

Viewpoint: Why the FDA should not be regulating genetically engineered animals (as drugs, no less)

[Editor's note: Henry Miller is founding director of the FDA's Office of Biotechnology. John Cohrssen is former counsel to the White House Biotechnology Working Group.]

[The FDA's] review of the salmon as a "new animal drug" required [more than 20] years. At the end of its two-decades-long review, FDA concluded what had been obvious from the beginning: that no health or environmental risks or food quality concerns existed.

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Because the FDA regulated the genetic insert in the Oxitec mosquito as a new animal drug, it, like other 'drugs', had to be shown to be safe and effective for the animal.

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FDA's failures in both policy formulation and in the actual reviews of the genetically engineered salmon and mosquito resulted from a lack of organizational expertise, technological skittishness, empire-building, and deference to political pressure. In contrast, USDA has a long history with genetically altered biocontrol agents, most notably the innovative screw-worm fly produced with sterile-insect techniques that was successfully developed by USDA >70 years ago to eradicate a devastating agricultural pest.

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Withdrawing the FDA guidance and assigning jurisdiction to USDA would be a logical and important advance for agriculture, the environment, and public health. All that is needed to get it done is resolve from the Trump administration.

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion, and analysis. Read full, original post: [FDA is the wrong agency to regulate genetically engineered animals \(behind paywall\)](#)