



POLICY & ACTION FROM CONSUMER REPORTS

**Comments of Consumers Union on the
Food and Drug Administration (FDA) Draft Guidance for Industry: Voluntary Labeling
Indicating Whether Food Has or Has Not Been Derived from Genetically Engineered
Atlantic Salmon
Docket No. FDA-2015-D-4272**

Michael Hansen, Senior Scientist
January 26, 2016

Consumers Union (CU), the public policy and advocacy arm of Consumer Reports,¹ welcomes the opportunity to comment on the Food and Drug Administration's (FDA's), Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon. We disagree with FDA's decision not to require labeling of genetically engineered (GE) Atlantic salmon. We also 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. 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 believe 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.

In addition, 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

¹ Consumers Union is the public policy and advocacy arm of Consumer Reports. Consumers Union 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. It conducts this work in the areas of food and product safety, telecommunications reform, health reform, financial reform, and other areas. Consumer Reports is the world's largest independent product-testing organization. Using more than 50 labs, auto test center, and survey research center, the nonprofit organization rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications.

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.

Finally, we agree with FDA that the words “genetic engineering,” “bioengineering,” and “bioengineered,” can be used to describe the use of “modern biotechnology” in the production of the GE organism, such as the GE Atlantic salmon. We also fully agree with FDA’s use of the definition of “modern biotechnology” as defined by the international guidelines developed by the Codex Alimentarius Commission. We strongly disagree with FDA’s view that the term “genetic modification” is “a much broader term that encompasses other means of altering the genome of an organism including selective breeding, and lab-based in vitro methods.” In fact, for the reason articulated below, we believe that the term “genetic modification,” (aka GM or GMO)—which is used widely used in the European Union as well as by the media—is synonymous with the use of “modern biotechnology,” or “genetic engineering.” In other word, GE = GMO.

Detailed comments

“Material fact” analysis

As FDA points out, the Food, Drug and Cosmetic (FD&C) Act notes that a food is misbranded (and so is prohibited from being marketed) if its labeling is false or misleading. Section 201(n) of FD&C Act states that labeling is misleading if, among other things, “it fails to reveal facts that are **material**” **bold** added. However, the FD&C Act does not define the term “material.” The Guidance notes that “Historically, FDA has interpreted the term, within the context of food, to mean information about the attributes of the food itself ... [and that] the fact that the animal from which food was obtained was genetically engineered would not be material information with respect to labeling.” We disagree with FDA’s interpretation of what constitutes “material information.” FDA maintains that “material information” refers to “attributes of the food itself,” such as a change in nutritional value, organoleptic properties, or functional characteristics, etc. We note that, in the past FDA has required labeling under the “material fact” analysis that did not entail “attributes of the food itself,” e.g., a change in nutritional value, organoleptic properties, or functional characteristics. In a final rule that required labeling of irradiated foods,² even though the FDA had ruled that irradiated foods were safe, FDA argued that a “material fact,” is information that consumers view as important and that, if such information is not on the label, then the label is considered to be misleading. In the case of labeling of irradiated foods, FDA stated in this final rule on food irradiation 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*

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

significance placed on such labeling by consumers”³ 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.⁴ 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.”⁵ If the FDA can require source labeling of protein hydrolysates 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 hydrolysates for Jews, Muslims, Hindus and Vegetarians, but deny labeling of GE salmon to the Karuk?

In 2007, FDA proposed a revision to their labeling requirements for irradiated foods, such that labeling would only be required on those irradiated foods in which the irradiation has lead to a “material change”—defined as a “change in the organoleptic, nutritional or functional properties”—in the food that is not obvious to the consumer at the point of purchase.⁶ Thus, not all irradiated food would be required to be labeled. This proposed revision to the irradiation labeling standard went nowhere. However, this attempted weakening of the food irradiation labeling standard clearly demonstrates that FDA is now trying to narrow the concept of “materiality,” so as to avoid the labeling of GE foods.

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."⁷ The NRC has realized that the labeling issue is very important to consumers as they point out

³ Pg. 13380 in IBID

⁴ At: <http://www.greenerchoices.org/pdf/foodpoll2008.pdf>

⁵ 56 Fed. Reg. 28592 (June 21, 1991).

⁶ 72 Fed. Reg. 16291-16306 (April 4, 2007). At: <http://www.fda.gov/ohrms/dockets/98fr/07-1636.htm>

⁷ pg 118 in National Research Council. 2002. *Animal Biotechnology: Science Based Concerns*. National Academy Press, Washington, D.C.

"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."⁸ **In sum, we believe FDA should admit that the “material fact” entails more. We believe that FDA should use the material fact criterion to require labeling of food derived from genetically engineered animals, including the GE Atlantic salmon.**

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 GE Atlantic salmon engineered to increase growth rate, for example. The genetic construct inserted in the GE 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 Atlantic salmon by an “act of man,” as the genetic construct does not exist, and could 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

⁸ Pg 118, Ibid.

ingredients. By “dissimilar sources” we mean simply sources such as Chinook salmon, Ocean pout, and *E. coli*, 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 Atlantic salmon. 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)⁹ 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 data on the AquaAdvantage genetically engineered salmon that, at present, there is significant uncertainty as to its possibly increased potential to cause allergic reactions, as well as data suggesting that its nutritional profile is different in terms of omega-3 and omega-6 fatty acids, something very important to health.¹⁰ 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 was 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

⁹ Available at: <http://www.codexalimentarius.org/standards/list-of-standards/>

¹⁰ See: <http://consumersunion.org/wp-content/uploads/2013/02/CU-comments-GE-salmon-0910.pdf>

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 hundreds 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.

Genetic modification is synonymous with genetic engineering

We agree with FDA that the words “genetic engineering,” “bioengineering,” and “bioengineered,” can all be used to describe the use of “modern biotechnology” in the production of the GE organism, such as the GE Atlantic salmon. We strongly support the FDA’s use of the definition of “modern biotechnology” as defined by the Principles for Risk Analysis of Foods Derived From Modern Biotechnology (CAC/GL 44, 2003) developed by the Codex Alimentarius Commission.¹¹ Documents/standards developed by the Codex Alimentarius Commission are referenced by the World Trade Organization in trade disputes involving foods, they constitute a globally accepted standard. In addition, the term “modern biotechnology” defined by Codex Alimentarius is also the same as the definition used by the Cartagena Biosafety Protocol under the Convention on Biological Diversity, clearly showing it to be a globally accepted standard. We commend FDA for using this definition.

We strongly disagree with FDA’s view that the term “genetic modification” is “a much broader term [than modern biotechnology] that encompasses other means of altering the genome of an organism including selective breeding, and lab-based in vitro methods.” In fact, we believe that the terms “genetic modification” and “genetic engineering” are synonymous. European countries having been using the term genetic modification since 1990. As noted in a 1990 Directive of the European Communities on the deliberate release into the environment of genetically modified organisms (GMOs), the term “'genetically modified organism (GMO)' means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/ or natural recombination. Within the terms of this definition: i) genetic modification occurs at least through the use of the techniques listed through the use of the techniques in Annex I A Part 1; ii) the techniques listed in Annex I A, Part 2 are not considered to result in genetic modification”¹² This EU definition, as well as the techniques listed in Annex 1 A, are basically synonymous with the definition of “modern biotechnology” as adopted by Codex Alimentarius Commission. In addition, Wikipedia notes that “a genetically modified organism (GMO) is any organism whose genetic material has been altered through genetic

¹¹ At: http://codexalimentarius.net/download/standards/10007/CXG_044e.pdf

¹² Pg. 2 in European Communities. 1990. COUNCIL DIRECTIVE of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. 90/220/EEC. *Official Journal of the European Communities*, No. L 117/15. At: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31990L0220&from=EN>

engineering techniques.”¹³ Thus, since at least 1990, the terms genetic modification (GM) and GMO has been used as synonyms for genetic engineering. Most of the media that have reported on this topic have used the term GM and GMO since that was the wording used in the European Union and by most of the non-governmental organizations that have worked labeling and regulation of genetically engineered organisms. We consequently feel that FDA is wrong is stating that “[g]enetic engineering is thus a subset of genetic modification.” On the contrary, we believe “genetic modification” is synonymous with the terms “modern biotechnology” and “genetic engineering.” In other word, GE = GM/ GMO. Consequently, we feel that FDA should allow the use of the label “Non-GMO” for salmon that have not been genetically engineered, and not require a longer informational statement, such as “not genetically modified through the use of modern biotechnology.” Thus, while we commend FDA for saying that they do not intend to take enforcement action against a labelling using the acronym “GMO” in a statement indicating that the product was or was not produced using modern biotechnology, we also urge FDA not to take enforcement action for the use of the terms “non-GMO salmon” or “GMO salmon” without the longer informational statement.

Conclusion

In summary, for the reason discussed above, we do not agree with FDA’s decision not to require labeling of GE Atlantic salmon. We believe that the process of genetic engineering constitutes a “material fact” and, thus, that fact must be on the label. Furthermore, we disagree with FDA that “genetic engineering” is a subset of “genetic modification.” In fact, we believe that genetic engineering and genetic modifications are synonyms. Thus, manufacturers and retailers should be allowed to label their products derived from Atlantic salmon that have not been genetically engineered as “Non-GMO” or “from non-GMO salmon” and not be required to have a longer explanatory statement such as

Thank you for your consideration of our comments.

Respectfully submitted,

A handwritten signature in black ink that reads "Michael Hansen". The signature is written in a cursive style with a large, prominent 'M' and 'H'.

Michael Hansen, Ph.D.
Senior Scientist
Consumers Union

¹³ Wikipedia. Genetically Modified Organism. Accessed January 21, 2016. At: https://en.wikipedia.org/wiki/Genetically_modified_organism

Michael Hansen, Ph.D.
Senior Scientist
Consumers Union