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What businesses and consumers need to know about genetically modified animals entering the marketplace

The USDA has extended the public comment period for its proposed regulation of certain genetically engineered animals until May 7.

Dawn Reiss / Apr 27, 2021

The safety of gene-edited animals produced for food and who will regulate the industry has been hotly debated.

Many from within the organic and natural food industry would like more regulation, stronger oversight and testing coupled with greater safety measures, including more transparent labeling so consumers (and those managing the supply chain) can better understand what is genetically modified and what isn't.

A potential shift in regulatory authority and oversight from the U.S. Food and Drug Administration to the USDA over genetically modified animals could dramatically change the industry. For nearly two more weeks, businesses and consumers have a chance to voice their opinion about the U.S. Department of Agriculture's proposed regulation and oversight of genetically engineered animals of "amenable species," which includes farm animals and catfish.

An FDA spokesperson told New Hope Network that the public comment period is intended to gather input on a potential proposed rule, because the USDA has not proposed a draft rule at this time.

"It's is the USDA's way to ask the public, 'We are kind of thinking about this, what do you think?'" says Jaydee Hanson, policy director for the Center for Food Safety. "This is the USDA lobbying for industry support to be regulators of the agriculture industry. Regardless of the administration, the USDA favors big agriculture and big agriculture favors genetic engineering because it allows the industry to raise more animals in a cheaper fashion."

The USDA extended the public comment period until May 7. Originally, it was scheduled to end on Feb. 26.

"It's quite a big deal to move oversight from the FDA to USDA," says Hans Eisenbeis, a spokesperson for the Non-GMO Project. "Between the two federal agencies, the FDA is more rigorous and stringent in how it regulates drugs, any products intended for human ingestion. It requires more testing around safety issues. So moving this on to the USDA is a clear form of deregulation."

Currently, the FDA regulates intentional genomic alterations – also called IGAs – in animals as drugs under the Federal Food, Drug and Cosmetic Act (FD&C Act).

On Jan. 19, the day before President Donald Trump left office, then-U.S. Secretary of Agriculture Sonny Perdue with Assistant Secretary for Health and Human Services Department of Public Health Service Admiral Brett Giroir announced it would shift regulatory authority from the FDA to the USDA via a Memorandum of Understanding.

Immediately after the announcement, then-FDA Commissioner Dr. Stephen Hahn took to Twitter stating the FDA does not support the MOU and "has no intention of abdicating our public health mandate." Hahn also tweeted that "FDA remains undeterred in our steadfast commitment to ensure that animal agricultural biotechnology products undergo independent and science and risk-based evaluation by our career experts."

Politico reported that the eleventh hour industry-backed plan effectively strips the FDA of oversight of certain genetically modified animals as "the latest instance of Trump political appointees overriding the agency's scientists."

A day later was President Joe Biden's inauguration.

Since then, Tom Vilsack, a former Iowa governor who ran as a presidential candidate in 2008, was reinstated as USDA's Secretary of Agriculture, after serving two terms during President Barack Obama's administration. Dr. Janet Woodcock, who previously served as director of Center for Drug Evaluation and Research – the FDA's top drug reviewer during the opioid crisis – was named Acting FDA Commissioner. No one has been officially nominated to permanently fill the role. Multiple senators, led by Joe Manchin (D-WV) and Maggie Hassan (D-NH), have asked President Biden to bring in new FDA leadership. Xavier Becerra, a California native who went to Stanford University, was installed as Secretary of Health and Human Services in March, after being narrowly confirmed 50-49.

In an April 21 email to New Hope Network, a FDA spokesperson said, "Both HHS and the FDA continue to consider the MOU and the issues surrounding regulation of animal biotechnology products, and have not yet determined next steps with respect to the MOU, which has not gone into effect. The FDA is committed to ensuring such products are safe for the animals themselves and for anyone that may eat food derived from them and to ensuring that they are effective (i.e., they achieve the developer's claimed intended effect)."

In the meantime, the clock is ticking for the public and businesses to comment on genetically modified animals and how regulatory oversight should be handled by the federal government.

Why a change in FDA to USDA oversight is a 'big deal'

More than 3,000 public comments by individuals and organizations are posted on "Regulation of the Movement of Animals Modified or Developed by Genetic Engineering" via regulations.gov.

The proposed changes cover a wide scope of regulatory framework and safety review process for "amenable species," which ranges from cattle, horses and sheep to catfish, geese, ducks, pigeons and swine and the regulation of biotechnology. That includes how the USDA should define "off-target changes" for the "purpose of expedited review of animals" in certain cases and what kind of genetic modification, entities or activities should be given exemptions from regulations. It is regulatory framework the USDA calls more "flexible" for the regulation of certain animals modified or developed using genetic engineering.

"During this public commentary period, people should be saying, 'We need a full assessment of any animal that's been genetically engineered in any way,'" says Jaydee Hanson, policy director for Center for Food Safety, a nonprofit environmental advocacy organization.

One of the biggest proponents in favor of the regulatory change: the pork industry.

Howard "A.J." Roth, president of the National Pork Producers Council, who on behalf of its 42 affiliated state pork association members, sent a five-page Jan. 13 letter that outlines its support for creating genetically engineered livestock and poultry.

In the letter, Roth says, "Given the known nature of this genetic material – or in the case of a deletion the high predictability of the result – there is no new or novel element being introduced into the genome of the species. There is therefore no new or novel risk or threat to animal health, human health and food safety, or the environment."

In December, the FDA approved the use of genetically engineered pigs – known as GalSafe – in foods and medical products. The pig was developed by Revivicor, a biotech company based in Blacksburg, Virginia, that was formed in 2003, according to its website, as a spinout from the UK-based PPL Therapeutics, which produced the first cloned animal, Dolly the Sheep, in 1996. Revivicor says it is using its livestock genetic engineering platform to produce genetically engineered pig organs, including kidneys and hearts for long-term use.

Along with salmon, "GalSafe' pigs are the only genetically modified animals approved for human consumption in the U.S.

Many in the natural food industry and environmental groups say more caution should be given before allowing more genetically engineered animals into the marketplace.

"GMOs are a gateway technology through which other far more powerful technologies are going to go through the portal," says Loren Israelson, founder and president of United Natural Products Alliance. "When you get into synthetic biology and a lot more sophisticated technologies, it's a one-way go, and if you pull the trigger, you can't pull it back."

Cloning, genetic engineering and environmental regulations

Since January 2008, the FDA has allowed meat and milk from cows, pigs and goat clones and offspring of their clones to be "as safe to eat as food from conventionally bred animals" and food labels do not have to state food is from animal clones or their offspring.

Genetic engineering is different than cloning because it alters the structure of function of the animal. In the future, the FDA says, "there may be other technologies developed over time that can make intentional genomic alterations (IGAs)."

An important court case further clarified the FDA's legal authority via the FD&C Act.

In 2016, a lawsuit jointly filed by the Center for Food Safety and Earthjustice, formerly the Sierra Club Legal Defense Fund, on behalf of a large coalition of environmental and industry groups, questioned the safety in FDA's authorization of AquaBounty Technologies Inc. to the first genetically engineered salmon – the first genetically engineered animal for human consumption – in Institute for Fisheries Resources v. Hahn. Thanks to a gene from an eel-like ocean pout fish and DNA from Atlantic salmon and Pacific King salmon, the "Frankenfish" can grow to full size in about half the time it takes for wild salmon.

"We argued that the FDA needed to do new regulations," says Hanson, who would like to see regulations that incorporate testing regimes required for new food additives. "Trying to fit genetically engineered animals into their new animal drug rubric just wasn't a good fit. Normally in new animal drugs, you test them and you have to quit feeding the animal the new drug so that people don't consume it. In this case, the drug is part of the animal, you can't pull the drug out of the animal before people eat it."

In November 2020, U.S. District Judge Vince Chhabria, Northern District of California, ruled the FDA had the authority to regulate genetically engineered animals as a drug under the Federal Drug and Cosmetics Act, even if the animal doesn't seem like a drug in the traditional sense. But Chhabria found the "FDA failed to adequately assess the risk that the salmon would escape and survive in the wild," which violated environmental protections under the Endangered Species Act and violated the National Environmental Policy Act because the FDA failed to take a sufficiently "hard look" at the environmental consequences of its decision to approve genetically-engineered salmon and should have prepared a more thorough environmental impact statement.

"The court ruled that FDA had the legal authority to review and approve genetically engineered animals based on its analysis of the Federal Food, Drug, and Cosmetic Act," says Erik C. Baptist, a partner at Wiley Rein LLP in Washington, D.C.

That means the FDA must approve a new animal "drug" application if it is safe for use, Baptist says.

The definition of "drug" is much broader than the everyday understanding of this term because creating genetically engineered animals requires the introduction of recombinant DNA (rDNA) into the genome of an animal.

"Even though the FDA had authority to regulate the genetically engineered salmon as a new animal drug, the FDA still needed to comply with its other statutory obligations, namely the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA)," Baptist says. "The court found that the FDA's NEPA and ESA analyses failed to meet the requirements of these two statutes. Therefore, the court sent the application and review of the GE salmon back to FDA to revise these analyses."

Since the ruling, an FDA spokesperson told New Hope Network, "the FDA made a determination that new regulations were not necessary at this time, in order to regulate intentional genomic alterations in animals."

A backlash over bulls

The decision of how genetically modified animals should be classified and regulated – as drugs or not drugs – comes in the wake of problems with genetically-edited Holstein bulls from the U.S. whose sperm was sold to Brazil with the intent to breed the first genetically dehorned dairy cows.

Minnesota-based Recombinetics, a privately-held biotech company known for its animal gene editing, used TALENs, a CRISPR-like technology to change the DNA of the cows in its lab. The idea: edit into dairy cattle traits traditionally found in beef cattle.

But besides being hornless, some of the genetic editing altered bacterial DNA called plasmid that was pasted into genes. The unintended consequence made it resistant to antibiotics.

The blind spot wasn't flagged until FDA scientists ran the genome sequence and stumbled on the problem.

The scientists, led by Alexis Norris, a bioinformatician at the FDA's Center for Veterinary Medicine, stated in the report, "Our finding underscores the importance of employing screening methods suited to reliably detect the unintended integration of plasmids and multiple template copies."

It is now at the heart of the debate of who should have regulatory oversight and screen the methods used by companies who are genetically modifying animals.

"A lot of companies take the stance that nobody can prove anything is wrong with genetically modified organisms. We take the precautionary principle approach, prove they do no harm first," Eisenbeis says. "And show that you've done the due diligence because there's good reason, with what the FDA caught with the Brazilian cattle, there's good reason there are off-target effects that could really threaten the food system."

The USDA and Recombinetics should have known that, Hanson says.

The situation led to all gene-edited animals being classified and regulated as drugs, and subject to FDA oversight, as President Barack Obama was leaving office in January 2017.

"Recombinetics was saying that they had checked everything out and they hadn't," Hanson says. "And the FDA scientists kind of went over the heads of their bosses and did the research that demonstrated that this was a transgenic animal, not just an ordinary hornless cow."

That's why Hanson and others within the natural food industry point to the Recombinetics scenario as a wake-up call and dire warning if regulatory oversight is moved from the FDA to the USDA.

In a Feb. 26 letter to the USDA, Hanson and William Freese, a senior scientist for the Center for Food Safety, say the USDA should know that gene editing techniques, such as use of engineered nucleases, cause off-target mutations.

They say the USDA's track record in this area, "speaks against investing it with regulatory authority over genetically engineered animals and fish." The letter cites the Department's Animal and Plant Health Inspection Service (APHIS) "declined to develop extensive regulations to oversee genetically engineered animals and developed only limited protocols to govern scientists' research on genetically engineered animals and insects, despite explicit recommendations from the USDA Inspector General to develop regulations."

Hanson says the pending decision on who will regulate what genetic modifications are or aren't regulated and what safety review process needs to be included could have a profound impact on the food system within the U.S.

"We all have a fundamental right to at least know what is in our food," Eisenbeis says. "And if we want to avoid GMOs, we want to know if they are in there or not. Otherwise it's not up to us. It's up to the companies and we have no idea what we're buying and putting on the table in front of kids."

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