## **SNR Policy Review debates the process of approving genetically engineered products**

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U.S. Federal regulators have approved a fast-growing transgenic salmon as the first genetically engineered animal raised for human consumption. While some are hailing it as a historic breakthrough, others are questioning whether the approval process for the technology is stringent enough to prevent risks to the environment. One of those doing the questioning is Auburn University's Conner Bailey. Bailey recently published a policy review entitled, "Transgenic Salmon: Science, Politics, and Flawed Policy," in Society & Natural Resources, in which he calls for reconsideration of the U.S. Food and Drug Administration (FDA) as the designated agency for approving genetically engineered animals. The policy review is currently available for free from Society & Natural Resources.

According to Bailey, the FDA has the lead regulatory role for <u>genetically</u> <u>engineered</u> products in the U.S. because of a Federal decision made in 1986 and updated in 1992 that established the Coordinated Framework for the Regulation of Biotechnology. This framework was designed to establish clear responsibilities over such products among the U.S. Department of Agriculture, the U.S. Environmental Protection Agency and the FDA. While Bailey's article was working its way through the peer review process, the Obama Administration ordered a reconsideration of how transgenic animals and plans are reviewed and subsequently approved, giving the three agencies one year to accomplish the task. This reconsideration, however, will not affect the FDA's Nov. 19 decision to approve production and consumption of a transgenic salmon.



Bailey contends the FDA should not be alone in making such a determination. "The FDA is ill-equipped, on its own, to make a <u>science</u>-based decision on ecological impacts," Bailey said. "While the agency has staff expertise on questions of food safety, they have zero staff expertise on issues associated with aquatic ecology and aquaculture. The risk of releasing what is essentially an exotic species into the wild is real and potentially significant." The agency's recent action is precedent setting, said Bailey, and likely will lead to the adoption of genetic engineering in other fish species and possibly other animals as well.

In his review, Bailey argues that a careful, comprehensive approach is needed to address transgenic fish—a process involving those federal agencies that have the requisite expertise to make a full evaluation of food safety, social impacts, and environmental risks. "But the more pressing need is to overhaul the existing approval framework to address the unique challenges posed by introducing transgenic fish," he said.

**More information:** An updated web link to a key resource used in preparation of this policy review can be found here: <u>envs.dartmouth.edu/sites/envs.</u> ... u/files/comments.pdf

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