

Excerpts from the Fisheries and Oceans Canada Risk Assessment 2019ⁱ
RE: Sale of transgenic (GM) and non-transgenic (non-GM) eggs

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Emphasis to text is added

The AquaBounty expressed its intentions to manufacture and sell non-transgenic (genetically modified) Atlantic Salmon eggs to external parties, referred to by Fisheries and Oceans Canada (DFO) as Scenario A:

“This raised the possibility of a containment failure resulting from human error, whereby transgenic eggs are accidentally shipped as non-transgenic, to **customers who could inadvertently release the organism into the environment.**” (page 6)

“There remains a possibility of human error resulting in the release of transgenic eggs to **customers who believe they have purchased non- transgenic eggs.**” (page 10)

“...the possibility of an exposure pathway due to the unintentional release (sale) of transgenic eggs as non-transgenic eggs to external parties resulted in a **low** likelihood of exposure (Scenario A). If non-transgenic eggs are not sold to external parties, the likelihood of exposure of EO-1 α Salmon to the Canadian environment would be ranked **negligible** (Scenario B). If non-transgenic eggs would be produced at the Rollo Bay facilities, but under conditions outlined in Risk Management below, the potential for escape and exposure would decrease relative to Scenario A. **If EO-1 α Salmon were present in the Canadian environment, the potential for their survival, dispersal, reproduction and establishment cannot be discounted,** but is limited by low potential for release.” (page 18)

“Under Scenario A, where non-transgenic fertilized eggs will be produced for external parties, **the potential for human error in shipping eggs increases potential exposure.** Consequently, the likelihood of exposure of EO-1 α Salmon to the Canadian environment is ranked low, and therefore results in **low to moderate risk of EO-1 α Salmon to Canadian environments** under Scenario A. An alternate use scenario (Scenario B) where non-transgenic eggs are not sold to external parties, resulted in the likelihood of exposure of EO-1 α Salmon to the Canadian environment to be ranked negligible and would result in negligible to low risk of EO-1 α Salmon to Canadian environments.” (page 26)

Under Scenario A, human error increases the likelihood of exposure to the Canadian environment. Consequently, the exposure assessment concludes with **low uncertainty** (Table 3) that the likelihood of EO-1 α Salmon exposure to the Canadian environment is **low** (Table 1). However, if non-transgenic eggs from the facility are not sold to external parties (Scenario B), the exposure to the Canadian environment would be reduced to **negligible.** (page 11)

“Risk Management

As containment is essential to minimizing risk of the EO-1 α Salmon to the Canadian environment, it is imperative that all physical, biological, and operational containment measures proposed by AquaBounty Canada Inc. be maintained. Any changes to containment or expansion of the manufacture and grow-out facilities beyond what is being currently proposed could change the outcome of the environmental risk assessment and would require additional information to be provided to ECCC

To mitigate the potential for human error that may result in the mixing of transgenic and non-transgenic fish under Scenario A, **the production of non-transgenic fish for use by external parties should be conducted under all of the following conditions:**

- a. be undertaken **in a different building, or a physically separate area** within a building, with **a separate and secured entrance**, and in locations where there is no production of transgenic fish, through the production cycle, from egg fertilization to the end of the egg shipping process;
- b. be undertaken where there is **no overlap in time** between transgenic and non-transgenic spawning events, and between egg shipping events;
- c. be undertaken with **staff trained** on all applicable SOPs;
- d. require a statistically appropriate **sampling methodology for validation of a non-transgenic genotype**, as close to the time of shipping as possible, and for all shipments; and
- e. **require labelling inside and outside of shipping boxes** to indicate contents, and shipping of eggs as soon as possible following validation (e.g., eggs are selected, sampled for genotyping, genotyped, packaged, and shipped prior to a new batch of eggs being selected for shipping).” (page 27)

ⁱ Fisheries and Oceans Canada, Canadian Science Advisory Secretariat. “Environmental and Indirect Human Health Risk Assessments for the Manufacture and Grow-out of EO-1 α Salmon, including the AquAdvantage® Salmon, at a Land-Based and Contained Facility near Rollo Bay, PEI.”, Science Advisory Report 2019/014. 2019. http://www.dfo-mpo.gc.ca/csas-sccs/Publications/SAR-AS/2019/2019_014-eng.pdf

The 2019 Science Advisory Report summarizes the results of the December 11 to 13, 2018 “Environmental and Indirect Human Health Risk Assessments for the Manufacture and Grow-out of Sterile AquAdvantage® Salmon at a Land-Based Facility near Rollo Bay, PEI” CSAS peer-review meeting. In advance of the meeting, a CSAS Science Response process was held to establish whether information provided by the company in the regulatory package was sufficient to determine invasiveness (DFO 2019).

Fisheries and Oceans Canada (DFO) conducts environmental risk assessment and provides science advice to Environment and Climate Change Canada (ECCC). The DFO advice is provided in the form of a Canadian Science Advisory Secretariat Science Advisory Report that is used to inform the Canadian Environmental Protection Act risk assessment.
