# Transgenic salmon inches toward finish line

A fast-growing Atlantic salmon developed by AquaBounty Technologies is poised to become the first transgenic animal to enter the food chain. After a ten-year wait, officials at the US Food and Drug Administration (FDA) reviewed the transgenic fish owned by the Waltham, Massachusetts company. This is the first time the agency has evaluated a transgenic animal destined for dinner tables, though it has done so not as a new food product but as a veterinary drug. Approval hinges mainly on safety of the gene construct for the fish, its effectiveness and food safety. However, some members of the US Congress, experts who advise FDA, environmental groups and activists, and plenty of surveyed consumers have expressed either uncertainty or outright opposition. Many are insisting on labeling of the fish if approved.

"This technology holds incredibly great promise for [boosting] the world's food supply," says Bernadette Dunham, who directs the FDA Center for Veterinary Medicine. Despite that favorable take on the technology, the regulatory review of the fish is continuing, with no decision rendered.

FDA officials made scrupulous efforts to explain the regulatory hoops through which the AquAdvantage salmon had to leap. But to consumer and environmental groups, activists and sundry other critics of this transgenic salmon, the FDA review process proved unpersuasive to some, and outright fishy to others. Qualms over the regulatory evaluation have also been voiced by at least ten US Senators and several members of the US House of Representatives. "There are a number of serious concerns with the current approval process and many potential human health and environmental risks that are associated with producing GE [genetically engineered] fish have not been fully or openly reviewed," they noted in a letter to FDA commissioner Margaret Hamburg. The members of Congress are insistent that the new transgenic species undergo a formal evaluation by the FDA's Center for Food Safety and Applied Nutrition so that its potential health effects on humans be assessed.

The transgenic Atlantic salmon, which AquaBounty constructed in 1989, contains a gene encoding growth hormone from Chinook salmon, a promoter from another fish species called Pout, and a gene terminator. That construct enables the fish to grow twice as fast selectively bred fish, and that accelerated growth is concentrated into its first year of life. AquAdvantage fish reach 200 g within 200 days, compared with 350 days, on average, for their unmodified counterparts. To reduce the chances that transgenic fish can breed, AquaBounty CEO Ronald Stotish says all the transgenic salmon are female and up to 99.8% are triploid, which renders them sterile.

About 1.5 million metric tons of commercially grown Atlantic salmon are harvested each year, with Chile and Norway the world leaders, followed by the US, the UK and Canada, according to fisheries expert Eric Hallerman of Virginia Polytechnic Institute and State University in Blacksburg. This harvest is mainly pen-grown fish, as there is little remaining wild Atlantic salmon to be found, he says. Aquaculture-raised fish are selectively bred, and grow about twice as fast as their dwindling wild relatives reaching full size in about half the time required for

An AquAdvantage salmon (in the background) and a non-transgenic Atlantic salmon sibling of the same age.

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## IN brief

### CIRM spurs translation

As the first US Food and Drug Administration–approved clinical trial of human embryonic stem (hES) cells gets underway, the California Institute of Regenerative Medicine in San Francisco (CIRM) is pushing forward with a second round of translational grants. The first round of Disease Team Research Awards, expected recipients to have an approvable investigational new drug (IND) application ready to file within four years. The second round, which will be announced this month, requires that programs have filed an IND or be in phase 1 or 2 by the end of the grant period. The lengthy application process, which includes a six-month planning period, is designed to give teams time to formulate ideas, establish collaborations, and prepare proposals and supporting documentation, according to Bettina Steffen, who, as associate director of development activities at CIRM, oversees the disease teams. CIRM also helps teams set milestones, and evaluate their progress. "We see ourselves as advocates. We want them to put their best foot forward," Steffen says. Geron's hES cell–derived clinical trial is based on work done at the University of California, Irvine, by Hans Keirstead, a CIRM grantee. The trial itself, however, is not funded by CIRM, as its first round of translational grants excluded clinical studies, says Steffen. *Laura DeFrancesco*

### Irish bait

The Irish government expects to lure venture capital (VC) firms to its shores with a €500 ($693) million fund to boost investment in local startups. Innovation Fund Ireland will focus on biotech, information technology, medical devices and cleantech. The exchequer and Ireland's National Pension Reserve Fund will contribute €250 ($346) million to the fund and interested VC firms are expected to match those contributions. "The Fund is being established to act as a catalyst for an increase in the availability of risk capital for startup and scaling companies," says Garret Murray from Enterprise Ireland, who manages the fund. Dirk Carrez, director for industrial biotech at the European Association for Bioindustries in Brussels, sees advantages in such local initiatives. "National initiatives can be better adapted to regional context and specificities," he explains. They can also be set up much faster than European programs, and "improving access to finance is an urgent problem to be solved for European biotech small and medium-sized enterprises," he adds. The initiative comes on the heels of an announcement in July that a €4.7 ($6.5) billion Global Pharmaceutical Centre of Excellence (GPCE) is proposed for Tralee, Kerry, Ireland. But funding for the project, promoted by Cork-based generics manufacturer Pharmadel, may be undermined by Ireland's 30 September 'Black Thursday', when the Irish deficit hit 32% of gross domestic product. *Christoph Schmitt*