Risk Assessment for the Introduction or Transfer of Fish and Associated Pathogens into the Great Lakes Basin

October 2014 (supersedes Horner and Eshenroder 1993)

Movement of fish and their gametes has been, and continues to be, the cornerstone of many fishery conservation and restoration programs within the Laurentian Great Lakes. Often, pathogens have invaded new geographic ranges as a result of fish importation or stocking, resulting in negative consequences for fish populations in those systems. Numerous examples can be found in the literature such as the incidence of whirling disease in the intermountain west (Bartholomew and Reno 2002). Recognizing this, the Great Lakes Fish Health Committee (GLFHC) developed and adopted a protocol to assess and minimize the risk of introducing emerging disease agents with the importation of salmonid fishes from enzootic areas (Horner and Eshenroder 1993). Outbreaks of emerging diseases in wild and cultured fishes within the basin (such as *Heterosporis* sp., largemouth bass virus, *Piscirickettsia* sp., *Nucleospora salmonis*, and viral hemorrhagic septicemia virus) have indicated a more quantifiable protocol is needed when assessing the pathogen risk of potential introductions or transfers of fish and their gametes.

National and international agencies have developed a standard, science-based process to accurately assess pathogen introduction risks associated with fish movement, collectively called Import Risk Analysis (IRA) (Amos 2004; Bondad-Reantaso 2004; Hine 2004; Kanchanakhan and Chinabut 2004; Olivier 2004; Perera 2004). Guided by this widely accepted process of IRA for fish importation and movements, the GLFHC adopted a revised Risk Assessment (RA) process in compliance with the World Animal Health Organization Aquatic Code (OIE 2013), the International Council for the Exploration of the Sea Code (ICES 2004), the Food and Agriculture Organization of the United Nations (Bartley et al., 2006), and the U.S. Fish and Wildlife Service Handbook of Aquatic Animal Health Procedures and Protocols. Specifically, the GLFHC sought to

- Develop a general Risk Assessment framework the Committee will follow to reach recommendations regarding introductions or transfers for which no standard procedures are established, or which fall outside of or in conflict with the Model Program.
- Archive each Risk Assessment for review and evaluation when similar cases arise in the future.

The GLFHC's Risk Assessment is designed to determine the likelihood of pathogen introduction into or spread within the Great Lake Basin associated with fisheries management actions such as fish and aquatic organism transfers. The Risk Assessment will also document likely risks of such actions and provide Great Lakes fisheries managers GLFHC recommendations about how to minimize any identified risks using the best available information at the time the Risk Assessment is performed.

The GLFHC Risk Assessment will not address any issues outside of the aquatic animal health considerations of any proposed introduction. The determination of the benefits of fisheries management actions along with the potential ecological or genetic effects, if any, must be part of the decision record and are the responsibility of the proponent fisheries agency(ies), appropriate Great Lakes Committee(s), and the Council of Lake Committees (CLC).

The GLFHC strongly recommends that a Risk Assessment be conducted well prior to the planned importation or transfer of fish or other aquatic organisms, particularly when the Model Fish Health Program does not provide clear guidance to fisheries managers on minimizing potential aquatic animal

health risks in receiving facilities and waters. This assessment is designed to support and assist in the decision record for the proposed fisheries management action. Based on all available information, the GLFHC will review, evaluate and provide recommendations on the proposed introduction exclusively focused on the potential aquatic animal health risks to the receiving facility or water body from the proposed management action. The term "introduction" is defined in this document to include any action in which fish and aquatic organisms and their associated gametes are being moved. These actions include fish or aquatic organism transfers, stocking, or importation.

Risk Assessment Objectives

- a. Identify pathogen(s) of concern that may be introduced or transferred into the basin as a result of the proposed introduction of fish or aquatic organism, including their gametes.
- b. Document potential aquatic organism disease issues to include epizootic risk associated with the proposed action.
- c. Determine the most likely aquatic organism disease risks, to include the likelihood of such risks, associated with the proposed transfer or introduction of fish or aquatic organism and their gametes into the new Great Lakes waters or facilities.
- d. Develop and provide Great Lakes basin fisheries managers with the GLFHC recommendation as to whether or not the proposed action to import or transfer fish or other aquatic organisms should proceed from a fish health standpoint.
- e. Develop and provide Great Lakes basin fisheries managers with risk management options to eliminate or reduce the effects of the proposed action.
- f. Facilitate responses to fish and aquatic organism disease questions from CLC members and other entities to the GLFHC on the proposed fish management action including the Risk Assessment process, supporting documentation, and recommendations.

Risk Assessment Procedure

The Risk Assessment is to be used in the following situations:

- A Level 1 Restricted Pathogen is detected at a member-operated facility,
- The Model Program does not provide clear guidance, or
- A proposed action is in direct conflict with the Model Program.

When one of these situations arises, the GLFHC Chairperson should be contacted by the affected agency's representative on the GLFHC to begin the Risk Assessment process. Once contacted, the GLFHC Chairperson will work with the requesting member to select the appropriate RA form (RA-1 or RA-2) and to complete a preliminary Risk Assessment. The GLFHC Chairperson will share the preliminary Risk Assessment with the entire GLFHC and solicit input from members to develop a final RA report.

Final Assessment of the Pathogen Risk Potential

The process results in a numerical score, which is placed into one of three categories of risk: low, moderate, or high. The GLFHC will provide a summary report (Form RA-3) which will focus and summarize only the most critical information that was used in the process, including its recommendation, documentation of fish health risks to naturally occurring populations of native or naturalized species, important fisheries or aquaculture resources, biological communities and habitats which may be impacted

by a proposed action, and potential options for mitigation (if applicable). The summary report will be provided to all member agencies, the appropriate lake committee(s), and the CLC.

Risk Communication

Risk communication represents the interactive exchange of information about risk among risk assessors, risk managers, and other interested parties. It begins when a risk assessment is requested and continues on after the implementation of a recommendation regarding the possible translocation of a pathogen of concern.

The communication of risk should be open, interactive, and involve transparent exchange of information that may continue after the decision on translocation is made. The uncertainty in the model, model inputs, and the risk estimates in the risk assessment should be communicated between the involved parties. The entire risk assessment process should include an evaluation of uncertainty and data sources.

Instructions for Risk Assessment Forms RA-1 and RA-2

Each of the RA forms should be scored as follows:

- 1. Choose the appropriate option for each situation and place its associated numerical value in the small box immediately to the right of that option.
- 2. Multiply the numerical value by the weighting factor (in parentheses) for the situational statement and place this value in the larger box on the far right.
- 3. Total all of the large box scores and place this value in the **Total Risk Score** box at the bottom of the worksheet.

Example for Form RA-1

In an instance where the prevalence of a pathogen in the source population is Medium and its pathogen transmission is vertical, the first part of Form RA-1 would be filled in as follows:

Current prevalence of pathogen in the source population (5)		
High (67-100) – 5		
Medium (33-66) – 3	3	15
Low (1-32) – 1		13
None – 0		
Pathogen transmission through fish or their gametes (10)		
Vertical (and assumed horizontal) – 5	5	
Horizontal – 1		50
Unknown – 5		

Final Scoring

Form RA-1: For pathogen movements into a facility, the following risk potential and general recommendations apply.

Risk Score	Risk Potential	Recommendation
387 and below	Low	Place fish or eggs into a standard facility; apply mitigation for pathogens as necessary. The movement
		must not result in a reduction of the health status of the

		facility. If the movement would result in a reduction of health status, the fish or eggs should be placed into isolation or quarantine.
388 - 646	Moderate	Place fish or eggs into isolation/quarantine. The fish should be tested a minimum of 3 times in 2 years with at least 4 months between tests without the detection of a pathogen listed in the Model Program before transfer or release. Sampling should be done at the 2% prevalence level (95% confidence).
647 and above	High	Place into quarantine. Fish may only be transferred or released based on recommendations made by the GLFHC in the Risk Assessment Summary document.

Form RA-2: For pathogen movements out of a facility, the following risk potential and general recommendations apply.

Risk Score	Risk Potential	Recommendation
667 and below	Low**	Allow unrestricted movement of the fish and their
		gametes.
668-1070	Moderate**	Allow fish and their gametes to only be transferred to
		facilities or released into waters that are positive for the
		pathogen(s) of concern.
1071 and above	High	Stocking and transfers are not recommended. Potential
		exceptions would allow fish and their gametes to only be
		stocked into the waters of origin or held in
		isolation/quarantine for further testing as suggested by
		the GLFHC.

**Note: For situations when the pathogen(s) is not currently present in the Great Lakes Basin, or if more than one pathogen is present, the Risk Potential shall be raised by one level (low becomes moderate, moderate becomes high).

Recommendations to Decision-Makers

A risk assessment can result in one of three outcomes:

- 1. The request is recommended for approval without conditions.
- 2. The request is recommended for approval with conditions such that specific preventive or mitigating measures are to be followed before the proposed translocation of a potential pathogen takes place.
- 3. The request is not recommended for approval owing to a level of risk estimated to be unacceptable.

References Cited

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

Bartholomew, J.L. and Reno, P.W. 2002. The history and dissemination of whirling disease. *In* Whirling disease: reviews and current topics. *Edited by* J.L Bartholomew and J.C. Wilson. American Fisheries Society, Symposium 29, Bethesda, Maryland, pp. 3-24.

Bartley, D.M., Bondad-Reantaso, M.G., and Subasinghe R.P. 2006. A risk analysis framework for aquatic animal health management in marine stock enhancement programmes. Fisheries Res **80**: 28-36.

Bondad-Reantaso, M.G. 2004. Development of national strategy on aquatic animal health management in Asia. *In* Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. *Edited by* J.R. Arthur and M.G. Bondad-Reantaso. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok. Pp. 103-108

Hine, M. 2004. The development of import risk analysis (IRA) in relation to the history of New Zealand. *In* Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. *Edited by* J.R. Arthur and M.G. Bondad-Reantaso. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok, pp. 131-133.

Horner, R.W. and Eshenroder, R.L. 1993. Protocol to minimize the risk of introducing emergency disease agents with importation of salmonid fishes from enzootic areas. Great Lakes Fishery Commission Special Publication **93**: 39-53.

ICES. 2004. ICES code of practice on the introductions and transfers of marine organisms. International Council for the Exploration of the Sea, Copenhagen, Denmark.

Kanchanakhan, S. and Chinabut, S. 2004. Strategies for aquatic animal health management in Thailand. *In* Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. *Edited by* J.R. Arthur and M.G. Bondad-Reantaso. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok, pp. 139-142.

OIE. 2013. Aquatic Animal Health Code. 16th edn. World Animal Health Organization, Paris, France.

Olivier, G. 2004. Canada's National Aquatic Animal Health Program. *In* Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. *Edited by* J.R. Arthur and M.G. Bondad-Reantaso. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok, pp. 115-117.

Perera, R. 2004 The import risk analysis process in Australia. *In* Capacity and Awareness Building on Import Risk Analysis for Aquatic Animals. *Edited by* J.R. Arthur and M.G. Bondad-Reantaso. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok, pp. 109-113.

Form RA-1. Risk Assessment for pathogen movements into a facility. Complete this form when importing fish or fertilized eggs into a hatchery from either the wild or from another hatchery.

1. Current prevalence of pathogen in the source population (5)	
High (67-100) – 5	
Medium (33-66) – 3	
Low (1-32) – 1	
None – 0	
2. Pathogen transmission through fish or their gametes (10) Vertical (and assumed horizontal) – 5	
Horizontal – 1	
Unknown – 5	
3. Current prevalence of the pathogen in the receiving facility (20)	
	1
High – 1 Medium – 3	
Low – 5	
None – 10	
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4. Current prevalence of the pathogen in the effluent receiving waters (20)	<i>)</i>
High – 1 Medium – 3	
Low – 5	
None/ Unknown - 10	
5. Confidence in the pathogen test methods in the hatchery (15)	
Standard methods (Blue Book and/or OIE protocols) – 1	
Non-standard (non-representative) methods – 3	
No testing methods available (clinical signs only) – 5	
6. Describe the known potential for disease to other aquatic animals (10) One fish species affected – 1	1
1	
One fish family affected – 3	
More than one fish family affected – 5	
Multiple classes affected – 7	
7. Are effective treatments available to control infection and transmission pathogen? (10)	with the
Yes (e.g., egg disinfection, vaccinations, etc.) – 0	1
No – 10	
8. Describe the potential for an epidemic in cultured and wild stocks (15)	
Known to cause elsewhere – 5	
Does not cause epidemics – 1	
Unknown – 5	
9. Knowledge of the fish species and its culture requirements (5)	
Adequate – 1	
Inadequate – 1 Inadequate/Unknown – 5	+
•	
10. Source fish health history (last 10 years) (10)	<u> </u>
Parental history with no other Model Program pathogens – 1	
Parental history with other Model Program pathogens – 5	+
No parental history – 5	

11. Population source location (10)	
Within the same Great Lake watershed – 1	
Between Great Lakes – 3	
An adjacent basin to the Great Lakes (e.g., Mississippi River,	
Hudson River, etc.) – 5	
Outside of the adjacent Great Lakes basins – 10	
Total Risk Score	

Form RA-2. Risk assessment for pathogen movements out of a facility. Complete this form when transferring fish to the wild during stocking events.

1. Current prevalence of the pathogen in the hatchery (10)		
High (67-100) – 5	T	
Medium (33-66) – 3		
Low (1-32) – 1	+	
None – 0	+	
Unknown – 5	+	
2. Current prevalence of the pathogen in the lot (10)		
High (67-100) – 5		
Medium (33-66) – 3	+	
Low (1-32) – 1	+	
None – 0		
Unknown – 5		
3. Pathogen transmission through fish or their gametes (10)		
Vertical (and assumed horizontal) – 5		
Horizontal – 1		
Unknown – 5		
4. Will effective treatment/disinfection measures be implemented for the p	athogen?	
(10)	\top	
Yes (e.g., egg disinfection, etc) – 0 No – 5		
	:- (10)	
5. Current geographic distribution of the pathogen in the Great Lakes base Presence – 0	in (10)	
Absence – 30		
6. Will introductions of these fish likely increase a pathogen's geographic the Great Lakes basin? (10)	range with	hin
Yes - 20		
Maybe (presumed presence of the pathogen within the geographic		
range) – 10		
No – 0	+	
7. Will introduction of these fish likely increase a pathogen's prevalence in	1 Question	#6
of the receiving water? (10)	C 1 1 1 1	
Yes – 10	\Box	
Maybe – 5		
No – 0		
8. Prevalence of the pathogen in the receiving water (5)		
High – 1		
Medium – 3		
Low - 5		
None – 10		
Unknown – 10	+	
9. Is the receiving waterbody a broodstock source? (10)		
Yes - 5		
No - 0		

10. Indicate which vectors enable transmission of the pathogen in the recei	iving water
(5) Choose all responses that apply and total the values.	
Commercial activities (ballast, weed harvesting, fishing) – 5	
Fish stocking and bait – 5	
Predators (birds and mammals) – 1	
Human activity (recreational fishing) – 3	
11. Describe the potential for disease transfer to other aquatic animals (10)
One fish species affected – 1)
One fish family affected – 2	
More than one fish family affected – 7	
-	
Multiple classes affected – 10	
12. Describe the potential for an epidemic in wild stocks (20)	
Known to cause epidemics elsewhere – 10	
Does not cause epidemics – 0	
Unknown – 10	
13. Confidence in the pathogen test methods in the hatchery (5)	
Standard methods (Blue Book and/or OIE protocols) – 1	
Non-standard (non-representative) methods – 3	
No testing methods available (clinical signs only) – 7	
14. Fish health history of the lot (the last 2 years) (5)	
No history of other Model Program pathogens – 1	
History of other Model Program pathogens – 5	
No history – 5	
15. Fish health history of the current broodstock (the last 10 years) (5)	1
No history of other Model Program pathogens – 1	
History of other Model Program pathogens – 5	
No history – 5	
16. Fish health history of the facility (the last 10 years) (5)	
No history of other Model Program pathogens – 1	
History of other Model Program pathogens – 5	
No history – 5	
17. Other pathogen presence (influence) in the receiving hatchery or water	body (10)
Comprehensive/Continual/Annual pathogen surveillance	
Other Model Program pathogen(s) detected – 7	
No other Model Program pathogen(s) detected – 1	
Limited/Sporadic pathogen surveillance	
Other Model Program pathogen(s) detected – 7	
No other Model Program pathogen(s) detected – 3	
No population/pathogen history – 7	
Total Risk Score	

Form RA-3. Risk Assessment Summary Information

Hazard Identification		
Viruses:		
Bacteria:		
Fungi:		
Parasites:		
r diasites.		
Other:		
Comments:		
G CAL D		
Summary of the Request:		
Summary of the Risk Assessment:		
Statement on Overall Risk:		
Succession of a verum rusk.		
Signature of GLFHC Chairperson	Date	