

Official documents

Documents produced by the US government

The full list of documents related to the approval process of AquAdvantage Salmon are available on the US FDA website <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon>

News:

1. *Apr 08, 2019* Statement from FDA Commissioner Scott Gottlieb, M.D., on continued efforts to advance safe biotechnology innovations, and the deactivation of an import alert on genetically engineered salmon <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-continued-efforts-advance-safe-biotechnology>
2. *March 8, 2019* Questions and Answers on FDA's Deactivation of an Import Alert for Genetically Engineered Salmon <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/questions-and-answers-fdas-deactivation-import-alert-genetically-engineered-salmon>
3. *Apr 26, 2018* FDA Approves Application for AquaBounty Salmon Facility in Indiana <https://www.fda.gov/animal-veterinary/cvm-updates/fda-approves-application-aquabounty-salmon-facility-indiana>
4. *Apr 16, 2020* Questions and Answers on FDA's Approval of AquAdvantage Salmon <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/questions-and-answers-fdas-approval-aquadvantage-salmon>
5. *Apr 15, 2020* AquAdvantage Salmon Fact Sheet <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-fact-sheet>

Approval documents:

1. *Apr 26, 2018* AquAdvantage Salmon Supplemental NADA Approval Letter <https://www.fda.gov/media/112639/download>
2. *Apr 26, 2018* AquAdvantage Salmon Supplemental NADA Approval Letter Appendix <https://www.fda.gov/media/112646/download>
3. *Apr 20, 2018* AquAdvantage Salmon Supplemental NADA Environmental Assessment <https://www.fda.gov/media/112655/download>
4. *Apr 25, 2018* AquAdvantage Salmon Supplemental NADA FONSI <https://www.fda.gov/media/112663/download>
5. *Dec 1, 2017* AquAdvantage Salmon Approval Letter and Appendix <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-approval-letter-and-appendix>
6. *Nov 12, 2015* AquAdvantage Salmon Supplemental NADA Environmental Assessment <https://www.fda.gov/media/93817/download>
7. *Apr 25, 2018* AquAdvantage Salmon Supplemental NADA FONSI <https://www.fda.gov/media/112663/download>
8. *Dec 1, 2017* AquAdvantage Salmon Approval Letter and Appendix <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-approval-letter-and-appendix>
9. *Nov 12, 2015* AquAdvantage Salmon FONSI <https://www.fda.gov/media/93823/download>

10. *Sept 14, 2018* AquAdvantage Salmon - Response to Public Comments on the Environmental Assessment <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-response-public-comments-environmental-assessment>
11. *Jan 16, 2018* AquAdvantage Salmon - FDA Response to Public Comments to the Veterinary Medicine Advisory Committee <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-fda-response-public-comments-veterinary-medicine-advisory-committee>
12. *Dec 1, 2017* AquAdvantage Salmon - FDA Analysis of Potential Impacts on the Environments of the Global Commons and of Foreign Nations not Participating in the Action for NADA # 141-454 <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-fda-analysis-potential-impacts-environments-global-commons-and-foreign-nations>
13. Earth Justice Petition Regarding Pending Application of AquaBounty Technologies for Approval of Genetically-Engineered Salmon <https://www.regulations.gov/docket?D=FDA-2011-P-0448>
14. Food and Water Watch Petition that the FDA deem AquaBounty Technologies' genetically engineered AquAdvantage Salmon an unsafe food additive <https://www.regulations.gov/docket?D=FDA-2015-P-1094>
15. *Dec 26, 2012* Notice of Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon

Other Documents

1. *Dec 26, 2012* Notice of Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon <https://www.govinfo.gov/content/pkg/FR-2012-12-26/pdf/2012-31118.pdf>
2. *May 4, 2012* AquAdvantage Salmon Draft Environmental Assessment <https://www.fda.gov/media/84810/download>
3. *May 4, 2012* AquAdvantage Salmon Preliminary Finding of No Significant Impact <https://www.fda.gov/media/84817/download>
4. Background on the Public Hearing on the Labeling of Food Made from AquAdvantage Salmon <https://wayback.archive-it.org/7993/20190422161554/https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm222608.htm>

Documents produced by the government of Canada

The full list of documents related to the approval process of AquAdvantage Salmon are available on the website of the Government of Canada <https://www.canada.ca/en/health-canada/news/2016/05/health-canada-and-canadian-food-inspection-agency-approve-aquadvantage-salmon.html>

1. Canadian Science Advisory Secretariat - Science Response 2013/023 Summary of the Environmental and Indirect Human Health Risk Assessment of AquAdvantage® Salmon https://www.dfo-mpo.gc.ca/csas-sccs/Publications/ScRS/2013/2013_023-eng.html
2. Summary of information submitted by the public to the New Substances program on the environmental and human health risks of the AquAdvantage® salmon <https://www.canada.ca/en/environment-climate-change/services/managing->

[pollution/evaluating-new-substances/voluntary-public-engagement-initiative/aquadvantage-salmon/summary-public-comments.html#shr-pg0](https://www.cbc.ca/news/technology/pollution/evaluating-new-substances/voluntary-public-engagement-initiative/aquadvantage-salmon/summary-public-comments.html#shr-pg0)

3. *May 19, 2016* Health Canada and Canadian Food Inspection Agency approve AquAdvantage Salmon <https://www.canada.ca/en/health-canada/news/2016/05/health-canada-and-canadian-food-inspection-agency-approve-aquadvantage-salmon.html>

Media

1. *Sep 13, 2010* **CBC News** Genetically modified salmon's safety defended <https://www.cbc.ca/news/canada/prince-edward-island/genetically-modified-salmon-s-safety-defended-1.882485>
2. *Sep 20, 2010* **The Associated Press** Genetically modified salmon hearings begin: AquaBounty, FDA and critics of GM salmon at advisory committee <https://www.cbc.ca/news/genetically-modified-salmon-hearings-begin-1.867071>
3. *Oct 25, 2010* Peter Nowak **CBC News** Making sense of 'Frankenfish': AquaBounty says its salmon means more efficient aquaculture <https://www.cbc.ca/news/technology/making-sense-of-frankenfish-1.939213>
4. *Nov 22, 2010* **CBC News** GM salmon analysis a secret, groups complain <https://www.cbc.ca/news/canada/prince-edward-island/gm-salmon-analysis-a-secret-groups-complain-1.947868>
5. *Dec 20, 2010* **CBC News** Genetically modified fish lawsuit threatened <https://www.cbc.ca/news/canada/prince-edward-island/genetically-modified-fish-lawsuit-threatened-1.913403>
6. *Jan 02, 2011* **CBC News** GMO salmon a top invention: Time <https://www.cbc.ca/news/canada/prince-edward-island/gmo-salmon-a-top-invention-time-1.1110406>
7. *Jun 22, 2011* **CBC News** U.S. Congress votes to block GM salmon <https://www.cbc.ca/news/canada/prince-edward-island/u-s-congress-votes-to-block-gm-salmon-1.1050891>
8. *Jul 15, 2011* **CBC News** GM salmon could breed in wild, study shows Grow GM fish in closed containers on land to minimize risk, researchers urge <https://www.cbc.ca/news/technology/gm-salmon-could-breed-in-wild-study-shows-1.1105598>
9. *Oct 24, 2011* **CBC News** GMO salmon farm called 'drug factory' <https://www.cbc.ca/news/canada/prince-edward-island/gmo-salmon-farm-called-drug-factory-1.1050888>
10. *Oct 26, 2011* **CBC News** 'Frankenfish' concern international delegation: Genetically-modified salmon could pose health and environmental hazards, groups says <https://www.cbc.ca/news/canada/new-brunswick/frankenfish-concern-international-delegation-1.1078664>
11. *Oct 27, 2011* **CBC News** GMO salmon egg sales plan alarms environmentalists: Producer hopes to sell eggs to approved fish farmers <https://www.cbc.ca/news/canada/prince-edward-island/gmo-salmon-egg-sales-plan-alarms-environmentalists-1.1096226>
12. *Dec 21, 2012* **The Associated Press** FDA says Newfoundland's 'Frankenfish' unlikely to be harmful: Health regulators 'clear the way' for approval of genetically modified salmon <https://www.cbc.ca/news/technology/fda-says-newfoundland-s-frankenfish-unlikely-to-be-harmful-1.1211992>

13. Dec 28, 2012 **CBC News** FDA deems Island 'frankenfish' egg facility safe
<https://www.cbc.ca/news/canada/prince-edward-island/fda-deems-island-frankenfish-egg-facility-safe-1.1211989>
14. Apr 18, 2013 **CBC News** Alaska's GM salmon protest comes to P.E.I.: Alaska concerned over economic impact of genetically-modified fish <https://www.cbc.ca/news/canada/prince-edward-island/alaska-s-gm-salmon-protest-comes-to-p-e-i-1.1354126>
15. Apr 25, 2013 **CBC News** GM salmon company losses mounting: Long wait discouraging investment in genetically modified food animal technologies, says scientist
<https://www.cbc.ca/news/canada/prince-edward-island/gm-salmon-company-losses-mounting-1.1354124>
16. Jun 06, 2013 **CBC News** GM salmon in wild might produce bold hybrids: Research shows current production safeguards 'sufficient' <https://www.cbc.ca/news/canada/prince-edward-island/gm-salmon-in-wild-might-produce-bold-hybrids-1.1371057>
17. Nov 25, 2013 **CBC News** Genetically-modified salmon eggs approved commercially
<https://cbc.radio-canada.ca/en/vision/governance/journalistic-standards-and-practices>
18. Nov 27, 2013 **CBC News** GMO salmon criticisms 'don't merit comment': Genetically modified salmon facility highly scrutinized, says company CEO
<https://www.cbc.ca/news/canada/prince-edward-island/gmo-salmon-criticisms-don-t-merit-comment-1.2441704>
19. Nov 27, 2013 Rick MacInnes-Rae **CBC News** GMO salmon firm clears one hurdle but still waits for key Oks: AquaBounty began seeking American approval in 1995
<https://www.cbc.ca/news/gmo-salmon-firm-clears-one-hurdle-but-still-waits-for-key-oks-1.2442553>
20. Sep 03, 2010 **Center for Food Safety** Public still in the dark on transgenic salmon
https://www.centerforfoodsafety.org/press-releases/800/public-still-in-the-dark-on-transgenic-salmon%22%20/t%20%22_blank
21. Dec 21, 2012 **USA Today News** FDA: Genetically engineered fish would not harm nature
<https://eu.usatoday.com/story/news/nation/2012/12/21/fda-salmon-nature/1784933/>
22. May 30, 2013 Bob Grant **The Scientist** GM Salmon and Wild Fish Can Reproduce
<https://www.the-scientist.com/the-nutshell/gm-salmon-and-wild-fish-can-reproduce-39259>
23. Nov 26, 2013 Abby Olena **The Scientist** GM Salmon Goes Commercial <https://www.the-scientist.com/the-nutshell/gm-salmon-goes-commercial-38356>
24. May 7, 2014 Amanda Cochran **CBC News** GMO food labeling: Inside the controversy
<https://www.cbsnews.com/news/gmo-food-labeling-inside-the-controversy/>
25. May 13, 2014 Jessica Firger **CBC News** Controversy swims around genetically modified fish
<https://www.cbsnews.com/news/controversy-swims-around-genetically-modified-fish/>
26. May 31, 2014 Tillmann Benfey **The Scientist** Opinion: Sizing Up GM Salmon
<https://www.the-scientist.com/news-opinion/opinion-sizing-up-gm-salmon-37424>
27. Nov 19, 2015 Tracy Vence **The Scientist** FDA OKs GM Salmon <https://www.the-scientist.com/the-nutshell/fda-oks-gm-salmon-34476>
28. Nov 19, 2015 Heidi Ledford **Nature magazine** Salmon Is the First Transgenic Animal to Win U.S.: Approval for Food <https://www.scientificamerican.com/article/salmon-is-the-first-transgenic-animal-to-win-u-s-approval-for-food/?print=true>
29. Oct 22, 2018 **Organic Authority** Maine Says No to GMOs, Bill Passes Through Senate
<https://www.organicauthority.com/energetic-health/maine-says-no-to-gmos-bill-passes-through-senate>
30. Feb 20, 2019 Heidi Ledford **Nature News** Gene-edited animal creators look beyond US market <https://www.nature.com/articles/d41586-019-00600-4>

31. *March 8, 2019* **CNN** FDA allows genetically engineered 'Frankenfish' salmon to be imported to US <https://edition.cnn.com/2019/03/08/politics/fda-approves-sale-genetically-engineered-salmon/index.html>
32. *March 9, 2019* Candice Choi **AP News** US regulators clear path for genetically modified salmon <https://apnews.com/1be7085378684f4990e240870e7c546c>
33. *March 11, 2019* Catherine Offord **The Scientist** FDA Lifts Import Restrictions on Genetically Engineered Salmon <https://www.the-scientist.com/news-opinion/fda-lifts-import-restrictions-on-genetically-engineered-salmon-65583>
34. *March 11, 2019* Jason Smith **UndercurrentNews** Hurdles cleared, genetically engineered salmon to hit US shelves by Q3 2020 <https://www.undercurrentnews.com/2019/03/11/hurdles-cleared-aquabountys-salmon-to-hit-us-shelves-by-q3-2020/>
35. *March 12, 2019* Anastasia Bodnar **Biology Fortified Inc.** Fast-growing genetically engineered salmon approved <https://biofortified.org/2019/03/gmo-salmon-approved/>
36. *March 14, 2019* **OrganicAuthority** FDA Approves GMO Salmon for U.S. Distribution <https://www.organicauthority.com/buzz-news/fda-approval-gmo-salmon-u-s>
37. *April 15, 2019* Zachary Comeau **Worcester Business Journal** AquaBounty's genetically modified salmon could hit U <https://www.wbjournal.com/article/aquabountys-genetically-modified-salmon-could-hit-us-shelves-next-year>
38. *Nov 3, 2019* Sam Bloch **The Counter** The FDA closed an import ban, opening the door to a product that's been decades in the making. <https://thecounter.org/fda-aquabounty-gmo-salmon-seafood-restriction-market/>
39. *Nov 6, 2019* **SalmonBusiness** Biomass of genetically modified salmon is now at 77 tonnes <https://salmonbusiness.com/biomass-of-genetically-modified-salmon-is-now-at-77-tonnes/>
40. *Oct 31, 2019* **IntraFish** Intrexon sells 100% of its shares in GM salmon producer AquaBounty <https://www.intrafish.com/finance/intrexon-sells-100-of-its-shares-in-gm-salmon-producer-aquabounty/2-1-698620>
41. *Nov 13, 2019* Nestor Arellano **RasTech** AquaBounty expects 'modest' GM salmon sales in 2020 despite US\$9.8-M net loss <https://www.rastechmagazine.com/aquabounty-expects-modest-gm-salmon-sales-in-2020-despite-us9-8-m-net-loss/>
42. *Dec 14, 2019* Zlati Meyer **USA Today** GMO 'Frankenfish' salmon could be in stores as early as next year, as FDA lifts import ban <https://eu.usatoday.com/story/money/2019/03/12/gmo-frankenfish-salmon-could-hit-store-shelves-early-next-year/3134439002/>
43. *Jan 5, 2020* Amy Nordrum **IEEE Spectrum** U.S. Consumers Might Get Their First Taste of Transgenic Salmon This Year <https://spectrum.ieee.org/energy/environment/us-consumers-might-get-their-first-taste-of-transgenic-salmon-this-year>
44. *Aug 6, 2020* **GlobeNewsWire** AquaBounty Technologies Announces Financial Results for the Quarter and Six Months Ended June 30, 2020, and Provides Corporate Update <https://www.globenewswire.com/news-release/2020/08/06/2074545/0/en/AquaBounty-Technologies-Announces-Financial-Results-for-the-Quarter-and-Six-Months-Ended-June-30-2020-and-Provides-Corporate-Update.html>
45. *Sept 4, 2020* Dan Flynn **Food Safety News** AquaBounty salmon is what's for dinner if you can find it <https://www.foodsafetynews.com/2020/09/aquabounty-salmon-is-whats-for-dinner-if-you-can-find-it/>
46. *Nov 9, 2020* Sam Hill **SeaFoodSource** Federal judge rules FDA must reevaluate effects of potential GE salmon escape <https://www.seafoodsource.com/news/food-safety-health/federal-judge-rules-fda-must-reevaluate-effects-of-potential-ge-salmon-escape>

47. Dec 3, 2020 Colin Czerwinski **OrganicAuthority** Downstream Environmental Risks Become Latest GMO Salmon Setback <https://www.organicauthority.com/buzz-news/downstream-environmental-risks-gmo-salmon-setback>
48. **Center for Food Safety** AquAdvantage Salmon <https://www.centerforfoodsafety.org/issues/309/ge-fish/aquadvantage-salmon>
49. Nov 6, 2020 Chuck Abbott **Agriculture** FDA must study what happens if GMO salmon escape, says judge <https://www.agriculture.com/news/business/fda-must-study-what-happens-if-gmo-salmon-escape-says-judge>
50. Aug 18, 2017 Emily Monaco **OrganicAuthority** Canada Becomes First Country to (Unwittingly) Consume GMO Salmon <https://www.organicauthority.com/buzz-news/canada-becomes-first-country-to-unwittingly-consume-gmo-salmon>
51. Aug 4, 2017 Jenna Gallegos **The Washington Post** GMO salmon caught in U.S. regulatory net, but Canadians have eaten 5 tons <https://www.washingtonpost.com/news/science/wp/2017/08/04/gmo-salmon-caught-in-u-s-regulatory-net-but-canadians-have-eaten-5-tons/>
52. May 7, 2019 Emily Monaco **OrganicAuthority** Costco Refuses to Sell GMO Salmon in Its 474 Warehouse Stores <https://www.organicauthority.com/buzz-news/costco-refuses-to-sell-gmo-salmon-in-its-474-warehouse-stores>
53. Aug 9, 2017 Ashifa Kassam **The Guardian** GM salmon hits shelves in Canada – but people may not know they're buying it <https://www.theguardian.com/world/2017/aug/09/genetically-modified-salmon-sales-canada-aqua-bounty>

Scientific articles

1. Aerni, P. Risk, regulation and innovation: The case of aquaculture and transgenic fish. *J Aquatic sciences* **2004**, 66, 327-341.
2. Bratspies, R.M. Farming the Genetically Modified Seas: The Perils and Promise of Transgenic Salmon. In *The International Governance of Fisheries Ecosystems Learning from the Past, Finding Solutions for the Future, Proceedings of the American Fisheries Society Symposium, Texas, TX, USA, 17–19 Januray 2008*; Taylor, B., Schechter, M., Leonard, N., Eds.; SSRN: Amsterdam, The Netherlands, 2008.
3. Clausen, R.; Longo, S.B.J.D.; Change. The tragedy of the commodity and the farce of AquAdvantage Salmon®. *Development and Change* **2012**, 43, 229-251.
4. Clifford, H. AquAdvantage® Salmon-a pioneering application of biotechnology in aquaculture. In *BMC proceedings, Oct 2014*; BioMed Central, **2014**, 8, 4, 1-2.
5. Entis, E. Aquadvantage salmon: A case study in transgenic food. *Animal Biotechnology* **1998**, 9, 165-170, doi:10.1080/10495399809525906.
6. Goubau, A. The AquAdvantage Salmon Controversy—A Tale of Aquaculture, Genetically Engineered Fish and Regulatory Uncertainty. **2011**.
7. Ignatz, E.H.; Dumas, A.; Benfey, T.J.; Hori, T.S.; Braden, L.M.; Runighan, C.D.; Rise, M.L.; Westcott, J.D. Growth performance and nutrient utilization of growth hormone transgenic female triploid Atlantic salmon (*Salmo salar*) reared at three temperatures in a land-based freshwater recirculating aquaculture system (RAS). *Aquaculture* **2020**, 519, 734896.
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10. Oke, K.B.; Westley, P.A.; Moreau, D.T.; Fleming, I.A. Hybridization between genetically modified Atlantic salmon and wild brown trout reveals novel ecological interactions. *Proceedings of the Royal Society B: Biological Sciences* **2013**, *280*, 20131047.
11. EFSA Panel on Genetically Modified Organisms; Naegeli, H.; Bresson, J.L.; Dalmay, T.; Dewhurst, I.C.; Epstein, M.M.; Guerche, P.; Hejatko, J.; Moreno, F.J.; Mullins, E. Adequacy and sufficiency evaluation of existing EFSA guidelines for the molecular characterisation, environmental risk assessment and post-market environmental monitoring of genetically modified insects containing engineered gene drives. *EFSA Journal* **2020**, *18*, e06297.
12. Sanderson, J.; Humphries, F. Unnaturally Natural: Inventing and Eating Genetically Engineered AquAdvantage® Salmon, and the Paradox of Nature. In *Intellectual Property and Genetically Modified Organisms: A Convergence in Laws*; Routledge: London, UK, **2015**.
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15. Van Eenennaam, A.L.; Muir, W.; Hallerman, E. *Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness? A Response to Tim Schwab's 'Is FDA Ready to Regulate the World's First Biotech Food Animal'?*; The Food and Drug Law Institute (FDLI) Food and Drug Policy Forum: Washington, DC, USA, 2013; Volume 3, pp. 1–20.
16. Van Eenennaam, A.L.; Muir, W.M. Transgenic salmon: A final leap to the grocery shelf? *Nat. Biotechnol.* **2011**, *29*, 706–710.
17. Waltz, E. GM salmon declared fit for dinner plates. *Nat. Biotechnol.* **2016**, *34*, doi:10.1038/nbt0116-7a.