

The Science and Regulation of Food from Genetically Engineered Animals

Genetically engineered (GE) animals were [first produced](#) in the late 1970s.

- Transgenic laboratory rodents have become increasingly important for biological and biomedical research.
- In 2009, the first GE animal producing a pharmaceutical product was approved by the U.S. Food and Drug Administration (FDA).
- To date, no GE animal intended for use as food by humans has received regulatory approval.

From the [viewpoint of diverse stakeholders](#), the FDA's regulatory approach has both strengths and weaknesses.

- Premarket review of safety is rigorous and mandatory; agency approval is followed by monitoring, and approval can be withdrawn if adverse outcomes are observed.
- A major criticism of the approval process is that the FDA lacks authority to consider social concerns falling under the heading of "ethics."
- The most often-expressed weakness is that there are no provisions dealing specifically with environmental risk.



In 1993, AquaBounty Technologies initiated discussions with the FDA seeking regulatory approval of a [GE Atlantic salmon](#).

- A formal application for an investigative new animal drug with intent to commercialize the AquAdvantage (AA) salmon occurred on September 14, 1995.
- The AA salmon application included mitigation measures to abate environmental impacts by limiting the "product definition" to triploid, all-female, hemizygous transgenic Atlantic salmon grown out in a freshwater, land-based culture facility in Panama.
- The unanimous conclusion of the FDA scientists was that food from AA salmon "is as safe as food from conventional Atlantic salmon."
- As of April 2011, the FDA had not yet made a decision regarding the environmental review of the AA salmon.

All technologies are associated with some form of risk, but all [risks are relative](#) to alternatives.

- The current regulatory process associated with GE animals focuses on potential risks, with little consideration of counterbalancing benefits or positive environmental impacts.
- Forgoing access to GE technology may jeopardize future access to improved genetic lines.
- The current regulatory approach has resulted in an inhibitory effect on commercial investment in the development of GE animals with ramifications for food security.

Experts to Contact for More Information:

Alison Van Eenennaam (alvaneennaam@ucdavis.edu); Eric Hallerman (ehallerm@vt.edu); William Muir (bmuir@purdue.edu)

To view the complete text of this CAST Commentary, click [here](#) or visit the CAST website (www.cast-science.org) and click on Publications. For more information about CAST, visit the website or contact the CAST office, at 515-292-2125.