pathogens) such as
 145 enclosed springs and wells.
 146 **Source:** any point or place of origin of fish or gametes including a fish hatchery or free ranging population.
 147 **Transfer:** the movement of fish from one location to another; the location may include a hatchery, lake or other
 148 waterbody.
 149 **Vertical transmission:** transfer of a pathogen from broodstock to offspring through gametes.
 150 **Wild broodstock population:** free ranging adult fish of one species or strain generally from one spawning location
 151 from which gametes may be collected.

152 **Emergency Fish Pathogens**

153 Emergency pathogens are as follows:

- 154 *Ceratomyxa shasta* (causes ceratomyxosis)
 155 infectious hematopoietic necrosis virus
 156 infectious salmon anemia virus
 157 *Tetracapsuloides bryosalmonae* (causes proliferative kidney disease)
 158 viral hemorrhagic septicemia virus (all strains EXCEPT IVB)
 159 white sturgeon herpesvirus
 160 white sturgeon iridovirus
 161
 162

163 **Restricted Fish Pathogens**

164 Restricted pathogens are as follows:

- 165 *Aeromonas salmonicida salmonicida* (causes furunculosis)
 166 *Heterosporis* sp.
 167 infectious pancreatic necrosis virus
 168 koi herpesvirus
 169 largemouth bass virus
 170 Lymphosarcoma
 171 *Myxobolus cerebralis* (causes whirling disease)
 172 *Renibacterium salmoninarum* (causes bacterial kidney disease)
 173 spring viremia of carp virus
 174 viral hemorrhagic septicemia IVb
 175 *Yersinia ruckeri* (causes enteric redmouth)
 176
 177

178 **Emerging Fish Pathogens**

179 Emerging pathogens are as follows:

- 180 Asian tapeworm
 181 *Nucleospora*
 182 EEDv
 183 *Piscirickettsia*-like organism
 184
 185
 186
 187

188 **Importation and Testing Requirements**

189 Before importation of fish or gametes, appropriate testing for all Emergency and Restricted pathogens is required.
 190 Specific guidance is offered in the following sections.

191
 192 **Emergency Fish Disease/Pathogen Management**

193
 194 **Importing Fish**

195
 196 If a member agency seeks to import fish from outside the Great Lakes basin but NOT from an area enzootic for an
 197 emergency pathogen, testing for emergency pathogens is not required. The determination of whether an area is
 198 enzootic for an emergency pathogen will be based on collective knowledge, a literature review, *and* contact with the
 199 exporter.

200
 201 If a member agency seeks to import fish from outside the Great Lakes basin and from within an area enzootic for an
 202 emergency pathogen or from a hatchery that has imported fish from an enzootic area:

- 203 • The source must be tested a minimum of 5 consecutive years without a positive detection for an
 204 emergency pathogen, sampling at the 5% prevalence level in the population with 95% confidence
 205 level; OR
- 206 • The source must be tested a minimum of 3 times in 2 years with at least 4 months between tests
 207 without a positive detection for an emergency pathogen, testing at the 2% prevalence level in the
 208 population with 95% confidence level.

209 OR

- 210 • Fish imported from adult broodstock populations or hatcheries with an incomplete testing history
 211 should be placed into a quarantine facility for 12 months.
- 212 • Testing should be done on these fish for appropriate emergency pathogens such that three negative
 213 inspections are recorded, with consecutive inspections separated by at least four months before
 214 release from the quarantine facility occurs. Sampling at the 2% prevalence level of the population
 215 with 95% confidence level. Stress testing is recommended⁶.

216
 217 **Importing Gametes**

218
 219 If a member agency seeks to import gametes from outside the Great Lakes basin and from an area enzootic for an
 220 emergency pathogen, and the emergency pathogen IS NOT vertically transmitted (i.e., *Ceratomyxa shasta*,
 221 *Tetracapsuloides bryosalmonae*, and all genotypes of viral hemorrhagic septicemia virus for salmonid eggs only),
 222 properly disinfected fertilized eggs may be imported.

223
 224 If the emergency pathogen IS vertically transmitted, properly disinfected gametes may be imported only if the adult
 225 broodstock population is tested according to the following:

- 226 • The source must be tested a minimum of 5 consecutive years without a positive detection for an emergency
 227 pathogen, sampling at the 5% prevalence level in the population with 95% confidence level;
 228 OR
- 229 • The source must be tested a minimum of 3 times in 2 years with at least 4 months between tests without a
 230 positive detection for an emergency pathogen, sampling at the 2% prevalence level in the population with
 231 95% confidence level.

232
 233 Properly disinfected gametes and their subsequent offspring imported from an adult broodstock population with an
 234 incomplete testing history should be placed into a quarantine facility for 12 months after fish reach testable size.
 235 Prior to release from the quarantine facility, testing should be done 3 times without a positive detection for an
 236 emergency pathogen with consecutive tests separated by at least four months.

237
 238 **Emergency Pathogen Detections**

239 If an emergency pathogen is detected at a hatchery, immediate steps should be initiated to eradicate the pathogen
 240 from the facility and adjacent water:

⁶ See Minimum protocol for stressing fish section.

- 241 • Refer to chapter 14 in the Great Lakes Fishery Commission Special Publication 83-2 for disinfection
 242 procedures,
 243 • Isolate all susceptible species from the infected fish as much as possible,
 244 • If the pathogen IS NOT reportable to the World Organisation for Animal Health (OIE), confirm the
 245 detection by another laboratory following standard procedures,
 246 • Eradicate the pathogen from source water and effluent water supplies if possible,
 247 • Notify the Great Lakes Fish Health Committee Chairperson, who in turn will advise the Great Lakes Fish
 248 Health Committee and the Council of Lake Committees,
 249 • Update the hatchery classification to reflect the new detection, and
 250 • Notify all transfer sources or recipients of the fish or gametes that an emergency pathogen has been
 251 detected.

252

253 To show freedom of the pathogen, the facility must:

- 254 • Test **all lots** of susceptible species 3 times with at least 4 months between tests, sampling at the 2%
 255 prevalence level in the population with 95% confidence level per lot,
 256 • Destroy all fish in infected lots,
 257 • Disinfect all gear used and all rearing units that contained the infected lots.

258 OR

- 259 • If appropriate biosecurity measure have been taken to isolate **rearing units**, test 3 times a minimum of 4
 260 months apart with 2% prevalence level in the population at 95% confidence level,
 261 • Destroy all fish in the infected rearing units,
 262 • Disinfect all gear used and all rearing units that contained the infected fish.

263

264 If a negative test result indicates the pathogen has been eradicated, the agency may consider stocking the fish as
 265 needed.

266

267 **Detections in the wild**

268

269 If an emergency pathogen is detected in the wild:

- 270 • Notify Great Lakes Fish Health Committee Chairperson, who will in turn advise the Great Lakes
 271 Fish Health Committee and the Council of Lake Committees and take appropriate steps to amend
 272 information in this Model Program,
 273 • If the pathogen IS NOT reportable to the World Organisation for Animal Health (OIE), confirm the
 274 detection by another laboratory following standard procedures,
 275 • Notify the competent authority if it IS OIE reportable,
 276 • Employ all necessary/reasonable means to contain the spread of the pathogen, including limiting
 277 movement of fish and/or gametes from the affected location,
 278 • Determine the geographic distribution of the pathogen and species susceptible to it, if possible, and
 279 • Eradicate the pathogen, if possible.

280

281 **Restricted Fish Disease/Pathogen Management**

282

283 **Importing/Transferring Fish**

284

285 If a member agency seeks to import or transfer fish from a source with a restricted pathogen, the pathogen should
 286 already be present at the receiving hatchery and the import or transfer should be accompanied with a health
 287 certificate, hatchery classification, or wild broodstock population classification.

288

289 If the pathogen is not already present at the receiving hatchery, the new pathogen will be added to the classification
 290 of the receiving hatchery.

291

292 Fish from non-tested sources that are enzootic for a restricted pathogen should be placed in a quarantine facility for
 293 8-12 months if the restricted pathogen is not present at the receiving hatchery. The fish should be stressed and
 294 standard laboratory tests completed without a detection of a restricted pathogen before fish are released. The exact
 295 quarantine plan will be developed by each member agency.

296

297

Minimum protocol for stressing fish

298

299

300

301

302

303

One stress test using 60-120 fish⁷ that are anesthetized, given a fin clip (do not disinfect equipment between fish) and immediately placed in a rearing unit at a density greater than normal rearing density for the species⁸. Fish should be held for 14 days and fed 75% of normal ration from days 1-12 with feed withheld on days 13-14. Exchange rate should be 1.5 exchanges and temperature stays at normal rearing temperature.

304

Importing/Transferring Gametes

305

306

307

308

If a member agency seeks to import or transfer gametes from a source with a restricted pathogen, and the restricted pathogen IS NOT vertically transmitted, properly disinfected fertilized eggs may be imported or transferred.

309

310

311

312

If a member agency seeks to import or transfer gametes from a source with a restricted pathogen, and the restricted pathogen IS vertically transmitted, properly disinfected fertilized eggs may be imported or transferred *if the restricted pathogen is already present in the receiving hatchery.*

313

314

315

316

317

If the restricted pathogen is not present in the receiving hatchery, gametes from non-tested sources should be placed in a quarantine facility for 8-12 months until appropriate testing can be done. It is recommended that fish be stressed and standard laboratory tests completed without a detection of a restricted pathogen before fish are released from the quarantine facility⁹.

318

Releasing Fish

319

320

321

322

323

Release of fish infected with restricted pathogens without clinical signs should take place only when necessary and only into locations where the pathogen has been detected, or in areas which have received infected fish within the last five years.

324

Release of fish into the Great Lakes basin should not be conducted if any of the following situations exist:

325

326

327

328

329

330

- Fish exhibit clinical signs of any disease,
- The mortality rates of fish in one rearing unit deviate from normal hatchery background levels (e.g., no fish should be stocked if losses in that rearing unit in the month preceding stocking exceeded 10%). It is advisable to test these fish to determine if a pathogen is present, or
- Fish are infected with a restricted pathogen that is resistant to multiple antibiotics.

331

Restricted Pathogen Detections

332

333

If a restricted pathogen is detected at a hatchery:

334

335

336

337

338

339

340

- Improve biosecurity measures as needed to limit the spread of the pathogen to other rearing units within the hatchery or to other hatcheries,
- Optimize rearing conditions,
- Treat infected rearing units to reduce the number of infected fish, if appropriate, and
- If it is a new detection, determine the origin of the pathogen, if possible, and take action to prevent further spread as appropriate.

341

If a restricted pathogen is detected in the wild:

342

343

344

345

- Limit the collection of fish and gametes from the location, if possible,
- Employ reasonable means to prevent the spread of the pathogen to new locations where it previously has not been detected, and
- Determine the geographic distribution of the pathogen, if possible.

⁷ Size dependent, use 60 fish if individuals are >10grams or 120 fish if size ranges from 2-10grams

⁸ For example if normal rearing density is 80g/L fish should be stressed at >100g/L. If normal rearing density is 25g/L, fish should be stressed at 50-60g/L.

⁹ See section above for a minimum recommended stress protocol for fish

346
347 When the guidance provided in this document concerning restricted pathogens is superseded by additional
348 information about the pathogen, the member agency should contact the Great Lakes Fish Health Committee
349 Chairperson. The Chairperson will use the most expedient way to provide appropriate recommendations to the
350 member agency. In the interim, the affected fish shall not be released or transferred and efforts should be made to
351 contain the pathogen.
352

353 **Emerging Pathogen Management**

354
355 An emerging fish pathogen is a pathogen which may or may not be found in the Great Lakes but is a concern to at
356 least one of the member agencies, primarily because the life history strategies and potential impacts of the pathogen
357 are unknown. A member agency must provide a short nomination document (see Appendix **Y**) providing information
358 on the pathogen, why it is a concern, and the rationale for defining it as an Emerging Pathogen. This nomination is
359 then brought to the committee chair, and in turn to the committee, to determine if the pathogen belongs on the
360 Emerging list.
361

362 Because of the lack of knowledge on the pathogen, the appropriate management actions may be uncertain. Possible
363 considerations include:

- 364 • Determining if appropriate diagnostic tools are available:
 - 365 ○ If yes, then request member agencies begin surveillance,
 - 366 ○ If no, develop a detection method,
- 367 • Identify the research needs and information gaps,
- 368 • Identify vectors and hosts in the Great Lakes basin and whether or not these are associated with agencies,
369 and
- 370 • Utilize the risk assessment to estimate the risk of a pathogen occurrence.

371 If an emerging pathogen is found within a hatchery, the agency should identify its threats, determine from where it
372 came, determine if it was transferred to another region/hatchery, and minimize the damage.
373

374 **Inspections and Testing**

375
376 Testing and inspection results should be used to develop classifications and inform decisions on collection, import,
377 stocking, transfer, etc. Testing for all emergency and restricted pathogens is encouraged before the release of fish.
378 Sample collection staff will be designated by the member agency, and collection and testing will be done using
379 approved methods.
380

381 The method of collecting subsamples and the number of samples (suggested samples sizes given in Table 1)
382 collected from rearing units to obtain a representative sample¹⁰ is left to the discretion of the member agency.
383 Sampling of wild broodstock populations and hatchery fish should be conducted throughout the year. Moribund fish
384 and fish with clinical signs of disease should be included in samples collected during routine testing and inspections
385 wherever possible.
386

387 Table 1. Minimum suggested sample sizes for populations or lots with 50 to greater than 100,000 fish within a
388 hatchery. Sample sizes are based on upon stratified random sampling that provides 95% confidence of
389 detecting a pathogen with an assumed minimum incidence of detectable infection, depending upon
390 conditions, of 2%-5%.
391

Population or Lot Size	Sample Size Assumed Incidence	
	2%	5%
50	50	30
100	75	45
250	110	50
500	130	55
1,000	140	55

10 Refer to the three documents listed in the Pathogen Detection section for proper representative sampling.

1,500	140	55
2,000	145	60
4,000	145	60
10,000	145	60
100,000 or greater	150	60

392

393

Classification of Hatcheries and Wild Broodstock Populations

394

395

396

397

398

399

The classification system is designed to facilitate an awareness of fish disease status of fish hatcheries and wild broodstock populations by compiling the results of testing in a simple, easy to follow format. It is recommended that all member agencies maintain up to date classifications (annual updates at a minimum) for each hatchery and wild broodstock population, use this classification system when moving fish and gametes, and provide the classification information to other agencies/hatcheries when transferring fish and gametes.

400

401

402

403

404

By using this classification system, the risk of acquiring a pathogen listed in the Model Program¹¹ will be better understood. It is recommended that importations and transfers not knowingly move pathogens. Classifications should be dated and include contact information for a person who may be called to provide additional information should it be required.

405

406

Each hatchery and wild broodstock population will obtain a letter-number classification.

407

The letter identifies the presence/absence of one or more restricted pathogen:

408

Class-A: no history within the last 2 years of any of the listed emergency or restricted pathogens

409

Class-B: a detection of one or more emergency or restricted pathogens

410

Class-C: pathogen history unknown (i.e., incomplete testing for a period of 2 years)

411

412

AND

413

414

the number identifies the water supply used at the hatchery

415

Class-1: the water supply is secure (i.e., free of fish and fish pathogens or treated to remove pathogens)

416

Class-2: the water supply is non-secure (i.e., may contain fish or fish pathogens)

417

418

Wild broodstock populations will always be class 2 because the water in which they live is non-secure.

419

420

To *obtain* an A-1 classification, the hatchery would have:

421

- no detections of a restricted pathogen within 3 calendar years with ongoing annual inspections/testing,

422

AND

423

- a secure water supply.

424

425

To *maintain* an A-1 classification, hatcheries must:

426

a) undergo a minimum of one annual inspection/testing period, AND

427

b) have no detections of restricted pathogens, AND

428

c) ensure that all fish are obtained from hatcheries classified as A-1 or its equivalent, AND

429

d) ensure that all gametes are properly disinfected after being obtained from hatcheries classified as A-1 or its equivalent.

430

431

432

To *obtain* an A-2 classification, the hatchery or wild broodstock population would have:

433

- no detections of a restricted pathogen within 3 calendar years, with at least two inspections/testing periods separated by a minimum of 4 months, AND

434

- a non-secure water supply.

435

436

437

To *maintain* an A-2 classification hatcheries must:

438

a) undergo a minimum of one annual inspection/testing period, AND

439

b) have no detections of restricted pathogens, AND

¹¹ Other pathogens not listed in the Model Program may be present.

- 440 c) ensure that all fish are obtained from hatcheries classified as A-1, A-2 or the equivalent, AND
 441 d) ensure that all gametes are properly disinfected after being obtained either from hatcheries classified as A-1,
 442 A-2 or the equivalent, or from wild broodstock populations classified as A-2¹².

443
 444 **To obtain a B-1 classification, the hatchery would have:**

- 445 • a detection of one or more restricted pathogens within the last 3 calendar years, with at least two
 446 inspections/testing periods separated by a minimum of 4 months, AND
 447 • a secure water supply.
 448

449 **To maintain a B-1 classification, hatcheries must:**

- 450 a) undergo a minimum of one annual inspection/testing period, AND
 451 b) have a detection of one or more restricted pathogens, AND
 452 c) ensure that all fish are obtained from hatcheries classified as A-1, A-2, B-1, or their equivalent, AND
 453 d) ensure that all gametes are properly disinfected after being obtained from hatcheries classified as A-1, A-2,
 454 B-1⁶, or their equivalent.
 455

456 **To obtain a B-2 classification, the hatchery and wild broodstock population would have:**

- 457 • a detection of one or more restricted pathogens within the last 3 calendar years, with at least two
 458 inspections/testing periods separated by a minimum of 4 months, AND
 459 • a non-secure water supply.
 460

461 **To maintain a B-2 classification, hatcheries and wild broodstock populations must:**

- 462 a) undergo a minimum of one annual inspection/testing period, AND
 463 b) have a detection of one or more restricted pathogens, AND
 464 c) ensure that all fish are obtained from hatcheries classified as A-1, A-2, B-1, B-2, or their equivalent, AND
 465 d) ensure that all gametes are properly disinfected after being obtained either from hatcheries classified as A-1,
 466 A-2, B-1, B-2, or their equivalent, or from wild broodstock populations classified as A-2 or B-2⁶.
 467

468 **To obtain a C-1 classification, the hatchery would have:**

- 469 • testing within the last 3 calendar years that does not meet standards of Class A or B classifications, AND
 470 • a secure water supply.
 471

472 **To obtain a C-2 classification, the hatchery and wild broodstock population would have:**

- 473 • testing within the last 3 calendar years that does not meet standards of Class A or B classifications, AND
 474 • a non-secure water supply.
 475

476
 477 For hatcheries and wild broodstock populations with the B classification the restricted pathogen(s) detected must be
 478 identified using a pathogen acronym (see Table 2).
 479

480 Table 2. Acronyms for pathogens listed in the Model Program to be used in hatchery and wild broodstock
 481 population classifications.
 482

Pathogen (Disease)	Code
<i>Aeromonas salmonicida salmonicida</i> (causes furunculosis)	BF
<i>Ceratomyxa shasta</i> (causes ceratomyxosis)	SC
Epizootic epitheliotropic disease virus	VL
<i>Heterosporis</i> sp.	SH
Infectious hematopoietic necrosis virus	VH
Infectious pancreatic necrosis virus	VP
Infectious salmon anemia virus	VS
Koi herpesvirus	VK
Largemouth bass virus	VB

¹² See Exceptions for Gametes section for additional information

<i>Myxobolus cerebralis</i> (causes whirling disease)	SW
<i>Nucleospora salmonis</i>	SN
<i>Piscirickettsia</i> -like organism	BP
<i>Renibacterium salmoninarum</i> (causes bacterial kidney disease)	BK
Spring viremia of carp virus	VV
<i>Tetracapsuloides bryosalmonae</i> (causes proliferative kidney disease)	SP
Viral hemorrhagic septicemia virus	VE*
White sturgeon herpesvirus	VW
White sturgeon iridovirus	VI
<i>Yersinia ruckeri</i> (enteric redmouth)	BR

483 *Would designate appropriate strain
 484

485 **Changing Classifications**
 486

487 As test results become available, classification records will be updated to include any restricted pathogens detected
 488 in the preceding 24 month period and to include the date of the classification. Classifications may change as new test
 489 results become available or when fish or gametes are brought into a hatchery.
 490

491 **Exceptions for Gametes**
 492

493 If fertilized eggs originate from a hatchery or wild broodstock population positive for the pathogens listed below
 494 AND the fertilized eggs are properly disinfected, the hatchery classification will not change because the following
 495 pathogens are not vertically transmitted and can be eliminated with proper disinfection:

- 496 • *Aeromonas salmonicida salmonicida*
- 497 • *Ceratomyxa shasta*
- 498 • *Tetracapsuloides bryosalmonae*
- 499 • *Yersinia ruckeri*
- 500 • Viral hemorrhagic septicemia virus (all genotypes)
- 501 • *Whirling disease*

502
 503 **Exceptions for Antibiotic Resistant Bacteria**
 504

505 If an antibiotic-resistant bacterium is isolated from a hatchery, the detection should be noted on inspection reports,
 506 classifications, and in annual reports.
 507

508 **Hatchery Depopulation and Disinfection**
 509

510 A hatchery that was depopulated and disinfected to eliminate a pathogen will initially become Class B following the
 511 disinfection. The hatchery must go through the required 3 calendar year inspection/testing period, during which time
 512 it will be considered suspect for the previously detected pathogen(s). The hatchery classification will included the
 513 acronym for the suspect pathogen and the disinfection date will be noted. Following the inspection/testing period
 514 without a detection of the suspect pathogen, the hatchery will be reclassified without the acronym for the suspect
 515 pathogen and the disinfection date will no longer be required.
 516

517 **Reporting**
 518

519 Each member agency shall provide to the GLFHC Chairperson an annual report, covering the calendar year January
 520 to December, describing the status of fish health within the area managed by the member agency. Member agency
 521 annual reports will be shared with the GLFHC. The annual report shall include summaries of the following:
 522

- 523 • The classification of agency hatcheries and wild broodstock populations,
- 524 • A list of known importations into the Great Lakes basin of fish and gametes from outside the Great Lakes
 525 basin,
- 526 • Any measures adopted for pathogen management,
- 527 • Any detections of emergency or restricted pathogens within the member agency jurisdiction including

- 528 information pertinent to fish sample collection, testing method(s), dates, and locations (including lat/long),
 529 etc,
 530 • Any cases of high mortality in fish hatcheries or in wild populations, including information on the causative
 531 pathogen(s), if detected, and
 532 • A summary of any fish disease issues for which the member agency requested input from the GLFHC
 533 members, including final decisions made following GLFHC input.
 534

535 Pathogen descriptions

537 *Aeromonas salmonicida salmonicida*

538 *Aeromonas salmonicida salmonicida* infects numerous freshwater fish species. In salmonids this bacterium causes
 539 the disease furunculosis, and the bacterium can cause disease in other fish species. This bacterium is distributed
 540 worldwide, is enzootic throughout the Great Lakes basin. Clinical signs include boil-like lesions (furuncles) on the
 541 skin and in the muscle tissue, exophthalmia, bloody discharge from vent, and multifocal hemorrhages in the viscera
 542 and muscle.
 543

544 *Ceratomyxa shasta*

545 *Ceratomyxa shasta* is a myxosporidian parasite that infects anadromous salmonids in the Pacific northwest of the
 546 United States and Canada causing the disease Ceratomyxosis. *C. shasta* initially infects the intestine but the
 547 infection generally becomes systemic over time. Ultimately, the spores displace functional tissue in the organs and
 548 the fish die. Clinical signs of disease include emaciation, lethargy, darkening of skin, ascites, and exophthalmia.
 549 The parasite requires an intermediate polychaete host (*Manayunkia speciosa*) (Willson et al. 2010) which has been
 550 reported from the Great Lakes basin (Hiltunen, 1965; Rolan, 1974; Spencer, 1976).
 551

552 Epizootic Epitheliotropic Disease Virus

553 Epizootic epitheliotropic disease virus (EEDv) infects numerous salmonids, particularly lake trout in North America.
 554 This virus has been detected in Lake Superior and in hatcheries in California, Michigan, Pennsylvania, Wisconsin,
 555 and Wyoming. Clinical signs have only been reported in juvenile lake trout and include lethargy, riding high in the
 556 water, hemorrhages of the eye and gray-white mucoid blotches on the skin and fins.
 557

558 *Heterosporis* sp.

559 *Heterosporis* sp. is a microsporidian parasite that infects the muscle of yellow perch walleye, northern pike, ciscoe,
 560 rock bass and pumpkinseed. This parasite is known to occur in a limited number of Wisconsin, Michigan, and
 561 Minnesota lakes, the Canadian waters of lakes Ontario and Erie and the U.S. (Minnesota) waters of Lake Superior. It
 562 has not been reported from fish hatcheries. The parasite causes disease to infected host fish in the form of infected
 563 flesh has patches of white, opaque muscle with the appearance of “freezer-burn” that is unpalatable to the public.
 564 Mortality has been induced in the laboratory but natural mortality has not been observed.
 565

566 Infectious Hematopoietic Necrosis Virus

567 Infectious hematopoietic necrosis virus (IHNV) infects salmonids in fresh and salt water, in the wild and in
 568 hatcheries. This virus is a pathogen of international concern. IHNV is present in salmon and steelhead along the west
 569 coast of Canada and the United States. Clinical signs of disease include exophthalmia, darkening of skin, petechiae
 570 on the skin, in the mouth, pale gills, ascites, pale viscera with/without petechiae (including the swim bladder, body
 571 wall and mesenteries). The virus is most likely vertically transmitted.
 572

573 Infectious Pancreatic Necrosis Virus

574 Infectious Pancreatic Necrosis virus (IPNV) has been isolated from wide range of fish species including salmonids,
 575 cyprinids and marine species. The pathogen has a wide geographic distribution, occurring in North and South
 576 America, Europe, Asia, and South Africa. In the Great Lakes basin IPNV has been found in Pennsylvania, Michigan
 577 and Wisconsin. Clinical signs include darkened body coloration, exophthalmia, petechiae on the skin, cessation of
 578 feeding and in the later stages show a loss of balance progressing to a corkscrew swimming motion.
 579

580 Infectious Salmon Anemia Virus

581 Infectious salmon anemia virus (ISAv) infects primarily Atlantic salmon in wild and farmed fish in the North
 582 Atlantic waters of Canada, the United States, Norway, the Faroe Islands and the United Kingdom. This virus is a
 583 pathogen of international concern. Clinical signs of disease include anemia, ascites, petechiae in the body wall and

584 eye. This virus is suspected to be vertically transmitted.

585

586

587 **Koi Herpesvirus**

588 Koi Herpesvirus (KHVv) infects carp, koi and goldfish causing the disease koi herpesvirus (KHV) in carp and koi.

589 The virus has been found worldwide and in the Great Lakes basin in Michigan, New York State, Ontario. It is a

590 pathogen of international concern. Clinical signs include skin discoloration, increased respiratory frequency, skin

591 lesions, appetite loss, erratic swimming, sunken eyes, notch on the nose, and swollen, pale, rotting gills.

592

593 **Largemouth Bass Virus**

594 Largemouth bass virus (LMBv) infects centrarchids east of the Rocky Mountains in the United States. In the Great

595 Lakes basin, LMBv has been found in Lake St. Clair, western portion of Lake Erie. The virus also has been found in

596 Illinois and Wisconsin hatcheries. Most fish with LMBv are carriers with no clinical signs. The mortality has only

597 been found in largemouth bass. Clinical signs include difficulty swimming, bloated abdomen, loss of buoyancy

598 regulation, hemorrhaging and discoloration of the swim bladder.

599

600 **Lymphosarcoma**

601 Lymphosarcoma is a malignancy of esocids in North America, the United Kingdom and Europe and is believed to

602 be caused by a retrovirus (Wolf 1988). It may take up to a year for infected fish to show external signs of disease.

603 Fish with lymphosarcoma do survive but the sores and growths associated with severe infections are unpalatable to

604 the public.

605

606 ***Myxobolus cerebralis***

607 *Myxobolus cerebralis* is a myxosporidean parasite of salmonids that causes whirling disease. It is found in Europe,

608 North America, and South Africa. *M. cerebralis* has been found in Great Lakes tributary waters and in fish

609 hatcheries in Michigan and inland waters in Pennsylvania, New York, and Michigan. *M. cerebralis* requires a

610 tubificid oligochaete to complete its life cycle. Clinical signs include darkened tails, skeletal deformities, and

611 “whirling” behavior in young fish.

612

613 ***Nucleospora salmonis***

614 *Nucleospora salmonis* is an intracellular microsporidian parasite reported from salmonid species in Europe, South

615 and North America. In the Great Lakes basin *N. salmonis* has been reported in National Fish Hatcheries in

616 Michigan. *N. salmonis* infects blood leukocytes, hematopoietic tissues in the kidney and spleen, and tubular and

617 glomerular epithelium in kidneys. Clinical signs include anemia and leukemia and can be associated with mortality.

618

619 ***Piscirickettsia* – like organism**

620 A *Piscirickettsia*-like bacterium was isolated from adult muskellunge in Lake St. Clair during the 2003 spawning

621 period and is a likely contributing factor in epizootic events. Clinical signs include quarter-sized rash-like skin

622 lesions.

623

624 ***Renibacterium salmoninarum***

625 *Renibacterium salmoninarum* infects salmonids, especially rainbow trout, brown trout, brook trout and coho

626 salmon, Chinook salmon. This bacterium causes bacterial kidney disease (BKD). It occurs in virtually all areas

627 where salmonids occur, except Australia, New Zealand and Russia. It is a serious problem in the northeast Pacific

628 and Japan. *R. salmoninarum* is enzootic and broadly distributed within the Great Lakes basin. Clinical signs include

629 dark coloration, exophthalmia, pale gills, ascites, skin lesions, white nodular masses in the kidney, abdominal

630 distension or hemorrhages at the vent or base of the fins. This bacterium is vertically transmitted.

631

632 **Spring Viremia of Carp Virus**

633 Spring viremia of carp virus (SVCv) primarily affects carp and other species in the Cyprinidae family, but has also

634 been found in a few species of other fish families such as Centrarchidae and Percidae. This virus causes the disease

635 spring viremia of carp (SVC). It has been reported from Europe, Asia, North and South America. It is a disease of

636 international concern. In the Great Lakes basin it has been found in healthy common carp from the Hamilton Harbor

637 region of Lake Ontario and has been associated with die-offs in several inland waters in Illinois, Ohio, New York

638 and Wisconsin. Clinical signs include darkened body coloration, pale gills, abdominal distension, exophthalmia,

639 inflammation of the vent, petechial hemorrhages of skin, gills and eyes.

640

641 ***Tetracapsuloides bryosalmonae***

642 *Tetracapsuloides bryosalmonae* is a myxosporidean parasite that infects salmonids in North America and Europe
 643 causing Proliferative Kidney Disease (PKD). The parasite infects the interstitial cells of the kidney and penetrates
 644 the lumen of the tubules. Clinical signs include distended abdomen, enlargement of the kidney, exophthalmia and
 645 anemia. This parasite is not vertically transmitted in eggs.

646

647 ***Viral Hemorrhagic Septicemia (all genotypes except IVb)***

648 The viral hemorrhagic septicemia virus (VHSv) infects wild and farmed freshwater and marine species of fish
 649 causing the disease viral hemorrhagic septicemia (VHS). There are four genotypes of VHSv: VHS genotypes I, II,
 650 and III occur in Europe, genotype IVa occurs in marine fish species in Japan and on the west coast of North
 651 America¹³. This virus is a pathogen of international concern. Clinical signs of disease include petechiae on the skin,
 652 in muscle, in and on the surface of the viscera, ascites, exophthalmia.

653

654 ***Viral Hemorrhagic Septicemia Virus (Genotype IVb)***

655 Viral hemorrhagic septicemia virus genotype IVb (VHSv-IVb) infects a wide range of freshwater fish species
 656 including several species of Centrarchidae, Esocidae, Percidae, Salmonidae, Coregonidae, Cyprinidae, Sciaenidae.
 657 Some species, such as muskellunge are quite susceptible to disease and mortality however signs of disease have not
 658 been reported from other species such as emerald shiner. VHS-IVb is enzootic and has now been found in all Great
 659 Lakes. It has been detected inland in Michigan, New York, and Wisconsin and in the Ohio River basin in Ohio. It is
 660 a pathogen of international concern¹⁴. Clinical signs of disease include ascites, exophthalmia, enlarged spleen, and
 661 petechiae in skin, muscle, and viscera.

662

663 **White Sturgeon Herpesvirus**

664 Two strains of white sturgeon herpesvirus, WSHv-1 and WSHv-2, occur in white sturgeon in west coast of the
 665 United States. Both viruses cause moderate to high mortality in cultured fish. No specific external clinical signs of
 666 disease. Fish continue to feed until death. Internally, stomach and intestine filled with fluid, but other organs appear
 667 normal. Affected wild white sturgeon become listless and appeared to have stopped eating. Other species of
 668 sturgeon, including shovelnose and pallid sturgeon, are also susceptible to WSHv.

669

670 **White Sturgeon Iridovirus**

671 White sturgeon iridovirus (WSIv) is known to be pathogenic to the genus *Acipenser* in the Pacific northwestern
 672 United States and to both cultured and wild white sturgeon and has been detected in Russian sturgeon. The virus is
 673 also known to be mildly pathogenic to lake sturgeon.

674

675 ***Yersinia ruckeri***

676 *Yersinia ruckeri* (serotype I and II) infects marine and freshwater fish in North America, Australia, Africa and
 677 Europe. Rainbow trout are especially susceptible. This bacterium causes the disease enteric redmouth (ERM) and is
 678 broadly distributed in the Great Lakes basin. Clinical signs include redness of the mouth, exophthalmia, pale liver,
 679 hemorrhages in the gills, skin and fins, swollen kidney and spleen. Chronic cases may demonstrate partial or total
 680 blindness, exophthalmia, distended abdomen, emaciation.

681

682

683 **References**

684

685 Hiltunen, J. K. 1965. Distribution and abundance of the polychaete, *Manayunkia speciosa* Leidy, in western Lake
 686 Erie. *Ohio Journal of Science* 65:183-185.

687

688 Rolan, R. G. 1974. The fresh-water polychaete, *Manayunkia speciosa*, in a thermal discharge channel, Cleveland
 689 Harbor, Lake Erie. *American Midland Naturalist* 92:207-213.

690

¹³ VHS genotype IVb is present in the Great Lakes basin and therefore is listed as a restricted fish pathogen.

¹⁴ VHS genotypes I, II, III, and IVa have not been detected in the Great Lakes basin and therefore are listed as emergency fish pathogens.

- 691 Spencer, D. R. 1976. Occurrence of *Manayunkia speciosa* (Polychaeta: Sabellidae) in Cayuga Lake, New York, with
692 additional notes on its North American distribution. *Transaction of the American Microscopical Society* 95:127-
693 128.
- 694
- 695 Beeton, A.M, C.E. Sellinger and D.E. Reid. 1999. An introduction to the Laurentian Great Lakes ecosystem. In,
696 Great Lakes Fisheries Policy and Management: A Binational Perspective. Taylor, W.W. and C.P. Ferreri, Editors.
697 Michigan State University Press, East Lansing, MI. Pages 3-54.
- 698
- 699 Willson, S.J., M.A. Wilzbach, D.M. Malakauskas and K.W. Cummins. 2010. Lab Rearing of a Freshwater
700 Polychaete (*Manayunkia speciosa*, Sabellidae) Host for Salmon Pathogens. *Northwest Science* 84(2):183-191.
- 701
- 702
- 703
- 704
- 705
- 706
- 707
- 708
- 709

710 **Import Risk Analysis for the Introduction of Non-Native Aquatic Animals into the Great** 711 **Lakes Basin**

712
713 By

714
715 Mohamed Faisal, Greg Wright, Natalie Bruneau, and Gary Whelan with input from current and previous members
716 of the Great Lakes Fish Health Committee

717 718 719 720 Summary

721 There is a growing concern in the Great Lakes basin regarding the introduction of serious pathogens along
722 with importation of aquatic animals from other areas. For this reason, the Great Lakes Fishery Commission Fish
723 Health Committee (GLFC-FHC) developed a process to assess the risks associated with importation and their
724 potential impacts on resident fauna. This Import Risk Analysis (IRA) is to be conducted prior to the arrival of
725 shipments and starts with the development of a proposal by the entity requesting the introduction of an exotic
726 species that specifies the location of the facility, planned use, and source of the species. Based on the information
727 provided, GLFC-FHC oversees the review and evaluation of the proposed introduction for its potential health risks
728 on resident fauna. This publication describes each component of the IRA, as well as risk communication, hazard
729 identification, risk assessment and risk management.

730 731 Background & Historical Perspectives:

732 Movement of live aquatic animals, bony fish in particular, and their gametes continues to be the
733 cornerstone of many conservation and restoration fishery programs in the Laurentian Great Lakes. Parallel to species
734 movements, pathogenic micro- and macro-organisms (will be collectively referred to as pathogens) have invaded
735 new geographic ranges, leading to exposure of native species that have often generated catastrophic consequences.
736 Control of fish stocking and importation in the Great Lakes Basin is the responsibility of those agencies that manage
737 the fishery resources. To coordinate efforts, the Great Lakes Fishery Commission (GLFC) established the Fish
738 Health Committee (GLFC-FHC) in 1973 to recommend measures and coordinate efforts aimed at protecting the
739 health of aquatic animal residents of the Great Lakes basin. Like other GLFC bodies, the GLFC-FHC is comprised
740 of representatives from Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, Wisconsin, and
741 Ontario, the governments of Canada and the USA, and Native American tribes authorities. Among the GLFC-FHC
742 mandates is the development of a comprehensive fish health plan and advocacy of policies regarding disease
743 control, fish transfer within the basin, fish importation, and introduction of non-native aquatic animal species. Final
744 recommendations are made by a consensus of the membership. In 1985, the Committee developed a Model
745 Program for controlling fish diseases in the basin. This Model Program was subsequently adopted as a policy of the
746 GLFC, and has been updated twice (Hnath 1993, Marcquenski and ???, in press). The Model Program provides
747 guidelines for health certification and fish stocking in the Great Lakes basin.

748
749 With the increasing interest in importation of fishes for conservation and restoration purposes, fisheries
750 management, and aquaculture purposes, and the emergence of serious diseases, the Model Program has, from time
751 to time, failed to provide clear directions over isolated introductions. For this reason, the GLFC-FHC developed a
752 protocol to minimize the risk of introducing emerging disease agents with the importation of salmonid fishes from
753 enzootic areas (Horner and Eshenroder 1993). This protocol was adopted by member agencies when a proposal to
754 release salmonid fishes from emergency disease enzootic areas into waters under their jurisdiction was presented.
755 Unfortunately, outbreaks of emerging diseases in wild and propagated fishes within the basin (such *Heterosporis*
756 sp., Largemouth Bass Virus, *Piscirickettsia* sp., *Nucleospora salmonis*, and Viral Hemorrhagic Septicemia Virus)
757 created a situation that requires the adoption of more stringent procedures to follow when a proposal for introducing
758 non-native fish or shellfish species is presented to the GLFC-FHC. National and international agencies have
759 developed a standard, science-based process to accurately assess pathogen introduction risks associated with fish
760 movement, collectively called Import Risk Analysis (IRA.) Guided by this widely accepted process of IRA in fish
761 movements, the GLFC-FHC proposes to adopt an IRA process that is accepted by its member agencies. In specific,
762 the GLFC-FHC seeks to:

- 763 • Develop a standard procedure for the application process for the introduction of a non-native aquatic
764 animal into the Great Lakes Basin.

- 765 • Develop a general risk assessment (RA) framework that the FHC will follow to reach its recommendations
766 regarding isolated introductions that falls outside of, or are in conflict with, the Model Program, or for
767 which no standard procedures are established.
- 768 • Archive a full account on each new assessment and introduction for permanent record keeping and to use
769 for periodical re-evaluation and evaluation of similar cases that may arise in the future.
770

771 It is important to emphasize that the proposed GLFC-FHC IRA:

- 772 • Does not address the benefits of the proposed introduction or transfer, for the final product of IRA is
773 restricted to determining the likelihood of serious pathogen introductions along with the proposed
774 introduction or transfer of aquatic animals in the Great Lakes basin.
- 775 • Applies to all activities in which aquatic animals or their products are introduced or transferred into fish
776 and shellfish (mollusks, crustaceans) bearing waters or fish rearing facilities and for commercial and
777 recreational fishing, including biological control programs.
- 778 • Focuses on risks associated with pathogen introduction and not the potential ecological or genetic impacts
779 caused by the introduced aquatic animal itself.
- 780 • Is designed to accommodate available financial resources, accessibility of the appropriate biological
781 information, and the risk assessment methods available at the time of the assessment.
- 782 • Recognizes the current knowledge gaps in the life cycle, host range, and ecology of the most serious fish
783 and shellfish pathogens and parasites. This lack of knowledge impedes accurate disease risk analysis,
784 increases the difficulty of differentiating between exotic and endemic infections, and hinders the selection
785 of disease management options.
- 786 • Allows the proposing entity to justify the introduction if the benefits outweigh the risks identified in the
787 IRA process.
- 788 • Has been adopted from a number of national and international aquatic animal health plans modified to fit
789 the needs of GFLC member agencies. Documents used include the World Animal Health Organization
790 Aquatic Code (OIE, 2009), the International Council for the Exploration of the Sea Code (ICES 2003), and
791 views adopted by the Food and Agriculture Organization of the United Nations (Bartley et al., 2006).
792

793 **Proposed Import Risk Analysis for the Introduction of Non-native Aquatic Animals into the Great Lakes**
794 **Basin:**

795 In some countries, national risk analysis frameworks are in place (Perera 2004, Hine 2004), while in other countries,
796 risk analysis is increasingly being recognized (Amos 2004, Bondad-Reantaso 2004, Kanchanakhan and Chinabut
797 2004, Olivier 2004).

798 The proposed IRA process formulated by all members of the GLFC-FHC calls for a) identifying serious pathogen(s)
799 that may be incidentally introduced into the Basin along with the introduced non-native aquatic animals, b) assessing
800 the disease risks associated with potentially introduced pathogens, and c) providing management options from which
801 to choose for the associated risks (Arthur and Bondad-Reantaso 2004; MacDiarmid 1997; Rodgers 2001; 2004). A
802 member agency may opt to implement the proposed IRA when considering the movement of aquatic animals within
803 its jurisdiction, particularly in cases where the import movements may spread pathogens into a new watershed,
804 drainage, or zone. The proposed IRA may be used not only for finfish, mollusks, and crustaceans, but also for other
805 aquatic animals including amphibians, reptiles, mammals, and other aquatic invertebrates.
806

807 The following sections of this document describe each step of the IRA process. Figure (1) depicts an overall view of
808 the proposed IRA process. The document also includes a list of relevant scientific references and three appendices.

- 809 • Appendix I outlines the nature and scope of information that the proponent of an introduction or transfer
810 should provide in support of the proposal.
- 811 • Appendix II outlines the Import Risk Analysis process. The objective of the Import Risk Analysis is to
812 identify whether the proposed introduction or transfer presents a low, medium or high risk for the receiving
813 environment.
- 814 • Appendix III is a summary of the whole risk assessment and it is used as the permanent record of the
815 proposal and the review process. It finishes with the GLFC-FHC recommendation to the decision-making
816 authority.

817
818
819
820
821
822
823
824
825
826
827
828
829
830
831
832
833
834
835
836
837
838
839
840
841
842
843
844
845
846
847
848
849
850
851
852
853
854
855
856
857
858
859
860
861
862
863
864
865
866
867
868
869
870
871
872

I. Process Initiation

The process is initiated by the proponent submitting a proposal to provincial or state agencies who evaluate the proposed introduction for potential benefits to fisheries or related industries. The agencies are encouraged to evaluate the proposed introduction by taking into consideration the GLFC joint strategic plan and the regulations of species transfer set forth by the USA and Canadian authorities. Should the state agency find the proposed introduction of potential benefit, the agency then briefs the Council of Lake Committees (CLC) of GLFC on the objective of the proposal. Concomitant with CLC notification, the proposal should be forwarded to the GLFC-FHC Chair.

If the request for introduction appears to be in conflict with the Model Program or has the potential to negatively affect a shared resource within the Great Lakes basin, then the GLFC-FHC Chair should initiate the process of risk assessment. The requesting agency and GLFC-FHC Chair should coordinate efforts to complete the Proposed Introduction Assessment Form (PIAF, Appendix I). PIAF describes details of the introduction under consideration including all data needed, arranged in a logical and structured format, in order to adequately address the risk taken by the introduction. In essence, the PIAF is the cornerstone of the assessment process. Filling out this form accurately and fully will insure that all appropriate information needed to assess risks and benefits associated with the proposed introduction have been provided in an organized single document.

Information of importance to be filled in the Proposed Introduction Assessment Form (PIAF):

The data to be filled in the PIAF is organized into six groups. These groups include:

1. General information on the proposed introduction:

This information is of a general nature such as; the purpose and details of the proposed introduction/transfer, reasons why the introduction is not covered by the Model Program, and the time schedule associated with introduction and stocking events

2. Information regarding the introduced aquatic animal:

This section focuses on information pertaining to the species to be introduced/transferred, such as anatomical and physiological characteristic of the introduced species/strain, features of the introduced species that would encourage dispersal such as migratory behaviours, description of the host defense mechanisms, known survival strategies of the introduced species, and pathogens reported to infect this species.

3. Information on the health history of the introduced animal and the serious pathogens it may carry:

This section provides a full health history of the introduced animals, fish health programs at source facility, pathogens/diseases associated with the organisms cultured at the source (if available), health history at the facility, loading level of pathogens, past imports to the source facility, and a list of other fish species prevalent at the source. Information is also needed regarding records of previous disease diagnosis, detection methods, and control/treatment measures used to combat infections. Additionally, information on pathogens known to be present in the introduced species, such as its prevalence at the source water/lot, ease of agent contamination, potential vectors and intermediate hosts needs to be provided. This section also includes questions pertaining to whether the stocking of this species is likely to increase a pathogens incidence or geographic range.

4. Receiving environment or contiguous watershed

This section is intended to describe the environment in which the host and/or pathogens are expected to occupy and includes; water flow characteristics which would enhance the dispersion of effects or hazards, presence of potential vectors, and potentially susceptible species. The applicant is requested to provide information on the potential adverse consequences to the natural ecosystems due to this introduction.

5. Potential damage/benefits:

In this section, the applicant is requested to provide information on potential fish losses from death or diseases as a result of the transmitted infection and to estimate costs resulting from the introduction. The applicant is urged to provide a list of potential negative outcomes if the proposal was denied.

6. Others

873 This category is for additional vital information not included above.
 874
 875

876 **II. Import Risk Analysis (IRA)**

877 The objective of this process is to identify whether the proposed aquatic animal introduction or transfer poses a
 878 low, medium or high risk for introducing a serious pathogen into the receiving environment. There are many IRA
 879 protocols and the example given here is just to demonstrate the rigor and validity of an IRA procedure that can be
 880 accepted by GLFC-FHC. Risk analysis experts may opt to follow other internationally-acknowledged IRA methods.
 881 IRA is to be performed on behalf of the proponent by technical experts and the GLFC-FHC will review it. In certain
 882 instances, the GLFC-FHC will perform it directly or through a subcontractor
 883

884 The IRA process encompasses three major steps (Appendix II):
 885

886 *Step 1: To assess the probability of establishment and release of a pathogen due to an aquatic animal*
 887 *introduction/transfer.*
 888

889 This step includes two types of analyses; release assessment and exposure assessment:
 890

891 The release assessment consists of describing the biological pathway(s) necessary for an introduced aquatic animal
 892 to release biological agents (e.g., pathogens) into a particular environment, and estimating the probability that it will
 893 take place.
 894

895 Release assessments typically include:

- 896 i. a description of the types, amounts, timing, and probabilities of the “release” of each of the potential
 897 pathogens under each set of conditions, and
- 898 ii. a description of how these might be affected by various actions, events or measures.
 899

900 Some of the inputs that may need to be considered in the release assessment include:

- 901 • the ability of pathogens to be transmitted to successive generations (i.e., vertical transmission)
- 902 • incidence or prevalence of the pathogen or agent
- 903 • incidence/prevalence of the same pathogen in adjoining lakes and/or watersheds
- 904 • susceptible species and age of fish
- 905 • ease of agent contamination
- 906 • effect of diagnostic testing
- 907 • effect of prophylactic and therapeutic treatment
 908

909 Exposure Assessment describes the relevant conditions and characteristics of native aquatic animals being
 910 exposed to an introduced pathogen released by an introduced, non-native aquatic animal, and estimating the
 911 probability they occur.
 912

913 Exposure assessments typically include:

- 914 • migratory behaviours of the introduced animal
- 915 • the presence of potential vectors
- 916 • the nature and properties of the pathogen
- 917 • routes of exposure, modes of transmission and routes of entry
- 918 • geographic and environmental characteristics
- 919 • presence of susceptible species in receiving waters
 920
 921

922 *Step 2. To assess the Consequence of Establishment of a Pathogen(s) in the Receiving Water/Facility.* This
 923 process is called Consequence Assessment.
 924

925 Consequence Assessment describes the relationship between specified exposures to a pathogen and the economic
 926 and ecological consequences of said exposures.

927 Factors to be considered include:

- 928 • transmission of infection to other aquatic animals
- 929 • subclinical production losses caused by the transmitted infection
- 930 • spread of infection or disease, and potential for an epizootic
- 931 • fish losses from death or disease
- 932 • losses from trade embargo, losses in fish marketability
- 933 • costs incurred from control and eradication, monitoring, laboratory testing, disinfecting, treatment,
- 934 and vaccination
- 935 • adverse consequences to the natural ecosystems
- 936

937 *Step 3. To estimate Pathogen Risk Potential*

938 This process is also called risk estimation, in which, the overall risk is assigned a single value.

939

940 **Risk Estimation**

941 Risk estimation consists of integrating the results from the release assessment, exposure assessment, and
 942 consequence assessment to assess the risks to naturally occurring populations of native species, important
 943 fisheries or aquaculture resources, and biological communities and habitats which may be impacted by a
 944 proposed introduction.

945

946 **III. Risk Assessment Summary Information**

947 The Risk Assessment Summary Information (Appendix III) draws on the data provided in the Proposed
 948 Introduction form and the findings resulting from the Risk Assessment Summary Report. The Risk Assessment
 949 Summary Information will be produced by the GLFC-FHC after the Risk Assessment Summary Report
 950 (Appendix II) is completed. This report will focus and summarize only the most critical information that was
 951 used in the decision making process. The information in this report will be the basis for determining the overall
 952 risk associated with the proposed introduction and make recommendations regarding the introduction. That is,
 953 the Risk Assessment Summary Information will recommend:

- 954 • the introduction proceed as requested
- 955 • the introduction proceeds only under certain criteria
- 956 • the introduction should not be made.

957

958 The report will document what criteria were used in the decision making process and describe why the
 959 recommendation was made.

960

961 **Risk Management**

962 The requesting agency should recommend that a request with risks estimated to be high is rejected.
 963 Approval for introduction should be recommended if the risk in each of the key areas of concern is estimated as
 964 low. The requesting agency may decide that requests of intermediate risk are modified by incorporating
 965 specific preventive or mitigating plans in the proposed application, or may require that additional information
 966 be generated in order to estimate the risks more conclusively.

967

968 The risk management decision on stocking should be based on the probability of adverse health effects on
 969 fisheries resources; that is, the health-associated output of the risk assessment. Elements of risk management
 970 include:

- 971 • Interpreting, comparing, judging the significance of, and deciding the tolerability of the risk
 972 estimated;
- 973 • Identifying and evaluating the efficacy and feasibility of mitigation measures, in addition to those
 974 that may have been considered in the initial risk assessment, in order to reduce the risk associated
 975 with an importation or introduction. The efficacy is the degree to which an option reduces the
 976 likelihood and magnitude of adverse biological and economic consequences.

977

978 **Low risk request**

979 A stocking request for which the hazards identified pertain only to diseases not capable of inflicting severe
 980 losses in fish stocks, or capable of inflicting severe losses in fish stocks but which are already widely distributed
 981 in the Great Lakes basin, including the region of concern, may be classified as of low risk.

982

983 **High risk request**

984 An introduction request for which hazards related to reportable diseases not presently detected in the Great Lakes
 985 basin or the receiving states/province have been identified, should be classified as high risk. Diseases or pathogens
 986 listed in the Emergency Fish Diseases of the Model Program can have serious deleterious impacts on fish stocks and
 987 must be kept out of the Great Lakes Basin. Reportable diseases, such as those listed by the United States
 988 Department of Agriculture and the Canadian Department of Fisheries and Oceans, must be prevented from
 989 spreading to new areas because of the serious negative impacts they can have on fish stocks and should be
 990 considered of high risk.

991

992 Other significant diseases of concern that should be evaluated as high risk include diseases that are of current or
 993 potential international significance but that have not been included in the diseases previously addressed. While
 994 the primary concern is the protection of health of fisheries resources, disease-related hazards that could impact
 995 other aquatic organisms should be taken into account as well. Adverse effects involving a wide range of
 996 species, a large number of individuals or target species (i.e., of special status) would be judged to have greater
 997 consequences/impacts than those that do not, and should be classified as high risk.

998

999 **Risk Communication**

1000 Risk communication represents the interactive exchange of information on risk among risk assessors, risk
 1001 managers, and other interested parties. It begins when a risk analysis is requested and continues after the
 1002 implementation of the decision on the acceptance or refusal of the stocking request.

1003 The main principles involved with risk communication include:

- 1004 • The communication of risk should be open, interactive, and involve transparent exchange of
- 1005 information that may continue after the stocking decision.
- 1006 • Peer review should represent a component of risk communication in order to obtain scientific and
- 1007 analytic critiques and to ensure the validity of the scientific data, methods, and assumptions.
- 1008 • The uncertainty in the model, model inputs, and the risk estimates of the risk assessment should be
- 1009 communicated.
- 1010

1011 **Recommendations to Decision-Makers**

1012 There are five possible final outcomes that can result following a risk assessment request:

- 1013 1. Hazard identification fails to identify potential hazards associated with the introduction. Thus, the request is
- 1014 recommended for approval and the import risk assessment process is terminated.
- 1015 2. The request is returned to the requesting agency prior or during consideration in order to obtain additional
- 1016 information required to assess the level of risk associated with the proposed introduction.
- 1017 3. The request is recommended for approval with no conditions.
- 1018 4. The request is recommended for approval with the condition that specific preventive or mitigating measures are
- 1019 followed before the proposed stocking takes place.
- 1020 5. The request is not recommended for approval if the level of risk estimated is deemed unacceptable. For
- 1021 qualitative assessment processes (as outlined in Appendix B), a stocking event will not be recommended for
- 1022 approval unless the risk in each of the key areas of concern is considered to be low or can be reduced to low or
- 1023 negligible with mitigating measures, and the overall confidence level for which the overall risk was estimated is
- 1024 Certain or Reliable. For quantitative assessment, because acceptability of a risk is a subjective decision about
- 1025 issues around which there may be substantial disagreement, it is recommended that a policy on standards of
- 1026 acceptable risk be developed. Questions to be considered in choosing a safety standard are outlined in Brunk
- 1027 (1992).
- 1028
- 1029

1030 **References Cited**

1031

1032 Amos, K. 2004. National Aquatic Animal Health Plan for the United States of America. p. 147-150. *In* J.R. Arthur
 1033 and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals.
 1034 Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan,
 1035 Mexico. APEC FWG 01/2002, NACA, Bangkok.

1036

- 1037 Arthur, J.R., and M.G. Bondad-Reantaso. (eds.) 2004. Capacity and Awareness Building on Import Risk Analysis
 1038 for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August
 1039 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok, 224 p.
 1040
- 1041 Bartley, D.M., M.G. Bondad-Reantaso, and R.P. Subasinghe (2006): A risk analysis framework for aquatic animal
 1042 health management in marine stock enhancement programmes. *Fisheries Research* 80: 28-36.
 1043
- 1044 Bondad-Reantaso, M.G. 2004a. Development of national strategy on aquatic animal health management in Asia. p.
 1045 103-108. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk
 1046 Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17
 1047 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.
 1048
- 1049 Brunk, G. 1992. Issues in the Regulation of Animal Health Risks. Report to Animal Health Division Agriculture
 1050 Canada, University of Waterloo, Ontario. 58 pp.
 1051
- 1052 Hine, M. 2004. The development of import risk analysis (IRA) in relation to the history of New Zealand. p. 131-
 1053 133-14. *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk
 1054 Analysis for Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17
 1055 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.
 1056
- 1057 Hnath, J.G. (ed.). 1993. Great Lakes Fish Disease Control Policy and Model Program. Great Lakes Fishery
 1058 Commission Special Publication 93(1):1-38.
 1059
- 1060 Model Program updated by whom and when
 1061
- 1062 Horner, R.W. and Eschenroder, R.L. 1993. Protocol to Minimize the Risk of Introducing Emergency Disease
 1063 Agents with Importation of Salmonid Fishes from Enzootic Areas. Great Lakes Fishery Commission Special
 1064 Publication 93(1):39-53.
 1065
- 1066 ICES. 2003. ICES Code of Practice on the Introductions and Transfers of Marine Organisms. International Council
 1067 for the Exploration of the Sea, Copenhagen, Denmark. 28 pp.
 1068
- 1069 Kanchanakhan, S. and S. Chinabut. 2004. Strategies for aquatic animal health management in Thailand. p. 139-142.
 1070 *In* J.R. Arthur and M.G. Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for
 1071 Aquatic Animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002
 1072 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.
 1073
- 1074 MacDiarmid, S.C. 1997. Risk analysis, international trade, and animal health. p. 377-387. *In* Fundamentals of Risk
 1075 Analysis and Risk Management. CRC Lewis Publ., Boca Raton.
 1076
- 1077 OIE. 2003. Aquatic Animal Health Code. 12th edn. World Animal Health Organization, Paris.
 1078
- 1079 Olivier, G. 2004. Canada's National Aquatic Animal Health Program. p. 115-117. *In* J.R. Arthur and M.G. Bondad-
 1080 Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the
 1081 Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG
 1082 01/2002, NACA, Bangkok.
 1083
- 1084 Perera, R. 2004. The import risk analysis process in Australia. p. 109-113. *In* J.R. Arthur and M.G. Bondad-
 1085 Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. Proceedings of the
 1086 Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG
 1087 01/2002, NACA, Bangkok.
 1088
- 1089 Rodgers, C.J. 2004. Risk analysis in aquaculture and aquatic animal health. p. 59-64. *In* J.R. Arthur and M.G.
 1090 Bondad-Reantaso. (eds.) Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals.
 1091 Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan,
 1092 Mexico. APEC FWG 01/2002, NACA, Bangkok.
 1093

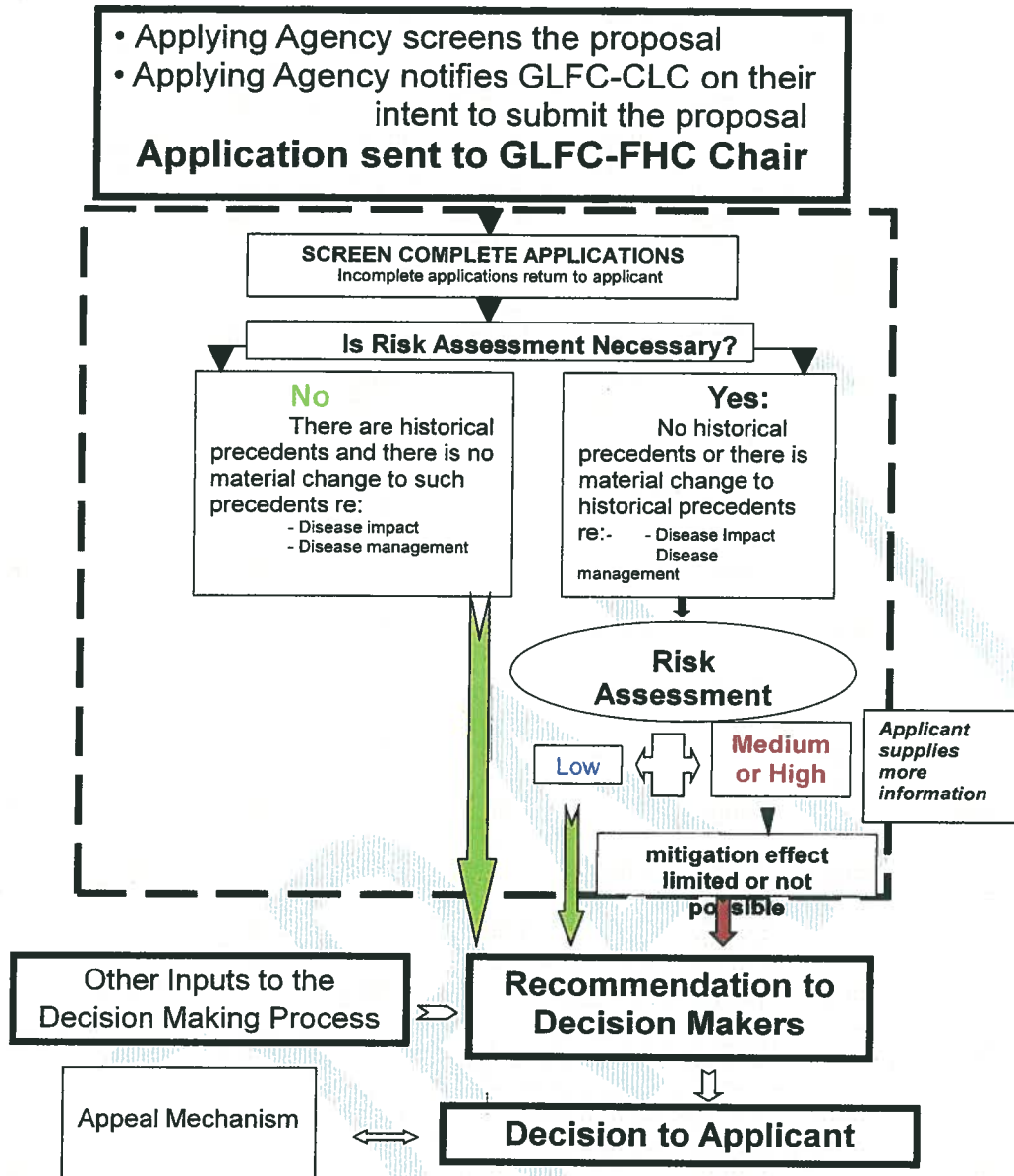
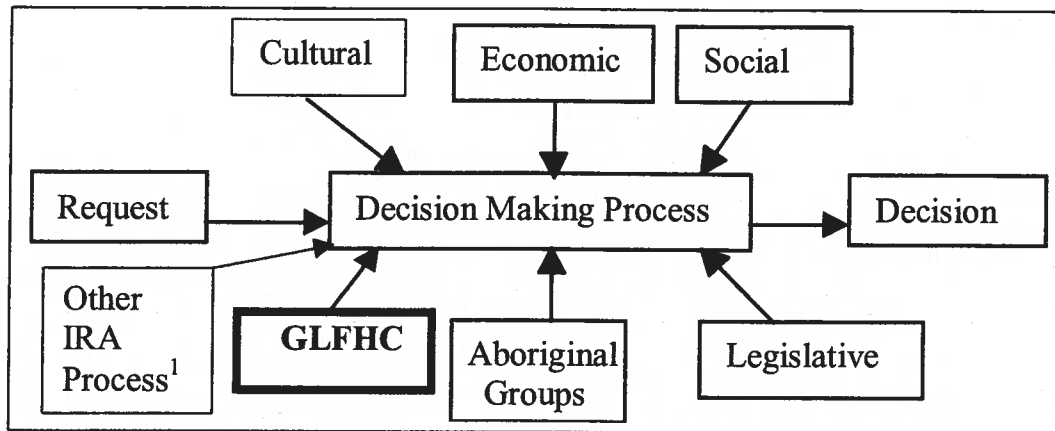


Figure 1. The Import Risk Analysis Process for the Great Lakes Basin.

1094
1095
1096

1097 **Figure 2. Inputs to the decision making process for introductions or transfers of aquatic organisms.**

1098
1099
1100
1101
1102
1103
1104
1105
1106
1107
1108
1109
1110
1111
1112
1113
1114
1115
1116



1117 **APPENDIX I. Proposed Introduction Assessment Form**

1118

1119 Information relevant to the proposed introduction. To be completed by the requesting agency, the GLFHC (in the
1120 case that GLFC is the requesting agency), or appropriate technical experts.

1121

1122

1123 From:

1124

1125 Prepared By:

1126

1127 Date submitted:

1128

1129

1130 **GENERAL**

1131 Name (common and scientific [genus and species]) of the organism proposed for introduction or transfer:

1132

1133 Describe the morphological characteristics of the species to be introduced, including distinguishing characteristics of
1134 the organism.

1135

1136 Describe the history in aquaculture, enhancement, or other introductions (if applicable):

1137

1138 Describe the objectives and rationale for the proposed introduction, including an explanation as to why such an
1139 objective cannot be met through the utilization of an indigenous species:

1140

1141 What alternate strategies have been considered in order to meet the objectives of the proposal? What are the
1142 implications of a “do nothing” option? Support your arguments by citation and mention the databases searched.

1143

1144 What is the geographic area of the proposed introduction? Include a detailed map.

1145

1146 Describe the numbers of organisms proposed for introduction (initially, ultimately):

1147

1148 Size or age of species being introduced:

1149

1150 Location or stocking sites: Justify the selection of the stocking sites

1151

1152 Last three years of health history of hatchery of origin if appropriate (highlighting known pathogens, disease etc.):

1153

1154 History of production (of requested species):

1155

1156 Pathogens currently found in introduced species:

1157

1158 Describe the ability of the pathogen(s) commonly present in the introduced species to be transmitted to
1159 successive generations:

1160

1161 Describe the incidence/prevalence of introduced species in receiving environment and contiguous watershed:

1162

1163 State why the introduction is not covered by the Model Program:

1164

1165 Time schedule associated with introduction/transfer event:

1166

1167 Names of other species at the source facility of origin

1168

1169 Past imports to the source facility, if available (list species of fish and sources) of origin

1170

1171

- 1172 **PATHOGEN (for each identified pathogen of concern)**
- 1173 Prevalence of pathogen(s) or its intermediate host in the source population
- 1174
- 1175 Describe how easily transmissible the pathogen is?
- 1176
- 1177 Describe the presence of potential pathogen vectors and reservoirs:
- 1178
- 1179 List potential routes of exposure, modes of transmission and routes of entry: Support your answer with references..
- 1180
- 1181 Is the activity of introducing these fish likely to increase a pathogens prevalence/intensity or geographic range
- 1182 (justify why not)?
- 1183
- 1184 List first and second intermediate hosts of the pathogen if applicable :
- 1185
- 1186 Describe the potential for transmission of infection to other animals or species:
- 1187
- 1188
- 1189 What is the likelihood of spreading the infection or disease
- 1190
- 1191 **HOST**
- 1192 Describe the native range and range changes due to introductions:
- 1193
- 1194 Record where the species was introduced previously and describe the ecological effects on the environment of the
- 1195 receiving area:
- 1196
- 1197 What factors limit the species in its native range:
- 1198
- 1199 Describe the physiological tolerances (water quality, temperature, oxygen, and salinity) at each life history stage
- 1200 (early life history stages, adults, reproductive stages):
- 1201
- 1202 Describe the habitat preferences and tolerances for each life history stage:
- 1203
- 1204 Describe the reproductive biology of the species or provide citations
- 1205
- 1206 Describe the migratory behavior of the species:
- 1207
- 1208 Describe the food preferences for each life history stage:
- 1209
- 1210 Describe the growth rate and lifespan (also in the area of the proposed introduction, if known):
- 1211
- 1212 Describe the known pathogens and parasites of the species or stock:
- 1213
- 1214 Describe the behavioral traits (social, territorial, aggressive):
- 1215
- 1216 List the native species in receiving waters that may be susceptible to the introduced pathogen
- 1217
- 1218 Describe the features of the stocked species that would encourage dispersal such as migratory behaviours:
- 1219
- 1220 List expected or observed sub clinical production losses caused by the transmitted infection:
- 1221
- 1222 What trend data is available on the recent history of this species with regards to the performance in the receiving
- 1223 waters (Growth, mean weight at age, survival, return to creel, return to weir, angler hours / commercial effort, etc.):
- 1224
- 1225 Describe the prognosis for the natural immune system to suppress the pathogen:
- 1226
- 1227 **RECEIVING ENVIRONMENT AND CONTIGUOUS WATERSHED**

- 1228 Describe physical information on the receiving environment and contiguous water bodies (e.g., seasonal water
 1229 temperatures, salinity, and turbidity, dissolved oxygen, pH, nutrients and metals):
 1230
- 1231 Do the parameters described above match the tolerances/preferences of the species to be introduced, including
 1232 conditions needed for reproduction?
 1233
- 1234 List species composition (major aquatic vertebrates, invertebrates and plants) of the receiving waters:
 1235
- 1236 Are any of these species known to be susceptible to the diseases and parasites found to affect the introduced species
 1237 in its native range?
 1238
- 1239 Describe the natural or man-made barriers that should prevent the movement of the introduced organisms to
 1240 adjacent waters:
 1241
- 1242 Describe the water flow characteristics that would enhance the dispersion of effects or
 1243 hazards:
 1244
- 1245 Describe the presence of potential vectors:
 1246
- 1247 How effective are prophylactic and therapeutic treatments to control infection with the introduced pathogen?
 1248
- 1249 List geographic and environmental characteristics:
 1250
- 1251 Describe the possible adverse consequences to the natural ecosystems:
 1252
- 1253 What is the history of the receiving water body with respect to this pathogen?
 1254
- 1255 Forage availability in receiving water:
 1256
- 1257 How does this species biologically match the receiving water (lake temperature, salinity,
 1258 forage, spawning area, nursery area, etc.)?
 1259
- 1260 Describe the general stability of the receiving environment (Lake Superior more stable than Lake Michigan, no
 1261 epizootics, stable growth rates, few exotics, extensive natural reproduction, etc.):
 1262
- 1263
- 1264 **DAMAGE / BENEFITS**
- 1265 List fish losses from death or diseases as a result of the transmitted infection:
 1266
- 1267 List the possible losses from trade embargoes:
 1268
- 1269 List the possible losses from inter-state/provincial fish movement/transfer restrictions:
 1270
- 1271 List the possible losses in fish marketability:
 1272
- 1273 List the possible control and eradication costs: of what and how future costs can be determined
 1274
- 1275 List the possible monitoring; surveillance, laboratory testing and trace back costs:
 1276
- 1277 List the possible quarantine and isolation costs:
 1278
- 1279 List the possible compensation costs:
 1280
- 1281 List the possible cleaning and disinfecting costs:
 1282
- 1283 List the possible treatment, vaccination costs:

- 1284
 1285 List the expected benefits or performance of the fish being requested (Survival, growth, mean weight at age, return
 1286 to creel, return to weir, etc.):
 1287
 1288 List the expected negative outcome of not stocking the species (Reduced creel, loss of ecological balance, loss of
 1289 unique genetic material etc.):
 1290
 1291 List the potential benefits of not stocking (lowers the prevalence of the pathogen in the system, improved growth
 1292 rates of wild or previously stocked fish, control the geographic range of the pathogen, etc.):
 1293
 1294 List groups that would benefit from taking the risk:
 1295
 1296 **MISCELLANEOUS**
 1297 Relevant data gaps (what important facts don't we know?):
 1298
 1299 Describe the biases or uncertainty of diagnostic testing:
 1300
 1301 Describe the potential for an epidemic in cultured and wild stocks:
 1302
 1303 What are the alternatives to stocking these fish in the Great Lakes:
 1304
 1305 List ways to mitigate the loss (stock alternative species, request assistance from other agencies, stock fewer fish,
 1306 etc.):
 1307
 1308 Provide a statement on the competency and integrity of the veterinary (health) infrastructure of the stocking agency:
 1309
 1310 Provide a statement on the competition of the introduced species with native species for forage fish.
 1311

1312 APPENDIX II. Risk Assessment Summary Report document

1313

1314 Step 1. Determining the Probability of Establishment–Release and Exposure Assessment for each Pathogen:

1315

1316 Complete the following table and provide a brief rationale with appropriate references to support the rating given.

1317

Element	Probability of Establishment (H to N) ¹	Level of Certainty (VC to VU) ²
Estimate the probability that a pathogen may be introduced along with the species proposed for introduction. Note that several pathways may exist through which pathogens or accompanying species can enter fish habitat. Each must be evaluated.		
Estimate the probability that the pathogen will encounter susceptible organisms or suitable habitat.		
Final Rating ^{3,4}		

1318

1319 Explanatory notes

1320

1. See Table 1.

1321

2. See Table 2.

1322

3. The final rating for the **Probability of Establishment** is assigned the value of the element with the **lowest** risk rating (e.g., a **Moderate** and **Low** estimate for the above elements would result in an overall **Low** rating).

1323

1324

Note that the calculation of the final rating follows the multiplication rule of probabilities (i.e., the probability that a given event will occur corresponds to the product of the individual probabilities). Thus the final risk of establishment is assigned the value of the lowest individual probability estimate. Again, both events – probability of the pathogen, parasite or fellow traveler successfully colonizing and maintaining a population in the intended area of introduction (be it in a confined environment such as a facility, or a natural habitat) and the probability of spreading beyond the intended area of introduction (estimated as explained above) – need to occur in order to have establishment beyond the intended area of introduction.

1325

1326

1327

1328

1329

1330

4. **As both events (probabilities) are dependent**, the final rating for the **Level of Certainty** is assigned the value of the element rating with the **Lowest** level of certainty (e.g., **Very Certain** and **Reasonably Certain** ratings would result in a final **Reasonably Certain** rating).

1331

1332

1333

1334

1335

1336 **Step 2. Determining the Consequence of Establishment of a Pathogen**

1337

1338 Complete the following table and provide a brief rationale with appropriate references to support the rating given.

1339 The final rating of the Consequences of Establishment is assigned a single rating based on environmental impacts.

1340

Element	Consequences of Establishment (C to N) ⁵	Level of Certainty (VC to VU) ⁶
Final Rating^{7,8}		

1341

1342

1343 Explanatory notes

1344 5. See Table 3.

1345 6. See Table 2.

1346 7. The final rating for the **Consequences of Establishment** is assigned the value of the element (impact) with the
 1347 highest risk rating (e.g. **High** and **Moderate** ratings for the above elements would result in a final **High** rating)
 1348 as both events are independent (i.e., additive probabilities).

1349 8. **As both elements (impacts) are independent**, the final rating for the **Level of Certainty** is assigned the value
 1350 of the level of certainty given to the element rating with the Highest rating. If both elements have the same
 1351 ratings but different level of certainty, the **Highest** level of certainty should be used.

1352

1353

1354

Note: It is recommended that the proposal be approved as presented (no mitigating measures, or additional mitigating measures, are required) only if the overall estimated risk obtains a rating of low or lower.

Note: It is recommended that the proposal be approved only if the overall confidence level for which the overall risk was estimated is VERY CERTAIN or REASONABLY CERTAIN.

Note: For higher category of risks, the application of mitigation measures, or additional mitigation measures, are required to lessen the risk to at least a low rating. However, it is recognized that this may not be possible for all proposals.

1355

1356 **Step 3. Estimating Pathogen Risk Potential**

1357

1358 The overall Risk is assigned a single value based on the **Probability of Establishment** and the **Consequences of**
 1359 **Establishment.**

1360

Component	Rating	Level of Certainty
Probability of Establishment estimate ⁹		
Consequence of Establishment estimate ¹⁰		
FINAL RISK ESTIMATE ^{11,12}		

1361

1362 Explanatory notes

1363

1364 9. As estimated in Step 1 – Use “final rating for probability of establishment” and “final rating for the level of
 1365 certainty”, respectively.

1366

1367 10. As estimated in Step 2 – Use “final rating for consequences of establishment” and “final rating for the level of
 1368 certainty”, respectively.

1369

1370 11. Under “element rating”, Table 4 below provides a matrix for categorizing the final risk estimate.

1371

1372 12. Under “level of certainty” The level of certainty for each component is carried over (e.g. a very certain and
 1373 reasonably uncertain estimate for the probability and consequences of establishment, respectively, would result in a
 1374 VC/RC rating).

1375

1376 Table 1. Rating Criteria for the probability of occurrence of an adverse event.
1377

1378	Rating	Definitions
1379		
1380	HIGH (H)	Event would be expected to occur
1381		
1382	MODERATE (M)	There is less than an even chance of the event occurring
1383		
1384	LOW (L)	Event would be unlikely to occur
1385		
1386	VERY LOW (VL)	Event would occur rarely
1387		
1388	NEGLIGIBLE (N)	Chance of event occurring is so small that it can be ignored in practical terms
1389		

1390
1391
1392 Table 2. Confidence level of rating level.
1393

1394	Rating	Definitions
1395		
1396	VERY CERTAIN (VC)	I am highly confident that my rating level is quite close to its true value
1397		
1398		
1399	REASONABLY CERTAIN (RC)	I am assuming my rating level is close to its true value, but there is some chance I am wrong
1400		
1401		
1402		
1403	REASONABLY UNCERTAIN (RU)	There is substantial chance that my response regarding the rating level is wrong
1404		
1405		
1406		
1407	VERY UNCERTAIN (VU)	My answer is trivial as a basis for decision and likely to be wrong
1408		
1409		
1410		
1411		

1412 Table 3. Rating criteria for the "Consequence of establishment".
1413

Rating	Definitions
1415 CATASTROPHIC (C)	associated with the establishment of hazards that would be expected to significantly harm economic performance at a national level. Alternatively, or in addition, they may cause serious irreversible harm to the environment.
1418 HIGH (H)	associated with the establishment of hazards that would have serious biological consequences (eg high mortality or high morbidity and causing significant pathological changes in affected organisms). Such effects would normally be felt for a prolonged period (greater than or equal to a normal production cycle) and would not be amenable to control or eradication. These hazards would be expected to significantly harm economic performance at an industry level. Alternatively or in addition, they may cause serious harm to the environment.
1425 MODERATE (M)	associated with the establishment of hazards that have less pronounced biological consequences. These hazards may harm economic performance significantly at an enterprise/regional level, but they would not have significant economic effect at the whole industry level. These diseases may be amenable to control or eradication at a significant cost, or their effects may be temporary. They may affect the environment, but such harm would not be serious or may be reversible.
1432 LOW (L)	associated with the establishment of hazards that have mild biological consequences and would normally be amenable to control or eradication. Such hazards would be expected to harm economic performance at the enterprise or regional level but to have negligible significance at the industry level. Effects on the environment would be minor or, if more pronounced, would be temporary.
1438 NEGLIGIBLE (N)	associated with the establishment of hazards that have no significant biological consequences, may be short-lived and/or are readily amenable to control or eradication. The economic effects would be expected to be low to moderate at an individual enterprise level and insignificant at a regional level. Effects on the environment would be negligible.
1443	
1444	

1445 Table 4. Risk Estimation matrix for categorizing the overall risk estimate.
 1446

Likelihood of entry and exposure	<i>High likelihood</i>	Negligible risk	Low risk	Moderate risk	High risk	Extreme risk
	<i>Moderate</i>	Negligible risk	Low risk	Moderate risk	High risk	Extreme risk
	<i>Low</i>	Negligible risk	Very low risk	Low risk	Moderate Risk	High risk
	<i>Very low</i>	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk
	<i>Negligible likelihood</i>	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk
		<i>Negligible impact</i>	<i>Low</i>	<i>Moderate</i>	<i>High</i>	<i>Catastrophic</i>

Consequences of entry and exposure

1447

1448 Explanatory note

1449 This table illustrates the Acceptable Level of Risk (ALOP) using a risk estimation matrix. The cells of this matrix
 1450 describe the product of likelihood and consequences – termed ‘risk’. When interpreting the risk estimation matrix it
 1451 should be remembered that although the descriptors for each axis are similar (low, moderate, high, etc), the vertical
 1452 axis refers to likelihood and the horizontal axis refers to consequences. One implication of this is that a negligible
 1453 probability combined with a catastrophic consequence is not the same as an extreme probability combined with a
 1454 negligible consequence – that is, that the matrix is not symmetrical. *The band of cells marked ‘low risk’*
 1455 *represents Canada’s ALOP, or tolerance of loss. This band of cells represents the maximum level of risk*
 1456 *considered to be ‘acceptable’.*
 1457

1458 **APPENDIX III. RISK ASSESSMENT SUMMARY INFORMATION**

1459

1460 **Hazard Identification**

1461

1462 Viruses:

1463

1464 Bacteria:

1465

1466 Fungi:

1467

1468 Parasites:

1469

1470 Other:

1471

1472 Comments:

1473

1474

1475 **Summary of the Request:**

1476

1477

1478

1479

1480

1481

1482

1483 **Summary of the Risk Assessment:**

1484

1485

1486

1487

1488

1489

1490

1491

1492

1493 **Statement on Overall Risk:**

1494

1495

1496

1497

1498

1499

1500

1501 **Signature of Chairmen GLFHC**

1502

Date

1503 Table 1. Rating Criteria for the probability of occurrence of an adverse event.
1504

Rating	Definitions
HIGH (H)	means that the adverse event is certain to occur, or almost a certainty.
MEDIUM (M)	means that the adverse event is as likely to occur as to not occur.
LOW (L)	means that the adverse event is unlikely to occur.

1514

1515

1516

1517 Table 2. Confidence of rating level.
1518

Rating	Definitions
CERTAIN (C)	I am highly confident that my rating level is quite close to its true value.
RELIABLE (R)	I am assuming my rating level is close to its true value, but there is some chance I am wrong.
SUBJECTIVE (S)	My answer is of pure subjective nature, and not validated against any evidence or data.
UNRELIABLE (U)	There is substantial chance that my response regarding the rating level is incorrect.

1535

1536 Table 3. Rating criteria for the “Consequence of establishment”.
 1537

Rating	Definitions
HIGH (H)	means that the magnitude of the effects associated with the proposed importation is considered of serious importance.
MEDIUM (M)	means that the magnitude of the effects associated with the proposed importation is considered substantial.
LOW (L)	means that the magnitude of the effects associated with the proposed importation is considered negligible and manageable.

1548
 1549
 1550
 1551
 1552
 1553
 1554
 1555

Table 4. Outline for categorizing the overall risk estimate.

Probability of Establishment	Consequence of Establishment	Risk Estimate
High	High	High Risk
High	Medium	High Risk
High	Low	Moderate Risk
Medium	High	High Risk
Medium	Medium	Moderate Risk
Medium	Low	Moderate Risk
Low	High	Moderate Risk
Low	Medium	Moderate Risk
Low	Low	Low Risk

1570
 1571
 1572
 1573