

**FEDERAL COURT**

Between:

ECOLOGY ACTION CENTRE and LIVING OCEANS SOCIETY

Applicants

- and -

MINISTER OF THE ENVIRONMENT, MINISTER OF  
HEALTH and AQUABOUNTY CANADA INC.

Respondents

**NOTICE OF APPLICATION**

**TO THE RESPONDENTS:**

A PROCEEDING HAS BEEN COMMENCED by the applicants. The relief claimed by the applicants appears on the following page.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the applicants. The applicants request that this application be heard at Ottawa.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must prepare a notice of appearance in Form 305 prescribed by the Federal Courts Rules and serve it on the applicants' solicitors WITHIN 10 DAYS after being served with this notice of application.

Copies of the Federal Courts Rules information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

Date: December 13, 2013

Issued by: Benoit Labelle  
(Registry Officer)

Address of local office:

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**AND TO:** AQUABOUNTY CANADA INC.  
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I HEREBY CERTIFY that the above document is a true copy of  
the original issued out of / filed in the Court on the 13<sup>th</sup>

day of December A.D. 20 13

Dated this 13<sup>th</sup> day of December 20 13

  
BENOIT LABELLE  
REGISTRY OFFICER  
AGENT DU GREFFE

## APPLICATION

This is an application for judicial review in relation to the unlawful assessment of the living organism identified as genetically engineered Atlantic salmon (*Salmo salar*) containing a single copy of the opAFP-GHc2 transgene at the EO-1a locus (hereinafter “AquAdvantage salmon”) by the Minister of the Environment and the Minister of Health (“the Ministers”) under section 108 of the *Canadian Environmental Protection Act, 1999*, SC 1999, c 33 (“CEPA”) (hereinafter the “Section 108 Toxicity Assessment”).

The Ministers failed to obtain and assess legally required information for their Section 108 Toxicity Assessment, which was intended to determine, *inter alia*, whether AquAdvantage salmon is toxic or capable of becoming toxic. The Ministers’ assessment and associated determination under section 108 have not been made public, but their existence was publically disclosed in a related notice in the *Canada Gazette* on Saturday, November 23, 2013.

The applicants make application for:

1. An order declaring that:
  - (a) The Ministers acted unlawfully and without jurisdiction in conducting the Section 108 Toxicity Assessment without having first received or assessed all information legally required by the *CEPA* and its *Regulations*;
  - (b) The Ministers’ Section 108 Toxicity Assessment is invalid and unlawful due to non-compliance with the *CEPA*; and
  - (c) In addition or in the alternative, the Ministers unlawfully or unreasonably failed to conduct a lawful, complete Section 108 Toxicity Assessment.
  
2. An order quashing and setting aside the Ministers’ Section 108 Toxicity Assessment.

3. In the alternative to paragraph 2 above, an order quashing and setting aside the Section 108 Toxicity Assessment and remitting the Section 108 Toxicity Assessment back to the Ministers, with any directions that this Court considers appropriate.
4. Pursuant to Rule 105 of the *Federal Courts Rules*, an order that this application be consolidated or heard together with a second closely related application issued on or about December 23, 2013.
5. An order requiring the respondents to pay the applicants their costs of this application if requested, or, in the alternative, an order that all parties shall bear their own costs.
6. Such further or other relief as this Honourable Court may deem just.

The grounds for the application are:

### **The respondents**

1. AquaBounty Canada Inc. (“AquaBounty”) is a biotechnology company operating an aquaculture facility in Prince Edward Island (“P.E.I.”) where AquAdvantage salmon organisms have been contained as research and development organisms. AquAdvantage salmon is a genetically engineered variety of salmon purported to grow to market size faster than either wild or farmed salmon.
2. AquaBounty intends to commercially produce and use AquAdvantage salmon eggs at its facility in P.E.I. to be exported and grown out at a facility in Panama, and subsequently exported to the U.S. for consumption as a food product, pending receipt of the necessary approvals in the U.S.

3. The Ministers are jointly responsible, under section 108 of the *CEPA*, for assessing required information in respect of a living organism in order to determine whether it is toxic or capable of becoming toxic.
4. The Minister of the Environment has additional powers and duties under Part 6 of the *CEPA*, including, under section 106, the ability to waive requirements to provide information for an assessment of whether a living organism is toxic or capable of becoming toxic [s. 106(8)], and the duty to publish in the *Canada Gazette* a notice of any such waiver granted to a person [s.106(9)].

**Legal framework under the *CEPA* for assessment of animate products of biotechnology**

5. New animate products of biotechnology must be evaluated pursuant to the *CEPA* before their manufacture, import, or use can lawfully proceed in Canada. Part 6 of the *CEPA*, found at sections 104-115, sets out the specific framework for the assessment of products of biotechnology.
6. The *CEPA* regime governs the assessment of the toxicity of various substances. “Toxic” is defined in section 64 of the *CEPA*. An organism is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that, *inter alia*, have or may have an immediate or long-term harmful effect on the environment or its biological diversity.
7. Under the *CEPA*, substances can include not just chemical substances but also animate matter. Specifically, in Part 6 of the *CEPA*, a living organism is defined to mean a substance that is an animate product of biotechnology.

8. Here, the living organism at issue is all life stages, genotypes and genders of AquAdvantage salmon.
9. Under the *CEPA*, the Minister of Environment maintains a list of substances manufactured, imported into or used in Canada, known as the Domestic Substances List [s.66].
10. Pursuant to subsection 106(1) of the *CEPA*, a person shall not manufacture or import a living organism that is not on the Domestic Substances List, unless the person has provided prescribed information to the Minister of the Environment by a prescribed date and the prescribed period for assessing that information under section 108 has expired.
11. Schedule 5 of the *New Substances Notification Regulations (Organisms)* (SOR/2005-248) (the "*Regulations*") established under the *CEPA*, lists the prescribed information that must be provided in respect of organisms that are not micro-organisms. Pursuant to paragraph 5(d) of the *Regulations*, a person must provide this information to the Minister of the Environment at least 120 days prior to the manufacture or import of the organism.
12. The assessment period, for the purposes of subsection 108(1) of the *CEPA*, is 120 days after the receipt of all of the information listed in Schedule 5, as prescribed by paragraph 6(d) of the *Regulations*.
13. Subsection 106(8) of the *CEPA* sets out the circumstances in which the Minister of the Environment may grant a waiver of any of the requirements to provide information for an assessment under section 108. These circumstances include where, in the Ministers' opinion: (a) the information is not needed to assess the organism's toxicity, (b) the organism is to be used for a prescribed purpose or manufactured at a location where it can be contained

so as to protect the environment and human health, or (c) it is not practicable or feasible to obtain the test data necessary to generate the information.

14. Only the Minister of the Environment has the legal authority to grant a person a waiver of the requirement to provide prescribed information for an assessment under of an animate product of biotechnology, and only after both Ministers have jointly formed the requisite opinion that the statutory criteria for such a waiver have been met.
15. Subsection 106(9) provides that the Minister of the Environment must publish in the *Canada Gazette* a notice stating the name of any person to whom such a waiver is granted and the type of information to which it relates.
16. Pursuant to subsection 108(1), the Ministers must jointly, within the 120 day assessment period, assess information provided under, *inter alia*, CEPA subsections 106(1) and 109(1)(c) and the *Regulations*, or that is otherwise available to them in respect of a living organism, to determine whether it is toxic or capable of becoming toxic.
17. Pursuant to subsection 109(1), where the Ministers have assessed information under section 108 and they suspect that an organism is toxic or capable of becoming toxic, they may, before the expiry of the 120 day assessment period:
  - a) permit any person to manufacture or import the living organism, subject to any conditions that the Ministers may specify;
  - b) prohibit any person from manufacturing or importing the living organism;  
or
  - c) request any person to provide any additional information or test results that the Ministers consider necessary for the purpose of assessing whether the living organism is toxic or capable of becoming toxic.

18. Subsection 110(1) provides that where the Ministers have assessed information under section 108 in respect of a living organism not on the Domestic Substances List, and they suspect that a significant new activity in relation to the organism may result in it becoming toxic, the Minister of the Environment may, within 90 days after the expiry of the 120 day period for assessing the information, publish in the *Canada Gazette* a notice indicating that subsection 106(4) applies with respect to the living organism.
19. Pursuant to subsection 106(4) of the *CEPA*, no person shall use a living organism for a significant new activity indicated in a published section 110 notice, unless the person has provided prescribed information to the Minister of the Environment by a prescribed date and the prescribed period for assessing that information under section 108 has expired. A section 110 notice may indicate significant new activities by inclusion or exclusion pursuant to subsection 110(3). Where section 106(4) applies to a living organism, activities not indicated as a significant new activity are permitted.

**On November 23, 2013, the Minister of Environment published a significant new activity notice**

20. On Saturday November 23, 2013, the Minister of the Environment published Significant New Activity Notice No. 16528 (the "SNAc Notice") in the *Canada Gazette*, under section 110 of the *CEPA*. The SNAc Notice indicates that that the Ministers have assessed information in respect of AquAdvantage salmon and that subsection 106(4) applies to the living organism.
21. The SNAc Notice was reported in the media on November 25, 2013 and it was after this time that the applicants learned of it.



22. The SNAc Notice discloses that the Ministers have already conducted their Section 108 Toxicity Assessment.
23. Before they learned of the SNAc Notice, the applicants did not know that the Ministers' Section 108 Toxicity Assessment had commenced or that it had concluded.
24. The SNAc Notice is the subject of the applicants' second closely related application, issued on or about December 23, 2013.

**The Minister of Environment did not grant any waiver under subsection 106(8), despite AquaBounty having requested a waiver of the requirement to provide pathogenicity, toxicity and invasiveness information**

25. In November of 2013, the Department of Fisheries and Oceans ("DFO") published a document titled *Summary of the environmental and indirect human health risk assessment of AquAdvantage® Salmon* (the "DFO Summary Risk Assessment").
26. The DFO Summary Risk Assessment was done for the purpose of contributing to the Ministers' Section 108 Toxicity Assessment. However, neither of the Ministers conducted the DFO Summary Risk Assessment.
27. As indicated in the DFO Summary Risk Assessment, AquaBounty submitted information set out under the *Regulations* in respect of AquAdvantage salmon to a delegate of the Minister of the Environment for an assessment under section 108 on April 30, 2013.
28. AquaBounty requested that it be granted a waiver, under subsection 106(8), of the requirement to provide prescribed information required under paragraph 5(a) of Schedule 5 of the *Regulations*.

29. Pursuant to paragraph 5(a) of Schedule 5 of the *Regulations*, AquaBounty was required to provide the Minister of the Environment, in respect of the ecological effects of the organism, data from a test conducted to determine its pathogenicity, toxicity or invasiveness.
30. As indicated in the DFO Summary Risk Assessment, AquaBounty's waiver request was based on the assertion that AquAdvantage salmon organisms are to be manufactured at a location where they can be contained satisfactorily to protect the environment and human health.
31. The DFO Summary Risk Assessment includes a section entitled "Waiver Assessment" which concludes that, given AquaBounty's proposed uses and the information it had provided in support of its waiver request, AquAdvantage salmon will be contained so as to satisfactorily protect the environment and human health, and that data on invasiveness, as prescribed by paragraph 5(a) of Schedule 5 of the *Regulations*, is not needed for the Ministers' Section 108 Toxicity Assessment.
32. The DFO Summary Risk Assessment concludes that there is uncertainty associated with the potential invasiveness of AquAdvantage salmon.
33. There is no evidence that the Ministers, as part of their Section 108 Toxicity Assessment, considered any data from a test conducted to determine AquAdvantage salmon's pathogenicity, toxicity, or invasiveness as required under paragraph 5(a) of Schedule 5 of the *Regulations*.
34. To date, the Minister of the Environment has not published, under subsection 106(9) of the *CEPA*, notice of a waiver granted to any person for any prescribed information or data required under Schedule 5 of the *Regulations* in relation to AquAdvantage salmon for the Section 108 Toxicity Assessment.

**The Ministers did not assess information on the potential uses of the organism or potential locations of introduction, as required by paragraph 3(b) of Schedule 5 of the *Regulations***

35. Pursuant to paragraph 3(b) of Schedule 5 of the *Regulations*, AquaBounty was required to provide the Minister of the Environment with information on the intended and potential uses of AquaAdvantage salmon for the Section 108 Toxicity Assessment.
36. The DFO Summary Assessment does not assess potential uses identified pursuant to paragraph 3(b) of Schedule 5 of the *Regulations*, nor other possible uses. Rather, the DFO Summary Assessment only assesses toxicity of AquaAdvantage salmon in relation to AquaBounty's intended use scenario at identified facilities.
37. There is no evidence that the Ministers assessed potential uses of AquaAdvantage salmon beyond the intended uses identified by AquaBounty as part of their Section 108 Toxicity Assessment.

**The Ministers erred in purporting to conclude their Section 108 Toxicity Assessment**

38. The Ministers erred in law to the extent that they purported to conclude their Section 108 Toxicity Assessment in the absence of information required under paragraph 5(a) of Schedule 5 of the *Regulations* or a waiver of such information granted in accordance with subsections 106(8) and (9) of the *CEPA*. The time period for the Ministers' Section 108 Toxicity Assessment cannot begin until AquaBounty provides all legally required information of in respect of AquaAdvantage salmon.

**The Ministers unlawfully or unreasonably failed to conduct a lawful, complete Section 108 Toxicity Assessment**

39. In addition or in the alternative to the grounds pleaded above, to the extent that the Ministers failed to assess information on, *inter alia*, invasiveness, as required under paragraph 5(a) of Schedule 5 of the *Regulations*, they unlawfully or unreasonably failed to perform their legal duties in their purported conclusion of the Section 108 Toxicity Assessment.
40. Further, to the extent that the Ministers failed to assess potential uses of AquAdvantage salmon identified pursuant to paragraph 3(b) of Schedule 5 of the *Regulations*, they unlawfully or unreasonably failed to perform their legal duties in their purported conclusion of the Section 108 Toxicity Assessment.

**Applicants' entitlement to the relief sought**

41. The applicants are environmental non-governmental organizations with a lengthy history of involvement and demonstrated interest in marine biodiversity, sustainable fisheries, protection and preservation of wild salmon stocks, and environmental protection. They are concerned about the lawful application of the *CEPA*, including in the context of the Ministers' Section 108 Toxicity Assessment of AquAdvantage salmon.
42. The applicants are public interest litigants and have no personal, proprietary or pecuniary interest in the outcome of this application.
43. The *Federal Courts Act*, RSC 1985, c F-7.
44. The *Federal Courts Rules*, SOR 98-106.
45. The *Canadian Environmental Protection Act*.

46. The *New Substances Notification Regulations (Organisms)*.

47. Such additional grounds as counsel may identify.

This application will be supported by the following material:

1. An affidavit on behalf of Ecology Action Centre, to be served;
2. An affidavit on behalf of Living Oceans Society, to be served;
3. The record of materials before the Ministers; and
4. Such additional materials as counsel may advise and the Court may allow.

December 23, 2013



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