

FOOD SAFETY

Genetically Modified Salmon and Full Impact Assessment

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As the U.S. Food and Drug Administration (FDA) considers approving a genetically modified (GM) Atlantic salmon (*Salmo salar*), it faces fundamental questions of risk analysis and impact assessment. The GM salmon—whose genome contains an inserted growth gene from Pacific chinook salmon (*Oncorhynchus tshawytscha*) and a switch-on gene from ocean pout (*Zoarces americanus*)—would be the first transgenic animal approved for human consumption in the United States (1, 2). But the mechanism for its approval, FDA's new animal drug application (NADA) process (2), narrowly examines only the risks of each GM salmon compared with a non-GM salmon (2, 3). This approach fails to acknowledge that the new product's attributes may affect total production and consumption of salmon. This potentially excludes major human health and environmental impacts, both benefits

and risks. Regulators need to consider the full scope of such impacts in risk analyses to avoid unintended consequences (4), yet FDA does not consider ancillary benefits and risks from salmon market expansion (2, 3), a result of what may be an overly narrow interpretation of statutes.

Alternatively, if FDA currently lacks the statutory authority to evaluate the full impacts of growth in the salmon market, then Congress should grant FDA the authority to evaluate these broader impacts of food innovations and should provide funding to build the necessary capacity. Because the approval of GM salmon will set an important precedent for GM animals intended for human consumption, it is essential to establish an approval process that assesses the full portfolio of impacts to ensure that such decisions serve society's best interests.

"Materially Equivalent" Assessment

Aqua Bounty Technologies, the developer of the product, claims that its AquaAdvantage Salmon is different from "standard" Atlantic salmon in two ways: It grows faster and it requires less feed to grow (5). FDA is evaluating these claims and whether each GM salmon is "materially equivalent" to a non-GM salmon (2, 3). Health risks are quantified by comparing the nutritional profile of a GM

Health and environmental impacts of GM salmon hinge on aggregate market size, which current regulatory processes ignore.

salmon to a non-GM salmon and screening for known toxins and allergens (2).

Although comparing health information for GM and non-GM salmon is essential, quantifying risks in this manner implicitly (and implausibly) assumes that the new product will simply replace the old one in the market and that the new product leads to no changes in aggregate market prices and quantities. In fact, the consequences of small differences in the nutritional and health profiles (if any) of one GM salmon compared with one non-GM salmon could be dwarfed by the public health benefits from substantial growth in the salmon market and from the eating of more salmon in place of other proteins such as beef.

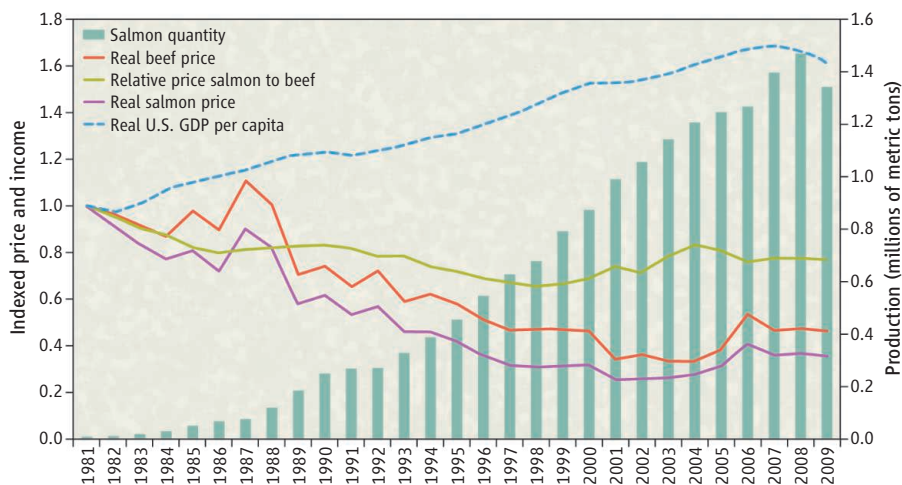
Market Transformation and Public Health

The AquaAdvantage Salmon could lower the costs of production by reducing the amount of feed and other inputs needed to produce one salmon. Declining costs from technological innovation have led to increased salmon production (6, 7), so much so that, despite increased demand from rising incomes, real salmon prices (i.e., adjusted for inflation) have declined [Supporting Online Material (SOM), see the figure]. U.S. per capita salmon consumption doubled between 1994 and 2004 (1.1 to 2.2 pounds/year or 0.5 to 1 kg/year) (8), even as real prices for substitute animal proteins like beef fell (SOM). Salmon prices fell faster than beef prices from 1981 to 2009. Because changes in relative price [e.g., salmon relative to beef (SOM)] drive changing patterns in animal protein consumption (9), these trends augur future market growth if GM salmon lowers production costs.

For adults, overall health benefits exceed health risks from consuming fish (4, 10). Of the 10 most frequently consumed fish in the United States, salmon has the highest levels of omega-3 fatty acids, which are thought to reduce coronary heart disease (9, 10). For American adults who currently eat no fish, consumption of just one serving of salmon per week can reduce risk of coronary death by 36% (10) (SOM). Omega-3s are also essential for fetal brain development (11). Thus, if GM salmon expands the aggregate salmon market, more consumers will eat more

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Prices, income, and salmon production. The real price (adjusted for inflation) of salmon and the relative price of salmon to beef have decreased as salmon production and real income have increased. Prices and GDP indexed to 1981 values. See SOM for details.

salmon and less of other proteins that are lower in omega-3 fatty acids, which would improve public health. GM salmon could put fresh salmon in reach as a protein source for low-income households susceptible to conditions linked to poor nutrition (12) (SOM).

If Congress wants FDA to promote healthier diets, lowering the price of healthy choices could be crucial. GM salmon could thus be not only the first transgenic animal approved for human consumption, but also the first GM food for which the price decrease from technological innovation itself promotes health benefits from increased consumption.

Environmental Impacts

FDA's focus on evaluating one GM fish with respect to one non-GM fish also presents an incomplete picture of aggregate environmental risks and benefits. FDA, like any federal agency, has a mandate to assess environmental impacts of its actions under the National Environmental Policy Act (NEPA) (13, 14). Environmental concerns about salmon farming, which would increase in an expanded market, include local pollution from waste effluents, disease, and potentially increased pressure on wild fish stocks that provide sources of feed for salmon (15, 16).

But potential impacts of escaped GM salmon on wild salmon (through either gene transfer or ecological competition) have dominated the discussion (1, 17). Because Atlantic salmon was only recently domesticated, gene transfer to its wild cousins appears plausible. The current NADA for AquAdvantage Salmon applies to only two particular facilities, from which the escape risks appear minimal (3, 5). Expanding production to other facilities (and increasing supply) could increase the risk of escape, but would also require FDA approval of an amended NADA (3).

The NADA for AquAdvantage Salmon neglects potential impacts of market expansion on the global commons that support the fish meal and/or fish oil trade as inputs (i.e., feed) to salmon farming. If each GM salmon substitutes for just one non-GM farmed salmon, as FDA's evaluation assumes, then waste effluent and pressure on wild sources of fish meal and oil would decline because the GM salmon require less feed to grow than do non-GM salmon (5). But if introducing GM salmon expands the aggregate market enough to compensate for the reduction of fish meal and oil input per salmon with the new technology, then demand for fish meal and oil will increase. The environmental risks of this increase are debatable (6, 18). Salmon farming currently consumes 40% of world fish

oil production. Commercial feed uses about 3 kg of wild fish to produce 1 kg of salmon. Although the ratio has decreased over time, the technology to produce feed without ingredients from fatty fish that only exist in the wild is not available (19).

The extent to which salmon market growth would pressure wild stocks (the inputs to salmon farming) will hinge on how well institutions manage these stocks (20). If well managed, increased demand will increase returns to fisheries; but if stocks are not well managed, demand growth will exacerbate overfishing (20, 21). Changes in product markets can lead to unintended environmental impacts in input markets. For example, policies to promote ethanol, intended to reduce air pollution and greenhouse gas (GHG) emissions from automobiles, may induce land use changes (to grow inputs for ethanol production) that release even greater GHG emissions (22). When environmental or health externalities of a new technology or policy depend on market size, a full impact assessment can help to avoid unintended consequences.

FDA Mandate and Congressional Action

FDA's mandate is to determine whether a new animal drug is "safe" (23) and to examine its environmental impacts (13, 14). The term "safe" is not defined in the statutes, which use it in reference to "health of man or animal" and "cumulative effect on man or animal" (24, 25). FDA is applying a narrow analysis of "safety" in which it compares a portion of GM fish to an equivalent portion of non-GM fish (2, 3). This narrow focus may derive from FDA's decision to treat GM fish as an animal drug rather than as a food; aggregate exposure to a drug is substantially shaped by disease incidence, whereas aggregate exposure to a food is driven more by market prices. Congress could facilitate broader analysis by giving FDA resources to better integrate biology and economics.

To expand its scope, FDA could broadly interpret the terms "safe" and "health" to include the overall safety of the new fish in the consumer's diet (compared with other foods that the new fish would replace, such as beef) and the overall public health effects of the new fish supply. A broader FDA interpretation of the ambiguous term "safe" could be upheld by the courts under longstanding doctrines of administrative law (26). If FDA declines to broaden its interpretation, or if it did so and the courts demurred, then Congress should amend the statute to empower and fund FDA to conduct a full impact assessment. Meanwhile, NEPA mandates FDA to assess the significant environmental impacts from market

expansion that it is currently ignoring (13).

A narrow definition of "safe" that does not consider aggregate market size ignores the reality that people need to eat some form of protein and may choose to eat more of a new product if it costs less. Instead of focusing on the safety of food taken one portion at a time (or whether it was produced with molecular GM techniques versus classic breeding methods), a more useful approach would be to evaluate whether society is better off overall with the new product on the market than without it (4). Although FDA's narrow analysis might lead it to a decision that promotes the overall best interests of the public anyway, sound decision-making in this and future cases warrants a broader analysis of the full set of important consequences.

FDA ultimately will need to decide on the scope of broader impacts to assess by weighing the benefits of more information against the costs of doing more analysis and delaying the decision. In the case of GM salmon, a reasonable compromise would be to use existing studies to develop scenarios of market growth and the resulting broader human health and environmental impacts.

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27. The authors thank R. Perez for research assistance.

Supporting Online Material

www.sciencemag.org/cgi/content/full/330/6007/1052/DC1

10.1126/science.1197769