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AQUACULTURE TECHNOLOGIES



The firm that developed this transgenic salmon has tried for years to bring it to market in the United States.

BIOTECHNOLOGY

Creators of gene-edited animals bypass US market

Regulatory confusion has prompted some US researchers to seek product approval abroad.

BY HEIDI LEDFORD

In a few weeks, reproductive biologist Charles Long will travel from Texas to São Paulo, Brazil, in search of collaborators willing to take on his studies of gene-edited cattle. He is reluctant to ship the project away from his laboratory at Texas A&M University in College Station. But after 20 years of struggling to win US government funding for his research, Long says that he is done.

“We’ve essentially given up,” he says.

“I’m going to move the entire damn project down there.”

US researchers who develop genetically engineered livestock have long dealt with a dearth of research funding and an uncertain path to market. Many had hoped that the advent of genome-editing technologies, which allow researchers to alter genomes with greater precision than ever before, would mean less oversight by the US Food and Drug Administration (FDA). The agency’s oversight has traditionally focused on organisms that have been modified

to contain DNA from other species.

But in 2017, the FDA released draft guidance that suggested it will regulate gene-edited animals, too, as ‘animal drugs’. The only animal that the FDA has approved by that pathway is a fast-growing genetically engineered salmon, in a decision that was decades in the making. The salmon predates gene editing: it was made by inserting genetic elements from other fish, including a gene that regulates growth hormone in another species of salmon.

The approval finally came in 2015, but ▶

► two months later, Congress blocked any marketing of the salmon by ordering the FDA to establish labelling requirements for genetically engineered meat.

The agency has not released those requirements, nor finalized guidelines for regulating gene-edited livestock. “The FDA is excited about the promise of some of these newer technologies and the products being developed, including genome-edited animals,” an agency spokesperson said. “While helping to bring innovative products to market, the FDA also needs to ensure they are safe and have consumer confidence.”

Meanwhile, researchers and companies are hesitant to wait for US approval. “Nobody wants to do it based on what’s happened to us,” says Sylvia Wulf, chief executive of AquaBounty Technologies, the company in Maynard, Massachusetts, that developed the fish.

That leaves US researchers in a bind. Federal funding for genetically engineered or edited livestock is in short supply. Geneticist Kevin Wells at the University of Missouri in Columbia can recall only one such grant in the past 30 years. To pick up the slack, researchers have leant on industry funding — but this, too, might run dry if companies can’t bring their animals to market.

AquaBounty’s salmon predates genome editing, but the company has since used the technique to develop another fish, a fast-growing tilapia. But instead of trying for FDA approval, AquaBounty sought to bring the fish to market in Argentina. In December, the company announced that Argentina would not regulate the tilapia as a genetically modified animal. Instead, the fish would fall under regulations governing new plant and animal breeds — a significantly shorter regulatory pathway.

Recombinetics, an animal-biotechnology company in St Paul, Minnesota, has also decided to look beyond the United States. The company’s gene-edited dairy cattle do not have horns, which could be a boon to both animal welfare and dairy farmers, who surgically remove the horns from conventional cattle to prevent the animals from hurting each other or their handlers.

In 2016, Recombinetics petitioned the FDA to declare its gene-edited cattle “generally recognized as safe”, a designation that would have

“We don’t need the United States. It’s just a reality.”

largely freed the animals from regulatory oversight. Hornless cattle also occur naturally, the company argued, noting that it used genome editing to turn off only one gene.

The FDA declined the petition, but the company has since received a green light from Brazilian regulators. The firm is focusing on Brazil and other markets — including Argentina, Australia and Canada — to market both its hornless cattle and its genome-edited heat-resistant cattle. “We don’t really need the United States,” says Recombinetics chief scientific officer Mitch Abrahamsen. “It’s just a reality.”

HAVE RESEARCH, WILL TRAVEL

It isn’t always easy to move a research project to a different country. About 10 years ago, difficulties finding funding for his research drove animal geneticist James Murray to relocate his transgenic goat project from the University of California, Davis, to Brazil. The goats were engineered to produce milk that contained lysozyme, an enzyme with antibiotic properties. Murray hoped that the milk could help to protect children from diarrhoea.

But Brazil bans the import of goats and even goat eggs or sperm. Murray and his collaborators then tried to clone their goats from cells that they were able to legally import. This proved unexpectedly difficult in the semi-arid climes of northern Brazil, says Murray, who thinks that the problems arose because of differences in the goats’ diet.

The team eventually sorted out its cloning problems and created a herd of transgenic, lysozyme-producing goats. Then the researchers’ grant ran out, and Murray’s collaborators moved to a different university. “At present, we are on hold,” he says.

And not everyone is convinced that it will be so easy to dismiss the powerful US market. Wells is working with a company called Genus to develop disease-resistant, gene-edited pigs. “To up and go to Brazil — that doesn’t help you at all in reality,” he says. “Anyone who claims that they’re going to get their animal into agriculture by moving to Brazil doesn’t understand where they’re going to be selling their product.”

Genus, which is based in Basingstoke, UK, is working with the FDA to gain approval for its pigs in the United States.

AquaBounty’s Wulf also doesn’t discount the value of the US market, which imports US\$3-billion worth of salmon every year. “It’s big to us,” she says. “But we’re not going to be put in a box just because we have a regulatory process that doesn’t work.”

Last October, the FDA pledged to finalize its guidance on genome-edited animals that will be used as food. But the announcement did nothing to dissuade Long from making his trip to Brazil.

“They move at the pace of molasses in January,” he says. “Why would I sit around and wait?” ■

SPACE FLIGHT

First private Moon lander sparks new lunar space race

Israeli craft heralds era of national and private cooperation to exploit lunar resources.

BY ELIZABETH GIBNEY

Israel is heading for the Moon — and a milestone. If all goes well, a lander that launched on 21 February will become the first privately funded craft to touch down on the Moon. The feat seems set to kick off a new era of lunar exploration — one in which national space agencies work alongside private industry to investigate and exploit the Moon and its resources.

The craft, named Beresheet — ‘in the beginning’ in Hebrew — was built by an Israeli non-profit company called SpaceIL that raised US\$100 million for its mission, much of it through philanthropic donations. Beresheet lifted off on a SpaceX Falcon 9 rocket from Cape Canaveral, Florida, and should reach Mare Serenitatis, a basaltic plain on the northern hemisphere of the Moon, in April (see ‘Moon shot’). There, it will study the presence of magnetism in lunar rocks, a phenomenon

that is puzzling, given the satellite’s lack of a global magnetic field.

The mission is not wholly private, because it involves government partners. And although the craft is little more than a demonstrator — its scientific mission is simple and the lander is expected to last just two days on the surface — the mission is symbolically important. It is Israel’s first Moon mission, and would be the first privately backed craft to ‘soft land’ on the Moon’s surface — until now, the preserve of an