GE Salmon Sets Stage For Future GMO Labeling Regime

Law360, New York (June 27, 2016, 11:46 AM ET) -- Over approximately the last two years, there has been a significant uptick in legislative activity, as well as much public debate, around whether to establish mandatory labeling for foods containing or produced with genetically modified organisms (GMO) or, more specifically, foods produced through the use of genetic engineering (GE) techniques.

In late 2015, the U.S. Food and Drug Administration (FDA) emphatically restated its regulatory jurisdiction over the labeling of food products produced using genetic engineering technologies by, among other actions, approving the first GE animal as safe for human consumption and for use in human food[1] and concurrently releasing a draft guidance that describes a voluntary labeling standard for food products that contain the aforementioned approved GE animal (the AquAdvantage salmon, an Atlantic salmon engineered to reach market size more quickly than a non-GE farm salmon through inclusion of a gene from Chinook salmon).[2] The FDA's voluntary GE salmon labeling guidelines follow the principles set out 15 years ago for the labeling of bioengineered plants and plant-based ingredients.

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On May 20, 2016, the Senate Appropriations Committee unanimously approved the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies fiscal year 2017 appropriations bill ("S. 2956").[3] Language included in the bill would require the FDA to mandate the labeling of GE salmon. Specifically, the relevant provision states that "the acceptable market name of any salmon that is genetically engineered shall include the words 'genetically engineered' or 'GE' prior to the existing acceptable market name;" and clarifies that "salmon is genetically engineered if it has been modified by recombinant DNA (rDNA) techniques, including the entire lineage of salmon that contain the rDNA modification."

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Sen. Lisa Murkowski, R-Alaska, proposed this amendment that would require labeling of GE salmon. Murkowski, who had proposed this statutory language twice before, has been at odds with the FDA ever since it approved the use of GE salmon as a human food, a disagreement to which she has referred as her "fight against Frankenfish."[4] At the Appropriations Committee markup of the bill, Murkowski stated that mandatory labeling of GE salmon would not correct the FDA's "wrong-headed decision," but could serve to calm consumers' concerns regarding the safety of GE salmon.[5]

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This appropriations bill now awaits a floor vote. Congress will be out of session after July 14th and will return to work in early September. If the various appropriations bills are not done before the summer recess (which political insiders consider to be highly improbable), S. 2956 and others likely won't be taken up until after the November elections are behind us.

## Likelihood Congress Will Enact Mandatory Labeling

Labeling of GMO foods, whether voluntary or mandatory, is an issue that has divided members of both houses of Congress over the past year. This reality alone indicates that there is no guarantee that Murkowski's labeling requirements for food products containing GE salmon will be enacted into law. In addition, the FDA has clearly embraced a regulatory scheme for GMO foods that includes voluntary labeling, meaning that a solid congressional majority would need to coalesce in order to spike the FDA's chosen system.
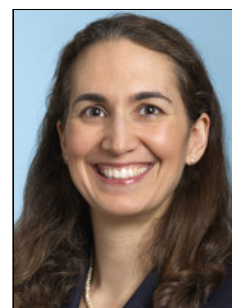
However, Murkowski, along with other members from the Pacific Northwest region, has already shown her tenacity in influencing the FDA to change its stance on GE salmon. The Alaskan senator originally blocked Dr. Robert Califf's confirmation as FDA commissioner, demanding greater assurances from the agency that it would specifically address regulation of GE salmon and develop more stringent labeling requirements.[6] She also introduced language into the 2016 Omnibus Bill (enacted in December 2015) that prohibited the FDA from allowing the introduction into commerce of any food containing GE salmon, which effectively forced the agency to impose an import ban on GE salmon for one year.[7]

These gambits have paid off, as the FDA has committed to working with Murkowski on mandatory labeling for GE salmon. In fact, the recent language included with S.2956, as with previous iterations introduced in legislation from earlier this year, is based on collaboration between the senator and the FDA. Thus, Murkowski has appeared willing to spend significant political capital in order to bring all sides of the issue together and to reach consensus around labeling requirements.

Murkowski's position stands to gain traction among fellow members of Congress and the public because, rather than requiring mandatory labeling of all GMO foods, her demands have been limited to only GE salmon. The labeling requirement would affect a minimal number of businesses that would produce or sell food products containing GE salmon, which is itself not yet commercially available, and therefore it should not create significant political resistance. Public opposition to GE salmon also appears to be growing due to many Americans' general distrust of GMO food products. In fact, approximately 80 retail stores and restaurants have publicly vowed not to sell GE salmon products.[8] This general opposition among voters could influence Congress to enact the mandatory labeling requirements in S.2956.

Potential Industry Effects

Although the FDA has not given any indication that it will make sweeping changes to its draft guidance outlining a voluntary labeling scheme for GE-derived foods and food ingredients, the agency's willingness to cooperate with Murkowski and any future passage of a mandatory labeling requirement for GE salmon signal more significant and far-reaching changes to the current labeling regime. Some general considerations include the following:

- The FDA's collaboration with Murkowski may indicate that the agency is willing to draw distinctions between food products derived from GE animals and other types of GMOs, and possibly to create two separate regulatory regimes for GE animals and GE crops. This would make it more likely that other attempts to introduce GE animals as safe for human consumption, if met with equally vigorous opposition, will be considered for mandatory labeling by the FDA.

- Depending on the amount of support it receives, enactment of a mandatory labeling requirement for GE salmon could be seen as a legislative rebuke to the FDA for being too cavalier about labeling requirements for GMO food products more generally, especially when such products are derived from GE animals. Overwhelming support for the bill could cause the FDA to reexamine its overarching position on GMO labeling.

- The mandatory labeling requirements — only one example of the political, legal, commercial and public opposition to the approval of GE salmon — may encourage the FDA to be more critical and demanding when evaluating future applications for approval of GE animals for human consumption. Increased FDA scrutiny would likely increase approval time, as well as research and development time and cost.

Conclusion

For businesses that develop, produce, import, distribute, or sell GMO foods — whether they are commonly available biotechnology-derived plant ingredients or, eventually, GE salmon and possibly other animals — the outcome of this mandatory labeling amendment to a FY2017 appropriations bill is more than just academic. Critics of Murkowski's actions and those of others who have decried the FDA's approval of the GE salmon argue that they are fomenting consumer fear and ignoring decades of science, as well as global realities that require sustainable approaches to farming and food production.[9] How we elect to handle the commercialization of GE salmon this year could very well set the course for the nation's policies in this area for decades to come.

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[1] FDA Has Determined That the AquAdvantage Salmon Is as Safe to Eat as Non-GE Salmon, FDA.gov (Nov. 19, 2015), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm472487.htm.

[2] U.S. Food & Drug Admin., Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon (2015), available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm469802.htm.

[3] S. 2956, available at https://www.gpo.gov/fdsys/pkg/BILLS-114s2956pcs/pdf/BILLS-114s2956pcs.pdf .

[4] https://www.murkowski.senate.gov/press/newsletter/senator-murkowski-e-newsletter-for-february-23-2016

[5] http://www.appropriations.senate.gov/hearings/markup-of-the-fy17-agriculture-appropriations-bill-and-the-fy17-legislative-branch-appropriations-bill

[6] http://www.adn.com/politics/article/murkowski-drops-nominee-hold-over-ge-salmon/2016/02/15/

[7] Import Alert 99-40, http://www.accessdata.fda.gov/cms_ia/importalert_1152.html

[8] https://ecowatch.com/2016/05/25/retailers-no-gmo-salmon/

[9] See, e.g., June 22 editorial by Hank Campbell, president of the American Council on Science and Health, available at http://www.sandiegouniontribune.com/news/2016/jun/22/agriculture-gmo-salmon/