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 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 enhancements. ons are reacting to rapid scientific innovations that may pose threats to human and environmental safety.

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

In 2006, approximately 110.4 million metric tons of fish were consumed, with almost half of that from aquaculture, the commercial farming of fish. Seventy percent of salmon consumed are from farmed sources. The Food and Agricultural Organization (FAO) of the United Nations has estimated that by 2030, annual commercial production will need to increase by an additional 28.8 million metric tons in order to maintain per capita fish consumption at current levels. Biotechnology company AquaBounty Technologies’ hopes to meet this demand through the production of a genetically engineered fish that grows twice as fast as conventional Atlantic salmon, an advantage that would significantly cut production costs for fish farmers while providing a potentially large source of revenue for the company.

AquaBounty Technologies first filed for U.S. approval of its AquAdvantage salmon in 1995. In 2010, the FDA announced that there was enough information available to review the GM salmon. However, criticisms of the FDA approval process have brought up issues of transparency and accountability. The FDA released 255 pages of technical information regarding the GM salmon on Sept 5, 2010, giving the public only 14 days to review the document before the public hearings would begin September 19. The Consumer Union, the nonprofit watchdog group and publisher of Consumer Reports, formally submitted comments noting the shortened time frame for public comments, the questionable composition of the review board, and lack of data rigor present in AquaBounty’s research.

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. This case also highlights how accountability frameworks within public institutions are reacting to rapid scientific innovations that may pose threats to human and environmental safety.

“The Magician’s Wand”: History of Agricultural Science and Genetics

The process of modifying crops through agricultural science has been occurring for several centuries. In the late 1840s, Justus von Liebig published Organic Chemistry and Its Applications in Agriculture and Physiology. Thousands of copies of the book were sold in America, and his letters were published in newspapers around the world, making Liebig a better known international figure than Abraham Lincoln by the start of the Civil War in 1861. The publication discussed soil fertilizer and its implications for agriculture, and the first application of agricultural science was coincidentally in fertilizer by James Murray in 1842. His treatment of fertilizer was further investigated by other scientists, which led to the advent of the modern nitrogen fertilizer industry, which has produced both greater yields and environmental problems.

Concerted scientific research on genetics can be traced back to the work of evolutionary biologist Charles Darwin, who in 1859 brought to light the laws of heredity and natural selection in The Origins of Species. Darwin’s research was influenced by William Youatt, an agriculturalist who understood the principle of selection as a tool that one could use to “not only modify the character of the flock, but to change it altogether.” In this sense, the laws of

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5 Ibid. Page 50. See Modern Applications of Genetics in Food section of this case for more information
heredity were a “magician’s wand” that enabled agriculturalists to alter their stock.

It was not until Gregor Mendel, the Moravian monk, that the significance of the hereditary factors, or genes, was established as he examined the breeding of two types of peas in his monastery garden. He mathematically documented the outcomes of crossbreeding round, yellow peas with wrinkled, green peas. His observations led to the development of Mendel’s laws of genetic inheritance, which was published in 1866. His work was mostly forgotten until 1886, when Dutch botanist Hugo De Vries recovered Mendel’s publication while Vries himself was developing his theories of plant heredity and mutation. Mendel’s work has been cited as the groundwork for contemporary molecular techniques for plant improvement.  

Traditional methods of crossbreeding and hybridizations as employed by Mendel involve artificial selection, which is the genetic improvement of cultivated plants and domesticated animals by way of direct human interference. Genetic modification, which began in the 1990s, is an extension of artificial selection, whereby new genetic material is created and directly inserted in plants and animals, a method not seen in traditional methods of hybridization and cloning. Biotechnology is thus the use of biological processes and living organisms to produce food. There are various names for foods that contain genetic engineering, the most popular being “genetically modified,” “genetically engineered,” “genetically altered,” “transgenic,” or “advance-hybrid.”

The FDA defines genetically engineered (GE) animals as “those animals modified by recombinant DNA (rDNA) techniques, including the entire lineage of animals that contain the modification.”

Modern Applications of Genetics in Food

The application of Mendel’s laws of plant breeding spurred the creation of high-yielding hybrid seed varieties that resulted in the dramatic increase in crop yields from 1950 to 1984. This period is known as the “Green Revolution,” and was particularly promising in the developing world. For example, wheat and rice production increased by about 75 percent between 1965 and 1980. In America, the hybrid seed varieties led to a 242% increase in production of the 17 most important domestic crops, while area only increased by 3 percent between 1940 and 1980.

Today, applications of biotechnology in foods are abundant. According to the International Service for the Acquisition of Agri-biotech Applications, a non-profit international organization that supports biotechnology as a means of helping farmers in developing nations, 14 million farmers in 25 countries planted 134 million hectares (i.e. 330 million acres) of biotech crops in 2009, a 80-fold increase from 1996.

In addition to biotech crops, the genetic modification of animals and fish is becoming a growing area of research. Transgenic cattle, sheep, pigs, chickens and other animals have been used in biomedical research, and show potential for farming. These animals have faster growth rates, lower fat levels and increased disease resistance.

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7 Ibid. Page 56.  
9 Biologist Stephen Nottingham differentiates the distinction between cross breeding and genetic modification as such: “[Traditional plant breeding] is constrained by limitations in sexual compatibility, which prevents cross-fertilization between species. This limits the potential gene pool, that is the total number of genes and their different alleles, available for crop improvements. Genetic engineering extends this potential by creating new genetic material for breeders to work on. Once a foreign gene has been engineered into a variety, it can be passed into hybrids like any other gene using traditional breeding methods.” Further reading can be found in: Nottingham, Stephen. 2003. *Eat Your Genes: How genetically modified food is entering our diet*, Second Edition. New York: Zed Books.  
10 Ibid. Page 1.  
transferred to the animals are generally ones that regulate the production of growth hormones, or chemicals that regulate growth, thus making the process of growing animals more economical.

The benefits of biotech foods have been established on several fronts. Proponents recognize biotechnological advancements as a way to increase crop yield, create herbicide- and insect-resistant crops, and design crops that are tolerant to various conditions, including droughts and frosts.\(^{16}\) Supporters of biotechnology see biotech crops as an innovative approach to world hunger. One example is the “Golden Rice” initiative, which began in 1984 by Dr. Peter Jennings. The goal of the venture was to alleviate Vitamin A deficiency by inserting beta-carotene into rice.\(^{17}\) Others, such as philanthropist Bill Gates and the Director-General of the FAO, endorse biotech advancements as an important method to tackle the problem of resource constraints. At the 2009 World Summit on Food Security, world leaders discussed key challenges facing the world, including the increase to a world population of 9 billion inhabitants by 2050. The goal of eradicating world hunger is paired with an emphasis on international development. A declaration stemming from the World Summit on Food Security, states,

> We recognize that increasing agricultural productivity is the main means to meet the increasing demand for food given the constraints on expanding land and water used for food productive. [...] We will seek to mobilize the resources needed to increase productivity, including the review, approval, and adoption of biotechnology and other new technologies and innovations that are safe, effective, and environmentally sustainable.\(^{18}\)

However, not all outcomes of biotech food production have been positive. Following the “Green Revolution,” the yield outputs after 1984 leveled off and declined due to the high levels of expensive agrochemicals, high water volumes for irrigation, and the increase in farm machinery. These new crops favored large farms, and poorer farmers could not benefit from new seed varieties. It was also found that agrochemicals degraded the environment and polluted water, and an overuse of pesticides created resistance in pests.\(^{19}\) Critics point to issues of resource efficiency, resource allocation, and ecological risks as downfalls of biotech advancements.

There are also several notable ecological concerns with regards to GM crops. For example, genetically modified crops may become weeds to agricultural or natural habitats, diverting nutrients from the crops in the soil. The new genes may also be transferred from the GM plants to the wild population, whose hybrid offspring could have an effect on the existing environmental landscape. For transgenic fish, there is also the potential for reproduction between GM and wild species because the fish are not domesticated. The Pacific Salmon, for example, are genetically engineered to no longer migrate annually from salt to fresh water. By increasing their growth rate—and economic value—of breeding in the ocean, the chance of salmon escaping into the wild may produce large-scale displacement of the wild salmon.\(^{20}\)

Additionally, opponents have cited GM foods as having negative impacts on human health. Biologist Dr. Stephen Nottingham notes the possibility of food allergies to GM foods and bacterial buildup in the human gut that could lead to antibiotic resistance.\(^{21}\) Critics also bring up the lack of labeling for genetically modified foods as another cause for concern. Consumer advocates believe the public should have the right to information about their food.

\(^{16}\) Ibid.


\(^{20}\) Ibid. Page 88.

\(^{21}\) Ibid. Page 91.
Currently, genetically modified crops do not require labeling, and the issue of labeling has been brought up again with regards to the potential of GM animals for human consumption. Further, Carol Tucker Foreman, director of the Food Policy Institute at the Consumer Federation of America, a consumer advocacy group in Washington, D.C., feels that when it comes to animals, labeling may not appease consumers—many individuals object to the genetic engineering of animals on humane or ethical grounds more so than on concerns for human safety.  

The Genetic Era and U.S. Regulations

The Genetic Era dawned when the U.S. Department of Agriculture approved Petition No. 92-196-01P on October 19, 1992, which approved the commercialization of the Flavr Savr Tomato by Calgene Incorporated. In 1994, the Flavr Savr tomato was the first genetically modified product to reach U.S. supermarkets. The tomato was supposed to soften at a slower speed compared to conventional tomatoes. The Flavr Savr tomato was not a success with the public, however, given its (ironic) lack of flavor.

The first profitable genetically modified plant was Monsanto Company’s Roundup Ready soybean, which was approved by the Department of Agriculture on May 19, 1994. This spurred subsequent government approval for GM corn, potatoes, cotton, squash, papaya, radicchio, and tomatoes. In 1996, the first GMO crops were grown commercially. These crops generally included two new gene traits. One was herbicide tolerance, mostly using the Monsanto-created Roundup formulation; the other was insect resistance, in which a bacterium, Bacillus thuringienis, would cause plants to produce a protein fatal to pests.

The United States leads all other countries in the production of genetically modified crops, planting 64.0 million hectares of GM crops. In 2009, over 75% of the 90 million hectares of soybeans and almost 50% of the 33 million hectares of cotton were biotech. An additional 32 countries granted regular approvals for biotech crops between 1996 and 2009. With regards to consumption, it is estimated that 70% of processed foods sold in the USA and Canada contain approved GM ingredients.

The Regulatory Framework of Genetically Engineered Foods in America

Coordinated Framework for Regulation of Biotechnology

Federal policy first addressed biotechnology in 1986. The “Coordinated Framework for Regulation of Biotechnology.” Stated that no new laws were needed to regulate the products of biotechnology. This piece of policy was based upon the assumption that “upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately.” Under the “Coordinated Framework,” three lead federal agencies—the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (USDA/APHIS), the Department of Health and Human Services’ Food and Drug Administration (HHS/FDA), and the Environmental Protection Agency (EPA)—have the responsibility for implementing the nation’s biotechnology regulatory framework.  

26 Ibid. Page 15.