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South Asia Biosafety Program

BANGLADESH

The Regulatory Journey from Laboratory to the Dining Table for Genetically Engineered Atlantic Salmon

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Atlantic salmon, Quebec, Canada © Dreamstime.com

The genetically engineered Atlantic salmon (GE salmon) was approved for human consumption by the United States Food and Drug Administration (FDA) in 2015 and by Health Canada in 2016. This is the first GE fish (and first GE animal) approved for human consumption. GE salmon has completed almost 30 years in development and 25 years on the regulator's table. During the regulatory journey, it went through independent sets of regulatory processes in the two countries where it has been approved. This journey has both positive and negative impacts on researchers. Some researchers argue that it suppressed animal biotechnology developments worldwide and puts a question mark on the commercial feasibility of a technique if it has to survive for so long to come to light. But, at the same time, they believe this salmon approval will open the doors for new research and development, and the learnings from this case will aid in the effective, focused, and efficient evaluation in the future regulatory processes.

Before describing GE salmon's regulatory journey, a brief background is necessary to address the context of its genetic modification. Salmon is one of the world's most popular fish and holds a unique place in the seafood market in terms of demand and delicacy. Due to excessive fishing, damming of rivers, habitat degradation, and pollution, wild Atlantic salmon populations have declined dramatically. The United States Fish and Wildlife Service and National Oceanic and Atmospheric Administration (NOAA) listed the distinct salmon populations of the Gulf of Maine as endangered under the Endangered Species Act.[1] To ensure a sustainable fish supply while at the same time allowing wild fish to repopulate, the seafood industry focuses on aquaculture, which allows farm raising of salmon in controlled conditions. Aquaculture now meets the demand of more than half of seafood production. In this context, genetic modification has been applied to achieve an accelerated life cycle of salmon raised in aquaculture. The development of fast-growing GE salmon started back in 1989 by researchers Garth Fletcher, Peter Davies, and Choy Hew at Memorial University of Newfoundland. They created a gene construct expressing Chinook salmon growth hormone under the control of an Ocean pout promoter and microinjected it into wild Atlantic salmon fertilized eggs. GE salmon grow all year round, reaching adult size in 16 to 18 months instead of 30 by utilizing 75 percent of the feed needed for regular farmed salmon.[2] The GE salmon is branded as AquAdvantage® and the technology is developed and owned by AquaBounty Technologies, Inc.

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The regulatory journey started after the establishment of the F1 generation of GE salmon in 1992. In the next year, AquaBounty

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BIOSAFETY DISCOURSES

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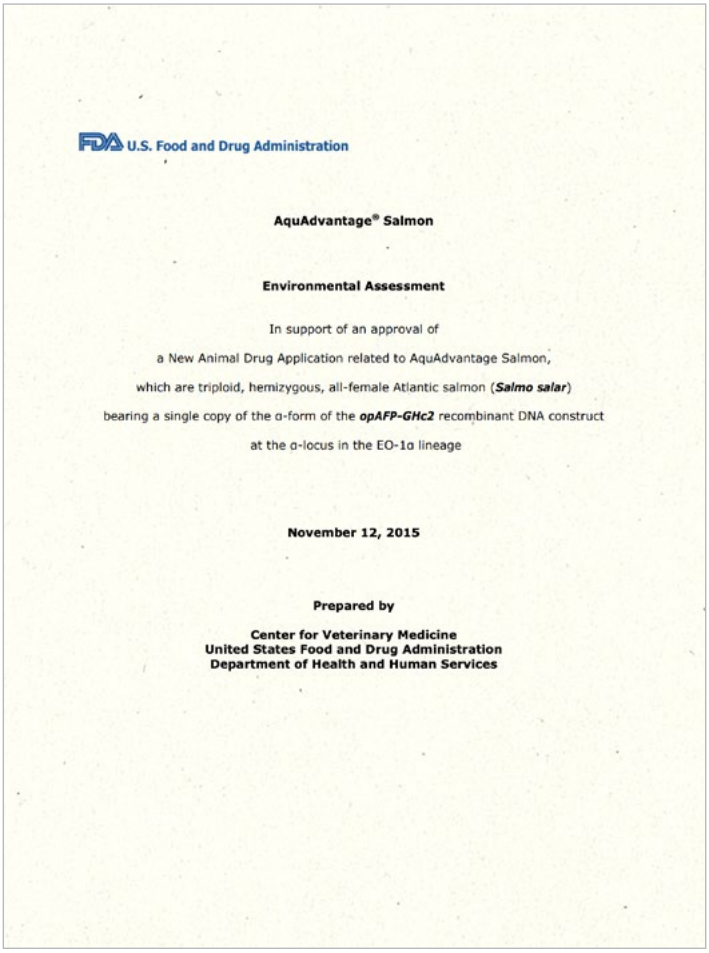
Technologies (then A/F Protein) started their discussions with regulators. In the USA, under the Coordinated Framework for Regulation of Biotechnology (1986), the U.S. Environmental Protection Agency (EPA), U.S. Department of Agriculture (USDA), and FDA were responsible for regulating GE products, where USDA was the lead agency to regulate GE plants but no defined regulatory guideline existed for GE animals at that time. AquaBounty submitted a petition for regulation under the FDA with the intent that the rigorous regulatory pathway may aid in more compliance with public concerns. Therefore, GE food animals were regulated as drugs and the regulatory route for evaluation was set to go through FDA's new animal drug approval process. In 1995, they started an Investigational New Animal Drug (INAD) file with the Center for Veterinary Medicine (CVM) of the FDA. They submitted their first study of the New Animal Drug Application (NADA) to the FDA in 2003. CVM finalized Guidance 187 for the evaluation of genetically engineered animals in 2009, while AquaBounty submitted their final regulatory documents consisting of more than 25 scientific studies.[3,4]

The Veterinary Medicine Advisory Committee recommended GE salmon as being as safe as conventional Atlantic salmon and indicated that there was a reasonable certainty of no harm from the consumption of food from this animal.

The FDA used a hierarchical risk-based approach to assess this GE salmon. In the assessment process, first they reviewed data and information on the recombinant DNA construct and its safety to the animal itself, the food derived from the animal, and their environmental impacts. The possibility of getting new proteins other than the desired ones that could possibly cause health concerns was also evaluated. The molecular characterization evaluated the stable inheritance of the construct over generations and phenotypic characterization evaluated the differences among GE salmon with wild and domestic salmon. In these steps, questions were raised on abnormalities, appearances, developmental similarities, and healthiness in comparison to their conventional counterpart. The food and feed safety assessment evaluated the composition of the edible portions to find out any differences and risk for allergenicity that are not present in non-transgenic counterparts. To comply with the National Environmental Policy Act (NEPA), FDA performed an evaluation through the National Marine Fisheries Service of NOAA and the U.S. Fish and Wildlife Service on the potential to cause any significant environmental impacts. The data submitted during the environmental assessment (EA) was about the production system, physical and biological confinement measures, and impact on the receiving environment. Particular attention was given to the likelihood of escape, survival, reproduction, and viability of transgenic salmon from the conditions of confinement. Finally, AquaBounty submitted their information and data in support of their claims that GE salmon grows faster than non-GE counterparts.[5-7]

After completion of the safety assessment in 2010, FDA released a 171-page summary of the health and safety data and 84-page summary of environmental assessment data for ensuring transparency. FDA employed the Veterinary Medicine Advisory Committee (VMAC) to provide scientific advice based on the assessment findings. VMAC recommended GE salmon as being as safe as conventional Atlantic salmon and indicated that there was a reasonable certainty of no harm from the consumption of food from this animal. Also, they suggested that there was substantial, reliable information available in the environmental assessment document to conclude that GE salmon were not expected to have a significant impact on the environment.[3-7] In 2012, FDA released the updated draft EA for public comment and a Finding of No Significant Impact (FONSI). Finally, in 2015, FDA approved the GE salmon as food and feed, with conditions on how and where to grow them. However, in 2016, the United States Congress directed the FDA not to allow into commerce any food that contains GE salmon until final labeling guidelines for informing consumers of the GE salmon content were published. In response, FDA issued an import alert on eggs or any other food from the salmon imported into the U.S. Subsequently, the enactment of the National Bioengineered Food Disclosure Standard required USDA to implement a mandatory standard for disclosing whether a food is "bioengineered." FDA was divested of its authority over voluntary labeling to indicate the presence of GE content in human foods. With the publication of this labeling standard in December 2020 indicating how human food containing GE salmon can be labeled, the requirements from the U.S. Congress can now be satisfied. Therefore, the import alert was deactivated on March 8, 2019, which enabled the selling of food derived from the salmon in the U.S. and the import GE salmon eggs to raise in an FDA-approved U.S. facility.[3,8,9]

In Canada, three assessments were performed, such as safety and nutrition of the GE salmon for use as food by Health Canada, safety and nutrition of the GE salmon for use as a livestock feed by the Canadian Food Inspection Agency (CFIA), and the potential risk to the environment by Environment and Climate Change Canada (ECCC).[10,11] AquaBounty submitted its request to regulators in 2012, where their application included information on identity, a detailed description of the transformation method, gene construct, its copy number and intactness, and levels of protein expression in the animal. Also, the molecular characterization of the novel protein, potential toxicity to humans, livestock, and non-target organisms, and potential allergenicity to humans and livestock were included. In the next year, the Canadian Science Advisory Secretariat (CSAS) released their environmental and indirect human health risk assessment, which suggested that GE salmon is safe to the environment. In 2016, GE salmon was approved in Canada as food and feed.[3,12,13]


FDA U.S. Food and Drug Administration

AquAdvantage® Salmon

Environmental Assessment

In support of an approval of

a New Animal Drug Application related to AquAdvantage Salmon,

which are triploid, hemizygous, all-female Atlantic salmon (***Salmo salar***)

bearing a single copy of the α-form of the ***opAFP-GHc2*** recombinant DNA construct

at the α-locus in the EO-1α lineage

November 12, 2015

Prepared by

Center for Veterinary Medicine
United States Food and Drug Administration
Department of Health and Human Services

AquAdvantage® Salmon Environmental Assessment (cover), U.S. Food and Drug Administration (November 12, 2015).

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To prevent potential adverse impact on the environment or breeding with wild salmon populations, biological, physical, and environmental containments will be used. To prevent breeding, the transgenic salmon will be raised as females and up to 99.8% will be triploid and therefore, will not produce gametes. Triploid females have a complete loss of reproductive ability and are not compatible to wild-type fish as most of them are diploids. To counteract the small percentage of GE salmon that could be diploids capable of reproduction, they will be grown in land-based tanks with redundant physical containments such as multiple filters, nets, jump fences, a closed septic system, and other barriers. In the unlikely event that fish escape the land-based facility, the chances of them surviving are very low because the water temperatures, water flow, and high salinity in nearby rivers are not favorable. Moreover, there are no Atlantic salmon in the water near the location of these facilities in Indiana, a landlocked state in the mid-Western U.S. Considering that farmed salmon are already being reared in ocean-moored net pens, the GE salmon does not pose more threat to the wild populations in comparison.

After getting the approval, 10 tons of GE salmon fillets were sold in Canada in the year 2017 and 2018. U.S. consumers might get the fish on their dining table in this year.

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BANGLADESH

SABP Webinar: Biosafety Guidelines in Biotechnology Research & Development

Md. Imran Hossain, Department of Biochemistry and Chemistry, Faculty of Biotechnology and Genetic Engineering, Sylhet Agricultural University

From lef to right: Speakers at the SABP webinar Biosafety Guidelines in Biotechnology Research and Development - Dr. Aparna Islam, Prof. Dr. Mohammad Mehedi Hasan Khan, Mr. Sheikh Rashel Ahmed, and Mst. Rubaiat Nazneen Akhand (September 22, 2020).

The Faculty of Biotechnology and Genetic Engineering, Sylhet Agricultural University (SAU) and the South Asia Biosafety Program (SABP) jointly organized the webinar "Biosafety Guidelines in Biotechnology Research & Development" on September 22, 2020 at 11:00 am to 12:30 pm. The chief guest of the program was Prof. Dr. Mohammad Mehedi Hasan Khan, Dean, Faculty of Biotechnology and Genetic Engineering, SAU. Mst. Rubaiat Nazneen Akhand, Assistant Professor, Department of Biochemistry and Chemistry was the moderator of the program and Mr. Sheikh Rashel Ahmed, Chairman and Assistant Professor, Department of Plant and Environmental Biotechnology, SAU was the chair of the event. The keynote speaker of the webinar was Dr. Aparna Islam, Country Manager, SABP. Fifty students from SAU's Faculty of Biotechnology and Genetic Engineering attended the program.

Mst. Rubaiat Nazneen Akhand introduced the audience to the program and its aim. She mentioned some biotechnological products such as insulin, Bt brinjal, and Flavr Savr tomato, along with their benefits and concerns. She also talked about SABP's activities related to biosafety in Bangladesh. The chair of the event, Mr. Sheikh Rashel Ahmed, described biosafety levels and their importance. The chief guest of the program, Prof. Dr. Mohammad Mehedi Hasan Khan, talked about GM products, their ethical issues, and possible risks. He mentioned the rules and regulations of biosafety guidelines and emphasized lab safety. Then, the keynote speaker, Dr. Aparna Islam, described SABP's work and told us how they function with government organizations in biosafety. In her talk, she mentioned the Cartagena Protocol and how it is applied in our country. She also told us about the process of policy implementation in application approval. An open discussion session followed the presentations. The attendees learned about biosafety policy and its implementation that would enable their research work.

VIDEO

Watch the full recording at:
https://foodsystems.org/event/sabp-webinar-2020-6/

INDIA

A One CGIAR Initiative to Unlock the Potential of Gene Editing for Agriculture

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From top left to bottom right: Panelists at the first webinar in the One CGIAR Webinar Series: Genome Editing in Agriculture - Innovations for Sustainable Production and Food Systems - Dr. Renne Lafitte, Dr. Neal Gutterson, Dr. Robert Bertram, Dr. Kingston Mashingaidze, Dr. Jacqueline Hughes, and Convener, Dr. Pooja Bhatnagar-Mathur (September 22, 2020).

A five-part global webinar series on *Genome Editing in Agriculture: Innovations for Sustainable Production and Food Systems* began on September 22, 2020.

Setting the context for the session and the series itself, Dr. Jacqueline Hughes, Director General, International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), in her opening remarks, recounted the beginnings of gene editing in crops and underscored the immense untapped potential of the technology by referring to what has been accomplished as the tip of what is possible with gene editing.

Dr. Marco Ferroni, Chair, CGIAR System Board, moderated the session. In his opening address, Dr. Ferroni urged CG centres to work without duplication, share expertise and infrastructure to realize CGIAR's vision of a world without hunger, poverty, and environmental degradation, while ensuring affordability of food. He also announced the creation of a One CGIAR Community of Practice (COP) on Genome Editing and New Breeding Techniques in Agriculture. The COP aims to bring together experts and teams working in genome editing and provides a platform for interactions about specific issues in the domain. Dr. Ferroni pointed to Columbia's recent recognition of CGIAR's gene edited rice lines as conventional lines.

Public breeding programs are lagging in implementation of new breeding techniques, owing to lack of trained personnel, inadequate investment in R&D, need for infrastructure, and in many situations, unfavorable regulatory landscapes.

Dr. Robert Bertram, Chief Scientist in USAID's Bureau for Resilience and Food Security, lauded science and technologies delivered through the Green Revolution for driving higher productivity and lowering the cost of food in the face of a growing population. However, after showing the annual yield gains needed in maize and wheat to keep food prices constant as populations grow and that agriculture is stressed by climate change, pests, and diseases, he also said that breeding programs in the public sector are 20-30 years behind state-of-art private sector programs. Dr. Bertram indicated that Crops to End Hunger (CTEH) is one way the CGIAR is upping its game through the work of its centres with the Excellence in Breeding platform. He advocated a crop improvement framework involving the development of tools of gene editing that can strengthen breeding pipelines.

Terming genome editing as the future, Dr. Kingston Mashingaidze, Senior Research Manager, Agricultural Research Council, South Africa expressed concern that public breeding programs are lagging in implementation of new breeding techniques, owing to lack of trained personnel, inadequate investment in R&D, need for infrastructure, and in many situations, unfavorable regulatory landscapes. Dr. Mashingaidze also shared a few examples of collaborations employing new breeding technologies (NBTs) in South Africa to demonstrate how strong partnerships can show the way ahead.

Dr. Neal Gutterson, Senior Vice President, Chief Technology Officer, Corteva Agriscience, and a CGIAR System Board Member, said gene editing can help harvest variations in nature very quickly. He said that knowing the specific sequence of any given genome that one wants to access and edit, the germplasm base, and understanding target traits as well as their underlying genetics is critical to being able to tap the potential of gene editing and the genomics knowhow and capabilities. He cited two examples of development of maize hybrids resistant to maize lethal necrosis and Striga-resistant sorghum being developed through public-private partnerships, including CG centres, CIMMYT, ICRISAT, and Corteva.

Dr. Renne Lafitte, Deputy Director, Crop R&D, Agricultural Development Program at the Bill & Melinda Gates Foundation, said neither the benefits of gene editing nor the decisions about whether to take advantage of them should be reserved only for developed countries. Such research should involve all stakeholders where it is likely to be deployed. Dr. Lafitte further said regulations may seem like hurdles to scientists but are needed for gene edited varieties to reach farmers.

Experts from public, private and non-profit research sectors emphasized the importance of working together and the need for supportive regulations and increased technical capabilities to enable a One CGIAR to use gene editing for exponential crop improvement to meet its 2030 goals.

For more information, please visit: https://www.icrisat.org/a-one-cgiar-initiative-to-unlock-the-potential-of-gene-editing-for-agriculture/

or contact: ***Dr. Pooja Bhatnagar-Mathur****, Theme Leader – Cell, Molecular Biology & Genetic Engineering, ICRISAT*

SWAYAM Portal E-Course: Biosafety Aspects of Genetically Engineered (GE) Plants

The e-course "Biosafety Aspects of Genetically Engineered (GE) Plants" was prepared and posted on the *Study Webs of Active Learning for Young Aspiring Minds (SWAYAM) Portal* (https://swayam.gov.in/) of the All India Council for Technical Education, Government of India. The course was prepared as part of the UNEP/GEF-supported Phase II Capacity Building Project on Biosafety implemented by the Ministry of Environment, Forest and Climate Change (MoEFCC), Government of India for enhancing awareness on biosafety. Biotech Consortium India Limited (BCIL) is the technical agency for the development of the e-course, and the Centre for e-Learning, Shri Guru Tegh Bahadur Khalsa (SGTB) College, University of Delhi designed the course.

The course is a useful resource for students, teachers, and other stakeholders in understanding factual information about the biosafety of GE plants. The course is available in two languages, i.e., English and Hindi. It has six modules of 15 minutes each. The course layout of the e-course includes:

- **Module 1 – Introductory Module:** Provides overview of Phase II biosafety capacity building project, its objectives, thrust areas, and activities undertaken to strengthen the biosafety management system in India regarding use of living modified organisms (LMOs), also referred to as genetically modified organisms (GMOs).
- **Module 2 – Introduction to GE Plants:** Provides basic information about genetic engineering, GE plants, and their development, safety assessment, and current status.
- **Module 3 – Regulatory Framework for GMOs:** Provides a comprehensive overview of the biosafety regulatory framework for GE plants in India, with a view to facilitate easy understanding of the key provisions of various Acts, Rules, Guidelines, and Sectoral Policies.
- **Module 4 – Cartagena Protocol on Biosafety:** Provides a comprehensive overview of the Cartagena Protocol on Biosafety (CPB), an international agreement to facilitate easier understanding of its key provisions and obligations of Parties. CPB, a legally binding environmental treaty, to the Convention on Biological Diversity entered into force on September 11, 2003. The Protocol provides for rules and procedures to ensure the safe handling, transfer, and use of living modified organisms resulting from modern biotechnology. India is a Party to CPB.
- **Module 5 – Confined Field Trials of GE Plants:** Emphasizes the importance of confined field trials (CFTs) for the product development pipeline and regulatory review process. GE plants have to be tested in contained facilities such as greenhouses and field conditions before its commercialization. The information and data collected during these trials is critical for assessing agronomic performance, as well as biosafety assessment required by the regulatory authorities.
- **Module 6 – Food Safety Assessment of GE Plants:** Provides concept and principles for safety assessment of foods derived from GE plants. Safety assessment of a GE plant is the most important step in its development process. Information/data is generated to make a comparative assessment and determine if a GE plant is as safe as its conventional non-GE counterpart.
- **Module 7 – Environmental Safety Assessment of GE Plants:** Provides an overview of the framework used for environmental safety assessment of GE plants. Guidelines and methodologies are in place for planning and conducting environmental risk assessment in support of the release of GE plants in India for purpose of cultivation.

To access the course, visit https://swayam.gov.in/ and search "biosafety" in the course catalog, or click the link below:
https://onlinecourses.swayam2.ac.in/aic20_ge07/preview

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
One CGIAR Global Webinar Series on Genome Editing in Agriculture: Innovations for Sustainable Production and Food Systems	CGIAR	October 20, 2020 via Webcast	https://register.gotowebinar.com/register/2415711018306101775
4th International Conference on NANOFORAGRI 2020 - Application of Nanotechnology for Sustainable, Productive and Safer Agriculture and Food System	The Energy and Resources Institute	November 5-6, 2020 Gurugram, Haryana	https://www.teriin.org/events/nanoforagri/
2020 International Agriculture Innovation Conference Webinar	International Association for Agricultural Sustainability (IAAS) and the University of Maryland, Asia-Pacific Association Of Agricultural Research Institutions (APAARI), in collaboration with other international organizations	November 6-9, 2020 via Webcast	https://www.eventbank.cn/event/2020-international-agriculture-innovation-conference-webinar-24843/ Registration: https://www.eventbank.cn/event/24843/register/
India Bio @ Bengaluru Tech Summit	Department of IT & Biotechnology, Government of Karnataka	November 19-21, 2020 Bengaluru	http://www.indiabio.in/
Indian Seed Congress 2021	National Seed Association of India	February 24-26, 2021 Bengaluru	https://isc2021.nsai.co.in/
International Conference on Sugarcane Research	ICAR-Sugarcane Breeding Institute, Tamil Nadu Agricultural University, and Society for Sugarcane Research and Development	June 19-22, 2021 Coimbatore	https://sugarcane.icar.gov.in/index.php/en/canecon-2020 https://tnau.ac.in/wp-content/uploads/2020/10/1601938688.pdf
INTERNATIONAL			
3rd Asian Short Course on Agri-Biotech, Biosafety Regulation, and Communication	ISAAA Southesat Asia Center	November 23-26, 2020 via Webcast	https://zoom.us/meeting/register/ tJMvcO6oqTgjG9UyXluukBoh57wUacbPLAoR
24th Meeting of the Subsidiary Body on Scientific, Technical, and Technological Advice	Secretariat of the Convention on Biological Diversity	March 2-7, 2021 Montreal, Canada	https://www.cbd.int/meetings/?thm=CPB
3rd Meeting of the Subsidiary Body on Implementation	Secretariat of the Convention on Biological Diversity	March 9-14, 2020 Montreal, Canada	https://www.cbd.int/meetings/?thm=CPB

SOUTH ASIA BIOSAFETY PROGRAM

The South Asia Biosafety Program (SABP) is an international developmental program implemented in India and Bangladesh with support from the United States Agency for International Development. SABP aims to work with national governmental agencies and other public sector partners to facilitate the implementation of transparent, efficient, and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds, and environmental protection.

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