Rules on Bioengineered Animals

FDA to Release Guidelines for Stages of Genetic Modification

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The Food and Drug Administration will release today long-awaited regulatory guidelines governing genetic engineering of animals for food, drugs or medical devices.

Although none of the provisions is likely to surprise the biotech industry, their formal appearance after years of discussion is expected to energize a field whose commercial potential is huge but so far unrealized.

The agency's regulatory control of animals will be considerably stronger than its oversight of genetically engineered plants and microorganisms. The latter -- or substances derived from them -- are on the market and, in some cases, have proved controversial.

The guidelines tell companies what the FDA wants to know about their work at virtually every stage of creating an engineered animal.

For example, biotech firms will be asked to provide the molecular identity of snippets of DNA inserted in an animal's genome, as well as where the genetic message lands and whether it descends unaltered through subsequent generations. The FDA also wants to be told how the genetic alterations might change an animal's health, behavior and nutritional value.

The companies also should inform the agency how they will keep track of animals, prevent them from mingling with their non-engineered cousins and dispose of them when they die.

Genetically engineered animals -- salmon, pigs, cows and goats are in development -- are expected to have two main uses. Some will be food animals whose new genetic endowment makes them disease-resistant, faster-growing or more nutritious. Others will be genetically engineered to produce medically useful substances, such as hormones or antibodies, in their organs or body fluids.

Pigs that are able to more easily absorb phosphorus, and therefore need less feed supplementation, are being developed in Ontario. Goats that produce spider silk in their milk are being made in Wyoming.

Food that is produced from genetically engineered animals will not have to be labeled as such. However, if the genetic manipulation changes the nutritional content -- for example, by increasing a beneficial form of fat -- that must be declared on the label.

The specific requests in the guidelines are not mandatory. However, biotech companies seeking FDA approval to commercialize genetically engineered animals must follow federal drug laws. The guidelines are meant to show how they can do that.

The FDA has been providing the advice on an informal basis for about 10 years, said Eric Flamm, a policy adviser at the agency. The guidelines will be open for public comment for 60 days.

"We are simply clarifying what we've always done, and will continue to do," he said.

There was general agreement that something in writing on the subject has been needed for a while.

"It is past due for the federal government to finally recognize that genetically engineered animals are on the horizon and need regulation and oversight," said Gregory Jaffe of the Center for Science in the Public Interest, a lobbying organization in Washington.

The action "will drive investor confidence," said Barbara Glenn of the Biotechnology Industry Organization. "They know that we will reach commercialization of a product." At the moment, about a dozen of the organization's 1,200 member companies are developing genetically engineered animals, she said.

But the new guidelines drew criticism from groups worried about possible environmental, ecological and physiological hazards of bioengineered animals. The experience of genetically modified plants is rife with examples of unintentional dissemination of the organisms, and their interbreeding with unmodified members of their species.

"The first time that the public will learn about a genetically engineered animal will be the day it is approved," said Margaret Mellon of the Union of Concerned Scientists. "This requires that you completely trust the FDA to do this right, and I don't think folks trust FDA that much."

Michael Hansen, a scientist with Consumers Union, publisher of Consumer Reports magazine, said that "there is very little transparency without [the FDA] laying out all the data" for the public to see. He does not think that transparency is assured.

The FDA is laying claim to regulatory authority over what it calls "GE animals" through an unusual legal argument.

The Food, Drug and Cosmetic Act defines a drug as anything that alters the "structure or function" of a person or animal. Adding a gene to an animal through recombinant technology changes at least the animal's structure and probably its function, as well.

In the new guidelines, the FDA argues that "recombinant DNA constructs" inserted into animals are by definition drugs. However, because the DNA constructs are physically inseparable from the whole animals, the latter also fall under the agency's regulatory control.

"You can't regulate the drug without regulating the animal," said Flamm, the FDA policy adviser. "So, effectively, we are putting controls on the animal rather than on the little piece of DNA."

With this strategy, virtually no genetically engineered animal will escape FDA scrutiny during its development and testing. This is not true with plants.

The FDA regulates genetically modified plants whose nutritional content is altered, in which case they become "food additives." The Environmental Protection Agency regulates them when the new genetic endowments provide pesticide-like actions.

Although the animal-is-drug strategy will allow the FDA to regulate genetically engineered animals without getting further authority from Congress, the unintended effects of that strategy worry some consumer groups.

Although companies will have to provide detailed information about their work starting from the earliest stage, the FDA is prohibited by law from revealing that information to the media or the public. That is because much of the information is proprietary, competitive and extremely valuable. The agency cannot even acknowledge that a company has a "new drug application" on file.

Consequently, discussions that occur during the development of a genetically engineered animal about its safety and effectiveness will not include consumer or watchdog groups.

Although the guidelines say that the FDA may ask a company to submit an environmental impact statement with its application for approval of a genetically engineered animal, the agency cannot reject a drug strictly on environmental grounds.

Some groups are worried about the effects of unanticipated mixing of genetically engineered animals with others -- for example, the escape of fast-growing salmon into the open ocean, where they could breed with wild species.

"I don't think what's being announced will protect humans and the environment from all the potential risks that a genetically engineered animal may pose," said Jaffe of the Center for Science in the Public Interest.