Summary Responses to Public Comments on the November 2022 AquAdvantage Salmon Draft Amended Environmental Assessment

I. General Overview of Status

On November 16, 2022, the Food and Drug Administration (FDA, the agency, or we) released a Draft Amended Environmental Assessment (EA) for public comment in response to an order by the United States (U.S.) District Court, Northern District of California, issued on November 5, 2020.[1] A public meeting related to the release of the draft amended EA also occurred on December 15, 2022, where FDA received oral comments from the public concerning the draft amended EA. The draft amended EA contained the agency's preliminary amended assessment of the potential for significant impacts on the human environment of the U.S. from the 2015 FDA approval of a New Animal Drug Application (NADA) 141-454 concerning AquAdvantage Salmon[2] (AAS), as required by the National Environmental Policy Act (NEPA) [42 USC § 4321 et seq] and FDA's environmental impact considerations regulations [21 CFR Part 25]. The draft amended EA expanded the original analysis in the 2015 EA to include a comprehensive and exhaustive analysis of the potential harm to the U.S. environment, including endangered Atlantic salmon, in the unlikely event that AAS and AquAdvantage broodstock (collectively referred to as "ABT salmon") escaped, survived and established in the natural environment. This assessment evaluated all currently operating and future planned changes to facilities on Prince Edward Island (PEI), Canada. This document was open for public comment for 60 days; the comment period closed on January 17, 2023.

FDA's Dockets Branch received and logged in comments according to the date of receipt. Once entered into the Docket's system, all comments were forwarded to the staff of FDA's Center for Veterinary Medicine (CVM or the Center) for review. In this document, we provide a general summary of public comments we received that are relevant to the draft amended EA, and our response to those comments.

Comments are available for the public to review at regulations.gov docket number [FDA-2022-N-2672]. Alternatively, comments may be viewed at Dockets Management, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, or by calling 240-402-7500 for assistance in finding a particular comment.

The agency thanks the public for the time and effort they put into providing these comments.

On September 27, 2024, FDA issued a final amended EA and final amended Finding of No Significant Impact (FONSI). Unless specified otherwise, references to the amended EA or amended FONSI refer to the final documents.

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[1] *Inst. for Fisheries Res. v. U.S. Food and Drug Admin.*, 499 F. Supp. 3d 657 (N.D. Cal. 2020)

[2] The NADA is for approval of a single copy of the α-form of the *opAFP-GHc2* recombinant DNA construct at the α-locus in the EO-1α line of triploid, all-female Atlantic salmon under the conditions of use specified in the application. For ease of reference, this document generally refers to the application as being for approval of the AAS.

II. Overview of Comments

According to the Dockets Branch, the FDA Docket [FDA-2022-N-2672] logged 1,744 comments as of the close of the comment period. Most of these comments were form letters (what Dockets logged as a single comment under one submission may have contained multiple copies of the same form letter) or expressed general concern or opposition to the approval of AAS or approvals of intentional genomic alterations (IGA) in animals in general. Other comments expressed a favorable opinion about the draft amended EA noting its thoroughness.

Of the 1,744 comments submitted to the Docket, the agency determined that approximately 17 specific comments from nearly 14 different organizations and individuals were responsive to the Federal Register notice requesting comments on the draft amended EA and were substantive in nature. We considered the comments responsive because they specifically addressed components of the draft amended EA, and substantive because they contained specific suggestions, criticisms, or positive substantiations of the agency's analysis or conclusions. FDA has summarized and responded to these comments by topic in the body of this document.

Several of the substantive comments also included suggestions or criticisms not specifically relevant to the draft amended EA but were relevant to other aspects of the environmental review of the NADA, including regarding production at the Albany, Indiana facility. Although not relevant to the draft amended EA or 2020 Court order, we have addressed these substantive comments in our responses in this document because the public may have interest in some of the issues raised. However, comments regarding human food safety and assumed future business plans of AquaBounty Technologies, Inc. (ABT) (e.g., their announced intention to construct a facility in Pioneer, Ohio) will not be addressed at this time.

Comments were submitted by individual scientists, individual technology providers, professional associations, individual consumers, and consumer and environmental advocacy groups.

III. Comment Summaries

The following is a summary of the substantive comments on the draft amended EA that FDA received during the December 15, 2022, public meeting and the public comment period that ended January 17, 2023.

1) Impacts on Wild Salmon around PEI and Maine

Comment Summary: Several comments stated that the draft amended EA fails to discuss the potential impacts on the increasing Atlantic salmon population around PEI and eastern Canada, as well as potential impacts on Maine's wild Atlantic salmon populations.

Response: In Section 9.3 of the amended EA, FDA identified all potential harms that could occur from the establishment and/or presence of ABT salmon in Maine and determined the likelihood of harms occurring assuming exposure occurs. Using this information, along with an evaluation of the likelihood of exposure from Section 9.2 of the amended EA, FDA re-evaluated risk of significant impacts occurring in the U.S. environment under NEPA (Section 9.4 of the amended EA) and whether the action would result in effects on endangered Atlantic salmon and their critical habitat in the U.S.

under the Endangered Species Act (ESA) (Appendix I of the amended EA). Based on this assessment, FDA has concluded that this action will not have a significant impact on the quality of the U.S. environment. FDA also concluded, and the National Marine Fisheries Service (NMFS) concurred, that this action may affect but is not likely to adversely affect U.S. populations of endangered Atlantic salmon or their critical habitat under Section 7 of the ESA.

FDA only evaluates potential impacts to the U.S. environment as required under NEPA. The Canadian government evaluates potential impacts to the Canadian environment. See footnotes 25 and 26 of the amended EA for additional reasoning.

2) Containment

Specific concerns regarding containment at the PEI facilities were categorized and are addressed in responses below. It is important to emphasize that, in the approximately 27 years from when the first facility opened to date, no fish have escaped from either of ABT's PEI facilities.

a) Factors Leading to Escape

Comment Summary: Several comments stated that the draft amended EA did not thoroughly assess the factors that may lead to escape, including human error and disposal of fish.

Response: FDA conducted a thorough analysis of the factors that may lead to the escape of ABT salmon, including due to human error and disposal of fish, and determined the likelihood of escape occurring is negligible in Section 9.2.1 of the amended EA.

b) Adequacy of Containment Measures

Comment Summary: Some comments questioned the adequacy and reliability of the containment measures at ABT's facilities and FDA's evaluation of those measures in the draft amended EA. Several commenters stated that FDA should conduct a quantitative failure mode analysis.

Response: ABT has provided FDA with detailed schematics and operating practices to demonstrate that the physical containment systems in the PEI facilities are more than adequate to provide physical containment of all life stages of ABT salmon. ABT has put into place security measures at both facilities to prevent unauthorized access, control movement of authorized personnel, and prevent access by predators. In addition, there are Standard Operating Procedures (SOPs) in place that describe the maintenance of all physical containment measures, as well as every other significant activity that occurs at each facility. FDA has verified and validated the physical containment measures (including presence and operational integrity), security and procedures used at the PEI facilities during several inspections and site visits. The most recent inspections of these facilities by FDA occurred in June 2023. This information is provided in detail in the 2015

EA for the Bay Fortune facility[3], the 2019 EA for the Rollo Bay facility[4], as well as in the current amended EA (see Sections 7.2, 7.3, and 9.2.1.1, and Appendices C and D).

ABT must maintain these containment measures as described in the application, ensuring that they are reliable. Because the containment was part of the NADA approval as a condition of use, it is legally enforceable under the Federal Food, Drug and Cosmetic Act (FD&C Act) (see additional details on enforcement under Comment 2.c below).

Regarding the need for FDA to conduct a failure mode analysis on the containment at the PEI facilities, FDA has relied on the failure mode analysis conducted by Fisheries and Oceans Canada (DFO) as part of their environmental risk assessment for ABT salmon. A description of the failure mode analysis for each facility is summarized in the amended EA at Section 9.2.1.1.a. Thus, there is no need for FDA to do a separate failure mode analysis. Further, the Court ruled in FDA's favor on this issue in the 2020 opinion, implicitly rejecting the requirement of failure mode analysis and finding that, because of the central aspect of minimizing the risk of escape in the application and FDA approval, "the agency's safety determination was not arbitrary and capricious."[5]

c) Enforcement of Containment

Comment Summary: One commenter states that containment measures outlined in the amended EA are by definition mitigation measures to prevent harms from escaped ABT salmon and it is unclear how FDA would enforce the containment measures to ensure their continuous efficacy.

Response: Containment is not a mitigation for this action. In the case of the AAS NADA, the action subject to NEPA review was approval of the NADA, including the conditions as proposed in the NADA and as included as conditions of the FDA approval. ABT must maintain their containment measures as described in their application. Under the FD&C Act, a new animal drug that does not comply with its approved application is "unsafe" and an unsafe new animal drug is "adulterated." 21 U.S.C. §§ 360b(a); 351(a). The FD&C Act also deems adulterated any food that contains an unsafe new animal drug or a "conversion product thereof." 21 U.S.C. § 342(a)(2)(C)(ii). FDA may take enforcement action against adulterated drugs and foods, including refusing admission to products that appear to be adulterated. If AAS did not comply with the conditions under the NADA approval it would be adulterated under these provisions and subject to FDA's enforcement action. It is therefore incumbent on the company to maintain their facilities. The Court agreed that containment is not a mitigation and is enforceable under the FD&C Act in the 2020 opinion, stating, "Arguments that the FDA improperly relied on mitigation strategies also fall short, because the agency did nothing but rely on the enforceable conditions of approval embedded in the application."[6]

[3] https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadEA/2243
[4] https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadEA/2264
[5] *Inst. for Fisheries Res.*, 499 F. Supp. 3d at 669.
[6] *Id.*, 499 F. Supp. 3d at 667 n.4.

d) Reports of Fish Escaping from Land-based Facilities, Including GE Fish in Brazil

Comment Summary: Some comments discuss fish escaping land-based facilities, including an example of the release of genetically engineered (GE) fish into natural waters in Brazil.[7]

Response: Reports of fish escaping from land-based facilities are not relevant to the analysis under the amended EA as the ABT facilities must adhere to strict physical containment measures (such as 4-10 levels of containment) that are not common in most land-based aquaculture facilities. For example, typical land-based aquaculture facilities may only employ top netting and a drain screen as containment. The report one commenter cited in a February 2022 article from Magalhães *et al.* (2002) regarding the establishment of transgenic fluorescent zebrafish[8] in the wild in Brazil is also not relevant to the amended EA analysis. These transgenic fish likely escaped from a local aquaculture production facility raising these fish and selling them illegally without any regulatory oversight relating to production and containment. Because the containment measures at the facilities in Brazil is unknown, this information is not relevant to AAS raised at ABT's facility and there is no need to consider this information in the analysis in the amended EA.

3) Disclosure of Fish Mortality Statistics, Use of Drugs and Other Chemicals, and Diseases at the PEI facilities

a) Fish Mortality Statistics

Comment Summary: Several comments stated that the fish mortality statistics for ABT salmon should be discussed in the amended EA and comprehensively assessed.

Response: Target animal safety is evaluated under the FD&C Act (not NEPA) and, therefore, was not included in the amended EA. The Court found FDA had adequately addressed "safety," including target animal safety, under the FD&C Act; "the only environmental effects at issue in the case relate to the effect of the AquAdvantage salmon on normal salmon."[9] Remand was limited to two aspects of the EA that do not implicate safety to ABT salmon themselves at PEI or U.S. facilities. FDA's 2015 Freedom of Information (FOI) Summary[10] includes an extensive discussion on mortality of ABT salmon.

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[7] Magalhães, A.L.B., Brito, M.F.G. and Silva, L.G.M. 2022. The fluorescent introduction has begun in the southern hemisphere: presence and life-history strategies of the transgenic zebrafish *Danio rerio* (*Cypriniformes: Danionidae*) in Brazil. *Studies on Neotropical Fauna and Environment*, pp.1-13.

[8] It is important to note that the commenter erroneously referred to the fish as GloFish, a commercial brand of GE fluorescent aquarium fish. GloFish is banned from sale in Brazil; therefore, it is unlikely that these fish were GloFish. (https://www.science.org/content/article/transgenic-glowing-fish-invades-brazilian-streams#:~:text=Despite%20Brazil's%20ban%20on%20sales,and%20northeast%20Brazil%20in%202020)

[9] *Inst. for Fisheries Res.*, 499 F. Supp. 3d at 664 n.2.

[10] https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadFoi/2541

b) Use of Drugs and Other Chemicals

Comment Summary: Several commenters stated that the draft assessment fails to include information on the use of drugs (antibiotics, antiparasitics, hormones), antivirals, pesticides, and fungicides in the production process at ABT facilities. The assessment should include an evaluation on release of these chemicals in the facility wastewater and potential impacts to the surrounding environment and wild salmon, as well as potential impacts on the health of consumers that ingest chemical residues in salmon.

Response: Drug use at the PEI facilities was included in the amended EA at Sections 7.5.1.2 and 7.5.1.3. There are no food safety concerns relating to drug residues in AAS grown in the PEI facilities and consumed by humans because no adult AAS are imported from the PEI facilities to the U.S. for food consumption. Potential impacts of drugs and pesticides in facility wastewater is discussed under Comment 10 below.

c) Diseases (Pathogens and Parasites) at the PEI facilities

Comment Summary: Several commenters stated that the amended EA should include a complete disclosure of diseases present in ABT salmon and the PEI facilities. FDA should consider the susceptibility and exposure of ABT salmon to disease, and the potential impacts on wild salmon due to transmission of known or new diseases from ABT salmon and the PEI facilities.

Response: The amended EA discloses all pathogens and/or parasites[11] recorded at the PEI facilities while owned by ABT. In addition, information and analyses related to exposure and transmission of pathogens and/or parasites from ABT salmon and the PEI facilities have been addressed at length in the amended EA in Sections 7.5, 8.2.2, 9.2.4, 9.3.1.5, 9.3.2.2.e. and 9.4.1.3.

4) Economic and Social/Cultural Impacts

Comment Summary: Several comments stated that the amended EA should have considered economic, social, and cultural impacts of approval of the NADA. Some commenters raised concerns about Indian Tribal rights with respect to wild salmon and the potential impacts that ABT salmon could have on wild salmon populations. A comment stated FDA must consult with Indian tribal governments under Executive Order 13175, while other commenters suggested FDA should consider Indigenous and traditional ecological knowledge in assessments that may not be captured in scientific literature.

Response: Because a finding of a likely significant impact on the physical environment is a condition precedent to further analysis of impacts in an EIS and because FDA has determined that its action in approving the NADA under the specified conditions of use

[11] Disease is the potential harm due to infection with a pathogen and/or parasite. In the amended EA, the term “pathogen” encompasses a bacterium, virus, or other microorganism, and can result in disease that can ultimately harm endangered Atlantic salmon (e.g., mortality). Parasites can function as pathogens when they are the direct cause of disease but can also act as vectors for disease by spreading other pathogens.

will not affect the physical environment of the U.S., further analysis of impacts, including socioeconomic impacts, in an EIS was not required.

With regards to Executive Order 13175 and consultation with Indigenous tribes, see Comments 11 and 12 of FDA's Response to Public Comments published for the 2015 EA.[12]

5) Scope of Alternatives

Comment Summary: One commenter asserted that the alternatives section of the EA was overly narrow and should have considered at least the "no action" alternative. Some commenters suggested additional alternatives not evaluated in the amended EA.

Response: FDA reviews a new animal drug that is the subject of an NADA under the conditions of use the applicant describes in the NADA. In this case, the action, the 2015 NADA approval, has already occurred and the court did not vacate it. FDA evaluated the "no action" alternative in the original 2015 EA, which was the only one available to it based on statutory constraints. In light of the public comments, FDA revised Section 5 of the amended EA to include feasible alternatives given the NADA approval has occurred. The only alternatives in the present context would be rescission or vacatur of the approval based on environmental concerns described in the amended EA that are both hypothetical and speculative. Neither is a preferred alternative for the reasons FDA stated in rejecting the original "no action" alternative in the 2015 EA. Additional alternatives suggested in the comments are not "reasonable" or feasible given that FDA only has authority to evaluate the action as proposed by the applicant (*i.e.*, FDA does not have authority to dictate the business practices of the applicants). Therefore, FDA continues to consider its original approval the preferred alternative.

6) Evaluation of Significance Factors

Comment Summary: One commenter stated that FDA failed to fully evaluate the significance factors when determining whether ABT salmon may have significant impacts necessitating an EIS.

Response: CEQ's regulations list several factors to be utilized in determining the intensity of an action's impact on the human environment (40 CFR 1508.27; 1978 NEPA implementing regulations). FDA has addressed this comment by including an evaluation of these significance factors in the amended EA under Section 9.4.5.

7) Environmental Impact Statement (EIS) is Needed

Comment Summary: Several comments stated that FDA must complete a more robust analysis in an EIS to evaluate the full range of risks and all direct, indirect, and cumulative effects from the PEI facility, as well as any future facilities, including those in Indiana and Ohio**.**

Response: FDA has conducted an expanded exhaustive analysis of the potential exposure, harms and risks from the production of ABT salmon at the PEI facilities in the

[12] https://www.fda.gov/animal-veterinary/intentional-genomic-alterations-igas-animals/aquadvantage-salmon-response-public-comments-environmental-assessment

September 2024 amended EA. The amended EA takes into account maximum production at all PEI facilities, including planned expansion at the Rollo Bay facility and planned changes at the Bay Fortune facility. It also takes production at the Indiana facility[13] into account via transport of AAS eyed-eggs for grow out, but the 2018 EA for Indiana found no viable exposure pathway for AAS to wild Atlantic salmon, so escape from Indiana was not further analyzed in the amended EA. Therefore, FDA has taken a hard look and carefully considered the potential impacts from the 2015 action, as well as previous supplemental actions and future proposed plans. FDA has determined that no significant environmental impacts are expected; therefore, a FONSI was prepared, and an EIS is not needed.

8) Endangered Species Act (ESA) Consultation

Comment Summary: Some comments stated that under Section 7(a) of the ESA FDA must consult with Fish and Wildlife Service (FWS) or the NMFS concerning potential impacts on Gulf of Maine Atlantic salmon, an endangered species.

Response: Appendix I of the amended EA contains information on FDA's informal consultation with NMFS, and NMFS concurrence with FDA's determination that the action "may affect but is not likely to adversely affect" endangered Atlantic salmon and their critical habitat.

9) Environmental Safety Evaluation under FD&C Act

Comment Summary: One comment stated that FDA should evaluate all information and make a separate environmental safety determination under the FD&C Act.

Response: In 2020, the Court found FDA had adequately addressed "safety" under the FD&C Act through its NEPA analysis: "[T]he only environmental effects at issue in the case relate to the effect of the AquAdvantage salmon on normal salmon."[14] The FONSI provides an explanation of the environmental conclusions. Therefore, no additional evaluation or separate determination under the FD&C Act is necessary.

10) Impacts of Land-based Aquaculture

Several commenters called for FDA to consider the environmental impacts of growing ABT salmon in land-based operations, including impacts from the release of waste (e.g., drugs and other chemicals, transmission of pathogens/parasites), energy and water usage, and greenhouse gas (GHG) emissions, especially given the proximity to habitat for wild Atlantic salmon. Each are discussed below.

a) Impacts from Facility Wastewater

Comment Summary: Several commenters stated that FDA should conduct a more thorough evaluation of the potential risks posed by ABT salmon facilities, including the

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[13] ABT officially closed their Albany, Indiana facility in April 2024 in order to secure funding for a future facility in Pioneer, Ohio.[13] The Albany, Indiana facility is currently for sale and does not contain any AAS. (https://investors.aquabounty.com/news-releases/news-release-details/aquabounty-technologies-provides-fundraising-update)

[14] *Inst. for Fisheries Res.*, 499 F. Supp. 3d at 664 n.2.

release of untreated wastes and nutrients, increased risk of disease and parasite transmission, and release of drugs and chemicals, on the environment and humans.

Response: The wastewater released from the PEI facilities should be no different than that for a facility raising an Atlantic salmon without the recombinant deoxyribonucleic acid (rDNA) construct, or any other fish, as the rDNA construct does not pose any unique hazards. Impacts due to the release of contaminants, such as drugs, chemicals and nutrients, from the PEI facilities was not specifically evaluated in the amended EA because the PEI facilities are not located in the U.S. and are under the jurisdiction of Canada. NEPA requires that FDA assess potential impacts to the U.S. environment and does not require analysis of effects on the environment of foreign sovereign countries, such as Canada (see footnotes 25 and 26 of the amended EA). Impacts from the facility itself, such as the release of drugs, would only impact the Canadian environment. Therefore, the impacts from contaminants in the wastewater is outside the scope of the amended EA. FDA evaluated the potential impacts due to the transmission of parasites and pathogens via the wastewater effluent from the PEI facilities in the amended EA. See Comment 3.c above for more information.

b) Energy and Water Usage

Comment Summary: One commenter stated that FDA should evaluate the environmental impacts of the water and energy usage of the PEI land-based facilities.

Response: The energy and water usage at the PEI facilities would be no different than if the facility was raising Atlantic salmon without the rDNA construct or any other fish. In addition, water and energy usage is not specifically evaluated in the amended EA because the PEI facilities are not located in the U.S. and their energy and water usage are under the jurisdiction of Canada.

c) GHG Emissions and Effects of Climate Change

Comment Summary: One commenter stated that FDA must consider the climate emissions of this project, including evaluating the likely GHG emissions from its preferred alternative, as well as other alternatives that it must develop. See Council on Environmental Quality (CEQ), National Environmental Policy Act Guidance on Consideration of Greenhouse Gas Emissions and Climate Change, CEQ–2022–0005.[15] Specifically, "when conducting climate change analyses in NEPA reviews, agencies should consider: (1) the potential effects of a proposed action on climate change, including by assessing both GHG emissions and reductions from the proposed action; and (2) the effects of climate change on a proposed action and its environmental impacts."

Response: The CEQ Guidance cited by the commenter was published in January 2023, well after the original and supplemental EAs were published. Regardless, a GHG analysis was completed by FDA and is provided below.

With regards to the impacts of climate change on the proposed action, the primary impact would be the potential for stronger and more frequent storms on PEI. Although it is possible that the severity of weather-related events, such as hurricanes and floods,

[15] https://public- inspection.federalregister.gov/2023-00158.pdf

may increase in the future, these events are unlikely to affect either facility in such a way as to compromise the integrity of the containment systems because of the locations of these facilities and the redundancy designed into their containment systems. The likelihood of the containment at the PEI facilities being affected by natural disasters was evaluated in Section 9.2.1.2.c of the amended EA.

GHG Analysis:

An assessment of GHG emissions was performed for the production of ABT salmon for all currently operating Units at ABT's Bay Fortune and Rollo Bay, PEI facilities. This analysis was conducted to address concerns expressed in public comments regarding the GHG impacts of the production of AAS and AquAdvantage broodstock. This assessment reports the emissions from the production and transport of AAS and AquAdvantage broodstock and contextualizes the emissions via comparison to an appropriate baseline and calculation of the social cost of emissions. The assessment was conducted in compliance with the 2023 CEQ interim guidance on consideration of GHG emissions for agency actions [88 Federal Register (FR) 1196; hereafter "CEQ Guidance"].[15]

Emissions from Production of AAS

The GHGs that were considered for this assessment are shown in Table 1 along with their global warming potentials (GWP).[16] The GWP of a GHG represents the heat-trapping impact of a GHG relative to carbon dioxide (CO_2) and are, therefore, reported in CO_2 equivalents (CO_2e). The GWP of a GHG can be determined over different timespans due to the lifetime of the specific GHG in the environment. For this assessment the 100-year time horizon GWP was used to provide for a consistent evaluation between GHGs and because it is the typical time horizon used in the U.S. for GHG assessments.[17]

Table 1. GHG considered in this assessment and their global warming potentials [GWP in CO_2 equivalents (CO_2e)]. All GWP were obtained from the 2021 Intergovernmental Panel on Climate Change (IPCC) Sixth Assessment Report (AR6; Table 7.15).[18]

Name	**Formula**	**GWP (CO_2e)**
Carbon Dioxide	CO_2	1
Methane (non-fossil sources)	CH_4	27
Methane (fossil sources)	CH_4	29.8

[16] Other GHG exist [e.g., hydroflurocarbons (HFCs)], but they are not relevant to the emissions that are considered in this assessment.

[17] https://www.epa.gov/ghgemissions/understanding-global-warming-potentials

[18] Forster, P., T. Storelvmo, K. Armour, W. Collins, J.-L. Dufresne, D. Frame, D.J. Lunt, T. Mauritsen, M.D. Palmer, M. Watanabe, M. Wild, and H. Zhang. 2021. The Earth's Energy Budget, Climate Feedbacks, and Climate Sensitivity. In Climate Change 2021: The Physical Science Basis. Contribution of Working Group I to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change [Masson-Delmotte, V., P. Zhai, A. Pirani, S.L. Connors, C. Pean, S. Berger, N. Caud, Y. Chen, L. Goldfarb, M.I. Gomis, M. Huang, K. Leitzell, E. Lonnoy, J.B.R. Matthews, T.K. Maycock, T. Waterfield, O. Yelekci, R. Yu, and B. Zhou (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA, pp. 923–1054, doi:10.1017/9781009157896.009

Name	Formula	GWP (CO_2e)
Nitrous Oxide	N_2O	273

There are no GHG emissions or effects on emissions from the recombinant rDNA construct itself (the *opAFP-GHc2* construct). The only relevant emissions are those related to production of the AAS eggs at the Bay Fortune and Rollo Bay facilities, including upstream (e.g., production of electricity), onsite (e.g., incineration), and downstream (e.g., transport of eggs) activities. All of these emissions are considered indirect emissions because they occur at a later time or are further in distance from the action (88 FR 1204).

To evaluate the magnitude of the emissions associated with production of AAS, a standardized framework was used. There are several frameworks established by the industry that are intended to evaluate GHG emissions from business activities, such as those published by World Resources Institute and World Business Council for Sustainable Development (WRI and WBCSD)[19] and the Smart Freight Centre (SFC).[20] These frameworks are used in environmental, social, and corporate governance (ESG) reporting and provide standardized methods to assess the emissions associated with a business or industry. Although the specifics of each individual framework may differ from each other, in general, the frameworks identify three Scopes of GHG emissions:

- Scope 1 – Direct emissions from owned or controlled entities
- Scope 2 – Indirect emissions from purchased electricity, heat, and steam, production and distribution
- Scope 3 – All other indirect emissions

Scope 1, 2, and 3 emissions for all currently operating Units at both the Bay Fortune and Rollo Bay facilities were determined by ABT, and follow the WRI and WBSCD framework.[18] The emissions for each scope are described in the following paragraphs and tables.

Scope 1 emissions encompass self-production of energy from generators and emissions from incineration of waste. The Scope 1 emissions are shown in Table 2:

Table 2. Scope 1 Emissions [in metric tons (MT)] from the PEI facilities. All emissions are for the year 2022.

Activity	Site	Emissions (MT CO_2e)
Stationary Combustion	Rollo Bay	151
	Bay Fortune	118
Mobile Sources	Rollo Bay	9
	Bay Fortune	7
Waste Incineration[*,†]	Total	15
TOTAL		**300**

[19] World Resources Institute and World Business Council for Sustainable Development. The Greenhouse Gas Protocol: A Corporate Accounting and Reporting Standard. Revised Edition. 2015. Available at https://ghgprotocol.org/corporate-standard

[20] Smart Freight Centre. Global Logistics Emissions Council Framework for Logistics Emissions Accounting and Reporting. 2019. Available at: https://www.smartfreightcentre.org/en/our-programs/global-logistics-emissions-council/calculate-report-glec-framework/

* Estimated from total weight of waste incinerated in 2020 (approximately 26.58 MT), default municipal solid waste characteristics, and emission factors for batch type incinerators.[21] For additional details and the equations used see Volume 5 Chapters 2 and 5 of IPCC 2006.
† Waste from the production of AAS was assumed to be equivalent to municipal solid waste. It was also assumed that 100% of the carbon content in the waste was oxidized to CO_2, which may overestimate the actual emissions of CO_2 from incineration.

Scope 2 emissions consist of energy purchased for operations that rely on the main power grid and are shown in in Table 3:

Table 3. Scope 2 Emissions [in metric tons (MT)] from the PEI facilities. All emissions are for the year 2022.

Activity	**Site**	**Emissions (MT CO_2e)**
Purchased and Consumed Electricity	Rollo Bay	364
	Bay Fortune	170
TOTAL		**534**

Finally, Scope 3 emissions (Table 4) are those related to transport of company-owned vehicles to and from the facility, and transport of eggs via air freight to other facilities. Although there are some emissions associated with transport of eggs to and from the air freight airports, these emissions represent *de minimis* amounts compared to those associated with air freight, *i.e.*, whether included or excluded, these emissions would not materially impact the overall GHG emissions from the production of AAS. Additionally, these emissions were not tracked by ABT and could be associated with many forms of transport (e.g., via car, truck, van); thus, any estimates would be unreliable. Therefore, estimates of emissions for land-based transport were not included in this assessment. Because there are two possible air routes for transport of eggs (see Scope 3 emissions in Table 4), a conservative estimate of the maximum possible emissions (0.167 MT CO_2e/shipment) was used in this analysis. The Scope 3 emissions provided in Table 4 are on a per shipment basis. As there are three shipments of three 25 kg packages of eggs per year (= three shipments of 75 kg total), the annual emissions for Scope 3 activities are 0.501 MT CO_2e.

Table 4. Scope 3 Emissions [in metric tons (MT)] from the PEI facilities. All emissions are for the year 2022.

Activity	**Route**	**Emissions (MT CO_2e/shipment)**
Freight Transport of Eggs (75 kg per shipment, 3 shipments per year)*	Halifax, Nova Scotia (CYHZ) to Chicago, Illinois (KORD) via Montreal, Quebec (CYMX)	0.151
	Halifax, Nova Scotia (CYHZ) to Chicago, Illinois (KORD) via Toronto, Ontario (CYYZ)	0.167

[21] Intergovernmental Panel on Climate Change (IPCC). 2006. 2006 IPCC Guidelines for National Greenhouse Gas Inventories. Prepared by the National Greenhouse Gas Inventories Programme, Eggleston H.S., Buendia L., Miwa K., Ngara T. and Tanabe K. (eds). Published: IGES, Japan.

* Estimated from the shipment departure, layover, and arrival airports using the International Civil Aviation Organization Carbon Emissions Calculator.[22]

The total GHG emissions associated with this action are the sum of Scope 1, 2, and 3 emissions, and are equal to 834.5 MT/yr (= 300 + 534 + 0.501). Regarding cumulative emissions, the emissions will continue at approximately the same rate until the PEI facilities are no longer in operation. Thus, the cumulative emissions are equal to the sum of the yearly emissions for the lifetimes of the facilities (e.g., if the facilities operate for two years, the cumulative emissions are 1669 MT (= 834.5×2).

Contextualization and Estimate of Social Cost

To contextualize these emissions, the CEQ GHG Guidance recommends comparing to a baseline and determining the social cost of GHG (SC-GHG) emissions. The context of the emissions reported above is discussed in the following paragraphs.

The baseline is the current global, national, sector, or other temporally or spatially scoped emissions that are relevant to the comparison being made. There are no industry-specific baselines to compare to the emissions derived above,[23] and the majority of the emissions (Scopes 1 and 2, and parts of Scope 3) occur in a foreign country (Canada). However, to contextualize the emissions, comparisons to overall U.S. emissions were made as discussed in CEQ's GHG Guidance. Comparison to several sectors of emissions could also be made, but such a comparison is prone to high uncertainty due to the broad categories of emissions reported in the draft 2024 U.S. Environmental Protection Agency (EPA) GHG Emissions Inventory.[24] According to the draft 2024 EPA GHG Emissions Inventory, in which the most recent reported emissions were for the year 2022, the total national gross emissions were 6,341.2 MMT (million metric tons) CO_2e. Of these emissions, only fuel combustion and systems (including power generation and combustion for transport), waste incineration, and wastewater treatment are relevant to the current analysis. The emissions associated with these activities are shown in Table 5.

Table 5. Relevant national (U.S.) emissions for the year 2022. All emissions are reported in million metric tons (MMT) carbon dioxide equivalents (CO_2e). Data obtained from the draft 2024 EPA GHG Emissions Inventory.[18]

Activity	**Emissions (MMT CO_2e)**
Fossil Fuel Combustion	4,689.9
Natural Gas Systems	209.7
Petroleum Systems	61.6
Stationary Combustion	19.2
Incineration of Waste	12.7
Wastewater Treatment	42.7
TOTAL	**5,035.8**

In comparison, it is estimated that a total of 834.5 MT/yr CO_2e (= 0.0008 MMT/yr CO_2e) would be emitted from the production of AAS. This amounts to 1.7×10^{-5}% (= 0.000017%)

[22] Available at: https://www.icao.int/environmental-protection/Carbonoffset/Pages/default.aspx
[23] Neither the EPA nor the IPCC delineate emissions from aquaculture from other emission sources.
[24] U.S. EPA. *Draft Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2022*, 2024. Document number 430-D-24-001. Available at: https://www.epa.gov/ghgemissions/draft-inventory-us-greenhouse-gas-emissions-and-sinks-1990-2022

of the U.S. emissions. As noted above, this estimate is likely a conservative estimate and may include emissions that are overestimated or irrelevant to the current proposal. The degree to which these estimates are over or underestimated is not clear and cannot be discerned based on the information available.

In addition to comparison to a baseline, the emissions were contextualized by calculating the SC-GHG associated with the production of AAS. Contextualization by calculating SC-GHG helps to "describe the net social costs of increasing GHG emissions as well as the net social benefits of reducing such emissions" (88 FR 1203). There are three assumptions that are important to note for the evaluation performed herein:

1. The costs of emissions used are those provided by the Interagency Working Group on Social Cost of Greenhouse Gases (IWG);[25]
2. The discount rate[26] used is the 2.5% average (IWG's most conservative value); and
3. The SC-GHG calculation used the total CO_2e for the action, rather than calculating the SC-GHG for emissions of each individual GHG and summing the costs.

These three assumptions are important to note because they each introduce uncertainty in the overall estimate of SC-GHG for production of AAS. The uncertainties associated with each assumption are discussed in the following paragraphs.

The first assumption fundamentally affects the estimate of SC-GHG and the uncertainty around any SC-GHG estimate. There are at least three separate estimates of the cost of CO_2, CH_4, and N_2O, each based on potentially different data and/or models and inherently tied to different interpretations of data and factors that should, or should not, be considered in estimating these costs. The IWG estimates were produced as part of Executive Order 13990 in February 2021 and, at the time, represented significantly more conservative estimates than those produced previously by the IWG. Since the time the 2021 IWG report was produced, both the EPA[27] and New York State (NYS)[28] have produced estimates of the social costs of these three GHGs. The EPA estimates are often substantially more conservative than those reported in the 2021 IWG document (e.g., at a 2.5% discount rate for emissions occurring in 2020, the IWG cost of CO_2 is $76/MT, whereas the equivalent EPA cost of CO_2 is $120/MT). As both IWG and EPA estimates have not been finalized, there is substantial uncertainty regarding which approach is most appropriate for this analysis and which approach yields the most

[25] Interagency Working Group on Social Cost of Greenhouse Gases (IWG). Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990. 2021. Available at: https://www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf

[26] The discount rate is used to "to determine how much weight is placed on impacts that occur in the future … A high discount rate means that future effects are considered much less significant than present effects, whereas a low discount rate means that they are closer to equally significant." From https://www.rff.org/publications/explainers/social-cost-carbon-101

[27] U.S. EPA. Report on the Social Cost of Greenhouse Gases: Estimates Incorporating Recent Scientific Advances. Docket number HQ-OAR-2021-0317). Available at: https://www.epa.gov/environmental-economics/scghg

[28] New York State (NYS) Department of Environmental Conservation (DEC). Establishing a Value of Carbon: Guidelines for Use by State Agencies. Appendix: Annual Social Cost Estimates. Available at: https://dec.ny.gov/regulatory/guidance-and-policy-documents/climate-change-guidance-documents

realistic estimates. The 2021 IWG estimates were chosen for this analysis because they are recommended in CEQ's GHG guidance (footnote 62 of 88 FR 1202).

The second assumption adds uncertainty because, as noted in the Executive Summary of the IWG report, "new data and evidence strongly suggests that the discount rate regarded as appropriate for intergenerational analysis is lower [than 2.5%]." Thus, the estimated SC-GHG is likely to be underestimated, but the degree of this underestimate cannot be determined. The 2.5% discount rate was chosen for this analysis because it represents the most conservative realistic estimate.[29]

The final assumption also adds uncertainty because each of GHG's GWP is not equally correlated with its social cost [e.g., the GWP for N_2O is 273 times higher than CO_2, but the social cost (at 2.5% discount rate) is 355 times higher than CO_2]. Thus, the true social cost is likely higher than that calculated herein. However, no data are available on the emissions of each individual GHG for production of AAS, and therefore, the uncertainty associated with this assumption cannot be addressed at this time.

The SC-GHG is calculated based on the total emissions (834.5 MT CO_2e) and the cost of CO_2 emissions ($76/MT in 2020). Thus, the social costs of the total GHG 2022 emissions associated with producing AAS is $63,422 per annum in 2020 dollars. This estimate will change with time (due to the value of the dollar) and as the cost of carbon values change. For example, if emissions do not change and continue to 2040, the social costs would be $80,112 per annum (2020 dollars).[30]

As noted above, this is likely a low end estimate due to the method used (i.e., using only CO_2e) and has high uncertainty (due to the assumptions used). However, at this time and with the information available, it represents the current best estimate of the costs associated with GHG emissions of production of AAS. However, it is also important to note, that these costs are due to the production of the fish itself as the rDNA construct does not directly affect GHG emissions. Some of these emissions are also associated with the production of eggs of Atlantic salmon without the rDNA construct, which ABT plans to produce at the Rollo Bay facility. Salmon without the rDNA construct is not subject to FDA's approval process. Because the Rollo Bay facility produces both Atlantic salmon with and without the rDNA construct, this analysis overestimates GHG emissions to the extent it includes GHG emissions related to the production of Atlantic salmon without the rDNA construct that is not needed for the production of AAS.

11) Whistleblower Report regarding Operations at ABT's Indiana Facility

Comment Summary: Many comments referred to the publication by #BlockCorporateSalmon Campaign of a whistleblower report (known as the

[29] The 2021 IWG Technical Support Document provides four discount rates: 5% average, 3% average, 2.5% average, and the 95th percentile of the 3% rate. Although the 95th percentile value is more conservative than the 2.5% average, the IWG describe this value as "[representing] higher-than-expected economic impacts from climate change further out in the tails of the SC-CO2 distribution." Thus, based on the rationale presented in the 2021 IWG Technical Support Document, the 95th percentile value is unlikely to represent a realistic social cost of GHG emission.

[30] The cost of CO_2e for 2040 at a 2.5% discount rate are reported by the 2021 IWG report as $96/MT in 2020 dollars.

"AquaBounty Exposed Report")[31] from a former employee at ABT's Albany, Indiana (IN) grow-out facility alleging violations of worker safety, product quality and consumer health risks, containment breaches, effluent water pollution, and animal abuse, among other concerns. The whistleblower report is cited throughout the public comments to support concerns regarding adequacy of containment at ABT facilities, adherence to SOPs by ABT employees, contaminants in effluent from ABT facilities, water flow and drainage issues at ABT facilities, and proper disposal of fish waste and carcasses. In light of this report, a commenter asks FDA to consider whether continued approval of GE salmon is safe, warranted, and in the public interest under the FD&C Act.

Response: ABT officially closed their Albany, IN facility in April 2024 in order to secure funding for a future facility in Pioneer, Ohio.[13] The Albany, Indiana facility is currently for sale and does not contain any AAS.

In October 2022, a report by the Block Corporate Salmon Campaign was released that outlined claims made by former ABT employee Braydon Humphrey. Mr. Humphrey was employed at the Albany, IN facility as an Aquaculture Technician from December 2018 to January 2020 (AAS have been housed in the facility from late May 2019 to present). Mr. Humphrey alerted management at ABT of several alleged safety issues he observed at the facility and filed an official complaint with the Occupational Safety and Health Administration (OSHA), which was later dismissed by that Agency. Mr. Humphrey then released text messages, photographs and videos of what Block Corporate Salmon Campaign categorized as violations of standards for food safety and consumer health, worker safety, animal welfare, and environmental impact. These alleged violations included staging the facility prior to site visits, breaches in containment, fiberglass contamination in the tanks, mold and iron buildup in systems, unacceptable mortality disposal, use of antibiotics, poor water quality, degradation of facility infrastructure and lack of pest control.

In response to this report, FDA conducted an unannounced (*i.e.*, ABT was not notified in advance) inspection of the Indiana facility in August 2023. The goal of the inspection was to verify the presence and operational integrity of physical containment systems and to verify and validate procedural containment, including review of SOPs, staff manuals and records to ensure that monitoring and safeguards are in place to guard against failures. The security and surveillance procedures at the facility were also inspected. In addition, during the August 2023 inspection, the claims made in the whistleblower report with regard to human and animal health risks, containment breaches and environmental impacts were evaluated by inspecting the SOPs, system operations, containment, appearance and behavior of AAS, and talking with current employees. The inspection focused on the regulated article itself (i.e., the rDNA construct), and its containment. FDA did not evaluate worker safety or animal welfare claims, as those are not within FDA's regulatory authority.

The final classification of the inspection was No Action Indicated (NAI); therefore, a Form FDA 483 "Inspectional Observations" was not issued at the close of the inspection. NAI means there were no objectionable observations found; however, "discussion items,"

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[31] https://cban.ca/wp-content/uploads/AquaBounty-Exposed-REPORT-public.pdf

which could result in future observations if not corrected, may be shared with the firm.[32] During the inspection, FDA verified and inspected all points of physical containment, which were present and well-maintained. FDA also compared the description of the containment in the SOPs to what was observed during the inspection and found no inaccuracies or omissions. Therefore, no issues were noted with regard to the physical containment. Area managers and technical staff were interviewed and found to be knowledgeable about the operation of the systems and maintenance of physical containment. It was clear from the inspection that the staff was capable of caring for the systems and ensuring that all levels of physical containment are in-place at all times. The security, surveillance and emergency operations plan at the Albany, IN facility appeared to be adequate to ensure unauthorized persons would not have access to the rearing areas of the facility and staff were properly trained to respond during emergency situations. SOPs were reviewed to ensure that the information aligns with that submitted in support of the NADA, and that current policies and procedures used at the facility were adequate to maintain containment of all life stages of AAS during day-to-day operations. The policies and procedures in place at the Albany, IN facility were considered sufficient to ensure physical containment of all life stages of AAS and aligned with information submitted in support of the NADA. However, some deficiencies in the SOPs and record keeping were noted and recommendations for corrections were provided by FDA to ABT management. These deficiencies did not rise to the level of issuing Form FDA 483 "Inspectional Observations" because animal and human health were not at risk, physical containment was in place and well-maintained, and the facility is meeting the requirements under the NADA.

Based on the inspection, it has been determined by FDA that the claims made in the whistleblower report were either a misrepresentation of ABT's procedures or the issues were subsequently addressed adequately by ABT.

[32] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-classification-database