

North American Commission

NAC(16)4

Annual Report

(Tabled by the United States)

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United States, 2015

Submitted by: National Marine Fisheries Service

Date:

1. Summary of salmonid disease incidences

There are no incidents to report for 2015.

U.S. Point of Contact on Disease:

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2. Summary of breaches of containment of salmonids from net cages

There were no reportable breaches of containment and no suspected aquaculture-origin captures in rivers in Maine in 2015.

Species (Strain, if applicable)	Number ¹	Average size of fish ²	Location ³	Result ⁴	Cause of the breach	Date

- 1. This should be the best estimate possible, though it is recognized that exact numbers may be difficult to obtain.
- 2. Based on the codes of containment, it was agreed that average size is a more accurate measurement than lifestage.
- 3. The more specific the information the better, however bay level is considered sufficient.
- 4. This refers to using recapture methods as detailed in the relevant code of containment and summarizing the results of the recapture attempt.

Notes:

Federal permits for U.S. commercial aquaculture operations in Maine require reporting any escapes of 50 fish or greater, and specifically for marine sites; only fish larger than 2 kg or a loss of greater than 25% of cage biomass for fish smaller than 2 kg are reported (i.e. reportable escape).

3. Summary of salmonid introductions from outside the Commission Area

Species (strain, applicable)	Number	Life Stage	Origin ¹	Destination ²	Purpose ³	Date
Salmo trutta (Iijoki River strain)	35,000	Eyed egg (to support culture and release of 2-year smolts)	Taivalkoski Hatchery, Finland	Two small streams that flow directly into Long Island Sound		January 2016

- 1. This would be the province or state for introductions from the west coast, or country for international introductions. It was decided that introductions between Canada and the US that are within the Commission Area (between Maine and NB, for example) would not be included here as those introductions would be captured in other avenues (ICES WGITMO, for example) and because these are not as relevant.
- 2. The more specific the information the better, however bay level is considered sufficient.
- 3. This refers to the intention for the introduction aquaculture, research, stock enhancement, etc.

4. Summary of Transgenic activities within the Country Annex 1 of NAC(10)6

The United States Food and Drug Administration (FDA) recently (November 2015) approved a New Animal Drug Application (NADA:141-454) for AquaBounty Technologies of Maynard, Massachusetts. The approval is for a single copy of the α-form of the opAFP-GHc2 recombinant DNA (rDNA) construct at the α-locus in the EO-1α lineage of triploid hemizygous, all-female Atlantic salmon known as AquAdvantage Salmon under the conditions of use specified in the application. This rDNA construct at this specific site in the genome is the new animal drug ("the article") that is the subject of the NADA, review and approval process under the authority of the Federal Food, Drug and Cosmetic Act. The FDA reviewed this application in regards to food safety issues focusing on consumption hazards and associated risks posed to the public. The approved NADA has conditions of use specified in the approved application, which includes: 1) production of eyed eggs in Prince Edward Island, Canada; 2) shipment of eyed eggs to Panama; and 3) grow-out of fish in the highlands of Panama. An FDA approval letter and appendix can be found on their website

(http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm466214.htm). Here you can find documents which describe certain provisions specified in the approved application (NADA 141-454) for use of the new animal drug described above, as well as applicable post-market requirements for records and reports of adverse events and other experiences.