

Teaching Notes

FISHY BUSINESS?

AquaBounty Technologies, the FDA, and Genetically Modified Foods

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On September 19, 2010, 13 members in a special Veterinary Medicine Advisory Committee (VMAC) of the Food and Drug Administration (FDA) convened for public hearings to discuss the potential approval for biotechnology company AquaBounty Technologies' AquAdvantage salmon. This particular salmon is genetically modified (GM) to grow twice as fast as conventional Atlantic salmon. If authorized, the product would mark the first FDA-approved GM animal for human consumption. To AquaBounty, the AquAdvantage salmon would be a profitable solution to meet increasing fish demand in the coming years. Critics of the GM salmon, however, pointed to the flawed FDA approval process—the public was only given 14 days to review all documents before the public hearing, and several organizations questioned the makeup of VMAC and whether the studies provided by AquaBounty adequately addressed ecological and human health concerns.

This case considers the FDA approval process for genetically modified animals in light of AquaBounty Technologies' push to bring AquAdvantage salmon to the market. Issues of effective governance, transparency, and antiquated policies highlight challenges for the FDA in regulating biotechnology advancements.

The case text and teaching notes for this case were completed under the direction of Dr. Rebecca Dunning, the Kenan Institute for Ethics.

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Teaching Notes

Target Audience

Public Policy
Public Management
Sociology
Genome Science
Organizational Studies
Organizational Ethics
Environmental studies

Learning Objectives

1. Familiarize students with public policies that contributed to the crisis.
2. Gain insight into the unique organizational structures of the Food and Drug Administration and how these structures facilitate its mission, value, and vision.
3. Explore the impact of changing resource conditions and the policy environment on biotechnology companies and the regulation of food production.
4. Consider the efficacy of human and environmental health and safety using the current regulatory structure.

Questions for class discussion

1. Topic: Accountability and Conflict of Interest

Notes for the instructor: “Accountability” is defined as the obligation to explain, justify, and answer questions about how resources have been used and to what effect.¹ In an organizational context, accountability refers to who is to be held accountable, for what, to whom, through what means, and with what consequences. An organizational system of accountability can strengthen institutional legitimacy by providing transparency of evidence to those within and outside the organization. For example, the FDA is held accountable to the public, who can exercise their right to participate in the legislative process or to comment on proposed regulations, as in the case of the AquAdvantage salmon.

Related to accountability is the issue of conflicts of interest. A conflict of interest is a situation in which considerations, whether financial or personal, have the potential to compromise or bias professional judgment and objectivity. As mentioned in the case, certain members of VMAC, including the temporary voting members, had clear conflict of interests that may have swayed the way they voted. Alison L. Van Eenennaam and Kevin G. Wells seem to have clear conflicts of interests because they are both part of companies that are also developing genetically modified animals. Perhaps approval of AquAdvantage Salmon would clear the road for approval of their own products. On the other hand, these individuals arguably have a great deal of expertise in the area, and would be able to provide valuable advice to the FDA. Some would argue that it is foolish to bar individuals with the most knowledge of the process from providing expertise and guidance.

¹ Trow, Martin. 1996. “Trust, Markets & Accountability in Higher Education: A Comparative Perspective.” *Research and Occasional Paper Series: CSHE.1.96*. University of California Berkeley: Center for Studies in Higher Education.

To whom or to what are regulatory agencies (e.g. the FDA), the oversight committees (e.g. VMAC), and individual committee members accountable? Do the bases of accountability differ across all three entities based upon changing contexts?

Notes to the instructor: U.S. food agencies are held accountable on various levels. They are accountable to the U.S. President, who has constitutional responsibility to assure that laws are faithfully executed, and that officials appointed to office are carrying out their duties.² Additionally, the food agencies are accountable to Congress, the courts, and the public. However, even with this system of checks and balances, it may not be enough. The example of the BP oil spill in June 2010 was brought up by Margaret Mellow in the case study, in which she pointed out that the deep-water well contained “simultaneous, multiple, redundant measures to keep a spill from happening. But despite all that, a spill happened.”³ This brings up questions of whether the accountability structures in place are truly effective.

“Accountability” typically refers to quantifiable measures of efficacy. The FDA may quantify the number of foodborne illness outbreaks as a measure of accountability. For the biotech industry, accountability is typically measured monetarily, through quarterly profit statements. The public social benefit, in this case, is often hard to measure. It is important to stress the fact that cost/benefit analyses with regards to human health and environmental concerns are difficult to quantify. This is particularly true for biotech advancements, since the technologies are so new, but the stakes can be quite high, as seen by the threat that GM salmon may pose to the wild salmon population.

2. Topic: Governance

Notes to the instructor: Governance refers to the explicit and implicit arrangements by which decision-making authority and responsibility within an organization are allocated among the parties who participate in the organization.⁴ With regards to the FDA, it is important to see how there is “shared governance” across agencies. In the “Guidance for Industry” document, the following footnote was provided:

The FDA does not intend to regulate rDNA constructs that meet the definition of a veterinary biologic and that are regulated by the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA). 21 CFR 510.4. FDA intends to develop a memorandum of understanding with APHIS that will clarify the division of responsibilities between FDA and APHIS for GE animals carrying such rDNA constructs. We also recognize that EPA may assert jurisdiction over certain GE animals as well. In addition, FDA is discussing with other agencies the best approach for oversight of GE insects. Future guidance may be developed to address them. FDA also will work with other relevant federal and state agencies should it receive a request for investigation or approval of a GE wildlife animal ultimately intended for release into the wild.

How are the issues of governance implicated in the crisis that may surround the AquAdvantage salmon approval process?

What are the implications of not having a single statute or regulatory agency looking at biotechnology?

² U.S. Food and Drug Administration. “United States Food Safety System.” Published in *The Ethics of Food: A Reader for the Twenty-First Century*. 2002. New York: Rowman & Littlefield.

³ <http://www.npr.org/templates/story/story.php?storyId=129939819>

⁴ Hirsh, Werner and Luc Weber, Eds. *Governance in Higher Education: The University in a State of Flux*.

Notes: Have students discuss the above statement and the potential implications for such a structure. It would also be useful to mention that the FDA takes into consideration environmental impacts, but that the EPA and other regulatory entities also have jurisdiction over the environment. Point out how the authority and responsibilities for environmental oversight are split between two agencies, and that there may be little formalized communication between the two regulatory bodies.

3. Public and Private Aims

What is the role of the FDA? What are its main concerns? What is the role of biotechnology companies? What are their main concerns?

Do you see a tension between the goals of biotechnology companies and that of the FDA? Are market-driven demands for productivity compatible with the public aims for human health and safety?

Vandana Shiva, a writer and science policy advocate, makes a distinction between private-interest and public interest science. Shiva states,

The conflict over genetically engineered crops and foods is not a conflict between “culture” and “science.” It is between two cultures of science: one based on transparency, public accountability, and responsibility toward the environment and people, and another based on profits and the lack of transparency, accountability, and responsibility.⁵

The differences between private and public interest are important to establish. Have students talk about the different mission statements of the FDA, an entity primarily accountable to the public and public health, and for AquaBounty and other biotechnology companies, which are accountable to shareholders. How can we as a society reconcile these competing missions?

4. Topic: The impact of biotechnology and genetic modification on perceptions of food.

What are your views of genetically modified foods, and how were these views developed?

What does it mean for food to be “natural”? Is this distinction useful when discussing food? Do you think genetically-modified foods should be labeled as such?

Notes: In talking about people’s views of food and whether they see food as being “natural,” it is important to keep in mind that cross-breeding and hybridization of plants are practices that have been around for many years. It may also be important to bring up the issue of food labeling here. In the discussion of food labeling, ask whether students see a distinction between “natural” foods and genetically modified foods. As noted in the text, GM foods (including vegetables) currently do not require labeling. Should a distinction be made, and where should the line be drawn? What are the pros and cons of such transparency, and what do people think are the government’s motivations for not requiring labeling? Also mention the appearance of other food labeling, such as “organic” and “fair trade.”

⁵ Shiva, Vandana. 2000. *Stolen Harvest*. Cambridge, Mass: South End Press.

It may be helpful to discuss four perspectives on food, as developed by scholar Gregory E. Pence,⁶ and connect the categories of perception to the organizations in the case study (FDA, Aquabounty, environmental NGO's, food safety interests, etc.):

Naturalists value low-tech, family-run farms that promote sustainable, environmental practices.

Progressives believe that scientific knowledge should be used to promote agricultural efficiency. They consider genetic modification to be safer and more environmentally sustainable than conventional breeding, such as hybridization.

Egalitarians' greatest concern is the unequal distribution of food worldwide. Biotechnology and other scientific innovations should be used when there are clear benefits to everyone.

Globalists believe well-functioning and dynamic economies will raise standards of living. The democratization of economies will help resolve hunger.

In contrasting the varying perceptions across groups, also consider how organizational members likely have very different conceptions of what “safe” means with regard to GM foods.

⁶ Pence, Gregory. 2002. “Designer Food: Mutant Harvest or Breadbasket of the World?” New York: Rowman & Littlefield Publishers.