EDITORIALS

THE HILL FRIDAY, OCTOBER 1, 2010 THE HILL



Regulatory procedure necessary for GE food

By Gregory Jaffe

he Food and Drug Administration held hearings recently on whether to approve a genetically engineered (GE) salmon for production and consumption. AquaBounty's AquAdvantage salmon is an Atlantic salmon which grows almost twice as fast as farm-raised salmon because scientists added a growth hormone gene from a Chinook salmon and an ocean pout fish promoter sequence. If adopted on a large scale, the company claims the salmon would reduce producers' costs and benefit the environment by reducing the feed that fish-farming operations use, the waste produced and the transportation costs to get the fish to market by growing them at local inland farms.

The AquAdvantage salmon is not the first, nor will it be the last, GE animal. Already, pet owners can purchase "glowfish," fish with an inserted gene that makes them glow in the dark. Medical patients with a rare clotting disorder are treated today with Atryn, manufactured by goats engineered with a human gene whose biologically active molecule is expressed in their milk GE animals on the horizon include a pig that produces environmentally friendlier waste and cattle resistant to mad cow disease.

The federal government regulates GE animals using FDA's "new animal drugs" process. Adding genes to an animal fits the legal definition of an "animal drug" even if the public and developers find this legal fiction confusing. The upside of that approach is the FDA's strong mandatory pre-market approval authority, which requires a company to demonstrate that any food from the animal is safe to eat and that the genetic changes don't harm the animal. The downside is that drug applications and the approval process are shrouded in secrecy, with limited opportunity for public participation, as pointed out by a recent letter sent by Sen. Mark Begich (D-Alaska) and ten colleagues to FDA Commissioner Hamburg (FDA released its analysis after more than ten years of private discussions with AquaBounty.)

While FDA has the expertise to address food-safety questions, it has less expertise to analyze environmental concerns presented by GE animals. The Environmental Protection Agency, the Fish and Wildlife Service, and other federal agencies with expertise conducting environmental assessments have been silent about any role they

might have in regulating GE animals. Congress should step in and provide FDA with adequate authority to address the range of environmental concerns GE animals might pose, including "recall" authority if problems arise after commercialization. Congress should eliminate the confidentiality requirements so safety data and FDA's analysis could be reviewed by outside $experts\, before\, granting\, approvals.\, And$ FDA should to consult with other agencies with expertise in assessing environmental risks of animals. Sen. Dick Durbin's (D-IIL) Genetically Engineered Foods Act, introduced in 2004, would do that, and Congress should take it up next year.

In the meantime, if FDA goes forward and approves the AquAdvantage salmon, the analysis released last month indicate that the filets are as safe to eat as filets from other salmon. The proposed conditions for rearing those fish -- in two facilities in Canada and Panama with multiple layers of physical, biological and geographical containment - make it unlikely that the salmon $would \, escape, reproduce \, and \, impact \, other \,$ salmon or the environment.

The FDA is unlikely to require labeling of AquAdvantage filets because they don't differ from other salmon in any "material" way that impacts consumers. FDA should work with industry representatives, however, to implement voluntary labeling. Going to the store and finding the GE salmon labeled "AquAdvantage salmon" or "fast-growing environmentally friendly salmon" (assuming those benefits can be verified) could satisfy consumers who are interested in knowing if they are purchasing GE salmon (without scaring other consumers by using 'genetically engineered"). Also, FDA needs to allow "absence" labeling that is truthful and not misleading if supermarkets label salmon that is not engineered.

GE animals, like GE crops (which encompass over 80 percent of U.S. corn, soybeans, and cotton), might become a significant part of American agriculture. But without regulatory procedures that are thorough and transparent, consumers will question their safety, handicapping a technology that potentially has beneficial applications for farmers, consumers and the environment. Congress should pass legislation that allows safe, beneficial products to reach the marketplace while protecting consumers and the environment.

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