Bioteknologinemnda
The Norwegian Biotechnology Advisory Board

FDA U.S. Food and Drug Administration

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Opinion on the assessment of AquAdvantage salmon

The genetically modified (GM) salmon AquAdvantage would, if approved, be the first genetically modified animal to enter the food supply chain anywhere in the world. The decision made by the FDA will influence future decisions on GM salmon and other GM animals for food in the U.S. as well as other countries, making this hearing of the FDA environmental assessment particularly important. Also, the possibility of genetic contamination of wild salmon stocks worldwide must be taken into account. It is of critical importance that the evaluation criteria for such a product are set to a high enough standard in order to avoid detrimental effects on health and the environment.

Salmon is generally considered as healthy food, and food authorities in many countries encourage people to eat more salmon. The AquAdvantage salmon may be sold without a label in the U.S. and other markets where no labelling regulation applies to GM foods. Considering the criticism raised against the health and environmental risk assessments, an approval may affect the consumers' general perception of salmon as food in a negative way.

Production of farmed salmon and research on farmed salmon have been conducted for more than 40 years in Norway. The selective breeding programs that have been developed build on experiences from farm animal breeding and focus on a number of qualities such as disease resistance, feed efficiency and slaughter properties, not only on growth. Thus, salmon farming is an industry where Norway has particular experience and expertise.

For the above reasons, The Norwegian Biotechnology Advisory Board[1] has decided to comment on the AquAdvantage salmon.

[1] The Norwegian Biotechnology Advisory Board (NBAB) is an independent body appointed by the Norwegian government. Among other tasks, the NBAB evaluates GMO applications according to the criteria listed in the Norwegian Gene Technology Act, paying particular attention to social and ethical consequences of GMOs and usage that promotes sustainable development. This document presents the consensus view of the members of the NBAB. This view does not necessarily coincide with Norwegian government policy. The board members represent a broad range of perspectives and expertise, and include individuals from several business sectors, major civil society organizations as well as academia.

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Sterility and escape into the environment

In the FDA Draft Environmental Assessment it is stated that the fish will be all female and triploid, thus effectively sterile, and that the possibility of the fish reproducing in the wild therefore is extremely remote. However, the data from AquaBounty indicate that five percent of the fish will not be sterile. Therefore, some of the fish may reproduce in the wild.

AquaBounty has applied for consent to produce the salmon in inland closed facilities in order to avoid the risk of GM salmon mixing with wild salmon. However, human error and mechanical failure may occur, and scenarios of intentional and unintentional escape should therefore be evaluated.

Furthermore, AquaBounty plans to sell eggs to third parties that may grow the fish in open facilities at sea. Most likely some of the fish will escape, as a great number of fish escape from salmon farms every year. Because salmon moves freely through bodies of water genetic contamination or replacement of wild fish stocks may occur in the U.S. as well as across the Atlantic Ocean.

Environmental consequences are not taken into account by the FDA because the production is not supposed to take place in the U.S. Based on the above, the consequences in the event of an escape and the impacts on wild salmon populations inside as well as outside the U.S. should be assessed in a comprehensive environmental risk assessment.

Social and economic consequences

In Norway, the Gene Technology Act states that a GMO, in order to be approved, must not be detrimental to health and the environment. In addition, considerable weight should be given to whether the GMO contributes to sustainable development, is a benefit to society and ethically acceptable. We note that under the US regulatory regime, social, economic and cultural effects of the proposed action occurring within the US should also be evaluated, although the FDA in the summary of the Draft Environmental Assessment states that “courts have held that under NEPA, social and economic effects must be considered only once it is determined that the proposed agency action significantly affects the physical environment.” Because the fish is not completely sterile, 100 per cent containment cannot be guaranteed, and the salmon may be produced in open facilities elsewhere, we believe that the possibility of the fish affecting the physical environment in the US as well as other countries cannot be ruled out. Thus, it appears to us that social, economic and cultural impacts should be evaluated. One relevant issue is: If an escape occurs from a facility abroad, who is liable for the contamination?

Furthermore, if the general perception of salmon is negatively affected, producers of non-GM salmon and manufacturers of non-GM and wild salmon in the US as well as other salmon producing countries might suffer economic losses.

Welfare of the salmon

AquaBounty claims that their GM salmon grows faster than non-GM salmon in the fresh water phase. Data from AquaBounty show increased malformations of bones and jaws of the GM salmon compared to non-GM salmon, most likely due to the increase in growth hormone. Such malformations are also seen among other animals that are given additional growth hormones. The FDA does not view the malformations as detrimental to the salmon because the increase is small. As mentioned by FDA, malformations have also been reported in studies of traditional salmon. However, these irregularities were linked to suboptimal culture conditions and could thus be prevented, whereas altering culture conditions could not prevent malformations due to increased growth hormone.

Quality of science

The data used by FDA to evaluate the GM salmon is provided by AquaBounty and not by independent scientists. FDA conducted an open hearing for the Veterinary Medicine Advisory Committee in 2010, where the majority of the scientists concluded that the data were insufficient and that more research was needed before the GM salmon could be considered for food production. For comparisons AquaBounty several times used only six or seven fish in each group, not evenly distributed according to sex, resulting in low statistical power and consequently a poor ability to identify any effects that might be present. Based on such insufficient analyses, the FDA draws the conclusion that "because no food or consumption hazard has been identified, there are no food consumption risks." We believe that a robust conclusion regarding such risks would require new and further studies using appropriate sample sizes and study designs, and that independent scientists evaluate the studies.

Impacts on human health

In the 2010 hearing scientists called attention to a number of disturbing data regarding possible impacts on human health that needed further investigation. In addition, evaluating the GM salmon as a veterinary drug rather than food leaves important issues out of the risk assessment. For instance, feeding studies for assessing health risks have not been done. In our view, such further studies, including feeding studies, are needed to draw robust conclusions regarding possible impacts on human health.

Correlated changes when selecting for growth alone

Among animal breeding professionals it is well known that selecting only for growth generally affects other properties negatively. In general, fish that grows faster in the first phase of the growth curve will also be bigger as adults and will reach slaughter weight earlier. Along with an increased growth rate, we would expect to see differences in quality of the meat such as more coarse structure, less fat and different fatty acid composition. The GM-fish that is going to be used for reproduction will be bigger than the normal fish, and this may have negative consequences that we do not yet know.

Also, the increased growth rate of the GM salmon claimed by AquaBounty is disputed. The breeding company Salmobreed asserts that its non-GM salmon that is selected for faster growth in a traditional breeding program gets as big as the GM salmon.[2] This suggests that similar growth can be obtained by traditional breeding programs. However, these breeding programs seek to avoid negative consequences of increased growth by selecting for many parameters, including health and meat quality parameters. The salmon industry does not see growth rate as a major challenge at the moment.[2] When evaluating the AquAdvantage salmon, we recommend that its properties, including growth performance, be compared with the results obtained by the best traditional breeding programs.

The International Salmon Farmers Association (ISFA) has declared that "[i]n accordance with sound environmental practice, the ISFA firmly rejects transgenic salmon production".[3] In line with ISFA's policy Norwegian fish farmers have stated that they do not want to produce GM salmon.[4]

Conclusion

Considering the criticisms that have been raised against the health and environmental risk assessments, in our opinion approval for the AquAdvantage salmon should not be granted.

Sincerely yours,

Lars Ødegård
Chairman

Sissel Rogne
Director General

[2] www.salmobreed.no/newsletters/en/newsletter_5_2011.pdf

[3] IFSA statement from the 17th General Meeting in 1996, reconfirmed in 1999. ISFA is an international association with the following members: Australia, Canada, Chile, Faroe, Iceland, Ireland, New Zealand, Norway, UK and USA.

[4] Letter from The Norwegian Seafood Federation 31 August 2004.