

How to Get Real about Biotechnology

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How to Get Real about Biotechnology

A commentary paper from the Council for Agricultural Science and Technology (CAST) neatly puts a finger on a commonly ignored disconnect between law and science. This disconnect has stymied not only US government regulation of genetically modified animals proposed for use as food—the subject of the CAST paper—but also, in some European and African countries, regulation of genetically modified crops. Considering that malnutrition kills more people than AIDS, malaria, and tuberculosis combined and that the world population is still growing, this disconnect deserves to be more widely understood by scientists, policymakers, and the public.

The CAST paper (available from www.cast-science.org/publications), written by a group chaired by Alison L. Van Eenennaam of the University of California, Davis, and titled *The Science and Regulation of Food from Genetically Engineered Animals*, describes how applications to deregulate the sale of food animals created through genetic engineering are evaluated for their potential risks. The applications are handled by the Food and Drug Administration (FDA). In the case of the first proposal known to be under review, the AquaAdvantage salmon developed by Aqua Bounty Technologies, the process has lasted for more than 15 years so far (it may be coming to a conclusion this year). FDA researchers have concluded that there is “reasonable certainty of no resulting harm” and no “significant impact on the quality of the human environment” from the fish. Nonetheless, the FDA must comply with the National Environmental Policy Act, which judges have sometimes interpreted to require consideration of social, economic, cultural, aesthetic, and historic concerns. Consequently, objectors may demand the evaluation of a proposal's possible harms on multiple large groups of people defined by their being vulnerable in principle.

The disconnect is that the regulatory process is unable to systematically balance ineliminable risk, which can be found for any technology if the net is cast widely enough, against the technology's estimated benefits to those same large groups. Many benefits are ignored. And as CAST notes, risks similar to those evaluated for genetically modified animals are commonly prominent in conventionally derived animals, which are subject to no regulatory approval. For example, any AquaAdvantage salmon that managed to escape despite the planned physical barriers are far less likely to breed successfully with (and thus threaten populations of) wild salmon than are ordinary farmed salmon, which often escape. But this projected advantage is not credited to the hi-tech fish's account. CAST reports that regulatory uncertainties “have essentially halted commercial and public investment in the development of genetically engineered animals for agricultural applications in the United States.” Similar complaints have been made recently in *BioScience* in regard to the approval process for genetically modified plants designed to sequester atmospheric carbon dioxide (60: 729–741).

Caution is laudable, but in a world already vastly affected by humans, the risks of new technologies should be compared with the existing—and expected—risks of current technologies, not with those of an imaginary utopia. The law is, famously, an inadequate animal. Policy leaders might seek an opportunity to make it less so if they want to see biotechnology achieve its potential.

TIMOTHY M. BEARDSLEY
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