FDA review on transgenic salmon too narrow: study

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The review process being used by the Food and Drug Administration to assess the safety of a faster-growing transgenic salmon fails to weigh the full effects of the fish's widespread production, according to analysis by a Duke University-led team in this week's *Science*.

The salmon, whose genome contains inserted genes from two other fish species, could become the first genetically modified animal approved for human consumption in the United States.

The FDA held two days of hearings in September to assess the fish's human and environmental health risks. The period for public comment ends this month. A final FDA decision could be imminent.

The concern, Duke economist Martin D. Smith says, is that the new animal drug application process FDA is using to review the transgenic salmon evaluates its safety only by comparing its nutritional profile to an equivalent portion of nonmodified salmon, and screening it for known toxins and allergens.

Smith said such a process ignores the potential health and environmental effects of salmon production and consumption -- both positive and negative -- that might stem from the fish's faster growth and less need for feed.

"These market impacts could dwarf any small differences in nutritional content," says Smith, associate professor of environmental economics at

Duke's Nicholas School of the Environment.

A smarter approach, Smith and his coauthors argue, would be for FDA – or if necessary, Congress – to broaden the interpretation of the terms "safe" and "health" in FDA statutes so its review process can include an evaluation of the overall safety of the new fish compared to other protein sources that it might replace, such as beef.

"Instead of focusing on the safety of a food taken one portion at a time or whether it was produced through genetic modifications or through classic breeding, a more useful approach would be to evaluate whether society is better off overall with the new product on the market than without it," says Jonathan B. Wiener, William R. and Thomas L. Perkins Professor of Law at Duke Law School.

This fuller assessment would require FDA regulators to take into consideration factors currently unaccounted for, such as public health impacts that could occur if, as is likely, increased production of transgenic farmed salmon leads to lower retail prices and increased consumption.

"Lower prices for salmon would have significant public health benefits," Smith explained. "Consumers would have access to a less expensive source of healthy protein and omega-3 fatty acids, which have well-documented health benefits."

A broader review would also allow a fuller assessment of potential environmental impacts, such as pollution from farmed salmon waste; disease; increased harvesting of the wild fish used to feed farmed salmon; and the escape of genetically modified salmon into the wild, where they could affect wild salmon stocks through gene transfer or increased competition for resources.

The National Environmental Policy Act mandates FDA to assess significant environmental impacts from market expansion of the products it approves, yet the narrow scope of the current review process for new animal drugs presents "an incomplete picture" of these risks and benefits for transgenic salmon, the researchers write in their analysis.

"The approval of genetically modified salmon will set an important precedent for other transgenic animals intended for human consumption," Smith says. "It's essential that FDA establishes an approval process that assesses the full portfolio of impacts to ensure that such decisions serve society's best interests." FDA administrators need to weigh the benefits of such assessments against the costs and delays they likely would incur, he says.

If conducting a full assessment of transgenic salmon would take too long, a reasonable compromise would be to use existing studies to develop scenarios of market growth and the broader impacts to human and environmental health that may occur as a result.

Provided by Duke University