U.S. FOOD AND DRUG ADMINISTRATION

PUBLIC HEARING ON THE LABELING OF FOOD MADE FROM AQUADVANTAGE SALMON

September 21, 2010

Hilton Hotel Executive Meeting Center

1750 Rockville Pike

Rockville, MD 20850

P R O C E E D I N G S

MR. LANDA: People, begin to be seated, please. It's just about 9:00 o'clock. We've got a long day ahead of us. We'd like to start on time.

Good morning, everyone. I'd like to call this hearing to order. My name is Michael Landa. I'm the Acting Director of FDA's Center for Food Safety and Applied Nutrition, and I'll be presiding at the hearing today. As I mentioned earlier, we have a very full agenda, so we want to not only start on time, but say on time throughout the day to the fullest extent possible.

To open our meeting, it's my great pleasure to introduce Dr. Joshua Sharfstein, who is FDA's Principal Deputy Commissioner, who will make some introductory remarks. Thanks, Josh.

DR. SHARFSTEIN: Thank you, Mike, and thanks, everybody, for coming. I'm Josh Sharfstein, the Principal Deputy Commissioner at FDA. Many of you were involved in the meeting yesterday, the VMAC meeting on the safety and effectiveness of this product. And I understand it was a very interesting meeting. The

input that we got was very valuable, and the agency has a lot to think about.

Today is a different topic. It is about if this application were approved, how the food from the salmon would be labeled. And this is a discussion that's only relevant if the application is approved, and it's obviously fair to ask, if you haven't made a decision, which we haven't, on approval, then why are you talking about labeling? And the answer to that is that because of the timing, we would want to make a decision about labeling at the same time, so that we could explain our approach. And so in order to be able to do that and to get public input, we have to do these things now. But it's not because we have made up our mind on the application, which is -- which we haven't.

I want to particularly thank all the FDA staff from the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the Office of Chief Counsel who are here, the Office of Policy, and others for really working hard on putting together the materials that are behind this hearing today, for being here at this hearing, and for actively participating.

You may all know this, but I will say this anyway: none of this is required under the law. It's not required that we put out a clear document that explains the approach the FDA takes to labeling and the reasons for that approach, the background for that approach. It is not required that we have a hearing like this at all. But we -- this is obviously the first application of this type to be considered, and we knew there was a lot of interest in this issue, and we wanted to give people a chance to give us their thoughts. And we thought that we would be in a position to make a better decision if we had people's thoughts. So this is definitely another situation where we have not made a decision, and we're very interested in getting public input.

Let me just conclude by saying, the Part 15 hearing, of which this is one, is one of my favorite types of hearings, you know? I was joking before. The Part 11 hearing is pretty good. There's no such thing as a Part 11 hearing.

(Laughter)

But the Part 15 hearing is a hearing where

people talk to the Agency, and the Agency can ask questions. And you're going to hear who is on the panel, and they will be asking questions. And the questions are generally intended to be clarifying questions. And I remember, actually one of my first introductions to FDA was when I came and presented to a Part 15 hearing on a topic that I am now recused from, because I'm at the Agency. And I got a chance to stand up and make my case, and I got some very good questions, some tough questions, from the panel. And I really felt like I had been heard, and I was very interested to see how what I said eventually translated into policy, which it did.

I've also participated in these hearings related to transparency, and they have been extremely useful hearings for our transparency initiative. And there's been a lot of clarification through questions that have been really helpful to our thinking on transparency.

So I really do think this is a very -- going to be a very productive day. I wish you all the best, and I thank Mike for his leadership, and I will turn it

back over to him.

MR. LANDA: Thanks, Josh. I want to now talk a little bit about today's hearing and its purpose. It is, of course, distinct from yesterday's VMAC hearing, in that the hearing today is focused specifically on the labeling of food from AquAdvantage salmon. The hearing is not about the safety or effectiveness findings that are relevant for the new animal drug application related to AquAdvantage salmon or any environmental issues regarding the salmon. These issues were the subject of yesterday's VMAC meeting.

I want to emphasize again that today's hearing will focus specifically on the labeling of food derived from AquAdvantage salmon, not the labeling of genetically engineered animals or genetically engineered organisms in general. Consequently, the questions on which we seek views and information from you are intentionally focused on facts and characteristics related to food derived from the AquAdvantage salmon.

The comments and information received during the hearing, as well as written comments submitted to

the hearing docket, may help inform the agency's analysis under the Federal Food, Drug and Cosmetic Act as to the appropriate labeling of food derived from AquAdvantage salmon, should the application that was the subject of the VMAC meeting, be approved. If it is approved, we'll provide a decision on food labeling, and in doing so, we'll consider the views and information provided here and submitted to the public docket. If we don't approve the application related to the salmon, then we will not need to consider the labeling of food derived from it.

A summary and explanation of the Agency's decision on the new animal drug application and, if applicable, the labeling of food derived from AquAdvantage salmon, will be posted on FDA's website.

We turn now to a few housekeeping items. When you arrived today, you should have received a folder of information. That packet contains today's agenda, the Federal Register notice announcing this hearing, a background document on food labeling, a list of attendees, and screen shots of the FDA websites which you can obtain more information. You should also know

that the hotel is providing complimentary parking. To receive that parking, take your ticket to the front desk for stamping. If there are media or press questions, please contact one of the FDA press officers on hand: Siobhan DeLancey, Sebastian Cianci, and Michael Herndon. Siobhan, Seb, and Michael, would you please stand so that members of the media will know who you are? Thanks.

If you have questions other than those related to media or press or need assistance, please contact Juanita Yates or other FDA personnel, staffing or registration desk. I don't know, is -- Juanita is in the back in the -- thank you.

Some ground rules: This is an informal hearing. It is called a hearing under Part 15 of the regulations, which Josh alluded to. But the rules of evidence don't apply. There is no direct examination; there is no cross. There is no re-cross; there is no re-direct.

(Laughter)

There are no objections to the admissibility of evidence, because there is no evidence to be taken.

(Laughter)

On the other hand, we do want to keep it orderly. We do want people, for example, to stay to the time allotted to them. There are really two reasons for that. One is so that we hear from everyone who signed up to speak. And another is really a fairness issue. If, as has been my experience with these hearings, the vast bulk of people limit themselves to the time allotted, it is unfair if someone who has not done so is permitted to go on, I don't mean 20 seconds beyond the limit, but two or three or five minutes beyond the limit when the limit itself is ten minutes. So when you see the red light come on, we do intend that you stop. If you want to finish the sentence, that's fine. But we do not intend that you continue for several minutes.

We have reserved the afternoon for members of the public to make oral presentations related to the questions FDA posed in the Federal Register notice announcing this hearing. If you'd like to make a presentation and have not already requested time to speak, please notify an FDA staff member at the

registration table before we break for lunch. The public commenters already scheduled to speak can be seen on the agenda included in your packet. If you previously requested time to speak today but have changed your mind, please let an FDA staff member know so we don't spend time waiting for you to show up to speak.

You can use your allotted time in whatever way you wish, consistent with a reasonable and orderly public hearing. That includes, if you wish to use your time to rebut statements or challenge statements, or indeed, agree with statements of a previous speaker, you're free to do that. Just remember that it all counts for your allotted time.

If a person is not present at the time specified for him or her to speak, the next person scheduled to speak will be asked to present, followed by all others who were scheduled to give an oral presentation, in their assigned order. The absence of one or more oral presenters may require that we make some adjustments in the actual beginning times of others who wish to speak, so don't count completely on

your assigned time as the time when you will begin. It's possible we'll ask you to start somewhat earlier.

After everyone who has registered to give an oral presentation has spoken, we'll make an attempt to hear any person who was late for their scheduled oral presentation. And as time permits, other interested persons attending today's hearing who didn't notify FDA prior to the hearing about their interest in speaking will be given an opportunity to speak, again as time permits.

The meeting will be transcribed, and the transcript will be made available to the public in the docket I previously identified for the hearing. Because it will be transcribed, it's important for you to give your full name and affiliation. It just makes it a lot easier for the people doing the transcribing when it comes time to actually produce the transcript.

If you have more information than you will have time to present, or if you have additional data or references, please submit them electronically to www.regulations.gov or provide them in a written format using instructions in the Federal Register notice.

Remember that comments are due by November 22 of this year. But again, that gives you substantial additional time to comment if you don't get to say everything you wanted to say today. The slides from today's presentations will be made available on the same docket that I noted earlier.

Let's turn briefly to the agenda. We'll have two presentations from FDA staff members, first, Abigail Brandel, and second, Jason Dietz. Ms. Brandel is an attorney in FDA's Office of Chief Counsel, and she'll explain the legal principles for food labeling relevant to the labeling of food derived from GE animals. Mr. Dietz is in the FDA Center for Food Safety and Applied Nutrition, and he will provide a very brief description of the technical data about the AquAdvantage salmon made available -- that is the data made available on the Agency's Internet site in advance of the meeting.

After these presentations, we'll introduce the questions on which the Agency is seeking views and information. FDA has invited the following three speakers to address these questions: Ronald Stotish,

Ph.D., President and CEO of AquaBounty Technologies, Inc.; Alison Van Eenennaam, Ph.D., Cooperative Extension Specialist, University of California at Davis; and Gregory Jaffe, Director of the Biotechnology Project at the Center for Science in the Public Interest.

We'll then break for lunch. Lunch is on your own. There's a restaurant in the hotel or other restaurants nearby. After lunch, we'll hear from members of the public who wish to give oral presentations at the hearing. As a reminder, we invite all members of the public, whether or not they choose to give oral presentations here, again to submit comments to the docket, and again by no later than November 22, 2010. The docket number is noted at the top of the F.R. notice announcing this hearing. The notice itself is included in your packet of information. Please note that this docket is different from the docket pertaining to the VMAC meeting announced in the Federal Register on the same day, the meeting held yesterday. Please be sure you identify the docket number corresponding to this public hearing

at the top of any written comments you submit, that is, this public hearing as opposed to the VMAC meeting.

Let me now introduce the FDA panel for the hearing. First we have Alta Charo, Senior Advisor, Office of the Commissioner. Alta, if you would?

Thank you.

Next, Felicia Billingsley, who is Director of the Food Labeling and Standards staff, the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition. Felicia?

Thank you.

Next, Abigail Brandel, who is an attorney with our Office of Chief Counsel.

And Jason Dietz, the previously mentioned science policy analyst, Office of Regulations, Policy, and Social Sciences, Center for Food Safety and Applied Nutrition.

And all the way to my left, William Jones, Ph.D., Acting Deputy Director, Office of Food Safety, Center for Food Safety and Applied Nutrition.

I'll be serving as an additional member of the panel.

Let me just say a couple of words about data and information made available before the hearing, and then we'll get on to the first presentation.

Before the hearing, we posted at the FDA website and filed in the public docket several resources to help inform public comment at today's hearing. One resource is a background document describing the legal principles for food labeling relevant to the labeling of foods derived from GE animals. This background document also identifies two specific questions on which FDA is seeking input today. Again, a copy of the background documents is included in your packet.

A second resource, a briefing packet produced by FDA's Center for Veterinary Medicine, provides information about the characteristics of AquAdvantage salmon that may be relevant to food labeling. A few copies of the briefing packet are available for viewing at the registration table.

With that, let's turn to Abigail Brandel of the Office of Chief Counsel at FDA, who'll provide an overview of the legal principles relevant to labeling

of foods derived from GE animals. For additional details, please also refer to the background document on food labeling. The background document is included in your information packet.

Abigail?

MS. BRANDEL: Good morning. I'm Abby Brandel. I work in FDA's Office of Chief Counsel, and as Mike said, I'm here today to provide an overview of the principles of food labeling as they relate to food derived from AquAdvantage salmon.

So first, a word about terminology. I'm a lawyer. We like definitions. And so I want to acknowledge, to start, that the Food, Drug and Cosmetic Act defines "label" and "labeling" differently, and the definitions appear here on the slide. This distinction matters under some circumstances, but doesn't matter much for our purposes here today. So for today, in the interests of simplicity, I'm going to use the terms "label" and "labeling" interchangeably.

So all of us are familiar with food labeling as a general matter. But just a brief reminder about its purpose from FDA's perspective: it's to provide

consumers with meaningful information about a food. And that's because, I think we all understand that the label can play an important role in consumer purchase decisions and dietary choices.

FDA has regulated the food label for more than a century, since 1906, and the core of its legal authority dates from 1938. And under that authority, there are three very broad categories of food labeling information.

The first category is mandatory information. This is information that must appear on a food label, such as the ingredients, the net quantity, and nutrition information.

The second major category is that of optional information. So this is information that doesn't have to appear, but if it does, some of that information can be governed by explicit FDA standards to ensure that the information is not misleading. And really the best example of this is nutrient content claims, such as low fat or high fiber. For example, for a good source claim, if a food is represented as a good source of a particular nutrient, it needs to contain somewhere

between 10 and 19 percent of the recommended daily intake for that nutrient.

And the third category, the third general category, is information that cannot appear on the food label.

And this slide lists the five key principles that we're going to talk about today. And these are the principles that will inform the Agency's decision making about the labeling of food derived from AquAdvantage salmon, should the Agency decide to approve the new animal drug application relating to the salmon.

So principles 1 and 2, food labeling cannot be false or misleading. Number 3, a company may include statements about production methods in the food label, provided the statements are not false or misleading. Number 4, a food label must bear the name of the food, and that name must accurately describe the basic nature of the food. Fifth, FDA cannot require additional labeling about production methods unless that information is necessary to ensure that the labeling is not false or misleading. And it's important to

understand that these principles apply to all food, whether or not the food is derived from a genetically engineered source.

So principle number 1 is the easiest. The law prohibits food labeling that is false. So, for example, the label of a chocolate bar cannot declare that the product includes ingredients like nuts if those ingredients are not, in fact, present. Pretty straightforward. Similarly, a food can't be represented as containing no preservatives if, in fact, the food contains preservatives.

The second principle is that the law prohibits food labeling that is misleading. And just that blanket prohibition doesn't tell us a whole lot about what constitutes misleading information. But we do have the language of Section 321(n) of the statute, which is quoted here in the first bullet on the slide. And essentially what that language tells us is that labeling can be misleading by virtue of either the inclusion of information or the omission of information. And with respect to omissions, labeling is misleading if it omits a material fact.

This language also tells us that there are two prongs of materiality: information that's material in light of representations made or suggested in the labeling, or information that is material with respect to the consequences that may result from the consumption of the food. And we have an example on the slide here. If a food is represented as saturated fat-free, it must also contain less than 0.5 grams of trans fat. And the reason for that is that a consumer otherwise -- or a consumer likely would assume, quite reasonably, that a saturated fat-free food is also low in trans fat.

Principle number 3: The law allows voluntary labeling about production methods, provided that labeling is not false or misleading. For example, if a food has not been processed in some way, such as being frozen or being pasteurized or being cooked, the food can be represented as fresh. Other examples of voluntary labeling that might be okay, depending, of course, on the particulars of the food and how it's made, are things like slow-churned butter or baked potato chips or hand-crafted sandwiches.

The fourth principle is that the law requires a food label to bear the common or usual name of the food, and that name has to accurately describe the basic nature of the food. And so here, we're pretty clearly not talking about brand names or proprietary names. We're talking about the more general terminology that describes what a food actually is. This concept is sometimes called the statement of identity.

So for example, products -- juice products that are made from concentrate and water are required to have a name that identifies that fact. So they have to be identified, for example, as orange juice from concentrate, or reconstituted orange juice. And this is to distinguish those products from juice that is simply expressed.

The fifth principle is that FDA cannot require labeling about -- information about production methods to appear on food labeling unless that information is necessary to ensure that the labeling is not false or misleading. And so, for example, in the 1990s, some farmers began using recombinant bovine somatotropin to

treat cows to stimulate milk production. But because there was no material difference between milk from the rbST-treated cows and other milk, FDA did not have the authority to require different or special labeling for the milk from the rbST-treated cows. And we'll talk a little bit more about that case in a minute.

The key concept underlying really all of these five principles is that of materiality. FDA generally has concluded that it is the information about the characteristics of a food itself, not necessarily the methods of production, that are material. And the Agency has recognized three of those kinds of differences. One is nutritional properties. So, for example, if an animal from a GE source has significantly higher protein levels than its traditional counterpart, FDA likely would conclude that the higher protein level, not necessarily the production method for the animal, was a material difference that required labeling. So in other words, it would be the protein content, the different content of protein, that would need to be presented on the label.

A second category is organoleptic differences. And organoleptic means capable of being detected by human senses, so things like taste, smell, texture. For example, if someone figured out a way to make Brussels sprouts taste like strawberries, FDA likely would require labeling to alert consumers to that effect.

And the third category is functional properties, meaning performance characteristics that change the use of the food. And a good example of this is that low-fat margarine is not good for frying foods, and so these products are required to have labeling that tells consumers this product isn't good for frying.

With respect to food from GE sources in particular, the Agency has said that if that food is significantly different from its traditional counterpart, such that the common or usual name no longer adequately describes the new food, the name will have to be changed to describe that difference. And here are two examples. In one case, a different name was required, and in the other case, it was not.

So the first example is the oil from a GE soybean. And this was a soybean that was modified to alter the fatty acid profile, such that it had a much higher concentration of oleic acid than conventional soybeans. And therefore, a phrase like "high oleic acid" is required to be a part of the common or usual name of that food.

In contrast, the FLAVR SAVR tomato, it was determined that there was no material difference between that tomato and conventional tomatoes, and therefore both products could be simply called "tomato." However, if there were, for example, a tomato that incorporated a peanut protein, and there were insufficient information to show that that protein would not cause an allergic reaction, then special labeling likely would be required to alert consumers to that information.

So, as those examples illustrate, FDA will consider each food that is derived from a GE plant or animal on a case-by-case basis. The Agency has not found that food from GE organisms, as a class, presents different or greater safety concerns than their

conventional counterparts. Nor has FDA found that these foods, as a class, differ materially in their nutritional, organoleptic, or functional properties.

Is consumer interest, in and of itself, a material fact? Courts have considered this question and determined that under current law, FDA does not have the authority to require labeling based solely on consumer interest or demand. And a good example of this is the rbST-treated milk case that I mentioned a moment ago. And here's a quote from that case, where the court said -- the court decided that if the milk from the rbST-treated cows does not differ in any significant way from what it purports to be, than it would be misbranding to label the product as different, even if consumers misperceive the product as different. In the absence of a material difference between rbST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug and Cosmetic Act.

And so finally, even though FDA may not be able to require this information, it's important to note that a company can choose to include this

information on a food label, can choose to provide information about whether a food is or is not made from a GE organism, provided that information is truthful and not misleading and the company can substantiate each claim.

So those are the five principles of food labeling. FDA is seeking comment here today on the application of these principles to food derived from AquAdvantage salmon, and we look forward to hearing your comments.

MR. LANDA: Thanks, Abby.

We'll now hear from Jason Dietz. He'll provide a very brief description of information the FDA made available about the characteristics of AquAdvantage salmon that may be relevant to the questions that are the focus of our food labeling discussion today. Jason?

DR. DIETZ: Good morning.

In its Federal Register notice announcing this hearing, FDA said that it would make scientific information about the AquAdvantage salmon available prior to today's hearing. FDA's Center for Veterinary

Medicine has posted on its website a briefing packet that provides summaries of all the data and information, as well as all of the analyses on which the Agency will be making its decision regarding the safety and effectiveness of AquAdvantage salmon. Contained in the briefing packet are data and information that describe the genotype and phenotype of AquAdvantage salmon, including detailed information on the physiology of the salmon, as well as its concordance with a commonly used tool for identifying species of fish in the marketplace, The Regulatory Fish Encyclopedia.

In the section on food safety, the Agency has presented detailed information on the chemical composition of AquAdvantage salmon. This information may help commenters consider how the labeling principles described in the background document, and as we just heard from Abigail Brandel, may help commenters consider how these data apply to food labeling.

We suggest that commenters consider this information when making their public comments. In addition to its availability on the FDA website, the

briefing packet is available at the public docket for this hearing, and a few hard copies are available for viewing at the registration table.

Thank you.

MR. LANDA: Thanks, Jason.

I just now want to turn to the questions on which we're requesting input. We like folks who submit comments to FDA on the questions to consider the relevant principles on food labeling that Abigail Brandel just described to you, as well as any relevant information about the characteristics of AquAdvantage salmon.

First question: Which facts about the AquAdvantage salmon seem most pertinent for FDA's consideration of whether there are any, quote, unquote, material differences between foods from this salmon and foods from other Atlantic salmon?" Again, recall Abigail Brandel's presentation making the point that the use of genetic engineering does not, in and of itself, constitute a quote, unquote, "material" difference under the law. And "material" is in quote, and I am saying "quote, unquote" because it is

statutory language. It's a term of art.

Second question we want people to focus on: If FDA determined that there are, quote, unquote, "material differences," how would those differences be described on a food label in a way that is truthful and non-misleading? Again, recall that the statute bars statements in labeling that are false or misleading in any particular, or more accurately, it makes -- if such statements appear in labeling, it makes the labeled product misbranded.

Also keep in mind that it's a difference in composition or in functional, organoleptic, or other, quote, unquote, "material" properties that must be described, not the underlying production process.

We are running significantly ahead of time. And I would -- each of the next presentations, I think, is scheduled -- let me just check -- I think for 25 minutes. And so what I would suggest is that we start with our first speaker. He is Dr. Ronald Stotish, Ph.D. He's President and CEO of AquaBounty Technologies. AquaBounty is the first that produced the AquAdvantage salmon.

DR. STOTISH: I've been handed a new device and given a two-sentence instruction, so if I make a mistake, please excuse me.

Good morning. And I'd like to begin by thanking the organizers of the meeting and the FDA for the opportunity to address this meeting this morning.

For those of you who were at the VMAC yesterday, my apologies. Because in talking with the organizers, we felt it was important to begin by talking about the product, or the product candidate. And because the audience may be different from the meeting yesterday, I will begin by going over the information on the company and the AquAdvantage salmon. The latter half of my presentation will address the substance and the questions that were just introduced as the topic of this meeting.

AquBounty Technologies is a -- is just what it says, a technology company. Our interest is in serving the needs of the global aquaculture industry by providing precise and molecular-based solutions to problems in that industry. Stated shortly, we're trying to supply tools to support what has become known

as the blue revolution, the increase of global aquaculture to meet the food supply, and particularly the seafood supply, needs of a growing population.

The company was founded in 1991 over some other technology, antifreeze protein technology. In 1996, they acquired the rights to the AquAdvantage technology from Toronto University -- University of Toronto and Memorial University in Newfoundland. That's really the technology that brings us here today, and that produced the product that we'll talk about, AquAdvantage salmon.

Over the years, the company was reorganized. The antifreeze protein subsidiary was spun out. And in 2004, the name AquaBounty Technologies was taken, and in 2006, the company went public on the London Stock Exchange and the alternet investment market.

Aquaculture is an important and emerging and growing aspect of food production, obviously seafood production. The FAO issues an annual State of the World Fisheries and Aquaculture report. FAO, as you know, is an agency of the United Nations. They're principally concerned with food and agriculture, as

their name implies, food and agriculture organization. And in the 2009 meeting in Rome, the Assistant Director General made some comments that are appropriate. He pointed out that we'd reached a milestone; that now, nearly 50 percent of the total seafood consumed around the world was produced by aquaculture. There are two reasons for this, one of them as you see from this very primitive graph that I copied from the U.S. Census Bureau, which also appears in FAO reports and other documents.

In 1960, the global population was about three billion people. The population had doubled in 40 years, by the year 2000, and will double again perhaps by the year 2045 or 2050. The FAO in its annual reports addresses a very fundamental issue: with limiting terrestrial and water resources and growing populations, we will need new technologies to meet the global food security needs of those emerging populations. That's further complicated by emerging economies such as China, for instance, where you have emerging middle classes that are demanding higher protein and higher quality diets. And without new

technologies, technologies that improve productivity and efficiency, it's hard to imagine how we will meet those global demands for a safe and secure food.

Capture fisheries have plateaued, and again, this is from the State of the World Fisheries, at approximately 90 million tons per year. The fishing countries around the world have become more efficient. We have technologically advanced fishing fleets. They fish more species, and they do so with remarkable and devastating efficiency. The world's oceans are stressed, according to all of the reports: NOAA's reports, FAO's reports, all of the assessments that have been made. But that's not to say that there aren't well-managed fisheries, as well, such as the Alaskan wild salmon fisheries, which is reasonably well managed.

The point here is that global aquaculture has been growing six to eight percent per year over the last three or four decades, and now does, in fact, contribute more than 50 percent of the total seafood consumed around the world. The consumption has been fairly steady at about 16 kilos per man, woman, and

child over the last ten years or so. And that's doubled from about 20 years ago. So seafood is an important source of food in our diet. It's a healthy food, and the consumption by humans is fairly significant. And the population continues to grow.

Atlantic salmon is the species that we're here to talk about. AquAdvantage is, after all, an Atlantic salmon. Atlantic salmon, it's important to point out, there are no wild-caught fisheries for Atlantic salmon in the United States. Atlantic salmon was declared an endangered species in Maine in 2000. That order was subsequently expanded over the years in 2009. All of the Atlantic salmon consumed, or 97 percent of the Atlantic salmon consumed in the United States, is farmed. Fifty percent of the total salmon consumed in the United States is Atlantic salmon. Almost all of the salmon that we consume, more than 97 percent, are imported from other sources. They're imported from Chile, from Norway, from Canada, from England, Farrel(ph) Islands, and Scotland. So this is an imported product. It's exclusively a cultured fish, and the American consumer consumes a significant

amount. In 2000, the United States imported over 450,000 tons of Atlantic salmon.

There are problems, however, associated with contemporary salmon aquaculture. It's a net pen or sea cage-based industry. That means that seals, sharks, and other predators get in, damage the nets, fish escape. Weather-adverse conditions and disasters, human or otherwise, affect the containment of the net pens and fish escape. That's a concern for impacts on biodiversity and interactions with wild populations. There are also environmental and ecological impacts of the coastal production systems associated with sea cages. Pollution of coastal areas, damaging of important ecological environments, and other issues associated with net pen aquaculture.

In 2007, there was an outbreak of ISAV, Infectious Salmon Anemia Virus, in Chile which devastated the industry. That led to a dramatic reduction in their capacity, perhaps as much as 70 percent, from which that particular industry has not recovered. The net effect was record-high prices in the United States this year for Atlantic salmon.

Some of the other issues associated with it, as you can see -- and these are simply headlines -- sea lice from cultured Atlantic salmon. That's an aspect of disease transmission. Sea lice are not really lice at all, but they're small invertebrates that attach themselves to young salmon and affect thriftiness and can even result in mortality. Those can be transmitted from farmed salmon to wild fish, as well. Escapes, recovery of sites from cultivation, accumulated food, waste products, and so forth in the coastal waterways.

One of the most interesting -- there are many aspects of sort of the social and economic considerations in the industry. The wild-caught industry in the north Pacific, for instance, is very opposed to any aquaculture. And even the appearance of the Fisheries Minister for British Columbia at an aquaculture meeting was a controversial event. So there are wheels within wheels in this industry, that the Atlantic salmon industry is primarily a cultured system, and it's a very desirable, appealing food, and there are issues associated with its contemporary production.

I'll talk a little bit about AquAdvantage so that everyone is aware of the product. AquAdvantage salmon contains a gene construct which consists of the growth hormone from the Chinook salmon under the control of the promoter from an antifreeze gene of the ocean pout. This construct was injected into developing salmon eggs in the selected progeny, identified fish that had taken up the construct into its genomic DNA, were capable of expressing that construct, and were capable of transmitting that construct in inheritable fashion to its progeny.

AquaBounty has bred the line drive from those initial founder animals for more than ten generations at our hatchery in Price Edward Island. During that time, we've conducted a number of regulatory studies, and obviously a lot of observations and recordings of fish health and fish characteristics over those years. As a part of our application, we've had to demonstrate the durability of both the phenotype and the genotype -- in other words, the insert stage, where it was originally inserted, it is unchanged in the documents that were released. The report was over seven

generations. We're up now nearly to ten. And the expression of the construct remains constant with time, as well. The rapid growth phenotype always follows the gene construct in the AquAdvantage salmon.

What does that mean for the fish? AquAdvantage salmon grow much more quickly than their nontransgenic sibs in the first year of life, primarily. That approximately means they reach market weight in about half the time. And I'll show you two growth curves. These are growth of juvenile stages. The AquAdvantage salmon -- and these fish are siblings. They're bred so that half of the fish are genetically equivalent to the AquAdvantage. They simply lack the AquAdvantage gene construct. The AquAdvantage fish in this example reach 200 grams, for instance, at about 175 days. The genetically identical, with the exception of the AquAdvantage gene, take 350 days to reach that same 200 grams.

Looking at the longer growing period of the salmon, again, to a two kilo body size, the AquAdvantage salmon something less than 500 days, and following out, again, the genetically identical non-

transgenic sibling, something close to 700 days. The growth rates do normalize as the fish gets larger. That's probably due to the regulation of the endogenous gene. But the important fact is that the AquAdvantage growth earlier in life confers an ability to reach market weight at an earlier time.

The product definition, and again this is very precisely defined, this is a triploid hemizygous all-female salmon. It contains a gene construct in a very specific location, and basically constitutes a very specific line bred from that original founder fish. The claim is very simple. It grows faster than its parent.

The limitations for use? These Atlantic salmon are produced as (inaudible) eggs for grow-out only in FDA-approved facilities. Part of the benefit of this fish is this can be grown in land-based contained aquaculture systems, which avoid or mitigate many of the concerns associated with that traditional net pen aquaculture that I talked about a few moments ago. These fish are offered as eggs. They're offered for sale in labeled containers, labeled just as any

veterinary drug would be labeled, through a secure distribution analogous to the deliver of veterinary drug. These are sold only to producers in FDA-approved facilities.

The commercial production basically is certification of the brood stock using the milk or sperm from that brood stock to fertilize wild-type eggs, rendering those eggs triploid, so they have three copies of the chromosome. And prior to release, the triplody is confirmed using fluorescence-activated self-sorter technology.

Again, the eggs are then shipped. Once they have been certified as meeting the release specification, the eggs are shipped in a secure package that is appropriately labeled to a site that has already been approved to grow these fish. So that is the AquAdvantage salmon.

It's being regulated under the Guidance for Industry 187, which is the document that was released in January of 2009, which was really the first regulatory paradigm for so-called genetically engineered animals. The fish has been around since

1989, and AquaBounty participated in the discussions on whether this technology needed to be regulated; if it were to be regulated; which agencies should regulate it. We think that this regulatory paradigm is not only appropriate, but in the best interests of the sponsor, of the government, and of our larger society.

This is the famous ziggurat that Rudenko from the FDA likes to show. This is our copy; it's not as pretty as the one that the CVM showed yesterday. They have now multicolored, very beautiful graphics. But the idea is, basically is an escalating risk assessment model starting with the gene construct and going up, examining essentially all of the properties of the organism, the stability of the gene construct, the safety to the animal, the safety as food and feed, and the safety to the environment. So this is an escalating risk assessment model that is a very robust and thorough regulatory process.

Through this process, the sponsor has to provide a number of studies. I'll talk to you about some of them this morning. This is just a partial list, but it gives you an idea. There are

environmental assessments on either end of this list. You have to characterize the nature of the genetic element that's been inserted; the inheritance and stability of that insert. You have to be able to identify your product in a unique way, and we have a very precise molecular method to identify and distinguish this food from all other foods. We demonstrate animal safety, and we have health records, obviously, from the time that this line was begun until the present day in our hatchery.

This is an example of the kinds of data that were provided to the FDA, for instance in demonstration of composition. And I'll talk about a few types of assays. I don't intend to show you a lot of data, because that data is available in the briefing packet. And frankly, your eyes will glaze over after going through table by table looking at very small differences that reflect variability in repeated measures in these sorts of studies. But the proximate analysis basically measured carbohydrate, ash, protein, moisture, and total fat, a fairly standard analysis composition of anything that's done in every livestock

and food industry, look at all of the vitamin components, minerals, amino acids and proteins, both total lipids and free fatty acids. In each study we compare what's called a farm control, which is a commercially available farmed Atlantic salmon already in the food supply, the sponsor control, which are basically the non-transgenic siblings that are raised in the same environment and are genetically identical to the AquAdvantage with the exception that they don't have the AquAdvantage gene, and basically conduct the study.

This is the tabular data from one of the tables that are in the briefing packet. And I don't intend, as I said, to go through the table line by line, but simply to remind you that we've looked at farm control, sponsor control. And the TX in this instance is, of course, the treated group or the AquAdvantage salmon.

In a slightly more appealing slide, the summaries of some of the analytes that were measured in that study. The study is statistically robust. There were 30 transgenic and 43 control salmon compared for

each parameter. And the way that I phrase this when I talk to lay audiences or just people in other walks of life in industry is that we basically measured everything that you can measure in a salmon, or for that matter, in a food. And we compared them to the traditional farm control that's already in the -- in commerce, as well as the sponsor control and the AquAdvantage salmon.

There is another relevant comparison, and that is that healthy fish make healthy food. And that's important in a consideration of a food animal, as well. In the context of prosecuting our application with the Center for Veterinary Medicine, we had to conduct animal safety studies. In addition to those animal safety studies, we have also had to evaluate the safety and health of our fish over generations. We're inspected annually by the Department of Fisheries and Oceans in Canada. Under the Canadian Fish Health Protection regulations, there are routine pathogens that are screened in this detailed inspection process. We've had ongoing staff and consulting veterinarian observations on fertility, viability, general health.

And those records were also reviewed by the Center as a part of their review process.

We've had contract studies and contract health specialists that have come out and helped us with issues, study design issues and fish observation issues, some of whom are in this room today. And in this instance -- and this is an old slide. I used it because this illustrates the kinds of data that we have, but a proposed GOP study addressing the target animal safety aspects of the juvenile and market weight salmon. In this study -- and again, I will not go through the entire thing -- but we looked at behavior; gross external examination; gross internal examination, obviously on necropsy; gastrointestinal tract; hematology; blood chemistry.

I'll point out, for those of you who've run these kinds of studies in any livestock species, that basically you're making measurements that there are not historical and well-established guidelines for, frequently the case. If you go to your doctor, for instance, and they run a blood chemistry analysis, you have normal values and normal ranges for every analyte

in human blood. That doesn't exist for most livestock species, and the data is fairly rudimentary for a species like salmon. However, we continued to measure everything that we could measure.

With again, not presenting the data, because you can look through the data tables that have already been released, the conclusions on their review, which were consistent with the sponsor's conclusions in submitting the study, is that AquAdvantage salmon meets the standard of identity for Atlantic salmon in the previous-referenced Fish Encyclopedia -- which I love that term, I'm not sure why, but the concept of having a fish encyclopedia to identify specific fish.

The food is the same as the food from Atlantic salmon. There are no biologically relevant differences. The food contains the expected amounts of nutritionally important Omega-3's and Omega-6. There are no biologically relevant difference between the food from AAS and conventional salmon, based on all of the criteria evaluated. That's been our historical experience, and that was the conclusion of the reviewers after reviewing the information. There don't

seem to be any consumption hazards, and this appears to be as safe to eat as food from any Atlantic salmon. Simply stated, this is a rapidly growing Atlantic salmon.

These are two sisters. They're the same age. One has the construct; one doesn't. This is, in fact, the AquAdvantage technology.

We did some other -- obviously over the years. We were curious, and we felt that we'd have to provide data on organoleptic properties. These were small, anecdotal, informal studies. Last year we did a slightly larger study, and we did it with a large American company that was -- I guess the term would be skilled in the art of preparing and evaluating seafood. It was a blinded comparison of Canadian, Chilean, and AquAdvantage salmon. Obviously we sourced the AquAdvantage; the other two were sourced commercially. We sent them the fish. Three of their chefs conducted a test with 19 tasters, nine of whom were sophisticated. And please don't ask me to define what that means. I think they thought they were somehow more sensitive than the other diners. Or elitists.

(Laughter) But 19 in total. There may be some sophisticated diners in the room, I don't know. Three coded samples tasted in no particular order, and they ranked them by preference and by attributes. The summary, and again, this -- the easiest is the straight analysis. The number of people that preferred the blue, which is the AquAdvantage salmon, was greater than the individuals who select either the Canadian or Chilean in a blind test.

Looking at the parameters of color, odor, texture, and taste, you can see it's fairly straightforward. The fact that we happened to come out best in this test does not mean that we think this is any way superior. We've done other tests where it's equivalent to or basically the same. The impression here is on organoleptic properties and processability in third party hands and in an objective blinded study, it's an Atlantic salmon. It looks like an Atlantic salmon; it acts like an Atlantic salmon; and most importantly, it tastes like an Atlantic salmon.

With that, I'll address sort of the charge of this meeting. What facts seem most pertinent for

considering whether there are any material differences? In our experience, we have not identified material differences. We do not believe that there is any material difference between AquAdvantage salmon and Atlantic salmon. This fish meets the definition, as defined and accepted by the FDA. And in every objective and organoleptic measure investigated by the firm over the last 15 years, this is an Atlantic salmon.

With that, I'll close and take questions.

MR. LANDA: Any members of the panel have questions? Alta? Alta Charo?

MS. CHARO: Thank you very much.

I'd like to ask you a question about that last portion of the presentation. Having talked about how the salmon is -- the AquAdvantage salmon is the same as other Atlantic salmon, you nonetheless seem to find a difference in the taste that allowed people to discriminate to the point of preferring one over the other. Do you have any thoughts about what might account for the different taste, or is this not a statistically significant sample so that we shouldn't

draw conclusions? I'm just trying to understand what's going on.

DR. STOTISH: That's actually a very good question. That's why I presented it with a caveat. These are 19 individuals with samples prepared by three chefs. We've done very limited, what I would consider anecdotal, informal testing. Over the years in our place in Prince Edward Island, we've evaluated, obviously on a very small level with panels. We're not implying that this is better than or different in any way. In our hands, and in the hands of independent reviewers, this seems equivalent. If you looked at the texture, taste, odor, and appearance and flavor graphs, those bars are very close to each other. We are not of the opinion that there is a statistical difference here. And if you'd had ten Atlantic salmon sourced from different locations, you might have gotten similar results if they were all just, you know, Atlantic salmon from one source, for instance.

MS. CHARO: So just to clarify, then, do you expect if this were -- if this application were approved, and both of these kinds of -- all these

different kinds of salmon were on the market, do you expect that there would be a discernible taste difference between the food from AquAdvantage salmon and food from other types of salmon?

DR. STOTISH: We -- unequivocally, we do not.

MR. LANDA: Felicia Billingslea has a question.

MS. BILLINGSLEA: Felicia Billingslea, FDA.

I guess somewhat along the same lines, in this -- this test that was done, were there any notes, comments made by the chefs in terms of how they handled the fish, prepared the fish; whether there were any differences in cooking attributes or anything like that?

DR. STOTISH: In other, again small-scale tests, some with third-party fisheries and seafood companies and some in local chefs in proximity to our hatchery, the comments -- and prepared by different methods, that it processes and tastes like Atlantic salmon. They do not see any difference in appearance, texture, and so forth.

It is important to note that within salmon,

and if you were to -- if you were to look at salmon, for instance, the wild salmon versus the farmed salmon, salmon at one kilo versus two kilos versus three kilos, you do see differences in appearance, and there are differences in color and differences in taste, if you were to examine salmon from a single source at different sizes. So we've tried to compare. In the example that I showed, those fish were selected so that they were the same size as the comparators. But it is possible to see natural variability in, for instance, fish at different ages from a single source. That's all part of the biological variation that's part of our food supply today.

MR. LANDA: Any other questions from the panel?

DR. STOTISH: Okay.

MR. LANDA: Thank you, Dr. Stotish.

We're going to take a break now until -- let's make it 10:25. If you would return promptly at 10:25 so we can resume, then, when we'll hear from Dr. Van Eenennaam.

One request, which is that if you did not sign

in at the registration desk, would you please do so.

Thank you.

(Break)

MR. LANDA: If people would please begin to take their seats so we can resume shortly? Thank you.

It's a little after 10:25. Let's get started again. We're going to hear next from Dr. Van Eenennaam, who is a molecular geneticist and animal scientist by training. She currently works as a researcher and Extension educator in the field of animal genomics and biotechnology. She was also a member of USDA's Advisory Committee on Agricultural Biotechnology and 21st Century Agriculture, and has served on FDA's Veterinary Medicine Advisory Committee.

Thank you.

DR. VAN EENENNAAM: All right. Good morning, everyone. As was mentioned, I'm Alison Van Eenennaam. I'm a Cooperative Extension Specialist at University of California. And my background is a bachelor of agricultural science from the University of Melbourne -- hence the accent -- and a master of animal science and a Ph.D. of genetics at UC Davis.

I've been asked by the FDA to give an oral presentation today relating to the two food labeling questions that have been identified as the focus of this Part 15 hearing on the labeling of food from AquAdvantage salmon from the perspective of academia. While, that's a fairly broad task to give, a somewhat daunting task, because academia, as you probably already heard from yesterday's meeting, has a fairly diverse range of views with regard to this and many different perspectives, and no doubt many different opinions regarding this particular topic. And so I will choose to give it from the perspective of this academician's, rather than general academia. But I will reiterate that my training is in molecular genetics and animal science, and I'm not a specialist in food safety, per se.

In preparing for this presentation and yesterday's VMAC meeting, I thoroughly reviewed the background materials that were provided by the FDA, and of particular relevance to today's meeting, some of the relevant things to do with the principles of food labeling. And Abigail Brandel went through these basic

tenets with regards to what can and cannot be said on a label, and of course of importance today is number four, that FDA cannot require, as in mandate, mandatory labeling to include information about production methods if there is no material difference in the products due solely to the production process. Of course, voluntarily labeling is allowed. And as evidenced by these photos that are in my home state of California, marketers are making great use of voluntary labeling to develop a wide range of products catering to the preferences of different groups of consumers.

So the question of today's meeting is the following two questions, as was mentioned prior to the break. And really, I think, which facts about the AquAdvantage salmon seem most pertinent to the FDA's consideration of whether there are any material differences is really focusing on what the issue at hand is, and that is "material." It's this term that is the trigger for labeling, and a concrete definition is somewhat elusive. The background document attempts to explain the term and uses some really clear examples of where the term would apply, like high oleic acid, in

the case of soybean, or higher or lower protein content levels. The background reiterates that the FDA has not found that foods from GE organisms as a class present a difference, nor has the FDA found that as a class they differ materially in nutritional value, organoleptic properties, or functional characteristics.

So it's not being GE that in and of itself is going to require labeling, but rather whether there's a material difference. So the question we're being asked is what facts about the salmon are pertinent to the consideration of a material difference?

Well, I guess I'm not a lawyer, but I do like definitions. And so I went and looked up what "material" meant. And in this case, we're talking about an adjective, and it means of substantial import; of much consequence; or directly relevant to a matter, especially as it relates to war. Not surprising.

I like the definition "of much consequence," because it would seem that if there was a consequence associated with a change, that labeling would seem to be desirable to alert purchasers of a change. For example, oil from the species of the Brassica genus can

be 50 percent high erucic acid, in which case it is commonly called rapeseed and can be used for industrial purposes. Or it can have low levels of erucic acid and gluconsinolates, in which case it is commonly called canola and is used for cooking.

All foods are going to vary slightly in nutritional value, organoleptic properties, and functional characteristics, depending upon composition. There are voluntary labeling programs that market a value-added product on this basis. For example, certified Angus beef. That's a voluntary labeling program that some consumers desire beef derived from the Angus breed of cattle, suggesting that it differs in some way from non-Angus cattle. But those differences do not require mandatory labeling, as the changes are not of much consequence from a nutritional or a food safety perspective.

I'm therefore going to consider what differences of much consequence exist between foods from the AquAdvantage salmon and foods from other Atlantic salmon. In order to examine that question, we need to know not only the facts about the food from the

AquAdvantage salmon, but also facts about foods derived from conventional Atlantic salmon. In the absence of information about the amount of variability that exists in the latter, it's really not possible to evaluate if the differences observed in the food derived from the AquAdvantage salmon are of much consequence. This is an inherent problem with this process, as we do not routinely measure or require documentation of the amount of biological variation that exists in non-GE sources of food derived from different individuals, different location settings, and/or production systems.

I am not going to show you Ziggy. I think if I see Ziggy one more time (audience laughter), I -- I couldn't go there. I'm sparing you Ziggy. But I will remind those of you that were here yesterday -- some may not have been -- that the FDA used a hierarchical risks-based approach to assess GE animals and their edible products, as detailed in the briefing package that we received. It doesn't rely on a single critical study, but rather a cumulative weight of evidence approach provided by all the steps of the review.

The food and safety step of this hierarchical

review process included data that examined the identity, composition, and levels of the expression product of the rDNA construct, potential downstream hazards as influenced by the expression product, and allergenicity. The conclusion, as is stated on the slide, was that the FDA found that the food from Atlantic salmon was as safe as food from conventionally produced non-transgenic salmon, and no animal food concerns were identified.

The data, then, on this safety review package and the scientific literature were the information sources that I used to determine if there are any material differences between foods from AquAdvantage salmon and foods from Atlantic salmon. The package that we received detailed both direct effects and indirect effects. And for those of you that were not in the audience the last two days, these are explained as follows: Direct effects were defined as those that arise from the consumption of edible products from the GE animal, including exposure to the construct and its gene product, or as indirect effects were defined as those arising from perturbations of the physiology of

the AquAdvantage salmon from the introduction of the rDNA construct or its gene product that alter the composition of food. So both of these effects could potentially materially affect the composition of food.

As was outlined by the previous speaker, in looking at the direct effects, the package included information on whether the food product met the definition of being an Atlantic salmon, and they also looked at various hormones, as listed on this slide. The data showed there was no significant difference detected in those analyses. Now, this might seem contradictory to the extensive discussion on insulin-like growth factor in the packet. However, there was no significant difference between the main insulin growth factor-1 level for the GE and non-GE-diploid salmon, as indicated on this slide. In fact, the IGF1 data are only reported for six of the 30 GE salmon analyzed, indicating that the IGF1 levels for the remaining 24, or 80 percent of the GE fish, were below the assay detection limit. Likewise, the majority of the farmed control fish and sponsor control fish had no IGF1 data, implying that their values were also below

the detection limit of the assay.

However, because the range of the IGF1 values for the triploid GE salmon exceeded that of the non-GE diploid salmon by 10 percent, further analyses were triggered in the package, which was justified on the basis that, quote, "As part of the heuristic method applied to assessing data and information, our initial decision to begin assessing the biological relevance of any measurement began with determining whether that measurement exceeded the comparator range by 10 percent or more," end quote. For those of you who are interested, "heuristic" is defined as an adjective for experienced-based techniques that help in problem-solving, learning, and discovery.

However, there was, as a result of this, quite an extensive follow-up on this 10 percent variation. But there doesn't seem to be any particular scientific basis for selecting that 10 percent. As noted in a footnote, this 10 percent exceedance was chosen as an arbitrary value that triggers additional investigation to determine whether the exceedance has any biological significance. It does not imply that beyond a 10

percent difference, there is an a priori safety concern.

The reason I really emphasized this particular piece of data is that this finding was picked up in a New York Times article that was published on the 3rd of September, and it focused on this IGF1 analysis. And I quote from that article, "One issue that might attract some discussion at the public meetings is that the engineered salmon have slightly higher levels of insulin-like growth factor, a hormone related to growth hormone," end quote. That was followed up in the article by a discussion of the link between IGF1 in the bloodstream and cancer, although the article did note that there is not clear how IGF1 protein in food, which will presumably be digested in the gut, contributes to hormone levels in the blood.

The reason I go -- I bring this up is I go back to the premise of what changes of much consequence exist. And so the question is whether a non-significant change averaging an increase of .341 nanograms of IGF1 per gram in six out of 30 diploid-controlled salmon with levels of IGF1 above the

detectable level of the assay is of much consequence.

As I mentioned at the outset, I'm not a food safety expert. But I did look up the scientific literature and found that on average, humans produce about 10,000,000 nanograms of IGF1 per day and consume about 380,000 nanograms of IGF1 per day from gastrointestinal secretions. Further, the briefing package showed a seven-fold range of levels of endogenous IGF1 plasma levels among Chinook salmon individuals, as is shown on this slide, and a 20-fold range amongst different fish species. Given the levels of natural variation that exist in traditional fish food sources, and in looking at all of the available information, I concur with the statement regarding -- FDA statement regarding IGF1, which concludes that the margin of exposure to this endogenous component of food would be well within the levels of exposure from other dietary sources of salmon and poses no additional risk.

The next step in the potential allergenicity was to look at the potential allergenicity of the product. They follow the Codex guidelines recommended to determine whether the inserted protein is homologous

to known allergens. This was performed, and no homologies to known allergens were found. The Codex also recommends testing the introduced protein with a pepsin-resistance assay. This was not performed for the native Chinook salmon growth hormone, which is also routinely consumed, that's expressed in the ABT salmon, based on the premise that there is no scientific rationale to suggest an altered resistance to pepsin when this protein is expressed in Atlantic salmon, rather than Chinook salmon. A similar argument was made by the authors of other peer-reviewed literature where they were looking at the allergenicity of growth hormone transgenic and non-transgenic Amago salmon.

So using this weight of evidence approach, the FDA concluded in this case that the expression of the Chinook's growth hormone in ABT salmon does not present a new risk of an allergic reaction to salmon-allergic individuals and is unlikely to cause cross-allergenicic -- cross-reactions. No direct food consumption hazards were identified.

The next section was a detailed compositional analysis of 23 market-sized Atlantic salmon. And as

mentioned by the previous speaker, there was a number of different nutrients that were looked at in the food. And to cut a long story short, everything looked much the same. The conclusions were that the levels observed for analytes were the result of natural biological variation and are highly unlikely to be associated with toxicological or nutritional hazards to humans consuming ABT salmon.

I'd like to go back to a point I made at the beginning of this presentation. And that is, we do not require this level of detailed compositional data on any of the fish we normally consume, and we do not have a good idea of the normal biological variation that exists in food from non-transgenic Atlantic salmon. In the absence of this information about biological variation and natural variation that exists in such non-transgenic populations, it's difficult to judge whether any of the differences observed in food derived from AquAdvantage salmon are of much consequence.

Endogenous allergenicity was the final part that was looked at in the food safety component of this package. Endogenous allergens exist in a number of

food groups. The eight main food groups that cause endogenous allergens include cow's milk, eggs, fish, crustaceans, peanuts, soybeans, tree nuts, and weight. This is one of my favorite bags of peanuts I got on a Southwest flight one time. It was dry-roasted peanuts, but if you flipped over the bag, it warns you that it was produced in a facility that processes peanuts and other nuts. (Audience laughter) I sure hope so! Otherwise, I'm not eating what's in that bag. (Laughter) But, you know, allergens, endogenous allergens, are real. And I understand that people that are allergic to peanuts would have a very real concern about not wanting to eat peanuts.

Endogenous allergenicity testing, in the case of this salmon, refers to an examination of whether the food from the AquAdvantage salmon has more endogenous allergenicic (ph)proteins than food from a non-transgenic comparator. The problem, as was noted in the briefing package, is that there is no consensus in the scientific and medical communities regarding the magnitude of the increase in endogenous allergens in an already allergenicic food that would present an

additional risk to public health, especially given that individuals that are allergic to a particular food would likely avoid that food. Despite this problem, there was an examination of endogenous allergens. And this was based on the premise that in this part of the evaluation, we will look to see whether GE animals are more allergenic, that is, pose more of an allergic risk than their non-GE counterparts.

This begs the obvious question when it comes to analyzing the data, or even determining the appropriate sample size, and that is: what level of change would be unacceptable or acceptable? We do not have any information on the natural levels of variation that exist for allergens in the food we currently consume. Few studies have examined the natural variability of allergenicity that exist in traditional food sources -- different breeds of dairy cattle, species of fish, cultivars of nuts. It is known that natural variation exists in the allergenicity of available food crops and plants due to differences in the genetics of commercial varieties and interactions with the environment. In plants, there is a wide

variation in IGE binding to different varieties of the same species, and apart from differences between varieties, natural variability in allergenicity can also occur due to when the product is harvested, storage conditions, and even between individual apples from a single cultivar, there can be up to ten-fold differences in allergenicity have been reported.

In fish, the major allergens responsible for cross-reactivity amongst different species of fish and amphibians are the parvalbumins. These proteins control calcium flow in the muscular cytoplasm of the white meat and have a molecular weight of approximately 12 kilodaltons. This is known to be the major allergen in the white muscle of Atlantic salmon. That is an endogenous allergen in Atlantic salmon.

A recent paper showed that parvalbumin content in most commonly consumed fish species varies considerably. Differences range from several-fold to a hundred-fold. And you can see here that there is a range where herring have the most, followed by carp, redfish, salmon, trout in the middle, cod, mackerel, and tuna. Differences in herring and tuna parvalbumin

levels have been found to vary by a factor of a hundred-fold. This table shows there is a lot of natural variability in allergenicity among species that we eat and within an individual species.

I therefore had a very hard time evaluating the data on endogenous allergenicity in the AquAdvantage salmon to determine whether material differences existed. Firstly, the data did not provide information on variability between fish, and second, because I had no criteria to assess what level of change would pose more of an allergic risk and therefore be of consequence. I did, however, read in a scientific justification for assessing the level of endogenous allergens in the absence of knowledge of what amount of natural variability exists has been questioned in the scientific literature.

So given that the FDA report actually states that there is no consensus regarding this level, I did not find this section of the evaluation very useful. I further question the logic of performing experiments to determine whether GE fish have higher levels of endogenous allergens than their non-GE counterparts,

when we do not have or require analogous information on the fish we currently consume. In the absence of data on variation in non-GE populations and a validated approach to address the question of what level of change would be unacceptable, there is no way to evaluate whether material differences exist in the level of endogenous allergens that exist in GE fish, or for that matter, non-genetically-engineered fish.

One final point I'd like to make is as it relates to sample size. I've seen several comments on the Internet and various blogs saying the sample sizes used to evaluate this particular package were too small. Sample size determinations are always going to be a trade-off between power -- that is, correctly rejecting a false null hypothesis -- and the cost of obtaining additional data points. However, they are also predicated on the magnitude of the difference or the size of the effect that exists between the two populations. If there is a large difference between transgenic and control fish, then a smaller sample size will be sufficient to detect a significant difference. If there's a small difference, then a larger sample

size will be required to detect a significant difference. If there are no differences between transgenic and control fish, then an infinite sample size will still not detect a significant difference, but will generate additional cost with no further reduction in risk to public health. It is necessary, therefore, to determine what size of effect is biologically relevant or of consequence, in my vernacular, and the desired power in order to adequately determine what size of sample should be used in these type of analyses. And as I've outlined, that's difficult to determine when there's no clear metric to say what level would be of concern with regard to nutrients and allergens.

So back to the two questions that are the focus of this Part 15 hearing. Based on my evaluation of the facts in the AquAdvantage briefing packet and relative scientific literature and my reading of the applicable principles of food labeling, I do not consider that the data show that there are material differences of consequence between the food derived from the AquAdvantage salmon and foods from other

Atlantic salmon. Therefore, in an answer to the second question, which is a kind of a moot point at this stage, in the absence of material differences, mandatory labeling is not required. Of course, as outlined at the beginning of this presentation, labeling is allowed if it's not false or misleading.

Having said that, I would note, when I was taking a break from getting ready for this preparation, I went shopping for my family, because I, too, am a consumer in my spare time. And I stopped at the seafood counter of my local grocery store. And the manager there explained to me that all fresh fish is required to be labeled with a country of origin, as in the COOL Labeling Act, and also whether it is farm-raised or wild-caught under the provisions of the Country of Origin labeling law. And here you can see this particular Coho salmon was a farm-raised product of Canada. As he explained the labeling requirements to me, and in looking at the proposed location of the hatchery and grow-out facilities of the AquAdvantage salmon, it did occur to me that this particular product will carry the somewhat unique COOL label, which would

probably read something like, "Farm-raised product of Canada and Panama." That's the end of my presentation.

(Audience laughter)

MR. LANDA: Thank you, Dr. Van Eenennaam.

Any of the panel members have questions?

Alta Charo?

MS. CHARO: First, just as a comment, I've got to tell you, you're getting a great price on salmon at your local market.

(Audience laughter)

DR. VAN EENENNAAM: Oh, I -- I went over to your Whole Foods here. I thought California was expensive, but we're cheap. It must be that recession.

MS. CHARO: I was -- I very much appreciate your very detailed exposition on the methodological issues associated with understanding allergenicity in both conventionally raised and the AquAdvantage salmon. Most of your discussion focused on the materials that were prepared in the briefing packet and on your own analysis. Yesterday there was a fairly lengthy discussion by the VMAC of the same issue. And I wonder if you can offer some comments on the highlights of

that discussion and your evaluation of that discussion, just so that we can all put all the pieces together?

DR. VAN EENENNAAM: Well, if we're speaking specifically about endogenous allergens, as in, was there an increase in endogenous allergens, not surprisingly I said similar things in the VMAC yesterday as what I said today. And that is, that it seems nonsensical to me to ask -- to design an experiment to answer a question that you don't know what the -- how to interpret the answer. Don't ask a question if you don't know what answer you're looking for in terms of, you know, what is a level of difference that's significant? In the absence of that, any difference could be construed as being significant or not. And so I think at this stage, it's premature to do endogenous allergenicity testing when you've got hundred-fold variation within species -- amongst species of fish. And we really have, as I said, no agreed-upon, medically-derived, validated protocol to determine what level would be of public health concern.

And so it just concerns me if you do an experiment and you don't know -- you get the answer and

you don't know what that means.

MS. CHARO: If I may follow up just briefly, just because I'm trying to make sure that I understood everything that happened yesterday, and I'm sure people in the audience as well. Was there any biological mechanism identified that would suggest that the GE salmon would be more allergenic in any way than the conventionally bred salmon? Anything that would make you hypothesize that this was likely true?

DR. VAN EENENNAAM: No. It's a fast-growing salmon. We naturally select fast-growing salmon, as we do fast-growing Angus cattle and Hereford cattle and -- I guess there's no a priori reason to expect the endogenous allergenicity would go up in these animals.

MR. LANDA: Any other questions from the panel?

Thank you, Dr. Van Eenennaam.

Our next and last invited speaker is Gregory Jaffe, Director of the Biotechnology Project, Center for Science in the Public Interest. Mr. Jaffe was a member of USDA's Advisory Committee on Agricultural Biotechnology and 21st Century Agriculture and has also

served on FDA's Veterinary Medicine Advisory Committee.

Mr. Jaffe?

MR. JAFFE: Before I begin the substantive portion of my presentation, I want to thank FDA and the CFSAN staff for inviting me to make this presentation today on behalf of the Center for Science in the Public Interest. CSPI supports all the different efforts at FDA to make their 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 provide its views on the labeling issues surrounding the AquAdvantage salmon. CSPI believes that a similar public hearing and 60-day comment period should be 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 CSPI Biotechnology Project. CSPI is a non-profit consumer organization which was established almost 40 years ago. We work primarily on food and nutrition issues and publish a nutrition action health newsletter ten times

a year to educate consumers on issues surrounding food, health, diet, and healthy eating. 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 conflicts 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 and has been a major issue. 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 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 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 consumer can speak for all consumers, especially on such a controversial issue as genetically engineered organisms.

Just as consumers are diverse and pick many different products in the food marketplace, consumers are extremely diverse in their views on genetically engineered organisms. They have different views on 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 non-genetically engineered crops.

Consumers also have different views on the

safety of food 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 food from genetically engineered organisms. Many individual consumers and consumer organizations have called for mandatory labeling of products from genetically engineered organisms. Those who advocate for mandatory labeling have many reasons for their viewpoints, including concerns over safety, principles such as consumer choice and consumer right to know, and other reasons. Other organizations and individuals believe mandatory labeling is not called for, but welcome voluntary labeling that is truthful and not misleading. And 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

consumers or all U.S. consumer 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 which 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 AquAdvantage salmon, I want to explain the food labeling principles which 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; that labeling also must not be misleading to the consumer. Let me give you a few examples from CSPI's past.

For example, a number of years ago, CSPI sent a letter to FDA about a food called Quorn, Q-U-O-R-N, which was a meat substitute. The company labeled the food as a, quote, "mycoprotein" which came from a mushroom family. In fact, however, the substance was a Fusarium and was not from the mushroom family at all. To us, this was untruthful and misleading.

As another example, CSPI has complained numerous times when products call themselves, quote,

"all natural," but contain large amounts of high-fructose corn syrup -- in our opinion, not a natural ingredient. And CSPI has found false and misleading labels for products such as 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 there is any question in FDA's mind about the safety of a new food product, FDA 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 that drug in that fish. Approving the fish and putting 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 has also pushed

for many years for FDA to include trans fat on the nutrition facts label, as there was overwhelming evidence on 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 genetically engineered ingredients. While CSPI supports the right of consumers to provide -- 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 than 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 marketplace, such as claiming that sunflower oil is GE free, when there are no GE sunflowers out there. Similarly, we objected to

labels using the term "GMO free" -- free of genetically modified organisms -- when the product contains no organisms at all. For example, we pointed out that a particular jarred baby food that claimed to be GMO-free when no apples or apricot baby food has any organisms in it.

Finally, CSPI has not generally 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 different types of cloning, both nuclear and somatic, and so forth. We don't believe FDA should mandate that a label includes all the different production methods of a particular product or every ingredient in it.

Now, when it comes to labeling genetic engineered foods, CSPI did one poll of consumer

viewpoints back in 2001. The survey did not address genetically engineered animals or the AquAdvantage salmon. But it did inform the position that CSPI takes regarding the labeling of food made from genetically engineered organisms. In particular, I want to share one question from that survey with FDA and then some of the conclusions that we obtained from that survey.

The question reads, and it's up there on the screen, "Most agriculture uses many technologies to increase productivity. Do you think the words below should appear on the label of a food where one or more ingredients were from crops which were" -- and then we gave the person the different options. The results were, when the option was sprayed with pesticide, 76 percent of people said "Yes." When it was genetically engineered, 70 percent said "Yes." When it was treated with plant hormones, 65 percent said "Yes." When we said, made from cross-bred corn, 40 percent said "Yes." And then 12 percent didn't know or didn't have a response.

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 are more educated about agricultural production methods, the answer might be different. So in our mind, education and labeling must go hand-in-hand.

Thirdly, the survey asked about four types of information about four different production methods. But if we had asked about ten different types of information from ten different production methods, we guess that a majority of the public would have likely said "Yes," to include all ten pieces of information on the label. However, labels can't contain infinite amounts of information, and having too much information can be confusing to the consumer, as well as that information can compete with the 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 single basis -- no basis to single it out for different treatment. If the reason for labeling is providing consumers information they are interested in, then all production methods need to be treated the same.

So now I turn my attention to the AquAdvantage salmon and the two questions presented to the public today by FDA. Based on the documents from FDA about the AquAdvantage salmon, the data and risk assessment released by FDA's CBM earlier, and FDA's current policy regarding mandatory labeling, as discussed this morning and also was provided to the public, CSPI does not believe that the AquAdvantage salmon requires any special mandatory labeling. CSPI cannot identify in the public record any material differences between food from this salmon and from other Atlantic salmon that

would require a mandatory labeling that is consistent with the FDA policy.

However, if FDA does determine that there are material differences between food from this salmon and from other Atlantic salmon that requires some mandatory label information, CSPI believes it is very important that the language required by that label be neutral and informative. FDA should not necessarily require that that label include the word "genetic 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 difference in this particular salmon.

In addition, whatever label information is required, it is 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 the 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 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 out there who want to know if their salmon has been genetically engineered. Some may want to know about information to avoid eating those fillets, and others may want to know about information to make sure to support that product and eat those fillets. 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 quote, unquote, "real" voluntary labeling scheme for the food product from AquAdvantage salmon. When I say "real," I mean a voluntary scheme that is actually implemented, not just a concept that food chain participants can label if they want it but actually don't do it, for reasons of

fear or protest or losing market share. Such a scheme probably would not use the term "genetically engineered," but would brand the product in the marketplace. It might be a positive label for the company, such as, quote, "AquaBounty Salmon," unquote, or, quote, "Panamanian inland salmon," unquote, which would identify this salmon as unique in the marketplace. The label might promote the proposed benefits of the product, such as calling it, quote, "fast-growing salmon," end quote, or, quote, "environmentally friendly salmon," if those claims are truthful and have a basis for them.

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 either legal contracts or other market mechanisms to ensure that label was affixed throughout the food chain, similar to the way that a meat producer of Angus beef might want to make sure that their Angus beef is differentiated in the marketplace.

Another area where FDA could 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 on 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 legal and factual analysis to the public, and do so shortly after the public comment period has ended.

If the panel has any questions, I would be happy to take them. Thank you.

MR. LANDA: Thank, Mr. Jaffe.

I have one question for you. Could you talk a little bit more about absence labeling and criteria for absence labeling? I'm referring to your last -- essentially your last set of comments about voluntary labeling for AquAdvantage salmon.

MR. JAFFE: I mean, I think that absence labeling is something that -- that companies and products out there should be able to do. They should be able to identify the absence of something, whether it's a genetically engineered ingredient or something else in it.

I do think it's very important that that labeling be truthful and not misleading. And we've seen instances, especially with genetically engineered foods in the past, where that hasn't been the case. Sometimes companies have put the equivalent of a skull and crossbones on their products saying "No GMOs," and big red circles with lines through them that suggested that their product was somehow safer or superior to those other products, and maybe consumers wanted to pay more for them. And our view a lot of times has been that that is misleading for the consumer, and they're trying to get a premium for something that doesn't deserve a premium based on the facts.

So to us, it's very important. In the past, FDA had a voluntary -- has a guidance on the labeling of food from genetically engineered crops, and I think

they haven't gone far enough in providing guidance on what. They did a lot of guidance of what isn't allowed in the label, and less about what they could do. Since we have a specific case here of a genetically engineered salmon, and we know this is going to go out there and that there will be members in the marketplace, food companies that may want to do an absence label, I think beforehand the FDA should identify exactly what that label should be. And I haven't given an example here. I haven't said, "These are the six words that should be used," or the four words. But I think that that's something that FDA could come up with and provide to those companies that will be uniform beforehand. We know that it's truthful, we know that it's not misleading, and it's something that consumers who want to avoid this will know where to look for. Does that help?

MR. LANDA: Thank you.

Any other panel members have a question?

MR. JONES: Just -- just a question of clarification.

MR. LANDA: William Jones.

MR. JONES: Thanks. You did give an example, and I'm sorry, I didn't follow it. You mentioned something about baby food, about apples and apricots. And I wasn't sure what the example was. Could you elaborate on that example?

MR. JAFFE: Yeah, there were -- years ago, I mean I haven't looked recently -- there were a lot of products that said they don't have a GMO, and they don't have an organism in them. And although that is a term that's used somewhat in this country and clearly used around the world to identify genetically engineered organisms, is a GMO, some of these products had put that they didn't have a GMO on it. And an organism is also a scientific term. I mean, it is a living thing that can reproduce. And yet that baby food, for example, said it didn't have GMOs, suggesting that other baby foods that were made of apples and apricots had GMOs. But there are no -- there are no organisms in that. There's nothing that reproduces in that. There is not -- it's not an organism. Its ingredients come from organisms, but they aren't -- the apple itself and the apricots that are in that, that

form the basis of that jar of baby food, weren't organisms. So we were saying that that was misleading and untruthful. And FDA did send some warning letters to some of those companies, I believe, about that at that time. This was back in 2001.

Yes?

MR. LANDA: Alta Charo.

MS. CHARO: I'm like the little question girl over here.

Again, on your very last point about voluntary labeling, if there were no skull and crossbones, no circles, if there were only the words, "This product does not contain any ingredients from a GE source," and if that was, in fact, capable of substantiation, would you consider that to be misleading, or not misleading, in the absence of any further information, disclaimer, or symbols of danger or anything like that?

MR. JAFFE: I think that that would be okay when there is a comparable GE product in the marketplace. As long as, again, depending on how it's -- as you all know, it's not just the words, but it's also how it's presented. And so if that was presented

in a neutral way --

MS. CHARO: Right.

MR. JAFFE: -- in comparable letters and so forth, and type as other things on the -- on the label.

MS. CHARO: And provided there's a comparable product on the market that it is differentiating itself from?

MR. JAFFE: Yes.

MS. CHARO: Thank you.

MR. LANDA: Any other questions from the panel?

Thank you, Mr. Jaffe.

MR. JAFFE: Thank you.

MR. LANDA: We are going to reconvene at 12:45. I ask people to be here at 12:45 sharp. The first scheduled speaker is Michael Hansen from Consumers Union.

Thank you.

(BREAK)

MR. LANDA: Let's get started, please. It's 1:45. We're going to begin this afternoon with the public comment portion of the hearing today. And our

first speaker is Michael Hansen from Consumers Union.

Michael?

DR. HANSEN: Thank you very much.

My name is Michael Hansen. I'm a senior scientist at Consumers Union. And what I'm going to talk about is the reasons to label genetically engineered animals, including the AquaBounty salmon.

I will argue that there's actually three rationales to require this labeling. First, with the -- I'll go through the material fact analysis. And we argue that the FDA is incorrect, and that material facts are more than just organoleptic or compositional changes. We think there's also an ingredient -- there's also a reason to label, to consider these as a food ingredient. And third, labeling would be consistent with Codex, which has said that GE labeling can be used as a risk management measure to deal with scientific uncertainty.

So let's -- let's look at the material fact analysis. We believe that it does not always entail a change in nutritional value, organoleptic properties, or functional characteristics. And two examples where

the Agency has used this: first, with food irradiation, in the final rule on April 18th, they said, quote: Whether information is material under section 201(n) of the Act depends not on the abstract worth of the information, but on whether consumers view such information as important, and whether the omission of label information may mislead the consumer." The large number of consumer comments requesting retail labeling attest to the significance placed on such labeling by consumers. This was part of the reason. They also said there were organoleptic changes. But this shows that materiality isn't just a physical change.

We would also point out that in this mode, Consumers Union, our natural research center, did a national poll in October of 2008 and found that 95 percent of consumers polled believe, quote, "Food products made from genetically engineered animals should be labeled as such," and with 70 percent -- 78 percent strongly agreeing.

The second example is protein hydrosylates. On June 21st of 1991, the Agency said, quote, "The food

source of a protein hydrosylate is information of material importance for a person who desires to avoid certain foods for religious and cultural reasons." So that means when hydrolyzed protein is added to a processed product, it can't just say "hydrolyzed protein." You have to say where it came from, because if you're a vegetarian, you want to avoid things coming from animals. If you're a kosher Jew or a Halal Muslim, you want to avoid anything that comes from pigs. This is, again, no compositional other changes. It shows that you can label for religious or cultural reasons. I would point out that there is -- one of the groups that some of the opposition has been working with is, there is a group -- there is an Indian tribe called the Karuk. They're in northern California and Oregon. They actually revere salmon as an incredibly part of their diet. It's part of their culture. They were on conference calls with us saying that they do not want to eat engineered salmon, and they would like it to be labeled.

And so my concern is, if you can label the source of hydrolyzed proteins for vegetarians, Jews,

and Muslims, why can't you label it for an indigenous people that want this information? It's important to them. It is a material fact that we would argue. If you look at the food ingredient analysis, section 401(i) of the Federal Food, Drug and Cosmetic Act requires labeling of, quote, "ingredients," which are defined as, quote, "those substances that have been used to manufacture a food." The exception is for inherent natural constituents.

There was a federal court case and the law distinguishes between substance presence in foods due to quote, "acts of man," and, quote, "acts of nature." The former are considered added substances and must be labeled. And that court said that there's a higher safety standard for substances present due to acts of man. The example they gave is if a coffee processor subjects coffee to a process in which the naturally occurring caffeine is removed and later replaced with an equal amount of identical caffeine, it seems Congress would have a stricter health standard apply. Therefore, it's an ingredient.

We would argue that the genetic construct of a

Chinook growth hormone gene with an oceaned pout promoter which has actually been rearranged with a little bit, a little segment of the PVC backbone in there. That is a genetic construct that does not occur in nature, cannot really occur in nature as it is. And so it's an act of man, not an act of nature. And so therefore, you could consider that a food ingredient, because that's the only way it can be put in. So again, the food ingredient analysis says you could do this.

If we also look at Codex Alimentarius, they have said -- these are two paragraphs from the Codex principles for risk analysis in foods derived from modern biotechnology. Paragraph 18 states, Risk managers should take into account the uncertainties identified in a risk assessment and implement appropriate measure to manage these uncertainties. The following paragraph reads, Risk management measures may includes, as appropriate, food labeling, conditions for market approval, and post-market monitoring.

So they're saying food labeling can be required as a risk management measure to deal with

scientific uncertainties. If we now look at the guideline for the conduct of food safety assessments of food derived from recombinant DNA plants, this same language is in the animal document. It talks about, quote, Unintended effects due to genetic modification may be subdivided into two groups. Those that are, quote, "predictable" and those that are, quote, "unexpected." And a variety of data and information are necessary to assess unintended effects because no individual test can detect all possible unintended effects or identity with certainty those -- or identify with certainty those relevant to human health.

And so that clearly says you can require this labeling. And we would argue that there is, actually, a lot of scientific uncertainty. The increase in potential endogenous allergenicity which was demonstrated, that's an unintended effect. And if -- we would argue if you use molecular and other techniques to look at a more fine level, we would probably see even more unintended effects. And so you need this labeling so that if there's a problem down the road, you can trace it back.

So in conclusion, we say that the FDA does have statutory authority to require labeling of engineered animals. We also believe that material fact does not always entail a change in nutritional value, organoleptic properties, or functional characteristics, and we would like the FDA to say that specifically.

Third, the genetic construct used in the AquAdvantage salmon is a, quote, "act of man," and not a, quote, "act of nature," and could be labeled as such as a food ingredient.

And then finally, well, third, Codex says that genetic engineering labeling can be used as a risk management measure to deal with scientific uncertainty and to track any potential unexpected adverse health effects associated with the consumption of genetically engineered animals.

And finally, so our bottom line is, the FDA should require labeling of the AquAdvantage salmon, and indeed, all genetically engineered animals. They have the legal ability to do this, and our analysis of the two court cases where they said the court told them that they couldn't label unless there was a physical

difference, we think that's a misinterpretation of what the court ruled, as what the court actually said in both those cases is, if you decide there is no material difference, then you don't have any other way to require this labeling. But it didn't tell the Agency that you can't decide that this is a material difference. And again, we would argue that there's already examples for hydrolyzed proteins and food irradiation, when you have used that. So we think that there really does need to be labeling.

And I'll end there. Thank you. I'll take any questions.

MR. LANDA: Thank you. Any of the panelists have questions?

Jason Dietz?

MR. DIETZ: Thank you. Jason Dietz.

Dr. Hansen, you mentioned the use of labeling as a risk management tool. Is -- can you clarify for me, is it your view that such labeling should be required for foods derived from genetically engineered animals and also for other methods of production?

DR. HANSEN: Actually, no. The reason we

think -- genetically engineering, we think, is fundamentally different than other forms of breeding. There's been a global agreement on this. Because at Codex, they have required that there -- that there should be required safety assessments. So they've recognized that difference. And because of the concerns over these unexpected effects -- insertional mutagenesis and other things, I could actually go into a lot of technical detail -- that's why we think it is appropriate here. It is consistent with international global law, and so -- no, not necessarily for other methods unless they could be shown to cause some of the same problems.

MR. LANDA: Alta Charo?

MS. CHARO: Thank you very much. I was struck by the number of different motivations that bring people to want to see these labels on the product. And you cited, in particular, some people who have particular religious concerns and others who have qualms about the safety of a food. There's another group of people, as I understand it, who want these things labeled for reasons distant from the food

itself, but more concerns about the industrialization -
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DR. HANSEN: Well --

MS. CHARO: -- or globalization of agriculture as a general matter. So what I'd like to ask you is to discuss briefly whether it matters what the motivation is for wanting the label placed there. That is, can the fact that something is participating in the industrialization of agriculture then become a material fact that would justify this analysis?

DR. HANSEN: Right. Actually, I took less of my time. But yes, we actually that's a important fact. Consumers have a whole range of reasons. There's religious, cultural, or ethics. So some people could say that don't want to support what they view as an industrialized food system. There could be other people that say that they want to support these salmon because of those reasons. So all these various reasons that people have, we think they're valid, and they shouldn't be considered irrational or other things. So they might have moral, ethical, or a whole -- a whole range of reasons. If they're strongly held, then we

think that they should be followed.

MS. CHARO: Then, in the same -- in the same vein that Jason Dietz has questioned, I'm just trying to understand the universe of how generalizable this is. Speaking not to the other reasons about the religious or physical --

DR. HANSEN: Right.

MS. CHARO: -- but just this. If -- if similar arguments were made that I want to know about whether the -- the agricultural workers were unionized, because that -- (inaudible) don't know that's relevant to my notion of whether it's an ethical source of food Is that -- is this the beginning of a concept of what constitutes material that would be to those kinds of concerns?

DR. HANSEN: You know, I think you do have to have a cutoff someplace. But if -- if you did surveys, and consistently 95 percent of the people said that that was something that was really important to them, and they actually wanted it, then I suppose so. But I don't see that happening. I don't think you're going to see this whole plethora of things. I do think that

many of those concerns can be dealt with with ecolabels, and those should be, you know, held to a very high -- high standard. But we already see labels like that. That's -- that's sort of fine, but when you move over to the mandatory, I think there's something that's fundamentally different about genetic engineering. There's global, all this global concern. And so that is a unique and special case.

MR. LANDA: Just a question, going back to Codex again, just to clarify. The Codex standard presupposes a risk -- a risk to manage; correct?

DR. HANSEN: Yes. I should make clear that this does not mean there should not be proper safety assessments. There should be, and in fact we point out if you look at drugs, you can require all the safety testing before drugs are put on the -- on the market. But once you go from testing on a hundred or a thousand to maybe exposure to millions or tens of millions or hundreds of millions, then that means that rare side effects can show up that you don't see in your initial pre-market phase. Even if you do very accurate safety testing that I would sign off on, you can still have

these unintended effects, that when you get to large populations you see them. You have to have some way to track that, and that's what we see with drugs, that people know which drugs they've been taking, so they -- they do that.

MR. LANDA: Thank you.

Any other questions? William Jones.

MR. JONES: I have just one point of clarification regarding your food ingredient concerns. Is the food ingredient the recombinant construct or the final product of gene expression?

DR. HANSEN: Well, they talk about the ingredients. Since this is this drug, they considering that the drug itself is the genetic construct. Then I would say yes, that's the ingredient. Because it's sort of the way that it's added. Just like the court said with caffeine, you know, that's an act of man even though the molecule might be the same. So the fact that it's a Chinook growth hormone protein and it's fine in salmon, the fact of the matter is is that's an act of man and not an act of nature. So even if what's the resulting thing is identical, there still should be

that different standard because it's an act of man, just as the court said in the Anderson Seafood case.

MR. LANDA: Thank you, Dr. Hansen.

DR. HANSEN: Thank you.

MR. LANDA: Our next speaker is Dr. David Groman, University of Prince Edward Island, Atlantic Veterinary College, Charlottetown.

DR. GROMAN: All right. I want to thank the panel for allowing me to present today as a commentary on this issue. I'm participating here as a person who actually did studies on the morphometry of these AquAdvantage salmon. And I'd like to present some of those results to you today and give you my personal and professional opinion on why I think this salmon should not be labeled as GE.

The primary objective of this study was to determine the health and welfare of diploid 2N and triploid 3N AquAdvantage salmon. These are called the treated ones at the stage of development that would facilitate the identification of acute treatment-related clinical relevant change, or lack thereof, associated with the AquAdvantage transgenesis.

Size-matched diploid and triploid non-transgenic salmon or sponsor controls were examined. They were grown under same conditions and used as comparators.

So, this is sort of the facility we worked in, just to show you the operation where we did the morphometry work, where we did the post-mortems. So here's a sample protocol. We had a single blind comparator controlled investigation of animal safety based on gross anatomy and histopathology, as well as clinical pathology parameters. I'm only going to speak today on the gross pathology, anatomy, and histopathology, not the clinical pathology parameters.

The external examination of the animals, subject animal population, was conducted, and it comprised a scoring system of eight individual physical characteristics: the jaw, the operculum, the gill, the fins, the vertebral column, the eyes, the skin, and color markings, et cetera. Internal examination, as well, was conducted on a scoring system of nine internal organs and structures. These included gonad, GI tract, liver, spleen, swim bladder, kidney, heart,

body wall, and cranium. Tissues were examined by brightfield microscopy, as well, in an unblinded manner with full access to the pertinent data from the necropsies.

So, some of the study findings. This would have to do with the gross observations externally. Of the 216 observations made during the internal examinations of each of the treated and sponsor controls -- let's go backwards, missed that. Of the 192 observations that were done for the external examinations of each of the treated and sponsor controls, abnormal findings were only reported 18 times, or 9 percent, for the former and 25 times, or 13 percent, for the latter -- the latter being the normal or -- normal salmon. The number of findings was considered larger for triploid fish, the 3N fish, for both treatments, which findings were related predominantly to abnormal gill structure in the triploids and a similar pattern of abnormal findings for the satellite controls in the triploids.

Internally, there were 216 observations made during the internal exam for the treated and sponsors,

and abnormal findings were 12 times, 6 percent of the time, for the former and 10 percent of the time for the latter, or the sponsor controls. The number of abnormal findings was similar among diploid and triploid fish in both treatments, and similar patterns of abnormal findings were observed for all the satellite controls.

So if we look at the gross observations, there was a wide variety of changes seen in the study, AquAdvantage -- more prevalent among AquAdvantage salmon, the sponsor size match or satellite H match controls. However, a few types of gross findings involving gill arches and fins were substantially more prevalent among triploids than diploid salmon, and marginally higher prevalence of cardiac, misshapen hearts, were found in triploids than in diploid salmon, as well. Histologically, when all these organs were examined by a consulting pathologist and myself, a wide variety of microscopic diagnoses were involving the systems and organs of the study were found. And in this case, the AquAdvantage salmon, more so than the sponsor satellite controls. Diploid AquAdvantage

salmon had an increased prevalence of local inflammatory lesions. A wide variety of other histopathological changes were recorded in this study, none of which appeared to be related either to genotype or ploidy of the fish. Most of these changes were consistent with anticipated background findings and of relatively low severity. This is typical of what you would find in aquaculture-reared fish worldwide.

So I just want to show you a few images here. Here are some diploid controls, lateral views. Here's some diploid treated lateral views. And just to blow that up a bit, there's a diploid control fish, your normal salmon, 2N. And here's your diploid treated or AquAdvantage salmon.

Again, if we look at the triploids, we have triploid controls here and triploid treated. And if we look at the triploid controls and triploid treated, no significant difference is noted morphologically.

So quickly in conclusion, the significant pathology findings in this study associated with the transgenesis included increased prevalence of minimal (inaudible) focal inflammation in the histological

sections of an unknown cause, especially among diploid fish, and a low occurrence of jaw erosions among both male and female diploids. The majority of other findings, were included gill and fin abnormalities, soft tissue mineralization, hepatic vacularization, cardiac shape abnormalities, were associated only with triploid fish and are typically found in triploid fish in production systems worldwide.

So from my perspective as a professional diagnostic fish -- morphological fish pathologist, I could find no significant differences between these two animals. And I would -- that indicates to me that there's really reasonable justification for labeling them as being different from the normal salmon being reared worldwide right now.

Any questions?

MR. LANDA: Members of the panel have any questions? Jason Dietz.

MR. DIETZ: Thank you. I was wondering if you could comment on the extent to which the pathological examination that you would have done, how that might inform the characteristics of food derived from the

fish?

DR. GROMAN: You're referring to what we found as far as the diversity of small lesions or minor lesions in the fish?

MR. DIETZ: I would say everything --

DR. GROMAN: Okay.

MR. DIETZ: -- that you found.

DR. GROMAN: Everything that we found would be typically found in a normal production facility, either in Chile, Norway, Scotland, Canada, or the United States, for that matter. The -- I have over 30 years of experience in this field of diagnostic fish pathology and 22 years specifically with Atlantic salmon. And I could safely say that if I get into any given population, I could find a more diverse range of lesions in normal fish. Normal, clinically healthy fish.

MR. LANDA: Any other questions from the panel?

Thank you, Dr. Groman.

Our next speaker is Patricia Lovera from Food and Water Watch, Washington, D.C.

MS. LOVERA: Hi, good afternoon. My name is Patty Lovera. I work with the consumer group, Food and Water Watch. We're a national non-profit organization. We have an office here in D.C.

So our members and supporters are extremely concerned about the prospect of genetically engineered salmon entering the food supply. Over 45,000 of them have submitted comments to say so to the FDA, and many other groups have also been submitting comments from their membership, really expressing the level of outrage they have about this potential product reaching the market.

In addition to that overall concern, which we think is worthy of a few more days of discussion rather than rushing towards this issue of whether or not to label it when it hits the market, we do have some thoughts on the labeling issue, which I'll go into now.

Labeling genetically engineered products or transgenic products is not a new controversy. Consumers are -- are growing, becoming more and more aware of it, and they're not happy about it. So our group, and lots of other groups you're going to hear

from today, are veterans of the battles over rBGH labeling for milk and dairy products, and we've been suffering the consequences of bad FDA policy on this labeling issue for a long time. So this is not new, and we think that that context is important and there are lessons to be learned from these previous battles. The first one being, we can't fix a bad approval decision with a labeling decision, but the least you can do if you put these products on the market is let consumers decide for themselves. We need labeling to do that.

So as I mentioned, we feel that this labeling discussion is a little premature. The Veterinary Medicine Advisory Committee discussion exposed a lot of gaps in what we have in terms of data and understanding about this product, and we think that there's a lot more that should be done to prove that this product is safe before we have this discussion of how to market it.

But since we're here and we're talking about labeling, we just want to put some context out there about what consumers want, what they expect, and how,

to date, the labeling policy of FDA has not been meeting those expectations.

American consumers have resoundingly, consistently voiced their distaste for genetically engineered food for as long as it's been on the market. And they've also resoundingly expressed their belief that genetically engineered food should be labeled. In just a small sampling of the consumer polls that are out there, I pulled a few up yesterday. Dr. Hansen mentioned one from Consumers Union that showed 95 percent of respondents believe these foods should be labeled. Another conducted in 2001 by ABC News showed that 93 percent of respondents want these foods labeled, and another even earlier poll by Novartis, Inc. in 1997 showed that 93 percent of respondents wanted foods that are genetically altered to be clearly identified with labels.

In addition to this consumer polling, every trend in the food industry shows that consumers want more information, not less. Whether you're talking about the growth of the local food movement, direct marketing -- everything that's happening in the world

of food is consumers saying, "I want to decide for myself, because I don't like things that are happening." They need information to do that, and in most product transactions, a label is the information they get. This is a critical issue for consumers to decide for themselves, and increasingly, they're being failed by these policies.

So overall on the question of material difference, we agree with Dr. Hansen that the act of genetic engineering is material. Consumer want to know that. We think that they have a right to know that. And in addition, to get more into the specifics of the discussion of what we've been talking about, this particular fish, even with the limited data, even with the quality problems that were exposed in the last two days of conversation and the hesitance that I think some members of the committee showed to make decisions based on that bad data, we've seen a lot of differences. And we need to let consumers know that if this product reaches the market.

So I'm not going to go chapter and verse through every page of this -- this summary that was put

out there. But there were a few highlights for us that we think consumers need to know about. One is the issue of hormone levels. We're having conversations about IGF1 in other products. The science there isn't finished, but consumers are concerned, and they have good reason to be concerned. And the movement that we've been seeing, and the fights we've been having about rGBH labeling, often the decision point for consumers is their concerns about hormone levels. Now we're talking about another food where we could be trying to parse how significant or not significant the hormone variations are. Consumers have these concerns. Those concerns are justified, and they information to act on them. Even if the science isn't complete, they deserve to know.

The market response to rBGH is in part a market response to consumer concerns about these hormones, and they're going to be concerned about this in fish, as well. So this is a material difference that matters to consumers. We've seen that in the marketplace as we have a lot of other discussions about labels.

In other parts of the assessment, whether it's the morphology of the fish, inflammation, potential allergy risk to consumers -- we saw example after example where even with limited data, even if all these questions about whether it was sufficient to make an assessment, that the FDA saw enough there to do further analysis, to talk about what the exposure models might be. They saw some differences there that they thought they had to pursue. That, to us, is a material difference, and it should trigger this labeling requirement.

If this product -- excuse me.

The other differences that we need to be talking about weren't covered in the summary documents that we've seen for the last week -- two weeks. And Dr. Hansen mentioned a few of these. There are other things that motivate consumers in addition to their very serious concerns about health, allergies, nutrition content, and all of the things where we think we've seen these differences. Those concerns are ethical issues, environmental issues -- that's material to consumers. They want to know that. They want to

know what's different in this food versus another food. And those have to be recognized, and we failed to have that discussion yet.

So I think it's worth pointing to one other expert source. The National Resource Council did a report a few years ago that noted some religious, spiritual, ethnic and cultural groups proscribe dietary norms or rules that include foods that are to be avoided. These norms or religious traditions might be violated by genetic engineering of animals used as food. And they go on to say that genetic engineering is an aspect of the identity of the food. That's the difference. That's what should trigger this labeling requirement, because consumers absolutely do want to know, and they deserve to know.

So finally, to wrap up and to deal specifically with the questions the FDA posed for this meeting, and the first question, which facts seem most pertinent for FDA's consideration? So we think that these differences in composition and potential nutrition issues, the allergy potential, the hormone levels, and these differences in production are -- are

material. And they are pertinent in this labeling discussion. They're significant to consumers who are looking for information about all of these issues when they make food decisions, and we think that they should trigger this labeling requirement.

For the second question, if FDA determined that there are these differences, how would that difference be described on the food label in a way that's truthful and non-misleading? I mean, even in the background paper for this meeting today, FDA described genetic engineering as something that's intended to introduce new characteristics or traits into an organism. And when those organisms are destined to be human food, these new characteristics and traits are significant to consumers; they're material to consumers; and they're very, very important for consumers to know about. So consumers are looking for labels that communicate these differences clearly, and they want to know what attribute has changed.

So in this case, we would suggest something along the lines of genetically engineered, farm-raised salmon as an accurate label that conveys something

meaningful and truthful. Additional information that we -- should be considered as included in that would be something along the lines of genetically engineered for faster growth, or genetically engineered for growth promotion.

You know, we've had a lot of complicated discussions over the last couple days, and that's what these debates tend to be about. But the bottom line for our members and our supporters and lots of other consumers around the country is that the burden should not be put on them to navigate all of these legal and statistical and, you know, biochemical discussions. They shouldn't have to bring a textbook to the grocery store to go shopping. These labels have to be clear. They shouldn't be misleading, but they should be there, because they deserve to have this information.

So we are not willing to settle for making other labels do double duty. We're not going to settle for country of origin labeling being used as code for how we're somehow supposed to educate people which countries are producing genetically engineered salmon this year. That is not acceptable. That's not a label

that discloses what we need.

So to wrap up, the FDA's past record on the labeling of genetically engineered foods has failed to provide consumers with what they need to know, and the material difference standard has been basically depriving them on the right to know. So we urge the Agency to change that standard. But if you're going to use that standard, then genetically engineered salmon meets it, and it should be labeled if it's approved.

Thanks.

MR. LANDA: Thank you. Are there any questions from the panel?

MS. BILLINGSLEA: Felicia Billingslea, FDA.

I would like for you, if you could, to elaborate a little more on really what the messaging is in terms of how to use the food, what specific attributes may be changed in the food if the food says genetically engineered. I mean, through your presentation you mentioned things like allergens. You mentioned that there was concern about hormone levels. But if the food simply says, genetically engineered, how does that convey that to a consumer?

MS. LOVERA: Well, we've heard a lot about education, and I assume that the industry is going to be trying to educate or market this product in a way. And then I think that consumers are starting to become much more savvy and much more inquisitive about what these technologies are. And so some of this is we're dealing with the real estate on a package of what you can fit. We'd like to say a lot more, but we have to be realistic about what you can fit on a package and what it says. So we need to, we think that's an accurate description of what's happened -- it's been genetically engineered. And then if the industry wants to put out there that this is the best thing ever and people should buy it, consumers can make that decision because they have the information. And if consumers have concerns about it because they've done some reading or done other investigating, and they see that label, then they can choose not to buy it. That's where the information and the awareness comes in. But at least they know the distinction between two different products.

MR. LANDA: Any other questions from the

panel? Alta Charo.

MS. CHARO: The last couple of decades, we've seen a number of companies respond to this consumer demand, motivated by many things, by a whole series of voluntary labels having to do with natural or organic and variations on that. Can you reflect a little bit on the experience with that voluntary labeling and talk to us about your thoughts on its strengths and weaknesses in terms of how well it responds to consumer desire?

MS. LOVERA: There's a huge array of consumer labels that we're dealing with. And we have -- we have opinions on lots of them. In the different agencies, we're talking about those labels all the time. Labels like natural absolutely have the potential to be misleading because they're so broad; they're not specific, and we've had lots of conversations with USDA about "natural" labels on meats, or "naturally raised" labels for animals. So there's a lot of, I think, consumer advocacy thinking about what meaningful labels are. The one example that is so contentious, and we spend so much time on, which is very frustrating, is

this rBGH example. Because we feel like the first mistake that was made, technically, was putting it on the market. The second mistake that was made that compounded that was by not requiring a labeling disclosure. And then on that, companies that wanted to put a voluntary label on, saying, We do not use milk from cows treated with this artificial hormone, their life has been very, very hard over the last 15 years trying to do that, because there's been lots of obstacles thrown up in them even voluntarily communicating that information. And that's been incredibly frustrating for lots of producers and incredibly frustrating for lots of consumers, to the point that we've had multiple states getting involved trying to outlaw, you know, producers saying something to their customers that their customers are looking for. It's a messy, messy area to put all the burden of this on a voluntary absence labeling regime, when the core issue that our members, at least, are looking for is to disclose who used it in the first place. So we're very frustrated with navigating the voluntary absence arena when the real issue should be an

affirmative label from folks that are using it.

MR. LANDA: Any other questions?

Thank you.

MS. LOVERA: Thanks.

MR. LANDA: Our next speaker is Richard Clothier from AquaBounty Technologies, Waltham, Mass.

MR. CLOTHIER: Thank you, Chairman. Good afternoon, ladies and gentlemen. I'm Chairman of AquaBounty Technologies and have been since 2006 when the company went to the London Stock Market to raise the funds for this part of the development of this product.

I've spent 40 years in the food industry, in most of the sectors, ranging from genetics to primary agricultural production, through processing and the management of food brands. And I've operated in companies and managed companies in most of the regions of the world, including the U.S.A.

And notably absent from this meeting, and also yesterday's, was the food industry. I mean, there's hardly a producer in sight. I don't believe there's a food producer here, although I'd be pleased to meet him

or her. And I know there's one would-be producer in the form of American Salmon Company. But that's all.

And as a food producer, I have to say I have not before seen a product with the potential that this one has to so effectively the issues in its food sector. These issues are driven partly by the fact that there's growing demand for this particular product for food. And the existing systems of production, whether it be wild-caught from the sea or whether it be from the sea cages and such like, are under considerable pressure. This has been resulting in some big disease outbreaks and things like that.

This -- this fish and the technology that it brings with it is -- allows a new production system to be established, one that would not be economically viable with the existing Atlantic salmon. And it also, at the same time, is a production system that substantially reduces pressure on the environment. So we've got a means of increasing production and the very means that reduces the pressure, the problems that we've heard about in our environmental discussions. That's quite unusual combination, and therefore a

proposition, I think, that should be taken seriously, and so it is.

On the matter of labeling, I hope that my chief executive won't be too irritated if I say that I don't really think AquaBounty is anything but neutral on this -- in principle on this issue. We will label the product that we supply to our customers, no question about that. That's clear in the information we've heard already, and it's obvious. So the eggs are going to go off with a clear label.

So it's the next stage, thinking about customers, the fish producer. Now, actually, he is very used to some very strict procedures in production processing, the traceability procedures that he has to follow. And if he had to label it, I doubt if it would be a great burden on him. It's the following stage, it's the stage of food processing and retailing, where the problems really arise. And the requirement to label AquAdvantage salmon might lead to the argument to do a whole lot of other things. It might lead to an argument that a lot of existing -- thousands of existing products -- that are on the supermarket

shelves need to be reconsidered for some kind of labeling. It would certainly lead to the argument that new products in the pipeline coming forward would have to consider this whole issue. Well, they will, but if it complicated the process, that would be a pity.

Following AquAdvantage salmon, there will be an increasing list of really quite elegant solutions, increasingly elegant solutions, more so than we've perhaps even got on the -- on the -- in question today. Solutions to the challenges of feeding the world, and a clear lead by the regulators will greatly help the planning and the financing, I have to say, of these projects and will avoid the confusion. There's no limit to the demands of labeling if everybody was to have their way. And if there is muddle and delay resulting from pressure from people who refuse to accept the very thorough work of the world's most respected food regulating agency, that would be a dreadful loss of opportunity and a waste of the great technical skills that this country has.

Thank you.

MR. LANDA: Would you wait just a minute,

please? See if there are any questions?

MR. CLOTHIER: I doubt there will be.

MR. LANDA: Are there any -- are there any questions from the panel?

MR. CLOTHIER: Thank you.

MR. LANDA: Thank you.

Our next speaker is George Kimbrell. Are you going to be speaking for the International Center for Technology Assessment?

MR. KIMBRELL: And the Center for Food Safety.

MR. LANDA: And the Center for Food Safety. All in ten minutes; correct?

MR. KIMBRELL: That's right. Right, you can hold me to it.

Hello, good afternoon. I am George Kimbrell, Senior Staff Attorney for the Center for Food Safety. I practice environmental and administrative law, with a focus on the impacts of industrial agriculture. I'm also an adjunct professor at Lewis and Clark Law School, where I teach sustainable food and agriculture law. But here today, I'm representing CFS.

Center for Food Safety is a nationwide public

interest organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and promoting organic and other sustainable agriculture alternatives. We will be filing formal comments, so this is kind of a summary and a preview of what we'll be filing by the deadline.

CFS has an active program in genetically modified organisms where we work on policy issues, scientific issues, outreach, in addition to being the leading legal public interest firm that litigates cases dealing with GE organisms. Among some of our case most recently in the last four or five years are Monsanto v. Geardson(ph) Seed Farms, which went to the Supreme Court this summer, the first case to do so on genetically modified crops, regarding genetic engineering of alfalfa; Center for Food Safety v. Vilsak, which is about genetically engineered sugar beets; Center for Biological diversity v. Vilsak, which is about the field testing of genetically engineered eucalyptus trees; Delaware Audubon Society v. Salazar --these are all 2009, 2010 cases -- which deals with the

planting of genetically engineered crops on National Wildlife Refuges in Delaware; International Center for Technology Assessment v. Johann, which deals with Scotts Grass Company and the field testing of genetically engineered grasses. Each of those cases, by the way, that are complete, the courts have held that the respective defendant agency's approval and/or use of the planting of the GE organism in question violated U.S. environmental laws.

CFS was also counsel in some of the earlier cases cited in the agency's background document, including the Alliance for Bio Integrity.

So before summarizing our labeling comments, to ensure context here, I want to return briefly to the last two days. CFS' fundamental position is that FDA should not approve the transgenic salmon. Our further position is that any approval of this salmon under the 2009 guidance, of any genetically engineered animal under that guidance as currently constituated (ph), including the salmon, will violate the FFDCA because the guidance as applied is arbitrary and capricious implementation of FDA statutory authority.

The Agency's misapplication of the guidance and the apples and oranges involved here was shown yesterday at the VMAC discussion as the expert panel struggled to apply the data and legal definition parameters of veterinary drug approvals to a genetically engineered animal. The inappropriate frame is also shown by the purported benefits of this drug, as we just heard about from AquaBounty's CEO, which include, quote, "feeding the world." Which, by the way, is a novel claim for a biotech crop that I've never heard before. Drug approvals are supposed to help the animal in question, animal drugs. They're not supposed to be general claims of feeding the world.

Finally, CFS' further position about the approval is that it currently violates the National Environmental Policy Act, and potentially the Endangered Species Act, since the agency is limiting its approval -- its review under those statutes to just the particular two sites that have been proposed thus far. It's very clear that AquaBounty's intentions go far beyond that in its production and that they can't make money just using the site in Panama. So in other

words, this is a part of a larger commercialization plan, and all of the aspects of that need to be assessed by the Agency at the outset.

On the process of having this labeling discussion today, I think one point I wanted to make is that it seems inappropriate to hold a hearing on the labeling of a product that the Agency has yet to approve. The assumption is that the -- yesterday's VMAC meeting essentially was a foregone conclusion. To ensure meaningful comment, the Agency should have had this meeting if and when it approved the AquaBounty salmon, and only after that initial decision had been made.

I wanted to talk a little bit about constitutional principles here. The Supreme Court, in Liquormart v. Rhode Island, 517 U.S. 484 (1996), said, quote: "The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives as their own good. Some of the ideas or information are vital. Some are of slight worth. But the general rule is that the speaker and the audience, not the

government, assesses the value of the information presented," unquote. This seems in stark contrast to FDA's position on materiality and when they have the authority to label, as was shown in the background document for this meeting.

I think in general, our view is that the Agency is not bound by that determination in any way. Dr. Hansen showed that in other contexts, the irradiation context being one of them, previously the Agency has had a different view of what materiality is. And certainly the one point I want to stress is that the FDA, using this 1990 interpretation of materiality, it's an outdated view. We've got a 21st century issue here to deal with, and we're using a 1990 interpretation, a 20th century policy position, to try to deal with it. And this is not -- this is kind of the tip of the iceberg. We have new issues like nanotechnology and synthetic biology that are also under FDA's jurisdiction and will further highlight this flaw. Modernize your view of materiality.

Something else has fundamentally changed since the early 1990s, as well. The litany of cases that I

just laid out at the beginning, in which courts have held that transgenic pollution, gene flow pollution, is a cognizable injury in varied legal contexts -- for purposes of standing, for purposes of the merits, and for purposes of relief -- in both the administrative law and tort law contexts. Gene flow harm is a cognizable injury. The courts have said it matters, and FDA should, too, in this context.

Additionally, the Grass concept, which underscores much of the labeling determination here. The decision to hold novel transgenic constructs such as the one at issue here is not forever set in stone, but rather a presumption. Presumptions are rebuttable, at the Agency level or in a court of law. Recent findings about the nature of non-coding DNA sections of the genome suggests that the Grass finding should require demonstration by the company, supported by clear data, not simply an assertion by the FDA as though it were a fact.

I'm not going to talk about the health effects and why they meet the Agency's definition of materiality, because I think other people have already

and will later on. So what I've tried to do with part of the presentation is cover different -- different area.

Another thing I wanted to raise was the issue of the potential environmental impacts. If health impacts are cognizable under the materiality determination, why shouldn't environmental impacts be, as well? In our view, the potential risks here of the escape of the transgenic -- and transgenic contamination from this salmon, a new form of an invasive species that risks the extinction of our salmon stocks, which are already teetering on the brink -- this type of harm is cognizable. It's material. It's matters. And so to that extent, the Agency should consider that in its materiality determination.

The court has also given us deference -- given us guidance in United States v. Ninety-five Barrels of More or Less Alleged Apple Cider, 265 U.S. 435, finding the relevant inquiry here was regarding whether a different name or label was whether the new product differs from what consumers would expect the product to be under its conventional name. The rationale here is

preventing deception, apart from and in addition to alerting to consumers to health and environmental impact concerns. Clearly for consumers, as you've heard, 171,000 of them in a very brief comment period, two weeks, said that this matters to them and would be deceptive to them. They would not expect a, quote, Atlantic salmon to contain genetics from other animals -- other salmons, much less an eel.

The bottom line for us is that absent further data and a new regulatory mechanism with binding regulations and GE animals specific data requirements in which to apply that data, as well as a programmatic EIS on the undertaking, the Agency should deny approval, deny approval of this transgenic fish under the parameters proposed or any other. If the FDA is not going to require more rigorous testing, a disinterested scientific study before approving the salmon for human consumption, they should at least require it be labeled differently -- like two-thirds of the world does, unlike us -- from other salmon to allow consumers to decide for themselves whether to take on these unknown health and environmental risks. The

public's right to know what they eat and feed their families, as supported by constitutional and statutory law, requires nothing less.

I also wanted to note that someone talked about the voluntary labeling that's been in some different contexts, non-GE labeling. And I wanted to say, in our view, the market is not an adequate substitute for proper regulation, and we have copious examples of that recently in Wall Street, the housing bubble, and the oil spill in the Gulf.

Thank you.

MR. LANDA: Thank you.

Are there any questions for Mr. Kimbrell?

Jason Dietz.

MR. DIETZ: Thank you. Jason Dietz.

You've articulated your view that you believe that food from this particular fish should be labeled. What exactly would that label disclose to address the concerns that you have raised?

MR. KIMBRELL: Well, I think, as others have argued today, we would want it say genetically engineered, transgenic, something of that nature.

Farmed GE fish -- some way to communicate that, because in our view, number one, that's a material fact. But beyond that, it would depend on what -- the spacing on the label, the practicality that was able to -- and the priorities of the Agency. If it's allergenicity, if it's -- whatever it is beyond that, but that's the baseline.

MR. LANDA: William Jones?

MR. JONES: Thank you. You mentioned the need for a modernized view of materiality. Could you elaborate just a little bit on what you would like that modernized view to be with respect to products from -- from this?

MR. KIMBRELL: Well, I think the bottom line is, it should encompass it. You know, but to the extent organoleptic means touch, taste, these -- it's an old way of looking at things. It needs to be updated to deal with emerging technologies. You've got nanotechnology right now where you've got fundamentally different properties with the same chemical molecular formula of substances, except they're a billionth of a meter in scale. You've got synthetic biology. A lot of

these new and emerging technologies are going to challenge our underlying paradigms about how we regulate things and how we label things. And so I think our agencies, we hope, are up for it, but they've got to adjust.

MR. LANDA: Any other questions?

Thank you.

Our next speaker is Lisa Weddig, with the National Fisheries Institute.

MS. WEDDIG: Thank you very much. My name is Lisa Weddig. I'm the Director of Regulatory and Technical Affairs with the National Fisheries Institute.

I'd like to thank FDA for the opportunity to address the labeling of the AquaBounty salmon at this important Part 15 public hearing.

The National Fisheries Institute is a trade association representing all aspects of the seafood industry. Our members range from harvesters, processors, importers, and distributors to retail and food service operations. NFI members work hard to ensure the use of practices that promote the

sustainability, quality, and most importantly, safety of their products. In addition, NFI members have made a public commitment to follow fair and lawful business practices and efforts to curb fraudulent practices in the industry, including ensuring the products are correctly labeled for identity and adhering to all labeling laws.

The decision made by FDA with regards to labeling genetically engineered fish, should it be approved, will be reflected in NFI's economic integrity parameters. NFI has reviewed the applicable principles of labeling foods as outlined in the Agency's background document issued in advance of this hearing and supports FDA's consistent interpretation of the pertinent labeling parameters of the federal Food, Drug and Cosmetic Act. These interpretations for what is false and misleading mirror other decisions by the Agency and the courts, such as the 2001 guidance to industry on voluntary labeling for foods that have or have not been developed using bioengineering; the April 2007 proposed rule revising labeling regulations for food processed with irradiation; and the court cases of

Stauber v. Shalala and Alliance for Bio-Integrity v. Shalala.

Unfortunately, in this industry, we periodically see false and misleading labeling on seafood products. Farm-raised Atlantic salmon being labeled as Pacific Chinook salmon is false and misleading. Frozen Atlantic salmon that is thawed and sold as fresh is misleading. But labeling AquAdvantage salmon as Atlantic salmon is truthful, and not false nor misleading. The summary of FDA's assessment of the AquAdvantage salmon as provided in the briefing packet for yesterday's VMAC meeting concludes that the AquAdvantage salmon meets FDA's standard for identity for Atlantic salmon under the criteria established for the regulatory fish encyclopedia. Based on the scientific isolectric focusing gel test that has served for many years as the means for identification of fish species, the AquAdvantage salmon is an Atlantic salmon. Therefore, labeling food from AquAdvantage salmon as Atlantic salmon would accurate describe the basic nature of the product as required by the FD&C Act.

In the August 26th Federal Register notice

announcing this public hearing, FDA posed two questions for comment, one of which was related to the facts about AquAdvantage salmon. Most pertinent for FDA's consideration of whether there are any material differences between foods from AquAdvantage salmon and foods from other Atlantic salmon, nutritional, organoleptic, or functional properties were attributes identified as being material.

Consumers select the type of fish to eat for many different reasons, two of which are taste and healthfulness or nutritional composition. The popularity of salmon, ranking as the third most commonly consumed seafood in the United States, has remained steady for many years, due in part to the healthful levels Omega-3 fatty acids that occur naturally in salmon. FDA's conclusion that AquAdvantage salmon are not materially different from other Atlantic salmon with respect to Omega-3 and Omega-6 fatty acid levels indicates that consumers will enjoy the same health benefits from AquAdvantage salmon as any other Atlantic salmon.

Therefore, we would support a decision from

the Agency that there are no nutritional material differences in the AquAdvantage salmon, thus eliminating the need for additional labeling.

Now, we don't envy the Agency's task in determining whether or not food from AquAdvantage salmon needs to be labeled in any -- in a unique manner. The labeling of genetically engineered foods, in general, has been debated internationally in the Codex Committee for Food Labeling for almost two decades. It has been the longstanding position of the U.S. government, not just FDA, to not support the labeling of food derived from genetically engineered techniques based solely on differences in the method of production. Whether or not a recommendation for the labeling of food obtained through genetically engineering will ever be finalized by the Codex Labeling Committee, it is interesting to note that new language is being considered which states that the Codex genetic engineering labeling recommendation document, quote, "is not intended to suggest or imply that foods derived from modern biotechnology are necessary different from other foods simply due to

their method of production," unquote.

We encourage FDA to maintain a consistent interpretation on both the domestic and international arenas of labeling principles when applied to foods derived from AquAdvantage salmon or for any future genetically engineered fish. The FD&C Act does not support treating foods from genetically engineered fish any differently than from other genetically engineered food products.

NFI supports FDA's determination that if there are no material differences, then it is not necessary to require any additional labeling for the food produced from genetically engineered fish.

We appreciate the opportunity to provide these brief comments for the record. We look forward to a final decision from the agency on both the approval of the first genetically engineered animal intended for human consumption, as well as the consistent application of our country's food labeling laws.

MR. LANDA: Thank you.

Any questions from the panel?

Thanks.

Our next speaker is Bruce Chassy , Food Science and Human Nutrition, University of Illinois, Urbana, Illinois.

MR. CHASSY: Good afternoon to all of you. I'd like to thank the FDA for the opportunity to offer a few comments on this labeling issue. I used to work just down the street for about 21 years at NIH. I left NIH to become head of Food Science and Nutrition at the University of Illinois, and during the '90s, I served on the FDA Food Advisory Committee. I've been Chair of the Institute for Food Technologists' expert panel on food safety and nutrition. I served on the WHO FAO expert panel on the safety of biotech foods, and spent a good part of the last 20 years thinking about the safety of biotech foods and labeling of biotech foods or genetically engineered foods. And I realized that words are important, and I don't often work in the area of legal and regulatory words, and I hope I get them all right.

I do have some passion about sound science as a basis for regulation. And I want to make some more broad philosophical comments -- I hope they are. So I

didn't bring a pyramid. I don't have a Powerpoint. I just have five points I'd like to consider that I think are really important.

The first is that we've been told that this salmon is an Atlantic salmon, and that seems to be the scientific conclusion. I've looked at the data. I don't disagree with that, and I think that leads us down a particular path. I'd like to turn back the clock a little bit and think about the early '90s, when FDA was formulating its policy about regulating food that had been genetically engineered. And when they articulated the basis for that policy, they made clear a point that we've heard several times. And that is that it is the safety of the product, not the safety of the process used to create that product, that is of primary concern to the Agency, and I would argue the consumer, as well. And I want to talk about this fish a little bit using that policy as a yardstick. And that'll come up several times in the next few minutes.

I'd also like to point out that that policy was driven by studies done at the behest of our government by the National Research Council and the

National Academy of Science. And the National Academy of Science has revisited this issue on three different occasions, and I have to say they've been joined by Royal Societies; they've been joined by medical societies, dietetic societies, scientific societies, and international collections of societies, as for example the International Council of Scientific Unions, in examining the issue of there really are or are not any special risks associated with genetic engineering. And this whole panoply of august scientific bodies have come to the same conclusion repeatedly, that this technology presents no new or different risks.

I understand that the people who are concerned about the technology do believe that it is materially different. To them it does pose new and different risks. But that is not in the mainstream of scientific thinking.

In addition, there is now emerging molecular evidence that supports all of those national academies, royal societies, scientific societies, and medical societies. And that is simply, as we have continued to collect genomic knowledge and analyze the genetic

differences between various plants, animals, and microbes, we have learned what the process of breeding, and for that matter, natural evolution, do to the genomes of plants and animals and microbes. Just for an example, we've learned that there are three million genetic differences between every one of us in this room. And I daresay there are lots of genetic differences between the fish that we eat and the cows that we eat and the broccoli, and everything else. In fact, we know that the process of domestication, breeding, and even farming of things, whether it be fish farming or terrestrial farming, leads to genetic divergence that's caused by translocations, deletions, multiplications, insertions, single-point mutations called snips. We sometimes use mutagens -- Greg Jaffe was -- and Alison both mentioned this this morning. The reason that we say that genetic engineering produces no new or different risks is because when you look at the genomes of the animals, the plants, the microbes we eat, they are far more changed by all those other processes of breeding and by natural processes that have been in place for four million years than

they are by the simple insertion of a small cassette of DNA. The actual fact is, this science is the more precise science, and is far less likely to introduce an unintended change or an adverse effect, than either history or deliberate breeding and manipulation using other modalities. And we can now see that at the sequence level.

So I think FDA is to be commended with sticking, or claiming to stick, with a product safety, rather than a process used to produce, because we're talking about the safer process when we talk about genetic engineering.

The problem is, and I'm going to argue in the next couple minutes, that I don't think FDA really lives up to their promise. I do not believe that they use a product safety criteria, even though I happen to agree with them about this particular topic. That's not to say they haven't done an effective job, however. FDA has had responsibility for ensuring that food produced using genetic engineering is safe. We've been eating it for 15 years. It's grown on billions of acres around the world, and we know of no adverse food

safety impact of doing that. And I think it's to their credit that they've developed a very good paradigm for looking at safety. I take no issue with the questions that they ask.

But I do have a question: why are we taking ten years to approve this salmon? Why, for that matter, is it in the Center for Veterinary Medicine instead of the Center for Food Safety and Applied Nutrition, who deals with the safety of foods? Because friends, to me, a salmon is food. It not a veterinary medicine.

Well, I think the reason is because FDA actually treats genetically modified foods differently than they treat any other food, even though they pose less risk. If I had made a promoter mutation in the growth hormone promoter of this salmon, it would have exactly the same phenotype and pose exactly the same risks. But if I had done that by mutagenesis, I wouldn't have had to spend ten years giving data to FDA. I wouldn't have had to have any regulatory approval. It's exactly the same phenotype, but I could put it on the market without question. And I think

that makes no scientific sense.

It's clear that a label depends upon whether you think the differences between these fish are material or not. I certainly concur with FDA that their authority does not allow them to see a material difference between these two fish based on any scientific assessment of the situation, and I'm not sure that the developer's First Amendment rights wouldn't be violated by being forced to put a label on their fish which can be interpreted as nothing better than a pejorative statement about the quality of the product. Because there's data that shows that that's how consumers interpret mandatory labels.

The issue isn't to label or not. Greg Jaffe made that clear this morning. Voluntary labels can do everything that a mandatory label can do. The only difference really is that the consumer who prefers the labeled product, who wants to make that choice, pays for the cost of the mandatory label. And don't think it doesn't cost. It isn't just printing the label. It's keeping separate identity. Remember that picture Alison had this morning of salmon sitting side by side

in trays in the fish counter? I don't know how you label. Do you do the flesh side or the scale side? I mean, you could very easily move those salmon from one bin to the next bin, and you wouldn't know which was transgenic and which wasn't transgenic.

So it becomes tough to preserve the identity and ensure, through testing for GE content, that the consumer gets what they're paying for. It's not free. And consumers who wish to eat non-transgenic salmon have absolutely every right. I totally defend that. But they should pay for the cost of that, because there is no material scientific difference between these fish.

I think very clearly had we not called these things Frankenfish and said that they were risky and scared the hell out of consumers about genetically engineered foods, then consumers could make a reasonable decision about the safety of genetically engineered foods. So I would call upon FDA -- and it's what we do at universities, as well -- to support better information and education about what the real risks and real benefits are, so that consumers can,

indeed, make informed choices.

Thank you.

MR. LANDA: Thank you.

Any questions from the panel?

Alta Charo.

MS. CHARO: In light of the long list of scientific societies that have come to the conclusions that you highlighted, and in light of how long people have been eating foods in the United States that have some GE ingredients, why is it that you think that there has not been some success at persuading the American public in general that there really is no concern about the production process or final product?

MR. CHASSY: I think we've spent very little effort on it. There are very little resources available to do that. I think the groups that oppose genetically modified foods for whom this is an issue have done a much better job of marshaling resources. I find them to be very articulate and passionate about their cause. I think they have every right to be heard on it. That's how we do things. I think having an open discussion-- FDA is to be commended for doing

this. The more we did this, the more we would, I think, understand other people's misgivings. But the piece that's missing from that is -- and maybe it's because professors are boring, I don't know -- we don't do a very good job of explaining the kinds of things I was talking about today, of demystifying, decryptofying, the fish, or any other biotech product. And I'll bet we're being outspent a thousand to one.

So given that, if it's your assertion that the consumers who oppose eating this food are simply misguided in their assessment of the science, whose responsibility -- you said that the label would be interpreted as pejorative, right? So whose responsibility is it to make sure that the label is not pejorative? The government's, or is it the industry's responsibility to figure out how to market the fish?

MR. CHASSY: I think government and industry have a dual responsibility to support informed discussion. I don't -- I'm sorry to, people in industry -- I don't believe industry has a huge amount of credibility with consumers who are hearing an argument between industry and its detractors, and I

don't believe it's our model that the government tells us what to believe or tries to instruct us about things. So what industry and FDA can do is provide support and a forum for informed discussion. I think at this point we haven't had informed discussion. Ninety-five percent of people wouldn't be concerned about this if they knew what the experts that sit in CVM knew about it. It's that simple.

MR. LANDA: Any other questions from the panel?

Our next speaker is Elliot Entis from the American Salmon Company.

MR. ENTIS: Good afternoon. Let me make a slight correction. I may represent the American Salmon Company, but I think I'm probably better known as the founder of AquaBounty Technologies back in 1992.

I realize that out here in this particular audience we have a number of people who are against aquaculture. We probably, or definitely have a number of people who are also against genetically modified foods. I think that puts AquaBounty in the eye of the hurricane, so to speak. So as we move forward, I think

it's important for us to really state how we feel that this product should be commercialized, should it be approved, and how it should be labeled.

First, for all the reasons that have been cited today, I do also reject mandatory government labeling. I feel that the government role historically has been one of showing safety, proving safety of our foods. That is a universal value to all of us. Also, it's been in the business of making sure that claims are what they are, and they're not false. And of course we've discussed ad nauseum what the definition of "material" is, but I accept what the government currently says is material, and that's of course the content that can be measured that has value, nutritional value. It can be seen.

For all of those reasons going beyond it and forcing the government to take a position on other issues and making them label issues gets us into the realm of taste, values, ideology. And I think that's the place where the government should leave the playing field. That's what the marketplace is geared to educate -- adjudicate, sorry. We have a couple of

lawyers in the room and I've got to be very cautious about that.

(Laughter)

But I am in favor of voluntary labeling. I am in favor of education and voluntary labeling. I think that Greg Jaffe earlier today made some excellent points. I think that if we work hard at it, we can devise ways to label. Labeling is a positive. And I prefer to think of labeling, by the way, as branding, and not labeling. Labeling somehow has that pejorative element to it. And I suspect that a number of people -- in fact, I know that a number of folks who have spoken before me today, they're operating out of the desire to delegitimize the product through labeling, to delay its commercial introduction or eliminate the technology entirely through labeling, rather than attempt to promote its values and its benefits.

So what we have is a lot of rhetoric that comes out of fear, that doesn't try and recognize the benefits. I suggest we all take a deep breath, sit back, and re-center. Because the honest truth is that many folks from advocacy groups who are -- who are

pushing values of environment and consumerism are on the same side of the fence as those of us who do work in the biotechnological areas. We also, believe it or not, shockingly or not, espouse those same values.

What divides us? Is it an ideological chasm that's bottomless, or is it a series of more small misunderstandings and disagreements that could possibly be bridged?

I don't know the answer. I suspect with some groups, definitely the chasms are pretty deep. I suspect, however, that for a number of us, it might behoove us to put away the fear card, put away the distrust card, and let's take out the dialogue card. I think that there's room to talk about some of the commonalities, some of the ways in which we can take a look together at whether or not benefits outweigh some of the risks, and that these products can make their way into the marketplace.

I have to make an admission at this point. I have shopped at Whole Foods. I have purchased organic products. I'm still alive; I like them. I have to tell you something else. You have been the

beneficiaries of genetically engineered products. Many of you have eaten papayas. If they're from Hawaii, they wouldn't exist today except for genetic engineering which eliminated a virus which otherwise would have made those papayas totally extinct. You may not have known it at the time, but I don't see anybody suffering with cramps and the aftereffect of having eaten genetically engineered food for the last 20 years.

So here's my proposition. We've been replaying the same roles now for 20 years. This reminds me of the rbST dialogues, reminds me of the dialogues before that in the early '90s about the dangers of escape of genetically modified microbes. It keeps getting played out. The lines are getting a little tired. Both sides line up, both sides say the same thing, and at the end of the day we have the same result. I think that's the definition of insanity. At the very least, it's not the definition of moving ahead and trying to see whether we can solve some of our problems in common.

So I'm going to propose, and I hope, that as

we move ahead, that we find a way to brand the AquAdvantage product and that it become a positive label or positive brand. I already suggested or considered one, but rejected it. And that was Panama Reds. I thought that might not go over as well as some other labels.

(Laughter)

But I'm sure we'll find one. And I really look to everybody here, and I say you represent those who are most interested in the subject. You each represent an organization that has an interest. You're advocates. Let's find a way to see where we can work together, get re-centered, and maybe push the reset button.

That's all I have to say.

MR. LANDA: Thank you.

Are there any questions from the panel?

MR. ENTIS: Thank you.

MR. LANDA: Thank you.

Our next speaker is Erin Friesen, the University of British Columbia, Vancouver, Washington.

DR. FRIESEN: Good afternoon. I'm Dr. Erin

Friesen. Actually, I am from British Columbia, and when I signed up, I couldn't pick BC as a state, so I had to pick the closest state, which is Washington.

(Laughter)

So just to clarify there.

To give you a bit of background on what my work experience has been, to start off with I worked for the Department of Fisheries and Oceans in British Columbia. And while I was working, that was where I did my Ph.D. I did quite a few feeding trials with studying the nutrition of salmon and looked at various differences, specifically on the diet and how diet affects nutrition. I was then also involved in two quite big projects where we went and sampled hundreds and hundreds of wild and farmed salmon from British Columbia. We're also beginning a study on the east coast of Canada, as well, so looking at nutritional differences between different types of salmon. So I have the knowledge of the data that was gained from those and those studies. Two of them have been published thus far.

Finally, after finishing my Ph.D. I have

worked in industry for three years. I worked for an aquaculture feed manufacturing company, where I was responsible for product development of new feeds. Part of my job was also to work with the customers, so there was growing the fish. We analyzed their fish, looked at the nutritional composition of the fish, and then told them whether or not their fish were on track and helped guide them to end up with products that they were nutritionally satisfied with.

So the two key things that I like to look at when I'm evaluating the nutritional differences between salmon is protein. Fish is a rich source of protein, so it's important that these fish still have high levels of protein. And also, fish are a great source of omega-3 highly unsaturated fatty acids. You do not find these in vegetable sources unless they're genetically modified. But -- so one thing when looking at them is we need to make sure that the levels of highly unsaturated fatty acid levels remain the same.

Just a bit of background for those of you who don't have nutritional knowledge, the American Heart Association recommends that humans consume 500

milligrams of EPA and DHA, eicosapentaenoic acid and docosahexaenoic acid, a day. Whereas the American Heart Association recommends that if you have coronary heart disease, you should actually consume 1,000 milligrams per day. Meanwhile, in North America, humans are only consuming 100 to 200 milligrams of EPA and DHA a day, so we're actually quite a bit deficient in our EPA and DHA and should be consuming more salmon.

So just going on a bit more detail on EPA and DHA, there are many health benefits. I'm not going to go into them, but they've been found to reduce coronary heart disease, important in the development of brain. They also have been found to prevent several types of cancer and are anti-inflammatory. So when I evaluate different types of salmon and compare them for nutrition, what I want to do is make sure that they still are rich sources of EPA and DHA, and also long-term, I want to make sure that there is a high availability and large supply of salmon so that humans can consume the recommended levels of EPA and DHA

Now, there are several variables that are going to influence the nutritional composition of all

salmon, particularly farmed salmon. Some differences we see is that there is differences in species. Different species deposit different levels of fat, and when you have different levels of fat, you're going to have different levels of EPA and DHA. Fish size, similarly -- a fish, different size of their growth, are going to have different levels of fat. The season when you harvest your fish, there's going to be differences in nutritional composition. How well the fish feed, as well as how fast they grow.

One of the big areas which I'm going to focus on in a bit is the fish feed. So what you feed the fish is going to have an influence on the nutrition composition of those salmon. And, as well, there is natural variability from each fish. So if you sample one fish under the exact same conditions, it's not going to have the same nutritional composition of another fish.

So this here is some data from a study that was published in 2008 that I was involved with. There's lots of data on here, but this is what we're looking at, is eicosapentaenoic acid and

docosahexaenoic acid. So those are the two fatty acids that are important for human health. On the right-hand side we have our wild Pacific salmon, showing the natural variability that you would see in different species of wild Pacific salmon. And on the left-hand side, we have some farmed Atlantic salmon.

So the difference here with these different farmed salmon, just to show you, the first thing I'm going to show you is the effect of diet. In 2003, farmed salmon were fed a more traditional diet. So salmon typically eat fish. So back in 2003, this diet was higher in fish oil and fish meal. However, due to the increase in the aquaculture industry and due to increases in sustainability concerns, industry is now moving towards more replaced diets, which fish meal and fish oil is being replaced with vegetable ingredients. So here we have a diet where 35 percent of the fish oil has been replaced with canola oil, and we see quite a big decrease in EPA and DHA. Also, if you then go and replace 50 percent, you're going to see even lower levels of EPA and DHA.

And the final thing I want to show in here is

that two groups of fish fed the same diet, if you harvest them at different sizes, this first one was harvested at a length of 77 centimeters. It has quite a bit higher levels of EPA and DHA than smaller fish, mainly because the level of fat is going to be different in these two groups.

Also to note when looking at the data from the AquAdvantage salmon, these fish, the data set is from approximately the same time here, so they were likely fed the same diet. And you'll see that the levels of EPA and DHA in the AquAdvantage salmon, as well as the control salmon from the farm, had very similar levels, indicating that they were likely fed the same or similar diet and that the levels of EPA and DHA were the same.

So summarizing the nutritional value, what I found was that the AquAdvantage salmon provided similar levels of EPA -- similar levels of highly unsaturated omega-3 fatty acids, and they will continue to be the same as long as they are fed conventional salmon diets equivalent to what salmon industry is using.

The AquAdvantage salmon were also a rich

source of protein, and they were no different than other farmed salmon. Farmed salmon generally have about 18 to 20 percent protein.

Looking at the other micronutrients, I did evaluate the data. There were some variation there, but the variation was very small in comparison to what you would expect when different diets are used.

So in conclusion, what I recommend is that the nutritional content of the feed and the other variables are actually going to result in large nutritional differences in farmed salmon, and meanwhile, under similar conditions, the AquAdvantage salmon are nutritionally equivalent to farmed salmon.

Also, I wanted to mention, I know it was brought up earlier about sensory work. I didn't put any in my Powerpoint, but I have done quite a bit of work with the sensory side of things for taste-testing trials. I also wouldn't see any difference in sensory work, as long as the diets are similar. That's where you're going to start to see differences in taste, is as soon as you start replacing different oils.

MR. LANDA: Thank you.

Any questions from the panel?

Felicia Billingslea.

MS. BILLINGSLEA: Yes. Just on your last point, you say you've done some sensory work. Is that something that's available? Would you be able to submit that?

MS. FRIESEN: I have sensory work for my Ph.D. It actually was done with a different species of fish. But in that, you'll find also a review of all of the literature that's been done on different species of fish, because there isn't too much literature out there on taste-testing, because it's a very difficult area to study, especially with fish, because how you cook the fish, how you present it to your panel -- there's so many different variables in there that it's a very challenging area to test. But I can give you the link for my thesis. It's available on line.

MR. LANDA: Any other questions?

Thank you.

I think we'll have one more speaker, and then we'll take a short break.

The next speaker is David Edwards from BIO,

Washington, D.C.

MR. EDWARDS: Thank you, and I appreciate the opportunity to represent BIO, the biotechnology industry organization, here at this hearing and for the opportunity to come before the panel.

Again, my name is Dr. David Edwards. I'm the Director of Animal Biotechnology at BIO, the biotechnology industry organization. We represent 1,100 member organizations that research, develop, and produce innovative health care, agricultural, industrial, and environmental technologies.

The application of technology to animal agriculture is not something that is new. It has allowed us to more effectively and sustainably produce food and fiber for a growing population. The question today concerns the application of labeling regulations to meat from this improved salmon. BIO strongly supports the U.S. Food and Drug Administration's science-based labeling requirements that apply to all foods. These requirements, as a recap -- no special label is required if a new food is substantially equivalent to its traditional counterpart. A label is

required if the food is materially different from its traditional counterpart in nutritional or safety attributes or in how it may differ under normal conditions of use. And voluntary claims are allowed on food labels, provided that such labels are truthful, do not mislead consumers, and are verifiable.

At issue today is the application of these well-established legal principles to labeling of foods derived from this improved growth rate salmon. Salmon grown from AquAdvantage eggs are nutritionally and biologically the same composition as any other Atlantic salmon the consumer purchases. It is prepared and cooked in the same way as other salmon, and there is no reason for it to be labeled as different. These salmon meet the standard of identity for Atlantic salmon established by the FDA's reference fish encyclopedia, which I also think must be a great book. And as reported by the FDA analysis, no biologically relevant references were noted in either the gross composition, the proximate analysis, or in any edible tissue components, including amino acids, minerals, and fatty acids between this salmon and the conventional

salmon.

The fact that genetic engineering was used in the breeding of these salmon is not a material fact that warrants labeling of salmon meat. To require special labeling of foods that are indistinguishable and only based on breeding methods would misled consumers by falsely implying differences where none exist. It also risks diverting consumer attention from important safety and nutritional information.

Since no biologically relevant differences were found in the allergenicity of edible products of AquAdvantage salmon, no label is required because of these allergy differences.

The FDA's analysis of safety, nutritional and other relevant data does not indicate a material difference. Since AquAdvantage salmon meat is not materially different than other salmon meat, differential labeling is not necessary, nor is it mandated by statue.

Thank you. I appreciate the opportunity to come before you.

MR. LANDA: Thank you.

Any questions from members of the panel?

Alta Charo.

MS. CHARO: Thank you. If -- if someone wanted to voluntarily label one of the conventionally farmed salmon as not coming from a GE source, with nothing more, would you consider that to be misleading?

MR. EDWARDS: The BIO's position is that they do support voluntary labeling by companies that would like to make that available, if it's something that's obviously not misleading and is truthful, and is something they can validate.

MR. LANDA: Any other questions from the panel?

Okay.

MR. EDWARDS: Thank you.

MR. LANDA: Let's resume at 2:40.

Thank you.

(Break)

MR. LANDA: It's actually a little after 2:40. If folks would take their seats so we can get started again? Thank you. That's the last ice cream break we'll ever have at one of these things.

(Laughter)

Our next speaker is Darrell Rogers, with the Alliance for Natural Health USA, Washington, D.C.

MR. ROGERS: Hello. My comments are brief. I'm the Alliance for Natural Health USA. It's part of an international organization dedicated to promoting sustainable health and freedom of choice in health care through good science and good law.

The FDA states that the AquAdvantage salmon must be proven materially different from regular Atlantic salmon in order for it to be labeled as an engineered food. Specific scientific data that would support material differences for this GE salmon were released only shortly before this hearing, which is hardly enough time for thorough scientific review. However, not all material differences may be apparent at first scientific review. The FDA stated that the genetically engineered FLAVR SAVR tomato had no material differences between it and its natural counterpart. It was only after the genetically engineered FLAVR SAVR tomato appeared on supermarket shelves that the material differences became apparent.

The FLAVR SAVR taste was bland in comparison to the non-genetically engineered version, bruised easily, and was susceptible to disease when grown in sandy soil. These material differences did not reveal themselves as the product went through the approval process. It was unfortunately up to consumers to find out what the FDA missed: that there are material differences between genetically engineered, new to nature substances and their natural counterpart.

Given the FDA's lack of adequate means and methods to assess the material differences of the first GE animal intended for human consumption, the FDA should, at minimum, inform the customers as to the food's origin.

Thank you.

MR. LANDA: Thank you.

Are there any questions from the panel?

Jason Dietz.

MR. DIETZ: Thank you.

Let me clarify, or may I ask you to clarify. Is it your view that there are material differences based on the information that you've seen, that would

warrant special labeling?

MR. ROGERS: I'm -- I would refer to the panel yesterday, that the science is incomplete, inconclusive, and there is simply not enough time to go through the materials that were provided by AquaBounty for a thorough review if there are material differences. I point out that the FDA in the past has said that there are no material differences between genetically engineered foods and its natural counterpart, and it was unfortunately up to consumers to find out that out. So as of right now, we don't know, because the science is incomplete.

MR. DIETZ: And then the second half of the question that we're posing today, what would that label have to communicate to communicate the message you would want communicated and to do so in a truthful and non-misleading way?

MR. ROGERS: That this food is a product of genetic engineering.

Thank you.

MR. LANDA: Our next speaker is Anna Zivian, Ocean Conservancy, Washington, D.C.

MS. ZIVIAN: Good afternoon, and thank you for the opportunity to speak today on the important issue of labeling genetically modified Atlantic salmon to be raised for human consumption. My name is Anna Zivian, and I am a senior manager at Ocean Conservancy working on aquaculture and coastal and marine spatial planning.

Ocean Conservancy supports responsible aquaculture undertaken pursuant to environmental and safety standards. Effective traceability and monitoring will allow regulators to provide information to consumers about the farming practices used and country of origin of the fish they eat.

As awareness of food production techniques, from organic farming to the production of genetically modified foods, grows, many people have shown a preference for foods reared under specific circumstances. It is therefore imperative to label this salmon.

While the FDA guidance on labeling suggests that only physical differences, including differences in the composition, nutritional, functional, or organoleptic properties of the food justify labeling,

past practice, as well as public policy, support labeling AquAdvantage salmon.

Three main issues figure prominently here. First, the question of labeling based on product versus process; second, the importance of traceability and monitoring; and third, consumer information and choice. In addition, the environmental assessment provided by the applicant contains some evidence that there may be developmental differences between the AquAdvantage salmon and conventionally farmed salmon, and does not adequately assess the potential causes and effects of these changes.

I will address these issues in turn. First, considering the process used to develop a product. While biotechnology labeling in the U.S. often focuses on the end product, not the process used to develop the product, this is not universally the case. Irradiated foods, for example, may not differ greatly from non-irradiated foods, but they are nonetheless labeled because the irradiation process does cause some minor changes in the food and uncertainties about these effects. The USDA notes on its website that, quote,

"This required labeling gives consumers the option to choose between irradiated and non-irradiated meat and poultry," unquote. Transgenic salmon, with multiple levels of manipulation of their genetic structure, raise at least as many issues of uncertainty as irradiated foods.

There is also some evidence that there are differences between the transgenic and non-transgenic fish. IGF1 levels, addition of a potential allergen from Chinook salmon -- ignored because it was claimed that salmon-allergic individuals are likely to avoid any salmon, but a change, nonetheless; increased Vitamin B6 levels; and morphological changes. Without additional certainty about the causes and effects of these differences, labeling is warranted.

Next, in the global fish market today, traceability is a major concern. Given that the application is limited to specific production facilities only, it is even more critical that we are able to effectively trace and monitor this fish as it moves through the global fish market. The current traceability system for the seafood trade is highly

suspect. As a result, we cannot be sure that transgenic fish produced outside of the Panama facility will not enter the food supply. If it does, we have no means to distinguish it from the approved fish. This can encourage broader production of genetically modified fish in scenarios where containment strategies are far less rigorous and escape is probable. It can also have serious economic consequences for wild fish sellers and conventional aquaculture farmers, who will have no guarantee that consumers will not mistake their product for the transgenic fish. Requiring labeling will necessitate more careful tracking, reducing environmental risks, and protecting the economic interests of those who fish for wild or farmed conventional salmon.

Finally, the issue of consumer information and choice is important. In this age of food scares, the massive egg recall is just the latest example. Consumers increasingly want more information about their food. The fact that a coalition of NGOs has received over 160 comments opposing the approval of this fish indicates that Americans want to have the

choice not to buy transgenic salmon.

In addition, salmon is an iconographic fish that also has religious and traditional importance to many people. Providing consumers with a choice of avoiding genetically modified salmon justifies clearly labeling transgenic salmon as such.

In sum, labeling of AquAdvantage salmon is imperative, both because of differences between the genetically modified fish and wild or conventionally grown salmon, and in order to give consumers the ability to avoid genetically modified salmon of uncertain origin that may pose unknown risks.

I welcome the opportunity to address any questions that you might have. Thank you.

MR. LANDA: Thank you. Are there any questions from the panel?

Jason Dietz.

MR. DIETZ: Thank you. Jason Dietz.

Thank you for your comments. In your comments, you asserted that there are material differences in the composition of AquAdvantage salmon. And as I understand it, you're suggesting that they be

labeled. How would those differences be labeled in a truthful and non-misleading way?

MS. ZIVIAN: I think that the main issue is indicating that the differences exist and that it is fish that is modified for increased growth. Until those studies are -- I think there was some question about whether those studies were complete enough, and until that determination is made and there is certainty about what the differences are, it's difficult to say exactly which of those differences should be included on any label.

MR. LANDA: If there were no differences, would that change you position?

MS. ZIVIAN: As I said, there are three issues that I think are of interest here, and one of them is that there are differences. And I believe that is the one that the FDA has chosen to make its decisions based upon and is required to make its decision on. I believe that the FDA should have different standards for making those decisions and that consumer choice, and in this case, the religious significance of the salmon, might have an expanded impact in that regard.

MR. LANDA: Thank you.

Any other questions from the panel?

MS. ZIVIAN: Thanks very much.

MR. LANDA: Our next speaker is Alexis Baden-Mayer with the Organic Consumers Association, Washington, D.C.

MS. BADEN-MAHER: Hello. I'm Alexis Baden-Mayer. I'm here on behalf of the 250,000 active members of the Organic Consumers Association.

The FDA is currently involved in a process of deciding whether to approve and how to regulate the first genetically engineered animal intended for human consumption. This is a very big deal. It's a huge change in food production technology. Not surprisingly, there is enormous public interest in this issue, and there is an overwhelming public demand for labels on food from genetically engineered animals.

So that, supposedly, is what we're here to talk about today. Except that the FDA says that if genetically engineered animals are approved and need to be labeled, they can't be labeled as genetically engineered, because that's not a material difference,

that's a production process. So advocates like myself, who are here on behalf of the 95 percent of the public who want food from genetically engineered animals to be labeled, were forced to try to fit our arguments into this discussion like square pegs into round holes. I really didn't want to testify today. What can I say on behalf of the Organic Consumers Association? Our members want food from genetically engineered animals labeled because it's genetically engineered. They want labels that say, "genetically engineered salmon." What could I possibly say on their behalf at this meeting?

Given the constraints the FDA wants to bind us with, the best I could come up with is, a label that says, "AquAdvantage Salmon" and a link to fda.gov/aquadvantage where the public could access the entire docket of information about how this food was reviewed, how it was approved, and how it's currently being regulated? I guess that's what I would do if I worked for the FDA and I was operating under these circumstances. But I can't say that on behalf of my members. They want food from genetically engineered animals labeled as genetically engineered.

So I've been very discouraged and frustrated. But I woke up this morning with the realization that it doesn't have to be this way. The FDA's idea that the fact that a food animal is genetically engineered isn't a material difference that distinguishes it from food animals that aren't genetically engineered is based on a legal fiction created in 1992 by the Bush/Quayle administration. Their reasoning was that because DNA is generally recognized as safe, then genetically engineered DNA is safe, as well. This policy was not based on science. The science hasn't been done to find out whether consuming genetically engineered DNA is just as safe as consuming normal DNA. So the human health impacts of consuming the AquaBounty construct are unknown and are not being investigated by the FDA because of the 1992 policy.

I'd like to call your attention to a human study conducted by the U.K.'s Food Standards Agency that found that a single meal of genetically engineered soy can result in horizontal gene transfer, where the bacteria of the human gut takes up the soy's modified DNA. Research must be done to determine this would

happen to people who ate AquAdvantage salmon and what the health impacts would be.

The Grass policy needs to be reevaluated now, before the FDA approves the first genetically engineered animal intended for human consumption. As long as the Grass policy is in effect, the FDA will be researching -- will not be researching the safety of consuming genetically engineered salmon DNA, and it will be more difficult to give the public the information that it wants about genetically engineered animals.

It's not too late. We're not eating genetically engineered animals yet. We need a new policy to properly review and label genetically engineered food animals. President Obama and Margaret Hamburg can create an appropriate policy before genetically engineered animals enter the food supply.

But even if the Obama administration decides to keep the old Bush/Quayle legal fiction and apply it to this brave new world, genetically engineered animals can and should be labeled. The court case that the FDA believes ties its hands on labeling does not apply

here. Stauber v. Shalala is about milk from an animal given a drug that contained genetically engineered DNA. The whole debate around recombinant bovine growth hormone is about whether the rGBH is in the milk. Since the rGBH couldn't be found in the milk, the FDA decided that if they said the milk was produced through the use of rGBH, it might mislead consumers and cause them to believe that there was rGBH in the milk. This is also the reason that the FDA prefers that farmers who raise milk cows without the use of rGBH say that, rather than labeling their milk as, "rGBH free."

There is no milk that contains rGBH. But there is salmon that contains recombinant DNA from an eel-like ocean pout that causes it to produce growth hormone year-round. So if the FDA does decide that it's safe to eat genetically engineered salmon, the Stauber vs. Shalala case wouldn't prevent it from labeling salmon as salmon that contains genetically engineered DNA.

There are other material differences between genetically engineered and normal salmon. The FDA review isn't over, but so far the food safety data

shows that genetically engineered salmon has 40 percent more IGF1, a hormone linked to prostate, breast, and colon cancers in humans. Genetically engineered salmon is less nutritious than normal salmon. It has the lowest ratio of Omega-3 to omega-6 of all the salmon in the studies FDA reviewed, greatly reducing the health benefits associated with eating genetically engineered salmon.

Genetically engineered salmon have mean allergenic potencies that are 20 percent and 52 percent higher than normal salmon, greatly increasing the risk of potentially deadly allergic reactions.

There are probably other differences that we don't know about. I've already mentioned that the FDA isn't requiring AquaBounty to do any tests on the human health impacts of consuming genetically engineered ocean pout DNA and salmon. Instead, the current FDA food safety review is a simple "quacks like a duck" style comparison of genetically engineered and normal salmon for hormone levels, nutrition, and allergenic potency.

Even using this elementary analysis, the data

used to support the FDA's conclusion that genetically engineered salmon is similar enough to normal salmon to be considered safe is seriously flawed.

Number one: The FDA didn't always segregate, and sometimes didn't even collect data from AquaBounty on the actual fish that people will be eating, the Panama-raised triploid mono-sex AquAdvantage salmon.

Number two: The FDA did not require AquaBounty to show that genetically engineered salmon is the same as normal salmon under the same conditions. In addition to AquaBounty's control salmon, the FDA also compared genetically engineered salmon to farmed salmon raised under unknown conditions and data from other salmon studies.

Number three: AquaBounty tested only a few fish, making it less likely that its food safety studies would reveal statistically significant differences between genetically engineered and normal salmon.

Number four: AquaBounty's detection levels were sometimes too low to produce food safety data for comparison.

And number five: AquaBounty selected which test to test in unblinded samples, which may have biased the food safety data.

Even with all the flaws and biases that are likely to have hidden some of the differences, the data showed the genetically engineered and normal salmon are not the same in hormone levels, nutrition, or allergenic potency.

So with all that we know and all that we know that we don't know about genetically engineered salmon, it is clear that it is important to inform consumers as to whether or not they are eating it. Right now, with genetically engineered salmon in the news, there is a fair amount of consumer awareness. But as time passes, if genetically engineered salmon isn't labeled, people won't suspect it's in the food supply.

Only 26 percent of the U.S. public is currently aware that there's food from genetically engineered plants in the food supply already. Consumers have a right to know, and we want to make informed choices. FDA has the legal power and the responsibility to label genetically engineered food

animals. To support that end, the Organic Consumers Association members will be submitting comments through the November 22nd deadline. Expect to be deluged.

I want to mention that the Organic Consumers Association receives no grant money or contributions from companies for our work on genetic engineering. All of our support from these campaigns come from small contributions from our members.

Thank you.

MR. LANDA: Thank you. Are there any questions from the panel members?

Felicia Billingslea.

MS. BILLINGSLEA: Yes. You mentioned that you thought there were material differences in the omega-3 levels, allergenicity, and growth hormone levels. If there was a label disclosing those differences to the consumer -- differences in omega-3, this product may be more allergenic -- is that sufficient to advise the consumer on making a purchase decision?

MS. BADEN-MAYER: Well, consumers want to know whether the food is genetically engineered. But I understand that if we operate under these constructs,

you all might decide we can't do that. So I guess it would be better than nothing to inform them of those differences. That's why I suggested, well, I guess you could just put "AquaBounty Salmon" on the package, and then link to the fda.gov site, where people could see the entire record, see all of the data points on nutrition, et cetera. Everything that we have learned. You now, I've learned a lot about genetically engineered salmon this week that I didn't know before, and so I feel like I can make an informed choice about whether or not to eat it. But most people -- they're not going to think about it unless it's on the label. And it should -- it probably -- just saying that it's AquAdvantage salmon, that's not enough to trigger some sort of interest in the consumer. People are concerned about genetic engineering. So it would be far, far preferable for it to say, "Genetically engineered salmon." But if you won't do that, yes, please inform us of all of the nutritional and allergenic and hormone differences that have been discovered through the FDA process.

MR. LANDA: Alta Charo has a question.

MS. CHARO: You talked a great deal about some concerns about the safety of this fish. Let me ask a hypothetical. If it were proven to your satisfaction that the fish indeed is safe and is entirely comparable to other Atlantic salmon, would you still advocate for labeling it as GE, and if so, on what basis, as it would no longer be a safety concern?

MS. BADEN-MAYER: Yes, if we knew that genetically engineered salmon really was just as safe as normal salmon, I don't have an argument any more. I mean, what do I say to people? I can't tell them, well, it's got IFG1 in it, and that's linked to cancer. I can't tell them that it's more allergenic. I don't have a good case to make. But you know, there's a lot of science missing. People want to know -- the reason why we're concerned about genetic engineering is because people want to know, what happens to me when I consume recombinant DNA? That's why I mentioned the U.K. food safety study. And that was a really interesting study done on people who had colostomy bags, so they were able to look at the digestive process and see how the recombinant DNA from the soy

actually transferred to the bacteria of the human gut. That's fascinating. I mean, that's really interesting. That's the kind of thing that people want to know. What happens to our bodies when we consume recombinant DNA? We want to know.

MS. CHARO: First I want to thank you for that after-lunch image.

(Laughter)

But just to be very clear, I really -- I understand that you have concerns about the quality of the science. I just wanted to clarify the basis for the request that there be labeling, and what I'm hearing, if I'm correct, is that the basis is a concern about safety. It's not a concern about genetic engineering per se. Because if it were completely safe to your satisfaction, you would no longer think there's a need for labeling. Or am I not hearing you correctly?

MS. BADEN-MAYER: I think that that's the number one consumer concern. You know, if genetic engineering is perfectly safe and we're convinced that it's been proven, I don't think that there would be

many people who would be concerned about genetic engineering any more. I mean, earlier you raised the whole factory farm model that people don't like. So that's one strike against genetic engineering, because in order to make money, the biotech industries have to produce products for that very lucrative industrial market. So - you know, there's - people don't like industrial farming. But I don't think that that would be there -- like genetic engineering wouldn't be the big concern with industrial farming if we knew that genetic engineering was safe.

MR. LANDA: Thank you.

Our next speaker is L. Val Giddings with PrometheusAB, Inc., Silver Spring, Maryland.

MR. GIDDINGS: Thank you, Mr. Chairman. Thanks to the Food and Drug Administration for on these two days of hearings. As a taxpayer, I thank you and appreciate your efforts.

The first thing I want to do is correct a misapprehension that has been repeated several times, the allegation that the omega-3 fatty acid content of the AquAdvantage salmon is substantially different from

what we had hoped for, what we would expect. I would direct folks not to talk my word for it, but to look at page 95 of the VMAC briefing book, and look at Table 28 and consult the data therein, wherein you will find that the values reported for the AquAdvantage salmon are well within the range of expected, and they are not as has been mischaracterized several times.

Having said that, I will disregard most of my prepared remarks and submit them for the record. Most of what I had planned to say has been said by others with greater eloquence. There's no need for me to repeat much of it.

I would like to take the opportunity to make a few brief comments and direct them at the political overseers of the FDA folks who are wrestling with this issue in the trenches. The Food and Drug Administration has a history that is not without blemish. It is an imperfect organization. But nevertheless, quite rightly has the reputation globally as the gold standard amongst agencies charged with ensuring the safety of our food. It is not irrelevant that we enjoy today, despite impressions that some may

have to the contrary, the most abundant, nutritious, and safest food supply in the history of humanity. The history of FDA has both bright spots and blemishes. I think it is significant to note that a review of this history would reveal that the bright spots are most often associated with times when the agency has stuck closely to its central mandate, which is to consider the data, to review the data with an unflinching eye, to follow those data where they lead, and make decisions on acceptance or approval, or the denial of approval of products on the basis of those data.

The blemishes on the history of the Food and Drug Administration have, unfortunately, all too often been associated with circumstances in which the agency allowed itself to be buffeted or swayed by the stampedes and currents of public opinion that had been moved by the merchants of fear in one direction or another. We've seen yesterday and today a well-orchestrated campaign by the merchants of fear to raise concerns in the absence of the data that would justify them. We have not seen any data adduced that would suggest the existence of any material difference

between AquAdvantage salmon and other salmon that has any relevance to health, safety, or nutrition. We have not seen any material differences adduced that would justify a mandatory label from the Food and Drug Administration that would be relevant to health, safety, or nutrition.

I do share strongly the conviction of many in the audience that consumers do have a right to know, but what they have a right to know, in my opinion, is that information contained on a food label be accurate, informative, and not misleading; that it not be manipulated in such a way that will aid and abet those who seek to raise concerns unjustified by data and unrooted in facts or experience.

I would therefore encourage the Food and Drug Administration to take advantage of the great opportunity they have right now, which is to add their decision on this product to the roster of bright spots in the Agency's history, and resist the temptation to be stampeded in the wrong direction by folks who, however, passionate, are expressing concerns that are not based in data or experience, nor justified by

science.

Thank you.

MR. LANDA: Any questions from panel members?

MR. GIDDINGS: Thank you.

MR. LANDA: Thank you.

Our next speaker is Bill Muir from the American Society of Animal Science, Champaign, Illinois.

MR. MUIR: So I'm here on behalf of the American Society of Animal Sciences. And being a long-term member of the society, I know their views and concerns, and they have been the same over many years. And they are good stewardship of resources; sustainability of agricultural production; production of wholesome, healthy foods; and minimizing environmental impacts. This has always been the goals of the American Society of Animal Sciences. The American Society of Animal Sciences believes this technology is needed to help achieve these goals.

I am here as a population geneticist. My area of expertise is in fact evolutionary biology and the impacts of genes on the environment and what would

happen if this fish were to escape into nature. So it's part of the environmental assessment, if you will, but also has to do with labeling.

So the data I reported yesterday to the VMAC and to the FDA showed across multiple environments that the net fitness of the AquAdvantage fish was reduced. What this means is that the transgene will be eliminated from the wild by natural selection over time. The product is environmentally safe. And what I want to do now is address the issue of labeling with that knowledge.

So the question is, should the FDA require AquaBounty to label their product from GE fish? The answer is no. The data shows that the product is substantially equivalent. To require labeling would be a contradiction for the FDA. That's all I have to say about that.

However, the FDA does allow voluntary labels if the label is neither false nor misleading. We've hard that. So my recommendation is to recommend AquaBounty label the product as AquAdvantage, the eco-friendly alternative. And I say this because it is

neither false nor misleading. And what I want to do is show you that it is neither false nor misleading.

So it's not false -- in other words, eco-friendly -- because it reduces pressure on our oceans for wild-caught salmon. It reduces the carbon footprint. This is part of the environmental stewardship. It has greater feed efficiency, produces less waste products, the same amount of food, has less food consumption for the same amount of product. That's feed efficiency. And therefore, it would have less impact. It would also have less impact on wild fish if it escaped.

I want to verify this final point, because this is a point that has escaped most people's attention. And that is, it's interesting that the transgene was inserted on a wild-type genetic background. In other words, what's the difference between domestication -- domesticated salmon and transgenic salmon? Are they the same? We've seen that the IGF level is essentially the same, growth hormone are the same between transgenic and domestic. But that's where the similarities end, if you will, because

the transgene is actually, you could think of as a mega-mutant. It's a single gene, monogenic inherited. It's Mendelian inherited, whereas the -- if a fish were to escape and interbreed with the wild fish, a fish with a wild-type background could be produced in one generation. In other words, it's monogenic, it's hemizygous, and we talked about the environmental -- the Endangered Species Act. What about, you know, the wild Atlantic salmon? What impact is it going to have? Well, if it does interbreed with wild, automatically half of its offspring are going to be the wild type. They're not going to be domesticated type or half domesticated. They are going to be wild, because it's on a wild-type background. So therefore, it actually helps with the endangered species. Of course, there is the other half that has the transgene in it. That's actually the nice thing about this. It's a mega-mutant, but it's also dominant. Natural selection can very readily and very quickly get rid of a (inaudible) mutant that's dominant in nature.

On the other hand, if we have a -- let me gone onto -- if you have a -- wait, I'm going backwards.

Okay. When you have domesticated fish with classic breeding, you have actually hundreds of genes involved. That is, it's polygenic Mendelian inheritance. In other words, the whole genome is impacted. We know, as a quantitative geneticist, hundreds and sometimes thousands of genes are involved in a quantitative genetic trait such as growth. Matter of fact, you may have seen science, the missing heritability in humans for height. There are thousands and thousands of genes that are influencing heights. What this means is that these genes are all across the entire genome. So if a domesticated salmon were to escape and breed with a wild fish, 100 percent of its offspring would contain 50 percent maladapted gene. It's not, half are wild and half have the transgene. One hundred percent of the offspring have maladapted genes. They're maladapted because when we breed things for captivity, the genes that are very important for growth are not important in the wild. Matter of fact, they're very detrimental. We've seen over and over again that escape of domesticated fish does have -- it's documented in literature -- negative impacts upon wild

fish.

So I submit to you that actually, the AquaBounty AquAdvantage fish will have less impact on the wild populations, and may actually help it. As opposed to domesticated fish, which we know will have a huge genetic load. It would actually take six generations of back-crossing to produce a fish with still one percent domesticated genes, whereas I said, the AquAdvantage fish will do that in one generation.

So from the genetic load impacts on wild populations, are much greater and long-lasting domesticated than the SGH fish. That's salmon growth hormone. That's my shorthand for the AquAdvantage fish. So essentially the AquAdvantage fish are as safe or safer than domesticated salmon as far as the environment goes.

So my conclusion is that you should voluntarily label the AquAdvantage fish the "eco-friendly alternative." This would give the consumers choice and is neither false nor misleading.

Thank you.

MR. LANDA: Thank you.

Any questions from the panel?

Alta Charo.

MS. CHARO: I just have to ask, so we have it on the record -- is this at all tongue in cheek, or are you quite serious?

MR. MUIR: Oh, I'm absolutely -- I'm 100 percent, you know. If I'd had time to publish this, I would have. I didn't. I was quizzed on it, but they talk about reporters asking questions. This question came to me and asked me, well, what's the difference? And sometimes you don't think about the answer until the proper question is posed to you. And the question came up a little while ago, "Why have we done such a poor job at educating the public about their fears?" Well, you know, when I stopped saying that there's Trojan genes, all of the media went away. They don't want to talk to me any more. If I said there's a Trojan gene here, I'd have 50 of them talking to me. I had one reporter who wanted to talk to me about, "Are you sure there's no Trojan gene?"

So if somebody came to me, you know, "What's the difference between a domesticated gene and a wild?"

That was asked of me. Well, once that was asked, I had to sit down and give it very serious thought. And then I figured it out, that it's very obvious that it's polygenic versus monogenic inheritance.

MS. CHARO: I wasn't questioning whether you were serious about the science, but serious about the labeling.

(Laughter)

MR. MUIR: Oh, no -- the labeling? I'm sorry. See, I misunderstood again. So no, I'm quite serious that I actually asked Elliot, tongue in cheek first off, but when you think about that, and he kind of laughed. I thought that he might be opposed to labeling. I said, "You're going to be surprised when I tell you that I think your product should be labeled voluntarily." And he actually accepted it. He said, "Well, that's an interesting alternative. We'll consider it." So maybe they'll do it. I don't know. You've got to find some positive way that isn't pejorative. Right?

MS. CHARO: Thank you.

MR. MUIR: Thank you.

MR. LANDA: Our next speaker is Mark Walton from VIAGEN, Inc., Austin, Texas.

MR. WALTON: Good afternoon, everybody. Thank you. I'd like to thank the FDA for the two days of hearings and the opportunity to participate in this. It's been very informative, and I appreciate the opportunity both as a citizen and as a representatie of the biotechnology industry in general.

My name is Mark Walton. I am the President of VIAGEN. We are a livestock cloning company, and we are also engaged in animal biotechnology research. I also have the honor of chairing the Animal Biotechnology Policy Committee for the Biotechnology Industry organization. And I would like to take just a minute and echo my colleague, Elliot Entis's comments from earlier this afternoon that I think that many of us in this room, in fact, have similar aims. We don't always agree upon the approaches to achieving those aims. But that we in the industry are more than happy, and in fact look forward to the opportunity to dialogue with anyone who is seriously interested in dealing with environmental, food safety, food security issues, and

looking at ways of approaching that through technology or otherwise.

The purpose of today, of course, is to talk about labeling and the need for labeling. The FDA policy on labeling is quite clear. In the absence of a material difference, there is no need, and in fact there is no obligation to label at all. It is equally clear that the method of producing a product, that is, including the use of biotechnology methods or bioengineering, does not constitute material difference. Therefore, in the absence of a finding of material differences between the AquAdvantage salmon and other farm-raised salmon, the FDA should not, and indeed cannot require the AquAdvantage salmon to be labeled.

As the President of an animal biotechnology firm, as the Chair of the Bio-Animal Policy Committee, and, as I might point out, a consumer, I support the policy -- the labeling policy of the Food and Drug Administration on labeling, and I respectfully request that the FDA adhere to that policy in this particular instance.

Thank you very much.

MR. LANDA: Thank you.

Any questions from the panel?

William Jones.

MR. JONES: Sorry to stick you with this question -- it's really a general question. Maybe it's just food for thought, but several people have maintained that there is no material difference. Could you think of an example that would constitute at minimum a material difference in a genetically engineered organism such as this?

MR. WALTON: Well, I think that if you had you -- if AquaBounty had engineered, for example, the fat-1 gene to change the omega-3/omega-6 levels and wanted to claim that in fact it had higher levels of omega-4 or omega-6 fatty acids, that would constitute a material difference.

Thank you.

MR. LANDA: Our next speaker is David Schmidt with the International Food Information Council, Washington, D.C.

MR. SCHMIDT: Good afternoon, and thank you

for the opportunity to share our perspectives. IFIC is an organization based in Washington, D.C. In fact, we're celebrating our 25th anniversary as an organization who communicates science-based information on food safety and nutrition issues to those opinion leaders consumers are most likely to trust -- government officials, journalists, educators, health professionals, and many others. We receive support from food, beverage, and agricultural companies, although we're unique as a Washington group and we don't play a role in lobbying or regulatory advocacy. It's primarily education, media relations, and consumer research around food safety and nutrition.

And I just beat my own slide there.

You see our website is www.foodinsight.org for our foundation's website, and that's where we have a more complete recap of the consumer data that I'll be presenting this afternoon, and lots of other information. So I would encourage you to go there.

I'm going to primarily touch on some points from this year's food technology survey that was conducted in April of this year. And the executive

summary of this is available on the website that I just showed you at foodinsight.org. And our purpose of this survey was to track awareness and perceptions of food technology, and primarily we've been asking about biotechnology over the year, but also reveal concerns, gaps in information related to food biotech, and new emerging technologies such as nanotech and others. A measure to the extent to which consumers' views of food technology change over time, and then identified benefits of food biotech that resonate with consumers.

And I will point out, while we call this a food technology survey this year because it's broadened in scope, we've actually been conducting consumer attitudes on food biotechnology since 1997. And I believe it may be the longest-running database of publicly available data on consumer perceptions on this topic.

There was a methodology. In recent surveys we've gone to online consumer surveys. They are statistically representative of the U.S. population, based on Census data. The most recent one was fielded in April of this year among 750 Americans. And I will

note, in past surveys we've interviewed 1,000 Americans, so it makes for a slight difference in the confidence level, but only slight. You go from a 3.6 percent spread to a 3.1 in past surveys. But you'll see from some of the results that the data are very consistent among particular -- among recent years.

Well, before I touch on the biotech area, just to give you some context, interestingly, despite all the recalls and certainly a lot of discussion about food safety over the past few years, when we ask consumers, "How confident are you about the safety of the U.S. food supply?," those who say that they are very confident or somewhat confident are in the majority, about 69 percent in the latest survey in 2010. And that has held pretty steady when you look at this in 2008 and 2007 as well. We have had surveys in the past -- for instance, we were in the field when the BSE incident hit. That did affect confidence for that part of the survey, probably by about 9 or 10 percent. But in recent years, this has certainly bounced back to a vast majority of consumers.

Now, one of the survey methods I do want to

point out, these are quantitative surveys, but we have some open-ended questions. And we believe it's more objective to ask consumers what's on their mind, versus giving them something off on a sensational statement and then asking whether they agree with it or not. So we just say, "What, if anything, are you concerned about when it comes to food safety?" And I think their responses are pretty common sense, you know, disease and contamination. If they were to state something about salmonella or E. coli that have been in the news, that's been the top, although it declined from a peak of 50 percent in 2008. Concerns about handling or preparation of food at 33. Chemicals increased a little bit to 10 percent, but because this is a technology survey, we were looking for any references to biotech or GMO, genetically engineered, something related to that. But only two percent consumers off the top of their heads offered anything up related to that.

And then each year we ask consumers, "Thinking about your diet over the past few months, are there any foods or ingredients that you've avoided or eaten less

of?" And we usually find about half of consumers say that they are, so 54 percent in the latest survey. And then we ask, again from an open-ended basis, "What foods or ingredients have you avoided?" And the top response for the last few surveys, sugars and carbohydrates, 51 percent; fats, oils, and cholesterol; then animal products, around 20 percent. Sodium has increased, from 15 to 20 percent. But again, looking for something related to biotechnology from the survey, and in this case, no consumers mentioned anything related to biotech foods, GE foods, anything like that in terms of foods that they were avoiding.

Now, we also asked about labels -- the subject of this hearing, of course. And again, we wanted to sort of logically ask before hitting them with some concepts. "Just in general, can you think of any information that is not currently included on food labels that you would like to see on food labels?" And this has been very consistent over the years. Eighty-two percent of consumers in the most recent survey cannot think of anything that they would like to see added. Of those, 18 percent who do indicate things,

it's generally nutrition information, ingredient information, which of course is already required to be on the label, and again here we're looking to see, do any people cite anything related to biotechnology? And we did find three percent of those 18 percent in the survey mentioned biotechnology. So it's certainly not any overwhelming demand for that information from an objective, open-ended basis.

And then specifically, we go on to ask about support of the FDA policy. And we've asked this for a number of years, and again the support has actually increased in more recent years. But 63 percent of Americans do say they support the FDA policy. And I'm actually going to read -- you've probably heard enough of this at this meeting, but I'll go ahead and read how we explained it to consumers. And in terms of labeling, we said, "The U.S. Food and Drug Administration requires special labeling when a food is produced under certain conditions, when biotechnology's use substantially changes the food's nutritional content, like vitamins or fat, or its composition, or when a potential safety issue is identified.

Otherwise, special labeling is not required. Would you say that you strongly support, somewhat support, neither support nor oppose, somewhat oppose, or strong oppose this policy?" So again, 64 percent were supportive; 24 percent were neutral; and just 12 percent were opposed.

In terms of awareness, I will say, and maybe because they're not commonly labeled in supermarkets, about 37 percent of consumers -- I'm sorry, 64 percent don't know if biotech foods are in the stores. About a third do. They cite vegetables, corn, fruits, et cetera.

And we do ask about animal biotechnology. Just one question here I thought that may be relevant. When we ask, "Animal biotech can increase farm efficiency, that is, it can increase the amount of food produced, while decreasing the amount of resources needed, such as animal feed. Please tell me whether that information has a positive effect on your impression, a negative effect, or no effect at all?" And in this case, the latest survey, 53 percent said it did have a positive effect on their feelings on animal

biotech.

So again, the summary of the survey is up on our website. And before I close, I guess I would just like to say from my years of being part of this and being a science-based organization that the food label is not a playground for every bit of information someone may want to know. We rely on the FDA to ensure that the precious real estate available on a food label is reserved for important health, ingredient, and nutrition information, and it is clear that a strong majority of Americans have confidence in the FDA's labeling policy for foods produced using technology.

So with that, thank you very much for the opportunity. I'd be happy to answer any questions.

MR. LANDA: Thank you. Any questions from the panel?

Felicia Billingslea?

MS. BILLINGSLEA: Yes. I had a clarifying question. These surveys were online. At any point during the survey, does the person taking the survey have the opportunity go look for information about biotech foods or gain information to help in

considering the questions?

MR. SCHMIDT: Right. This survey does have to be taken all at once, so unless they were -- generally they don't know what they're being surveyed about. They may know broadly it's about food. So unless they had come prepared to their computer to do that all, they actually -- the respondents are thrown out if there's a delay in their -- an unusual delay in response. So for the most part, I would say probably not.

MR. LANDA: William Jones?

MR. JONES: Would you expect there to be a difference if you use the term "genetic engineering" rather than "biotechnology"?

MR. SCHMIDT: We have -- we have done this qualitatively as well as quantitative over the years. Genetic engineering actually plays better than GMO -- that's the one that doesn't play too well. But food biotechnology, agricultural biotechnology is generally better received than genetic engineering. But I think consumers do like the idea with genetic engineering, you're being straight with them. If you talk about

what the benefit is, that also has a big difference on how it's received by the consumer.

MR. LANDA: Alta Charo?

MS. CHARO: Thank you. And keeping in mind that the polls on consumer attitudes may well not be usable as information that informs the legal interpretations under the statute as it now stands, I'm still interested in them. And I found myself wondering as I was listening to this, how much people knew before they were answering the open-ended questions. That is, if they answered a question about the FDA policy, how would they know what the FDA labeling policy was? They're asked questions about what they're worried about, how much do they actually know about their current consumption of biotech foods, like the Haagen-Dazs ice cream outside? So I wonder if you can just explain a little bit about the context so we can better understand the results?

MR. SCHMIDT: Right. Well, again, we were looking for a statistically representative population in the U.S., not a special group of shoppers, or women, or highly educated. So you're really going to get a

mix of education levels, income levels. And so you are going to have a lot of people who don't know a lot about these topics. So very much so, it's a reflection, I think. A lot of their responses are a reflection of what they hear in the news, what they hear from their friends, you know, if they're online, and on social media sites. So the information that people process can be from many different sources, and it's often the replication of messages among those sources that really determines how they feel about an issue. But certainly, I think, it's more than half the public, you would have to say, is not that close -- certainly as close as anybody in this room, to the issues that we deal with in and out every day. So we can't expect them to be experts.

MR. LANDA: William Jones.

MR. JONES: One quick follow-up question to that. Have you done enough of this over time and temporally to correlate what is going on in the news? For example, I would guess that if you had asked people some of these questions last week, especially here locally, you'd get maybe a different response than you

would get if you asked them these questions tomorrow. Especially folks who rode the Metro this morning and saw this issue on the front of the paper they hand out there. Have you seen any differences that you can correlate with what's going on?

MR. SCHMIDT: Yes. So we do this generally annually over time. And there have been some swings. I would say awareness of the technology has actually gone down some in recent years as the debate about technology has gone down. I recall, again being around these issues for a long time, the FDA public hearings I want to say around 1999, 2000 were about the peak of awareness. That was really a lot of debate going on in the country, lots of media coverage. So the slide I showed you about most consumers not being aware of foods in the supermarket, that is definitely a higher number of those not aware than it was back at that time. But we could certainly go back and take a look at the data, and I believe we have summaries of most of our past research on our website, or else be happy to pull up more of that if that would be of interest.

MR. LANDA: Thank you.

MR. SCHMIDT: Thank you.

MR. LANDA: Our next speaker is David Conley with The Aquaculture Communications Group, LLC, in Novi, Michigan.

MR. CONLEY: Thank you, and thanks for the opportunity to give my comments today.

My name is Dave Conley. I am a senior consultant and founding partner of The Aquaculture Communications Group. We have offices in Novi, Michigan and Ottawa, Ontario, Canada, and associates around the world globally that are experts in aquaculture science and technology. Our focus is aquaculture S&T, and I've been involved in this industry since 1985. So I've seen a lot of the developments over the years. I follow the trends. I read an awful lot of material, hence the thick eyeglasses.

And I just wanted to give a couple of comments. And I wrote these over a week ago, and they're just bullet points. But based on what I've heard today and yesterday, they kind of summarize some of the stuff that we've gone through. So I'd just like

to start off -- I don't believe that there's -- or we have no special labeling of food for Aquaculture Advantage -- no special labeling of food from AquAdvantage fish should be mandated by government, because I believe this is a marketing decision and not a regulatory decision. AquaBounty Technologies will label AquAdvantage salmon eggs that they sell to salmon farmers as being genetically engineered salmon. They do not have a problem labeling their product.

When the salmon are harvested and processed for sale to consumers, the decision to label them so as to differentiate them from conventional Atlantic salmon should be the choice of the producer and/or the retailer. Labeling the process by which a food is produced is not currently required by FDA, we discussed this. The primary issue of labeling food products is to make consumers aware of nutritional values and additives in foods that could be detrimental to health.

Today, scientific analysis has concluded that there is no material difference between AquAdvantage Atlantic salmon and conventional Atlantic salmon as food. For all intents and purposes, they are the same.

To require labeling is to signify that there is, in fact, a material difference when none exists. Government does not currently mandate that foods be labeled as "organic" or "non-organic." They have not been proven to be materially different. I've eaten conventional foods all my life. I haven't gone out of my way to eat organic. I'm still here. Most of us have grown up with eating foods from the '50s, '60s, and '70s. We're probably the greatest population of experimental animals for everything that's gone into the food since after the second World War. We have much healthier lives. We live longer. In fact, obesity is the issue of the day. This product actually can reduce some of that. So I don't believe that AquAdvantage salmon present a health risk based on the analysis today.

A 2008 review published by the Royal Society of Medicine noted that GE foods have been eaten by millions of people worldwide for over 15 years with no reports of ill effects.

This was discussed earlier today.

A 2004 report from U.S. National Academies of

Science stated, "Today, no adverse health effects attributed to genetic engineering have been documented in the human population."

If government mandates that AquAdvantage salmon be labeled as GE salmon, will it also mandate that all other GE products be labeled as well? We cannot single out one and not everyone. Everyone else is playing in the same market.

So I want to shift a little bit and talk about why a producer or a retailer may want to label GE salmon, because AquAdvantage salmon has many positive attributes and benefits that a producer or retailer may want to promote. For example, traceability. This thing can be traced from the egg right through the value chain to the consumer. Traceability in the seafood industry is non-existent. We have a big problem with fishing that's taking stuff that's unreported, questionable stuff switch and what-not, fraud in the marketplace. So traceability is a huge issue. In fact, I'm organizing a session at Agriculture America in New Orleans the end of February, 2011, if you want to go for that. A plug for there.

But traceability on this product can be highly integrated, and you can follow it through its entire lifespan.

Food safety: This thing will be grown in a facility which is well monitored, well maintained, well managed. If it's done in the United States rather than overseas, we even have a greater benefit because it's done here at home, according to our laws, our regulations, and we know exactly what we're getting. This is a positive thing.

Food security: Again, if we were to domestically produce this, and this is not what we're talking about here, but down the road if this was domestically produced in these facilities rather than in other regions of the world that have different regulations, again, we know what we're getting because we can actually investigate the entire process.

What's been mentioned before about environmental safety: These animals will be grown in closed, contained facilities on land in freshwater. The environmental critics of salmon farming since 1985, when I got into this business, has talked about getting

then pens out of the ocean and onto land, primarily to reduce all the concerns that they have with disease transfer, fouling of the coastal environment, and on and on. Here you have an animal that now gives you the opportunity to make money, whereas this is not possible. There is no existing example of a financially viable salmon farm on land anywhere in the world. I visited several in Norway. They've been bankrupt several times, and they're research facilities. They do not produce as a production for-profit facility. This animal now changes the economics and addresses the environmental concerns of many people.

Energy savings: Domestic production near consumer markets eliminates much of the energy associated with shipping salmon from other producing regions outside of the U.S., and both the dollar cost and the carbon footprint are significantly reduced. If we look at the balance of trade, the U.S. spent $1.6 billion to import farmed salmon in 2007. And this number is increasing every year. Producing AquAdvantage salmon domestically can significantly

reduce this trade balance. And if we look at the "Made in America," the fact that if these things are produced here at home, for all of the reasons that I've just said, they are produced by Americans, for Americans, creating jobs, economic and social benefits for communities here in the United States, instead of Canada, U.K.., Norway, Chile, and other places. And I think this is a good thing.

Thank you very much.

MR. LANDA: Thank you.

Any questions from the panel?

Thanks.

Our next speaker is Richard Carnevale, Vice President, Regulatory Scientific and International Affairs, the Animal Health Institute.

DR. CARNEVALE: Thank you, Mike.

I'm a late addition to the speakers group, and I really appreciate the opportunity that CFSAN will give me, and particularly Juanita Yates that allowed me time here. I will be brief.

My name is Dr. Richard Carnevale. I'm a veterinarian and Vice-President for Regulatory

Scientific and International Affairs at the Animal Health Institute. AHI is a national trade association that represents the manufacturers of animal health products: the pharmaceuticals, vaccines and feed additives used in modern food production and the medicines that help veterinarians keep your pets healthy.

Since the FDA has chosen to regulate this technology to produce AquAdvantage salmon using the regulatory pathway for new animal drugs, AHI has a very strong interest in the labeling of foods resulting from this new technology.

I come at this issue from a little bit different perspective than other speakers today, because we are very -- obviously very involved in the animal drug process at AHI, and we know how previous decisions on foods that FDA and USDA have looked at and regulated and labeled have traditionally handled this issue.

ANI appreciates the scientifically based review by FDA of this new animal drug application for the rDNA construct that results in the AquAdvantage

salmon, a genetically engineered Atlantic salmon produced by AquaBounty Technologies. AHI also supports FDA's applicable principles of labeling foods as listed in their background document. Of course, we've heard these all day. The law prohibits food labeling that is false. The law prohibits food labeling that is misleading. The law does allow voluntary labeling about production methods so long as the labeling is not false or misleading. And I would mention that absence labeling can, in fact, be inherently misleading if the technology that is claimed by the absent labeling, there has been a regulatory decision that that technology is safe, such as the use of an animal drug.

The law requires that the label include a name that accurately describes the basic nature of the food. So given those principles, we agree that FDA cannot require additional labeling about production methods unless it is necessary to ensure that the labeling is not false or misleading. Using these principles, neither the FDA or USDA has required that foods derived from animals that received drugs or supplemented feed reveal this fact in labeling. And this would include

several anabolic agents approved to enhance meat or milk production. All the applicable statutory provisions, administrative precedents, and judicial decisions have supported FDA's decisions regarding new animal drugs.

New animal drugs are approved after FDA has determined that they present no risk to consumers. If the FDA -- if this NADA for AquAdvantage salmon is approved by FDA, the food made from AquAdvantage salmon should contain no labeling reflecting the use of the rDNA construct which is the new animal drug used in producing the salmon. Additionally, if FDA determines that the AquAdvantage salmon is materially no different from Atlantic salmon, no new name should be required for the food made from AquAdvantage salmon.

Thank you.

MR. LANDA: Any questions from the panel?

Alta Charo.

MS. CHARO: Same question I've asked several people -- I'm just kind of getting my own little non-statistically well-designed survey.

(Laughter)

If a purveyor chose to put a label on some salmon that said, "This salmon does not come from a genetically engineered source," with nothing further, just that statement, would you consider that intrinsically misleading or not?

DR. CARNEVALE: It could be. It depends on whether that statement implies a measure of safety or a level of safety that is being communicated to the consumer.

MS. CHARO: And given that -- given that - the hypothetical is that's the only statement there. There's nothing else. There's no signs, symbols, whatever. How would you determine, then, whether it is making, you know, it has such an implication intrinsically or implicitly?

DR. CARNEVALE: Well, I guess it's a judgment call in each case. But I guess I would point to the rBST example that came up earlier. And we know that there are companies out there, milk producers that label their product with "No use of growth hormone or rBST." And FDA has required this disclaimer statement on those milk labels that say by the way, FDA has

determined that milk using rBST is not unsafe, or words to that effect. So it would be a decision, I think, by the agency as to whether they think this absence labeling that this product is produced without genetically modified microorganisms is implying a level of safety beyond what FDA has determined GE organisms to be. So I guess in that case, it'd be a judgment call. I don't know that I can give you a direct answer. But I would -- I would say that listening to the discussion today, that would probably to me be an inherently misleading statement.

MR. LANDA: Any other questions from the panel?

Our next speaker, also an addition from today, is Thomas Redick with the Global Environmental Ethics Counsel.

MR. REDICK: Thank you for making time. I would like to say that there's been very thorough discussion. I did attend the VMAC hearing yesterday.

It's important to remember, though, as I am an attorney and I did write a book on GM food labeling entitled, the case against it. And I'm sorry to say

for those who think that everything should be included on a label that you lose the label's efficacy when you put every single thing that 90 percent of the people think they want to have. And unfortunately, it's a risk. Homeostasis is the word, if you want to Google it. At some point you overwhelm the reader, and labels by FDA policy are tailored to a certain level of triage. And the triage is, you find that which is relevant to the content of the food. If you start adding process because 90 percent of the people wanted it or said they wanted it, thought they wanted it, eventually they're going to say, "Why did we want that?"

And I think fortunately, the World Trade Organization feels the same way. Under the Sanitary/Phytosanitary Agreement, which would relate to anything relating to health and safety of food, you do have to have a scientific basis for a process and production type label. Fifteen years ago I was a dolphin lawyer. Or I'm sorry, tuna lawyer. But I was a dolphin lawyer, too, and we went dolphin-safe. And we did it as a voluntary label, because we knew that --

at that time it was the general agreement on tariffs and trade had, through developing countries complaining, ruled that you can't do a governmental mandated process, basically.

Well, now, the law's evolved since then. I'll be the first to agree. There's a law review article, it's 80 pages long, saying maybe we can fit it under the technical barrier in the trade agreement. But I'm sorry, if it's a health issue, it's clear, you need a scientific basis. And process and production method labeling is very much discouraged internationally. And the last thing we need at our FDA at this point is to have an anti-biotech labeling directive come out of our government. I'm in the middle of negotiating a bio-safety protocol as part of a great big coalition with our State Department and everyone else. And there, there are a lot of folks who think the bio-safety protocol, which is the Cartagena Protocol on -- to regulate genetically modified crops and other organisms, should impose a labeling system and change the World Trade Organization's structure of law. I think that is a problematic thing to try to do out of

the United States, and we should be the last country on the earth to do a discriminatory labeling law that's anti-biotechnology.

Thank you.

MR. LANDA: Any questions for Mr. Rednick?

MR. REDICK: Oh, maybe I should stay up.

MR. LANDA: Apparently not.

(Laughter)

Well, Mr. Redick was our last speaker today. No applause?

(Laughter)

I want to thank all of our presenters today, including the invited speakers, members of the audience who spoke, those who signed up in advance and those who decided this morning that they would speak with us. As we've explained probably ad nauseum, if the NADA for AquAdvantage salmon is approved, FDA will make a decision about food labeling. If it's not approved, there won't be any need to reach a decision about food labeling and we won't reach it.

I would also reiterate that if you did not get a chance to speak today, there's still plenty of time

to express your views on the questions we have posed, the questions that were the focus of today's hearing. We'll be taking written comments until November 22, 2010. The docket is Docket Number FDA 2010N-0385. That's the docket that pertains to the labeling issues, as distinct from the CVM docket number for the VMAC meeting. And you will find instructions for submitting comments to that docket in the August 26 Federal Register notice announcing today's hearing.

Two other points. First, I want to thank Juanita Yates and her staff for once again organizing just perfectly yet another meeting that from my standpoint, went like clockwork. The effort it takes to organize one of these meetings is never seen except by those of us who benefit from it. So if -- but it takes a huge amount of effort. Juanita is in the back. If Juanita would stand up and take a bow?

(Applause)

Thanks again. With that, we'll conclude the meeting. Thank you all for coming and for your interest in this important matter, and have a safe trip home.

CERTIFICATE OF NOTARY PUBLIC

I, NATASHA KORNILOVA, the officer before whom the foregoing meeting was taken, do hereby certify that the testimony that appears in the foregoing pages was recorded by me and thereafter reduced to typewriting under my direction; that said meeting is a true record of the proceedings; that I am neither counsel for, related to, nor employed by and of the parties to the action in which this testimony was taken; and further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

_____

NATASHA KORNILOVA

Notary Public in and for the

State of Maryland

My commission expires: October 1, 2011