

September 19, 2013

Environmental Petition

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I hereby submit this petition to the Auditor General of Canada under section 22 of the Auditor General Act.



Signature of petitioner: _____ **Date:** _____ **Sept 19, 2013** _____

Title of petition

Risk assessment of AquaBounty's genetically engineered AquAdvantage salmon eggs

Acronyms used in this petition

AGA: Auditor General Act
AIA: Access to Information Act
CEPA: Canadian Environmental Protection Act
EC: Environment Canada
GE: genetically engineered
US FDA: United States Food and Drug Administration

Structure of this Petition

- I. Introduction and overview of the issue
- II. Background information
 - II.1. The Government has a duty to monitor sustainability of development
 - II.2. AquaBounty has developed a GE salmon for human consumption
 - II.3. AquaBounty plans to grow GE salmon eggs in Canada
 - II.4. The risk assessment process for GE animals
 - There is no risk assessment process specific to GE aquatic organisms
 - *CEPA* requires the federal government to undertake a risk assessment

- The Minister may disclose information despite a confidentiality request
- What constitutes “environment” under *CEPA*?

II.5. AquaBounty asking Canada to take on a potentially large risk for a small payoff

- III. Federal departments and agencies that need to respond
- IV. Contact information

I. Introduction and overview of the issue

A US biotechnology company, AquaBounty, has developed a transgenic Atlantic salmon trademarked “AquAdvantage” salmon that they claim grows at twice the rate of wild Atlantic salmon. The company hopes it will become the first ever genetically engineered (GE, also commonly referred to as genetically modified or GM) animal approved for human consumption. AquaBounty has requested approval from the US Food and Drug Administration (FDA), outlining a plan for production whereby the company will produce the eggs in Prince Edward Island, for grow-out and processing in Panama before being sold into the US consumer market.¹ Under the *Canadian Environmental Protection Act*, Environment Canada would conduct a toxicity risk assessment to determine whether the commercial production of AquAdvantage salmon eggs in PEI are “toxic or capable of becoming toxic” before allowing this new activity in Canada.² Such an assessment could already be underway. The concern with this project is that the health and environmental risks associated with GE food animals are not well understood, and AquaBounty’s application to the US Food and Drug Administration (FDA), a summary of which was released to the public by the FDA, has been criticized for not being scientifically sound.

Scientists, experts and organizations have identified the following problems with AquaBounty’s application:

- **There is no such thing as total confinement**, but AquaBounty insists that their GE fish and eggs will not escape. The company’s environmental assessment is based on this assertion.³ Scientists have pointed out however that confinement can never be completely guaranteed. While the company insists that its fish will be produced in land-based facilities in Panama, and elsewhere into the future, Environment Canada and the FDA have no legal authority to require that other countries producing the GE fish or eggs do so in land-based facilities. AquaBounty itself states in its application to the FDA that there is no such thing as total confinement, but argues that having multiple types of confinement should be enough to ensure no escape.⁴ Rather than considering the worst-case scenario, AquaBounty deems it unnecessary to consider the potential consequences of escape because they say the risk of escape is “highly unlikely”.⁵ The “failure mode analysis” technique popular in modern risk assessment requires a more

¹ Aqua Bounty Technologies, Inc. “Environmental Assessment for AquAdvantage® Salmon” Submitted to

² *Canadian Environmental Protection Act, 1999*, SC 1999, c. 33. [*CEPA*], s. 108(1).

³ Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 10-11.

⁴ Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 59, 72.

⁵ Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 59.

thorough investigation of the consequences of exposure, and many scientists are displeased with AquaBounty's reliance on an assumption of confinement.⁶

- **Any escape would lead to unpredictable consequences.** Department of Fisheries and Oceans' Dr. Robert Devlin and other researchers have emphasized the importance of containment, because if escape of GE organisms occurs, there is no way to accurately predict the outcome.⁷ Laboratory results do not necessarily depict the scenario that would occur in the wild, because there is a strong interaction between an organism's genetics and its environment.⁸ AquaBounty admits that if escape were to occur, the results would be difficult to predict because of the interactions of genetic and environmental factors.⁹ Again, they downplay these potentially dangerous scenarios by asserting that the risk of escape is too low to cause concern.¹⁰ As previously discussed, this goes against the accepted failure-mode analysis method.
- **The populations cannot be completely sterile.** AquaBounty assures the public that its fish will not reproduce in the wild because the population will be all-female and sterile. The company admits, however, in their FDA application that inducing triploidy is not completely effective at inducing sterility.¹¹ The US FDA allows for a 5% error rate, which means that potentially only 95% of GE salmon would be sterile.¹²
- **There is a possibility of reproduction in the wild.** Transgenic coho salmon have been able to spawn in simulated natural environments.¹³ Thus there is a chance that transgenes could be transmitted to wild populations if the GE fish escape and breed with wild fish.¹⁴ Furthermore, researchers have recently shown that transgenes are passed on to offspring when GE Atlantic salmon are mated

⁶ Michael Hansen, "Is the GM Salmon Safe? A look at the data on the health and environmental risks". Presentation, Charlottetown PEI. 2013-05-13. Online: <http://www.cban.ca/Resources/Topics/GE-Fish/Michael-Hansen-Presentation-Slides-May-13-PEI>; Paul Voosen, "Modified-salmon fight showcases risks, rewards of engineering wild species" *New York Times* October 7, 2010. Online: <http://www.nytimes.com/gwire/2010/10/07/07greenwire-modified-salmon-fight-showcases-risks-rewards-o-2072.html?pagewanted=all>; Ari Levaux, "Genetically modified super salmon tries to swim through a hole in the regulatory net" *Monterey County Weekly*, January 17, 2013. Online: http://www.montereycountyweekly.com/news/cover/article_650d1d3e-45d8-5b37-a382-cf1ef41a3943.html

⁷ Robert H. Devlin, L. Fredrik Sundstrom and William M. Muir. "Interface of biotechnology and ecology for environmental risk assessments of transgenic fish" *Trends in Biotechnology*. Vol. 24, Issue 2, 89-97 1 Feb 2006. Online: <http://www.cell.com/trends/biotechnology/retrieve/pii/S0167779905003306?returnURL=http://linkinghub.elsevier.com/retrieve/pii/S0167779905003306?showall=true>

⁸ Cindy Bessey, Robert H. Devlin, N. Robin Liley and Carlo A. Biagi. "Reproductive Performance of Growth-Enhanced Transgenic Coho Salmon" *Transactions of the American Fisheries Society*. Vol. 133, Issue 5, 2004. Online: <http://www.tandfonline.com/doi/abs/10.1577/T04-010.1#.Ue7VztL2bYU>

⁹ Aqua Bounty Technologies, Inc. "Environmental Assessment" *supra*, page 57.

¹⁰ Aqua Bounty Technologies, Inc. "Environmental Assessment" *supra*, page 59.

¹¹ Aqua Bounty Technologies, Inc. "Environmental Assessment" *supra*, page 60.

¹² US Food and Drug Administration, "AquaAdvantage® Salmon Draft Environmental Assessment" 4 May 2012. Online: http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333102.pdf_page_98.

¹³ Bessey, *supra*.

¹⁴ Bessey, *supra*.

- with wild brown trout.¹⁵ The potential for mating with wild fish is not discussed at length in the AquaBounty FDA application, which states that, “because AquaAdvantage salmon are all sterile females, they will be unable to reproduce or contribute their genes to conspecifics”.¹⁶ However, as previously discussed, the induction of sterile females is not 100% effective.
- **GE fish could survive in the wild.** AquaBounty argues that if their GE fish eggs end up in waters surrounding their PEI facility, the water would be too salty to accommodate them. However, because PEI was home to wild Atlantic salmon, and still is home to some populations, it is possible that AquaBounty’s GE salmon could also survive there.¹⁷ There is also a chance that transgenic salmon will be able to withstand different temperatures than wild salmon because the two strains “would experience different selective forces should they ever enter natural ecosystems,” according to a study that compared transgenic and wild coho salmon.¹⁸ In its FDA application, AquaBounty assumes that wild and GE Atlantic salmon will react similarly to a natural environment, but the coho salmon study calls this assumption into question.¹⁹

II. Background information

II.1 The Government has a duty to monitor sustainability of development

Sustainable development is defined in the *Auditor General Act (AGA)* as being “development that meets the needs of the present without compromising the ability of future generations to meet their own needs.”²⁰ One of the functions of the Commissioner of the Environment and Sustainable Development, as stated in section 21.1 of the *AGA*, is to “provide sustainable development monitoring and the progress of ... departments towards sustainable development, which is a continually evolving concept based on the integration of social, economic and environmental concerns”.²¹ While eight GE food crops are currently grown and sold in North America, never has a genetically engineered food animal been available on the market anywhere in the world. If approved, AquaBounty’s AquaAdvantage salmon would be the first GE food animal. However, a project cannot be sustainable if the government does not understand the toxic risks it imposes on the environment, because it would be impossible to know how the project would affect future generations. Furthermore, because sustainable development is defined as a “continually evolving concept,” we cannot know what is sustainable without first

¹⁵ Krista B. Oke, Peter A.H. Westley, Darek T.R. Moreau and Ian A. Fleming. “Hybridization between genetically modified Atlantic salmon and wild brown trout reveals novel ecological interactions” *Proceedings of the Royal Society B: Biological Sciences* Vol. 280, No. 1763, 29 May 2013. Online: <http://rspb.royalsocietypublishing.org/content/280/1763/20131047.abstract>

¹⁶ Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 58.

¹⁷ Hansen, *supra*.

¹⁸ Mare Lohmus, L. Fredrik Sundstrom, Mats Bjorklund and Robert H. Devlin. “Genotype-temperature interaction in the regulation of development, growth and morphometrics in wild-type, and growth-hormone transgenic coho salmon” *PLoS One*, Vol. 5, Issue 4, 2010. Online: <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0009980>

¹⁹ Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 68-69.

²⁰ *Auditor General Act*, RSC 1985, c. A-17 [AGA], s. 2.

²¹ *AGA*, *supra* at s. 21.1.

identifying the “social, economic and environmental concerns” of Canadians through a transparent process that includes open consultation.

II.2 AquaBounty has developed a GE salmon for human consumption

AquaBounty is a Massachusetts-based company with a research facility in PEI, that has developed what it hopes will be the first GE food animal, initially to be sold in the United States.²² The technology was developed in Canada, and AquaBounty obtained the license to grow GE salmon from the University of Toronto and Memorial University in Newfoundland.²³ The new organism is trademarked the “AquAdvantage” salmon and is an Atlantic salmon was engineered with genetic material from ocean pout and a growth hormone gene from Chinook salmon, which trigger the fish to produce growth hormone at an earlier life stage compared to its wild counterparts.²⁴ AquaBounty claims that its farmed GE salmon are able to reach market size in half the time of natural Atlantic salmon.²⁵ In other words, the fish grow twice as quickly as natural populations of Atlantic salmon. AquaBounty also asserts that their GE salmon will require less feed to grow to market size when compared to wild salmon.²⁶

II.3 AquaBounty plans to grow GE salmon eggs in Canada

At this point, AquaBounty has requested approval to sell its GE salmon as food in the United States. The company is likely to be granted approval by the US FDA, which has released a “Preliminary finding of no significant impact”.²⁷ AquaBounty’s application to the FDA outlines a plan to grow the GE salmon eggs at facilities in Prince Edward Island, then ship the eggs to Panama where they will be raised and processed.²⁸ The current US application only proposes to send the processed fish, ready for the consumer market, to the US.²⁹ The company has, however, articulated in the media, an expanded business plan to produce the fish in other countries in the future, including the US.³⁰

²² AquaBounty Technologies “The Company” 2013. Online:

<http://www.aquabounty.com/company/company-292.aspx>

²³ AquaBounty Technologies, *supra* note 25.

²⁴ Hansen, *supra*; AquaBounty Technologies, “Frequently Asked Questions”, 2013. Online:

<http://www.aquabounty.com/technology/faq-297.aspx>

²⁵ AquaBounty Technologies “AquAdvantage® Fish”, Online:

<http://www.aquabounty.com/products/products-295.aspx>

²⁶ AquaBounty Technologies “AquAdvantage® Fish”, Online:

<http://www.aquabounty.com/products/products-295.aspx>

²⁷ US Food and Drug Administration, “For Public Comment – Preliminary Finding of No Significant Impact – AquAdvantage® Salmon” 4 May 2012. Online:

<http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333105.pdf>

²⁸ Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 10.

²⁹ Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 10.

³⁰ Bryan Walsh, “Frankenfish: Is GM Salmon a Vital Part of Our Future? Times. July 12, 2011

<http://content.time.com/time/health/article/0,8599,2082630,00.html>

AquaBounty claims that there is no risk to wild salmon populations because their AquAdvantage salmon will be grown in closed land-based facilities with redundant containment measures, which will “ensure that the probability of escape and establishment” is “essentially zero”.³¹ They also say that their AquAdvantage salmon populations will be sterile and all female, so that there will be no chance of reproducing in the wild should the fish manage to escape.³²

Question 1:

At this point, has AquaBounty requested permission from the Government of Canada to produce its AquAdvantage salmon eggs, and/or to grow out the AquAdvantage salmon themselves, in Prince Edward Island, or elsewhere in Canada?

Question 2:

- a) Has Environment Canada begun an assessment of the risks of growing AquaBounty’s GE salmon eggs and/or AquAdvantage salmon on Prince Edward Island, or elsewhere in Canada?**
- b) If yes, when will the results of the assessment be made available to the public?**

II.4 The risk assessment process for GE animals

There is no risk assessment process specific to GE aquatic organisms

In 2002, the Government of Canada responded to Petition No. 38A submitted by Greenpeace Canada entitled “Genetically engineered fish.” The government wrote that the Department of Fisheries and Oceans (DFO) had plans to “develop Regulations under the *Fisheries Act* for new biotechnology-derived aquatic organisms, which includes genetically engineered fish.”³³ The response stated that “until such time as the regulations are developed under the *Fisheries Act*, any request to develop genetically engineered fish for commercial purposes would be subject to the New Substances Notification (NSN) Regulations under the *Canadian Environmental Protection Act, 1999*.” A 2004 audit by the Commissioner of the Environment and Sustainable Development in the Office of the Auditor General found that DFO had made little progress in developing its own regulations and in response to a follow-up audit in 2007 DFO stated that it no longer intended to develop a policy and had instead decided that CEPA 1999 would provide the federal regulatory framework for GE fish.³⁴ As per a Memorandum of Understanding with the Department of Fisheries and Oceans, Environment Canada, and Health Canada, DFO will contribute to the regulation of

³¹ Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 71.

³² Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 58.

³³ Greenpeace Canada, “Genetically Engineered Fish”, Petition No. 38A, 22 November 2001. Online: http://www.oag-bvg.gc.ca/internet/English/pet_038A_e_28741.html

³⁴ Office of the Auditor General. 2008 March Status Report of the Commissioner of the Environment and Sustainable Development, Chapter 14—Previous Audits of Responses to Environmental Petitions—Genetically Engineered Fish http://www.oag-bvg.gc.ca/internet/English/parl_cesd_200803_14_e_30140.html

aquatic organism products of biotechnology, including genetically engineered fish, under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999) and the *New Substances Notification Regulations (Organisms)* [NSNR(O)].³⁵ Therefore, a risk assessment involving GE fish or eggs must comply with *CEPA* standards.

Question 3:

The AquaAdvantage salmon would be the first GE animal grown for human consumption and the first GE fish. What are the criteria for a risk assessment of this type of new, potentially toxic animate substance being produced in Canada? How does EC intend to ensure that the precedent for risk assessment of GE fish toxicity is strong?

CEPA requires the federal government to undertake a risk assessment

Before new substances are imported or manufactured in Canada, the Government of Canada requires that the appropriate governmental department complete a risk assessment to fulfill its commitments under *CEPA*.³⁶ Part 6 of *CEPA* addresses the use of animate products of biotechnology, and requires the party introducing new live organisms to Canada to provide the appropriate Minister with information about the organism prior to its introduction.³⁷ This allows the relevant government agency to do a proper toxic risk assessment before approving the use of the organism. Under *CEPA* s. 106(8), the third party may request that the Minister waive the requirements to provide information on various grounds.³⁸ If the Minister believes that “the person requesting the waiver is able to contain the living organism so as to satisfactorily protect the environment and human health” then a waiver may be granted.³⁹ The Minister may also waive the informational requirements if he/she does not believe the data is necessary to decide whether the substance is toxic or capable of becoming toxic, or if it is not practical for the third party to run the necessary tests to gain information.⁴⁰

Question 4:

- a) Has AquaBounty applied for a request under s. 106(8), asking that the Minister of the Environment waive its requirement to provide information under s. 106 because they claim their organisms will be contained and will not be a risk?**
- b) Will the government make these documents public? If not, why not?**

Therefore, unless a waiver has been granted under s. 106(8), AquaBounty must provide information about its product to the Government of Canada. This information would be in the form of a New Substances Notification (NSN) package sent to Environment Canada.⁴¹ The Minister of the Environment has a duty to complete an

³⁵ Office of the Auditor General. *supra*.

³⁶ *CEPA, supra*.

³⁷ *CEPA, supra*, s. 106(4).

³⁸ *CEPA, supra*, s. 106(8).

³⁹ *CEPA, supra*, s. 106(8)(b).

⁴⁰ *CEPA, supra*, s. 106(8)(a), (c).

⁴¹ *New Substances Notification Regulations (Organisms)*, SOR/2005-248 [NSNR(O)].

assessment within 120 days unless otherwise specified.⁴² The first step is for the Minister to determine if the new substance, in this case AquaBounty's GE salmon eggs, is toxic or capable of becoming toxic.⁴³

The Minister may disclose information despite a confidentiality request

Third parties providing data about a product may choose to make a request for confidentiality under s. 313 of *CEPA*. If the confidentiality request is made by AquaBounty, s. 314 holds that the Minister will not disclose the information provided by AquaBounty about its AquaAdvantage eggs unless the Minister makes a discretionary determination pursuant to sections 315, 316 or 317.

CEPA sections 315 and 317 both apply in AquaBounty's case. Under s. 315(1)(a), the Minister has the ability to disclose information in the interest of public health, safety and protection of the environment, despite the company having made a request for confidentiality. Section 315(1)(b) says that the information may be disclosed if the public interest outweighs the financial loss, competitive disadvantage, and/or damage to individual privacy resulting from the disclosure.⁴⁴ As discussed below, the consequences of allowing a genetically engineered animal organism to be grown in Canada are not well understood, but could have the potential to cause damage to the environment. Under such circumstances, it is reasonable for the Minister to disclose the information in the interest of environmental protection, despite any prospective confidentiality request made by AquaBounty.

Section 317(1) further states that the Minister may disclose information despite a request for confidentiality under s. 313 if the Minister determines that the disclosure would not be prohibited under s. 20 of the *Access to Information Act (AIA)*.⁴⁵ According to s. 20 of *AIA*, the government can disclose confidential scientific or technical information supplied by a third party if the disclosure would be in the public interest (based on health, safety and environmental protection) and if the public interest outweighs any financial loss to a third party.⁴⁶ Therefore, s. 20 of *AIA* reinforces s. 315 of *CEPA*, and the information provided confidentially by AquaBounty may be released to the public if the Minister determines, as we believe she should, that its disclosure would be in the public interest with respect to environmental protection and broader societal and ethical concerns about the introduction of GE animals into our food system.

Question 5:

Is our understanding of the risk assessment process, as outlined in the preceding sections, correct and complete? If our understanding of the process is inconsistent with the Government's, please explain.

What constitutes the "environment" under CEPA?

⁴² *CEPA, supra*, s. 114(2) and s. 106.

⁴³ *CEPA, supra*, s. 108.

⁴⁴ *CEPA, supra*, s. 315.

⁴⁵ *CEPA, supra*, s. 317(1).

⁴⁶ *Access to Information Act*, RSC 1985, c. A-1, s. 20(6).

Under *CEPA*, the Minister of the Environment may disclose confidential information in the interest of protecting the environment. However, what exactly is covered by the term “environment” within the scope of a *CEPA* toxicity risk assessment remains unclear. An *Access to Information* request revealed that Environment Canada has discussed whether a *CEPA* risk assessment requires “consideration of potential environmental effects not just within Canada but also to the global environment” or simply the risk to “Canada and OECD countries” and not when potentially toxic substances are being transported.⁴⁷ Because the production of AquaBounty’s GE salmon would be international, with eggs produced in Canada and shipped to Panama, and with the final product sent to the US, it is of considerable interest to know how Environment Canada defines the term “environment” in the context of a *CEPA* risk assessment.

In *R v Hydro Quebec*, the Supreme Court of Canada reminds us that, “broad wording is unavoidable in environmental protection legislation” because “the effect of requiring greater precision would be to frustrate the legislature in its attempt to protect the public against the dangers flowing from pollution”.⁴⁸ Thus it can be concluded that the word “environment” must be interpreted as broadly as necessary to effectively protect the public. *CEPA* defines “environment” as being “the components of the Earth” including “interacting natural systems”.⁴⁹ This definition does not suggest an observance of geopolitical boundaries. The Federal Court of Appeal stated in *Great Lakes United v Canada* that “environmental protection in Canada has moved incrementally towards greater inclusiveness”.⁵⁰ *CEPA*’s definition of “environment” is intentionally broad to allow for an interpretation that will effectively protect Canadian waters. It is reasonable for the government to consider international waters in its definition of “environment” because international waters and Canadian waters interact, which should be captured by the “interacting natural systems” mentioned in *CEPA*’s definition. .

Question 6:

- a) What is the “environment” that is contemplated in the context of a *CEPA* risk assessment?**
- b) How does Environment Canada evaluate the potential for, and the risks associated with, GE fish (including but not limited to salmon) migrating from another country into Canadian waters?**
- c) If EC approves the production of GE egg production in PEI, knowing the eggs will be exported and grown into salmon elsewhere: i) does it evaluate/accept the risk to international waters? ii) how does EC take into account the risk it is helping to create in another country when conducting a *CEPA* risk assessment? iii) On what policy basis is the acceptance of such a risk justified?**
- d) How does EC evaluate the risk that egg shipments from Canada to other countries will pose to Canadian and international waters? If this is not a part of the risk assessment, why not?**

⁴⁷ Protected B document, “Scope of Environmental Risk Assessment of Aqua Bounty GE Fish”, page 000005 of Access to Information, Previously Disclosed A-2010-01412.

⁴⁸ *R v Hydro-Quebec*, [1997] 3 SCR 213 at para 134.

⁴⁹ *CEPA*, *supra*, s. 3.

⁵⁰ *Great Lakes United v Canada (Minister of the Environment)* [2010] 2 FCR 515 at para 183.

The Canadian government has international legal obligations regarding the aquatic environment

Canada has adopted the United Nations Food and Agriculture Organization's *Code of Conduct for Responsible Fisheries* ("the Code"), and must live up to its obligations under the Code.⁵¹ Article 7.5.1 of the Code declares:

"States should apply the precautionary approach widely to conservation, management and exploitation of living aquatic resources in order to protect them and preserve the aquatic environment. The absence of adequate scientific information should not be used as a reason for postponing or failing to take conservation and management measures."⁵²

In other words, nations must be careful not to damage their aquatic resources by acting hastily in the absence of scientific data. Under Article 9.3.1, Canada has an obligation to

"...conserve genetic diversity and maintain integrity of aquatic communities and ecosystems by appropriate management. In particular, efforts should be undertaken to minimize harmful effects of introducing non-native species or genetically altered stocks used for aquaculture...into waters."⁵³

Question 7:

How will the Canadian risk assessment process regarding GE salmon fulfill the international obligations Canada has with respect to the *Code of Conduct of Responsible Fisheries*?

AquaBounty will be asking Canada to take on a potentially large risk for a small payoff

Several groups have argued there is a serious lack of data in AquaBounty's application to the US FDA.⁵⁴ Dr. Michael Hansen, senior scientist with the US group Consumers Union, stated in a presentation in PEI that AquaBounty did not make use of the most effective available techniques and so they were not able to obtain data for certain parameters.⁵⁵ For example, the level of growth hormone in the AquaAdvantage fish

⁵¹ Fisheries and Oceans Canada, "United Nations Food and Agriculture Organization Code of Conduct for Responsible Fishing Operations", 2012-06-08. Online: http://www.dfo-mpo.gc.ca/international/media/bk_fao-eng.htm

⁵² United Nations Food and Agriculture Organization, "Code of Conduct for Responsible Fisheries", Article 7.5.1. Online: <http://www.fao.org/docrep/005/v9878e/v9878e00.HTM>

⁵³ United Nations Food and Agriculture Organization, "Code of Conduct for Responsible Fisheries", Article 9.3.1. Online: <http://www.fao.org/docrep/005/v9878e/v9878e00.HTM>

⁵⁴ Tim Schwab (Food and Water Watch), "Is FDA Ready to Regulate the World's First Biotech Food Animal?" in Food and Drug Policy Forum, Volume 3, July 24, 2013; Michael Hansen, "Comments of Consumers Union to Genetically Engineered Salmon Food, and Drug Administration Docket No. FDA-201034-N-0001" Veterinary Medicine Advisory Committee Meeting, September 16, 2010.

⁵⁵ Hansen, *supra* note 6.

was not detectable based on the test AquaBounty used, even though a more sensitive test was available.⁵⁶ The US Fish and Wildlife Service has commented that the application did not properly account for risks during transport and the consequences of an escape.⁵⁷

AquaBounty did not adequately address potential consequences of their GE fish escaping because they assume the risk to be so low that it will not happen.⁵⁸ For example, AquaBounty states in their FDA application that because the risks of fish and egg escape are negligible “at and around the associated facilities [i.e. the facilities in PEI and Panama], there are no risks beyond these sites that would extend to the global commons.”⁵⁹ If AquaBounty makes a similarly data-deficient, low quality application to Environment Canada and it is approved, it would set a very low standard for GE food animal applications into the future.⁶⁰ Future companies could get away with submitting low-quality data, or virtually no data, endangering the environment and public safety. This concern is exacerbated by the prospect of a confidential *CEPA* risk assessment process that leaves Canadians in the dark about toxicity issues and their evaluation.

The societal benefits of developing GE salmon are minimal. Hansen argues that there is no evidence that the AquaAdvantage salmon grow as quickly as AquaBounty suggests/faster than salmon currently used in farming, because the company’s comparison is made against wild Atlantic salmon, not other farmed Atlantic salmon.⁶¹ Also, when compared with farmed salmon, AquaBounty’s own data shows that the GE salmon have a lower ratio of omega-3 to omega-6 fatty acids.⁶² Moreover, the Canadian Aquaculture Industry Alliance has stated that there is no market demand.⁶³ In fact, several US food suppliers have already stated that they will not sell GE salmon, if it is approved.⁶⁴ It is possible that more retailers will avoid selling a controversial product like GE salmon when other non-GE fish are available. The payoff of allowing GE salmon and/or GE salmon eggs to be grown in Canada does not outweigh the serious risks it presents to Canadian and international ecosystems.

⁵⁶ Hansen, *supra* note 6. See also: Michael Hansen, “Comments of Consumers Union to Genetically Engineered Salmon Food, and Drug Administration Docket No. FDA-201034-N-0001” Veterinary Medicine Advisory Committee Meeting, September 16, 2010.

⁵⁷ Michael Hansen, “Comments of Consumers Union on Department of Health and Human Services (HHS) Food and Drug Administration (FDA) Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon” Docket No. FDA-2011-N-0899. 2013-04-26. Online:

http://consumersunion.org/wpcontent/uploads/2013/04/GE_salmon_Comments_0413.pdf

⁵⁸ Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 69.

⁵⁹ Aqua Bounty Technologies, Inc. “Environmental Assessment” *supra*, page 69.

⁶⁰ Hansen, *supra* note 6.

⁶¹ Michael Hansen, “Comments of Consumers Union to Genetically Engineered Salmon Food, and Drug Administration Docket No. FDA-201034-N-0001” Veterinary Medicine Advisory Committee Meeting, September 16, 2010.

⁶² Hansen, *supra* note 6. See also “Salmobreed challenges GMO salmon” in Newsletter from SalmoBreed, Year 7, nr.5, November 2011. Online: http://www.salmobreed.no/newsletters/en/newsletter_5_2011.pdf

⁶³ Angela Johnston, “Genetically engineered salmon still seem fishy to Canadians”. Nourish, November 8, 2011. Online: <http://nourishottawa.wordpress.com/2011/11/08/genetically-engineered-salmon-still-seem-fishy-to-canadians/>

⁶⁴ Andrew Pollack, “Grocers won’t sell altered fish, groups say” *New York Times*, March 20, 2013. Online: http://www.nytimes.com/2013/03/20/business/grocery-chains-pledge-not-to-sell-modified-salmon.html?_r=0

Question 8:

- a) How does Environment Canada apply a precautionary approach in the context of a GE salmon risk assessment?
- b) A “failure-mode” analysis risk assessment requires evaluators to consider the consequences of an escape of GE eggs/fish. In its environmental risk assessment, the US FDA assumed there would be no escape, but scientists insist there can be no 100% effective confinement. Would Environment Canada evaluate a risk assessment that is based on an assertion that there is no chance of the eggs escaping into the environment? How would Environment Canada go about assessing a “low probability, high risk” prospect such as this? If there is a lack of data, will Environment Canada request that AquaBounty conduct further research and provide more data before a decision is made regarding AquaBounty’s ability to grow its eggs and/or AquaAdvantage salmon in Canada? Will such data be made public?
- c) How does EC evaluate the overall environmental benefit or social contribution of such a project and weigh this against environmental risk?

Question 9:

It was recently determined that GE salmon are able to transmit transgenes to offspring when crossed with wild brown trout.⁶⁵ If this data is not presented in AquaBounty’s application to EC, will EC request that AquaBounty provide the data? If not, how will EC rationalize its decision based on an incomplete application?

III. Federal departments and agencies that need to respond

Environment Canada
Department of Fisheries and Oceans

IV. Contact information

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⁶⁵ Oke, *supra*.