STATE OF MAINE
DEPARTMENT OF MARINE RESOURCES
MARINE RESOURCES LABORATORY
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04575-0008

PATRICK C. KELIHER
COMMISSIONER

April 19, 2022

Elizabeth M. Ransom, P.G.
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RE: Chapter 24 and 12 M.R.S.A §6071(4) Review of AquaBounty

Dear Ms. Ransom:

The Maine Department of Marine Resources (the Department or DMR) has reviewed the materials you submitted on March 22, 2022, in response to the Department's requirement that American Aquafarms provide documentation demonstrating: 1) that AquaBounty meets the criteria for a "Qualified Source/Hatchery" as defined in DMR Rules Chapter 24 and 2) that the proposed source can satisfy the genetic requirements of 12 M.R.S.A §6071(4).

After careful review of the documentation provided, the Department finds that AquaBounty does not meet the Chapter 24 requirements of a "Qualified Source/Hatchery". A detailed description of the deficiencies and incomplete and omitted information follows:

1. The source facility is said to have two stocks of salmon: one transgenic and one non-transgenic. The documentation provided does not specify which stock(s) were screened, however, it appears that documentation was provided for only one stock. Chapter 24.21(1)(E) requires inspection of all production lots at least annually, including visual inspection of tanks/raceways.[1] Furthermore, farm lot numbers to track lots over sampling years were not provided. The description of "Broodstock" in table 1 should have listed actual year class(es) that brood comprised. Details regarding all production lots are needed.
2. The cover letter references additional testing conducted for USFWS Title 50 and Canadian Provincial requirements. It was unclear if additional testing has been

[1] DMR Rules Chapter 24.21(1)(E)(1)

conducted for any pathogens listed as reportable in Maine. If so, this information should have been provided.

3. Appendix A (2020 year class, July 2020 screening): Report notes indicate that viral isolation on CHSE cell line is "in progress". A final report from 2020 should have been submitted. Date ranges reported suggest an inadequate time period for bacterial culture and subsequent identification, or poor data entry/recording.[2]
4. Appendix B (2020 year class, December 2020 screening): The report states that fish were euthanized on "27-May-2021". However, samples were processed in December of 2020 and January 2021. It seems this may have been a typographical error and the fish were euthanized on May 27, 2020. With analysis not occurring until December 2020 and January 2021 it appears these samples were frozen prior to screening. Although freezing does not invalidate PCR assays, it does invalidate bacterial and viral isolation with cell culture and does not meet the standard of methodologies approved by the Commissioner.[3]
5. Appendix C (2019 year class, December 2020 screening): The pathology report section of this document indicates samples were received as "Frozen". Although freezing does not invalidate PCR assays, it does invalidate bacterial and viral isolation with cell culture and does not meet the standard of methodologies approved by the Commissioner.
6. Appendix D (2018 year class, December 2020 screening): The "Pathology Report" section of this document, which provides valuable information, including sample condition and lot information, has been omitted. Date ranges reported suggest an inadequate time period for bacterial culture and subsequent identification, or poor data entry/recording.
7. Appendix E (2021 year class, March 2021 screening): The "Pathology Report" section of this document, which provides valuable information, including sample condition and lot information, has been omitted.
8. Appendix F (2020 year class, October 2021 screening): The "Pathology Report" section of this document, which provides valuable information, including sample condition and lot information, has been omitted. Furthermore, the report references the possibility of contaminated samples, bringing into question the validity of these results. How are samples from AquaBounty collected and by whom? What are their qualifications for the collection of biological samples? Finally, this report states that viral culture on the ASK cell line is "in progress". A final report from 2021 should have been submitted.
9. Appendix G (2019 year class, November 2021 screening): The pathology report section of this document indicates samples were received as "Frozen". Although freezing does not invalidate PCR assays, it does invalidate bacterial and viral isolation

[2] AFS Fish Health Section Blue Book, 2020
[3] OIE Manual of Diagnostic Tests, 2021 and AFS Fish Health Section Blue Book, 2020

with cell culture and does not meet the standard of methodologies approved by the Commissioner.

In consideration of the lack of complete information, and due to the use of frozen samples for year class 2019 (Appendices C and G) and possibly for other year classes (Appendix B and possibly for those Appendices for which sample information was not provided), the proposed source does not meet the Department's Chapter 24 requirements of a qualified/source hatchery. To meet Chapter 24 requirements of a qualified source/hatchery, a facility must have three consecutive annual inspections in which pathogens as described in Chapter 24.21(1)(D), 24.32(3), and 24.34(3) have not been detected.[4] Furthermore, facilities which intend to serve as a qualified source/hatchery for import or transfer to other fish cultures facilities or that stock fish into the coastal waters of the State shall complete an inspection of all production lots at least annually.[5] Documentation only provides evidence for one strain and the source facility is said to have two; one being transgenic and the other non-transgenic. Based on the information provided or the lack thereof, apparent invalidation of viral and bacterial screening of at least the 2019 year class in 2020 and 2021 due to use of frozen samples, submission of reports indicating incomplete virology screening, missing report sections, and date inconsistencies, it was determined that the source facility documentation provided does not meet standards for a qualified source/hatchery designation.

Based on the cover letter submitted with the above referenced materials on March 22, 2022, American Aquafarms recognizes AquaBounty does not meet the requirements of Chapter 24 for a qualified source/hatchery and is instead relying upon the exemption clause in Chapter 24.21 which, if approved by the Maine Aquatic Animal Health Technical Committee and the Commissioner, would allow for the importation of eggs into an approved quarantine facility. However, American Aquafarms has not provided any information with regard to an established or planned quarantine facility in Maine.

You also stated in your March 22nd cover letter that American Aquafarms plans to source eggs from the USDA National Coldwater Marine Aquaculture Center (NCWMAC) in Franklin, Maine; and asked the Department to consider the NCWMAC as an alternative approved and available source of organisms.[6] However, Dr. Peterson (USDA) clearly states in his March 15, 2022 letter to Tom Brennan that the NCWMAC could only supply enough eggs to American Aquafarms to "form the foundation of a broodstock program". In fact, Dr. Peterson has stated to Director Nelson that he would anticipate only being able to provide up to "a couple hundred thousand eggs" to American Aquafarms, with the actual number available being dependent upon a multitude of factors, including the pathogen status of broodstock and the egg needs of

[4] DMR Rule 24.16(C)
[5] DMR Rules Chapter 24.21(1)(E)(1)
[6] Ford to Keliher, February 23, 2022

USDA. Dr. Peterson further stated that the NCWMAC was never designed to supply the full production needs of commercial farmers and they will need to develop a plan to fairly distribute eggs to growing commercial interests.[7] As you know, the development of a broodstock program capable of producing the volume of eggs necessary to supply American Aquafarm's net-pen proposals will take years. Furthermore, in his March 15th letter to Mr. Brennan, Dr. Peterson conditioned the receipt of eggs upon American Aquafarms having a fully permitted and licensed facility in the United States. To date American Aquafarms does not have a facility that can receive the eggs and the Department has seen no plans for the development of such. Therefore, the USDA NCWMAC is not considered an alternative and available source of organisms to be cultivated at the proposed lease sites.

Finally, the Department clearly stated in writing on more than one occasion that evidence the proposed source can satisfy the genetic requirements of 12 M.R.S.A §6071(4) was also required.[8] However, none of the information provided addresses the genetics questions with regard to eggs sourced from AquaBounty. In fact, not even basic strain identification was provided for any of the "lots" of fish for which pathology reports were submitted. Genetic standards that apply to net-pen producers in the State apply to American Aquafarms.

Because American Aquafarms failed to supply the Department with the required information by the deadline provided and because AquaBounty does not meet the standards of a qualified source/hatchery under DMR Rules Chapter 24, the Department has determined that there is not an available source of organisms to be cultivated[9]. Thus, because the application cannot be granted on its face, no further action will be taken on it by the Department in accordance with 12 M.R.S.A. §6072(5) and Chapter 2.08(6)(D) of the Department's rules. Should American Aquafarms identify an approved and available source of organisms to be cultivated, it may submit a new lease application in the future.

Sincerely,

Patrick C. Keliher

Cc: Keith Decker, American Aquafarms
Thomas Brennan, American Aquafarms
Benjamin Ford, Archipelago Law
Bill Keleher, Kennebec River Biosciences

[7] Telephone conversation, April 15, 2022
[8] September 27, 2021, October 1, 2021, November 15, 2021, January 24, 2022, and March 3, 2022
[9] 12 M.R.S.A. §6072 (7-A) (E) and DMR Rules Chapter 2.37(1)(A)(6)