

Maine Organic Farmers and Gardeners Association

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Crop Certification • Education and Technical Services

Bernard A. Schwetz
Acting Principal Deputy Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20857

February 7, 2002

Re: Docket No 01P-0230

Dear Deputy Commissioner Schwetz:

The Maine Organic Farmers and Gardeners Association (MOFGA) has joined in the petition of the Center for Food Safety for a moratorium on marketing and importing genetically engineered (GE) salmon, and opposes the pending application of A/F Protein/Aqua Bounty Farms for "new animal drug" approval of its GE salmon. Aqua Bounty has claimed that these GE fish grow up to 600 percent faster than non-transgenic salmon and can reach harvest size in about 16-18 months compared with the typical grow-out period of farmed and wild salmon of three years. MOFGA has been long an opponent of the commercialization of genetically engineered crops until a full environmental impact statement and human safety analysis have been completed. We believe that the cultivation of these fish in Maine or Canadian waters will spell the end of the endangered Atlantic salmon, may jeopardize other marine species and ecosystems, and may present unknown and unstudied risks to human consumers.

We were interested to note that in the January/February 2001 issue of the FDA Consumer, FDA staff writer Carol Lewis stated that "making a transgenic animal is deceptively simple, especially when compared to traditional breeding approaches." Deceptive, yes; simple, no. We suggest that FDA staff study carefully the article just published by Barry Commoner (Harper's Magazine, Feb. 2002, "Unraveling the DNA Myth: The spurious foundation of genetic engineering"), which reveals that genetic engineering is, if anything, deceptively, and dangerously, *complex*. Commoner explains how the drive for commercialization of genetically engineered products has distorted normal scientific processes, resulting in continued adherence to a genetics model that has been long refuted by a wealth of research. The relationship between genetic sequencing and ultimate plant or animal traits is far more complex than industry would have us believe, and subject to more variability, unpredictability, and risk. Genetic engineering, in effect, creates new proteins that we are unable to predict, and that industry is not required to identify or test for: "[I]n that alien genetic environment [of the host organism], alternative splicing of the bacterial gene might give rise to multiple variants of

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the intended protein – or even to proteins bearing little structural relationship to the original one, with unpredictable effects on ecosystems and human health.” *Id.* at 45.

We in Maine are faced with the disturbing fact that more fish farm escapees are trapped in some Downeast rivers than native endangered wild salmon; the prospect of a new breed of farmed salmon that grows much faster and competes more effectively for resources and mates than wild salmon is truly devastating. Aqua Bounty’s solution of farming only sterile females is no solution at all, because there can be no guarantee of sterility. This was demonstrated most pointedly in research by Aqua Bounty’s own scientists. In Sutterlin, Fletcher, Hew and Benfey, “Environmental Risks in Using GH Transgenic Atlantic Salmon and Rainbow Trout for Commercial Marine Production in Canada,” [www.nbiap.vt.edu/brarg/brasym96/sutterlin96.htm], lead authors Sutterlin and Fletcher are employed by Aqua Bounty and A/F Protein, respectively. The authors acknowledge a fact well understood in Maine: “unless the aquaculture operation is entirely land-based with rigid containment methods in place, there is always the possibility of sterile transgenic fish escaping into the wild.” They go on to admit, moreover, that assurance of sterility is impossible: “the magnitude of risk will depend on the nature of the gene construct and its phenotypic effect, and will vary between different salmonid species and ecological regions. Present sterility techniques will probably be adequate for some species in most circumstances, but may not sufficiently reduce risks (or be commercially viable) for other species under other conditions. Considering the lack of present understanding of the fitness (behavioral, physiological and genetic) of such transgenic fish, it may be exceeding difficult to predict impacts in many situations.” Cold comfort for endangered cold water fish.

MOFGA would like to take this opportunity to reiterate a more systemic comment on the inadequacy of FDA and other federal oversight on transgenic fish. Seven years ago, the undersigned served on the Maine Commission to Study Biotechnology and Genetic Engineering, and spent the better part of a day with FDA biotech policy chief James Maryanski, receiving assurances that the system of federal regulation of biotechnology was adequate. At the time, Maryanski conceded that it was unclear whether the FDA had any authority to regulate genetically engineered marine species, but stated that the agency was “considering the position” that the FDA could regulate transgenic fish under the category of “new animal drugs.” (Maine Commission Report, March, 1996, at 21). The FDA has subsequently adopted that position, but as many commentators have observed, squeezing the round peg of creation and regulation of new animal species into the square hole of regulating *animal drugs* is fraught with problems. The Maine Commission concluded in 1996 that there were three major “areas of concern” regarding the adequacy of federal regulation of genetic engineering, and one of those was the need for “an effective system of federal legislation...to assess the risks of environmental release [of genetically engineered fish] and regulation to address those risks.” The report was forwarded to the FDA.

To date, no legislation has been enacted to address the unprecedented issues presented by genetically engineered marine species. We further understand that a proposal for a legislative overhaul of the government’s approach to regulating genetically

engineered plants and animals, proffered in 2000 by the Interior Department, was *opposed* by the FDA. In response to an FDA case study on regulation of genetically engineered salmon, the Interior Department staff noted that the FDA's authority to approve "new animal drugs" "precludes consideration of potential adverse environmental effects except to the extent they, directly or indirectly, pose risks to humans or animals." As William Y. Brown, Science Advisor to Interior Dept. Secretary Bruce Babbitt, observed, "trying to account for environmental effects comprehensively by looking for indirect effects on humans or animals is an inefficient and ineffective—not to mention somewhat twisted—formula." (Brown, "Promise and Peril," *The Environmental Forum*, Sept/Oct 2001; FDA case study available at www.ostp.gov/html/ceq_ostp_study2.pdf). Brown's article, reflecting the Interior Department's recent analysis of the adequacy of the federal system of GE regulation, is a powerful critique of your agency's oversight of GE fish. A fundamental problem is the FDA's treatment of "new animal drug" applications as confidential and not subject to public scrutiny or comment. As Brown summarized: "the laws currently applied to review of transgenic organisms that may escape into the environment, reproduce and spread...are woefully deficient for this purpose – filled with gaps, nearly incomprehensible, and stretched beyond legal credibility by the agencies that implement them." *Id.* at 30. This criticism is all the more significant, coming not from "outsider" activist groups, but from within the federal agency charged with the protection of federal lands and the fish, wildlife, and plant species within our borders.

The FDA case study (cited above) states that "culture locations for transgenic salmon are likely to exist both within and outside the U.S., as well as in areas of shared coastal waters, such as the Bay of Fundy on the United States and Canadian borders." Elliot Entis, president of Aqua Bounty Farms, has stated that he "expects approval from the U.S. Food and Drug Administration within a year but Canadian approval is 'less likely.'" ("Island groups oppose plan to produce genetically modified salmon eggs," *The Winnipeg Sun*, March 28, 2001). Sebastian Belle, Executive Director of the Maine Aquaculture Association, has stated that "none of our members has ever indicated an interest in using GMO products." However, Maine needs absolute assurance that these transgenic fish will not be released in or anywhere near our coastal waters.

The Maryland legislature has led the way on this issue, by enacting in 2001 a five year ban on the release of GE fish in any state waterway connecting to another body of water. We urge you to similarly adopt a moratorium on the introduction of any GE fish or shellfish into the waters of the United States, and to reexamine and overhaul the system of federal regulation of these and other genetically engineered products.

Very truly yours,



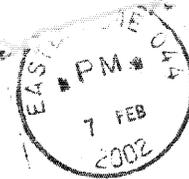
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