Labeling of Food Made for AquAdvantage Salmon

Comments of Consumers Union on
Food and Drug Administration Docket No. FDA-2010-N-0385; Public Hearing

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Summary

Consumers Union [1] (CU) welcomes the opportunity to comment on labeling of food derived from AquAdvantage Salmon, a salmon genetically engineered with a growth hormone to reach mature size more quickly. We disagree with both FDA's assertion that genetic engineering itself does not, in and of itself, constitute a "material" difference under the law and also with their definition of what constitutes a "material" difference. In a Consumers Union nationwide poll, 95 percent of respondents said they thought food from genetically engineered animals should be labeled, and 78 percent strongly agreed with this. There are two legal rationales for requiring labeling of genetically engineered salmon: genetic engineering constitutes a "material fact;" and the NAD (New Animal Drug, e.g. the genetic construct with the Chinook growth hormone gene) and/or its expression product constitutes a food ingredient. Thus, for the reasons articulated below, we feel that the process of genetic engineering constitutes a "material fact" and, thus, that fact must be on the label.

Even if FDA decides that genetic engineering does not constitute a "material fact," the FDA should require labeling based on the fact that the inserted genetic material for the Chinook growth hormone gene, and the resulting expression product(s) (e.g. Chinook growth hormone) are food ingredients, because the drug itself (e.g. the genetic construct) constitutes an act of man rather than an act of nature.

Finally, FDA should require labeling to insure that any unexpected or unintended effects of engineering this salmon, the first genetically engineered animal to request a New Animal Drug Approval, come to FDA attention. Such labeling is authorized by international guidelines developed by the Codex Alimentarius Commission. Recently certain drugs approved by FDA as safe have turned out to have unexpected health

effects after they were widely used by consumers. It is essential to label a genetically engineered animal so that any unexpected effects will be recognized and consumer health protected.

Background

FDA tries to frame the issues surrounding labeling of foods derived from GE animals, by saying that five principles apply: 1) law prohibits false labeling; 2) law prohibits misleading food labeling, particularly in light of material facts about the product; 3) law allows voluntary labeling about production methods, as long as it is neither false nor misleading; 4) label must include a name that accurately describes the basic nature of the food; and 5) FDA cannot require additional labeling about production methods unless it's necessary to ensure labeling is not false or misleading.

"Material fact" analysis

We agree with first two principles, but disagree with FDA's interpretation of what constitutes a "material fact." In the background document, FDA maintains that a "material fact" means that there must be some change in nutritional value, organoleptic properties, or functional characteristics. We strongly disagree with FDA and feel that they are trying to ignore their own history. In the past FDA has required labeling under the "material fact" analysis that did not entail a change in nutritional value, organoleptic properties, or functional characteristics. A material fact, in FDA's view, is information that consumers view as important. If such information is <u>not</u> on the label, then the label is considered to be misleading. FDA articulated this position in a final rule that required labeling of irradiated foods [2], even though the FDA had ruled that irradiated foods were safe. FDA has stated in this final rule on food irradiation (April 18, 1986, 51 FR 13376 at 13380) that the large number of respondents who asked for labeling of retail products was one factor indicative of the materiality of food irradiation: "***Whether information is material under section 201(n) of the act depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer. The large number of consumer comments requesting retail labeling attest to the significance placed on such labeling by consumers***" emphasis added. **Thus, materiality clearly does not always include "some change in nutritional value, organoleptic properties, or functional characteristics.**" In October, 2008, the Consumer Reports National Research Center polled over 1,000 people nationwide on various food labeling issues; some that 95% of consumer polled believed that "food products made from genetically engineered animals should be labeled as such" with 78% strongly agreeing with this statement. [3] This clearly shows consumers overwhelmingly desire food from GE animals to be

labeled; in other words, whether an animal has been genetically engineered is a material fact that should be displayed on the label.

FDA has used the material fact rationale to require source labeling for protein hydrolysates. Labeling the source of protein hydrolysates was required because of the concern of vegetarians and observant Jews and Muslims. As the FDA stated, “the food source of a protein hydrolysate is information of material importance for a person who desires to avoid certain foods for religious or cultural reasons.” [4] If the FDA can require source labeling of protein hydrosylates for religious and cultural reasons, then it should also label the GE salmon for similar reasons. There are two Native American tribes in the Pacific Northwest, the Karuk, whose diet and culture revolve around salmon. Indeed, salmon have a religious significance for these tribes. These peoples have stated that they do not want to eat genetically engineered salmon and want to know if this sacred fish has been engineered. How can FDA require source labeling of protein hydrosylates for Jews, Muslims, Hindus and Vegetarians, but deny labeling of GE salmon to the Karuk?

Food derived from genetically engineered animals should be labeled to address religious, moral, and ethical concerns, as well. People are very concerned about genetically engineering animals, because of a range of ethical issues. Indeed, the National Research Council's (NRC’s) 2002 publication, Animal Biotechnology: Science Based Concerns, has a chapter that deals, in part, with socioeconomic, cultural, religious, and ethical factors raised by rDNA animals, which contains a box on labeling. As the NRC report noted, "Some religious, spiritual, ethnic, or cultural groups prescribe dietary norms or rules that include foods that are to be avoided. These norms or religious traditions might be violated by genetic engineering of animals used as food. [5] The NRC has realized that the labeling issue is very important to consumers as they point out "that there reasons--beyond safety or nutrition--for a consumer to want labeling of food derived from genetically plants or animals, including religious, ethical, right-to-know, or simple preference reasons. It could be argued that in the current climate surrounding biotechnology, the fact of genetic engineering is an aspect of the identity of a food derived from a genetically engineered organism. The committee notes, however, that while any one or all of these reasons might provide a legitimate basis in public policy for requiring labeling of biotechnology-derived foods . . . whether they justify labeling is beyond the committee's charge." [6] **In sum, we believe FDA should admit that the “material fact” entails more.** However, we believe that FDA could use the material fact criterion to require labeling of food derived from genetically engineered animals.

Food ingredient analysis

The ingredients labeling provision of the Food Drug and Cosmetic Act (Sec. 403(i)) requires that any food made from two or more ingredients must have a label with the common or usual name of each ingredient. The law defines an ingredient broadly as all "those substances that have been used to manufacture a food." Included in this definition would be all added substances. Added substances are all those substances present in food with the exception of those that are an "inherent natural constituent" but not intrinsically part of the food. Since there is some grey area here, a federal court has ruled that the law distinguishes between substances that are present in the food due to "acts of man" and those present due to "acts of nature;" the former are considered added and therefore subject to labeling while the latter are not (U.S. v. Anderson Seafoods, Inc. 447 F. Supp. 1151, [ND Fla 1978]). This distinction is important because the law requires a higher safety standard for substances present by reason of "acts of man." As the court pointed out, "[I]f a coffee processor subjects coffee to a process in which the naturally occurring caffeine is removed and later replaced with an equal amount of identical caffeine, it seems clear that Congress would have the stricter health standard apply" (Anderson).

Given this logic, we feel all genetic material moved into an animal via genetic engineering techniques, and any expression products from the genes, should be considered added and therefore, treated as an ingredient. Take the AquAdvantage salmon that is engineered to increase growth rate, for example. The genetic construct inserted in the AquAdvantage Salmon consists of a Chinook growth hormone gene, a promoter sequence from the Ocean pout and a small stretch of the PUC plasmid. This genetic construct was added to the pig by an "act of man," as the gene does not exist in nature. Obviously, the process whereby these different genetic materials were spliced together to form a single stretch of DNA was an act of man. Even though some might argue that the Chinook growth hormone is "natural," the process by which it is added to the Atlantic salmon renders it an "act of man" in the same way that the caffeine artificially added to a coffee bean is considered added, while the naturally occurring caffeine is not.

In our view, the added genetic material, as well as the expression products, should be considered as ingredients. In a commonsensical consumer understanding of the word ingredient, something that contains genetic material from at least two dissimilar sources contains at least two ingredients. By "dissimilar sources" we mean simply sources such as Chinook salmon, Ocean pout, and *E. coli*, that have a breeding barrier between them that is not already breached by traditional breeding.

Labeling as risk management measure to deal with scientific uncertainty

We also believe that FDA should require labeling for food derived from GE animals as a risk management measure to deal with scientific uncertainty and to track any potential unexpected adverse health effects associated with consumption of GE animals. This would be consistent with the recommendations developed by the Codex Alimentarius Ad Hoc Intergovernmental Task Force on Foods Derived from Modern Biotechnology and adopted by the Codex Alimentarius Commission in 2003. The *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*(CAC/GL 44 2003) [7] clearly state that labeling can be used as a risk management option to deal with scientific uncertainties associated with the risk assessment of GE foods: "18. Risk managers should take into account the uncertainties in the risk assessment and implement appropriate measures to manage these uncertainties. 19. Risk management measures may include, as appropriate, food labeling, conditions for market approval and post market monitoring" (pars 18, 19 in CAC/GL 44 2003).

Significant scientific uncertainty exists in the risk analysis of foods derived from GE/GM, and this is recognized in the Codex. In fact, the *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Animals* has a whole section on unintended effects which clearly states that they can have an unintended effect on human health: "*Unintended effects due to genetic modification may be subdivided into two groups: those that are "predictable" and those that are "unexpected" . . . A variety of data and information are necessary to assess unintended effects because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to human health.*" italics added (paras 17 and 18, CAG/GL 68 2008). Furthermore, this section recognizes that the unintended effects could also be caused by changes in genes are expressed at the molecular level and how the gene products are processed: "Molecular biological and biochemical techniques (that) can also be used to analyse potential changes at the level of gene transcription and message translation that could lead to unintended effects" (para 16, CAG/GL 45 2003).

It is clear from the summary FDA has presented for the AquaAdvantage genetically engineered salmon that at present there is significant uncertainty as to its possibly increased potential to cause allergic reactions, and also data suggesting that its nutritional profile is different in terms of omega-3 and omega-6 fatty acids, something very important to health. We strongly urge FDA to insist on more data on these topics before it allows this salmon on the market and to reject this product if it has increased potential for causing allergic reactions or shows adverse nutritional changes, since it would not meet the safety criteria for approval of a New Animal Drug. However it is essential to require labeling of these salmon to be able to detect unexpected or

unintended effects where FDA may not even have requested safety data. If the genetically engineered salmon caused an unexpected allergic reaction, or other adverse health effect, a consumer would have no way of linking their reaction to the salmon if it were not labeled, and FDA would have no way of learning of it. A consumer might eat conventional farmed salmon one week, and have no reaction, and eat the engineered salmon the next week and have a reaction, but would never attribute the reaction to the engineered salmon because it would carry no special label, and would appear to be just like the conventional salmon that the consumer had eaten without incident many times before. Thus adverse effects would occur but never be recorded, while unnecessary illnesses and possibly even deaths might be occurring.

In this regard we also urge FDA to consider the history of certain medications that were approved based on clinical trials but when widely used by consumers turned out to have caused hundred of thousands of heart attacks. It is clear that an adverse effect may not show up until a drug is used by a large population. In order to be able to track unexpected effects with genetically engineered salmon, we strongly urge FDA to require labeling as a post marketing risk management measure, as recommended by Codex guidelines.

What should be on the label

For the reasons articulated above, FDA should require the labeling of AquAdvantage salmon and all genetically engineered animals. The label should contain: i) the common, or usual, name of the gene product being transferred, ii) the source (type of organism or synthetic [if made completely in the lab]) of each type of genetic material transferred, iii) the purpose or function of the genetic material transferred, and iv) the fact that genetic engineering was used, even if no gene products are found in the food in question. So, for example, we would suggest that the AquAdvantage salmon be labeled “Contains genetic material from Chinook salmon (a growth hormone) and Ocean pout (enhancing action of other genes).” In the case of foods which come from a genetically engineered plant but the food itself does not contain any foreign genetic material or their expression products, such as canola oil from a genetically engineered plant, the label should state “produced using genetic engineering.” This last requirement is necessary because the use of the process of genetic engineering can be considered a “material fact” in the FDA’s usage of that word, as evidenced by overwhelming support in a survey for such information on a label.

Conclusion

For the reasons articulated above, FDA should require the labeling of AquAdvantage salmon and all genetically engineered animals.

FOOTNOTES:

[1] *Consumers Union, publisher of Consumer Reports, is an expert, independent nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. To achieve this mission, we test, inform, and protect. To maintain our independence and impartiality, Consumers Union accepts no outside advertising, no free test samples, and has no agenda other than the interests of consumers. Consumers Union supports itself through the sale of our information products and services, individual contributions, and a few noncommercial grants. Over 7 million people subscribe to Consumer Report or Consumer Reports online.*

[2] 51 Fed. Reg. 13376-88, (April 18, 1986).

[3] At: http://www.greenerchoices.org/pdf/foodpoll2008.pdf

[4] 56 Fed. Reg. 28592 (June 21, 1991).

[5] pg 118 in National Research Council. 2002. *Animal Biotechnology: Science Based Concerns.* National Academy Press, Washington, D.C.

[6] Pg 118, Ibid

[7] Available at: http://www.codexalimentarius.net/web/standard_list.do?lang=en