



THE CENTER FOR  
FOOD SAFETY



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November 22, 2010

Margaret A. Hamburg, M. D.  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

RE: Docket No. FDA-2010-N-0385 Food Labeling: Labeling of Food Made from AquAdvantage Salmon; Request for Public Comments

Dear Dr. Hamburg:

The Center for Food Safety (CFS) welcomes the opportunity to comment on the Food and Drug Administration's (FDA's) analysis of whether it can and should require labeling for the genetically engineered AquAdvantage® Salmon. CFS strongly opposes the approval of genetically engineered (GE) salmon without independent, broader, and more scientifically rigorous testing than FDA has required to date. Additionally, CFS believes that the decision whether to approve GE salmon for human consumption—the first ever genetically engineered

animal food—requires the preparation of an environmental impact statement (EIS).<sup>1</sup> Nonetheless, should FDA choose to approve GE salmon, CFS urges FDA to require descriptive labeling indicating that AquAdvantage® Salmon is genetically engineered.

## **I. Summary of Comments**

The AquAdvantage® Salmon is the first genetically engineered (GE) animal produced for human consumption. Accordingly, the question of whether to require labeling for this GE salmon is a critical issue which will set a precedent for the labeling of future GE animals. Despite the widespread use of genetic engineering in some U.S. crops today, the scientific community's understanding of genetic engineering of food products, particularly of animals, remains in a state of flux. The risks to human health and the environment are not yet fully understood and there is sufficient scientific evidence for consumers to question the safety of consuming GE salmon.

In light of scientists' and the public's rapidly changing understanding of GE foods, FDA's regulatory regime for food labeling as applied is woefully inadequate. In effect, FDA is using 19<sup>th</sup> century ideas to regulate 21<sup>st</sup> century foods. Modern consumers' preferences and purchasing decisions are based not only on sensory perceptions, but also on concerns related to latent or unknown health risks, animal welfare, and harm to the environment. New and emerging technologies—not only genetic engineering, but also nanotechnology, synthetic biology, and more—alter food organisms at the genetic level in ways both defined (to confer given traits) and undefined (e.g. insertional mutagenesis), and thus have brought about significant changes that may or may not be detectable by sight, taste, touch, or smell. Furthermore it is impossible for GE food producers to disclose on a label what they themselves do not yet know about their product. Accordingly, as consumers seek to avoid both known and unknown risks associated with new food technologies like genetic engineering, they increasingly base their food purchasing decisions not just on what is currently known about the product itself, but also on what they can find out about how that food was produced. Unfortunately, the absence of required labeling for GE foods makes it exceedingly difficult, if not impossible, for consumers to decide for themselves whether or not to take on the risks—known and unknown, to themselves or to the environment—associated with GE foods.

The power and duty to modernize the oversight of food lies with FDA. FDA's authority under the Federal Food, Drug & Cosmetic Act (FFDCA)<sup>2</sup> to require labeling based on

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<sup>1</sup> CFS has previously submitted comments addressing these points. *See* Food and Drug Administration, Veterinary Medicine Advisory Committee: Notice of Meeting (Aug. 26, 2010) (Docket No. FDA-2010-N-0001-0094). CFS's comments are also available at <http://stopgefish.files.wordpress.com/2010/09/cfs-icta-review-of-fda-packet-to-vmac.pdf>.

<sup>2</sup> 21 U.S.C. § 301 *et seq.*

production processes goes well beyond the Agency’s antiquated definition of “material” differences. FDA has the authority to require GE salmon to be labeled based on its production process in order to prevent consumer deception. Moreover, although FDA can and should form its own opinion about the safety of GE salmon, it cannot mandate that same opinion for all consumers by withholding information consumers find relevant to identifying the product they truly want to purchase. Failure to require that GE salmon be labeled would amount to a paternalistic effort by the Agency to hide information from the public based on the offensive assumption that Americans cannot be trusted to act rationally. For the reasons outlined below, the Center for Food Safety respectfully submits that FDA has not just the statutory authority, but also a duty to the public to require that products of new food technologies be labeled differently from their conventional counterparts.

However, even under FDA’s current understanding of “materiality,” FDA has the authority to require labeling of GE salmon, specifically. Should FDA decide that GE salmon is generally safe for humans to eat, important differences between GE salmon and conventional salmon remain and should be disclosed. These differences have implications for the identity and proper classification of GE salmon, its nutritional qualities, and the human health risks associated with consuming GE salmon. Under FDA’s current interpretation of its authority under FFDCA, these differences are sufficiently “material” to warrant labeling GE salmon as the product of genetic engineering.

Part II argues for a broader definition of “material” differences, which would enable FDA to more effectively prevent deceptive labeling omissions. Part III discusses differences between GE salmon and non-GE salmon that qualify as “material” under FDA’s current definition. Part IV clarifies that a mandatory disclosure for GE salmon would not violate AquaBounty’s First Amendment rights. Part V concludes.

**II. FDA can and should adopt a more reasonable interpretation of FFDCA Section 201(n) that would enable it to mandate labeling based on factors that affect consumers’ purchasing decisions**

**a. A broader interpretation of “material” is a permissible reading of FFDCA, and FDA may alter its stance as long as it provides reasoned explanation**

FDA’s statutory authority to mandate labeling based on how a food is produced is derived from its authority to mandate labeling for foods that are misbranded because they are misleading.<sup>3</sup> A label may be misleading if it fails to reveal facts that are “material” either (1) in light of representations made on the label, or (2) with respect to the consequences that may result

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<sup>3</sup> 21 U.S.C. § 321(n).

from using or consuming the food.<sup>4</sup> Congress has not given any guidance regarding the meaning or limits of the term “material.” FDA’s authority to mandate labeling therefore turns entirely on which reasonable interpretation of “material” the agency chooses to adopt, and nothing else.

An interpretation of “material” that encompasses information about production processes that consumers find significant to identifying the product they want is a reasonable interpretation of section 201(n). Indeed, FDA previously adopted this very interpretation when issuing its rule requiring irradiated foods to be labeled. In its record of decision, FDA stated, “[w]hether information is material under [section 201(n)] . . . 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.”<sup>5</sup> The fact that FDA has already adopted this interpretation once without being judicially overturned demonstrates that it is at least a reasonable interpretation of section 201(n).

Moreover, this interpretation is reasonable because the very purpose of section 201(n) is to mandate labeling for information the absence of which would mislead consumers.<sup>6</sup> What consumers will find misleading necessarily depends on what *they* perceive as significant differences from what a food normally is. As these Comments demonstrate in Part II.b.1 *infra*, the readily apparent physical properties of a given food product are not the only concerns that consumers take into account to identify and differentiate between foods. Adopting an interpretation of “material” that corresponds to what consumers find relevant would enable FDA to prevent the many varieties of deception that have nothing to do with sensory perception.

FDA is not limited to its current interpretation of materiality under section 201(n). First of all, existing FDA policy regarding the safety and labeling of GE foods by its own terms only governs plant-derived bioengineered foods.<sup>7</sup> Here, the Agency is considering the legal status of the first ever genetically engineered *animal* for human consumption. Accordingly, FDA can and should take this opportunity to closely consider what its policy on GE animals should be, instead of hastily adopting the policy used for GE plants.

Even if it adopts the same policy for GE plants and GE animals, FDA should reconsider its current interpretation of materiality under section 201(n). An agency may change its

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<sup>4</sup> *Id.*

<sup>5</sup> Food and Drug Administration, “Irradiation in the Production, Processing, and Handling of Food,” 51 Fed. Reg. 13376, 13388 (April 18, 1986).

<sup>6</sup> *See, e.g.*, Food and Drug Administration, “Statement of Policy: Foods Derived From New Plant Varieties,” 57 Fed. Reg. 22984, 22991 (May 29, 1992).

<sup>7</sup> *See* Food and Drug Administration, “Statement of Policy: Foods Derived From New Plant Varieties,” 57 Fed. Reg. 22984 (May 29, 1992); *accord* “Premarket Notice Concerning Bioengineered Foods,” 66 Fed. Reg. 4839 (Jan. 18, 2001) (“The Food and Drug Administration (FDA) is proposing to require the submission to the agency of data and information regarding *plant-derived bioengineered foods* that would be consumed by humans or animals.”).

interpretation of a statute as long as it provides a reasoned explanation for its altered stance.<sup>8</sup> Moreover, such a change in agency policy need not be justified by reasons more substantial than the reasons for adopting the existing policy in the first place.<sup>9</sup> In these Comments and countless other submissions in this docket, FDA will find myriad reasons supporting a modernization of its labeling regime, which would include an interpretation of “material” that more closely resembles the reasonable interpretation adopted in the irradiated foods rulemaking. Modernizing FDA’s reading of section 201(n) would give FDA the authority it needs to adequately prevent deceptive labeling, in all its forms.

**b. FDA’s current definition of “material” applies 19<sup>th</sup> century scientific methods to 21<sup>st</sup> century food processes**

*1. FDA’s current definition fails to take into account the extra-sensory concerns that drive modern consumer purchasing choices*

FDA’s current labeling regime for GE foods is woefully arcane as applied and out of touch with the concerns of an increasingly scientifically literate public. According to FDA’s current understanding of “materiality,” a consumer can only be deceived by a label if what is inside the package looks, smells, tastes, or feels different from what the label says the product is.<sup>10</sup> However, even lay persons’ conceptions of product identity and sameness have transcended mere sensory perception since the 1800s. Consumers today attach value judgments to how food is produced, differentiating products based on information that cannot be gleaned by the senses. Just as many consumers actively seek out foods based on extra-sensory preferences, they likewise actively avoid certain foods that conflict with these preferences. This trend is borne out by the growing number of companies that voluntarily label their products with claims about the social justice, environmental sustainability, or simplicity of their production methods. If consumers distinguish between foods based on production processes, the labels on those foods must do so, as well. Otherwise, consumers are at risk of being deceived by producers’ failure to disclose information that would contradict consumers’ reasonable assumptions about the food they are about to purchase.

Recent public opinion polls overwhelmingly demonstrate that consumers base purchasing decisions on whether a product was genetically engineered. To illustrate, several polls suggest that Americans are overwhelmingly against approving GE salmon in the first place. In one poll conducted by Lake Research Partners, 91% of those polled said they believe that FDA should not

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<sup>8</sup> Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co, 463 U.S. 29, 42 (1983).

<sup>9</sup> F.C.C. v. Fox Television Stations, Inc., 129 S. Ct. 1800, 1810-11 (2009).

<sup>10</sup> See Food and Drug Administration, “Background Document: Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon,” (August 2010), *available at* [http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm#Applicable\\_Principles](http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm#Applicable_Principles) (last visited Nov. 10, 2010).

approve genetically engineered fish or meat for the marketplace.<sup>11</sup> The Puget Sound Business Journal found 77.78% of respondents at least generally opposed to FDA’s approval of GE salmon without further study, with 51.46% opposed to approving GE salmon under any circumstances.<sup>12</sup> Across eleven polls conducted by both national and local news media outlets, in every one a solid—and often overwhelming—majority of respondents said they would not even consider eating genetically engineered salmon.<sup>13</sup>

The public consensus becomes even more overwhelming and consistent on the issue of mandatory labeling of GE foods, including GE salmon. A recent poll by the Washington Post found that 95% of respondents think GE salmon should be labeled.<sup>14</sup> In another poll conducted by a Minneapolis news organization four days later, the same percentage of respondents believed GE salmon should be labeled.<sup>15</sup> These results cannot be written off as an overreaction to recent news coverage. In a 2008 Consumer Reports poll, two years before FDA’s consideration of GE

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<sup>11</sup> Lake Research Partners, “Americans in near unanimity on their disapproval of genetically engineered fish and meat in the marketplace,” Commissioned by Food and Water Watch, 9/20/10, *available at* <http://documents.foodandwaterwatch.org/release-FWW-Omnibus.pdf>.

<sup>12</sup> Puget Sound Business Journal, “Poll: Should FDA approve genetically modified salmon?” (Sept. 20, 2010) *available at*

[http://seattle.bizjournals.com/seattle/blog/2010/09/poll\\_should\\_fda\\_approve\\_genetically\\_modified\\_salmon.html](http://seattle.bizjournals.com/seattle/blog/2010/09/poll_should_fda_approve_genetically_modified_salmon.html).

<sup>13</sup> Lake Research Partners, *supra* note 11; Puget Sound Business Journal, *supra* note 12; WASHINGTON POST Poll, “If Genetically Engineered Salmon Wins FDA Approval, Will You Buy It?”, (Sept. 17, 2010), *available at*

<http://views.washingtonpost.com/post-user-polls/2010/09/would-you-eat-genetically-modified-salmon.html>; TIME

Poll, “Do You Think the FDA Should Approve Genetically Modified Salmon?” *available at*

[http://www.timepolls.com/hppolls/archive/poll\\_results\\_771.html](http://www.timepolls.com/hppolls/archive/poll_results_771.html); CBS News Poll, “Would You Eat Genetically Altered Fish?” (Sept. 14, 2010), *available at* <http://www.cbc.ca/news/pointofview/2010/09/genetically-altered-food-would-you-eat-it.html>; MSNBC Poll, “Would You Eat Food That Has Been Genetically Engineered?”, (Sept. 20, 2010), *available at* [http://health.polls.newsvine.com/\\_question/2010/09/20/5143473-would-you-eat-seafood-that-has-been-genetically-engineered](http://health.polls.newsvine.com/_question/2010/09/20/5143473-would-you-eat-seafood-that-has-been-genetically-engineered); HUFFINGTON POST, “Would You Eat Genetically Modified Salmon?”, (Sept. 22, 2010), *available at* [http://www.huffingtonpost.com/2010/09/20/gm-salmon-fda-hears-argum\\_n\\_731224.html](http://www.huffingtonpost.com/2010/09/20/gm-salmon-fda-hears-argum_n_731224.html); CBS-

4, S. Florida, Poll: “Would You Eat Genetically Modified Salmon?”, (Sept. 20, 2010), *available at* <http://cbs4.com/national/salmon.genetically.modified.2.1921995.html>; NW Cable Network Poll, “Would You Eat Genetically Altered Salmon?”, (Sept. 20, 2010), *available at* <http://www.nwcn.com/news/environment/Genetically-engineered-salmon-now-on-FDAs-plate-103281914.html>; Naples News (FL), Poll: “Would You Eat Genetically Modified Salmon?”, (Sept. 20, 2010), *available at* <http://www.naplesnews.com/polls/2010/sep/genetically-modified-salmon/results/>; PALM BEACH POST, “Would You Eat A Genetically Engineered Salmon?”, (Sept. 20, 2010), *available at* <http://blogs.palmbeachpost.com/opinionzone/2010/09/20/fda-to-consider-genetically-engineered-salmon/>; NBC 17, Raleigh, Poll: “If the FDA Approved Genetically Modified Salmon, Would You Eat It?”, (Sept. 20, 2010), *available at* <http://www2.nbc17.com/news/2010/sep/20/poll-fda-to-consider-approval-of-modified-salmon-ar-471768/>; TDN.com, Poll: “Should the FDA Allow the Sale of Genetically Engineered Salmon for Human Consumption?”, (Sept. 20, 2010), *available at* [http://tdn.com/news/local/article\\_cafece46-c51b-11df-bdfe-001cc4c002e0.html](http://tdn.com/news/local/article_cafece46-c51b-11df-bdfe-001cc4c002e0.html); Reno.MomsLikeMe.com, Poll: “Would You Feed Your Kids Genetically Engineered Salmon That Grows Twice As Fast As Conventional Salmon?”, (Sept. 20, 2010), *available at* <http://reno.momslikeme.com/members/pollactions.aspx?g=1133316&m=14445113&grpcat=&poll=results>; Change.org, Poll: “Would You Eat Genetically Engineered Salmon?”, *available at* [http://food.change.org/blog/view/would\\_you\\_eat\\_genetically\\_engineered\\_salmon](http://food.change.org/blog/view/would_you_eat_genetically_engineered_salmon).

<sup>14</sup> WASHINGTON POST, “Should genetically-modified food be labeled?” (Sept. 17, 2010), *available at* <http://views.washingtonpost.com/post-user-polls/2010/09/should-genetically-modified-food-be-labeled.html>.

<sup>15</sup> KSTP – St. Paul/Minneapolis, “Should Genetically Modified Salmon Carry a Different Label?” (Sept. 21, 2010), *available at* <http://kstp.com/news/stories/S1754678.shtml?cat=1>.

salmon was covered by mainstream news media, 95% of respondents agreed that food from genetically engineered animals should be labeled.<sup>16</sup>

In this country of sharply divided opinions, a consistent finding that 95% of Americans want GE salmon to be labeled conclusively demonstrates that for consumers, the use of genetic engineering represents a material fact affecting their purchasing decisions. Moreover, that so many Americans are either opposed to the use of genetic engineering in their food or believe it should be disclosed reveals just how far outside the common understanding of foods genetic engineering is. The fact that FDA does not currently consider this process to be a “material” difference demonstrates just how antiquated and ill-suited its current labeling scheme is to preventing consumer deception in today’s market.

2. *FDA’s presumption that genetic constructs are GRAS and therefore do not represent a material difference incorrectly assumes that genetic material is equally safe no matter where it occurs in the genetic sequence.*

To presume that genetic constructs are GRAS because they consist of deoxyribonucleic acid (DNA) that is not, by itself, inherently unsafe, is to exclude from consideration as completely irrelevant the process by which those constructs are introduced into the genome, and the widely divergent effects attendant upon insertion at different positions therein. Like words in a sentence, the significance of genetic constructs—positive or negative—depends on the context in which they exist. The introduced transgene may “knock out” an endogenous gene, reducing or eliminating expression of the associated protein or regulatory RNA, and thereby dysregulating metabolic processes mediated by that protein (e.g. enzyme) or regulatory RNA, with potentially harmful consequences. For instance, production of low-level, naturally occurring toxins or allergens may be increased, or nutrient levels reduced. Indeed, FDA’s own scientists have cautioned the Agency about the possible hazards of GE foods, as well as flaws in how it arrived at its policy regarding bio-engineered foods,<sup>17</sup> and our evolving knowledge of molecular biology over the two decades since (e.g. functional significance of much “junk DNA,” for instance as encoding regulatory RNA that modulates gene expression) has only given us more reason for caution. The fact that the AquAdvantage genetic construct itself is composed of “harmless” DNA and is therefore designated GRAS should not lead FDA to conclude that its use in food production can never be a material fact warranting mandatory labeling.

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<sup>16</sup> Consumer Reports – National Research Center, “Food-Labeling Poll 2008,” (Nov. 11, 2008), *available at* <http://www.greenerchoices.org/pdf/foodpoll2008.pdf> (last visited Nov. 10, 2010).

<sup>17</sup> Comments of certain members of FDA staff on the 1992 Policy were revealed during the discovery process in *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000). The Alliance for Bio-Integrity has since posted these documents on its Web site. Alliance for Bio-Integrity, Key FDA Documents Revealing (1) Hazards of Genetically Engineered Foods and (2) Flaws with How Agency Made Its Policy, *available at* <http://www.biointegrity.org/lists.html> (last visited Nov. 17, 2010).

The AquaBounty data on the insertion of the genetic construct into two different locations help make the point that location in the genome matters. Transgene insertion at the  $\beta$  locus did not trigger increased growth, while insertion at the  $\alpha$  locus did. However, the company did not determine where in the salmon genome the transgene was inserted, and therefore cannot rule out the possibility of gene deletion or disruption at the insertion site, with potentially harmful consequences. The 35 bp repeated sequence flanking the transgene may represent DNA introduced or rearranged by the insertion event; and even if the 35 bp repeat flanking sequences are native DNA, AquaBounty's assumption that interruption of such sequences is incidental because they are "junk" DNA without functional significance is illegitimate, hearkening to long-discredited notions in molecular biology.<sup>18</sup> Moreover, using even slightly different transgenes can have different effects, too. Two papers by Robert Devlin looking at the effects of different promoter sequences on the morphology of Coho Salmon, make clear that even choice of the transgene promoters makes a significant difference in the health of the resulting fish. In the first study, transgene expression was controlled by the same antifreeze protein (AFP) promoter from eelpout (*Zoarces americanus*) as in the AquAdvantage Atlantic Salmon.<sup>19</sup> In the second study, transgene expression was controlled with the metallothionein-B (MTH) promoter from sockeye salmon (*Oncorhynchus nerka*).<sup>20</sup> Although similar abnormal health symptoms were observed in both fish, the abnormalities were less pronounced in the MTH promoter fish.

As these examples demonstrate, the location of a genetic construct matters as much as its composition. The fact that a transgene itself is designated GRAS should not lead the FDA to conclude that its use in food production can never be a material fact warranting mandatory labeling. FDA's insistence that it cannot mandate labeling of GE foods because the genetic construct is presumed GRAS is contrary to science and contrary to common sense.

**c. Voluntary labeling, by itself, is an inadequate solution to consumers' current inability to seek out non-GE foods**

Consumers seeking out non-GE, conventional foods presently lack sufficient information upon which to base their purchases because FDA's current labeling regime forces them to rely solely on producers' inconsistent voluntary labeling.<sup>21</sup> Proponents of GE foods have argued incorrectly in several contexts that allowing producers of conventional foods to label their

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<sup>18</sup> Appendix 1 to Comments submitted to FDA by the Center for Food Safety (Sept. 16, 2010), available at <http://stopgefish.files.wordpress.com/2010/09/cfs-cfs-appendix1-aquadvantage-risk-assessment.pdf>.

<sup>19</sup> Devlin, R. H., T. Y. Yesaki, E. M. Donaldson, and C.-L. Hew (1995). "Transmission and Phenotypic Effects of an Antifreeze/GH Gene Construct in Coho Salmon (*Oncorhynchus kisutch*)," *Aquaculture* vol. 137, pp. 161-9.

<sup>20</sup> Devlin, R. H., C. A. Biagi, T. Y. Yesaki (2004). "Growth, Viability, and Genetic Characteristics of GH Transgenic Coho Salmon Strains," *Aquaculture* vol. 236, pp. 607-32.

<sup>21</sup> In some cases, even voluntary labeling of non-GE foods is strictly regulated. See Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839, 4840 (January 2001), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059098.htm> (last visited Nov. 10, 2010).



products “non-GE” will act as a de facto “GE” label for foods not bearing the “non-GE” label.<sup>22</sup> However, this argument represents a skewed understanding of both consumer behavior and fundamental fairness in the marketplace.

Voluntary labeling is effective when producers have a marketing incentive to disclose information that identifies the product as something consumers actively seek out as beneficially different from the norm. For example, meat producers whose livestock are humanely raised can anticipate that including “humanely raised” on their label will yield higher sales. Consumers respond to such affirmative disclosures because they distinguish the product from the norm, which in this case they find less desirable. Unfortunately, the same principle does not apply to the *absence* of information.

In the absence of labeling indicating otherwise, consumers assume that the food they purchase is produced conventionally—that is, without the use of novel food technologies like genetic engineering. Conventional varieties of foods have been produced and purchased since several thousand years before the introduction of genetic engineering. Genetic engineering is still widely perceived by consumers as a new, mysterious process.<sup>23</sup> As a consequence, consumers justifiably assume that, by default, conventionally produced foods are the norm, and GE foods are the exception. Too few consumers will correctly deduce that only the products with “non-GE” labels correspond to conventional varieties of food. Therefore, the context provided by voluntary “non-GE” labels on some surrounding foods is too ambiguous to serve as an adequate substitute for affirmatively disclosing that a food is the product of genetic engineering. Voluntary labeling belongs in our markets, but relying *solely* on voluntary labeling of non-GE foods will not act as a de facto label for GE foods. Instead, continuing to rely solely on voluntary labeling will engender more consumer deception, not less.

**d. Consumers’ desire to purchase food based on whether it is the product of genetic engineering cannot be dismissed as mere “consumer interest”**

Consumers avoid GE foods based on legitimate scientific opinions expressing doubts about their safety for humans and the environment. Others wish to avoid GE foods because of dietary restrictions rooted in undeniable religious or cultural convictions that prohibit them from eating genetically modified foods. Previous efforts by FDA and proponents of GE foods to minimize these concerns as mere “curiosity,”<sup>24</sup> “consumer interest,”<sup>25</sup> or “philosophical”

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<sup>22</sup> See, e.g., *International Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996); Donna M. Byrne, “Cloned Meat, Voluntary Food Labeling, and Organic Oreos,” 8 PIERCE LAW REVIEW 31, 48 (Jan. 24, 2010), available at <http://law.unh.edu/assets/pdf/pierce-law-review-vol08-no1-byrne.pdf> (last visited Nov. 15, 2010).

<sup>23</sup> See discussion *supra* Part II.b.1.

<sup>24</sup> Cf. *International Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996).

differences of opinion are not only offensive to our nation's ideals of tolerance and diversity, but also demonstrate a fundamental misunderstanding of the role of consumer choice in our market economy.

1. *Scientific reasons to doubt the safety of AquaAdvantage® GE salmon*

FDA repeatedly criticizes AquaBounty for numerous fatal flaws in the experimental design and conduct of its safety studies, yet inexplicably fails to draw the logical conclusion: that scientifically and statistically sound studies must be conducted prior to any further consideration of approving AquaBounty's GE salmon for commercialization. Two key deficiencies that render most of the company's data useless for risk assessment are as follows: undocumented culling procedures and small sample sizes.<sup>26</sup>

High rates of deformities have been repeatedly observed in transgenic growth hormone salmon, including AquaBounty's. In 2005, over 13% (217 of 1624) of the company's GE salmon had otherwise undescribed "severe irregularities;" another 71% had slight to moderate irregularities; and only 16% were normal.<sup>27</sup> Visible deformities might well be accompanied by invisible irregularities, and/or point to correspondingly high rates of invisible abnormalities in fish that appear normal. Some of these invisible abnormalities (e.g. high white blood cell counts indicative of infection) could be markers of or lead to consumer health risks (consuming infected salmon, or consuming salmon with high levels of antibiotic residues), and in fact AquaAdvantage salmon exhibit a number of troubling differences vis-à-vis non-GE salmon (discussed below). If the GE salmon that are chosen for testing do not accurately represent the range of GE salmon phenotypes (e.g. including a representative sampling of sick and/or deformed animals) that would actually be reared and potentially consumed (assuming commercialization), the test results for that unrepresentative group are at best meaningless, at worst positively misleading.<sup>28</sup>

It might be argued that AquaBounty and/or commercial fish farm operations that raise AquaBounty GE salmon would, in the normal course of business, remove sick and/or deformed animals prior to marketing, and that these animals need not be tested because they would not be consumed. FDA in fact appears to tacitly (although not explicitly) rely on this presumption,<sup>29</sup>

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<sup>25</sup> *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 178-79.

<sup>26</sup> For further discussion of these matters, see Comments submitted to FDA by Center for Food Safety, including Appendix 2 (Sept. 19, 2010), available at <http://stopgefish.files.wordpress.com/2010/09/cfs-cfs-appendix1-aquadvantage-risk-assessment.pdf>.

<sup>27</sup> VMAC at 28, Table 4, diploid and triploid GE salmon combined. Note that the salmon tested by AquaBounty for the safety study were all from the 2007 cohort (see VMAC at 27, title of Table 3), which for some unexplained reason had a lower rate of "irregularities" than other year-cohorts.

<sup>28</sup> VMAC at 16. "...the adult fish in the study may not reflect the nature or incidence of abnormalities of the initial population."

<sup>29</sup> VMAC at 26. Note, however, that FDA admits that the culling procedures employed for broodstock development (AquaBounty) may well differ from those used in "commercial grow-out facilities" (e.g. fish farm operations that purchase GE salmon eggs from AquaBounty). While somewhat more stringent culling might be economically

which is completely unjustified for several reasons. First, FDA cannot condition its safety analysis of AquaAdvantage salmon on completely undocumented assumptions about the commercial operating procedures that AquaBounty or other companies might employ; these procedures would obviously be influenced by profit, logistical, and numerous other extra-scientific considerations. FDA's job is to ensure that any GE salmon AquaBounty or other firms could legally market are reasonably healthy and do not pose health risks to consumers. Second, AquaBounty's failure to document the culling procedures it used in the multi-stage process of selecting animals for safety testing (in the knowledge that FDA would wish to review this information) suggests an intent to deceive by excluding abnormal animals from testing.<sup>30</sup> Finally, commercial considerations would obviously push companies raising AquaBounty's GE salmon to maximize sales by culling as few salmon as possible, which would mean lax culling criteria that leave moderately sick and/or deformed animals, and remove only the most severely sick or deformed specimens. The potentially much higher rate of abnormalities among GE growth hormone salmon would likely lead to much greater consumer exposure to such animals than is presently the case with non-GE salmon. If FDA has not required testing of such GE salmon, they cannot be presumed safe.

Small sample size is the second key deficiency undermining the legitimacy of most of AquaBounty's data. AquaBounty included only 24 or 12 GE salmon in various safety tests. These GE groups comprised 12 or 6 GE diploid and 12 or 6 GE triploid salmon, respectively. Even if these groups have been selected in a blind, unbiased way (which as we have seen above is highly unlikely), they are far too small to deliver statistically significant results with any sensitivity. In effect, results that may indicate real problems with GE salmon could be interpreted and written off as a chance statistical fluke with small samples, whereas larger samples would not permit such chicanery. AquaBounty attempted to dismiss GE salmon's higher incidence of jaw erosions with reference to overly small sample size.<sup>31</sup>

2. *Inadequate data that are available point to increased susceptibility to infection and disease in AquaBounty salmon*

Even with extensive and likely biased culling of abnormal GE salmon, the uncharacteristically normal test population that remained exhibited a number of troubling differences vis-à-vis unmodified salmon. For one, GE diploid salmon exhibited a 33% incidence (4 of 12) of jaw erosion,<sup>32</sup> a condition in which the soft tissue between the jaw bones disintegrates, exposing the bone, versus none of the three control groups of salmon. Salmon with

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advantageous for broodstock development (though in years with high rates of abnormalities, like 2005, this might not be true), lax culling would prove more profitable for commercial operations that grow out and sell GE salmon.

<sup>30</sup> Appendix 2 to Comments submitted to FDA by the Center for Food Safety (Sept. 19, 2010), *available at* <http://stopgefish.files.wordpress.com/2010/09/cfs-appendix-2-aquaadvantage-risk-assessment.pdf>.

<sup>31</sup> *Ibid*, see example of jaw erosions.

<sup>32</sup> VMAC at 37, Table 6; VMAC at 40.

this deformity may well be more vulnerable to infection, a serious disadvantage in stressful, disease-conducive fish farm operations. Another clear sign of increased susceptibility to disease is the increased prevalence of focal inflammation in a number of GE salmon tissues, including the abdominal mesentery, cranium and trunk (posterior) kidney.<sup>33</sup> Inflammation is a sign of immune system activity, and hence potentially infection. Other immune system parameters that differed between GE salmon and control groups include two classes of infection-fighting white blood cells, lymphocytes and neutrophils, with the former higher and the latter lower in diploid GE salmon versus controls.<sup>34</sup> FDA offers nothing but undocumented speculation as to the reasons for such effects, yet fails to demand studies and data to clarify the situation, noting merely that: “Comprehensive disease challenge studies have not been conducted on these fish.”<sup>35</sup> There is no excuse for not requiring submission of comprehensive disease susceptibility studies, particularly give the signs of increased disease in GE salmon noted above. As detailed below, increased disease incidence leads to increased use of antibiotics, meaning potentially higher levels of antibiotic residues in GE salmon tissue, and increased risk for evolution of resistant bacteria.

The fact is: AquaBounty has not yet provided the quantity or quality of data necessary for FDA or anyone to seriously evaluate the safety of GE salmon. Until that happens, consumers have ample reason beyond mere “curiosity” to demand labeling so that they may differentiate fish that they *know* are safe from fish that *no one* is sure are safe. FDA’s role in the regulation of food labeling requires risk *assessment* before risk *management*. Until FDA performs the former, the latter is best left to the consumers themselves.<sup>36</sup>

## 2. *Many religious consumers need GE foods to be labeled to avoid consuming them*

Members of several established religions in the United States also want mandatory labeling of genetically engineered foods because their deepest held beliefs prohibit them from consuming such foods. In order to avoid genetically engineered foods, these groups need to be able to identify with certainty which foods are produced with genetic engineering. Many religious groups have specific policies adopted at the highest levels of their faith that call for labeling of genetically engineered food products. These groups include the United Methodist Church, the Presbyterian Church USA, and the World Council of Churches which includes more than 350 denominations around the world. The consumption of GE foods is also offensive to

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<sup>33</sup> VMAC at 38, Table 7; VMAC at 39.

<sup>34</sup> VMAC at 35 (Figures 4 and 5); and 146-147.

<sup>35</sup> VMAC at 41.

<sup>36</sup> See Jeffrey K. Francer, “Frankenstein Foods or Flavor Savors? Regulating Agriculture Biotechnology in the United States and European Union,” 7 Va. J. Soc. Pol’y & L. 257, 310-13 (2000) (discussing the relationship between consumer trust of regulators and the effectiveness of labeling requirements).

many Native American cultures, as it represents an usurpation of the life-giving role that belongs to the creator (whose proper name varies by tribe). Consuming a GE food is particularly offensive when the food in question has central cultural significance, as the salmon does in some tribes.<sup>37</sup>

Moreover, despite the gradual acceptance of GE foods by the leaders of some religious institutions, many consumers of those religions still believe their faiths prohibit consuming GE foods. According to a poll conducted by the Pew Initiative on Food and Biotechnology, 57% of Protestants, 52% of Catholics, 46% of Muslims and 35% of Jews in America believe their faiths prohibit them from consuming GE foods.<sup>38</sup> The governmental interest in providing these consumers with the information that would enable them to eat in accordance with their beliefs provides FDA with the authority to require labeling of GE salmon.<sup>39</sup>

FDA's failure to recognize the validity of these consumers' convictions seriously compromises consumer choice and our government's religious and cultural tolerance, both of which lie at the heart of our thriving pluralistic society. To earn these consumers' dollars, AquaBounty should have to convince them that GE salmon is desirable, not trick them by concealing which salmon is the product of genetic engineering. FDA and AquaBounty cannot create a market for GE salmon by excluding information from the label so that consumers wishing to avoid GE foods unwittingly buy it anyway, in some cases in violation of their deeply held religious beliefs. This kind of short-cut amounts to outright deception and compromises these consumers' ability to choose for themselves whether GE salmon is consistent with *their* criteria for a desirable product, including their religious convictions.

**e. Failure to label GE salmon deceives the many consumers who base their purchases on the environmental impacts of their food**

In recent years, increased awareness about the environmental impacts of food production has transformed the way consumers identify and differentiate foods. As discussed *supra*, many consumers now base their purchasing decisions not just on the physical characteristics of a food, but also on what they understand about the environmental impacts of the food. GE salmon poses

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<sup>37</sup> See, e.g., Marc Dadigan, "How a Native American Tribe Got Their Salmon Back, by Way of New Zealand," CHRISTIAN SCIENCE MONITOR (May 25, 2010) (discussing Winnemem Wintu tribe of Northern California), available at <http://www.csmonitor.com/World/Global-News/2010/0525/How-a-native-American-tribe-got-their-salmon-back-by-way-of-New-Zealand> (last visited Nov. 15, 2010); Caleen Sisk-Franco, "To Restore Salmon, Follow the Creator's Plan, Not Frankenfish," CALIFORNIA PROGRESS REPORT (Sept. 27, 2010), available at <http://www.californiaprogressreport.com/site/?q=node/8204> (last visited Nov. 15, 2010).

<sup>38</sup> AGBIOWORLD, "Views on Genetically Modified Food and Animals Differ By Religious Beliefs," (July 26, 2001), available at <http://www.agbioworld.org/biotech-info/religion/pew.html> (last visited Nov. 15, 2010).

<sup>39</sup> Moreover, the holding in *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000), does not preclude FDA from considering some consumers' desire to avoid GE foods for religious or cultural reasons, because the court in that case only addressed the question of whether FDA was *required* to accommodate those consumers' beliefs. *Id.* at 179-180.

immeasurable risks to the environment above and beyond those posed by conventional farmed salmon, including multiple threats to wild salmon stocks, disrupting delicate ecosystems, and inundating our waters with industrial chemicals. These impacts fall outside the realm of what well-informed consumers typically expect from conventional salmon. Accordingly, failure to provide consumers with the means to differentiate GE salmon from conventional salmon is misleading, providing FDA additional authority to mandate labeling of GE salmon.

1. *The inevitable escape of GE salmon into the wild threatens the already endangered wild salmon*

As years of studies and observations of farmed salmon have demonstrated, millions of farmed salmon inevitably escape from their open water net pens into the wild, despite the aquaculture industry's best efforts.<sup>40</sup> Even in land-based facilities, salmon have the ability to escape, at which point they will be virtually impossible to recover. Moreover, the federal government's own biologists have advised FDA that AquaBounty's proposed containment measures are inadequate, and that the risk of escape is "huge."<sup>41</sup> Assessing the environmental impact of GE salmon production is therefore not a question of *if* they will escape, but rather *how many* will escape.

Experience has demonstrated conclusively that the influx of additional salmon into the wild—genetically modified or not—creates a number of ripple effects that strain the ecosystem and deplete the natural resources that wild salmon depend on for survival.<sup>42</sup> In fact, wild salmon were placed on the Endangered Species List in large part due to genetic and fitness impairments caused by inbreeding with escaped farmed salmon.<sup>43</sup> However, because GE salmon are engineered to grow twice as fast as conventional salmon, their inevitable introduction into the wild will overwhelm the natural habitat of wild salmon even more. GE salmon will also consume more oxygen and will out-compete wild salmon for food.<sup>44</sup> The production and eventual escape of GE salmon into the wild will deal the final blow that pushes this endangered

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<sup>40</sup> See National Marine Fisheries Service, Biological Opinion: Proposed Modification of Existing ACOE Permits Authorizing the Installation and Maintenance of Aquaculture Fish Pens Within the State of Maine (Nov. 19, 2003), available at <http://stopgefish.files.wordpress.com/2010/10/corp-bo-full-file.pdf>.

Letter to FDA from Environmental Coalition and sources cited therein (Nov. 8, 2010), available at <http://stopgefish.files.wordpress.com/2010/11/environmental-group-letter-to-fda-ge-salmon-final.pdf>.

<sup>41</sup> Email correspondence from Deborah Burger, Manager, Chattahoochee Forest National Fish Hatchery, U.S. Fish and Wildlife Service (FOIA response), available at <http://www.foodandwaterwatch.org/press/press-releases/troubling-emails-reveal-federal-scientists-fear-fda-approval-of-genetically-engineered-salmon/>.

<sup>42</sup> See, e.g., Devlin, R.H., M. D'Andrade, M. Uh & C.A. Biagi, "Population effects of growth hormone transgenic coho salmon depend on food availability and genotype by environment interactions," *Proceedings of the National Academy of Sciences* 101:9303-9308 (2004).

<sup>43</sup> See, e.g., McGinnity, P., P. Prodöhl, A. Ferguson, R. Hynes, N. O'Maoláidigh, N. Baker, D. Cotter, B. O'Hea, D. Cooke, G. Rogan, J. Taggart & T. Cross, "Fitness reduction and potential extinction of wild populations of Atlantic salmon, *Salmo salar*, as a result of interactions with escaped farm salmon," *Proceedings of the Royal Society B: Biological Sciences*, 270(1532): 2443–2450 (2003).

<sup>44</sup> VMAC at 43.

species to extinction. This conclusion has been confirmed by two biological opinions issued by the National Marine Fisheries Service and the Fish and Wildlife Service.<sup>45</sup>

Escaped GE salmon pose an additional threat to wild salmon: genetic pollution resulting from what scientists call the “Trojan gene” effect. Research published in the Proceedings of the National Academy of Sciences notes that a release of just sixty GE fish into a wild population of 60,000 would lead to the extinction of the wild population in less than 40 fish generations. If approved, GE fish will likely be among the millions of salmon that currently escape into the wild every year. This could be the last blow to wild salmon stocks.

According to information provided to FDA by AquaBounty, the company will raise the GE eggs in a facility on Prince Edward Island in Canada, and then it will ship those fish to be raised in a land-based facility in Panama where the fish will be grown out and the processed before being shipped for commercial sale. However, these GE fish are intended for use on a global scale,<sup>46</sup> and a reliable containment regime following commercialization is just not conceivable. For example, according to a 2001 report, the Environmental Risk Management Authority in New Zealand identified flaws in the safety system of the GE salmon tanks of the private company King Salmon where GE salmon eggs could have come into contact with sperm before escaping into the environment. This example highlights the difficulties in designing containment measures that are 100% effective.

AquaBounty has provided FDA with no reason to believe that its containment of GE salmon will be any more effective than these past failed attempts. By AquaBounty’s own admission, its salmon eggs will be only 95% sterile. Given the scale on which the company plans to produce GE salmon, even a 5% fertility rate will translate into enough escaped fertile eggs that the escape and proliferation of GE salmon into the wild is inevitable.

## *2. Escaped GE salmon pose additional threats to the environment*

In addition to the threat of these GE salmon displacing native salmon populations, GE fish farming will facilitate the propagation of parasites and deadly fish diseases, as well as the escape of high concentrations of harmful wastes, industrial drugs, and chemicals into open waters. Also, because carnivorous GE salmon will consume up to five times as much as conventional salmon, commercial production of GE salmon will lead to over-fishing of vast

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<sup>45</sup> See National Marine Fisheries Service, Biological Opinion: Proposed modification of ACOE permits authorizing the installation and maintenance of aquaculture fish pens within the state of Maine (Nov. 19, 2003), *available at* <http://stopgefish.files.wordpress.com/2010/10/corp-bo-full-file.pdf>; Fish and Wildlife Service, Biological Opinion: U.S. EPA’s proposed approval of State of Maine’s NPDES permit program (Jan. 12, 2001), *available at* <http://stopgefish.files.wordpress.com/2010/10/epa-bo.pdf>.

<sup>46</sup> AquaBounty Chairman’s Statement, Sept. 25, 2009, *available at* <http://www.aquabounty.com/documents/financial/2009-InterimResults.pdf> (anticipating global-scale production of GE salmon).

quantities of non-commercial fish. If and when GE salmon escape, they will effectively act like an invasive species, in many cases putting additional stress on ecosystems already infested with Asian carp and Northern snakehead.

Despite AquaBounty's insistence to FDA that it only plans to produce a few hundred thousand GE salmon, the company has made clear to its investors that it ultimately intends to produce GE salmon on a commercial scale.<sup>47</sup> There are currently over 4,000 fisheries in the United States. If GE salmon are approved for production on a commercial scale, neither the company nor any government agency will have the resources to contain GE fish or the environmental impacts of their escape. For modern consumers, these impacts are as much a part of the identity of the fish as the taste and texture. Failure to disclose them will therefore mislead consumers.

3. *NEPA provides FDA with supplemental statutory authority to consider these environmental impacts when deciding whether to require labeling of GE salmon*

At least one federal court decision has held that FDA has not just the authority, but also a statutory mandate to base substantive decisions like mandatory labeling on environmental concerns. In *Environmental Defense Fund v. Mathews*,<sup>48</sup> the plaintiffs challenged FDA's regulations implementing NEPA, arguing that FDA improperly limited the scope of its obligations under the Act. FDA had amended its implementing regulations to state that NEPA did not provide the Agency with any additional authority to act apart from authority otherwise granted in authorizing statutes, such as FFDCA. The court disagreed, stating that "This limitation of the agency's discretion to act in accordance with environmental considerations directly contravenes the mandate of NEPA . . . ."<sup>49</sup> The court then elaborated:

"The FDCA does not state that the listed considerations are the only ones which the Commissioner may take into account in reaching a decision. [ . . . ] It merely lists criteria which the Commissioner must consider in reaching his decision. In the absence of a clear statutory provision excluding consideration of environmental factors, and in light of NEPA's broad mandate that all environmental considerations be taken into account, we find that NEPA provides FDA with supplementary authority to base its substantive decisions on all environmental considerations including those not expressly identified in the FDCA and FDA's other statutes."<sup>50</sup>

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<sup>47</sup> AquaBounty Chairman's Statement, Sept. 25, 2009, available at <http://www.aquabounty.com/documents/financial/2009-InterimResults.pdf>.

<sup>48</sup> 410 F. Supp. 336 (D.D.C. 1976).

<sup>49</sup> *Id.* at 338.

<sup>50</sup> *Id.*



Thus, NEPA is not merely a procedural hurdle for FDA; it is also a mandate to make substantive decisions based on environmental factors, even when such considerations are not mandated by FDA's authorizing statute.

**f. Requiring GE foods to be labeled is not misleading to consumers**

Contrary to claims previously made by proponents of GE foods, mandatory labeling of GE salmon will not mislead consumers. Many in the industry have claimed that including truthful information on the package about how GE salmon is produced will invariably cause consumers to irrationally attribute health and safety risks to their product that do not exist. This argument must fail for several independent reasons.

First, requiring that GE salmon be labeled as the product of genetic engineering does not necessarily suggest additional risks because there are myriad value-neutral ways to disclose that salmon is the product of genetic engineering. For example, disclosing the true fact that GE salmon is the result of inserting transgenes to activate growth hormone year-round does not mislead consumers. Indeed, FDA itself has previously found that such labeling disclosures are not misleading;<sup>51</sup> there is no reason that they should somehow become misleading if they are mandatory rather than voluntary.

Mandatory labeling of GE salmon would be misleading if the label itself led a reasonable person to believe something about GE salmon that was not true. A required label for GE salmon would do just the opposite: it would apprise consumers of a fact that *is* true. If consumers draw inaccurate inferences about GE salmon based on that label, it is the result of preconceived notions about genetic engineering that have nothing to do with the nature of the label.<sup>52</sup> The notion that the inclusion on the label of true facts that consumers find important is misleading because some will respond to them irrationally rests on the offensive assumption that the public cannot be trusted to make rational decisions when presented with true and complete information. Therefore, this justification for excluding GE status from the label must be rejected.

Second, a required disclosure is not misleading simply because members of the public form an opinion about the product that is different from FDA's. Although FDA is the primary agency charged with ensuring the safety of America's food, it should hardly be a consumer's only line of defense. Although the FDA conducts its own independent pre-market review of food products and forms a data-based, scientific opinion about them, consumers also rely on

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<sup>51</sup> See Center for Food Safety and Applied Nutrition, FDA, "Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or have Not Been Developed Using Bioengineering," (Jan. 2001), *available at* <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/foodlabelingnutrition/ucm059098.htm>.

<sup>52</sup> Cf. *Int'l Dairy Foods Ass'n*, 622 F.3d at 638-39, 641 (finding that consumer comment demonstrating her confusion about rBST did not demonstrate that the label was to blame for her confusion).

additional sources of information to determine for themselves whether a given food meets their personal standards of safety and desirability. FDA is not empowered to mandate one scientific opinion for all, nor should it perform any agency action that would have a similar effect. Many consumers have their own criteria for purchasing food and will seek out the legitimate opinions of other scientists who may disagree with FDA's ultimate conclusions when deciding whether GE salmon is a food they are willing to purchase. One of the issues that consumers are especially concerned about is the presence of additional hormones in foods. This fish is designed to express additional growth hormone throughout its body. To deprive consumers of the means to purchase based on a second scientific opinion would amount to a paternalistic fiat by FDA: "GE salmon is safe – case closed." Our government, our scientific community, and our markets cannot function on the basis of such one-sided information.

Finally, any unfavorable public perceptions about GE salmon that may persist are the responsibility of the aquaculture industry to change, not FDA's. A recurring theme in our nation's tradition of free speech has been that "people will perceive their own best interests if only they are well enough informed, and . . . the best means to that end is to open the channels of communication rather than to close them."<sup>53</sup> As former Justice Stevens once wrote, "*The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products.*"<sup>54</sup> Moreover, "honesty and fair play are prominent arrows in America's quiver of commercial and personal ideals."<sup>55</sup> If the public forms opinions about GE salmon that AquaBounty feels are inaccurate or even irrational, then the proper response is for AquaBounty to make its case to the public through informative marketing like every other merchant. It is not FDA's job to boost AquaBounty's sales by consciously excluding information that matters to consumers from their main source of product information: the label.

**g. The historical role of federal regulation of deception, and of food labeling in particular, provides additional support for FDA's authority to require label disclosures for information that falls outside the common understanding of the food**

As discussed in Part II.a *supra*, the stated purpose of 21 U.S.C. § 321(n) is to prevent consumer deception that occurs as the result of misleading food labels. However, FDA's rulemaking on irradiated foods, discussed *supra*, was not the only time regulators looked to consumers' subjective concerns to determine what was misleading. Beginning as early as the start of the last century, and in a wide variety of contexts, the federal government and the courts

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<sup>53</sup> Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976).

<sup>54</sup> Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503 (1996).

<sup>55</sup> Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 941 (3d Cir. 1993).

have demonstrated that the relevant focus for laws aimed at preventing deception is consumers' subjective expectations, not the government's objective assessment of the facts. The examples below serve to illustrate why FDA's current, narrow interpretation of "materiality" fails to effectively target the many forms deception takes today.

In *U.S. v. Ninety-Five Barrels of More-Or-Less Alleged Apple Cider Vinegar*,<sup>56</sup> the federal government brought an enforcement action for deceptive labeling against a producer of apple cider vinegar who made his product from re-hydrated apples, not whole pressed apples as was the custom at the time. The label read, in pertinent part: "Apple Cider Vinegar Made from Selected Apples."<sup>57</sup> The trial court sampled both the defendant's apple cider vinegar and a representative sample of conventional apple cider vinegar, and found no significant difference between the two.<sup>58</sup> Nonetheless, the United States Supreme Court ruled in favor of the government. It held that the common understanding of apple cider vinegar was that it was made from whole pressed apples, and as such the label was misleading because it failed to reveal that the defendant's vinegar was not identical to the common understanding of "apple cider vinegar."<sup>59</sup> Thus, even though the defendant's product and conventional apple cider vinegar were virtually indistinguishable to the senses, the consumer's expectation that apple cider vinegar would be made from whole apples rather than re-hydrated apples had decisive implications for the proper identity of the defendant's product, and therefore rendered the failure to disclose this difference on the label misleading.

The Seventh Circuit adopted similar reasoning more recently in *Abbott Laboratories v. Mead Johnson & Co.*<sup>60</sup> In that case, the defendant had created an electrolyte solution derived from rice and was advertising it by emphasizing that its product, and not its competitor's product, was made from rice. (Then-recent medical studies had demonstrated the superior health benefits of electrolyte solutions made from rice carbohydrates as opposed to those made from glucose.) However, as the court noted,

"... Ricelyte contains rice syrup solids, not rice or rice carbohydrates. Mead appears to have had some difficulty grasping this distinction, as most vividly illustrated by its comparison of Ricelyte to chicken soup:

[Just as Ricelyte does not contain whole rice,] chicken soup does not contain whole chickens. No one can dispute that the feathers are important to the chicken, but no consumer is mislead [sic], and no competitor has the temerity to argue that Campbell's should rename its soup because it only uses part of the chicken.

This analogy misfires. Chicken soup is made from chicken meat and chicken fat, the

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<sup>56</sup> 265 U.S. 438 (1924).

<sup>57</sup> *Id.* at 439.

<sup>58</sup> Chemical testing confirmed the trial judge's initial assessment. *Id.* at 443-44.

<sup>59</sup> *Id.* at 444.

<sup>60</sup> 971 F.2d 6 (7th Cir. 1992).

business end of the chicken. *Most consumers*, we presume, *expect* that Campbell will not make its chicken soup with feathers. Mead, in contrast to Campbell, takes the business end of rice (*i.e.*, rice carbohydrates) and chemically breaks it down into rice syrup solids, which are not a “part” of rice or rice carbohydrates, but rather a completely different carbohydrate, both structurally and functionally. *The expectations of consumers* receiving the message that Ricelyte contains rice carbohydrates *are not fulfilled.*”<sup>61</sup>

Significantly, the *Mead* court based its finding that the advertising was misleading not just on the fact that the advertising made factual assertions that were untrue (*e.g.*, that Ricelyte contained rice carbohydrates), but also based on the fact that the product differed from what consumers expected based on the advertising.

This country’s history of regulating consumer deception in other, non-food contexts provides additional support for using consumers’ subjective expectations as the barometer for detecting consumer deception. The following cases are illustrative:

- *Murray Space Shoe Corp. v. F.T.C.*, 304 F.2d 270, 272 (2d Cir. 1962): “In deciding whether petitioner’s advertising was false and misleading we are not to look to technical interpretation of each phrase, but must look *to the overall impression* these circulars are likely to make *on the buying public.*”
- *Association of National Advertisers, Inc. v. Lungren*, 44 F.3d 726, 734-35 (9th Cir. 1994): California’s statute setting standards for the use of ecological claims on labels and in advertising “shields ecologically-oriented firms from unfair price competition. Rivals will no longer be able to negate such firms’ green marketing edge by representing as ‘recycled’ products consisting of dross recaptured from the factory floor rather than—in keeping with the more *common understanding of the term*—a significant (*i.e.*, ten percent or more) portion of costlier reprocessed post-consumer waste.”
- *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 957-58 (3d Cir. 1993): When determining whether a motor oil company’s advertisements were misleading, the court rejected the district court’s use of industry standards to evaluate the company’s claims. “Here, the audience is the general public, not a specific industry. ‘*[T]echnical industry standards are often irrelevant to consumer expectations.*’” (Citing *W.L. Gore & Assoc. v. Totes, Inc.*, 788 F. Supp. 800, 807 (D. Del.1992).)
- *Commodity Futures Trading Commission v. R.J. Fitzgerald & Co., Inc.*, 310 F.3d 1321, 1328 (11th Cir. 2002): “Whether a misrepresentation has been made depends on the ‘overall message’ and the ‘*common understanding of the information conveyed.*’”

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<sup>61</sup> *Id.* at 14 (emphasis added).

As noted *supra*,<sup>62</sup> the purpose of the “materiality” inquiry is to mandate on-the-label disclosures of information the absence of which is likely to mislead consumers. Accordingly, the common understanding of foods—not FDA’s understanding—is the proper focus for determining material differences. Using genetic engineering as one example of the many novel food technologies that are either currently in use or on the horizon, this Part has demonstrated two crucial findings: (1) that many, if not most consumers, care enough about the use of genetic engineering to make their food purchasing decisions on that basis alone; and (2) that, in the absence of labeling, consumers are likely to assume that a product is *not* genetically engineered. Consumers are deceived when the use of food technologies like genetic engineering goes unlabeled, whether FDA chooses to recognize this difference as material or not. Therefore, in order to effectively carry out its mandate to prevent deceptive labeling, FDA must exercise its authority to expand its interpretation of “material” differences to include the use of new food technologies that fall outside the common understanding of the food.

### **III. Even if FDA maintains its current interpretation of “material,” GE salmon falls outside the category of foods for which genetic engineering is not “normally” a “material” fact**

For the reasons just discussed, FDA’s current labeling regime is not only acutely ill-suited to preventing deception of modern consumers, who are increasingly conscious of and responsive to extra-sensory concerns, but also easy to fix by modernizing its definition of “material.” Yet, even FDA’s current reading of “material” gives it the authority to require labeling of GE salmon. CFS recognizes that FDA’s current policy regarding GE foods—that, *as a class*, they do not *normally* present any significant differences that would warrant mandatory labeling—has been upheld by the courts.<sup>63</sup> However, both *Alliance for Bio-Integrity v. Shalala* and FDA’s 1992 Statement of Policy leave FDA the authority to require labeling for individual GE foods that are significantly different from their conventional counterparts.<sup>64</sup> As this Part will demonstrate, GE Salmon is significantly different from conventional salmon, not due to the fact that its genetically engineered, but due to concrete physiological differences. Consequently, requiring labeling of GE salmon is well within the FDA’s authority under FFDCA.

#### **a. GE salmon differs materially from both the common and scientific understandings of what Atlantic salmon is**

Labeling requirements are effective at preventing consumer deception when they enable the consumer to correctly identify what the food is.<sup>65</sup> For this reason, FFDCA requires that food

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<sup>62</sup> Part II.a.

<sup>63</sup> *Alliance for Bio-Integrity*, 116 F. Supp. 2d 166 (D.D.C. 2000).

<sup>64</sup> *See, e.g., Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179, n. 8 (“ . . . should a material consequence exist for a particular rDNA-derived food, the FDA has and will require special labeling.”)

<sup>65</sup> *See, e.g., Ninety-Five Barrels*, 265 U.S. at 443 (“[The FFDCA] was enacted to enable purchasers to buy food for what it really is.”).

labels include a name that accurately describes the basic nature of the food.<sup>66</sup> To achieve this purpose, the words on the label identifying the food must match the consumer’s understanding of what the food is.<sup>67</sup> Otherwise, the consumer may be misled about what it is she is buying even if what appears on the label is technically factually true information. Labels are therefore most effective when they identify the product based on the common or usual understanding of what the food is.<sup>68</sup>

GE salmon falls outside the common or usual understanding of Atlantic salmon because that understanding of Atlantic salmon does not include genetic material from non-salmon fish. As noted above, AquaBounty’s AquAdvantage® salmon is the first genetically engineered animal for human consumption. GE salmon contains not only genes from the unrelated Chinook salmon (*Oncorhynchus tshawytscha*), but also DNA from an eelpout (*Zoares americanus*).<sup>69</sup> Ocean eelpout is not only a different genus and species from Atlantic salmon, it is not even in the Salmonidae family of fishes. Although the typical consumer may not readily understand all of these distinctions and classifications, public opinion polls demonstrate that consumers understand enough about genetic engineering that they would not expect Atlantic salmon to contain genetic material from completely unrelated fish.<sup>70</sup>

However, even if FDA rejects this “common understanding” approach, there are several scientific reasons for labeling AquaBounty’s GE salmon based on material differences vis-à-vis Atlantic salmon.

**b. There are important compositional and nutritional differences between GE salmon and non-GE farmed Atlantic salmon**

*1. GE salmon contains fewer healthy fatty acids than do other farmed salmon.*

FDA claims that the omega-3 / omega-6 ratios in its GE salmon are “similar” to the ratios found in scientific literature for farmed Atlantic salmon.<sup>71</sup> In fact, the ratio for farmed Atlantic salmon is 4.1, nearly than 15% higher than the 3.6 recorded for the AquAdvantage® salmon.<sup>72</sup>

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<sup>66</sup> 21 U.S.C § 343(i) (requiring that a food label must bear the common or usual name of the food); 21 C.F.R. § 102.5(a) (“The common or usual name of a food . . . shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food . . .”).

<sup>67</sup> *Cf. Ninety-Five Barrels*, 265 U.S. at 444.

<sup>68</sup> *Id.*

<sup>69</sup> Veterinary Medicine Advisory Committee, Briefing Packet – AquAdvantage Salmon, at 9, *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf> (last visited Nov. 17, 2010) (hereinafter “VMAC”).

<sup>70</sup> See public opinion polls, *supra* note 13.

<sup>71</sup> VMAC, at 95.

<sup>72</sup> *Id.*

Many consumers are interested in eating salmon for the fatty acids that it usually contains. Moreover, the levels of healthy fatty acids in salmon affect the flavor of the fish, a difference which many consumers may notice. Accordingly, this compositional and nutritional difference should be considered significant, and therefore “material,” under FDA’s current interpretation of section 201(n) of FFDCA.

2. *GE salmon contains levels of healthy vitamins and minerals inferior to the levels present in other farmed salmon.*

The FDA study provided to the Veterinary Medicine Advisory Committee (VMAC) identified six chemicals (folic acid, niacin, Vitamin B6, magnesium, phosphorus, and zinc) for which the levels present in the AquAdvantage® salmon differed from non-GE salmon by more than 10%. The maximum level for Vitamin B6 was more than 20% greater than the upper range found in other wild and farmed Atlantic salmon.<sup>73</sup> This compositional and nutritional difference, combined with the other compositional differences mentioned, is sufficiently “material” to warrant mandatory labeling of GE salmon.

**c. The scientific evidence currently available indicates that eating GE salmon presents myriad risks to human health—both known and unknown—that neither FDA nor the aquaculture industry yet fully understands**

It is well established that FDA has the authority to require labeling for foods that impart additional health risks because health risks constitute a “material” difference.<sup>74</sup> The question of whether any additional risks to consumer safety exist at all is a separate question from whether those additional risks, in FDA’s judgment, are nonetheless minimal enough to allow the product to reach the market. The latter question is relevant to approving a food product as safe; the former is relevant to whether an approved product should nonetheless be labeled.<sup>75</sup>

1. *The health risks resulting from the routine and heavy use of antibiotics on farmed salmon will be exacerbated by increased use on GE salmon.*

Farmed fish, including farmed salmon, are already pumped with more antibiotics than any other livestock by weight. This practice already presents myriad risks to human health—some documented, many still being studied. For example, the antibiotics in fish feed accumulate in the fish’s tissue, rather than being flushed out of the salmon’s system as would happen with smaller, normal doses. Consequently, the antibiotics are often still present in the salmon tissue at

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<sup>73</sup> *Id.* at 79, 87-88.

<sup>74</sup> *See e.g.*, 49 Fed. Reg. 13679 (pertaining to FDA requirement in 21 C.F.R. § 101.17(d)(1) that a special warning statement appear on the label of protein products intended for use in weight reduction due to health risks associated with very low calorie diets).

<sup>75</sup> *See id.*

the point of purchase. Human consumption of these residual antibiotics can have a range of side-effects—both immediate and long-term—depending on the type and amount of antibiotics present. Allergic reactions or poisoning due to undetected toxicity are among the known side-effects.<sup>76</sup> Additionally, ingestion of these residual antibiotics can eventually trigger evolution of bacteria resistant to antibiotics used to treat human illness.<sup>77</sup>

Antibiotic resistance is a critical public health issue. Even FDA realizes the potential severity of the antibiotic-resistance epidemic and its connection to animal agriculture and fish farms. To address this growing phenomenon, FDA issued a Draft Guidance<sup>78</sup> this summer promoting a phase-out of certain antibiotics in animal agriculture and requiring veterinary intervention for the administration of antibiotics.

The significant non-therapeutic use of antibiotics in food animal production is creating an environment in which bacteria, exposed to antibiotics at low doses for prolonged periods, are developing antibiotic resistance, a dangerous trait enabling bacteria to survive and grow instead of being inhibited or destroyed by therapeutic doses of a drug. This resistance reduces the effectiveness of important antimicrobials in human medicine.<sup>79</sup> Scientific understanding of antibiotic resistance is growing. Researchers believe these organisms acquire resistance to antibiotics while in an antibiotic-treated animal; the resistant strain is then passed to humans through food or through direct contact with animals or animal waste. In addition to this direct transfer of antibiotic resistant organisms, some research indicates that the use of antibiotics in food animals may reduce the effectiveness of related antibiotics when used to treat humans.<sup>80</sup> Growing evidence reveals the impact of drug resistance on human health.

The human health risks attendant to farmed fish are even higher for GE salmon. By AquaBounty's own admission,<sup>81</sup> GE salmon will be weaker and more susceptible to disease than conventional salmon. This fact will require salmon farms to increase their use of antibiotics on the GE salmon they raise in order to prevent the spread of disease within their tanks or pens.

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<sup>76</sup> See, e.g., \_\_\_\_\_, Food and Agriculture Organization of the United Nations: Fish Utilization and Marketing Service, "Responsible use of antibiotics in aquaculture," Rome (2005).

<sup>77</sup> *Id.*

<sup>78</sup> Food and Drug Administration, CVM Draft Guidance, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals," (June 28, 2010), available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>.

<sup>79</sup> Report on Infectious Diseases, WORLD HEALTH ORGANIZATION, at Chapter 3 (2000) (2000 WHO Report on Infectious Diseases), available at <http://www.who.int/infectious-disease-report/2000/index.html>.

<sup>80</sup> The Agricultural Use of Antibiotics and Its Implications for Human Health, GOVERNMENT ACCOUNTING OFFICE (April 1999)(1999 GAO Report on Antibiotics).

<sup>81</sup> See, e.g., VMAC p. 42-43, 46, 47; see also VMAC Hearing Transcript, Sept. 21, 2010, (p. 341) (Dr. Allen Mathew: "[T]here appears [sic] to be some health issues and I do not know whether it is possible then to look at longer-term health effects or if approval is granted, should the approval include slaughter at the age or size that is relevant to the animal safety data; in other words, not growing the salmon out beyond a certain size or age to ensure that the animal health is not impacted down the road.")



Consequently, the health risks posed by the routine and heavy use of antibiotics on farmed salmon will be even greater for GE salmon.

2. *GE salmon's higher tolerance to environmental toxins presents a greater risk that those toxins will be ingested by consumers.*

Studies of transgenic fish suggest that they have a higher tolerance to toxins that occur in the environment.<sup>82</sup> This means that concentrations of these toxins in the GE salmon tissue may reach higher levels before the salmon succumbs to death or disease. These toxins would often still be present in the GE salmon tissue by the time the salmon reaches the market. Consequently, food from GE salmon is more likely to contain higher levels of toxins from the environment in which the salmon is raised than food made from conventional farmed salmon. The presence of higher levels of toxins in GE salmon at the point of sale constitutes a material difference from conventional salmon.

3. *Currently available data suggests that the AquAdvantage® salmon may be more allergenic than Atlantic salmon*

FDA's current position regarding labeling of food allergens is that, "[i]f a new food contains an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed in the labeling."<sup>83</sup> The FDA study of the GE salmon suggests that it might contain just such an allergen.<sup>84</sup> The study warns ominously:

"One potential indirect hazard that may result from the insertion of the AquAdvantage construct at the  $\alpha$ -locus is a possible increase in the endogenous levels of allergens in ABT salmon due to insertional mutagenesis in a region of the genome that may act as a regulator of the expression of one or more of these proteins. Although the previous study attempted to address this point, its various technical deficiencies make it difficult to determine whether the allergenicity of salmon, or the prevalence of any known endogenous protein that has been implicated in allergic responses (i.e., parvalbumin) have changed, thereby somehow increasing the allergenicity of the fish."<sup>85</sup>

By FDA's own admission, the study conducted to evaluate the allergenicity of GE salmon was botched, making it impossible to come to a conclusion. However, the possibility that insertion of the genetic construct triggered increased levels of endogenous allergens such that the

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<sup>82</sup> See, e.g., CORDIS, *supra* note 22.

<sup>83</sup> Food and Drug Administration, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839 (Jan. 18, 2001).

<sup>84</sup> VMAC at 75-76.

<sup>85</sup> VMAC at 105.

AquaAdvantage salmon is allergenic in a way, or to a degree, that consumers would not expect from salmon is a material difference and militates in favor of mandatory labeling.

4. *The sparse biological data currently available suggests that GE salmon may contain higher levels of the growth hormone IGF-1*

The FDA study suggests that GE salmon may contain higher levels of insulin-like growth factor, or IGF-1, which has been linked to a number of cancers.<sup>86</sup> To date, neither FDA nor AquaBounty has conducted the kind of testing that would be able to conclusively confirm whether GE salmon contains higher levels of IGF-1.<sup>87</sup> The company used a very insensitive test for IGF-1 and failed to find any IGF-1 in the farm controls or the triploid GE salmon (although some was found in the diploid fish). Moreover, the study did not even say how many of the triploid fish were among the 30 GE fish tested. Hormone levels, including IGF-1, can be affected by the environmental conditions in which the fish are raised. None of the tested fish were grown in Panama, where the FDA proposes to have the fish produced. In short, an insensitive test was used with a poor research design to study a fish different from the one that the FDA proposes to approve. If GE salmon does in fact contain higher levels of IGF-1, it would present the kind of additional health risk that would qualify as a “material” difference warranting mandatory labeling.

Rather than require further testing of fish raised in Panama and using better methods to detect IGF-1 prior to approval, FDA, in its assessment of the biological data provided by AquaBounty, instead stated in a conclusory manner:

“The apparent difference in IGF1 in mature diploid ABT salmon compared to sponsor control non-GE salmon was relatively small. No differences were observed in levels of growth hormone in edible tissues at the level of quantitation for the analytical method.”<sup>88</sup>

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<sup>86</sup> *Id.* 68-72; see also Velcheti V, Govindan R. (2006), “Insulin-like growth factor and lung cancer,” *Journal of thoracic oncology: official publication of the International Association for the Study of Lung Cancer* 1 (7): 607–10, available at <http://www.ncbi.nlm.nih.gov/pubmed/17409926>.

<sup>87</sup> The FDA reviewed two tests of IGF-1 levels in AquaBounty salmon; both tests are inadequate for testing IGF-1 levels. One test from 1992 tested extremely small fish, only 2 ounces in size (not the size that people would eat), and the sample size included only 5 GE salmon. The plasma levels of growth hormone in the GE salmon (39.9 ng/ml) was 41% higher than that of their non-GE siblings (28.2 ng/ml) control fish and 95% higher than the control fish, but neither difference was statistically significant, due to the extremely small sample size.

The second study looked at a number of hormones, including growth hormone and IGF-1 in GE salmon (both diploid and triploid), non-engineered counterparts raised at the company’s Canadian facility and in non-salmon from another commercial fish farm. This study used market size fish, used a larger sample size (30 GE salmon, 33 sponsor controls and 10 farmed controls), and looked at hormone levels in the skin and muscle rather than plasma. Unfortunately, however, the sensitivity of the test methods used were inadequate and the detection limit was inappropriately high. We should have seen some growth hormones in these fish that produce growth hormones year round, but the detection limit was so high that no growth hormone was detected in any of the 73 samples. (see Table 15 in VMAC briefing packet).

<sup>88</sup> VMAC at 74.

Without additional certainty about the levels of growth hormones and IGF1, labeling is warranted.

5. *Problems in the morphology of the fish indicate additional health risks not present in non-GE salmon.*

FDA identified several possible problems in the morphology of the AquAdvantage® salmon that could compromise the health of the fish. At least two significant findings from this inadequate study demand additional study before the AquAdvantage® salmon is considered for approval. First, fish with the AquAdvantage® genetic construct showed a higher prevalence of jaw erosion.<sup>89</sup> Second, increased prevalence of focal inflammation of various tissue types had the strongest correlation with the presence of the AquAdvantage® construct.<sup>90</sup> Although the limited data available severely limits what any biologists can determine about the consequences of these findings, this second difference in particular could increase the fish's susceptibility to disease. Rather than requiring AquaBounty to produce more data so that FDA could adequately test for human health risks, FDA instead excused the company by stating:

“There is no practical way ABT could have generated the appropriate data without producing—and destroying—commercial lots of fish. Nonetheless, we believe that incorporating an appropriate surveillance/durability plan will provide sufficient data and information to the Agency to minimize this uncertainty.”<sup>91</sup>

If FDA is truly serious about guarding against human health risks in food, it must require more complete data from AquaBounty before approving GE salmon for the market. Failing that, if FDA wants to implement an effective post-market surveillance program for GE salmon, GE salmon must be labeled in order to properly track and document the human health consequences of consuming the fish.

#### **IV. The First Amendment does not prohibit FDA from mandating labeling of GE foods**

##### **a. *Zauderer v. Office of Disciplinary Counsel*<sup>92</sup> controls mandatory labeling of GE salmon**

Although the First Amendment prohibits the government from requiring an individual to speak about “politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein,”<sup>93</sup> the courts have long held that “an advertiser’s [First

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<sup>89</sup> VMAC at 40.

<sup>90</sup> VMAC at 41.

<sup>91</sup> VMAC at 45.

<sup>92</sup> 471 U.S. 626, 105 S. Ct. 2265 (1985).

<sup>93</sup> *Id.* at 651.

Amendment] rights are adequately protected as long as disclosure requirements are *reasonably related* to the State’s interest in preventing deception of consumers.”<sup>94</sup>

This distinction between commercial speech and other forms of protected speech exists because protection of commercial speech is justified largely by its value to consumers and the benefit to the market from the free flow of factually true information.<sup>95</sup> Accordingly, a merchant’s “constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal.”<sup>96</sup> Moreover, as several circuit courts have held,<sup>97</sup> *Zauderer* controls mandatory labeling of GE salmon regardless of whether FDA finds that failure to differentiate GE and conventional salmon is inherently misleading or potentially misleading.

**b. A requirement that GE salmon be labeled is reasonably related to preventing consumer deception**

Mandatory labeling of GE salmon meets the standard articulated in *Zauderer* because, as discussed *supra*, consumers who wish to avoid GE salmon are likely to be deceived by the absence of a label differentiating it from conventional salmon. A requirement that producers of GE salmon label their product at the point of sale is reasonably related to consumer deception because disclosure that the fish is genetically engineered will allow consumers to know that what they are buying corresponds to their reasonable expectations.

Therefore, should FDA decide to require labeling of GE salmon, such a requirement would be well within the bounds of constitutionally permissible regulation of commercial speech.

**c. *Central Hudson Gas & Electric v. Public Service Commission*<sup>98</sup> applies to prophylactic bans on commercial speech, and therefore is inapplicable in this context**

The more restrictive standard for regulation of commercial speech that was articulated in *Central Hudson Gas & Electric v. Public Service Commission* provides that government regulation of commercial speech must satisfy a four-part test in order to be valid under the First Amendment.<sup>99</sup> Specifically, a reviewing court first determines if the banned commercial speech

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<sup>94</sup> *Id.* (emphasis added); *see, e.g.,* *Milavetz, Gallop & Milavetz, P.A. v. U.S.*, \_\_\_ U.S. \_\_\_, 130 S. Ct. 1324, 1339, 1340 (2010).

<sup>95</sup> *See* *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*, 447 U.S. 557, 562-563 (1980).

<sup>96</sup> *Zauderer*, 471 U.S. at 651.

<sup>97</sup> *See, e.g.,* *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 640 (6th Cir. 2010); *Nat’l Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 113-14 (2d Cir. 2001) (citing *Zauderer*); *United States v. Wenger*, 427 F.3d 840, 849 (10th Cir. 2005) (quoting *Zauderer*).

<sup>98</sup> 447 U.S. 557, 100 S. Ct. 2343 (1980).

<sup>99</sup> *Id.* at 564, 566.

is misleading or concerns unlawful activity. If the banned commercial speech is neither, then the government must demonstrate a substantial interest, that the regulation directly advances that interest, and that the regulation is not more extensive than necessary to serve the asserted interest.<sup>100</sup>

However, subsequent cases have clarified that *Zauderer*, and not *Central Hudson*, applies to disclosure requirements.<sup>101</sup> As noted above, the courts have consistently held that a merchant's First Amendment interest in *not* disclosing true information is not as strong as his interest in disclosing true information, and have therefore applied different standards to these two situations. Here, FDA has a statutory mandate to prevent deceptive labeling and ample evidence that requiring GE salmon to be labeled is necessary to prevent consumer deception, as illustrated by these Comments above. Because these comments seek a disclosure requirement, FDA need not meet the *Central Hudson* standard in order to justify mandatory labeling of GE salmon.

## V. Conclusion

AquaBounty's AquAdvantage® genetically engineered salmon calls attention to a larger problem with FDA's regulatory scheme for food labeling. Contrary to what FDA's standing policy suggests, consumers can be deceived by more than just differences in texture and taste. Consumers purchase based on what they can find out about how their food is purchased, and most consumers would avoid new food production technologies like genetic engineering if only they had the information to do so. Omitting such disclosures from labels is misleading to consumers, whether FDA chooses to recognize new food technologies as "material" differences or not. FDA can and should change its interpretation of FFDC section 201(n) to the reasonable interpretation proposed in these Comments.

AquaBounty's AquAdvantage® genetically engineered salmon has nutritional and human health differences from conventional salmon that qualify as "material" under FDA's current interpretation of section 201(n). Even the paltry data provided by AquaBounty points to important potential human health impacts; more in-depth, scientifically rigorous study would likely reveal more causes for concern. Although post-market surveillance is never a substitute for rigorous pre-market testing and analysis, the very least FDA can do if it approves GE salmon is to require labeling at the point of consumer purchase so that the fish's impacts on human health can be distinguished from the human health impacts of other salmon. We recommend that the FDA require a label clearly indicating that the AquAdvantage® salmon is genetically engineered and contains growth hormone genes from the Chinook salmon and genetic material from an Ocean eelpout.

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<sup>100</sup> *Id.*

<sup>101</sup> *Milavetz, Gallop & Milavetz, P.A. v. United States*, \_\_\_ U.S. \_\_\_, 130 S. Ct. 1324, (2010); *see also* *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113 (2d Cir. 2001) ("[T]here are material differences between purely factual and uncontroversial disclosure requirements and outright prohibitions on speech.")

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