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Questions about genetically engineered animals

BY GREG JAFFE

Milk from cows treated with hormones, irradiated ground beef, cloned animals -- what's next on our technological wheel of progress involving food animals?

GTC Therapeutics is one of a growing number of biotechnology firms that is planning on using animals -- including animals commonly eaten as food -- as miniature pharmaceutical factories. In this case, the company transplants genes from a human into goats, which then produce milk that contains anticoagulants and other human drugs. The company hopes this approach will be much cheaper and easier than producing the drugs in the factory, yielding a real benefit.

Before you look askance at your next helping of chevre or curried goat, consider some of the other possible environmental or health benefits that genetically engineered (GE) animals may provide.

AquaBounty has engineered a salmon by adding a gene from another fish species so that it reaches market size in half the time. That may reduce producer costs and generate an environmental benefit by cutting down on the feed that fish-farming operations use and on the waste that the fish produce. Other companies are seeking to engineer pigs to produce less polluting waste, and engineer cows to be resistant to mad cow disease.

And scientists are engineering pigs so that their meat contains healthy omega-3 fatty acids.

Companies have been experimenting with GE animals for over 20 years. Last month, after spending five years studying the issue, the federal government finally acknowledged that these engineered animals are trotting (and swimming) toward the marketplace and that regulation is required.

The Food and Drug Administration announced that it will regulate GE animals as "new animal drugs," which requires FDA approval before companies could market any products made from those animals. The upside of that approach is that companies must demonstrate that milk or meat from these animals is safe to eat. The downside is that new animal drug applications and the approval process are shrouded in secrecy, with limited opportunity for public participation. Such a closed process is unlikely to instill consumer confidence that AquaBounty's salmon is safe to eat.

The FDA has had a hard enough time ensuring that conventionally grown tomatoes, spinach, and other foods are free of bacterial pathogens. After all the recent outbreaks, should consumers trust the FDA if companies' safety data are not made public and its decisions cannot be reviewed? Should supermarkets, restaurateurs, or other players in the food business?

While the FDA does have the expertise to deal with food safety questions, it has much less expertise and authority to deal with the environmental concerns presented by GE animals. A National Academy of Science report described environmental issues as the "greatest science-based concerns" associated with GE animals due to the inability to identify all potential problems early on and the difficulty of solving problems after they arise. For instance, might the fast-growing salmon escape from their pens and disrupt native fish populations?

Other federal government agencies that have greater expertise on environmental issues, however, have remained silent on whether they, too, will regulate GE animals.

Clearly, technology has outpaced our laws. The FDA announcement provided a welcome framework for regulating GE animals, but that framework by itself won't ensure safety or consumer acceptance. Congress should step in and provide the FDA with adequate authority to address the full range of environmental concerns that engineered animals might pose, including the power to "recall" such animals if problems arise after commercialization. Congress should also eliminate the current confidentiality requirements so that safety data submitted to FDA and the agency's analysis of that data can be reviewed by outside experts before GE animals are approved. And the FDA should be directed to consult with other agencies, such as the Environmental Protection Agency and the U.S. Fish and Wildlife Service, about potential risks.

Senator Richard Durbin's Genetically Engineered Foods Act, first introduced in 2004, would do all that, and Congress should take it up next year. Developers, the food and farming industry, environmentalists, and consumers alike should support it. Without a regulatory process that is thorough and transparent, there is no chance that American consumers will -- or should -- have confidence in the safety or environmental-harmlessness of these animals.

Greg Jaffe is the director of the biotechnology project at the Center for Science in the Public Interest.