FDA Hearing on the Labeling Food from AquAdvantage Salmon September 21, 2010

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Before I begin the substantive portion of my presentation, I want to thank FDA and the staff at CFSAN for inviting me to make this presentation today on behalf of the Center for Science in the Public Interest. CSPI supports all of FDA's efforts to make the policy and regulatory decision-making processes as transparent and participatory as possible. We applaud FDA for conducting this public hearing today and for providing the public a 60-day comment period to offer its views on the labeling issues surrounding the AquAdvantage Salmon. CSPI believes a similar public hearing and 60-day comment period should have been provided to the public for the regulatory approval decision on the AquAdvantage Salmon by the Center for Veterinary Medicine.

I am here today as the Director of the Biotechnology Project at the Center for Science in the Public Interest. CSPI is a non profit consumer organization, which was established almost 40 years ago. We work primarily on food and nutrition issues and publish the Nutrition Action Healthletter, which educates consumers on issues surrounding food, health, diet, and healthy eating, 10 times per year. We also advocate on behalf of consumers to federal agencies, Congress, and international governmental organizations. Our education and advocacy activities are based on the best available science, which informs the positions we take and the messages we promote. We receive no funding from industry or the federal government and never have in our almost 40

years of existence. This policy is important to us as it prevents any real or perceived conflict of interest when we lobby the government for changes in policy or criticize and call for changes by companies. Our funding comes from individuals who subscribe to our newsletter or make individual contributions. We also receive some funding from independent philanthropic foundations.

For CSPI, food labeling is currently a major issue and has been a major issue for years. We have advocated for different kinds of food labeling over the years. In addition, we have requested that FDA take action against untruthful and misleading label information provided to consumers by numerous different companies. Some examples where CSPI has become involved in food labeling policy will be given a little later in my presentation.

Today I have been asked to come and give a consumer perspective on the AquAdvantage Salmon, which is a genetically engineered organism. I want to point out, however, that no one consumer organization – such as CSPI – or any one individual can speak for all consumers, especially on an issue as controversial as genetically engineered organisms. Just as consumers are diverse and choose many different products in the food marketplace, consumers are extremely diverse in their views on genetically engineered organisms. They have different views on the use of genetic engineering. For example, many consumers embrace insulin made from genetically engineered microorganisms. Some of those consumers, however, may avoid genetically engineered foods. Some farmers, who are also consumers, embrace genetically engineered crops, such as

herbicide tolerant soybeans or pesticide producing corn. Other farmers, grow only nongenetically engineered crops. Consumers also have different views on the safety of food
that comes from genetically engineered crops. Some consumers believe those foods are
safe and don't hesitate to purchase and consume them. Other consumers question their
safety and avoid them by purchasing organic products or products without genetically
engineered ingredients. Finally, consumers and consumer organizations have different
views on the labeling of foods from genetically engineered organisms. Many individual
consumers and consumer organizations have called for mandatory labeling of products
made from genetically engineered organisms. Those who advocate for mandatory
labeling have many reasons for their viewpoints, including, among others, concerns over
safety, and principles such as "consumer choice" and "consumer right to know." Other
organizations and individuals believe mandatory labeling is not called for but welcome
voluntary labeling that is truthful and not misleading. Finally, some consumers believe
labeling is unnecessary.

By presenting today before FDA as a representative of a consumer organization, I don't want FDA to take my comments as representative of all US consumers or all US consumers organizations. I will present one of many perspectives on the labeling of the AquAdvantage Salmon, which may or may not be consistent with the viewpoints of other groups FDA may hear from later today or during the 60-day comment period.

Now, before I get to CSPI's views on the labeling of the AquAdvantage Salmon, I want to explain the food labeling principles that are important to CSPI and form the basis

of the viewpoint expressed here today. Most important to CSPI is that any food labeling must be **TRUTHFUL**. The label must also not be **MISLEADING** to the consumer. Let me give you some examples from CSPI's past.

For example, a number of years ago CSPI sent a letter to FDA about a food called QUORN. The company labeled the food as a "mycoprotein" which came from the mushroom family. However, the substance was a fusarium and not from the mushroom family at all. This labeling was untruthful and misleading. As another example, CSPI has complained numerous times when products call themselves "all natural" but contain large amounts of high fructose corn syrup, which is not a natural ingredient. CSPI has also found false and or misleading labels for products like carrot cake mix with little or no carrots; or frozen blueberry waffles that have no blueberries.

CSPI also believes that food labeling can and should convey information about safety and nutrition. We don't believe food labeling should be a substitute for safety. If the FDA is at all questioning the safety of a new food product, it should not allow that product to be marketed. Labeling that product is not an acceptable substitute if there is any safety concern. If there is any potential food safety risk from the AquAdvantage Salmon, FDA should not approve the drug in that fish. Approving the fish and attaching a warning label would not be acceptable. With that in mind, however, CSPI does support labeling that conveys information about safety and/or nutrition. For example, CSPI has supported labeling on egg cartons that will describe safety concerns and cooking instructions for eggs. CSPI also pushed for many years for FDA to include 'trans fat' on

the nutrition facts label as there was overwhelming evidence of the harmful effects of that compound.

CSPI has also asked FDA on numerous occasions to make sure "absence" labeling is truthful and not misleading. "Absence" labeling occurs when a product claims to not contain certain items. For example, in the past some food product labels have tried to identify for the consumer that they did not contain any genetically engineered ingredients. While CSPI supports the right of companies to provide consumers with information in the form of an absence label, we have not supported label claims that are untruthful, misleading to the consumer, or suggest that products made with genetically engineered ingredients are in some way less safe than other products. For example, we asked FDA to make sure that products could not be claimed GE-free if there was not a comparable GE product in the market — such as claiming that sunflower oil is GE free when there are no GE sunflowers. Similarly, we objected to labels using the term GMO free (free of genetically modified organisms) when that product contains no organisms at all. For example, we pointed out a particular jarred baby food that claimed to GMO free when no apple and apricot baby food has any organisms.

Finally, CSPI has generally not supported labeling based solely on production method. Foods today are made using many different technologies. New seed varieties can be made by irradiation, by chemical mutagenesis, by wide crosses, by genetic engineering, through the use of genomics, and many other production methods. Animal agriculture uses many different production technologies, including genetic engineering,

in-vitro fertilization, artificial insemination, several types of cloning, and so forth. We don't believe FDA should mandate that a label include all the different production methods of a particular product or ingredient.

Now when it comes to labeling of genetically engineered foods, CSPI did one poll of consumer viewpoints in 2001. The survey did not address genetically engineered animals or the AquAdvantage Salmon but it did inform the positions that CSPI takes regarding the labeling of foods made from genetically engineered organisms. In particular, I want to share one question from that survey with FDA and then some of our conclusions from the survey. The question reads: "Modern agriculture uses many technologies to increase productivity. Do you think the words below should appear on the label of a food product where one or more ingredients were from crops which were... (1) sprayed with pesticides (76%); (2) genetically engineered (70%); (3) treated with plant hormones (65%); (4) made from cross-bred corn (40%) or (5) don't know/no response (12%).

So what conclusions can be reached from this? First, consumers want information. If asked, what consumer would say they don't want additional information, especially if it is about something they are not familiar with. Second, education is essential. Almost half of the respondents said they wanted cross-bred corn to be labeled. Americans have been eating cross-bred corn for decades and virtually every corn ingredient comes from cross-bred corn. If consumers were more educated about agricultural production methods, the answer might be different. So, in our mind,

education and labeling must go hand and hand. Thirdly, the survey asked about four types of information but if we had asked about ten different types of information, it is likely that a majority of the public would have said yes to the inclusion of all ten pieces of information on the label. However, labels cannot contain infinite amounts of information and having too much information can be confusing to the consumer and competes with essential information that is most important to the consumer. Finally, as mentioned earlier, consumers want information about many different production methods, not just genetic engineering. So if production method labeling is going to be required, it should be for all different production methods. Genetic engineering is not necessarily unique in the minds of consumers and there may be no basis to single it out for different treatment. If the reason for labeling is to provide consumers information they are interested in, then all production methods need to be treated the same.

Now I will turn my attention to the AquAdvantage Salmon and the two questions FDA has presented to the public. Based on the document from FDA about the AquAdvantage Salmon – the data and risk assessment released by FDA earlier, and FDA's current policy regarding mandatory labeling, CSPI does not believe that the AquAdvantage Salmon requires any special mandatory labeling. CSPI could not identify in the public record any "material" differences between foods from this salmon and from other Atlantic salmon that would require a mandatory label.

However, if FDA does determine that there are "material" differences between food from this salmon and from other Atlantic salmon that require a some mandatory

label information, CSPI believes it is very important that the language required on the label be neutral and informative. FDA should not require that the label include the words "genetically engineered." As mentioned earlier, there are many production methods for food products and many production methods for salmon. Identifying this production method without requiring all the other production methods to be identified would needlessly discriminate against genetic engineering and not provide the consumer with information about the "material" differences in this particular salmon. In addition, whatever label information is required, it will be important that FDA, the salmon industry, the sponsor and other food chain participants educate consumers about the label and the information it conveys. Providing information without education about what that information means is not particularly helpful to the consumer.

So now I come to the end of my presentation. If we put aside the science around the AquAdvantage Salmon and the food products derived from it (the issues of its safety and its material differences) as well as the legal arguments about FDA's mandatory labeling policy, the reality is that there are consumers who want to know if their salmon has been genetically engineered. Some may want to know that information to avoid eating those filets and others may want to know that information to make sure to support that product and eat those filets. CSPI believes that it is very important that consumers who want information about their food and its production methods be able to get that information. Therefore, CSPI advocates that the FDA and the sponsor put in place a "real" voluntary labeling scheme for the food products from AquAdvantage Salmon.

When I say "real" I mean a voluntary labeling scheme that is actually implemented, not

just a concept that food chain participants can label if they want (but none actually do it for fear of protests or losing market share). Such a scheme probably would not use the term "genetically engineered" but would brand the product in the marketplace – it would be a positive label for the company such as "AquaBounty Salmon" or "Panamanian Inland Salmon" which would identify this salmon as unique in the marketplace. The label might promote the purported benefits of the products, such as calling it "fast-growing salmon" or "environmentally friendly salmon." While FDA would not be able to require such a label, they could work with AquaBounty to come up with a truthful and not misleading voluntary label and then AquaBounty, could use legal contracts to ensure the label was affixed throughout the food chain (similar to the way that a meat producer of angus beef might make sure that their "Angus beef" is differentiated at the supermarket).

Another area where FDA can be helpful regarding voluntary labeling is for "absence" claims. If a supermarket is selling salmon that is not AquAdvantage Salmon and wants to provide that information to the consumer in a truthful and non-misleading fashion, they should be able to do so. FDA should provide very specific guidance about the language that would be acceptable in advance so that such claims are uniform and meet all legal requirements.

In conclusion, I want to thank FDA for allowing me to speak this morning at this important public hearing. Whatever decision is made by FDA, I hope they will provide

their complete analysis to the public and do so shortly after the public comment period has ended. If the panel has any questions now, I would be happy to answer them.