

Government of Canada input to questions from PEI as written in May 26 correspondence

Questions	Response
<p>The only PEI representative involved in the 2013 DFO CSAS process appears to represent the commercial aquaculture perspective. Please indicate how expertise related to local/regional recreational fisheries impacts have been considered during this review and what the conclusions were.</p>	<p>Participants at CSAS meetings are invited based on their expertise rather than as representatives of a particular group or organisation. Prior to the 2013 DFO CSAS process on the risk assessment of the environmental and indirect human health effects of AquAdvantage Salmon, a steering committee was established to identify the participants with the expertise required to peer review the risk assessment. The purpose of CSAS science advisory process is to evaluate the scientific merit of work, such as a risk assessment, that had been completed prior to providing science advice on a particular topic. The meetings are not consultations, all participants at scientific peer review meetings are expected to participate as objective and knowledgeable individuals on the subject matter under review; not advocates or representatives of any interest group.</p> <p>The <a href="#">Terms of Reference</a> for the 2013 CSAS process for AquAdvantage Salmon specify the objectives and questions addressed. Note that the risk assessment was a comprehensive scientific assessment and considered all potential biological impacts as part of the hazard assessment as well as an exposure assessment. Potential socio-economic impacts such as impacts to the recreational or commercial fishery are outside of the scope of CSAS scientific peer review processes. All participants in the CSAS process reached consensus on a final conclusion of low risk to the environment and indirect human health, and that the living organism was contained so as to satisfactorily protect the environment and indirect human health.</p> <p>Results of the 2013 DFO CSAS process have been published on line as a DFO National Science Response Process (<a href="http://waves-vagues.dfo-mpo.gc.ca/Library/361091.pdf">http://waves-vagues.dfo-mpo.gc.ca/Library/361091.pdf</a>). Proceedings of the peer review process have also been published on line (<a href="http://www.dfo-mpo.gc.ca/csas-sccs/Publications/Pro-Cr/2017/2017_007-eng.pdf">http://www.dfo-mpo.gc.ca/csas-sccs/Publications/Pro-Cr/2017/2017_007-eng.pdf</a>).</p>
<p>Please indicate if the following comment received from the public was/is a concern or consideration for ECCC as part of the risk assessment process:</p> <ul style="list-style-type: none"> <li>o "The effluent treatment at this site also does not meet recommended effluent treatment for fish as per the EU Commission vet review</li> </ul>	<p>Effluent must be free of AquAdvantage eggs and sperm (genetic material) as specified in <a href="#">Significant New Activity Notice 16528</a>. Effluent treatment would also be subject to provincial laws and regulations.</p>

<p>panel recommendations that suggested chlorination followed by dechlorination and geofiltration or evaporation as the only method acceptable for viral titres to be sufficiently low."</p>	
<p>The use of an open settling pond at a GMO salmon facility does not respect the WHO "One Health" policy. Is this a concern to ECCC?</p>	<p>See response above to question #2 as an open settling pond would appear to be part of effluent treatment.</p>
<p>Please provide a link to the list of documents used in the 2013 Federal risk assessment on AquaAdvantage salmon.</p>	<p>See response above to question #1.</p>
<p>Please clarify if the current legislation in Canada requires GM salmon to be labeled as such.</p>	<p>Health Canada requires labelling for food products, including genetically modified foods, where clear, scientifically established health risks or significant nutritional changes have been identified that can be mitigated through labelling. For example, a priority allergen present in a food must be labelled to alert consumers.</p> <p>In Canada, voluntary labelling is permitted to provide consumers with information that is not related to the safety of the product. The national standard, "Voluntary Labelling and Advertising of Foods that Are and Are Not Products of Genetic Engineering", states that products can be voluntarily labelled as GE or non-GE, provided conditions are met and the claim is understandable, informative, accurate and not misleading.</p> <p>As no health risk or significant nutritional change was identified in food derived from AquaAdvantage salmon, the decision of whether or not to proceed with voluntary labelling is that of AquaBounty Technologies Inc.</p>
<ol style="list-style-type: none"> <li>1. Does ECCC believe there is significant risk to Atlantic salmon populations from eggs which will be produced at the facility?</li> <li>2. In the opinion of ECCC, are the</li> </ol>	<ol style="list-style-type: none"> <li>1. Requirements in <a href="#">Significant New Activity Notice 16528</a> must be met. Given compliance with the conditions specified in that Notice, there is not a significant risk to salmon populations from sterile eggs which may be produced at the facility.</li> <li>2. Safeguards proposed that are in compliance with the Notice above are adequate.</li> </ol>

<p>safeguards proposed adequate to address the risk?</p>	
<p>The Federal risk assessment that was prepared for the original facility appears limited in scope and not valid for the proposed grow out operation. The original risk assessment document was specific in that it dealt with an egg production process only with fish raised in Panama where escapees could not interact with wild salmon. Given that the facility is now proposing a grow-out operation and that the original risk assessment was based on egg production only, please explain why a new risk assessment is not required. Also please clarify the Federal government's position on this issue- is the 2013 risk assessment still applicable?</p>	<p>The result of the federal decision on risk prepared for the original facility was implemented in <a href="#">Significant New Activity Notice 16528</a> and it is valid for the proposed grow out operation. All persons growing the AquAdvantage salmon are required to comply with it. This includes the provision that only euthanized fish can leave the facility.</p>
<p>Please indicate if the results of any ECCC inspections are made public and, if so, where the results can be accessed. If not currently available to the public, is public access to inspection results possible?</p>	<p>Statistics regarding ECCC's enforcement activities are published in the annual reports for the relevant legislation. Information about prosecutions is made publically available via enforcement notifications. For more information about the enforcement of the <i>Canadian Environmental Protect Act</i>, please consult this section of the ECCC web site: <a href="https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&amp;n=66B8D849-1">https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&amp;n=66B8D849-1</a>. The results of individual inspections are not made public and may be protected by the privacy rights of those inspected. The appropriate mechanism for public access to inspection records is the access to information process (<a href="https://www.canada.ca/en/treasury-board-secretariat/topics/access-information-privacy/access-information.html">https://www.canada.ca/en/treasury-board-secretariat/topics/access-information-privacy/access-information.html</a>).</p>
<p>Please indicate if the proponent's request for funding from ACOA triggers the requirement for a Federal EA.</p>	<p>This project is not one that falls on the list in the <i>Regulations Designating Physical Activities</i> of the <i>Canadian Environmental Assessment Act</i> – these Regulations define what is subject to a federal EA by a responsible authority.</p>

	<p>With respect to Atlantic Canada Opportunities Agency (ACOA), that agency will have to determine if s. 67 of the CEAA would result in them examining the project to determine if there is a significant environmental effect. It is up to each department/Agency to determine if its activity is one that requires them to determine if there are likely significant adverse environmental effects.</p>
<p>Please clarify the following points regarding the potential escape or release of GM salmon:</p> <ul style="list-style-type: none"> <li>o Is Aqua Bounty required to report an escape/release of GM salmon to ECCC?</li> <li>o Is Aqua Bounty required to have a contingency plan in the event of the escape and/or release of GM salmon?</li> <li>o Is Aqua Bounty required to post a bond ensuring that they will pay for any costs associated with the execution of the contingency plan?</li> <li>o Is any escape/release of GM salmon recorded in a Federal public registry?</li> </ul>	<p>All persons growing the AquAdvantage salmon are required to comply with Significant New Activity Notice 16528 which is available <a href="#">here</a>.</p>
<p>Please confirm that ECCC is not concerned about the off-site processing of GM salmon and the possible release of disease or unknown organisms into the environment.</p>	<p>All persons growing the AquAdvantage salmon are required to comply with Significant New Activity Notice 16528 which is available <a href="#">here</a>. This includes the provision that only euthanized fish can leave the facility.</p>
<p>Please indicate if the document <i>Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada - An Expert Panel Report on the Future of Food Biotechnology prepared by The Royal Society of Canada at the request of Health Canada, Canadian</i></p>	<p>A link to the science advice received from the Fisheries and Ocean Canada was provided in above. The list of references does not include the 2001 Royal Society of Canada report on Food Biotechnology.</p>

<p><i>Food Inspection Agency and Environment Canada, January 2001</i> was referenced as part of this current review or the 2013 Federal risk assessment process.</p>	
<p>Please clarify the requirements for monitoring of disease, parasites, pathogens and pharmaceuticals in the effluent and the natural environment and list the Federal agency responsible for each.</p>	<p>The Canadian Food Inspection Agency (CFIA) is the internationally recognized Competent Authority for aquatic animal health in Canada. The CFIA mandate includes preventing the introduction and spread of federally regulated diseases of concern to wild and farmed aquatic animals.</p> <p>The CFIA has the ability to prevent the introduction and spread of any animal disease to any animal, including GMO animals. In particular, the CFIA conducts surveillance for the presence and absence of reportable and immediately notifiable aquatic animal diseases in Canada. The list of these diseases can be found at <a href="http://inspection.gc.ca/animals/aquatic-animals/diseases/eng/1299156296625/1320599059508">http://inspection.gc.ca/animals/aquatic-animals/diseases/eng/1299156296625/1320599059508</a>. Owners, veterinarians and laboratories are required to report suspicion of such diseases to the CFIA. Upon receipt of a notification, or detection during surveillance, the CFIA initiates an investigation. Disease response options may require effluent controls in facilities, such as processing plants, culture sites, and diagnostic and research laboratories to dispose of animals safely. For diseases that occur in Canada, day to day domestic movements of live or dead aquatic animals to closed (biocontained) facilities require the implementation of effluent controls. More information on disease response and domestic movement controls can be found at <a href="http://inspection.gc.ca/animals/aquatic-animals/diseases/investigations/eng/1338313604809/1338313669210">http://inspection.gc.ca/animals/aquatic-animals/diseases/investigations/eng/1338313604809/1338313669210</a> and <a href="http://inspection.gc.ca/animals/aquatic-animals/domestic-movements/eng/1450122972517/1450122973466">http://inspection.gc.ca/animals/aquatic-animals/domestic-movements/eng/1450122972517/1450122973466</a>, respectively.</p> <p>For the purposes of international trade, the CFIA establishes the conditions for import to prevent the introduction and spread of disease which can include testing for federally regulated diseases in imported aquatic animals or products.</p> <p>The CFIA is also responsible for certifying the animal health status of exported aquatic animals and their products in accordance with the import requirements of foreign trade partners.</p>