Food & Water Watch • 1616 P St. NW, Suite 300 • Washington, DC 20036
T +202.683.2500 • F +202.683.2501 • www.foodandwaterwatch.org

Sean McKessy, Chief
Office of the Whistleblower
Office of Enforcement
U.S. Securities and Exchange Commission
100 F Street NE
Mail Stop 5971
Washington, DC 20549-5631

July 28, 2015

Dear Mr. McKessy:

This letter serves as a follow-up to several letters we sent your office last year regarding omissions, errors and false statements found in Form 10 regulatory filings submitted to the SEC by AquaBounty Technologies.

We are writing today to inform the SEC of additional errors that have come to light with the public release of an environmental assessment drafted by the Canadian Department of Fisheries and Oceans (DFO). This government risk assessment contains scientific data and risk determinations that conflict with or contradict the statements AquaBounty Technologies has made concerning its only commercial product, AquAdvantage Salmon (AAS), putting investors at risk.

To the great detriment and endangerment of investors, AquaBounty routinely inflates and exaggerates the benefits and commercial potential of AAS and routinely downplays or omits unfavorable information, data and facts. By failing to provide relevant business information regarding the company's operations, liabilities and risks, AquaBounty puts consumers at great financial risk.

Yet AquaBounty's most recent annual report states that it believes it has fulfilled its regulatory requirements with the SEC, stating that "[t]he Company has filed a registration

statement with the SEC and received no further comments from the Commission" and "hopes to be able to fulfill the criteria for listing on NASDAQ in the coming months."[1]

We respectfully ask the SEC to compel AquaBounty to revise its Form 10 filing to correct its false statements and include an adequate disclosure and discussion of the risk factors facing its AquAdvantage Salmon product. AquaBounty's pattern of distortions, half-truths and omissions about AAS indicate that the company cannot or will not provide potential investors with accurate, honest and complete information they need to make sound investment decisions.

**The Canadian DFO Risk Assessment**

Though published in July 2013, the DFO draft risk assessment only became public in recent years through an ongoing legal case in Canada. The DFO risk assessment reveals that Canadian scientists have made determinations about AAS that are often at odds with the information AquaBounty has presented in Form 10 submissions.

1) The DFO found that there is no scientific evidence demonstrating that AAS do not grow larger than conventional Atlantic salmon.[2] This statement openly contradicts AquaBounty's statement in its Form 10 filing that "The AquAdvantage® Salmon do not reach a larger final size than their traditional counterparts, but by accelerating growth in the early stages of rearing, these fish can reach a marketable size sooner."[3]

The lack of scientific evidence to support this assertion raises a welter of issues related to the commercial and regulatory success of AAS. New risk questions emerge regarding environmental impacts of potential escaped AAS, as larger-than-normal salmon may have expanded diets, for example, and, hence, greater ecological impacts. These concerns may delay or derail the Food and Drug Administration's (FDA) ongoing environmental risk assessment,

[1] AquaBounty Technologies. Annual report 2014. July 2015 at 4, 5 (attached as Exhibit A).
[2] Department of Fisheries and Oceans Canada, Office of Aquatic Biotechnology. "Environmental and indirect human health risk assessment of the AquAdvantage Salmon." Draft in Revision. July 2, 2013 at 84 (attached as Exhibit B).
[3] AquaBounty Technologies. SEC filing Form 10. November 18, 2014 at 7 (attached as Exhibit C).

which is critical to the commercial success of AAS.

There are other commercial considerations for investors, as academics have noted that "[a]n overall large size would indeed foster the stigma of abnormality associated with the GE fish."[4] Media articles about AAS very frequently cite the pejorative "frankenfish" descriptor, a reference to the fictional, monster-like character Frankenstein.[5] If AAS, in fact, does grow larger than normal Atlantic salmon, AquaBounty may experience heightened consumer resistance to AAS, with the public viewing it as an unnatural and undesirable food source.

The commercial importance of this point has not been lost on AquaBounty, and academics have commented the company's "constant need to reassure the public of the fact the actual size of its trademarked salmon is not out of proportion when maturing and entering into the market."[6] The company frequently transmits this message to journalists, stressing that AAS grows faster—but not bigger—than normal salmon.[7] As noted, the company also stresses this point to investors in its Form 10 filings. Clearly, the company believes that the ultimate size of AAS is a salient and relevant commercial dimension of the success of AAS.

As such, the SEC should compel AquaBounty to revise its Form 10 to say that independent government scientists have stated that there is no scientific evidence demonstrating that AAS do not grow larger than conventional Atlantic salmon. More importantly, AquaBounty must inform investors that if AAS are found to grow larger than conventional salmon, it could result in greatly increased consumer resistance as well as additional regulatory scrutiny.

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[4] Benessia, Alice and Giuseppe Barbiero. "The impact of genetically modified salmon: from risk assessment to quality evaluation." *Visions for Sustainability*. June 21, 2015 at 43 (attached as Exhibit D).

[5] Derbyshire, David. "How long before YOU are eating frankenfish." *Daily Mail*. December 2, 2013; Perrone, Matthew. "Aquabounty, GMO salmon company, struggling to stay afloat." *Associated Press*. December 4, 2012; Nowak, Peter. "Making sense of 'Frankenfish.'" *CBC News*. October 25, 2010; Lupkin, Sydney. "Genetically engineered salmon nears FDA approval." *Good Morning America*. ABC News. December 28, 2012 (all attached as Exhibit E).

[6] Exhibit D at 43.

[7] Pollock, Andrew. "Genetically altered salmon get closer to the table." *New York Times*. June 25, 2010; Zajac, Andrew. "Genetically engineered salmon under FDA consideration." *Chicago Tribune*. August 26, 2010 (all attached as Exhibit F).

2) The DFO review includes new data showing that AAS are exhibiting dramatically diminished growth rates from what AquaBounty has claimed.[8] In its Form 10 filings, AquaBounty asserts that AAS "can grow to marketable size in about half the time of traditional farmed Atlantic salmon" and that AAS production "can reduce farming time from 28 to 36 months to 18 to 20 months."[9]

The only publicly available source for this assertion is an AquaBounty graph that the company claims is based on empirical data and which the company has presented to the FDA.[10] This graph shows AAS reach close to 4 kilograms in size at 20 months, while "standard salmon" reach only a little more than 1 kilogram at 20 months and take 28 months to reach 4 kilograms.[11]

However, the DFO risk assessment indicates that AAS, when grown in a commercial facility, reach around 2 kilograms at 20 months of age, not 4 kilograms.[12] And the "standard salmon" reach 1.4 kilograms not 1 kilograms. Hence, AquaBounty's statements in its Form 10 filings have greatly inflated the growth rates of AAS and grossly deflated the growth rates of standard salmon. AquaBounty needs to be clear that the only publicly available data on the growth rates of AAS in a commercial-scale setting indicate that extremely minimal growth-rate advantage over the "standard salmon" it used it its growth-rate trials. The company must also remove its hyperbolic rhetoric about AAS reaching market weight in half the time as standard salmon.

As importantly, AquaBounty must also be clear with investors that AAS, almost certainly, will offer no growth-rate advantage over Atlantic salmon grown in competing commercial aquaculture facilities. As noted in previous complaint letter that Food & Water

[8] Exhibit B at 125-129.
[9] Exhibit C at 7.
[10] Stotish, Ron. AquaBounty Technologies. PowerPoint presentation to the FDA Veterinary Medicine Advisory Committee. September 20, 2010; AquaBounty Technologies. Products. Available at http://aquabounty.com/company/products/ and on file. Accessed July 14, 2015. (Attached as Exhibit G).
[11] *Ibid.*
[12] Exhibit B at 129.

Watch has submitted to the SEC, the "standard salmon" used by AquaBounty in its growth-rate trials grow far slower than commercially raised Atlantic salmon, meaning AquaBounty's comparisons are highly misleading. A variety of growers in the salmon industry—using both in-land and offshore production models—are producing standard, unmodified Atlantic salmon at the rates surpassing AAS.[13] One commercial-scale, in-land aquaculture facility (very similar to AquaBounty's) has been able to grow standard Atlantic salmon to 4.3 kilograms in as few as 22 months—about twice the size that AAS grows in AquaBounty's commercial facility during this same time period, according to DFO's data.[14] The overwhelming evidence now clearly indicates that the growth-rate claims AquaBounty has made in its Form 10 filings are grossly distorted, giving investors the impression that AAS will have a competitive advantage in the commercial marketplace based on faster growth rates. The commercial potential of AAS is almost entirely wrapped up in the product's principal benefit claim of fast growth rates, so AquaBounty's misleading growth-rate information puts investors at tremendous risk.

AquaBounty must also inform investors that new evidence of diminished growth rates should have an impact on the company's regulatory application with the Food and Drug Administration—because the application's only benefit claim was that AAS can grow more quickly than normal Atlantic salmon.[15] In light of the new evidence showing AAS cannot grow more quickly than normal salmon, which confirms a substantial body of exist evidence, FDA could delay or deny AquaBounty's regulatory application based on the new evidence. Investors need this information.

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[13] Steven Summerfelt et al., Freshwater Institute, Research and Developments in Closed Containment Aquaculture at the Freshwater Institute, Presentation to the Multi-State Aquaculture Forum (January 25 to 26, 2013) (attached as Exhibit H); Correspondence from Freshwater Institute (time is given from first feeding to mirror the way AquaBounty reports its growth rates. First feeding for Freshwater Institute fish was on day 34 and first premium harvest was on day 679); Press Release, Salmobreed, Salmobreed Challenges GMO Salmon (November 2011) (attached as Exhibit I).

[14] *See* Exhibit H and correspondence from Freshwater Institute, *supra* n.13.

[15] Food and Drug Administration Center for Veterinary Medicine. Veterinary Medicine Advisory Committee. "Briefing Packet: AquAdvantage Salmon." September 20, 2010 at 133-135 (attached as Exhibit J).

3) Scientists at the DFO determined that AAS are more susceptible to a type of disease-causing bacteria than are domesticated salmon, a new scientific determination that has great ramifications for the commercial potential and regulatory approval of this product.

DFO scientists concluded with "reasonable certainty that AAS is more susceptible to *A. salmonicida* than domesticated comparators…"[16] *Aeromonas salmonicida* is a bacteria that causes furunculosis in salmon, a common disease in aquaculture.[17] The DFO review also noted "it is highly certain that AAS is highly susceptible to [Infectious Salmon Anemia virus],"[18] and that "we have no data on the relative susceptibility of AAS to other disease agents of environmental significance [compared to wild Atlantic salmon]."[19]

AquaBounty acknowledges that disease is a crucial issue in commercial aquaculture in its Form 10 filing.[20] Additionally, the president of AquaBounty Technologies, in a 2010 presentation to the Food and Drug Administration's Veterinary Medicine Advisory Committee, noted at length how disease can affect commercial aquaculture production of Atlantic salmon.[21] Therefore AAS's heightened susceptibility to disease clearly presents a significant potential commercial liability, which could compromise the success of AAS and the profitability of AquaBounty. The company has a clear responsibility to inform investors of the significant—and, to some extent, unique—disease risks that commercial producers of AAS will face, including stating clearly that government scientists have determined AAS have heightened disease susceptibility.

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[16] Exhibit B at 99.
[17] FDA CVM. New animal drug application 125-933. Finding of no significant impact for Romet-30 medicated premix for salmonid fish (trout and salmon). September 28, 1984; Cruz, Patricia et al. "Use of probiotics in aquaculture." *ISRN Microbiology*. October 16, 2012 at "Commercial preparations." (attached as Exhibit M).
[18] Exhibit B at 99.
[19] *Ibid.* at 305.
[20] Exhibit C at 6-7.
[21] Food and Drug Administration. Transcript of Veterinary Medicine Advisory Committee Meeting on AquAdvantage Salmon. Monday, September 20, 2010 at 101 (attached as Exhibit K).

Troublingly, AquaBounty has never disclosed this information to investors. This confirms a disturbing pattern of failing to disclose relevant business information that is unfavorable to the company. AquaBounty's Form 10 asserts AAS production actually offer an economic benefit to aquaculture associated with "more effective control of disease,"[22] and "[t]he closed, contained, land-based production systems proposed for the grow-out of AquAdvantage® Salmon are less susceptible, though not immune, to the same disease-related pressures because this type of culture system is isolated from the environment."[23] But as DFO scientists have noted, AAS exhibit higher, not lower susceptibility to disease. Moreover, AquaBounty has already experienced one major disease outbreak at one of its closed, land-based production facilities.[24] Given the company's difficult history controlling disease and the new scientific findings about increase disease susceptibility, AquaBounty's statements are extremely misleading and put investors at risk.

AquaBounty has also failed to disclose to investors that these disease susceptibility findings also raise environmental, animal health and public health concerns that should have bearing on the regulatory approval of this product, vital to its commercial success. The FDA did not examine the issue of furunculosis susceptibility to the same extent as DFO, and the agency, now aware of the DFO findings, should be revisiting its risk assessment of AAS on this point, which could delay or derail AquaBounty's pending regulatory application.

4) The DFO found that AquaBounty's ongoing breeding program is producing AAS with a variable phenotype, including inconsistent growth rates, raising serious questions about the performance of AAS, which has bearing on the commercial and regulatory success of AAS.

[22] Exhibit C at 6-7.
[23] *Ibid.* at 7.
[24] Food and Drug Administration Center for Veterinary Medicine. "Draft Environmental Assessment for AquAdvantage® Salmon." May 4, 2012 at 33, 43-44 (attached as Exhibit L).

The DFO assessment notes variability in the performance of AAS, which indicates the gene construct does not appear to be presenting a predictable, consistent phenotype.[25] DFO scientists noted that there "is limited data on the stability of accelerated growth over generations . . . ," that "there appears to be noteworthy variation in growth rate of AAS fish between generations[]"and that "further work is required to determine the phenotypic stability of high growth in AAS fish across standard culture conditions."[26] DFO concluded that, "[t]aken together, size and growth rate appears to vary to a degree between and within generations in AAS fish than in non-transgenic fish, although further work is required to confirm this."[27]

AquaBounty's stated business plan is to "produce and sell AquAdvantage® Salmon eggs for commercial production."[28] If AAS perform in an inconsistent manner in commercial aquaculture facilities, this could have major negative repercussions on the commercial success of AAS.

Once again, this point also has bearing on the regulatory success of AAS, as the FDA articulates that it has in place a specific durability assessment "to ensure that future animals in commerce are equivalent to those evaluated for safety and effectiveness during the pre-market review."[29] FDA has long noted its legal requirement to establish that genetically engineered animals like AAS exhibit a durable phenotype and genotype, stating that the durability assessment:

> *addresses some additional components of the manufacturing requirements codified in 21 CFR 514.1(b)(5). It is intended to provide information to ensure that the rDNA construct in the GE animal resulting from the specific transformation event and defining (identifying) the GE animal being evaluated is*

[25] Exhibit B at 38.
[26] *Ibid.* at 123-125.
[27] *Ibid.* at 125.
[28] Exhibit C at 7.
[29] Exhibit K at 265, 267.

*durable—that there is a reasonable expectation that the rDNA construct is stably inherited, and the phenotype is consistent and predictable.*[30]

The uncertainties that DFO notes regarding the phenotypic durability of AAS has great bearing on the success of AAS and the commercial profitability of AquaBounty. Investors need this information.

**Conclusion**

In light of AquaBounty's pattern of misleading and deceptive statements about its principal commercial product, which put investors at great financial risk, we respectfully ask the SEC to reject AquaBounty's Form 10 filing, until the company corrects its false statements to include an adequate disclosure and discussion of the risk factors facing its AquAdvantage Salmon product.

We are happy to talk to you further about this important matter. Please do not hesitate to call FWW's Senior Staff Attorney, Zach Corrigan at (202) 683-2451, if you have any questions.

Sincerely,

Wenonah Hauter
Executive Director

[30] Food and Drug Administration. Guidance 187 for Industry Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs. January 15, 2009 at 22 (attached as Exhibit N).