Title

The evolution of transgenic food

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On November 19 2015, the United States Food and Drug Administration (US-FDA) approved AquaBounty Technologies Inc. application for the use of the AquAdvantage salmon for human consumption. The AquAdvantage salmon, an Atlantic salmon genetically engineered (GE) to express the Chinook salmon growth hormone gene and thus grow faster and more efficiently, was developed in 1992 (Du et al., 1992).These salmon are bred to be sterile and are farmed in land-locked aquaculture facilities with multiple barriers for physical containment. Scientists and scientific bodies have overwhelmingly welcomed the FDAs decision after extensive reviews of food and environmental safety and endorsed AquAdvantage salmon as a safe and more sustainable product than existing farmed salmon, which helps to relieve the pressure of overfishing on wild populations.

This landmark decision by the US-FDA is the first approval of the use of a GE animal for food anywhere in the world. However, while this is certainly an important regulatory action, the implication of this decision worldwide for the development of GE animals, and possibly gene edited animals, for use in agriculture remains to be seen.

To put this regulatory action into perspective one needs to remember that the first GE livestock (Hammer et al., 1985) and fish (Zhu et al., 1985) were reported in 1985. AquaBounty Technologies first approached the US-FDA for regulatory approval of the AquAdvantage salmon in 1995, but it was not until 2009 that the US-FDA issued Industry Guidance 187 (FDA 2009) outlining the process they planned to use to regulate GE animals. In 2010 the US-FDA announced that the AquAdvantage salmon was as safe to eat as conventionally grown Atlantic salmon, but a further five years elapsed before approval was given.

The world-wide regulatory dysfunction around GE animals for use in agriculture to produce food for human consumption has effectively limited advancement in this field and resulted in a cessation of work and capacity building in virtually all of the developed countries first associated with this technology (Australia, Canada, Germany, New Zealand, the United Kingdom, and the United States). For example, in the mid-1980s there were strong programs of research directed at developing transgenic livestock in Sydney, Adelaide and Melbourne, but by the late 1990s only the South Australian program was left and it was, and has continued to be, largely focused on xenotransplantation and the creation of bio-medical research models. The past decade has seen a growth in laboratories world-wide undertaking the creation of GE livestock for use in agriculture, but this new activity is almost exclusively limited to China, Brazil, and Argentina, with one new laboratory focused on GE chickens emerging in CSIRO. The CSIRO team is based at the Australian Animal Health Laboratory in Geelong where they are applying GE technology to health, welfare and food safety issues that impact poultry industries. They have been combining GE and gene silencing technology to develop avian influenza resilient chickens, and via collaborative Australian Poultry CRC projects have been developing precision genome engineering approaches to sex selection for the egg laying industry and the removal of allergens from eggs to provide safer food products for the growing number of Australians that are allergic to eggs.

As noted above, the implication of the US-FDA decision to approve AquAdvantage salmon for

human consumption on the development of GE animals for use in agriculture is not clear. At present there appears to be little corporate support for using GE animals in agriculture and in the face of steep regulatory costs and long-time frames this single decision may not be sufficient to ease either of these burdens. The real impact at this point, and the one that may most affect Australia, is whether or not economies like China and India will now move forward more rapidly. Over the past decade China has put more resources into developing GE animals for agriculture than the rest of the world combined and India is now moving to establish laboratories in this area as well.

Biotechnologies such as GE have an important role to play in the future of agriculture, including ensuring food safety and security, improving animal health and welfare, and enhancing the nutritional benefits of various foods. These benefits can be realised only through appropriate investment, which will occur only when the animal agriculture industries have confidence in a suitable, clear-cut, and timely regulatory process for those animals and food products. With many nations poised to take steps forward in deployment of animal biotechnology harmonisation of regulations will be critical in a global trade environment.

[illegible] Guidance Document – 57: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs. www.fda.gov/cvm/guidance/published.htm

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