EXAMINING FDA'S ROLE IN THE REGULATION OF GENETICALLY MODIFIED FOOD INGREDIENTS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

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HOUSE OF REPRESENTATIVES

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EXAMINING FDA'S ROLE IN THE REGULATION OF GENETICALLY MODIFIED FOOD INGREDIENTS

WEDNESDAY, DECEMBER 10, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:16 a.m., in room 2123 of the Rayburn House Office Building, Hon. Joe Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Burgess, Shimkus, Murphy, Blackburn, Lance, Guthrie, Griffith, Bilirakis, Ellmers, Pallone, Engel, Capps, Schakowsky, Matheson, Green, Butterfield, Barrow, Castor, Sarbanes, and Waxman (ex officio).

Also present: Representative Pompeo.

Staff present: Nick Abraham, Legislative Clerk; Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Leighton Brown, Press Analyst; Karen Christian, Chief Counsel, Oversight; Noelle Clemente, Press Secretary; Brad Grantz, Policy Coordinator, Oversight and Investigations; Sydne Harwick, Legislative Clerk; Brittany Havens, Legislative Clerk; Peter Kielty, Deputy General Counsel; Carly McWilliams, Professional Staff Member, Health; Tim Pataki, Professional Staff Member; Chris Sarley, Policy Coordinator, Environment and Economy; Macey Sevcik, Press Assistant; Adrianna Simonelli, Clerk; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Health; Tom Wilbur, Digital Media Advisor; Ziky Ababiya, Democratic Staff Assistant; Eric Flamm, Democratic FDA Detailee; Debbie Letter, Democratic Staff Assistant; Karen Lightfoot, Democratic Communications Director and Senior Policy Advisor; Karen Nelson, Democratic Deputy Committee Staff Director for Health; and Rachel Sher, Democratic Senior Counsel.

Mr. PITTS. The subcommittee will come to order. Before we begin, I would like to take a moment to address the guests in our audience. First of all, thank you all for coming. We think engaged citizens are a welcome and valuable part of the political process, and I only wish every hearing drew this much interest.

The purpose of this hearing is to examine FDA's role in regulating genetically-modified food ingredients, and it is an opportunity for this committee to ask questions and have a thoughtful discussion on this issue. The number of people in this audience and in the hallway this morning demonstrates the strong interest in

this topic, and we welcome that interest and your attendance here today. I do want to remind our guests that the chair is obligated, under the rules of the House and rules of the committee, to maintain order, preserve decorum in the committee room, and I know that we all may not agree on this topic, but I ask that we all abide by these rules and be respectful of our audience members, our viewers and our witnesses, and the chair appreciates the audience's cooperation in maintaining order as we have a full discussion on this important issue this morning.

The chair will now recognize himself for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. The genetically-modified organisms, or GMOs, is a term that refers to ingredients sourced from crops that have been genetically engineered to express certain traits or characteristics. A number of people have an instinctive distrust of food that has been genetically modified, and are asking questions about its safety. Others see great promise for better nutrition and the alleviation of hunger around the world.

There are real sensitivities around this issue, and all issues regarding the food we eat and feed our children and our grandchildren. It is our job as policymakers, particularly as it relates to the public health, to establish a factually and scientifically sound foundation prior to taking any action that would impact consumers and our economy, and this hearing provides a great opportunity to put rhetoric aside and do just that.

GMOs have been a part of the U.S. food supply since the mid-1990s. In fact, as much as 90 percent of our corn, sugar beet, and soybean crops are now genetically engineered, and about 70 percent of processed foods contain such ingredients. The U.S. Food and Drug Administration oversees the safety and the labeling of all food products from plant sources, including those from genetically-engineered crops. These products must meet the same safety requirements as foods from traditionally bred crops. The Food and Drug Administration currently has a consultation process in place in which developers of the underlying technologies address any outstanding safety or other regulatory issues with the agency prior to marketing their products. FDA has completed approximately 100 of such consultations. No products have gone to market until FDA's safety-related questions have been resolved.

According to FDA Commissioner Margaret Hamburg, FDA has "not seen evidence of safety risks associated with genetically-modified foods." Further, FDA has no basis for concluding that bioengineered foods are different from other foods in any meaningful way, and the World Health Organization has stated that "no effects on human health have been shown as a result of consumption of such foods." In fact, they can grow faster, resist diseases and drought, lower reliance on pesticides, cost less, and prove more nutritious. Even President Obama has stated that "advances in the genetic engineering of plants have provided enormous benefits to American farmers" and that "investment in enhanced biotechnology is an es-

sential component of the solution to some of our planet's most pressing agricultural problems."

Nonetheless, there have recently been a number of state initiatives calling for the mandatory labeling of food products that contain GMOs, and we will hear today from a number of witnesses who can speak to such actions and the impact they would have.

Food labeling is a matter of interstate commerce and is, therefore, clearly a federal issue that rightfully resides with Congress and the FDA. I am concerned that a patchwork of 50 separate state labeling schemes would be impractical and unworkable. Such a system would create confusion among consumers and result in higher prices and fewer options.

Finally, I want to commend Representative Mike Pompeo and Representative Butterfield for their leadership on these issues, and I look forward to learning more about H.R. 4432, the Safe and Accurate Food Labeling Act of 2014, and I would seek unanimous consent of the committee that Mr. Pompeo, who is on the full committee but not on the Health Subcommittee, be able to sit with us today in this hearing.

Without objection, so ordered.

I would like to welcome all of our witnesses for being here today. I look forward to your testimony.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Genetically modified organisms, or GMOs, is a term that refers to ingredients sourced from crops that have been genetically engineered to express certain traits or characteristics. A number of people have an instinctive distrust of food that has been genetically modified, and are asking questions about its safety. Others see great promise for better nutrition and the alleviation of hunger around the world.

There are real sensitivities around this issue, and all issues regarding the food we eat and feed our children and grandchildren. It is our job as policymakers, particularly as it relates to the public health, to establish a factually and scientifically sound foundation prior to taking any action that would impact consumers and our economy. This hearing provides a great opportunity to put rhetoric aside and do just that.

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Finally, I want to commend Rep. Mike Pompeo (R–KS) and Rep. G.K. Butterfield (D–NC) for their leadership on these issues, and I look forward to learning more about H.R. 4432, the Safe and Accurate Food Labeling Act of 2014.

I would like to welcome all of our witnesses for being here today. I look forward to your testimony.

Mr. PITTS. And at this time, I yield 5 minutes to the ranking member for his opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Chairman Pitts.

Today's topic is one of thoughtful consideration of this committee. Many Americans are interested in the regulation and labeling of foods with genetically-modified ingredients, and while it is an emotional issue for many, the facts can lead reasonable people to different conclusions.

For policymakers, there are a number of considerations involved, so I am glad that we are able to convene a panel to share the range of perspectives on the issues, and I hope we can engage in an honest and respectful discussion.

Genetically-modified foods have been in our food supply for decades. In fact, some estimate that over 70 percent of processed foods contain GMOs, however, they are not labeled as such. In the wake of growing concerns from consumers, the Food and Drug Administration issued a policy statement on its regulatory oversight and labeling policies for GM foods in 1992, and in 2001, issued draft guidance on voluntary industry labeling.

I fully understand why consumers want to know what goes into the food they serve their families. For people to make informed decisions about what they eat, they need information, and that is why we required food labels to include nutrition facts, and that is why they must use common rather than technical names for ingredients whenever possible so that this information is, in fact, useful. It is also why several states have enacted their own regulations mandating the labeling of these foods. Three states have put new laws on their books, while many more have considered doing so, either through ballot initiative or state legislation. None of the state labeling laws have gone into effect yet.

While such laws give voice to the many who are concerned, I am troubled by the net effect of the inconsistent state standards. America's agricultural production and food distribution chains necessarily cross state lines, and conflicting regulations could cause difficulties, resulting in higher cost for consumers.

Like the advances in medical technology that we deal with as a subcommittee, innovations in biotechnology have a real potential to address current problems and improve the quality of life for people

across the globe. And as representatives of the American people, we must also be sure that the application of these technologies does not put consumers at risk, and that information is available to those seeking it out. In the end, the science must remain the arbiter of any safety concerns, and our regulations must reflect a rigorous evaluation of the evidence.

So again, I am glad that we are having this hearing. I look forward to the panel's testimony. I hope that we can weigh the merits of all recommendations presented, and evaluate just how any regulatory approach would best serve the interests of the American people.

I would like to yield the remainder of my time to the gentleman from North Carolina, Mr. Butterfield.

Mr. BUTTERFIELD. Thank you, Mr. Pallone, for yielding. Thank you, Mr. Chairman, for your kind words, and thank all of you for coming today.

Mr. Chairman, access to safe and affordable food is very important to every consumer in America. I think at least we can agree on that fact. I begin this conversation by saying that I represent an agricultural district in North Carolina. It is also a low-income district, and so I have a very keen interest in this subject. A large portion of my North Carolina district is agriculture. Farmers all across my state and across my district remind me that North Carolina farmers don't just grow crops for North Carolinians, they grow crops for America. And so the food supply chain is vast. It is interconnected. The work necessary to get an apple or an ear of corn to the produce section at the supermarket is absolutely staggering. From sea, to farmer, to wholesaler, to processor, to packer, to distributor, even to the store shelf itself, it is easy to appreciate the intricate system that feeds America, and I am beginning to learn more and more about this.

But several states have proposed regulations, and that I worry, if enacted, would cause significant disruption to the Nation's food supply. It would cause confusion, it would cause uncertainty among consumers, and ultimately will result in increased costs at the checkout line. Depending on what state regulations mandate, separate supply chains will likely have to be developed, beginning at the farm, and at every state—step, all the way to the supermarket.

The new infrastructure requirements are as daunting as they are costly, and you can bet that all of those costs will be passed on to the consumer, with studies showing that the average cost topping $500 a year. For many of my constituents, that would be impossible.

So I have worked with my friend, Mr. Pompeo, and others to propose what I believe is a measured approach that gives consumers certainty while taking into account the delicate balance and sheer size and complexity of the food supply chain that employs many Americans.

The proposal, my friends, is very simple. The FDA, our Nation's foremost food safety authority, should have the authority to require labeling on genetically-modified foods, and establish federal standards so that consumers, regardless of where they live or work, will clearly understand the options.

Finally, I would say, Mr. Chairman, that I will be the first to say that this proposal is not perfect. This proposal is not perfect. It will certainly evolve as it progresses. We don't legislate in a vacuum, but I believe a national, a national labeling standard makes the most sense for our highly-integrated and interdependent food supply. I am confident that we will take what we learn from today's hearing, as well as the input we are sure to receive, to inform out work as we move forward. We need commonsense legislation.

Thank you very much. I yield back.

Mr. PITTS. Gentleman's time has expired.

The chair now recognizes the vice chairman of the full committee, the gentlelady from Tennessee, Mrs. Blackburn, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman.

The people who are going to be harmed the most by the anti-GMO activist movement are those who can least fight against it. For example, there is a rice, it is called golden rice, which was developed with genetic engineering. One of the benefits to this rice, and the reason that it is called golden rice, is that it has a level of vitamin A that is not found in other rice. Golden rice has fed millions of starving people around the world, and additionally, prevented blindness and death because of the presence of vitamin A. The rice has been shown to be safe by multiple tests, and yet the anti-GMO activists have opposed its use simply because they do not like the idea of genetically-modified food.

Farmers have genetically modified food for centuries. Farmers would breed cattle to get the best traits. Crops were developed which are most resistant to drought, pests, and weeds. George Washington Carver did research and taught at Tuskegee for over 40 years. While there, he developed techniques to improve soil, give farmers alternative cash crops, improve the nutrition of people living in the south. He did this by experimenting with different varieties of peanuts and sweet potatoes. Of course, different varieties are simply products with different genetic makeup.

To bring reason to this discussion of different varieties of food, my colleagues and I have introduced legislation, H.R. 4432, the Safe and Accurate Food Labeling Act of 2014, introduced by Representative Pompeo and myself, along with Representatives Matheson and Whitfield, would prohibit genetically-modified plants intended for food use to be sold without first complying with a safety review process at the FDA. Under this Bill, if the FDA were to find a difference between the new product and a comparable non-GMO food that might affect safety, the FDA would require a label. The bill would do the following. Number one, advance food safety. Address the questions that consumers have about the safety of GMO food by requiring the FDA to conduct a safety review of all new GMO traits before they are introduced to the marketplace. Number two, inform consumers. Help consumers make sense of GMO labeling claims and their choices in the marketplace by asking the FDA to establish federal standards for companies that want to volun-

tarily label their product for the absence of or the presence of GMO food ingredients. Number three, provide consistency. Improve food labels using the term natural by requiring the FDA to define the term for its use on food and beverage products, thus creating a consistent legal framework to guide food labels and inform consumer choice. Fourth, eliminate confusion, which is what all good legislation should do, and remove the uncertainty of the 50 state patchwork.

Thank you for holding the hearing, and at this time, I yield my remaining time to Mr. Pompeo.

Mr. POMPEO. Thank you for yielding, Mrs. Blackburn. Thank you to you and to Mr. Butterfield for being cosponsors of this bill. You can see today that we are engaged in a bipartisan effort to get to the facts and the science surrounding this incredibly important issue. I want to thank all the witnesses for coming. I especially want to thank Stacey Forshee, fellow Kansan. It is her second trip to Washington to help do good work on behalf of consumers all across the country. Thank you for being here today.

Look, at the end of the day, this is a Bill that is needed to make sure that folks all across America can afford food. We in America have known for a long time that absent innovation and technology, the food prices will rise dramatically. We won't be able to feed the next billion people in the world either, something that I think we take great pride in here in America. Studies have shown that absent this legislation, the average family's food bill will go up by $500, and while I know there are some for whom that is not a lot of money, there are a lot of folks that I represent for whom that it is an awful lot of money, and who are living day-to-day and paycheck to paycheck, and who care deeply to make sure that their food prices, one of the things that they have to make hard decisions about from time to time, doesn't get even more difficult in this economy that we know is struggling so much. And it is also to help folks who are the producers of this food, to make sure that they have a way to get this product from their cattle ranch or their farm, or wherever it may be, to our store shelves in a way that they can do profitably, so that they can continue to invest in their products, so that America continues to be the leader in world production of food in an affordable way.

The science is not debatable here. There has been lots of research, lots of studies. Even those who oppose this bill don't make much of a case about the science. And that is what FDA is all about; it is about getting the science right. This bill gives them the opportunity to continue to review that, and I think it is really good policy and will make our food supply chain enviable all around the world.

I yield back.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the ranking member of the full committee, Mr. Waxman, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Today's hearing is on a topic about which many Americans have strong feelings. Twenty years ago, the first genetically-engineered food, the slow-ripening Flavr Savr tomato, went on the market. Today, the vast majority of corn and soybeans and cotton and canola and sugar beets and papaya grown in the U.S. are genetically engineered. All of these foods have been assessed by the Food and Drug Administration in a voluntary consultation process, and FDA has found no significant differences between them and their traditionally-bred counterparts.

Some 70 to 80 percent of packaged foods contain ingredients from genetically engineered, or GE, plants. Yet, despite their ubiquity and FDA's OK, many consumers remain uncomfortable with these foods and want mandatory labeling so they can avoid them.

As we consider the questions on GE foods at today's hearing, I will examine them in the context of some important principles I have long supported. First, I believe it is critical that our actions be based on science. As with so many other matters pertaining to products we use and consume every day, we need to rely on the expertise of FDA and other scientific regulatory agencies. Second, when we consider requiring labeling on food, that label should provide useful, science-based information to consumers. I certainly believe that food labels should enable consumers to make informed choices. I fought hard to pass legislation that gave consumers useful information about the nutritional content of food. Third, unless there is a compelling policy reason otherwise, we should maintain the ability of states to make a decision that is different from the Federal Government. All three of these concepts are at play here today, and I think we should examine each carefully.

On the first concept, what does the science tell us about GE foods? From what I understand, genetic engineering is not an inherently dangerous technology. Certainly, when it is used to give new properties to plants, we need to make sure those new properties don't affect the safety or nutrition of food from those plants, but if FDA has done that and finds that GE food does not differ in any significant way from traditional food, why should there be a label that marks it as different? If there are safety questions about a food, then it shouldn't be allowed on the market at all.

I look forward to hearing more from FDA and other witnesses on this today. Nevertheless, I understand that people may still want information about how their foods are produced. So let us look at the second concept of whether there is a way to give them meaningful and useful science-based information. On the one hand, I am concerned that people have the information they want or need. On the other hand, I am concerned that mandatory GE labeling could be inherently misleading. Mandatory labeling could lead consumers to believe that if the government is requiring a GE label, it must mean that GE foods are riskier or somehow fundamentally different from non-GE foods, and to date, scientists have concluded that they are not.

Furthermore, given that up to 80 percent of packaged foods contain GE ingredients, if we require labels, most food on the shelves would have a label declaring the presence of GE ingredients. I am not sure what good that does us. Under our current system, if consumers want to avoid GE foods, they can. They can buy organic

foods which, by law, cannot contain GE ingredients. Or they can search out the foods that manufacturers have certified and labeled as non-GE. That more targeted information may, in fact, be more useable, and I would like to hear what our witnesses think about that.

Now let us turn to the third principle of preserving the ability of states to make decisions that are right for their citizens, absent a compelling policy reason to the contrary. Even if there is not a compelling reason to require GE labeling at the federal level, that doesn't necessarily mean Congress should tell Vermont and other states that they cannot require such labeling. I have always believed states should have the right to act in the best interests of their residents. And I want to hear from our industry witnesses why the Vermont legislation, and potentially similar legislation in other states, is so harmful to some legitimate public interest that Congress should override them. Absent a compelling reason otherwise, I support letting states make their own laws and govern themselves.

I remain open to hearing the view of all of our witnesses today on these three points, and any other points pertaining to this issue. I think today's hearing will be very interesting and informative, and I thank the chairman for holding it.

Mr. PITTS. Chair thanks the gentleman.

That concludes the opening statements of the Members. As always, the written opening statements of the Members will be made a part of the record.

I have a unanimous consent request here, a statement from the Corn Refiners Association, to enter into the record.

Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. We have two panels today, and I would like to call our first panel, and I will introduce him at this time. We have Mr. Michael Landa, Director, Center for Food Safety and Applied Nutrition of the U.S. Food and Drug Administration. Thank you for coming today. You will have 5 minutes to summarize your testimony. Your written testimony will be placed into the record.

So at this point, Mr. Landa, you are recognized for 5 minutes for your summary.

STATEMENT OF MICHAEL M. LANDA, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Mr. LANDA. Good morning, Chairman Pitts, Ranking Member Pallone, and members of the subcommittee. I am Michael M. Landa, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. Thank you for the opportunity to be here today to discuss FDA's regulatory program for genetically engineered, or GE, foods.

Over the last 20 years, FDA has reviewed data and information on more than 150 plant-derived GE foods. These range from herbicide-tolerant soybeans to canola oil with a modified fatty acid profile. Based on our evaluations, we are confident that the GE foods in the U.S. marketplace today are as safe as their conventionally-

bred counterparts. The selection and genetic improvement of plants for agricultural use has been going on for thousands of years.

Mr. PITTS. Could you pull the mic a little closer to you please?

Mr. LANDA. Sorry.

Mr. PITTS. Yes, thank you.

Mr. LANDA. That better?

Mr. PITTS. That is better, thank you.

Mr. LANDA. Typically, plant breeding has involved cross-breeding and hybridization. Many of the foods that are already common in our diet, such as hybrid corn or nectarines, are obtained from plant varieties that were developed using such conventional genetic techniques, but during the breeding process, undesirable traits, such as poor yield or poor disease resistance, may appear. These unwanted traits can often be eliminated through additional breeding and selective reproduction, but the process is painstaking and time-consuming.

Today, by inserting one or more specific genes into a plant, scientists are able to produce a plant with new, advantageous characteristics. These techniques give scientists the ability to isolate specific genes of interest, and introduce them and their corresponding traits into plants without introducing undesirable genes or traits. This important improvement over traditional plant breeding can reduce the time needed to develop a new variety, and expand the range of new proteins and other substances that can be introduced into plants.

Any of these genetic modification techniques has the potential to change the composition of food in a manner relevant to food safety. FDA, however, has well-established scientific procedures for evaluating the safety of new foods, including any new substances in food, and our guidelines help developers address any safety concerns prior to marketing.

FDA regulates the safety of all foods, including those derived from GE plants, under the Federal Food, Drug, and Cosmetic Act, to be called the Food and Drug Act. Foods developed from genetically-engineered plant varieties, such as fruits, vegetables, grains and their byproducts, are subject to the same safety requirements as foods derived from non-GE plants. The Agency relies primarily on two sections of the Food and Drug Act to ensure the safety of food and food ingredients produced by genetic engineering—the adulteration provisions in Section 402 of the Act, and the food additive provisions in Section 409.

Food growers, manufacturers, and distributors are responsible for taking the steps necessary to ensure that their food products are safe. The law places primary responsibility for ensuring safety of food on industry. To help developers of food derived from GE plants comply with their obligations under the Food and Drug Act, and FDA's regulations, the Agency encourages them to participate in a voluntary consultation process prior to commercial distribution. Since the process was created, developers of GE plants have completed the process more than 100 times as they sought to introduce plants into the U.S. market. Typically, the consultation begins early in development when the Agency advises the company on what tests would be appropriate to assess the safety of the new food. After the studies are completed, a summary of the data re-

flecting safety and nutritional assessment are provided to FDA for its review. FDA expects developers of GE foods to analyze the composition of the foods from their new crop varieties to ensure that any changes compared to the foods' conventionally-derived counterpart are appropriately considered and addressed before marketing such foods. As part of our review and analysis, we consider whether any newly-introduced protein is likely to be allergenic or toxic, and whether levels of important nutrients or anti-nutrients have been changed in a way that is important to food safety or nutrition. We also consider whether any newly-introduced protein requires premarket approval as a food additive.

Examples of the information evaluated by FDA include the name of the food and the crop from which it is derived, the source, identities, functions and stability of introduced genetic material, the purpose of the modification and its expected effect on the composition and characteristics of the food, the identity and function of any new substances introduced by the genetic material, a comparison of the composition and characteristics of the GE food to that of food derived from the parental variety, and information on whether the genetic modification altered the allergenic or toxic potential of the food.

Let me just speak for a minute or so about FDA regulation of labeling. We regulate labeling including labeling of GE foods under the Food and Drug Act and our regulations. The Act establishes that a food is misbranded if its labeling is false or misleading in any particular. The Act also provides that labeling is misleading if it, one, fails to reveal facts that are material with respect to representations made or suggested in the labeling, or two, fails to reveal facts that are material with respect to consequences that may result from use of the food, whether that is a labeled use or a customary use.

Historically, FDA has taken the position that the use of genetic engineering in the development of food is normally not, by itself, material information within the meaning of the Food and Drug Act. Federal courts have held that absent a material fact or a difference in food derived from a GE source, the Act does not require labeling indicating that the food has been developed through genetic engineering.

In closing, let me reiterate that the consultation process for foods derived from GE plants is working well, and provides for a rigorous food safety evaluation of such foods. The Agency will continue to be vigilant, ensuring the safety and integrity of the food supply.

And with that, I am happy to answer any questions.

[The prepared statement of Mr. Landa follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT OF

MICHAEL M. LANDA, J.D.

DIRECTOR

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

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FOR RELEASE ONLY UPON DELIVERY

Good morning, Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee. I am Michael M. Landa, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss FDA's regulatory program for genetically engineered (GE) food.[1]

Over the last 20 years, FDA has reviewed and evaluated data and information on more than 150 GE plant-derived foods, ranging from herbicide-tolerant soybeans to canola oil with a modified fatty acid profile. In a 1992 policy statement on foods derived from new plant varieties (including GE plant varieties), FDA stated that the Agency was not aware of any information showing that foods derived by these methods (i.e., genetic engineering) differ from other foods in any meaningful or uniform way or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding. This 1992 statement and its scientific underpinnings still reflect FDA's current thinking about foods derived from GE plants and, based on our evaluations, we are confident that the GE foods in the U.S. marketplace today are as safe as their conventional counterparts.

BACKGROUND

The selection and genetic improvement of plants for agricultural use has been going on for thousands of years, although plant breeding as a science only began in the late 1800s. Typically,

[1] Genetically engineered foods are also referred to as biotech, bioengineered, and genetically modified (GM) foods. Because from a scientific perspective, the term "genetic modification" means the alteration of the genotype of an organism using any technique, new or traditional, and therefore also encompasses plants altered through methods such as conventional breeding and selection, FDA uses the term "genetically engineered," or "GE," to distinguish organisms that have been modified using genetic engineering (also known as modern biotechnology) from those modified through traditional breeding.

plant breeding has involved crossbreeding and hybridization, in which two related plants are cross-fertilized, and the resulting offspring have characteristics of both parent plants. In the breeding process, however, many undesirable traits often can appear in addition to the desirable ones. Some of those undesirable traits can be eliminated through additional breeding, which is time-consuming. Breeders can then further select and reproduce the offspring that have the desired traits. Many of the foods that are already common in our diet are obtained from plant varieties that were developed using conventional genetic techniques of breeding and selection. Hybrid corn, nectarines (which could be considered genetically altered peaches), and tangelos (a genetic hybrid of a tangerine and grapefruit) are all examples of such breeding and selection.

Today, by inserting one or more specific genes into a plant, scientists are able to produce a plant with new characteristics. These techniques give scientists the ability to isolate specific genes of interest and introduce them and their corresponding traits into plants without simultaneously introducing undesirable genes and traits. This is an improvement over traditional plant breeding because it can reduce the time-consuming process of breeding out undesired genes and traits when developing a new variety. Genetic engineering also expands the range of new proteins and other substances that can be introduced into plants.

Any genetic modification technique, including both traditional methods and genetic engineering, could change the composition of a food in a manner relevant to food safety. However, FDA has well-established scientific procedures for evaluating the safety of such new substances, and our guidelines help developers identify these issues and address such concerns prior to marketing. It is important to note that the kinds of testing typically conducted by developers of a GE food

crop to ensure that their foods meet applicable requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) also address food safety concerns. In the event that something unexpected does occur, this testing provides a way to detect such changes at the developmental stage and defer marketing until any concerns are resolved. FDA expects developers of GE foods to analyze the composition of the foods from their new crop varieties to ensure that any changes compared to the food's conventionally derived counterpart are appropriately considered and addressed before marketing such foods.

As part of our review and analysis, we consider whether any newly introduced protein is likely to be allergenic or toxic and whether levels of important nutrients or anti-nutrients have been changed in a way that is important to food safety or nutrition. We also consider whether any newly introduced protein requires premarket approval as a food additive. Later in my testimony, I will describe the Agency's rigorous premarket consultation process and discuss in more detail how it helps us ensure the safety of foods derived from GE plants.

LEGAL AND REGULATORY FRAMEWORK

FDA regulates the safety of foods, including foods derived from GE plants, under the FD&C Act and other applicable laws and regulations. Under the FD&C Act, FDA is also responsible for enforcement with respect to unlawful pesticide chemical residues in foods. Foods, such as fruits, vegetables, grains, and their byproducts, derived from plant varieties developed through genetic engineering, are subject to the same safety and labeling requirements as foods derived from non-GE plants. The Agency has broad authority to initiate regulatory action if a product fails to meet the requirements of the FD&C Act, as discussed in more detail below.

FDA regulates foods from GE crops in conjunction with the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) under the Coordinated Framework for the Regulation of Biotechnology, adopted by the agencies in 1986.[2] Pesticides, including those genetically engineered into food crops, are regulated by EPA, which reviews the safety of pesticides and sets tolerances for pesticides (or establishes exemptions from the requirement of a tolerance). USDA's Animal and Plant Health Inspection Service oversees the agricultural, plant health, and environmental safety of planting and field testing of GE plants.

FDA relies primarily on two sections of the FD&C Act to ensure the safety of foods and food ingredients, including those that are produced using genetic engineering:

The adulteration provisions of section 402(a)(1) [21 U.S.C. 342(a)(1)]. Under this post-market authority, FDA has the power to remove a food from the market (or sanction those marketing the food) if the food poses a risk to public health. It is important to note that the FD&C Act places a legal duty on developers, manufacturers, and distributors to ensure that the foods they market to consumers are safe and comply with all legal requirements.

The food additive provisions of section 409 [21 U.S.C. 348]. Under this section, a substance that is intentionally added to food is a food additive, unless the substance is generally recognized as safe (GRAS) or is otherwise excluded (e.g., a pesticide, the safety of which is overseen by EPA). The FD&C Act requires premarket approval of any food additive, regardless of the

[2] 51 FR 23302, June 26, 1986

technique used to add it to food. Use of an unapproved food additive renders the food unsafe and subject to the adulteration provisions in 402(a)(2)(C) of the FD&C Act.

FDA's *Statement of Policy: Foods Derived from New Plant Varieties*[3] explains how existing legal requirements apply to plant-derived food products developed using the tools of biotechnology. The policy was designed to answer questions about these products and to assist developers, prior to marketing, to meet their legal duty to provide safe and wholesome foods to consumers. The basic principle of the policy is that the traits and characteristics of the foods should be the focus of safety assessment for all new varieties of food crops, no matter which techniques are used to develop them.

Under FDA policy, a substance that would be a food additive if it were added during traditional food manufacturing is also treated as a food additive if it is introduced into food through genetic engineering of a food crop. Section 409 requires premarket approval of any food additive and, thus, requires premarket approval of any substance intentionally introduced via genetic engineering that is not GRAS.

Examples of substances intentionally introduced into food that would not be considered GRAS and, therefore, would be reviewed as food additives include those that have unusual chemical functions, have unknown toxicity, or would be new major dietary components of the food. In general, substances intentionally added to or modified in food via genetic engineering to date have been proteins and fats that are, with respect to safety, similar to other proteins and fats that

[3] 57 FR 22984, May 29, 1992, accessible at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm*

are commonly and safely consumed in the diet. Therefore, these substances have not been subject to the food additive approval process. In our experience with GE foods to date, we have approved only one substance as a food additive for human consumption—an enzyme produced by an antibiotic resistance gene (kanamycin). We are currently reviewing several substances under the food additive approval process for use in animal food.

VOLUNTARY PREMARKET CONSULTATION PROCESS

Food growers, manufacturers, and distributors are responsible for taking the steps necessary to ensure that their food products marketed in the United States are safe. To help developers of food derived from GE plants comply with their obligations under the FD&C Act and FDA regulations, the Agency encourages them to participate in a voluntary consultation process with FDA prior to commercial distribution. The goal of the voluntary premarket consultation process is to ensure that any safety or other regulatory issues associated with food from the new plant variety are resolved *prior* to commercial distribution. Although the premarket consultation is voluntary, in our experience, most developers utilize this pathway. FDA also retains the authority to regulate and ensure the safety of foods derived from new plant varieties under existing adulteration and misbranding provisions of the FD&C Act.

The results of FDA's consultations are public information and are available on the Agency's website. Since the consultation process was created, developers of GE plants (which include private companies, academic institutions, and government agencies) have completed the process more than 100 times as they sought to introduce plants representing more than 150 different crop varieties into the U.S. market. These evaluations have included varieties of soybean, corn,

cotton, canola, papaya, alfalfa, creeping bent grass, plum, potato, sugar beet, wheat, rice, cantaloupe, flax, squash, and radicchio with traits such as herbicide tolerance, insect resistance, virus resistance, altered ripening, altered nutritional profiles, altered plant fertility, and altered plant growth properties. Where the traits are pesticidal, FDA directs developers to work with EPA, which evaluates the safety of pesticides under section 408 of the FD&C Act.

Typically, the consultation begins early in the product development stage, well before it is ready for market. Developers meet with FDA scientists to describe the product they are developing. In response, the Agency advises the company on what tests would be appropriate for the developer to assess the safety of the new food.

After the studies are completed, a summary of the data and information on the safety and nutritional assessment are provided to FDA for review. The Agency evaluates the information for all relevant food safety hazards, including potential unintended effects on plant composition and nutritional properties, since plants may undergo changes other than those intended by the developers. For example, FDA scientists evaluate data and information to assure that the newly expressed compounds are safe for food consumption and that there are no allergens new to the food, no increased levels of natural toxicants or anti-nutrients, and no reduction of important nutrients.

The safety assessment approach FDA applies during its evaluation of consultation submissions is consistent with the approach laid out in the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003), established

by the Codex Alimentarius Commission, a food standard-setting body established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

Some examples of the information evaluated by FDA include:

- The name of the food and the crop from which it is derived;
- The uses of the food, including both human food and animal feed uses;
- The sources, identities, and functions of introduced genetic material and its stability in the plant;
- The purpose or intended technical effect of the modification and its expected effect on the composition and characteristic properties of the food or feed;
- The identity and function of any new substances introduced by the genetic material, including an estimate of its concentration;
- A comparison of the composition and/or characteristics of the GE food to that of food derived from the parental variety or other commonly consumed varieties with special emphasis on important nutrients, anti-nutrients, and toxicants that occur naturally in the food;
- Information on whether the genetic modification altered the potential for the GE food to induce an allergic response; and
- Other information relevant to the safety and nutritional assessment of the GE food.

These examples are not meant to be exhaustive, but are sufficiently broad so as to provide FDA with an indication of any safety or other regulatory issues that may require additional

investigation. This flexibility allows FDA's consultation program to ask the necessary questions to understand any uncertainties that may exist concerning safety or other attributes of the food in order to ensure the safety and lawfulness of food from a new plant variety.

If FDA scientists have questions about the safety data, the developer may, for example, provide more detailed answers or conduct additional studies. The fact that participation in the process is voluntary should not mislead individuals to believe that the process does not provide for a rigorous food safety evaluation. It is not uncommon for FDA to request additional data and information or clarification about the data and information submitted by the developer. This iterative process makes for a rigorous safety evaluation. FDA considers a consultation to be complete only after all safety and other legal issues have been resolved. The premarket consultation process is working well and protects public health by helping FDA ensure that firms are making market-entry decisions in compliance with the law.

LABELING OF GE FOODS

FDA also regulates the labeling of food under the FD&C Act. Section 403 of the Act [21 U.S.C. 343] sets labeling requirements for foods subject to the FD&C Act. In general, all foods, whether derived from genetic engineering or not, are subject to these labeling requirements. Section 403(a)(1) establishes that a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) provides, in relevant part, that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food

under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual.

In its 1992 Policy Statement, FDA explained that it found no basis to conclude that foods derived from new plant varieties using genetic engineering techniques, as a class, differ from other foods in any meaningful or uniform way or pose any different or greater safety concern than foods developed by traditional plant breeding. Therefore, the use of genetic engineering in the development of a food is normally not, by itself, material information within the meaning of section 201(n) of the FD&C Act. Scientific studies, information, and data FDA has reviewed since then, including data and information evaluated through the voluntary premarket biotechnology consultation process, reflects the same conclusion.

Federal courts have held that, absent a material fact or difference in a food derived from a GE source, sections 403(a)(1) and 201(n) of the FD&C Act do not require labeling indicating that the food has been developed through genetic engineering. Further, courts have held that consumer desire to know such information is not, by itself, sufficient to require such labeling. FDA may require special labeling for a GE food, just as we would for a non-GE food that has been genetically modified through traditional methods, when the genetic change results in a material difference in the food, such as a difference in nutritional content of the food (e.g., altered fatty acid profile) or a difference in functional characteristics of the food (e.g., suitability for frying). We note that the Agency has received two Citizen Petitions regarding the labeling of genetically engineered foods. We are currently reviewing those petitions and considering the issues presented.

We recognize and appreciate that many consumers are interested in knowing whether their food is produced using genetic engineering. Currently, food manufacturers may indicate through voluntary labeling whether foods have or have not been developed through genetic engineering, provided that such labeling is truthful and not misleading. The Agency is supportive of such voluntary labeling and, in 2001, issued draft guidance to industry to help food manufacturers who wish to voluntarily provide such information in food labeling to help ensure that such labeling is truthful and not misleading. FDA received more than 155,000 comments on the draft guidance. The Agency has considered the comments we received and is currently revising the draft guidance with the goal of publishing a final guidance document to assist food manufacturers who want to provide such labeling statements.

GE ANIMALS

FDA regulates GE animals under the new animal drug provisions of the FD&C Act and the Agency's implementing regulations. When the genetic material, or recombinant DNA (rDNA) construct, used to engineer the animal is intended to affect the structure or function of that animal, the rDNA construct meets the definition of a drug in the FD&C Act. The new animal drug approval process provides a rigorous review for such products.

The FD&C Act generally requires sponsors to demonstrate the safety and effectiveness of a new animal drug for the proposed conditions of its use prior to marketing. For new animal drugs that are intended for use in food-producing animals, FDA's evaluation of safety includes not only an evaluation of target animal safety, but also an evaluation of food safety. In addition, FDA is

required to comply with the National Environmental Policy Act prior to taking any major actions, such as approval of an application.

In January 2009, FDA issued a final guidance for industry on the regulation of GE animals. The guidance explains the process by which FDA is regulating GE animals and provides a set of recommendations to producers of GE animals to help them meet their obligations and responsibilities under the law.

As the company has publicly noted, FDA is currently reviewing a new animal drug application related to AquAdvantage Salmon, an Atlantic salmon developed by AquaBounty Technologies, Inc. which is genetically engineered to grow more quickly than its conventional counterpart. In December 2012, the Agency made its draft environmental assessment (EA) and a preliminary finding of no significant impact (FONSI) available for public comment. The draft EA and preliminary FONSI are the Agency's initial assessment of the potential impacts of the proposed product on the environment of the United States under the specific conditions of use proposed by the sponsor, and they are one part of the evaluation of the new animal drug application. FDA received over 35,000 comments on the draft EA and preliminary FONSI. We are reviewing these comments in order to determine whether any changes in the draft EA are warranted or if there is any new information that would cause the Agency to change its preliminary findings related to the environmental assessment.

On September 19-20, 2010, the Agency held a public meeting of its Veterinary Medicine Advisory Committee (VMAC), a body comprised of independent outside experts who advised

FDA on scientific, technical, and policy matters, to discuss AquAdvantage Salmon. The presentations made by Agency experts, the transcript of that meeting, the Chair's report, and VMAC documents containing detailed information on the review process are all posted on FDA's website for public review. At the public meeting, the Agency did not indicate any preliminary views or determination on the product application. It did, on the safety question, provide a preliminary indication noting that based on the data and information available at that time, food from AquAdvantage Salmon appears to be as safe to eat as farmed, conventionally bred Atlantic salmon. FDA will make a final food safety determination before reaching any final decision on whether to approve the new animal drug application for AquAdvantage Salmon. We also note that at that time, the Agency will provide information to the public regarding any labeling of AquAdvantage Salmon, in the event that the new animal drug application for this product is approved.

CONCLUSION

FDA's consultation process for foods derived from GE plants provides for a rigorous food safety evaluation of GE foods. As a result of these premarket consultations, we are confident that GE foods in the U.S. marketplace today are as safe as their conventional counterparts. The Agency, in cooperation with EPA and USDA, will continue its oversight of new and emerging GE food products and will be vigilant in ensuring the safety and integrity of the food supply.

Thank you for the opportunity to discuss FDA's regulation of GE foods. I am happy to answer any questions you may have.

Mr. PITTS. The chair thanks the gentleman.

We will now begin questioning. I will recognize myself 5 minutes for that purpose.

Mr. Landa, you state in your testimony that FDA has reviewed and evaluated data and information on over 150 genetically-engineered foods. Based on these reviews and the data that has been compiled over the past 20 years, is the Agency more or less confident today in the safety of the underlying technology?

Mr. LANDA. I think its confidence remains strong. It has been and remains strong.

Mr. PITTS. How do you know that genetically-engineered foods are no different in terms of safety than their conventional counterparts?

Mr. LANDA. Well, we know this based on the reviews we conduct. We are looking at the genetic material, we are looking at products of that material, new proteins, for example, at their safety. We look at potential toxicity and allergenicity. We look at chemical composition to see whether it is different from the conventional counterpart. We look at the safety of the whole food, if you will, and we look to see whether there are any differences in the nutrients that might require disclosure, for example.

Mr. PITTS. And how long, typically, does your evaluation take?

Mr. LANDA. I will have to get back to you with detailed information, if I may.

Mr. PITTS. All right. Are there any material differences between genetically-engineered ingredients and those derived from traditionally-bred crops?

Mr. LANDA. In general, no. We have found that there have not been such differences.

Mr. PITTS. Does the FDA support the various state, legislative and ballot measures that would require the labeling of genetically-engineered foods, or would these initiatives interfere with FDA's authority over food production or labeling?

Mr. LANDA. We haven't reviewed the initiatives. We don't have any view about them and, therefore, we don't know whether they would interfere or not.

Mr. PITTS. Would state-specific labeling requirements change anything as far as your evaluation is concerned?

Mr. LANDA. I do not believe so.

Mr. PITTS. All right. Let me ask if there currently is a lack of consensus about the validity of the research and science behind the safety of foods derived from genetically-engineered plant varieties.

Mr. LANDA. I think there is not. That is, I think there is a consensus.

Mr. PITTS. There is a consensus——

Mr. LANDA. Yes.

Mr. PITTS [continuing]. In the scientific community?

All right, at this time, I will recognize Mr. Pallone 5 minutes for his questions.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. Landa, some who oppose mandatory GE labeling argue that such labeling would be inherently misleading. They argue that such a requirement would easily be taken to imply that the government considered food from GE plants to be so fundamentally dif-

ferent from food from non-GE plants as to warrant a special designation. And I guess I agree that if the GE designation had to look like a warning, it would be misleading. However, in the next panel, Mr. Faber testifies that his organization is not asking for anything like a warning label, but rather a modest disclosure on the back of the package. And I guess I would like to get your view based on your experience with food labeling whether it would be possible to design the size and wording of a mandatory GE designation in such a way as to be innocuous, in other words, those who look for it could find it, those who don't care about genetic engineering would have no reason to pay attention to it. I am not asking whether FDA could require such a label, nor whether you think any form of mandatory GE labeling would be appropriate from a scientific perspective, just that if Congress were to decide that the best way to avoid multiple state GE labeling requirements would be to impose a federal GE labeling requirement, do you think it would be possible to do so in a way that would be neutral and would not tarnish the product. And also as part of your answer, if you could describe the FDA's experience with irradiation labeling and whether we could learn from that experience.

Mr. LANDA. I certainly have not thought about the question you posed with respect to the nature of a statement about GE labeling. I don't think the Agency has considered that question because our focus has been on whether there is a difference——

Mr. PALLONE. The material. The material definition.

Mr. LANDA [continuing]. Allowing us to require disclosure. I think one way of looking at that question is whether there are data on similar efforts, or whether one could design a study to answer that question so that people would look at different formulations of labeling, and you would learn what they would take away from those different formulations.

Mr. PALLONE. I mean I—the reason I asked the question, I know you—I guess you don't really feel you can answer it at this point, is because, you know, a lot of people that approach me that would like the labeling requirement don't necessarily make the argument that there is a scientific difference, but just that they should—or that it is bad, but just that they should know.

Mr. LANDA. No, I understand, but one might, for example—again, I think maybe one could develop different formulations and do experimental studies surrounding them, the types of studies that are typically done over the internet with panels that are set up, they are large numbers, to see what people would take away from a different mock label.

Mr. PALLONE. OK. Now, I know you say that the FDA's consultation process is—right now is obviously voluntary, but what does that mean in practice? In other words, if it is voluntary why would companies choose to use it? Do you have an estimate of how many manufacturers choose not to use it? In other words, what are the pros and cons of this voluntary approach?

Mr. LANDA. Well, we think for people intending to commercialize product, we think those people do come to us for several reasons. One, there is the basic statutory requirement on companies to market food that is safe. Another is that we learn a great deal from EPA and from APHIS and from others about what is going on in

this area, which is another incentive for people also to come to us. And finally, we think that growers are going to be reluctant to use seeds where there isn't a no-questions letter from us because if, at the end of that growing season, they have a crop that turns out to be either unlawful or unmarketable because questions have arisen, better to start with a product that has been through the consultation process. So we think there are lots of drivers that make the voluntary process one that people do subscribe to, at least people who are intending to commercialize.

Mr. PALLONE. Now, you say that you—the FDA hasn't required the genetically-engineered label because they don't believe the information is material. Does the FDA have the authority under the Act to change its assessment that information is not material? Do you think you have the authority to do that?

Mr. LANDA. Yes, certainly in a given case. And let me also say, the policy I have been describing and we have been discussing, it has been in place for roughly 20 years, but we have been asked to change it. We have before us several citizen petitions asking to change our view on the law with respect to materiality, and asking us to change our view with respect, in some cases I think, to the facts. And we are considering those petitions. We haven't responded yet, but we certainly have the authority to change a position as long as the change is appropriately grounded in the science and interpretation of the law.

Mr. PALLONE. Thank you.

Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the vice chairman of the full committee, Mrs. Blackburn, 5 minutes for questions.

Mrs. BLACKBURN. I thank you, Mr. Chairman.

Mr. Landa, thank you so much for your time. I have to tell you, I find this an absolutely fascinating debate, and am so appreciative that you would take the time and the FDA would take the time to talk with us on it.

I grew up in south Mississippi with a grandmother who, when she went to college at the turn of the century, the 19th century, chose to audit agriculture classes. So then buying a farm and with her savings from being a teacher, and married, she has five boys from—and then my mother, five more boys. Big farm. During the Depression, she helps feed our hometown. So being someone who enjoys growing things, as I was, and very active in 4H club, which I was, and going on to be a part of a crop judging team, I learned to appreciate what goes into having good-looking food, because we eat with our eyes. I also grew to appreciate yield per acre, that I would learn from my grandmother, and having foods that would be more drought-resistant, that would take less chemicals, that would take less pesticides, things of that nature, and the importance of that so that you had a good-looking and good-tasting food product that did not, as readily and easily, spoil.

So I come to this debate from that background, and today even in my district, I visited a lot of the farmers' markets, and every once in a while someone will come up and talk about genetically-engineered food or genetically-modified food, and I enjoy asking them what that means to them. And I have found it so fascinating

that it means something different to nearly everyone that I talk to, because we don't have that federal standard, if you will. And I hope that you all at the FDA are going to be able to work with us on this. Basically, everything we eat is genetically-modified, whether it is corn or wheat or any variety of tomatoes, which were mentioned earlier, it all has been genetically modified. If you want to go back and eat original wheat or barley, it is not going to give you very much of a yield, and it is not going to be the desirable product that you are looking for today. So we have to realize that as a part of this debate.

So moving forward, let us go back to Mr. Pallone's question on the labeling. I would love to hear from you what you all at the FDA, what your team thinks should be conveyed in those labels to the consumer, what should be there about health, about safety, and about nutritional content of those products?

Mr. LANDA. Well, the statute tells us as a general matter that labeling is not to be false or misleading. That is sort of the basic proposition. And since then, there have been many changes to the law, including NLEA, which has directed us to write the nutrition facts label or nutrition facts panel, which has information about macronutrients and micronutrients. And, in fact, we are in the process now of updating that label. We proposed earlier this year to do that, and we are reviewing comments on it.

Mrs. BLACKBURN. And when do you anticipate having those recommendations?

Mr. LANDA. I would certainly hope that the Agency could issue final rules updating nutrition facts by 2016. It is a complicated—it is called informal rulemaking, which is less difficult than formal rulemaking, but it is still a——

Mrs. BLACKBURN. OK.

Mr. LANDA [continuing]. Very resource-intensive process.

Mrs. BLACKBURN. I am about to run out of time. I want to get to a couple of other things. I am certain you all go through reams of information on analyzing data on the GE foods, and I wonder how often do your FDA analysts go back in and request additional information when you have a submission?

Mr. LANDA. I don't know. I can't answer that, but we will get that information for you.

Mrs. BLACKBURN. OK. Does the FDA distinguish foods based on the method of breeding or the material composition of the food?

Mr. LANDA. Not for labeling purposes, unless there is a material fact.

Mrs. BLACKBURN. OK. Are you satisfied that your agency is capable of understanding genetic engineering and determining whether or not a plant is safe?

Mr. LANDA. Yes.

Mrs. BLACKBURN. Thank you.

I yield back.

Mr. PITTS. Chair thanks the gentlelady.

Now recognize the ranking member of the full committee, Mr. Waxman, 5 minutes for questions.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Landa, in many of the articles on GE foods, people claim that the science is unsettled, controversial or new, with the impli-

cation that there may be unknown risks and, therefore, consumers are justified in being uneasy with GE foods. And yet from your testimony, we get a different impression. However, while you point out that genetic engineering is just one of many techniques used in plant breeding, I don't think FDA has a consultation process for any of the others.

How new is the science behind GE foods, and what are the risks from them, and if genetic engineering is not especially risky, why do you encourage companies to go through your consultation process prior to marketing foods from GE plants?

Mr. LANDA. I think it is largely that there certainly is some possibility, for example, of a material difference. I think we identified one with a product where there wasn't a safety issue, but there was a difference in how the food performed in the consumer's hands. I think it had to do with friability. And we have completed over 100 consultations. There have been a handful that have not gone to completion where we were asked to stop the review, or the submitter withdrew. I think in general, the process, which has been in place for some time, was one that enabled us to learn and also to build confidence, and we would hope to transmit some confidence in this technology.

Mr. WAXMAN. Is this a new area of science?

Mr. LANDA. No. Certainly, it is decades old.

Mr. WAXMAN. As you know, many consumers believe they have a right to know whether a food was manufactured using genetically-engineered ingredients, irrespective of all the science in the world showing them to be no different from non-GE ingredients. I would like to understand more about such a requirement and how it would fit in with FDA's traditional stance toward labeling requirements if Congress were to respond to this consumer demand and pass a law requiring the label—labeling of genetically-engineered foods.

How would mandatory labeling of genetically-engineered foods compare with existing labeling requirements, such as to reveal the presence of allergens in a food, or that a food has been irradiated? Would FDA be concerned about a new law that requires the labeling of GE foods, and if so, why?

Mr. LANDA. There isn't any administration position on such legislation. It would be obviously new for us. We would implement it as best we could. I suppose the question it would raise would be what is sort of the limiting principle. If what animates this is right to know, the question then becomes what is it that people do not have a right to know on the food label, and I am not sure how one answers that question.

Mr. WAXMAN. There are just some foods that are irradiated. Why would anybody irradiate their food? Why would a manufacturer want to irradiate food?

Mr. LANDA. For safety reasons.

Mr. WAXMAN. To keep the food from spoiling?

Mr. LANDA. Spices. Spices are irradiated, for example.

Mr. WAXMAN. OK. Now, is there any harm from that? Any——

Mr. LANDA. No.

Mr. WAXMAN [continuing]. Consequences that are problematic?

Mr. LANDA. No.

Mr. WAXMAN. Yet, we require labeling. Why do we require labeling on foods that have been irradiated?

Mr. LANDA. It has been thought that irradiation could as a process change some properties of the food and so that was the thinking behind that.

Mr. WAXMAN. But there is no evidence of that?

Mr. LANDA. I would have to go look at what we said at the time we issued the labeling requirement.

Mr. WAXMAN. Now, why is this any different? You don't think there is a problem. You said there may be a problem but you don't know of a problem. What is the difference between informing people that their spices have been irradiated if they want to know that information, even though you don't think it is particularly helpful for them to know it?

Mr. LANDA. I think at the time with irradiation, we thought that there was a possibility of a change in characteristics of the food which people would not know about. We do not think that is the case with genetic engineering.

Mr. WAXMAN. Do you think we should remove the labels from irradiated foods?

Mr. LANDA. The Agency has issued a proposal to do that. It has not finalized that.

Mr. WAXMAN. OK, thank you, Mr. Chairman.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Thank you for being here. I—a question I have is, I understand the state debate, but does—do you know of any state that has the capability to do the research and the findings to the same standard as the FDA?

Mr. LANDA. I don't, but I wouldn't have any reason to know that one way or another.

Mr. SHIMKUS. Yes. I can tell you I am from a big state of Illinois, and we can't do it. There may be one—maybe—well, maybe California has some capability, but my guess is smaller states, they don't have nearly the ability to do the research that you all do. And I think that is part of this whole should states be able to have their own labeling restrictions and requirements because, as we have found, it is really based upon emotion and not based upon a scientific evaluation.

Let me ask about—do you distinguish foods based upon the method of breeding, or the material composition of the food?

Mr. LANDA. We don't require labeling based on method of production alone.

Mr. SHIMKUS. Why not?

Mr. LANDA. Because we have found that it is not material to safety or nutritional composition.

Mr. SHIMKUS. Yes, and I appreciate that. Let me—in the case of sugar, right, we—sugar processors require to label whether refined table sugar comes from—I am—I guess the questions is, are sugar processors required to label whether refined table sugar comes from a certain species or plant?

Mr. LANDA. I am sorry, I don't——

Mr. SHIMKUS. So if you have—are we—you don't require fine table sugar to label whether it comes from sugar beets or from cane.

Mr. LANDA. No.

Mr. SHIMKUS. Why?

Mr. LANDA. Again, I think it is a question of materiality, to safety or nutrition.

Mr. SHIMKUS. So if we were—would the consumers be any—would they get any benefit if that labeling requirement for fine table sugar also had a requirement, well, this is beet-produced fine table sugar or sugar cane fine table sugar.

Mr. LANDA. Again, what we focus on is the attribute of the food as the consumer would——

Mr. SHIMKUS. And——

Mr. LANDA [continuing]. Would eat it.

Mr. SHIMKUS [continuing]. For the genetically-engineered ingredients in foods today, is there any evidence that they vary in their objective characteristics in any meaningful or uniform way?

Mr. LANDA. No, not as a class.

Mr. SHIMKUS. Can you explain why FDA's regulatory focus is on the food or food product as opposed to the process in which it was grown?

Mr. LANDA. Because, of course, in the end, it is the food that we eat.

Mr. SHIMKUS. Right. Yes, and I appreciate—I think you are going to keep getting the same questions from members here on trying to understand—you are Food and Drug Administration, you all come before us on a lot of different aspects. You are our trusted advisors. We respect the job that you do. I know this is a very difficult and emotional debate for some folks on both sides because it deals with some individual consumers, it deals with the agricultural community that many of us represent. We have to have an impartial, you know, observer based upon health and safety effects to the consuming public. We appreciate the work you do.

Mr. Chairman, thank you, and I yield back.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentlelady from California, Mrs. Capps, 5 minutes for questions.

Mrs. CAPPS. I thank you, Mr. Chairman, and thank you, Mr. Landa, for your appearance here with us today, and your testimony.

I understand that FDA's position that under the Food, Drug and Cosmetic Act, the breeding methods by which a plant was developed is not material information about food from that plant. However, in their testimony, Mr. Faber and Representative Webb point out that many consumers do believe that foods labeled as natural—in quotes, "natural", are not genetically engineered, and sometimes buy such foods because of that belief. They also say that many such foods do contain GE ingredients.

I can understand FDA's reluctance to wade into the argument as to what constitutes natural, but if many consumers believe that the term natural implies non-GE, and are making purchasing choices based on that belief, shouldn't the use of that term on a food label be considered a representation that the food is, in fact, non-GE? I

know that is kind of a packed question, and I am going to continue just for a little bit more to give you plenty to deal with. This is my only question, actually. And if so, wouldn't the use of the term natural on a food containing GE ingredients be, as the statute says, failing to reveal facts and material in light of such representation if it does not state that it contains GE ingredients? Gets convoluted. In other words, and this is the question, even though the use of genetic engineering may not be material information, per se, doesn't it become material information in those circumstances in which the rest of the labeling of the GE food implies that the food does not contain GE ingredients?

If you can sort that out, kudos to you, but this is the topic I wish to hear from you. And take your time because for the next few minutes.

Mr. LANDA [continuing]. There is a short answer to this, which is that we have pending several citizen petitions related to the question of what is natural, including one going to the very question I think you are getting at which is, is the food that contains a genetically-engineered ingredient, or ingredient derived from a genetically-engineered plant, a food that may properly be labeled as natural. There is a big debate about that. We have been petitioned to say yes. I am sure we have been petitioned to say no. We have been petitioned to establish a definition for natural, and we are considering those petitions. That is really all I can say at the moment.

Mrs. CAPPS. Is there any—can you shed any light on this topic for the sake of our constituents as to where you are going in your—I mean I agree, it is very confusing.

Mr. LAND. One possibility, and we have not committed to this, but to take you back a little bit, the Agency embarked on an effort to define natural years ago. That did not result in a codified definition. It resulted in a statement and a preamble that natural can't be either added or synthetic, I think was the language. We have been asked on many occasions to develop a definition. I personally have been asked on many occasions. I have always said that we really don't have the resources to do that.

We now have petitions before us. I think if we decide to reconsider this issue, it will necessarily have to be a public process. Whether we would embark on rulemaking, which has to be a public process, or guidance, there will be some public process if we decide to revisit this.

Mrs. CAPPS. Well, I actually applaud that. I think the public is already engaged, I believe that, and would be welcoming—this is my opinion now, but from what my constituents are telling me, that they are already engaged, and a signal from FDA that—maybe you don't have black-and-white kind of answers to give, that you are seriously considering this, and maybe that we can carry on this kind of conversation throughout the country. It appears to me the consumers are clearly confused by the current labeling system. I mean we can perhaps all agree on that; it is complicated today. And they are making purchasing decisions based on, sometimes I believe, misleading or unclear labeling. And I am not blaming, necessarily, here, but it leads to a state of confusion. And I hope that you can find the resources in FDA to take a broader look at what

is happening with respect to consumers' experiences so that they can have confidence in this system that we have and work with you to strengthen the labeling system to reduce the kind of confusion that we are talking about.

With that, I will yield back. Thank you.

Mr. LANDA. Thank you.

Mr. PITTS. Chair thanks the gentlelady, and now recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you, Mr. Chairman.

OK, I eat a fair number of odd foods, and a number of those are labeled non-GMO. Is there a distinction between genetically modified and genetically engineered?

Mr. LANDA. I think as a technical matter, GMO refers to an organism, as opposed to genetic engineering which we think of as having to do with sort of modern biotechnology.

Mr. GRIFFITH. OK. In that regard, one of the concerns that I have, and I want to know if it is a concern for you, is that I come from a family where just about half of us have some kind of food allergy. If you are changing proteins around and you have things that are, for the general public, generally recognized as safe, are you able in what you all do to be able to distinguish if a protein that someone may be allergic to has been added to a product which they may not know that protein has just been included?

Mr. LANDA. That is part of the evaluation process, and if there were to be an addition that might prompt an allergic reaction that one would not expect, we would require a label disclosure.

Mr. GRIFFITH. So you would pick out those things which people arehighly allergic to, or which there is a significant percentage of folks that have a problem with, and you say, OK, you can't put the strawberry ingredient into this tea?

Mr. LANDA. Or we would require disclosure.

Mr. GRIFFITH. Or disclosure.

Mr. LANDA. Most likely would be the——

Mr. GRIFFITH. And I apologize if I missed this in one of your earlier answers, are you all looking at the possibility of—for those people who may be concerned, saying or labeling a product as something that is, in fact, as opposed to saying it is genetically engineered or genetically modified in some way, having those companies that want to, obviously you pay more for it, but have some process where they can actually say we have used all products that are not genetically engineered or modified?

Mr. LANDA. We have had draft guidance since about 2001 on voluntary labeling. So there isn't any prohibition on a voluntary label that your food does not contain——

Mr. GRIFFITH. OK.

Mr. LANDA [continuing]. GE ingredients. So the basic requirement is that statement not be false or misleading.

Mr. GRIFFITH. OK. And I appreciate that. You indicated earlier that it was pretty much a consensus that this was not something that was dangerous, if I understood your testimony correctly, and yet I know there are a number of countries around the world that have concerns about products, and sometimes will ban our exports if they think that there has been some crosspollination or something. Can you explain why they are concerned?

Mr. LANDA. I think different countries have different regulatory systems. There are obviously different cultures with different attitudes towards different aspects of foods, from production to consumption to preparation and everything else.

Mr. GRIFFITH. Other than culture, have any of those countries had studies that indicated there was some danger to the general human——

Mr. LANDA. Not to my knowledge, no.

Mr. GRIFFITH. All right. I appreciate that. And I think you said earlier you are looking at finalizing some guidance by 2016?

Mr. LANDA. The nutrition facts?

Mr. GRIFFITH. Yes, sir.

Mr. LANDA. Yes.

Mr. GRIFFITH. All right. And I am going to switch just briefly, because I have a little bit of time left, into a different subject but it is tangentially related, and that is, what do you do about the grocery stores that are fixing food and selling things, and they have to do nutrition facts, and then you get into the whole allergens and then the GE or GMO foods? How do you deal with all of that as a part for grocery stores that fix the food——

Mr. LANDA. The processed food is subject to nutrition facts.

Mr. GRIFFITH. Right.

Mr. LANDA. What we have called restaurant-type food made and sold in a grocery store is now subject, or will be when it becomes effective, to menu labeling requirements.

Mr. GRIFFITH. I will just tell you, I think that even though I am concerned about it, and I might not eat the food if I didn't know what was in it, I am not sure how a grocery store is going to be able to comply with that when they may be using all kinds of different ingredients, and somebody walks up and says can I have X, Y or Z, it may be easier for—like a McDonald's where they have certain ingredients and every one of them has a label, a grocery store may not have that capability.

Mr. LANDA. Well, we are talking about standard menu items.

Mr. GRIFFITH. Standard menu items, so if it is some kind of specialty item they would have an exemption?

Mr. LANDA. Right.

Mr. GRIFFITH. All right.

Mr. LANDA [continuing]. Again, the requirement is 20 or more establishments, a restaurant and similar retail establishments is the language in the statute, and it is standard menu items.

Mr. GRIFFITH. All right, I appreciate that.

Thank you very much, and I yield back.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentleman, Mr. Butterfield, 5 minutes for questions.

Mr. BUTTERFIELD. Thank you very much, Mr. Chairman.

Let me just remark on the statement made by Mrs. Blackburn a few minutes ago about this being a fascinating debate. Mr. Chairman, this is certainly a fascinating debate by any measure.

In my former life, I served as a trial judge down in North Carolina, and every day for 15 years I had to look at the evidence and had to decide the facts. That was my job description, and I did it for 15 years. And I have tried to do that in this debate. And I have

read large amounts of well-informed publications over the last several months, and I for one, I am just convinced that GE plants are as safe as any other foods.

But, Mr. Landa, I need to interpose this question to you. Do you have any evidence that foods derived from GE plants are as safe as other foods? I have heard you mention it throughout your testimony, but is there any scintilla of evidence that would suggest that these foods are unsafe?

Mr. LAND. I I heard you correctly. Is there any evidence that suggeswant to make surets that these foods are unsafe?

Mr. BUTTERFIELD. Yes. Yes. That GE foods are unsafe.

Mr. LANDA. Not to our knowledge, no.

Mr. BUTTERFIELD. All right. And how long does your agency, and how large is the division that handles this task?

Mr. LANDA. Well, the office that handles that task has maybe 135 or 140 people, but those people also handle a variety of tasks related to food additives, generally recognized as safe substances.

Mr. BUTTERFIELD. But these are not politicians, these are career employees at your agency?

Mr. LANDA. Correct.

Mr. BUTTERFIELD. Yes. Have you encountered anyone, anyone who advocates a 50-state approach to mandatory labeling?

Mr. LANDA. I am not sure I——

Mr. BUTTERFIELD. You have talked to a lot of people, both formally and informally, about this, and——

Mr. LANDA. Anyone who advocates——

Mr. BUTTERFIELD. Who advocates a——

Mr. LANDA [continuing]. That we have 50 separate——

Mr. BUTTERFIELD. Fifty separate sets——

Mr. LANDA [continuing]. Sets of requirements?

Mr. BUTTERFIELD [continuing]. Of regulations, plus the District of Columbia.

Mr. LANDA. I have not.

Mr. BUTTERFIELD. I happen to find it to be——

Mr. LANDA. I don't know that I have a reason to encounter such a person, but no.

Mr. BUTTERFIELD. It seems to me illogical and irrational and I am wrong from time to time, but I don't see how that would ever work, even in California.

I yield back.

Mr. PITTS. Chair thanks the gentleman.

Chair recognizes the gentlelady from Illinois, Ms. Schakowsky, 5 minutes for questions.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

I am trying to sort out the science here. I have lots of passionate constituents who are very concerned about GE products. I have experts that we will hear on the next panel who have great scientific credentials themselves, who will argue about consumer information being provided about GE products.

I want to follow up on another word. Mrs. Capps was talking about natural, I want to ask you about material difference. And you said that the FDA could change its view that GE status of food is not material, which it is—that is the position right now, there is no material difference, and that the Agency is evaluating citi-

zens' petitions that report to do that. So can you elaborate on why the FDA has not believed this is a material difference, and have the courts said anything about it, what kind of different information might change your mind?

Mr. LANDA. Well, we haven't found any differences in relation to safety or nutritional composition. Again, considering these foods as a class, any differences in safety or nutritional composition, or any other attribute of the food.

Ms. SCHAKOWSKY. Can I ask you one thing? What about food allergies? Since we are putting in a—into the DNA something from perhaps a peanut into something else.

Mr. LANDA. In that case we would require disclosure. That would be material.

Ms. SCHAKOWSKY. And would that prevent, in this consultation process, from that particular formulation going to market?

Mr. LANDA. No. What would happen is there would be a disclosure of the allergic potential of the food.

Ms. SCHAKOWSKY. I see.

Mr. LANDA. That would be a material fact.

Ms. SCHAKOWSKY. OK, and a seed that—I know Mr. Pitts said you can use less pesticide. That is sometimes true, although the FDA has just approved use of a seed that would make it more tolerant of a lot more pesticide. Does the FDA have any concerns about that?

Mr. LANDA. I am not familiar with that matter, I am sorry.

Ms. SCHAKOWSKY. 2.4–D and Glyphosate. Anyway, OK. So in material, meaning even in the peanut issue, then a disclosure would be required because of safety?

Mr. LANDA. Typically, with respect to allergens, yes. First of all, there is a 2004 statute that requires disclosure of what we call the big eight allergens, but if you were to find another allergen, typically, we would require disclosure of it rather than ban the food.

Ms. SCHAKOWSKY. And who does the research? I have to tell you, my constituents who are against GMOs will say Monsanto, DuPont, and can we really trust these companies that benefit so much?

Mr. LANDA. The data that are supplied to us are supplied by the companies doing the consulting, and sometimes they will do the studies, sometimes they will pay to have the studies done. I will say that is true across all FDA-regulated products. FDA does research, but it does not do research on the scale that would be required to support voluntary submissions, much less marketing applications.

Ms. SCHAKOWSKY. Let me ask one more question. Does the Food and Drug Administration have the authority to implement a mandatory premarket approval process of any food to ensure that it is safe for consumers?

Mr. LANDA. We proposed a number of years ago a mandatory notification program for the types of products we have been talking about this morning. That proposed rule is still in existence. We have not found the need to finalize it, given what we think is how well the voluntary program works, but that proposal necessarily maintained that we had the authority to establish a mandatory program.

Ms. SCHAKOWSKY. I yield back. I can put some more questions in writing. Thank you.

Mr. PITTS. Chair thanks the gentlelady.

Just for clarification, when you say it requires disclosure, does that mean on a label?

Mr. LANDA. On a label. I am sorry, yes. Thank you for that question. Yes.

Mr. PITTS. Yes. OK. Thank you.

Gentleman, Mr. Matheson, is recognized 5 minutes for questions.

Mr. MATHESON. Well, thanks, Mr. Chairman.

And, Mr. Landa, I appreciate you coming here today.

You just said this with Mr. Butterfield, but I just want to be clear, from the FDA perspective to date, you have found no scientific evidence that there is a health and safety issue with genetically-engineered foods?

Mr. LANDA. That is correct.

Mr. MATHESON. OK. I appreciate that. If there is this consumer demand for wanting to know, if there is a producer of a non-GMO food in the organic industry, they can label their product as such that it is non-GMO, is that correct?

Mr. LANDA. So long as the labeling is not false or misleading, that is correct.

Mr. MATHESON. So if the marketplace wants this, there is a private sector opportunity for the organic food industry to provide that information to consumers if they so choose?

Mr. LANDA. That is correct.

Mr. MATHESON. Does the FDA have any regulatory authority over that type of labeling?

Mr. LANDA. It is the general authority that labeling must not be false or misleading.

Mr. MATHESON. How long has the FDA been involved in managing food labeling?

Mr. LANDA. Well, the false or misleading provision dates from either 1906 or 1938.

Mr. MATHESON. Long time.

Mr. LANDA [continuing]. I am not sure which.

Mr. MATHESON. We will stipulate it is a long time. And how is the FDA's role in terms of, if I am in the food industry, and there are a lot of different people in it, how does the FDA's role give signals to the food industry for how they do labeling? They look to you for guidance, they look to you for consistency, is that correct?

Mr. LAND. Correct. They look to the statute, they look to regulations we issue, they look to guidance we issue, and they certainly, when they have particular questions, companies will call our experts in labeling.

Mr. MATHESON. So how do your guidances work? How do you come up with those labeling guidances and how do they work?

Mr. LANDA. Typically, on a significant issue, we would issue what is called a draft guidance. We would call for comment on it. We would analyze the comments we receive, and issue it in final, with or without changes, or perhaps decide not to issue it at all, or to reissue it with substantial changes and calling for more comment.

Mr. MATHESON. And the food industry relies on that. That is where they get their direction for how they do labeling is from your guidances?

Mr. LANDA. First the statute, then the regulations——

Mr. MATHESON. Got you.

Mr. LANDA [continuing]. And then guidance, yes.

Mr. MATHESON. How do food manufacturers—I want to address this issue about a national system versus a 50-state patchwork system. How do food manufacturers, from the big guys to the little guys, how do they benefit from a national system?

Mr. LANDA. There is a benefit to uniformity, but I think the answer is that they are in a better position to tell you how much of a benefit that is to them than I am.

Mr. MATHESON. How do consumers benefit from a national system compared to 50 different sets of rules around our country?

Mr. LANDA. You see the same labeling for the same product——

Mr. MATHESON. There you go. People do cross state lines, don't they?

Mr. LANDA [continuing]. Wherever you purchase it.

Mr. MATHESON. Yes. Yes. Funny how that works. I go 2,000 miles every week back and forth. Yes, so I think that I would suggest, not to answer for you, that you are going to confuse consumers if you have 50 different standards. That would be my suggestion.

Let me ask you a question. How do you in the FDA resolve a situation if a product is mislabeled? What do you do if some manufacturer mislabels a product?

Mr. LANDA. Typically, we might call the manufacturer, we might issue what is called a warning letter——

Mr. MATHESON. Yes.

Mr. LANDA [continuing]. Depending on how serious we thought the infraction was. If the label were not corrected, ultimately we can, through the United States Department of Justice, seize the product that is misbranded because of a misleading label——

Mr. MATHESON. Right, so you have just——

Mr. LANDA [continuing]. And we can enjoin further distribution.

Mr. MATHESON. You have just defined, as the regulator in this industry for food labeling, you have just defined you have the tools in the toolbox you have to address situations or mislabeled, that is what I would suggest.

There have been claims by some consumer groups that the FDA is too closely aligned with the industry and it can't be trusted. How would you respond to that criticism?

Mr. LANDA. I have been at FDA for almost 30 years. I work with people who have been there much longer, by the way. I believe, and my colleagues believe, that we are civil servants, that we are engaged in an honorable professional and an honorable activity. It does not mean we get every decision right any more than anyone on the planet gets every decision right, but we try to make decisions to the best of our ability based on what the science tells us, and based on the law and the regulations and sound policy.

Mr. MATHESON. Well, Mr. Landa, I appreciate that answer, and I thank you for your civil service. I think there are a lot of folks

in the agencies who are trying to do the right thing, and appreciate your forthrightness in these questions today.

I will yield back, Mr. Chairman.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman, and Ranking Member Pallone for having the hearing today, and our witness for being here.

Ensuring the safety of my constituents has always continued to be the top priority as a member of Congress, and I hope that your testimony today, we can come to a greater understanding of the vital role that bioengineering plays in our food supply and the economy.

Mr. Landa, thank you for taking your time to be here, and like my colleagues, we appreciate your 30 years of service to the FDA. I find this issue, as heated as it is, often leads to passionate claims, and I hope your years of experience at FDA can shed some light on the science of genetically modified organisms, and the safety process behind their approval.

How many new plants are reviewed by the FDA each year, and how much time does it take to conduct those reviews?

Mr. LANDA. We will have to get back to you on that.

Mr. GREEN. OK.

Mr. LANDA. The number of completed reviews is about now, I think, 103. I think in five cases submissions were withdrawn or people asked us to cease the review. We will get back to you on——

Mr. GREEN. OK.

Mr. LANDA [continuing]. Yearly figures and average times.

Mr. GREEN. OK. Do you believe changing from the voluntary reviews to mandatory reviews would change the number of reviews performed by the FDA each year?

Mr. LANDA. I don't know, but I don't see why it would.

Mr. GREEN. OK. A coordinated frame work was developed by the White House Office of Science and Technology Policy to leverage the regulatory safety expertise present in the Federal Government agencies like the FDA. In the 30 years that the Agency has been part of this, are you satisfied that your agency is capable of understanding genetic engineering and determining whether or not a plant is safe?

Mr. LANDA. Yes.

Mr. GREEN. Do you feel the FDA has the staff and capabilities to be the voice of authority when it comes to GMO safety?

Mr. LANDA. In connection with foods in my center, yes.

Mr. GREEN. Food safety. Do you feel that the coordinated frame work requires adequate safeguards for consumer health and safety, and gives companies the regulatory certainty they need to develop new products?

Mr. LANDA. Yes.

Mr. GREEN. Has a GMO plant been deemed unsafe in the past voluntary review process?

Mr. LANDA. I am sorry, I didn't——

Mr. GREEN. Has a GMO plant been deemed unsafe in the past voluntary review processes?

Mr. LANDA. Not that I am aware of.

Mr. GREEN. OK. Was a safety issue due—if it did, and it hasn't been, but is it due to the genetic engineering or is other factors that you look for when you are inspecting them?

Mr. LANDA. Again, I am not aware of any consultation that has resulted in a finding of lack of safety. The ones we have completed, we obviously have concluded we don't have any questions. There were a handful that did not go to completion. They were either withdrawn or we were asked to stop the review, and I simply don't know the details of the reasons.

Mr. GREEN. What happens when you are asked to stop the review?

Mr. LANDA. We stop the review and the products do not go to market.

Mr. GREEN. OK. So by just stopping your review, they don't go to market, OK. So effectively, you are doing what a regulator is supposed to do.

Was the frame work rooted in congressional enactments like the Federal Food, Drug, and Cosmetic Act, Federal Meat Inspection Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and do you feel that these statutes all, to some extent, preempt state requirements?

Mr. LANDA. It varies enormously across statutes. I simply can't answer that question.

Mr. GREEN. And have each of these statutes, including the one from 1906, been instrumental in consumer protection?

Mr. LANDA. I can speak to the Food and Drug Act. I think the answer to the question is yes. It dates from 1906, was amended in 1938. Multiple, multiple times since then. I think in order to protect and promote the public health.

Mr. GREEN. Do you have any suggestions on how we might look at some of these Acts and make your job more effective? You can get back to us if you want because I know—because that is our job is, if you don't have——

Mr. LANDA. We are certainly happy to——

Mr. GREEN [continuing]. The tools to do it——

Mr. LANDA [continuing]. Provide technical assistance whenever you ask us to do that.

Mr. GREEN. OK. Thank you.

And, Mr. Chairman, I will yield back my time.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentleman from Maryland, Mr. Sarbanes, 5 minutes for questions.

Mr. SARBANES. Thank you.

Thank you, Mr. Landa. This is kind of a random question, just picking up on your allergy discussion. Presumably, I mean now you were suggesting that most ingredients, to which there is an allergy of any significance, you require that that be disclosed, right?

Mr. LANDA. Congress required it in 2004.

Mr. SARBANES. OK, but FDA would determine at some point that if the number of people affected by that ingredient, in terms of an allergy, reached a certain percentage of the population or something, then it would flip into a banning of the ingredient? Like sort of where is that line? Just——

Mr. LANDA. No, it is not banning, it is a disclosure requirement. Disclosure in the labeling, as the chairman was reminding me earlier, so that if we were to conclude that a food ingredient that is not on the list in the 2004 statute, that—met a certain threshold, and I can't answer what that threshold is in terms of percentage of population, we would require a disclosure of it on the label.

Mr. SARBANES. So you are talking about meeting a certain threshold in terms of requiring disclosure. I am asking you whether there is a threshold that one might meet that would suggest that——

Mr. LANDA. That we would ban it?

Mr. SARBANES [continuing]. You just ban it. I mean if 95 percent of the population is allergic to a certain ingredient——

Mr. LANDA. Of course.

Mr. SARBANES. OK.

Mr. LANDA. Let me give you an example. The oldest adulteration provision in the law says, among other things, if a food bears or contains a substance that renders the food ordinarily injurious to health, the food is adulterated. And if it is adulterated, it is prohibited from interstate commerce. So sure, of course, if there was an ingredient that caused illness in 90 percent of the population, people who ate the food containing the ingredient, we would ban the ingredient.

Mr. SARBANES. All right.

Mr. LANDA. I am sorry. I thought you were sort of——

Mr. SARBANES. Right.

Mr. LANDA [continuing]. Trying to get at the disclosure question.

Mr. SARBANES. I got you. So let me switch. I am curious about when the industry has to go change labels in response to, say, some consultation exercise where everybody realizes that that is the right thing to do, or something more prescriptive that you require—well, first of all, is it the case that these labels get created and they are sort of static for extended periods of time, or in your experience, is labeling constantly being revised and updated, both with respect to content potentially, but also just in terms of the form of it, the way it looks on packaging and all of this?

Mr. LANDA. I really don't know.

Mr. SARBANES. Yes.

Mr. LANDA. I am just not familiar enough with industry practice——

Mr. SARBANES. Can you——

Mr. LANDA [continuing]. To answer that question.

Mr. SARBANES. In your 30 years, when was the last time that you can remember that something the FDA did, or some realization that the food industry came to, resulted in a significant, across-the-board change in labeling?

Mr. LANDA. Well, the one that comes immediately to mind is nutrition facts——

Mr. SARBANES. Yes.

Mr. LANDA [continuing]. Which is a regulation that the heart of which is now I guess about 20 years old. We required disclosure of trans fat, 8, 9——

Mr. SARBANES. So that was pretty significant.

Mr. LANDA [continuing]. Eight, 9, 10 years ago, as I mentioned earlier——

Mr. SARBANES. Yes.

Mr. LANDA [continuing]. With the revising of nutrition facts.

Mr. SARBANES. So if you revise what is required in the nutrition fact panel in this rulemaking period between now and 2016, or whatever it was and you decide there are some additional things that ought to be in there, then that would cut across the entire food industry in a significant way in terms of revising its labels, right?

Mr. LANDA. Correct.

Mr. SARBANES. Thank you.

Mr. PITTS. Gentleman's time has expired.

The chair recognizes gentleman, Mr. Pompeo, 5 minutes for questions.

Mr. POMPEO. Great, thank you.

Thank you, Mr. Landa, for being here today. Thanks for your 30 years of service. I understand you are closer to the end of your service than the beginning at this point, and——

Mr. LANDA. Yes, thank you.

Mr. POMPEO [continuing]. And thank you for your good work. Thanks for your testimony this morning too. It has been interesting to watch. I think lots of folks watching this hearing this morning have been surprised by the certainty you are expressing around the science. You used the word initially that there is a consensus. I thought I would try and parse into that just a little bit more.

So when you—I have heard consensus, and that can be 70/30 or 80/20 or 90/10, where—tell me how much science there is that would refute your position with respect to the materiality of genetically engineered foods being safe.

Mr. LANDA. We do not believe, again, as a class that there is any question about safety, based on the reviews we have done.

Mr. POMPEO. And that would include just—go ahead.

Mr. LANDA. There are obviously people, scientists, who differ with that point of view. I don't know how many of them there are.

Mr. POMPEO. But it is a tiny fraction.

Mr. LANDA. It certainly is.

Mr. POMPEO. And not folks that the FDA, at least, gives significant credit to, certainly enough that you would change your view with respect to the safety of this food. You all have been very decisive.

Mr. LANDA. To date, we have seen nothing to change the view that we have had for a number of years now.

Mr. POMPEO. And that would include—there were questions about what other countries have done——

Mr. LANDA. Yes.

Mr. POMPEO [continuing]. And how their regulatory practice would include studies performed all across the world as well.

Mr. LANDA. That is correct.

Mr. POMPEO. I have heard some of my colleagues talk about a patchwork of 50 sets of rules and what that might do. Just so we are all clear, it wouldn't just be 50 sets of rules, it is potentially thousands of sets of rules; cities, counties, townships, neighborhood associations. One—the mind reels with respect to folks who might want to confirm their theory of a right to know through some sort

of statutory or municipal rule. Tell me what you think that complexity would do the safety of the food supply chain.

Mr. LANDA. I don't know that it would have an effect on safety.

Mr. POMPEO. Right the confusion consumers—we were talking about this, Mr. Matheson, he said he had to go 2,000 miles. You might only have to go 2 miles to pass into a city that had a different set of rules. I think there would be massive confusion, and the impact that that would have on consumers' ability to understand what they were consuming would be pretty significant.

Mr. LANDA. I suppose it could be. My point was that the underlying safety of the food would not be——

Mr. POMPEO. Wouldn't change. Absolutely.

You have talked a bit about your premarket consultation process. Today you said that most of the folks are—entering this into commercial service have provided that for you. You said you have gone through 100. A few have been withdrawn. I want to make sure, no one has run through the stop sign today where FDA has said, hey, we have a question or a concern, and they have said, good for you, we still want to introduce this product to the marketplace.

Mr. LANDA. That is correct.

Mr. POMPEO. No one has run through the stop sign. It is——

Mr. LANDA. That is correct.

Mr. POMPEO [continuing]. Not your expectation that anyone ever would because it would be very difficult for a commercialized food product to have run through an FDA letter that says, hey, we think we have a health or safety issue.

Mr. LANDA. That is our view, yes.

Mr. POMPEO. You talked about petitions for—and actually, we are going to give you another one if I get this Bill passed into law, this law contains a provision which would require the FDA, within 24 months, to propose a regulation with respect to natural. I agree with some of my colleagues, frankly, on both sides of the aisle that I think we ought to clear that up so that consumers have a good idea what that really means. I understand the difficulty of that task and why you all have not come to fruition on that yet, but know that if we are successful in getting this particular Bill passed, you will get to be successful in your endeavor as well.

So there have been proposals in some cities and some states about labeling for genetically-engineered products. Have any of those folks come to you or to the FDA to ask for your wisdom about what that label ought to look like, or about the safety or science behind genetically-engineered foods?

Mr. LANDA. Not that I am aware of.

Mr. POMPEO. So to the best of your knowledge, none of the states have come to you to say, hey, what do you—what does the FDA think about this?

Mr. LANDA. Not that I am aware of. It is certainly conceivable that someone from——

Mr. POMPEO. Sure.

Mr. LANDA [continuing]. A state would have come somewhere in the agency, but not that I am aware of.

Mr. POMPEO. And I guess my last question is, this Bill proposes that we would make the review process at FDA mandatory as opposed to voluntary. Assuming that we provide the resources to the

FDA, such that they can handle all of the requests for review, do you think that is an improvement, that is, do you think it is the case that each of these products ought to be submitted for FDA review before commercialization?

Mr. LANDA. Yes, and we think that is happening now.

Mr. POMPEO. Right. Thank you.

I yield back, Mr. Chairman.

Mr. PITTS. Chair thanks the gentleman.

That concludes the questions of the members who are present. I am sure we will have follow-up questions, other questions from members. We will submit those to you in writing. We ask that you please respond promptly. Thank you very much for coming this morning.

We are going to take, while the staff sets up the second panel, a 3-minute recess. The subcommittee is in recess.

[Recess]

Mr. PITTS. The subcommittee will come to order. We will ask our guests to please take their seats, and I will introduce the second panel at this time.

First of all, Dr. Alison Van Eenennaam, Cooperative Extension Specialist in Animal Genomics and Biotechnology, Department of Animal Science, from the University of California Davis. Secondly, Mr. Scott Faber, Senior Vice President of Government Affairs for the Environmental Working Group. Representative Kate Webb, Assistant Majority Leader in the Vermont House of Representatives. Ms. Stacey Forshee, the Fifth District Director of the Kansas Farm Bureau. And finally, Mr. Tom Dempsey, President and CEO of the Snack Food Association.

Thank you all for coming. We appreciate your patience. You will each have 5 minutes to summarize your testimony. Your written testimony will be made a part of the record.

So, Dr. Van Eenennaam, I think is the way you pronounce your name, right? I am sorry for the mispronunciation. We will start with you. You are recognized for 5 minutes for your summary.

STATEMENTS OF ALISON VAN EENENNAAM, PH.D., COOPERATIVE EXTENSION SPECIALIST, ANIMAL GENOMICS AND BIOTECHNOLOGY, DEPARTMENT OF ANIMAL SCIENCE, UNIVERSITY OF CALIFORNIA, DAVIS; SCOTT FABER, SENIOR VICE PRESIDENT OF GOVERNMENT AFFAIRS, ENVIRONMENTAL WORKING GROUP; REPRESENTATIVE KATE WEBB, ASSISTANT MAJORITY LEADER, VERMONT HOUSE OF REPRESENTATIVES; STACEY FORSHEE, FIFTH DISTRICT DIRECTOR, KANSAS FARM BUREAU; AND TOM DEMPSEY, PRESIDENT AND CEO, SNACK FOOD ASSOCIATION

STATEMENT OF ALISON VAN EENENNAAM, PH.D.

Ms. VAN EENENNAAM. All right. Good morning, Mr. Chairman, and members of the subcommittee. My name is Alison Van Eenennaam, and I am a biotechnology and genomics cooperative extension specialist at the University of California in Davis, and I appreciate the opportunity to speak on this topic here today.

I work in the public sector as a scientist performing research and education on biotechnology, and one of the reasons I am testifying

here today is that I was the taskforce chair and the lead author of the CAST Issue Paper number 54, entitled, The Potential Impacts and—of Mandatory Labeling for Genetically-Engineered Food in the United States, that was released in April of this year, and it is included as an attachment to this testimony. And it basically explores the scientific, legal and economic aspects of requiring food labeling in the United States, based on the use of a breeding method, that is, genetic engineering, rather than on some specific attribute of the food product itself. And it also looks at the implications of state versus national labeling laws, and the potential economic impacts, and so I think it is very germane to today's discussion.

As a scientist speaking here today, I do want to clarify that GE food, commonly, but less precisely, referred to as genetically-modified food, is food derived from crops produced using a breeding method, based on the movement of useful genes from one species into another using recombinant DNA technology. This method is used routinely in medicine, and many pharmaceuticals such as insulin and food processing aids, such as renin used in cheese production, have been made by GE microbes.

Although most commercialized crops that have been developed using GE thus far have been made to resist insects or herbicides, this breeding method can be used for many purposes. And public sector scientists in Hawaii and New York, for example, use GE to produce a virus-resistant papaya, a papaya that virtually saved the Hawaiian papaya industry. Other introductions include drought-tolerant corn, virus-resistant squash, and consumer traits like a non-browning apple, a low-acrylamide potato, and crops that produce improved oils for nutrition.

Land grant university researches in California, Florida, and Texas are working to use genetic engineering to develop oranges that are resistant to Citrus Greening Disease, something that is devastating the Florida orange industry, and grape varieties that are resistant to Pierce's Disease.

In New York, researchers are using a wheat gene to develop an American chestnut tree that is resistant to the imported chestnut blight. These disease-resistant GE applications focus on controlling disease with genetics rather than with chemicals, and importantly, they don't involve the use of chemical pesticides, an issue that often gets conflated with GE as a breeding method.

In 2013, genetically-engineered crops were cultivated worldwide by 18 million farmers, and in the United States, GE varieties were planted on 95 percent of sugar beet acreage, 93 percent of soy, and over 90 percent of both cotton and corn acreage.

What has been the impact of this widespread adoption? As a scientist, I look to the peer reviewed independent literature, especially meta-analyses and review articles that present a summary of many independent studies. In 2014, German university professors published a comprehensive analysis of 147 studies that have assessed the impact of the adoption of genetically-engineered crops. They found the benefits were significant and, in summary, on average, GE technology adoption reduced chemical pesticide use by 37 percent, increased crop yields by 22 percent, and increased farmer

profits by 68 percent. This would explain their widespread adoption by farmers globally.

As a result of this widespread use in American agriculture, many food products in the United States include ingredients that might be from corn oil or sugar that have been derived from GE crop varieties. And it has been said before, it has been estimated 70 to 80 percent of processed foods likely contain such ingredients.

Importantly, many highly-processed ingredients, such as sugar and oil, contain no detectable traces of DNA or protein, and hence, there is no way to test these refined products to determine their genetic origin; meaning, labeling of these products would require entire supply chain tracking and segregation to keep track of the products derived from genetically-engineered crops, a very expensive and complicated proposition.

There is a broad scientific consensus about the safety of food produced from GE crop varieties, and solid data to support that consensus. A 2013 review article, written by independent Italian public sector scientists, reviewed over 1,700 safety records of GE crop safety published this past decade, and concluded that the scientific research conducted so far has not detected any significant hazards directly connected with the use of GE crops.

The American Association for the Advancement of Science, the world's largest and most prestigious scientific society, stated in 2012 the science is quite clear; crop improvement by the modern molecular techniques of biotechnology is safe. The World Health Organization, the American Medical Association, the U.S. National Academy of Sciences, the British Royal Society, and every other major scientific body and regulatory agency in the world that has examined the evidence has come to the same conclusion.

To date, no material differences in composition or safety of commercialized crops developed using GE has been identified that would justify a label based on the use of GE as a breeding method in the development of that crop variety. While this conclusion will not satisfy those who consider the insertion or manipulation of genes in a laboratory a material difference, per se, the science of food safety does not support mandatory process-based labeling of GE food and, by extension, is not required by the Food and Drug Administration.

Thank you for the opportunity to speak here this morning, and I would be pleased to take questions from the subcommittee.

[The prepared statement of Ms. Van Eenennaam follows:]

Testimony of

Dr. Alison Van Eenennaam, Ph.D.

Cooperative Extension Specialist, University of California, Davis

House Committee on Energy and Commerce; Subcommittee on Health

"Examining FDA's Role in Regulation of Genetically Modified Food Ingredients"

December 10, 2014

Summary Points

The Council for Agricultural Science and Technology (CAST) Issue Paper Number 54 entitled "**The Potential Impacts of Mandatory Labeling for Genetically Engineered (GE) Food in the United States**" explores the scientific, legal, and economic aspects of requiring food labeling in the United States based on the use of a breeding method (i.e., GE) rather than on some attribute of the food product itself, the implications of state versus national labeling laws, and the potential economic impacts. The conclusions of the paper were:

1. There is no science-based reason to single out foods derived from and feeds crops that were developed using the GE breeding method for mandatory process-based labeling.
2. Mandatory labeling based on process (i.e. use of a particular breeding method) abandons the traditional U.S. practice of providing for consumer food preferences through voluntary product differentiation and labeling.
3. Mandatory labeling could have negative implications for First Amendment rights and trade issues.
4. Market-driven voluntary labeling measures are currently providing interested consumers with choices to purchase products produced from crops developed using conventional plant breeding technologies.
5. Mandatory labeling will increase food costs.

Testimony

Good Morning Mr. Chairman and Members of the Subcommittee. My name is Alison Van Eenennaam and I am a Biotechnology and Genomics Cooperative Extension Specialist at the University of California, Davis. I appreciate the opportunity to speak to you today regarding the science of genetic engineering (GE) and its relationship to the role of the Food and Drug Administration (FDA) in the regulation of GE food ingredients.

I hold a Bachelor of Agricultural Science, a Master of Science and a Ph.D. in Genetics, and I work as a public sector scientist performing research and education on biotechnology. One of the reasons that I am testifying here today is that I was the Task Force Chair and lead author for the Council for Agricultural Science and Technology (CAST) Issue Paper Number 54 entitled "**The Potential Impacts of Mandatory Labeling for Genetically Engineered Food in the United States**"[1], which was released in April of 2014 and is included as an attachment to this testimony. CAST is a nonprofit organization that is composed of scientific societies, individual and student members, company, nonprofit, and associate society members. CAST (www.cast-**science**.org) assembles, interprets, and communicates science-based information by using volunteer scientific experts, such as myself, as authors and reviewers.

As a scientist speaking here today I want to clarify that GE food, commonly but less precisely referred to as Genetically Modified food, is food derived from crops produced using a breeding method based on the movement of useful genes from one species into another using recombinant DNA technology. This method is used routinely in medicine and many pharmaceuticals such as insulin and food processing aids such as rennin (used to separate curds and whey in 80-90% of

all cheeses made in the United States) are made by genetically engineered microbes. Many other breeding methods "genetically modify" plants including widely used methods such as radiation and chemical mutagenesis, protoplast fusion, embryo rescue, and induction of polyploidy. Although these methods often create extensive and largely unknown genetic modifications to DNA, plant breeding has never been considered to be inherently dangerous, nor is it specifically regulated.

Although most commercialized crops that have been developed using GE thus far have been made to resist insects or herbicides, this method can be used be used for many purposes. Public sector scientists in Hawaii and New York used GE to produce a virus-resistant papaya, a product which has literally saved the Hawaiian papaya industry. Other introductions include drought-resistant corn, virus resistant squash, and consumer traits like a non-browning apple, a low-acrylamide potato, and crops that produce improved oils for nutrition. Land grant university researchers in California, Florida and Texas are working to use GE to develop oranges that are resistant to citrus greening disease – something that's devastating the Florida orange industry; and grape varieties that are resistant to Pierce's disease. In New York, researchers are using a wheat gene to develop an American Chestnut tree resistant to the imported chestnut blight.

There are many publicly-funded groups around the world using GE to develop disease-resistant varieties of crops including apples, bananas, cassava, cowpea, eggplant, grapes, potatoes, rice, sweet potatoes and wheat. Some of these staple crops are an essential source of nutrients in the diets of the poor. These disease-resistant GE applications focus on **controlling disease with genetics rather than with chemicals** and importantly do not involve the use of chemical pesticides, an issue that often gets conflated with GE as a breeding method.

In 2013 approximately 433 million acres (175.2 million hectares) of crops developed using were cultivated worldwide by 18 million farmers, and. in the United States GE varieties were planted on 95% of sugar beet, 93% of soy, and over 90% of all cotton and corn acres. What have been the impacts of this widespread adoption? As a scientist I look to the peer-reviewed scientific literature to answer such questions, especially review and meta-analyses that present a summary of many independent studies.

In 2014 German University professors published a comprehensive analysis of 147 studies that have assessed the impact of the adoption of crops developed using GE. They found that the benefits were significant, not only in the US but especially in the developing world -- "**On average, GE technology adoption has reduced chemical pesticide use by 37%, increased crop yields by 22%, and increased farmer profits by 68%.**"[2] This would explain their widespread adoption by farmers globally.

As a result of the widespread use of this technology in American agriculture, many food products in the United States include ingredients such as corn oil, soy protein, or beet sugar that might have been derived from a crop variety developed using GE. It has been estimated **that at least 70% of processed food items in the supermarket contain** at least one ingredient derived from a crop produced using GE, often the additive soy lecithin or various oils. Importantly, many highly processed ingredients such as sugar and oils contain no detectable traces of DNA or protein and hence there is no way to test these refined products to determine their genetic origin – meaning labeling of these products would require entire supply chain tracking and segregation to keep track of products derived from GE crops – an expensive and complicated proposition.

In the United States, the Food, Drug, and Cosmetic Act (FDCA) grants authority for food labeling to the FDA. The FDA has stated that it has no basis for finding that foods developed by GE "**differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.**"

There is broad scientific consensus about the safety of food produced from GE crop varieties and solid data to support that consensus. A 2013 review article, written by independent Italian public-sector scientists, reviewed 1783 scientific records on GE crop safety published this past decade and concluded that "**The scientific research conducted so far has not detected any significant hazards directly connected with the use of GE crops.**"[3] There has been an abundance of independent research over the years, see the GENERA database at BioFortified.org which is a searchable database of peer-reviewed research on GE crop safety, and a compilation of more than 130 research projects underwritten by the European Union (EU) which states "**The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not *per se* more risky than e.g. conventional plant breeding technologies.**"[4]

My own 2014 review paper examined both well-designed animal feeding studies, and the field performance and health trends of the over one hundred billion food producing animals that have been consuming feed derived from crops developed using GE over the past decade in the United States, and found no credible evidence of harm.[5]

The American Association for the Advancement of Science (AAAS), the world's largest and most prestigious scientific society, stated in 2012 **"The science is quite clear: crop improvement by the modern molecular techniques of biotechnology is safe".** The World Health Organization, the American Medical Association, the U.S. National Academy of Sciences, the British Royal Society, and every other major scientific body and regulatory agency in the world that has examined the evidence has come to the same conclusion consuming foods containing ingredients derived from GE crops is no riskier than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques.

To date, no material differences in composition or safety of commercialized crops developed using GE have been identified that would justify a label based on the use of GE as a breeding method in the development of the crop variety. While this conclusion will not satisfy those who consider the insertion or manipulation of genes in a laboratory a material difference *per se*, the science of food safety does not support mandatory process-based labeling of GE food and, by extension, neither does the Food and Drug Administration.

Thank you again for the opportunity to speak with you today. I would be pleased to take questions from the Subcommittee.

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CAST Issue Paper Number 54 April 2014

The Potential Impacts of Mandatory Labeling for Genetically Engineered Food in the United States

No label is currently required for genetically engineered food in the United States. This Issue Paper discusses the potential legal and economic implications of mandatory GE labeling. (Source photo and artwork from Shutterstock.)

Abstract

Although genetically engineered (GE) products are used around the world, their use in food products has become a contentious issue for some consumers. A key point in the resulting debate centers on proposals regarding the mandatory labeling of GE food.

Many U.S. states are considering legislation to mandate such labels. This publication examines arguments for and against labels, the costs involved with labeling, and experiences in countries that use mandatory labeling. The authors start from the premise that hundreds of independent studies have determined that foods made using GE ingredients are safe. They gather factual information to produce a peer-reviewed publication that clarifies the potential impacts of mandatory labeling.

Proponents of mandatory GE labeling cite the right to know what is in their food as an important attribute of a democratic society. Opponents think that such a label will increase the cost of food and confuse consumers with no corresponding improvement in human health or food safety. Seemingly contradictory studies are cited to support opposing views—informed discourse about this emotional issue is hard to find. The authors examine key aspects of the arguments:

- Public opinion, polls, and methods used
- Consumer choice and interpretations that support both sides in this respect
- Right-to-know issues—and the complications inherent with the right to know "what" and "at what cost"
- Food safety and testing—and the lack of any evidence that GE foods have harmful effects

Many state labeling initiatives suggest there are remaining food safety concerns about GE organisms and, therefore, mandatory labeling

CAST Issue Paper 54 Task Force Members

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should be implemented. Some say these products are intrinsically different because they would not have occurred in nature through natural processes. To date, no material differences in composition or safety of commercialized GE crops have been identified that would justify a label based on the GE nature of the product. Whereas this conclusion will not satisfy those who consider the insertion or manipulation of genes in a laboratory a material difference per se, the science of food safety does not support mandatory process-based labeling of GE food and, by extension, neither does the Food and Drug Administration.

This paper examines legal issues—the Commerce Clause, the First Amendment, label location, state versus national jurisdictions—and economic impacts. The authors conclude the following:

1. There is no science-based reason to single out GE foods and feeds for mandatory process-based labeling.
2. Mandatory labeling based on process abandons the traditional U.S. practice of providing for consumer food preferences through voluntary product differentiation and labeling.
3. Market-driven voluntary labeling measures are currently providing consumers with non-GE choices.
4. Mandatory labeling could have negative implications for First Amendment rights and trade issues.
5. Mandatory labeling will increase food costs.

The authors finish with a call for better communication about this issue: "Independent objective information on the scientific issues and the possible legal and economic consequences of mandatory GE food labels need to be provided to legislators and consumers, especially in states with labeling initiatives on the ballot, to help move the national discussion from contentious claims to a more fact-based and informed dialog." All legislative references in this document were current as of March 1, 2014, at the completion of writing.

Introduction

Genetic engineering (GE) can be defined as the manipulation of an organism's genes by introducing, eliminating, or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant deoxyribonucleic acid (rDNA) techniques. Genetically engineered microorganisms, and products derived from them, have found widespread use in the pharmaceutical (e.g., human insulin used by diabetics), chemical, and food (e.g., rennin used to produce cheese) industries with no documented reports of adverse impacts. In general, GE labels are not required on these products, or the foods resulting from their use in food processing, in any part of the world (Mansour and Key 2004).

The use of GE in the production of these widely used products is relatively noncontroversial; however, the application of rDNA technology to produce GE or transgenic plants and animals that are used as food has proved to be highly contentious for some consumers. The purposes of this paper are to (1) explore the scientific, legal, and economic aspects of requiring food labeling in the United States based on the use of a process (i.e., GE) rather than on some attribute of the food product itself, and (2) clearly discuss the complex considerations that come into play when contemplating mandatory GE food labeling in the United States.

Genetically engineered organisms and products made from them go by many names, including genetically modified (GM), genetically modified organism (GMO), transgenic, biotech, bioengineered, or products made with modern biotechnology. Given that traditional breeding techniques also result in genetic modifications and hence this term is not specific for the use of rDNA, in this document the term GE is used rather than the more common and pervasive, but less precise, term GM. Typically, food produced using GE food processing aids or enzymes, and the meat, milk, and egg products derived from animals that have eaten GE feed or been treated with GE therapeutics or vaccines, have not been considered to be GE foods.

A total of 165 GE crop events in 19 plant species (alfalfa [2], canola [20], chicory [3], corn [38], cotton

[27], creeping bentgrass [1], flax [1], melon [2], papaya [3], plum [1], potato [28], rice [3], rose [2], soybean [19], squash [2], sugar beet [3], tobacco [1], tomato [8], and wheat [1]) have been approved in the United States (ISAAA 2013), although not all of these events are being grown commercially, and no GE animals have yet been approved for food purposes as of the time of this writing.

The first GE food product to come to the U.S. market in 1994, the MacGregor's brand of tomato grown from GE seeds, bore a voluntary GE label. It was branded with the Flavr Savr® name and was accompanied by in-store information about the delayed-softening characteristic. Since that time, growers have adopted approved GE crops extensively. For example, in 2013 GE varieties were planted on 95% of sugar beet, 93% of soy, and 90% of all cotton and corn hectares in the United States (USDA–NASS 2013a), and similar rates of adoption were observed in other major agricultural producing countries such as Argentina, Brazil, Canada, and South Africa.

In 2013, approximately 175.2 million hectares (433 million acres) of GE crops were cultivated worldwide (James 2014) by 18 million farmers. More than 90% (>16.5 million) were small-scale resource-poor farmers in developing countries. This planting was greater than a 100-fold increase from the 1.7 million hectares that were planted in 1996, making GE the fastest-adopted crop technology in recent history. Farmers have planted these GE varieties to enable the adoption of improved agronomic practices (e.g., no-till agriculture, decreased insecticide applications, use of less toxic herbicides) providing environmental, economic, and food security benefits (Ali and Abdulai 2010; Burachik 2010; Carpenter 2013; Fernandez-Cornejo et al. 2014; Huang et al. 2010; Kathage and Qaim 2012; Qaim and Kouser 2013). For the period 1996–2011, it has been estimated that the cumulative economic benefits from cost savings and added income derived from planting GE crops was US$49.6 billion in developing countries and US$48.6 billion in industrial countries (Brookes and Barfoot 2013).

As a result of the widespread use of this technology in agriculture (Figure 1), many food products in the United States include ingredients such as corn oil, soy protein, or beet sugar that might have been derived from a GE crop variety. It has been estimated that at least 70% of processed food items in the supermarket contain at least one ingredient derived from a GE crop, often the additive soy lecithin or various oils (Cornell Cooperative Extension 2003).

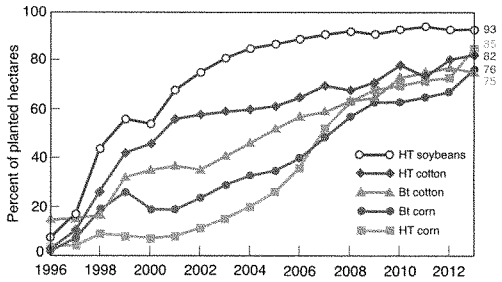

Figure 1. Adoption of GE crop varieties in the United States, 1996–2013 (HT = herbicide-tolerant; Bt = *Bacillus thuringiensis*). Data for each crop category include varieties with both HT and Bt (stacked) traits. Sources: USDA–Economic Research Service using data from Fernandez-Cornejo and McBride (2002) for the years 1996–1999; USDA–National Agricultural Statistics Service, June Agricultural Survey for the years 2000–2013. (Figure adapted from USDA–ERS [2013a].)

At least 25 states have considered proposed legislation to require GE labeling (see Figure 2). Many of these were bills that progressed through the legislative process to hearings, or even committee or floor votes in some cases, but were eventually defeated, withdrawn, or held. Three statewide initiatives requiring labeling—one in Oregon in 2002 (Measure 27), one in

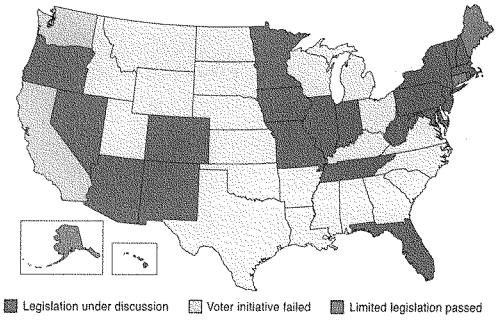

Figure 2. Food labeling activity—2013. (See Table 1 [Appendix] for sources that provide details, including selected text and exemptions from proposed and defeated legislation.)

California in 2012 (Proposition 37), and one in Washington in 2013 (Initiative 522)—were not supported by a majority of the voters. The only mandatory labeling law enacted to date is an Alaskan law that requires labeling of GE fish (none of which has yet been approved for food purposes by the Food and Drug Administration [FDA]) sold in the state. Connecticut and Maine have passed bills with limitations (e.g., one bordering state and three other states with a total population collectively exceeding 20 million people must enact similar labeling rules), and several others are still pending (Wattles 2013).

Proponents of mandatory GE labeling cite the right to know what is in their food as an important attribute of a democratic society. Opponents have countered that such a label will increase the cost of food and confuse consumers with no corresponding improvement in human health or food safety. Various seemingly contradictory studies are frequently cited to support opposing views, and civil, informed discourse about this important and frequently emotional issue is hard to find. There are three main themes that are associated with mandatory GE labeling, with the following arguments for and against it:

Public Opinion

- PRO: Polls show an overwhelming majority of people support mandatory labeling of GE foods when specifically asked if "the federal government should require labels on food saying whether it's been genetically modified, or 'bioengineered'" (Langer 2013).
- CON: In unprompted polls in which participants are asked what additional labeling they would like to see on food, more than 99% of respondents do not volunteer a desire to see mandatory labeling of GE foods (IFIC 2012).

Consumer Choice

- PRO: People should have a choice regarding what types of products they purchase and consume. Many believe that this should include the choice to "vote with their wallets" about how the food was produced even if it does not result in any change or consequence for the food product itself.
- CON: Consumers in the United States who want to avoid GE products already have that choice available through voluntary non-GE and organic labeling. In countries that have implemented mandatory GE labeling, GE products have generally been removed from the market; so choice has decreased (Marchant, Cardineau, and Redick 2010).

Right to Know

- PRO: People have the right to know what is in their food (Raab and Grobe 2003). Mandated calorie and nutritional content panels on packaged foods are examples of labels to inform consumers about food composition.
- CON: The right to know what is in food is different from the right to know how it was produced. Furthermore, this uniquely singles out GE technology—not other production methods and processes—for right to know.

Polls suggest consumers would like to see label information about many production methods and processes (e.g., sprayed with pesticides) (CSPI 2001). There is, however, no prima facie case that consumers have the right to know everything through mandated labels or that labels be required at any cost (Kalaitzandonakes 2004). Mandating process-based food labeling is a very complex topic with nuanced marketing, economic, and trade implications depending on how the labeling laws are written and how the market responds.

Food Safety

The premarket food safety assessment of GE foods and feeds evaluates risks that might be associated with newly introduced nucleic acids, novel proteins encoded by the inserted genetic material, and both intended and unintended changes in composition that might be associated with the development process (CAST 2001; Chassy 2010; Chassy et al. 2004). There is general agreement that novel components introduced through GE, as well as any changes in endogenous metabolites, must be demonstrated to be safe for humans and animals to consume.

Safety assessment focuses on the safety of newly introduced components and any intended changes in composition as well as evaluating if any potentially harmful unintended changes have occurred. It is accepted that all breeding produces unintended changes; however, the great majority of these are without safety implications. Thus, changes per se are not considered to pose new risks. Questions that must be addressed in such regulatory evaluations include the following:

- Does the GE food, and/or the newly introduced substance, have a traditional counterpart that has a history of safe use?
- Have any toxins or allergens been introduced and has the concentration of any naturally occurring toxins or allergens in the food changed?
- Have biologically significant compositional changes occurred and, in particular, have levels of key nutrients changed?

According to the American Association for the Advancement of Science, GE crops are "the most extensively tested crops ever added to our food supply" (AAAS 2012). During the past 20 years, the FDA has found that all 148 transgenic gene/crop combinations evaluated by the agency (including all biotech crops commercialized to date, despite the fact that this premarket safety review is technically voluntary) are equivalent to their conventional counterparts. Japanese regulators independently reached the same conclusions for 189 submissions they reviewed. These submissions spanned biotech corn, soybean, cotton, canola, wheat, potato, alfalfa, rice, papaya, tomato, cabbage, pepper, raspberry, and mushroom, and they included traits of herbicide, drought and cold tolerance, insect and virus resistance, nutrient enhancement, and expression of protease inhibitors (Herman and Price 2013).

There is also an extensive body of scientific research performed by independent scientists from around the globe on this topic (Nicolia et al. 2013). Hundreds of peer-reviewed publications involve GE feeding studies on a wide variety of species—including laboratory rodents, chickens, quail, pigs, sheep, dairy cows, beef cattle, goats, rabbits, buffalo, and fish—measuring feed intake, nutrient digestion, performance,

and health (Flachowsky, Shafft, and Meyer 2012). These studies, including some long-term research spanning multiple generations and many years, generally support the conclusion that there are no detrimental effects from the consumption of the currently available biotech crops (Snell et al. 2012).

Additionally, no differences in the composition of animal products—including meat, milk, and eggs—have been observed between animals fed conventional or biotech crops or their products (CAST 2006). A 2011 summary report from the European Commission, covering a decade of publicly funded research, 130 research projects, and 500 research groups, similarly concluded that there is no scientific evidence of higher risks from GE crops to the environment or for food and feed safety (European Commission 2011). This report found no evidence that GE foods have any harmful or long-term effects over multiple generations. Although a handful of widely publicized small studies have claimed to find some adverse health impacts of GE foods on animals, these studies have been retracted and/or severely criticized by government and mainstream scientific organizations as poorly designed and unreliable.

The U.S. National Academy of Sciences concluded in 1987, and reaffirmed in 2000 and 2004, that GE poses no new or different risks to food safety (NAS 2004). Likewise, the American Medical Association wrote the following in 2012: "There is no evidence that unique hazards exist either in the use of rDNA techniques or in the movement of genes between unrelated organisms.... The risks associated with the introduction of rDNA-engineered organisms are the same in kind as those associated with the introduction of unmodified organisms." The association then went on to conclude that "... there is no scientific justification for special labeling of bioengineered foods, as a class" (American Medical Association 2012).

Food Labeling

Despite these scientific assessments by independent and authoritative scientific organizations globally, many of the state labeling initiatives have included text suggesting that there are remaining food safety concerns about GE food and, therefore, mandatory labeling should be required. In the United States, the Food, Drug, and Cosmetic Act (FDCA) grants authority for food labeling to the FDA. The FDCA Section 403(a)(1) states that a food is misbranded if its labeling is untrue or misleading, whereas Section 201(n) states that a label is misleading if it fails to reveal "material facts" about a product. Material facts have been interpreted by the FDA to mean (1) changes in health or environmental safety posed by the product, (2) statements that might mislead the consumer in light of other information on the label, and (3) a food label that might cause a consumer to expect that the product closely resembles a food product from which it differs in one or more significant characteristics. The FDA would require labels on products that demonstrably pose novel hazards that might affect safety or have significant unexpected differences in composition. These are material facts. In contrast, production methods that create no material difference in products require no special labeling.

The FDA has stated that it has no basis for finding that GE foods "differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding" (USFDA 1992). Therefore, since GE production methods create no material difference in products, no label is required for GE foods. In the two decades since this initial finding, the FDA has not encountered any evidence or data that have caused it to change its position despite having reviewed regulatory packages on more than one hundred GE events (Herman and Price 2013).

If a new GE process changed a product such that it differed significantly from its conventional counterpart, the FDA could require labeling for those specific qualities. For instance, since high omega-3 and high oleic vegetable oils differ significantly in composition from their conventional counterparts, the FDA could require that these oils be labeled—not because they were produced using GE, but because there is a material difference in the oil products.

The FDA could also require labeling for potential allergenicity if the food contained a novel allergen that a consumer would not expect to be present in a specific type of food. As an example, if a peanut protein was inserted into a tomato, the product would need to be labeled to warn individuals allergic to peanuts that the GE tomato may present an allergenic risk unless the developer could demonstrate that there was no allergy risk from that peanut gene. To date, no GE products have required such a specific label.

It should be noted that the FDA allows voluntary process-based labeling as long as it is not false or misleading. In 2001, the FDA put out a draft guidance that set forth requirements for industry as to acceptable language for voluntary labels on products not containing any GE ingredients (USFDA 2001). The guidance stated that it is not possible to demonstrate a zero level of GE ingredients and therefore prohibits claims that a food is GE "free." It also advised that "a label statement that expresses or implies that a food is superior (e.g., safer or of higher quality) because it is not bioengineered would be misleading" given the lack of evidence that GE foods are materially different from non-GE foods. It was also considered that it would be misleading to label a food or ingredient as being non-GE, when in fact no commercialized GE varieties of that food or ingredient exist on the market.

Although the food safety of GE crops and animals, and ingredients derived from them, has been reviewed by the FDA prior to introduction of all new GE varieties commercialized to date, some have expressed concerns that GE crops are inherently less safe than those produced by other plant-breeding techniques. Their major safety contention is that the process of GE per se can produce unintended changes resulting in long-term adverse consequences. Advocates of mandatory labeling have argued that GE foods are by definition altered in composition by virtue of the presence of genetic material introduced through rDNA methods. A key driver of concern about GE food safety is that these products are intrinsically different because they would not have occurred in nature through natural processes.

Charles Darwin observed that very few of the world's cultivated crops arise from nature; most have been extensively genetically modified by human intervention. First, genetic modifications

resulting from spontaneous mutations were selected by breeders based on their effect on phenotype; then, in more recent times, genetic modifications were created through mutagenesis breeding techniques (exposing seeds to chemicals or radiation in order to generate mutations). New genes have been acquired by plants through horizontal gene transfer throughout evolution and more recently have been introduced through plant breeding among related species. New genes have arisen spontaneously—at least three new plant genes in the last century (Weber et al. 2012). Domesticated plants are thus not unchanged, nor would they exist today without extensive human intervention. There are no published scientific studies providing evidence that passive or natural genetic and phenotypic changes pose fewer hazards than those introduced by in vitro rDNA methods. In fact, some studies have found that plant mutagenesis induces more changes than rDNA GE technologies (Batista et al. 2008; Ricroch, Bergé, and Kuntz 2011).

To date, no material differences in composition or safety of commercialized GE crops have been identified that would justify a label based on the GE nature of the product. While this conclusion will not satisfy those who consider the insertion or manipulation of genes in a laboratory a material difference per se, the science of food safety does not support mandatory process-based labeling of GE food and, by extension, neither does the FDA.

Legal Issues

No comprehensive GE labeling law has yet passed in any state. Alaska's law requires labeling of any GE food made from a GE fish—although none is yet available on the market in the absence of a regulatory decision from the FDA regarding the approval or otherwise of the fast-growing GE AquaBounty Salmon (Anthes 2013). In Connecticut and Maine, conditional legislation has been passed stipulating that GE labels would be required to appear on products in the state's supermarkets only after two conditions are met: (1) four other states, including a bordering state, must enact similar labeling rules; and (2) the aggregate population of any Northeast states (Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, or Vermont) that enacts such a law must collectively have a total population of more than 20 million people. In passing such conditional laws, states likely recognized the potential threat of litigation to overturn a single state GE labeling law and perhaps also the difficulty companies might face complying with food labeling laws that differ among states.

Whatever the scope, the passage of state-based GE labeling laws is likely to be associated with legal challenges. There are three major legal issues associated with state laws mandating process-based GE labeling.

Commerce Clause of the U.S. Constitution

The Commerce Clause of the U.S. Constitution grants Congress the power to regulate interstate commerce and forbids individual states from unduly burdening interstate commerce (U.S. Const. art. 1, sec. 8, cl. 3). So even if consumers in a given state vote to support mandatory GE labeling legislation, federal law may not allow it. In general, a U.S. state violates rules on interstate commerce if it passes laws mandating that food manufacturers who create products for national and international markets must label them for a single state. Pending cases are defining the boundaries—generally, a state law may not discriminate against out-of-state products or unduly burden interstate commerce. Courts will limit a state law that impedes trade and forces companies to label their products to comply with only a few U.S. states' laws. Although the oldest of the legal barriers, this one may be weaker than those that follow in light of recent decisions (e.g., a California federal court recently allowed Alameda County to maintain a drug take-back program) [Karst 2013], and a similar challenge to California's low carbon fuel standard may be surviving legal debate [Griffin 2014; *Rocky Mountain Farmers Union v. California Air Resources Board* 2014].

Supremacy Clause of the U.S. Constitution and FDCA Preemption

Under the Supremacy Clause of the U.S. Constitution, federal law prevails in any conflict with state law. As discussed earlier, the federal FDCA grants the FDA authority over food labeling and expressly prohibits states from imposing labeling requirements that are different from the FDA's requirements. The FDA has taken the position that process-based labels would not be required for GE food products that are comparable in composition to similar food products. At a 2010 hearing to reconsider GE labeling, FDA officials suggested doing so would open the door to any number of processes that interest consumers. It is likely that state GE food labeling requirements would be preempted by the FDCA because the FDA has explicitly decided not to require labeling of GE foods. In recent court cases, the potential preemptive effect of the FDCA has also been discussed. Most notably, the Ninth Circuit, which covers the West Coast (California, Oregon, Washington, etc.), has recently ruled that the FDCA preempts unfair competition claims (*Pom Wonderful LLC v. Coca-Cola Co.* 2012) in a decision that could be applied to a state's attempt to label GE food.

The First Amendment Protection of Commercial Speech

This legal barrier was actually used to stop a state (Vermont) from imposing mandatory labeling for a process used on dairies in the production of milk in 1996 (administration of recombinant bovine somatotropin [rBST], a type of growth hormone). The First Amendment prohibits government compulsion of commercial speech unless the speech is factual, uncontroversial, and reasonably related to a legitimate government interest. Although commercial speech is accorded less protection than political expression under the First Amendment, "the right not to speak inheres in political and commercial speech alike, and extends to statements of fact as well as statements of opinion" (*International Dairy Foods Association v. Amestoy* 1996).

As noted earlier, Vermont's mandatory process-based labeling of a product produced using a GE protein was found to violate the First Amendment. Dairy manufacturers contested a law that read "if rBST has been used in the production of milk or a milk product for retail sale in this state, the retail milk or milk product shall be labeled as such."

They demonstrated a likelihood of prevailing on a First Amendment challenge to a law requiring them "to identify products which were, or might have been, derived from dairy cows treated with a synthetic growth hormone used to increase milk production," arguing that the compelled speech violated their First Amendment rights and that the state had not advanced a governmental interest sufficient to require the speech. The state did not argue that the requirements were to raise public health, but it instead argued that Vermont citizens had a right to know whether or not the milk products were produced using rBST. The court held that gratifying "customer curiosity" by mandatory labeling of an accurate factual statement was insufficient to compel speech if it "involves neither health concerns nor other substantial interests" and thus failed to demonstrate a substantial government interest (*International Dairy Foods Association v. Amestoy* 1996).

Genetic modification labeling advocates argue that the FDA has previously mandated labeling for a production process, irradiation. This mandate was based not on safety concerns about irradiated food, but rather on the fact that the irradiation process can cause changes in flavor or shelf life of finished foods. These changes could be significant and material in light of the consumer's perception of such foods as unprocessed. This distinction explains the differential FDA policies toward the use of mandatory labels for irradiation and GE processes.

National GE Labeling Law

An alternative to state-by-state laws would be the implementation of a national GE labeling law. In 2013, a proposed federal labeling bill entitled The Genetically Engineered Food Right-to-Know Act was introduced simultaneously in the Senate (S 809) and House (HR 1699) to require the FDA to mandate GE labeling. The bills have 9 cosponsors in the Senate and 22 cosponsors in the House.

There are some international trade implications that would result from the passage of such a law. If the United States were to mandate labeling of GE food, the United States would have to show a scientific health threat in order to be in compliance with international trade law. Many of the GE labeling laws in the 64 countries around the world that require GE labeling likely violate the World Trade Organization (WTO) and its 1994 Sanitary and Phytosanitary Agreement, which frowns on process-based labels mandating disclosure of information on production-process issues that do not relate to food safety (CSPI 2000).

Indeed, the United States has lost two recent WTO decisions that ruled against U.S. laws requiring production-process labeling on dolphin-safe products and country-of-origin labeling (COOL). Both laws were designed to inform consumers about process or origin information not impacting the food itself. These interests could have been better served by voluntary international standards, if the market justified them. These WTO decisions point toward potential future challenges of GE labeling laws that disrupt trade (Jurenas and Greene 2013).

The United States has not challenged a GE labeling law at the WTO, despite calls from major U.S. commodity trade associations to do so and the fact that it is estimated that European Union (EU) labeling laws prevent billions of dollars in U.S. trade to the EU (Bernauer 2003). Canada and Mexico could similarly assert that a U.S. GE labeling law violates the WTO, just as they challenged U.S. laws on dolphin-safe and COOL. Both the WTO and U.S. interstate commerce laws favor voluntary standards, and the existing voluntary Non-GMO Project (www.nongmoproject.org) and other similar certification and labeling programs provide a "less burdensome" alternative to mandatory labeling.

Indeed, in recent years a large number of food products indicating the absence of GE ingredients through non-GE or organic labels have also been offered in the U.S. market. Food manufacturers and retailers have voluntarily labeled such products, and often third-party organizations have certified the accuracy of the claims and labels. More than 14,800 food products and 800 brands are reported to have been certified as meeting the Non-GMO Project standard alone (Brown 2013). Another option consumers have is to buy organic products, because the use of GE is not allowed in certified organic production systems. Additionally, some manufacturers are doubly verifying their certified organic products with the Non-GMO Project Verified and other non-GE certification programs (Gallo 2013).

Some U.S. food merchants have gone even further. In March 2013, the retail chain Whole Foods Market set a deadline that all products sold in its U.S. and Canadian stores must be labeled to indicate if they contain GE ingredients (using a ≥ 0.9% GE content threshold for labeling) by 2018 (Robb and Gallo 2013; *The Organic and Non-GMO Report* 2009). Altogether, these voluntary measures provide consumers with non-GE choices in the U.S. marketplace at commercially achievable standards (*The Organic and Non-GMO Report* 2007).

In February 2014, the Grocery Manufacturers Association announced the creation of a 33-member group called The Coalition for Safe Affordable Food (www.CFSAF.org), which is calling for federal legislation that would require mandatory premarket approval of GE food ingredients by the FDA and grant authority to the agency to label products that raise safety concerns, set up a voluntary program for food companies to label foods for the absence or presence of GE ingredients, and define the term "natural" for its use on food and beverage products.

Location of the Label

A final issue is that of the GE label placement. Some of the proposed legislation requires the GE designation to be conspicuously present on the front of the package or retailer's display (for raw produce). For example, the failed Washington State initiative (Washington Initiative Measure No. 522 2012) required the following:

> In the case of a raw agricultural commodity, on the package offered for retail sale, with the words "genetically engineered" stated clearly and conspicuously on the front of the package of such a commodity, or in the case of such a commodity that is not separately packaged or labeled, on a label appearing on the retail store shelf or bin where such a commodity is displayed for sale; In the case of any processed food, on the front of the package of such food produced by a manufacturer, with the words "partially produced

with genetic engineering" or "may be partially produced with genetic engineering" stated clearly and conspicuously.

No rationale or justification has been advanced for this label placement, which would separate the GE label from preexisting nutritional and ingredient information. Consumers tend to overstate the importance of labels that are placed only on the front of a package and separated from nutritional and health information (Costanigro, Deselnicu, and Kroll 2012). Mandating producers and retailers to prominently display such a label implies that consumer knowledge about GE is more important than nutritional content or ingredients. In the absence of an identified material difference in GE products, such prescriptive compelled speech would likely increase the chance of a Constitutional First Amendment objection.

Economics

The Costs of Non-GE Foods

Adequate information that allows consumers to make choices consistent with their preferences is an essential feature of well-functioning food markets. Food labels can contribute useful information and can assist in consumer decision making. Organic and non-GE foods provide interested consumers information and choices, but they are more costly than conventional foods. Non-GE and organic products are more expensive in part because of lower yields (Seufert, Ramankutty, and Foley 2012); higher average production costs; segregation costs incurred in order to keep such products from commingling with GE or conventional products across the food supply chain; and various testing, certification, and traceability costs that must be paid to demonstrate the authenticity of such products when they are bought and sold (Kalaitzandonakes, Maltsbarger, and Barnes 2001). Suppliers of non-GE and organic products are compensated for their higher costs through price premiums they receive from buyers. For instance, the prices received by U.S. non-GE corn and soybean producers in recent years have averaged 15% more than the prices received by conventional commodity producers. Likewise, the prices received by U.S. organic corn and soybean growers have at times been more than twice the prices received by the nonorganic growers (Figure 3).

Premiums paid to suppliers of non-GE and organic agricultural products along with certification costs are carried all the way to the final processed, prepared, and ready-to-eat foods that make use of such ingredients and are paid by consumers in the form of higher prices. For example, according to analysis of scanner data, the prices U.S. consumers paid for organic ice cream, margarine spreads, and eggs were, respectively, 120%, 100%, and 80% higher than the U.S. average prices of conventional products for the 2008–2011 period (Vickner, S. 2013. Personal communication). Likewise, organic fruit and vegetable prices averaged 50 and 100% higher than conventional prices, respectively, in 2012–2013 (USDA–ERS 2014).

The Costs of Alternative Purity Standards and Tolerances

The incremental costs associated with the production and distribution of non-GE foods are not fixed and are heavily dependent on the GE purity standards and tolerances used (Giannakas et al. 2011). Purity thresholds and tolerances are used to recognize that perfect avoidance (or zero tolerance) of GE material is difficult to achieve in practice. Agricultural land, transport, storage, and processing facilities are broadly shared in the food sector, and perfect segregation of any agricultural product is typically not possible. Tolerances set for the presence of GE material are determined with best industry practices in mind and permit small unintended GE amounts that can be present in non-GE or organic foods.

When GE tolerances are set to be very low, segregation methods must become more stringent. When that occurs, the incremental production, segregation, and certification costs of non-GE products increase disproportionally, however, because the relative effectiveness of more stringent segregation methods diminishes with lower tolerances (Huygen, Veeman, and Lerohl 2004; Kalaitzandonakes, Maltsbarger, and Barnes 2001). Increasingly higher production and segregation costs are therefore applied to a progressively lower volume of non-GE products that can meet the stricter tolerances and purity standards. Production and segregation costs for non-GE corn, for instance, are estimated to increase by as much as 20% by lowering the tolerance for any unintended GE

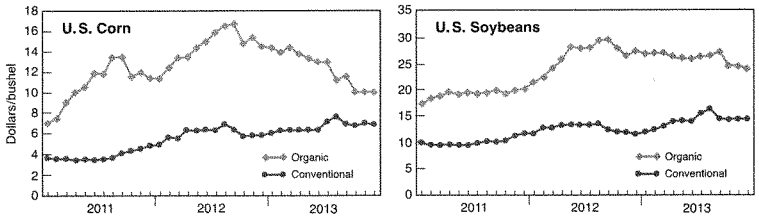

Figure 3. Prices received for conventional and organic corn and soybean (dollars/bushel), 2011–2013 (USDA–LPS 2013; USDA–NASS 2013b).

content from a maximum of 1% to 0.5% (Kalaitzandonakes, N. 2013. Personal communication) and much more than that for tolerances below 0.5%.

It is unclear what tolerance levels are being used in the various non-GE products that are currently on the market because they are not always reported. Some have argued that a zero tolerance is appropriate. A zero or near-zero tolerance for GE content would be commercially challenging, if not impossible, to achieve at a large scale and would greatly complicate the procurement of food ingredients. The legal doctrine of commercial impossibility could be used to render contracts unenforceable, and such legal challenges could further increase the costs of non-GE products. These issues are recognized where mandatory GE labeling has been implemented in practice. Although a number of countries have laws requiring GE food labeling (Just Label It 2012), none has tried to enforce a zero tolerance (the strictest is the EU at a maximum of 0.9%, whereas many Asian nations use 5%).

The Costs of Mandatory GE Labels

The potential economic impact of state and other initiatives that would mandate labeling for the presence of GE ingredients in foods has also been of much interest. Opponents of mandatory GE labeling schemes have argued that they would be very costly and that their costs would be paid by all consumers, including those who do not wish to avoid GE. Proponents have argued that the implied costs would be minimal. Indeed, a handful of studies has sketched out the potential costs of the mandatory labeling initiatives in California and Washington. The results have varied from more than $1 billion per year to a few thousands of dollars (Alston and Sumner 2012; Robertson 2013).

The widely differing calculations in the estimated costs of the proposed mandatory labeling schemes are explained by fundamentally different conjectures about the responses of key players in the food supply chain and the changes they could bring about in the U.S. food market. Much depends on how food manufacturers, food retailers, and other food merchants would choose to act if mandatory GE labeling was put in place. On the one hand, they could choose to maintain the current composition of their products, placing GE labels on them when necessary. On the other hand, they could choose to change the composition of their products in order to avoid the use of GE labels.

The reactions of food manufacturers and retailers could be shaped by expectations of negative consumer response toward GE labels (Marchant, Cardineau, and Redick 2010), targeting of their products by activists (Gruère and Rao 2007), exploitation of GE labels by competitors (Kalaitzandonakes and Bijman 2003), and concern that a mandated label might be mistakenly interpreted by consumers to confer a food safety warning (Marchant, Cardineau, and Redick 2010). If manufacturers choose to maintain their products and place labels on them, the cost impact of mandatory labeling would be the relatively minor cost of the ink to print new labels and the more significant costs associated with tracking and monitoring to ensure compliance. If manufacturers choose to substitute GE ingredients with non-GE ingredients to avoid labels, the cost impact of mandatory labeling would be substantial and associated with new product formulation and sourcing non-GE ingredients. [1]

Changing the composition of foods sold in the market today in order to avoid the use of GE labels would involve the replacement of GE ingredients with others derived from commodities that have not yet been genetically engineered (e.g., wheat or rice) or with non-GE and organic ingredients. Such changes are both difficult to implement and costly. Changes in ingredients may alter the final product as it is not always possible to achieve identical appearance and functionality when reformulating and redeveloping a product using alternative ingredients (e.g., changing from corn starch to tapioca or potato starch).[2] Moreover, as discussed previously, non-GE ingredients tend to be more expensive and may have more uncertain and inconsistent supplies. The added costs of avoiding mandatory GE labels are therefore more or less the same as those incurred by products voluntarily labeled non-GE, as described earlier. In effect then, appraisal of the added costs for mandatory labeling involves (1) an estimation of the share of the food market that might become non-GE, and (2) an estimation of the costs that would be incurred to procure non-GE ingredients and reformulate products.

If a significant share of the prepared and ready-to-eat foods sold in supermarkets today were to require non-GE ingredients, the demand for certified non-GE and organic products would increase well beyond its current levels.[3] The markets of non-GE and organic food ingredients are, in effect, specialty markets, and as such they can exhibit noticeable price jumps even under modest changes in their demand and supply conditions. Hence, under expanded markets and increased demand conditions, price premiums for such ingredients could well exceed their current levels.

It is unclear how much U.S. consumers are willing to pay for mandatory GE labeling, although if a mandatory GE labeling law is enacted there will be little choice but to pay the resulting costs, especially if products containing GE ingredients are removed from the market. At the beginning of the decade, 77% of the public indicated that they would not be willing to pay more than

[1] It is worth noting that although mandatory GE labeling is often assumed to enable consumer choice, mandatory GE labeling laws in other countries have had the opposite effect in that they resulted in the virtual disappearance of any labeled GE product from the shelves, thereby decreasing choice and increasing price for those consumers unconcerned about GE food (Marchant, Cardineau, and Redick 2010). In the EU, Greenpeace and other anti-GE organizations quickly launched negative campaigns targeting GE-labeled products and publicized supermarkets or food brands carrying GE labels. In response, retailers decided not to stock brands with GE labels to avoid the risk of losing sales because of such campaigns and boycotts, and food processors avoided using GE ingredients to decrease their risk of loss in market share (Gruère and Rao 2007).

[2] Processed foods often contain a number of ingredients that are derived from different commodities such as corn, soybean, canola, and sugar beets. Ensuring that all ingredients used in any given processed product come from non-GE commodities can complicate their supply chains. For example, chicken bouillon today might include sugar from GE sugar beets, maltodextrin and hydrolyzed protein from GE corn, and tocopherol (vitamin E) from GE soybean, whereas peanut butter might contain sugar from GE sugar beets, molasses from GE corn, and vegetable oils from GE canola and corn varieties. If food manufacturers were to reformulate such products, they would have to ensure that all individual ingredients are certified non-GE. Many highly processed ingredients and oils contain no detectable traces of their GE origin (e.g., no DNA is present in oil), which further complicates certification of non-GE ingredients.

[3] For instance, organic production of corn and soy constitute 0.26% and 0.17% of total U.S. production, respectively (USDA–ERS 2013b).

$50 per year per household for GE labeling, with 44% of respondents not willing to pay anything extra for GE labeling (CSPI 2001). Furthermore, analysis of the unsuccessful California and Washington GE labeling initiatives indicates that the concern about potential food price increases figured in their defeat (*The Elway Poll* 2013).

Potential Changes in the Costs of Mandatory Labeling

The cost consequences of any mandatory GE labeling scheme could change over time. The state labeling laws that have passed in Connecticut and Maine, as well as the proposed 2014 Oregon ballot measure, include time-limited exemption language that originated in the failed California Proposition 37, which can change the labeling standards and their cost implications over time. Specifically, they state the following:

> Until July 1, 2019, any processed food that would be subject to this section solely because it includes one or more materials produced by GE, provided that the engineered materials in the aggregate do not account for more than nine-tenths of one percent of the total weight of the processed food.

This clause, a version of which has commonly been included in the text of other states' proposed GE labeling legislation (see Table 1 [Appendix]), effectively introduces a time limit allowing products containing less than 0.9% GE content to be exempt from labeling for a few years. This tolerance would have expired on July 1, 2019, after which presumably all covered food products containing any level of GE content (i.e., zero tolerance) would have required GE labeling. As explained previously, trying to achieve a zero tolerance would lead to greater costs from mandatory labeling and would be difficult, if not impossible, to achieve in practice (Kalaitzandonakes, Kaufman, and Miller, in press).

Zero tolerances would also increase uncertainty in the food supply chain. When food manufacturers and retailers choose to use non-GE ingredients in order to avoid GE labeling, they depend on testing and certification to guarantee the authenticity of such ingredients. Sampling, testing, and certification depend on statistical processes, however, and hence all are subject to some error, which increases at very low tolerances (Lamb and Booker 2011). Under some state GE labeling laws, this type of error could open up firms to potential liabilities for misbranded products. To the extent that such state laws provide for citizens to file suit—seeking restitution, attorneys' fees, and potentially punitive damages—they could add to the segregation, testing, and certification costs borne by the food supply chain. State laws enacting such consumer fraud approaches to enforcing GE content in the food supply could therefore further increase the economic impact of mandatory GE labeling through litigation on food producers and manufacturers. Such an effect was seen following the passage of Proposition 65 in California.[4]

The Cost Implications of Labeling Exemptions

Some of the state labeling bills contain labeling exemptions for different categories of food, and these would affect the cost of mandatory labels (see Table 1 [Appendix]). One exemption includes food products obtained from animals raised on feed derived from GE crops. This is an especially large category because virtually all conventional livestock industries in the United States (and most other countries) use predominantly GE feed. Approximately 40% of total U.S. corn production and more than 80% of total soy production is used for animal feed. Corn grain, silage, gluten feed, gluten meal, soybean meal, cottonseed, alfalfa, and sugar beet pulp are common GE components of animal feed. Including and tracking products such as meat, milk, and eggs from animals that might have consumed GE feed at some time in their lives would add a significant level of complexity and expense to mandatory GE labeling of these animal products.

Other exemptions have variously included alcoholic beverages, foods sold in restaurants, and/or certified organically produced foods. The last exemption is particularly important because it might inadvertently lead to further increases in the cost of food. If certified organic products do not require GE labeling irrespective of whether or not they contain trace amounts of GE content (whereas nonorganic non-GE products have to be tested and may still be subject to liability if testing reveals misbranding), then food manufacturers and retailers may favor more expensive organic ingredients to avoid any potential liabilities associated with misbranding, thereby further increasing the overall cost impact of mandatory labeling.[5]

Who Pays?

Over time, food prices would rise to cover the incremental costs of any mandatory GE labeling regime in the U.S. market. An important question then is who would be most affected by such price hikes. So far, state initiatives have called for mandatory GE labeling of foods bought at the grocery store and consumed at home but do not generally require the same for foods consumed in restaurants, cafeterias, catered events, schools, and the like. And, as explained earlier, they also invariably exclude all organic foods from mandatory GE labeling, irrespective of where they are consumed or their potential GE content. Given these exemptions and the proposed rules on what foods would actually need the GE labels, the proposed mandatory labeling schemes would have a greater impact on low-income households.

Specifically, data from the 2012

[4] Proposition 65 (California's Safe Drinking Water and Toxic Enforcement Act of 1986) requires the State of California to promulgate a list of chemicals known to be carcinogens of reproductive toxins. It provides a financial incentive for private enforcers to bring lawsuits because it allows them to recover the litigation costs and retain for their own personal benefit 25% of the money obtained in each lawsuit. Between 1988 and 2006, more than 1,550 lawsuits were filed and companies paid approximately $406 million settling Proposition 65 cases (Walsh and Sanford 2008).

[5] It should be noted that there may be other costs associated with mandatory GE labeling that have not been discussed in this document. For example, there could be costs associated with the use of natural resources and the environment if American agriculture reverts to using conventional non-GE varieties of corn, cotton, canola, sugar beet, and soybeans to meet an expanded non-GE market. The adoption of insect-resistant and herbicide-tolerant GE crops by U.S. farmers has resulted in decreased insecticide use and has enabled the substitution of more effective and less persistent herbicides, respectively (Fernandez-Cornejo et al. 2014). Alston and Sumner (2012) discuss these issues in some detail, including how the reversion to non-GE varieties could also impact private and public investment into biotechnology and other agricultural research and development, and U.S. agricultural competitiveness—especially if major contenders such as Brazil and China continue to adopt and develop GE technologies.

Bureau of Labor Statistics Consumer Expenditure Survey (USDL–BLS 2012) show that low-income households across the United States spend a larger portion of their income on food than high-income households and spend most of these dollars for food at home. High-income individuals spend more at restaurants and eateries. For example, U.S. households with an annual income of $10,000–$20,000 spend between 21 and 26% of this income for food. Two out of three such dollars are spent at the grocery store for food cooked and consumed at home. By contrast, affluent households with an annual income of more than $70,000 spend less than 8% of their income for food and only about half of that at the grocery store.

Similar trends exist for older relative to younger consumers. For instance, U.S. households headed by consumers 65 or older have, on average, less than $40,000 in annual income and spend more than 12% of that for food, and two out of three such dollars are spent for food at home. Younger households headed by consumers 35–54 years old have, on average, 50% more income and spend about 10% of it for food, and almost half of such food dollars are spent away from home. Finally, research shows that younger, more affluent consumers spend more on organic food than older, poorer ones.

Given the proposed rules and exemptions, younger and more affluent consumers who spend more on organics and food away from home would be least affected by the costs resulting from mandatory GE labeling. Poorer and older consumers would instead pay more of the added costs associated with mandatory GE labeling while spending a larger portion of their limited income in doing so. Indeed, regardless of the reason for price increases, elevating food cost has a greater impact on the poor as a proportion of their income.

Summary and Conclusion

- All domesticated crops and animals have been genetically modified in some way; there is no science-based reason to single out GE foods and feeds for mandatory process-based labeling. Wide-ranging evidence shows that GE technology is equally safe to conventional breeding.
- Mandatory labeling based on process abandons the traditional U.S. practice of providing for consumer food preferences through voluntary product differentiation and labeling (i.e., marketing and promotion of products with specific attributes).
- Market-driven voluntary labeling measures (e.g., organic, Non-GMO Project, Whole Foods initiative) currently provide consumers with non-GE choices in the U.S. marketplace.
- Current labeling authority is federal; state mandatory labeling laws may be invalidated for conflicting with preemptive federal authority and may also violate First Amendment rights. If courts invalidate such locally imposed laws, it may be seen that courts are thwarting consumer will. Litigation seems a likely outcome if states pass mandatory labeling laws.
- Labeling at the national level has trade implications and needs to be harmonized with international trade agreements that frown on mandatory labeling for a production process when there is no scientific evidence that the process relates to food safety.
- Mandatory GE labeling would increase U.S. food costs. The size of this increase will depend on choices made in the marketplace by suppliers and marketers, and what products are included in labeling requirements. If, as in other countries, sellers move to non-GE offerings in response to mandatory labeling, food costs could rise significantly and these increased costs would exact a greater burden on low-income families. If, on the other hand, food suppliers choose to label virtually all products as containing GE without testing or segregation, increases in costs might be minimal.
- Independent objective information on the scientific issues and the possible legal ramifications and economic consequences of mandatory GE food labels needs to be provided to legislators and consumers, especially in states with labeling initiatives on the ballot, to help move the national discussion from contentious claims and counterclaims to a more fact-based and informed dialog.

Appendix

See Table 1.

Table 1. States with food labeling legislation, selected exemptions from the proposed legislation text, status, and source of text.

State	Legislation Citation	Selected Text and Exemptions	Status
Alaska	Alaska Legislature 2013	Labeling of GE fish	Passed 2005
Arizona	Arizona Senate 2013	Exempts food consisting entirely of, or derived entirely from, animals that have been fed with any GE feed or treated with any drug that has been produced through means of GE	
		Exempts GE processing aids or enzymes	
California	California 2012	SB 1381 exempts food derived entirely from animals that are not themselves GE, regardless of whether they have been fed or injected with any feed or drug that has been produced through means of GE	11/6/12—Proposition 37 defeated
	California 2014		2/21/14—Senate Bill 1381 introduced
		Exempts "packaged food in which the materials produced through GE account for nine-tenths of 1 percent" and "food lawfully certified to be labeled, marketed, and offered for sale as 'organic'" pursuant to the federal Organic Foods Production Act of 1990	
Colorado	Colorado General Assembly n.d.	Exempts food that contains less than 1% of GE material	
		Exempts food certified as "organic"	

Table 1. (continued)

State	Legislation Citation	Selected Text and Exemptions	Status
Connecticut	Connecticut General Assembly 2013a,b,c	Exempts food products derived from animals fed GE feed Exempts GE processing aids or enzymes Until July 1, 2019, exempts packaged processed food if the total weight of the processed food that was GE is less than 0.9% of the total weight of the processed food	6/25/13—Signed by governor; requires four other contiguous states with a combined population of more than 20 million to enact similar legislation before it can be implemented
Florida	Florida House 2013; Florida Senate 2013	Exempts food consisting entirely of, or derived entirely from, animals that have been fed with any GE feed or treated with any drug that has been produced through means of GE Exempts GE processing aids or enzymes Until January 1, 2015, exempts any single ingredient that accounts for no more than 0.5% of the total weight of any processed food and the food does not contain more than 10 GE ingredients	1/10/14 (Senate)—Introduced and referred to the Committees on Agriculture, Commerce and Tourism, Regulated Industries, and Community Affairs 3/4/14 (House)—Introduced
Hawaii	Hawaii House 2013a,b,c; Hawaii Senate 2013a,b,c	Exempts animal or any animal product, milk or any milk product	1/13—Referred to committees 1/30/13—House Bill 733 hearing held by the Committee on Agriculture February 4, 2013 4/12/13—Report from Committee on Finance recommending adoption; adopted in final form
Illinois	Illinois House 2013; Illinois Senate 2013	Identical bills exempt food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE	3/22/13—House Committee Amendment No. 1 Rule 19(a) and re-referred to Committee on Rules 3/22/13—Senate Rule 3-9(a) and re-referred to Committee on Assignments
Indiana	Indiana House 2013	Exempts food consisting entirely of, or derived entirely from, animals that have been fed with any GE feed or treated with any drug that has been produced through means of GE Until July 1, 2019, exempts packaged processed food if the total weight of the processed food that was GE is less than 0.5% of the total weight of the processed food	
Iowa	Iowa Senate n.d.	Exempts meat, fish, or poultry that originated from an animal that consumed GE feed	
Maine	Maine House 2013a,b	Exempts food products derived from animals fed GE feed Until July 1, 2019, exempts packaged processed food if the total weight of the processed food that was GE is less than 0.9% of the total weight of the processed food	1/9/14—Signed by governor; requires four other contiguous states with a combined population of more than 20 million to enact similar legislation before it can be implemented
Maryland	Maryland House 2013	Exempts food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE Until July 1, 2019, exempts packaged processed food if the total weight of the processed food that was GE is less than 0.5% of the total weight of the processed food and it does not contain more than 10 ingredients that have been produced with GE	2/26/13—Unfavorable report from committee; withdrawn
Massachusetts	Massachusetts House 2013a,b,c,d	Multiple bills. HB 808 specifically requires labeling of food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE; whereas 1936 and 2037 allow these exemptions Until July 1, 2019, exempts any processed food provided that no single GE ingredient accounts for more than 0.5% of the total weight of the processed food and that the processed food does not contain more than 10 GE ingredients	1/22/13—Referred to Joint Committee on Environment, Natural Resources and Agriculture; concurred in committee referral
Minnesota	Minnesota House 2013; Minnesota Senate 2013	Exempts GE processing aids or enzymes Until July 1, 2019, exempts packaged processed food if the total weight of the processed food that was GE is less than 0.9% of the total weight of the processed food	2/21/13 (House)—Introduction, first reading, and referred to Committee on Agriculture Policy 2/28/13 (Senate)—Introduction, first reading, and referred to Committee on Jobs, Agriculture and Rural Development

Table 1. (continued)

State	Legislation Citation	Selected Text and Exemptions	Status
Missouri	Missouri House n.d.; Missouri Senate 2013	Specifically requires labeling if milk comes from cows that have been fed GE feed or treated with GE hormones or drugs	2/14/13—Both bills withdrawn
Nevada	Nevada Assembly 2013	Exempts food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE Exempts GE processing aids or enzymes Exempts processed foods in which ingredients or materials produced with GE in the aggregate do not account for more than 0.9% of the total weight of the processed food	4/13/13—Pursuant to Joint Standing Rule No. 14.3.1, no further action allowed
New Hampshire	New Hampshire House 2013; New Hampshire Senate 2014	Does not include exemptions and requires the Commissioner of the Department of Agriculture to develop a list of GE products and best practices for labeling	4/30/13—Committee retained the bill 1/8/14—Senate bill introduced 1/23/14—House killed the bill
New Jersey	New Jersey Assembly 2012a,b; New Jersey Senate 2012	Exempts food composed of less than 1% of GE material	
New Mexico	New Mexico Senate 2013	Specifically requires labeling of animal feed that contains GE material Exempts food that is composed of less than 1% GE material No specific exemption for certified organic food products	2/1/13—Withdrawn
New York	New York Assembly 2013a,b; New York Senate 2013a,b	Exempts food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE Exempts GE processing aids or enzymes Exempts any single ingredient that accounts for less than 0.9% of the total weight of any processed food	2/21/13—Senate Bill 3835 referred to Committee
Oregon	Oregon House 2013a,b,c; Oregon Office of the Secretary of State 2013	Specifically requires labeling of food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE Exempts GE processing aids or enzymes Until July 1, 2019, exempts packaged processed food if the total weight of the processed food that was GE is less than 0.9% of the total weight of the processed food	7/8/13—Left in Committee upon adjournment
Pennsylvania	Pennsylvania Senate 2013	Exempts food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE Exempts GE processing aids or enzymes Until July 1, 2019, exempts packaged processed food if the total weight of the processed food that was GE is less than 0.9% of the total weight of the processed food	4/3/13—Referred to Committee on Agriculture and Rural Affairs
Rhode Island	Rhode Island House 2013a,b	Exempts food composed of less than 1% of GE material	
Tennessee	Tennessee House 2013; Tennessee Senate 2013	Specifically requires labeling of food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE	3/13/13—House bill placed on Committee calendar for March 20 3/19/13—Senate bill assigned to General Subcommittee
Vermont	Vermont House 2013; Vermont Senate 2013	Exempts food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE Exempts GE processing aids or enzymes Until July 1, 2019, exempts packaged processed food if the total weight of the processed food that was GE is less than one half of 0.9% of the total weight of the processed food and the food contains less than 10 such ingredients	2/8/13—Senate bill filed, read first time, and referred to Committee on Agriculture 5/10/13—House bill amendments offered and disagreed to, read third time, and passed
Washington	Washington Initiative Measure No. 522 2012; Washington Senate 2013	Exempts food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE Exempts GE processing aids or enzymes Exempts any single ingredient that accounts for no more than 0.9% of the total weight of any processed food	11/5/13—Initiative defeated
West Virginia	West Virginia House 2013	Specifically requires labeling of food products derived from animals fed GE feed or treated with any drug that has been produced through means of GE	2/13/13—Introduced and referred to Committee on Agriculture

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Mr. PITTS. The chair thanks the gentlelady.

Now recognize Mr. Faber 5 minutes for his opening statement.

STATEMENT OF SCOTT FABER

Mr. FABER. Thank you, Mr. Chairman. Mr. Chairman, Ranking Member Pallone, members of the committee, thank you for the opportunity to testify. First, let me thank you for the tremendous work you and your staff performed on the Sunscreen Innovation Act. We greatly appreciate your work on that important piece of legislation. And let me thank you for dedicating your time to this important issue. As you can tell, people are incredibly passionate about their food.

Consumers simply want the right to know what is in their food and how it is produced. More than 90 percent of consumers, regardless of age, gender, income, or even party affiliation, routinely tell pollsters that they want—simply want the right to know what is in their food. But this isn't simply a question of right to know. It is also a question of consumer confusion. As Mrs. Capps mentioned earlier, misleading claims like natural claims have led to significant consumer confusion. Roughly 60 percent of consumers, when buying a package with a natural claim, believe that all natural foods are GMO-free. And we believe that a factual, informative, nonjudgmental disclosure on the back of the package would help address this confusion.

Now, let me be very, very clear. We are not seeking a warning of any kind; we are simply seeking a factual, nonjudgmental disclosure on the back of the package, and we are confident, as Mr. Pallone suggested earlier, that food companies, farmers, FDA, consumer groups can work together to craft a disclosure that provides consumers basic information without rendering a judgment on the technology.

And fortunately, FDA has the authority to require such a disclosure, and as Mr. Waxman alluded to earlier, has used this authority in the past. And that is fortunate because we would greatly, greatly prefer a national GMO labeling solution. But in the absence of leadership from FDA, we believe that states should and can act or require a mandatory disclosure. Congress has long recognized a role for the states, a leading role for the states, in food labeling, and that is why the NLEA was carefully crafted to not preempt state labeling laws, such as the GMO disclosure laws that have been passed by states like Vermont.

Now, you have certainly heard arguments made today, and will hear more arguments made by this panel, that GMO labeling will increase food prices, but you don't have to work for the Grocery Manufacturers Association or work for the food industry to know that food companies change their labels all the time to highlight new claims or new innovations.

You will also hear today that GMO labeling will create costly new farm and food—the need for costly new farm and food segregation systems, but those systems have been in place for decades, to address allergens and to meet growing demand for non-GMO and organic choices, all the way from the farm to the elevator, to the processor, to the retailer. In fact, the snack food industry has

launched more non-GMO project offerings in the last decade than any other segment of the food industry.

You will also hear—and also have heard, and will hear again, that we need GMO crops to feed the world. First, let me say, no one, no one is seeking a ban on GMO crops, and let me point out also that many farm groups, including the National Farmers Union, support mandatory GMO labeling. But it is also worth noting that we have run the experiment for the last 20 years, and so far yields of conventional crops have kept pace with yields of GE crops.

Now, I agree with testimony you will hear from Ms. Forshee that farmers should have choices, but so should consumers. We need a national GMO labeling system that works for farmers, that works for food companies, but that also works for consumers. Unfortunately, H.R. 4432 does not provide a national mandatory labeling system. In fact, H.R. 4432 narrows FDA's ability to work with us, to work with farmers, to work with the food industry to craft such a system. It fails to restrict the misleading natural claims that have fueled so much consumer confusion, and it preempts state laws that are ultimately designed to protect consumers from this confusion.

Mr. Chairman, people simply want to know what is in their food, they want to be able to make choices for their families, and I hope that you will work with us to give consumers the right to know whether or not their food contains genetically-modified food ingredients.

Thank you.

[The prepared statement of Mr. Faber follows:]

Testimony of Scott Faber

Senior Vice President
Environmental Working Group

Before the Subcommittee on Health

Of the House Committee on Energy and Commerce

on

"Examining FDA's Role in the
Regulation of Genetically Modified Food Ingredients"

December 10, 2014

Thank you for the opportunity to testify.

My name is Scott Faber and I am Senior Vice President of Government Affairs for the Environmental Working Group. Today, I am testifying on behalf of Just Label It, a coalition of more than 700 businesses and organizations dedicated to mandatory GMO labeling.

Consumers simply want to know what is in the food they are buying and how it was produced.

Because our food choices dramatically shape our lives, unprecedented consumer interest in food is a trend that should be welcomed, not frustrated. Consumers are not merely interested in nutrition and health. They are also interested in how our food choices impact the treatment of animals, the fate of food and farm workers, and the impacts of agriculture on the environment.

This interest extends to whether or not our food contains genetically modified ingredients.[1] Consumer surveys routinely show that more than 90 percent of Americans -- regardless of age, income, gender or even party affiliation -- want to know whether the ingredients in their food have been genetically modified.[2] More than 1.4 million Americans have joined a formal petition to the Food and Drug Administration to assert this right.[3] Over the past two years, state legislators in 30 states introduced more than 70 bills to require GMO labeling.

Although the right to know what's in our food is a value held by all Americans, accurate food labeling is not simply a matter of consumer interest. Accurate food labeling allows us to use our buying power to shape our lives and the world around us, enhances our trust in food products, and helps reduce confusion in the marketplace.[4]

Let me be clear: we are not seeking a warning label. Rather, we are asking for a modest disclosure on the back of the package that simply conveys factual information. More than 70 percent of packaged foods contain genetically modified ingredients, including commonly used oils, flours, proteins, sweeteners, and

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[1] NATURAL MARKETING INST. (NMI), 2014 GMO CONSUMER INSIGHT REPORT 28 (2014).
[2] *See, e.g.*, The Mellman Group, Inc., *Support for Mandatory Labeling of Genetically Engineered Foods Is Nearly Unanimous*, JUSTLABELIT.ORG (Mar. 22, 2012), http://justlabelit.org/wp-content/uploads/2012/01/Mellman-Survey-Results.pdf.
[3] *See Petition Seeking Mandatory Labeling for Genetically Engineered Foods*, JUSTLABELIT.ORG, http://justlabelit.org/wp-content/uploads/2011/09/gelabelingpetition.pdf.
[4] NATURAL MARKETING INST, *supra* note 1, at 4 (More than half of consumers are looking for foods that are "natural," and that consumer interest in "natural" claims is exceeded only by consumer interest in food featuring "local" claims)

[2] *See, e.g.*, The Mellman Group, Inc., *Support for Mandatory Labeling of Genetically Engineered Foods Is Nearly Unanimous*, JUSTLABELIT.ORG (Mar. 22, 2012), http://justlabelit.org/wp-content/uploads/2012/01/Mellman-Survey-Results.pdf.
[3] *See Petition Seeking Mandatory Labeling for Genetically Engineered Foods*, JUSTLABELIT.ORG, http://justlabelit.org/wp-content/uploads/2011/09/gelabelingpetition.pdf.

preservatives.[5] But, the widespread use of misleading claims like "natural" have led many consumers to believe "natural" foods are GMO-free.[6]

A recent survey by NMI found that 58 percent of respondents believed that "natural" foods are GMO-free.[7] A similar survey for by Consumer Reports' found that 64 percent of respondents believed that "natural" foods are GMO-free.[8] Currently, FDA policy does not explicitly prohibit the use of genetically modified ingredients in foods labeled as "natural." Many so-called "natural products" recently tested by Consumer Reports contained GMOs.[9]

A modest disclosure on the back of food packages will not only give consumers basic information about what's in their food and how it was produced but will also cure the consumer confusion caused by the widespread use of misleading claims like "natural."

The FDA has the authority to make such a disclosure mandatory and has done so in the past.[10] Sec. 403 (a) of the Food, Drug and Cosmetics Act prohibits the "misbranding" of food, including food labeling that "is false or misleading in any

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[5] *See* http://www.centerforfoodsafety.org/issues/311/ge-foods/about-ge-foods#
[6] CONSUMER REPORTS NATIONAL RESEARCH CENTER, FOOD LABELS SURVEY 4 (2014), *available at* http://www.greenerchoices.org/pdf/ConsumerReportsFoodLabelingSurveyJune2014.pdf.
[7] NATURAL MARKETING INST., *supra* note 1, at 27.
[8] CONSUMER REPORTS NATIONAL RESEARCH CENTER, FOOD LABELS SURVEY 7(2014), *available at* http://www.greenerchoices.org/pdf/ConsumerReportsFoodLabelingSurveyJune2014.pdf
[9] *See New Consumer Reports Study Finds GMOs in Many Common Food Products*, CONSUMERSUNION.ORG (Oct. 7, 2014), https://consumersunion.org/news/new-consumer-reports-study-finds-gmos-in-many-common-food-products/.
[10] For example, FDA has compelled disclosures unrelated to nutrition and health, including mandatory labeling for irradiation. When issuing the rule requiring irradiated foods be labeled, FDA concluded that irradiation was "material" because consumers view such information as important. 51 Fed. Reg. 13376, 13388 (Apr. 18, 1986). FDA has also required mandatory labeling for protein hydrolysates, noting that "the food source of a protein hydrolysate is information of material importance for a person who desires to avoid certain foods for religious or cultural reasons." 56 Fed. Reg. 28592, 28600 (June 21, 1991).

particular."[11] To assess whether the label is misleading, the act requires the FDA to take into account whether or not the label "fails to reveal facts *material* in the light of such representation or *material* with respect to consequences which may result from the use of the article (emphasis added)."[12] The legislative history of the Act clearly demonstrates that Congress understood "material" to mean a fact to which a "reasonable [person] would attach importance in determining [their] choice."[13]

Without doubt, the presence of genetically modified ingredients is a fact which many consumers are seeking in order to make choices in the marketplace. Recent surveys support the conclusion that consumers want information about GMOs in their food and would use this information to shape their choices.[14] The FDA has confirmed "the strong interest that many consumers have in knowing whether a food was produced using genetic engineering."[15]

Yet the FDA's decision-making regarding GMO labeling is rooted in outdated policy and science, developed without statutory support, creating a presumption that mandatory labeling is not required unless genetic modifications produce "organoleptic" or physical changes that can be detected with the senses.[16]

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[11] 21 U.S.C. § 343(a).
[12] 21 U.S.C. § 321.
[13] § 538 of the 1938 Restatement of Torts defines a fact as material if "its existence or nonexistence is a matter to which a reasonable man would attach importance in determining his choice of action in a transaction in question." *See, e.g.*, Milton Handler, *The Control of False Advertising Under the Wheeler-Lea Act*, 6 Law & Contemp. Probs. 91, 97-98 (1939). Other statutes also define "material" in this way. See e.g. TSC Industries v Northway, 426 U.S. 438 (1976) (finding a fact is "material" if there is a "substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote.")
[14] NATURAL MARKETING INST., *supra* note 2, at 43.
[15] U.S. Food & Drug Admin., *Questions and Answers on Food from Genetically Modified Plants*, FDA.GOV http://www.fda.gov/food/foodscienceresearch/biotechnology/ucm346030.htm (last updated July 22, 2014).
[16] U.S. Food & Drug Admin., 57 Fed. Reg. 22984 (1992)

Whether food contains genetically modified ingredients should not be limited to consumers in Vermont and Oregon. We strongly support a national mandatory GMO disclosure system. We hope that President Obama will follow through on his 2007 commitment to require GMO labeling,[17] and believe that FDA has a duty to act.[18] But, in the absence of leadership from the FDA and the Obama Administration, states have properly given consumers the right to know and to prevent consumer confusion.

Congress has long recognized a role for the states in food labeling.[19] State laws requiring GMO labeling or prohibiting certain "natural" claims are not pre-empted by the National Labeling and Education Act of 1990.[20] Congress explicitly recognized the longstanding role that states have played in food labeling in the NLEA and the Supreme Court recently reiterated the narrowness of NLEA's preemption provision in *POM Wonderful LLC v. Coca-Cola.*[21]

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[17] *See* Food Democracy Now, *Obama Promises to Label GMOs*, YOUTUBE.COM (Oct. 6, 2011), https://www.youtube.com/watch?v=zqaaB6NE1TI.

[18] 21 U.S.C. § 393 Sec. 406 of the FDA Modernization Act of 1997 makes "proper food labeling" a "mission" of the FDA.

[19] *Holk v. Snapple Beverage Corp.*, 575 F. 3d 329, 334 (3rd Cir. 2009). States have required state-specific labels for food containing potentially hazardous ingredients, *see, e.g.*, Cal. Health & Safety Code § 25249.6 (for food that has been previously frozen), *see, e.g.*, Md. Code., Health-Gen. § 21-210(b)(11) (for cheese), Wis. Stat. §97.177(3), as well as "cottage industry" foods, *see, e.g.*, Tex. Health & Safety Code § 437.0193. In addition, states set different requirements for "use by" and "sell by" dates. See, e.g., 105 Mass. Code Regs. 520.119.

[20] Sec. 343-(1)(a)(2) of the NLEA prevents the addition of the term "genetically modified" from the ingredient list, not from the food package. NLEA expressly preserved a role for the states to regulate food labeling. Pub L. No. 101-535, Sec. 6(c)(1), 104 Stat. 2353, 2364 (1990) (providing that the NLEA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted."). In addition, courts have held that FDA's natural policy is not "entitled to preemptive effect." *Holk v. Snapple Beverage Corp.*, 575 F. 3d 329, 240 (3rd Cir. 2009).

[21] *Pom Wonderful LLC v Coca Cola*, 572 U.S. ___ (2014) (finding "it is significant that the complex preemption provision distinguishes among different FDA requirements.") *See also Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009) ("the case for federal preemption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.").

What's more, these state laws meet legitimate state interests[22] – such as facilitating religious dietary choices[23] or curing consumer confusion[24] – without placing an impermissible burden on interstate commerce.[25] There are many other reasons consumers want a disclosure, including both economic[26] and environmental[27] reasons.

In particular, consumers are deeply concerned that widespread adoption of GMO corn and soybeans has increased the use of herbicides by 527 million pounds between 1996 and 2012.[28] The overuse of glyphosate has contributed to herbicide-resistant "super weeds" that have caused farmers and regulators to turn to even more toxic herbicides that have been linked to serious health problems.[29]

Contrary to claims by some food companies, neither state nor federal labeling requirements will increase food prices. Food companies frequently change their labels to make new claims or highlight new innovations.[30] What's more, labor,

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[22] *Zauderer v. Office of Disciplinary Council of the Sup. Ct. of Oh.*, 471 U.S.C. 626 (1985). *Zauderer* establishes that an informational disclosure is subject to "rational" review – that is, whether the required disclosure is reasonably related to the state's interest. Act 120's legislative findings are that genetically modified foods pose potential risks to agriculture and the environment, and legislative findings are entitled to deference. *See also Walters v. Nat'l Ass'n of Radiation Services*, 473 U.S. 305 (1985).

[23] *See Cutter v. Wilkinson*, 544 U.S. 709 (2005).

[24] *See Edenfield v. Fane*, 507 U.S. 761 (1993) (state has a substantial interest "in ensuring the accuracy of commercial information in the marketplace.")

[25] *National Electronic Manufacturers Association v. Sorrell*, 272 F. 3d 104, 110 (2nd Cir. 2001). The Second Circuit held that a similar labeling requirement that could lead manufacturers to "arrange their production and distribution processes to label products solely for Vermont" did not create a burden for commerce clause purposes.

[26] *See, e.g., Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2741, 2756 (2010) (affirming that gene flow "injury has an environmental as well as an economic component").

[27] *See e.g.* John M. Pleasants & Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, Insect Conservation and Diversity (2012), *available at* http://www.mlmp.org/results/findings/pleasants_and_oberhauser_2012_milkweed_loss_in_ag_fields.pdf.

[28] *See*, Charles Benbrook, *Impacts of Genetically Modified Crops of Pesticide Use in the U.S. – the First Sixteen Years*, 24:24 ENVIRONMENTAL SCIENCES EUROPE (2012), *available at* http://www.enveurope.com/content/pdf/2190-4715-24-24.pdf.

[29] See David Mortensen, *Navigating a Critical Juncture in Sustainable Weed Management*, Bioscience (2013), available at http://bioscience.oxfordjournals.org/content/62/1/75.short; *See also* http://www.ewg.org/24D.

[30] Kai Robertson, *Why Label Changes Don't Affect Food Prices*, JUSTLABELIT.ORG (Sept. 11, 2013), http://justlabelit.org/wp-content/uploads/2013/09/Kai-Roberston-Food-Labeling-Study-2013.pdf. *See also* Andrew Dyke & Robert Whelan, *GE Foods*

ingredient and transportation costs as well as retail pricing strategies have a far greater impact on food prices than routine label changes.

There is no evidence to support arguments made by some food companies that people will simply reject foods that contain a factual GMO disclosure on the back of food packages. In fact, the evidence and experience to date suggest that the opposite is true. Studies show that people reading food packages tend to seek certain food attributes – such as the presence of fiber – and typically ignore the rest of the package.[31] Studies of consumers in other nations[32] that require GMO labeling confirm that consumers do not broadly reject foods produced with genetically modified ingredients.[33]

The debate over GMO labels is not about technology but rather about transparency. Although we would prefer a national food labeling solution, such as the solution proposed in H.R. 1699,[34] we strongly support state efforts to require GMO labeling and oppose H.R. 4432, the Safe and Accurate Food Labeling Act.

Labeling Cost Study Findings, CONSUMERSUNION.ORG (Sept. 12, 2014), https://consumersunion.org/wp-content/uploads/2014/09/GMO_labeling_cost_findings_Exe_Summ.pdf.

[31] Elise Golan & Fred Kuchler, *The Effect of GM Labeling Regime on Market Outcomes, in* GENETICALLY MODIFIED FOOD AND GLOBAL WELFARE (FRONTIERS OF ECONOMICS AND GLOBALIZATION, VOLUME 10) 263-81 (Emerald Group Publishing Limited 2011).

[32] *Labeling Around the World*, JUSTLABELIT.ORG, http://www.justlabelit.org/right-to-know/labeling-around-the-world/.

[33] *See, e.g.*, Carolina Gonzalez, Nancy Johnson, & Matin Qaim, *Consumer Acceptance of Second Generation of GM Foods: The Case of Biofortified Cassava in the Northeast of Brazil*, 60 J. of Agric. Econ. 604 (2009), *available at* http://ciat-library.ciat.cgiar.org/Articulos_Ciat/JAE_GonzalezJohnsonQaim_Finalrev.pdf (finding that Brazilian consumers more likely to purchase some foods labeled as genetically modified); *See also* Charles Noussair et al., *Do Consumers Not Care About Biotech Foods or Do they Just Not Read the Labels?*, 75 Econ. Letters 47 (2002); Nicholas Kalaitzandonakes et al., *Sentiments and Acts Toward Genetically Modified Foods*, 7 Int. J. of Biotechnology 161 (2005).

[34] HR. 1699, The Genetically Engineered Food Right to Know Act introduced by Rep. Peter DeFazio (D-Ore.), would render packaged food containing genetically modified ingredients misbranded if the package does not include a disclosure.

Supporters of H.R. 4432 claim their bill creates a "federal solution" that would "protect consumers by eliminating confusion."[35] In reality, H.R. 4432 would keep consumers in the dark by preempting state labeling laws, narrowing FDA's authority to craft a *mandatory* GMO labeling solution, and codifying the current *voluntary* labeling system that has fueled consumer confusion.

- **H.R. 4432 would not require *mandatory* food labeling.** Instead, H.R. 4432 codifies draft FDA guidance that permits *voluntary* GMO and *voluntary* non-GMO claims. The current system, which has permitted voluntary GMO and non-GMO disclosures since 2001, has failed consumers who believe "natural" and similar claims means "GMO-free" and who often fail to understand that the term "organic" bars the use of genetically modified ingredients.[36]

- **H.R. 4432 limits FDA's ability to craft a mandatory food labeling system.** H.R. 4432 codifies a 1992 policy that misinterprets Sec. 201 (n) of the FDCA to define "material" to mean "the attributes of the food itself." By codifying this policy, H.R. 4432 narrows rather than expands FDA's authority to work with food companies and consumer advocates to craft a national labeling solution.

- **H.R. 4432 fails to restrict "misleading" natural claims.** It merely requires the FDA to review the agency's current definition for "natural" and does not

[35] *See http://pompeo.house.gov/news/documentsingle.aspx?DocumentID=376238*
[36] NATURAL MARKETING INST., *supra* note 2, at 8.

prohibit the use of the word "natural" on foods containing genetically modified ingredients.[37]

- **H.R. 4432 pre-empts state labeling laws.** In addition to limiting FDA's authority, H.R. 4432 completely pre-empts states from giving consumers the right to know or from addressing consumer confusion. In particular, H.R. 4432 would preempt state actions from prohibiting misleading "natural" claims while the FDA develops new rules. This provision contradicts Congress' longstanding recognition of a state role in food labeling.

- **H.R. 4432 fails to reform FDA's food ingredient review system.** While we generally support more mandatory FDA reviews of food ingredients, H.R. 4432 fails to address longstanding flaws in FDA reviews[38] and allows foods with genetically modified ingredients to be sold even if FDA has not completed safety evaluations.

In conclusion, we strongly support mandatory GMO labeling. In the absence of federal action to create a mandatory GMO labeling system, we urge the Committee

[37] Even Monsanto defines genetically modified ingredients as "[p]lants or animals that have had their genetic makeup altered to exhibit traits that are not naturally theirs." *Glossary*, MONSANTO.COM, http://www.monsanto.com/newsviews/pages/glossary.aspx

[38] *See* Doug Gurian-Sherman, *Holes in the Biotech Safety Net* (2004), http://www.cspinet.org/new/pdf/fda_report_final.pdf. *See also* Tom Neltner & Maricel Maffini, *Generally Recognized as Secret*, NRDC.ORG (2013), http://www.nrdc.org/food/files/safety-loophole-for-chemicals-in-food-report.pdf.; Michael Hansen, *Reasons for Labeling of Genetically Modified Foods* (2012); William Freese & David Schubert, *Safety Testing and Regulation of Genetically Modified Foods*, CENTERFORFOODSAFETY.ORG (2004)

to support state laws that protect Americans' right to know and that protect them from misleading claims like "natural."

Thank you for the opportunity to testify.

Summary of Testimony of Scott Faber

- Consumers want to the right to know what is in their food and how it is produced.
- More than 90 percent of consumers want the right to know whether their food contains genetically modified food ingredients.
- GMO labeling will also help reduce consumer confusion created by misleading "natural" claims.
- Approximately 60 percent of consumers believe "natural" foods are GMO-free.
- A factual GMO disclosure on the back of food packages will give consumers information about genetically modified food ingredients and address consumer confusion.
- FDA has the authority to require a mandatory GMO disclosure.
- In the absence of FDA leadership, states can require a mandatory GMO disclosure.
- Congress has long recognized a role for the states in food labeling and the NLEA does not preempt state GMO labeling laws.
- State labeling laws meet legitimate state interests, such as addressing consumer confusion.
- GMO labeling will not increase food prices. Food companies routinely change labels to make new claims and consumers will not broadly reject foods with genetically modified ingredients.
- H.R. 4432 does not create a national *mandatory* labeling system. In fact, H.R. 4432 narrows FDA's ability to craft a national *mandatory* GMO labeling solution, preempts state GMO labeling laws, codifies the current *voluntary* labeling system that has failed consumers, and fails to restrict misleading "natural" claims.
- We strongly support a national *mandatory* GMO labeling system and, in the absence of federal leadership, support state laws to require GMO disclosures.

Mr. PITTS. The chair thanks the gentleman.

Now recognize Representative Webb 5 minutes for opening statement.

STATEMENT OF KATE WEBB

Ms. WEBB. Thank you, Mr. Chair, and committee. My name is Kate Webb. I am a Representative and Assistant Majority Leader from the good state of Vermont, and I was the lead sponsor on Act 120, a law that simply gives consumers the right to know if the food they purchase in Vermont is genetically engineered. The law is at risk should H.R. 4322 become law. Because Vermont is involved in litigation regarding this very issue, I want to be clear that I am not a lawyer, not a scientist, and not here as a representative of my state or my government. I am here as a Vermont citizen to tell you of the importance of this right to the citizens of my state, and other states whose citizens seek this simple request for transparency.

Vermont's Act 120, an act relating to the labeling of foods produced with genetic engineering, was signed into law this May to great fanfare and celebration on our State House steps. This Bill grew from grassroot efforts of tens of thousands of Vermonters seeking to have a right to make an informed choice about the food they purchase. This desire was not limited to a handful of Vermonters. Survey upon survey has shown that more than 75 percent of Vermonters were in favor of such labeling.

I personally became involved in this legislation in 2012, and over the next 3 years, we developed draft legislation to gain the fundamental right to know how our food is produced; drafts that traveled through six legislative committees who received testimony from over 100 people, including scientists, lawyers, academics, consumers, manufacturers, and food producers on both sides of the issue. Act 120, in its final form, is the result of many hours, weeks and years of work, and it passed the Senate, I want you to hear this, the Senate on a vote of 28 to 2. It passed the House on a vote of 114 to 30. These are large numbers.

Why is it that Vermont wants this right? It is about transparency and truth in labeling. Even though the World Health Organization defines genetically-modified food as foods derived from organisms whose genetic material has been modified in a way that does not occur naturally. And Monsanto defines genetically-engineered organisms as plants or animals that have had their genetic makeup altered to exhibit traits that are not naturally theirs. However, many genetically-engineered products continue to carry the word natural, or variations of this word, on their labels. I believe this is misleading, and Act 120 would prohibit the use of this term for products produced or partially produced with genetic engineering.

Because GE is a relatively new and evolving science, consumers concerned about unintentional environmental and health effects want the right to exercise this precaution.

And finally, we heard testimony that without labeling, members of many religious communities could not tell if products they purchased violated their faith's dietary prohibitions. There is nothing in our law that restricts anyone from producing or selling geneti-

cally-engineered products. There is nothing in our law that says that it is good or bad. Business and farming will go on as business and farming does.

One of the great strengths of a capitalist democracy is not only do we cast a vote at the polls, we also do by—so by selecting the products we purchase. Transparency allows us to see how things work, be it government, financial institutions or the food we eat. This transparency allows us to make informed decisions, and ultimately build trust.

States have historically, and continue today, to lead the way on food labeling. Forty-one states regulated the use of sell-by and use-by data on—dates on food labels. Before Congress mandated our current federal county of origin—country of origin label, which also doesn't state whether it is good or bad, nor does our Bill, these requirements existed in Alabama, Mississippi and Arkansas, who required labeling disclosure about the source and production of catfish. And many states regulate the labeling of cottage foods. I believe Tennessee and Mississippi do this. And many states are already regulating the labeling of bottled water before the FDA set standards of identity.

While the USDA and AMS issue voluntary grading standards for some agricultural products, many states also issue these grading labels. Vermont's legislature did so with maple syrup this year.

Mr. Chairman, our state is already involved in litigation with the Grocery Manufacturers Association, among others, and if this will help to answer if Vermont and any other state has the constitutional right to label.

I urge you to defeat H.R. 4432 and promote federal labeling. Thank you.

[The prepared statement of Ms. Webb follows:]

Testimony of Representative Kate Webb
Vermont House of Representatives

Before the

Subcommittee on Health

Of the

House Committee on Energy and Commerce

December 10, 2014

Thank you for the opportunity to testify. My name is Kate Webb and I am a representative and Assistant Majority Leader in the Vermont House of Representatives. I was the lead sponsor of Act 120, a law that simply gives consumers the right to know if the food they purchase in VT is genetically engineered. This law is at risk should H.R. 4322 become law. Because Vermont is involved in litigation regarding this very issue, I want to be clear that I am not a lawyer, not a scientist, and not here as a representative of my state or my government. I am here as a Vermont citizen to tell you of the importance of this right to the citizens of my state, and to states whose citizens seek this simple request for transparency in order to make an informed choice about the food they purchase and feed to their families.

Vermont's Act 120, an act relating to the labeling of foods produced with genetic engineering, was signed into law on May 8, 2014 to great fanfare and celebration on our State House steps. This bill grew from the grass roots efforts of tens of thousands of Vermonters seeking to have a right to make an informed choice about the food they purchase.

This desire was not limited to a handful of Vermonters. A 2013 survey by a University of Vermont professor with 30 years experience in research about consumer choice, found that more than 75% of Vermonters were in favor of such labeling.

I personally became involved in this legislation in 2012. Over the next three years, we developed draft legislation to gain this fundamental right to know what is in our food; drafts that traveled through 6 legislative committees who received testimony from over 100 people, including scientists, lawyers, academics, consumers, manufacturers and food producers on both sides of the issue. Act 120 in its final form is the result of the many hours, weeks and years of work. It passed the Senate on a vote of 28-2. It passed the House on a vote of 114-30. Of note: many of those voting against the bill explained on record their belief that Vermonters deserved the right to know what was in their food, but voted against the bill due to the heavy cost the state of VT would bear in the face of the threat of litigation – a threat that was actualized only 5 weeks after the bill was signed into law.

Why is it that Vermonters want this right? It is about transparency and truth in labeling. Even though the World Heath Organization defines genetically modified foods as "foods derived from organisms whose genetic material (DNA) has been modified in a way that does not occur naturally;" and Monsanto defines Genetically Engineered Organisms as "plants or animals that have had their genetic makeup altered to exhibit traits that are not naturally theirs," many genetically engineered products continue to carry the word "natural" or variations of this word on their labels. I believe this is deceptive and Act 120 prohibits the use of this term for products produced or partially produced with genetic engineering.

Because genetic engineering is a relatively new and evolving science, consumers are concerned about unintended environmental and health effects and want the right to exercise precaution. And finally, we heard testimony that without this labeling, members of many religious communities could not tell if products they purchased violated their faith's dietary prohibitions.

There is nothing in our law that restricts farmers, producers, manufacturers, or retailers from producing or selling genetically engineered products. Business and farming will go on as business and farming does, responding to the market.

Most people would greatly prefer a national mandatory GE labeling system and national rules designed to restrict misleading claims of products being "natural." To

date, neither the current Administration nor this Congress has acted to inform and protect consumers with this labeling.

Unfortunately, H.R. 4432, the Safe and Accurate Food Labeling Act of 2014, does not create a national *mandatory* GE labeling system. Instead, H.R. 4432 codifies the broken *voluntary* GE labeling system and robs states like Vermont of the ability to inform and respond to our citizens who need this information.

One of the great strengths of a capitalist democracy is not only do we cast a vote at the polls, we also do so in selecting the products we purchase. Transparency allows us to see how things work, be it government, financial institutions or the foods we eat – what is in them, where they comes from, and how they are produced. This transparency allows us to make informed decisions, and ultimately build trust.
I urge you to oppose H.R 4432 and to support mandatory labeling of products produced through genetic engineering. Thank you for the opportunity to testify.

Mr. PITTS. Chair thanks the gentlelady.

Ms. Forshee, you are recognized 5 minutes for your opening statement.

STATEMENT OF STACEY FORSHEE

Ms. FORSHEE. Chairman Pitts and Ranking Member Pallone, and all the other committee members, it is an honor and privilege to sit in front of you today. My name is Stacey Forshee. My husband, David, and I are fifth generations to farm in Cloud County, Kansas, in north central Kansas. We live in—near the small community of Delphos, and just to put it in perspective, I am 20 miles away from my nearest grocery store.

I am a member of the Cloud County Farm Bureau Association. I serve on the Board of Directors for Kansas Farm Bureau for a 10-county area. I am also a part of the Cloud County Community College Ag Advisory Board, CloudCorp Board of Directors, and I also sit on my Concordia High School Booster Club Board. But my most important job is as wife of my husband, David, for 24 years, who I farm right alongside, as well as my—our children, Kendra, Lauren and Wyatt. But raising our children on our farm hasn't always exactly been easy, but we are very proud of what we have accomplished.

Today, we farm approximately 2,000 acres that we grow corn, soybeans, alfalfa, wheat and other feed crops for our cattle. We operate a feed cow calf operation that has about 700 cows, that my husband is home finishing calving for me right now, but the majority of them will calf in the spring.

We also operate a small feed lot that enables us to feed our own cattle, and actually, much of what we grow, sometimes we are able to feed them. We also custom feed other producers' cattle. We have a custom hay-grinding operation where we grind area cattlemen's hay for them, and we also buy and sell quality alfalfa and we have supplied dairies and feedlots throughout Kansas.

But first, and most importantly, I am a mom and I am a consumer, and a farmer, so I would never want my children to eat anything, or anybody else's children to consume something that was bad for them, that was unsafe. And as a farmer, my family would never want anything to enter the food supply that we raised or that we grew that would be proven to be unsafe. And there has been, very many—all the credible studies have shown that genetically-modified ingredients and products are safe.

On our farm, we use this biotechnology to be able to conserve moisture. We also have found that by using this technology, up to 40 percent we can save on fuel, on fertilizer and on pesticides. We have seen that drop over the last 24 years. We also are stewards of the land. The environment is very important to us, so the less we use of all of these things are very important, and we owe that to biotechnology.

Labeling a safe product, to me as a consumer, just does not make any sense. So I just feel that this, making a mandatory label is going to mislead consumers into thinking that it is unsafe, which we have heard today that that is wrong.

With the future projections of our growing world, farmers and ranchers around the world are going to have to double their food

production to meet those growing demands, and on my farm, biotechnology is a way that we feel like we can make this happen.

On our farm, we also have the ability to store more than 20,000 bushels of grain. So when we harvest our crops, we store that grain in different bins. Due to crop insurance regulations, there are certain things that we need to abide by, but we can store all one kind of grain in one bin. And the same is true for my local elevators and all our rural communities. For us, we do this so that we can market that crop later, or feed it to our livestock, but it would cost billions of dollars in infrastructure and new technology to be able to just absolutely trace a biological trait from my farm to the consumer's table.

As a mother and a farmer, I urge Congress to pass this H.R. 4432, the Safe and Accurate Food Labeling Act. For me to be able to continue to farm like I do, and to meet the growing future's needs, I really urge you to do this.

And I really thank you for your time.

[The prepared statement of Ms. Forshee follows:]

Stacey Forshee

Owner/Operator of Forshee Farms LLC in Kansas

House Committee on Energy and Commerce; Subcommittee on Health

Hearing entitled "Examining FDA's Role in Regulation of Genetically Modified Food Ingredients"

December 10, 2014

Chairman Pitts, Ranking Member Pallone, and members of the committee. It is an honor and privilege to sit before you today. My name is Stacey Forshee. I live in North Central Kansas near the small town of Delphos that has a population of 350 people. We are 20 miles from the nearest grocery store and my children's school. I am a member of the Cloud County Farm Bureau and serve on the Kansas Farm Bureau Board of Directors. I also serve on the Cloud County Community College Agricultural Advisory Board, the CloudCorp Board of Directors, and the Concordia High School Booster Club Board. But, most important to David, my husband of 24 years, and me are our three children, Kendra, Lauren and Wyatt. Raising our family on the farm has not always been easy, but we are proud of the hard work each one of us has put in. Today, we have approximately two thousand acres of farm ground that produces alfalfa, corn, grain sorghum, soybeans, wheat and other feed silage crops. Our cow-calf herd consists of seven hundred cows that are divided into two calving seasons – spring and fall. Additionally, we operate a small feedlot that allows us to background our own calves and sell them in January of each year. And, if that is not enough to keep us busy, we do custom back-grounding in our cattle pens, and custom grind hay for cattlemen in the area and operate a custom alfalfa business, where we buy and sell high-quality alfalfa from area producers and then deliver ground or baled hay to feedlots and dairies across Kansas. These additional business opportunities allow us to hire one full-time employee as well as keep our 17 year old son as an active employee.

First, and most importantly, as a mother I would never allow my children, or any other children, to consume a product I knew was unsafe. Second, as a hard working American family who lives off the land and the products it provides we would never want a product we grew or raised to enter the food supply if the product were unsafe. Watching the recent battles in Oregon, Vermont and Colorado has been eye-opening and frightening.

As I understand it, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) mandate labels be put on products for important safety, health and nutrition information. Since its establishment in 1907, the FDA has served as America's (and I would argue the world's) ultimate and most trusted food safety authority. FDA's science-based approach requires labels only if there are material differences in food, such as changes to nutritional content or inclusion of known allergens. For more than twenty years, every credible scientific study - and United States and international food safety authorities - have proven genetically modified products and ingredients are safe. To require food manufacturers and grocery stores to label a safe product based solely on the technology it took to grow or produce that product would only lead to consumer confusion, increase costs on budget-conscious families and do absolutely nothing to further food safety or prevent illness. Additionally, mandatory labeling of food products that contain biotechnology traits will mislead consumers into believing such food products are materially different, create undue risk and should be avoided – all of which are scientifically false. The FDA must be the voice of consumer safety on this important issue.

In 2010, the FDA reiterated its longstanding position on biotechnology food labels by saying: "FDA has no basis for concluding that bioengineered foods differ from other foods in any meaningful or

uniform way, or that, as a class, foods developed by the new techniques present any or greater safety concern than foods developed by traditional plant breeding."

The fact of the matter is with more than seven billion people living on the planet today, and every projection showing more than nine billion living on the planet by 2050, farmers and ranchers all across the world must double our food production to provide the food, fuel and fiber to sustain a growing world population. On my farm, biotechnology is a way to make this happen. Technology has allowed us to realize higher yields on fewer tillable acres; improved our use of limited natural resources such as water and essential nutrients; reduced usage of fertilizers and pesticides; and improved our conservation of soil and ecosystems.

On my family farm, using the latest biotechnology allows us to no-till farm, which conserves moisture and increases yields by curtailing pests and weeds. Globally, the facts back this up:

- Since 1996, biotech traits have added more than 110 million tons of soybeans and 195 million tons of corn to a hungry and malnourished world's food supply.
- Currently, more than 17 million farmers in 28 counties grow biotech crops on more than 420 million acres.
- In the United States, more than 93 percent of soybeans, 90 percent of cotton and 90 percent of corn are biotech varieties.
- Famers who use biotech seeds have seen their farm income increase by 49 percent due to yield increases and reduced production costs.
- Crop biotechnology has reduced pesticide spraying by 1.2 billion pounds since 1996 and the environmental impact associated with herbicide and insecticide use on areas planted with biotech crops has decreased by 18 percent.

The decisions this committee makes send signals across the country. We have seen a number of states try to legislate biotechnology labeling regulations in a piecemeal and patchwork fashion. Like it or not, we live in a global economy and interstate commerce is very much a part of that. America's food safety laws should not be determined by political campaigns. As the saying goes, "all politics is local" and I am a strong believer in that. But as an active member of my community, where I know my county commissioner, my state legislators and my secretary of agriculture – all on a first name basis I might add – food labeling requirements at the state and local level are not something I am willing to take a chance on. Going this route would be costly, misleading and offer limited science-based rationale to a politically charged situation.

For a real life example, on our family farm we have the ability to store 20,000 bushels of grain. When we harvest our crops, we often use this on-farm storage to be able to market the crop throughout the year or feed it to our livestock as conditions warrant. The same is true for my local grain elevator and small rural communities all across the nation. Elevators and storage facilities take all types of commodities, every month of the year, from just about every farmer in the region. These commodities are placed in bins and comingled in a safe manner that protects the grain from the elements and allows farmer-owned cooperatives to market the grain for the highest value to an end user. It would cost billions of dollars in new technology and infrastructure to maintain absolute traceability of a certain biotechnology trait from farm to fork. This cost would be passed along to the consumer at every step of the food chain.

This committee and this legislative body must determine a federal solution so farmers and ranchers, the food manufacturing companies, the grocery stores and ultimately the consumer understand the

scientifically-proven difference between true food safety concerns such as food-borne pathogens and a fear mongering, marketing ploy such as a biotechnology label.

As a mother and farmer, I urge Congress to find a national solution that ensures farmers and ranchers will continue to have the tools and technologies needed to solve the challenges of the future. Without action from Congress, my livelihood as a farmer and cattle rancher risks being undermined by non-scientific, unsubstantiated accusations. I strongly urge the House to pass H.R. 4432, the Safe and Accurate Food Labeling Act.

Mr. PITTS. Chair thanks the gentlelady, and now recognizes Mr. Dempsey 5 minutes for your opening statement.

STATEMENT OF TOM DEMPSEY

Mr. DEMPSEY. Thank you. First, I would like to thank the subcommittee, Chairman Pitts and Ranking Member Pallone, for holding this hearing to provide a balanced review of one of the most critical issues facing the food industry today, the labeling of genetically-modified organisms, or GMOs.

My name is Tom Dempsey. I have served as the President and Chief Executive Officer of the Snack Food Association, the SFA, since 2013. Prior to joining SFA, I was the President of one of the largest privately owned snack food brands in the United States.

Today at SFA, I represent over 400 companies who produce snacks ranging from potato chips to granola bars. My members include both billion dollar, multi-category companies, and small, family-owned businesses in the second and third generation of management. More than half of SFA members have sales of less than $100 million a year, and many are the primary employers in their community.

While voters have rejected ballot initiatives calling for mandatory GMO labeling in 4 states, the state of Vermont recently approved the Nation's first mandatory labeling law. Mandatory GMO labeling at the state level would impact nearly every aspect of my members' business, upping costs by requiring increased product inventory, added complexity for packaging and distribution processes, and extensive new regulatory and training requirements.

Absent a federal solution, manufacturers will have essentially three options to comply with a state GMO: redesign their packaging, reformulate products so that no labeling is required, or halt sales to that state. Each option is difficult, costly, time-intensive, and at worst, could eliminate jobs and consumer choice in the marketplace. Smaller companies may not have these options at all. A patchwork of GMO labeling laws would pose significant burdens on the manufacturing process itself. They would require separate storage for GMO and non-GMO products throughout the entire supply chain, beginning with the farmer, and extending through various states of production and distribution. Aside from new administrative and recordkeeping burdens, snack makers will be forced to clean and boil the sheeting, baking, frying, and seasoning lines between GMO and non-GMO production to ensure there is no contamination. This could take up to 2 hours, and would lead into a loss in valuable production time. Duplicative food labeling for the same stock keeping unit, or SKU, assigned to each product line is also a problem. Film, which is our industry's term for snack packaging, would need to be changed mid-production, and 2 separate inventories of the same finished product must be kept. Significant lead times and costs would go into bag changes. The cost in plate charges, new film, administrative oversight could be more than $750,000 for 800 SKUs, and the process could take 20 to 26 weeks.

GMO and non-GMO products must continue to be segregated from the factory to the grocery store, resulting in increased distribution costs and heightened opportunity for mistakes.

To be clear, the hardest hit by this will be the one plant operators with a single line of production. These costs could put family-owned businesses out of business, thereby increasing consolidation in the industry. While it is sometimes assumed that companies could remove the GMO ingredients from their products, this is unrealistic because the availability of non-GMO crops is limited. Over 80 percent, although I heard today 90 percent, of the corn, cotton, and soybean crops in the United States are produced with biotechnology, all products which are staple items in the snack production. Our members will not have the opportunity to increase their contract with farmers or mills for non-GMO corn for a minimum of 2 years. Transitioning to GMO-free production will not happen overnight.

Some manufacturers may choose to end distribution in states that require GMO labeling, resulting in fewer product options for consumers, and causing a ripple effect in the grocery industry. Even if manufacturers notify grocers of their intent to stop selling in a state, manufacturers could run the risk of being fined if retailers do not comply or if mistakes happen in the distribution process. Fewer players in the aisle could mean less incentive to keep quality high and prices low. Fewer products could disproportionately cause job losses for some in the distribution chain. Ultimately, a patchwork of state GMO laws will hit consumers the hardest, and would result in either increased costs at the grocery store, or less availability of products in their stores.

In addition, it is important to note that consumers already have options to purchase non-GMO foods, and these options continue to expand. For over a decade, both the USDA's natural organic program and the independent non-GMO project have certified foods that are organic and GMO-free respectively. The process to gain these certification seals is not only rigorous but expensive. Many SFA members have already made the significant investment to display these voluntary labels. Forcing companies to re-label more than 80 percent of the products does nothing but add cost, confusion and may limit choices to consumers.

SFA does not have a single member company that manufactures, distributes, and sells in just one state, which makes state labeling law incredibly complex. Multiply these challenges by 5, 10, or even 25 states, and an insurmountable burden is placed on the supply chain. SFA supports the Safe and Accurate Food Labeling Act, which eliminates the proposed patchwork of state laws by creating one federal GMO standard, and provides much-needed consistency for manufacturers and consumers alike.

Thank you for your time.

[The prepared statement of Mr. Dempsey follows:]

Thomas W. Dempsey Jr., President and Chief Executive Officer

Snack Food Association

U.S. House of Representatives Energy and Commerce Subcommittee on Health

"Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients"

2123 Rayburn House Office Building

December 10, 2014

Introduction

First, I would like to thank the Energy and Commerce Subcommittee on Health, Chairman Pitts, and Ranking Member Pallone for holding this hearing to provide a balanced review of one of the most critical issues facing the food industry today, the labeling of genetically modified organisms, better known as GMOs. I appreciate the opportunity to be here.

My name is Tom Dempsey. I have served as the President and Chief Executive Officer of the Snack Food Association (SFA) since 2013. Prior to joining SFA, I was the President of one of the largest privately owned snack brands in the United States (U.S.) where I spent 24 years in total, 5 of which I served as the President overseeing all areas of sales, marketing, finance, human resources, manufacturing, distribution, research and development, and purchasing. Today at SFA, I represent more than 400 companies who produce a wide variety of snacks ranging from potato, tortilla, and pita chips to pork rinds and meat snacks, to crackers, popcorn, granola bars, and trail mix, as well as dried fruit and nut mixtures. SFA members range from billion-dollar multi-category companies to small family owned and operated businesses, some of which are in the second and third generation of management. More than half of SFA members do less than $100M/year in sales and many are the primary employer in their community.

GMO Labeling Debate

Over the last several years there have been a number of state ballot initiatives calling for mandatory GMO labeling. While voters have rejected ballot initiatives calling for mandatory GMO labeling in four states: California, Washington, Colorado, and Oregon (pending final recount), the Vermont state legislature approved the nation's first mandatory GMO labeling law, Act 120, in April 2014. Mandatory GMO labeling at the state level would impact nearly every aspect of SFA members' business, upping costs by requiring increased product inventory, added complexity for packaging and distribution processes, and extensive new regulatory and training requirements.

Absent a federal GMO solution, manufacturers will have essentially three options in order to comply with a state labeling law such as Vermont's Act 120: order new packaging for products, reformulate products so that no labeling is required, or halt sales to that state. Each option is difficult, costly, time-intensive, and at worst, could eliminate jobs and consumer choice in the marketplace which I will further discuss. I will also outline why some food manufacturers, most likely small and midsize family businesses, do not have all of these options available and could be impacted the most.

Production Processes

One of the biggest barriers that prevents a company from complying with state by state GMO labeling laws is the manufacturing process itself.

First, it would require separate storage for GMO and non-GMO products throughout the entire supply chain. Farmers will need to separate their crops in planting and when transporting to grain elevators or manufacturers. Once a grain elevator or manufacturer receives the raw materials from farmers they too will need to store and produce GMO and non-GMO materials separately. Aside from new administrative and recordkeeping burdens, manufactures will need to add separate storage areas to their facilities in order to segregate these products. Tortilla processing provides an excellent example. The story begins with the corn. There are two ways to begin the process: one, by cooking the corn into a mash and the other by purchasing corn masa (flour), adding water to it, and then sheeting it for cutting into the triangle shapes we all know as tortilla chips. A mandatory labeling scheme would require two different silos to hold GMO and non-GMO bulk corn and masa (flour).

Given the expense of manufacturing machinery, snack makers would be forced to use the same equipment and conduct thorough cleaning of the sheeting, baking, frying, and seasoning lines between GMO and non-GMO production runs to ensure no contamination occurs. Such a process could take nearly two hours and would lead to a loss in valuable production time. It is not likely a manufacturer would have the financial means or the floor space to invest in separate equipment for GMO and non-GMO production.

Another complicating factor is the need for duplicative labeling film for the same stock keeping unit or SKU assigned to each product line. In order to comply with a state labeling law, our members will need to change film in mid-production and then keep two separate inventories of the same finished product: one with GMO identification specifically for sale in a state that enacts mandatory GMO labeling, and the other for the rest of the distribution area. Companies would not be able to use a single state-required label for all of its products if a patchwork of varying state rules were enacted.

Significant lead times and costs also go into a bag design change. One SFA member estimated they would need to change over 800 SKUs to continue to sell in Vermont alone. The cost in plate charges, new film, and administrative oversight in this instance could be more than $750,000. The actual cost of the run after converting the film would be approximately 25 percent higher due to the shorter production runs of non-GMO product that would be required to fulfill orders in Vermont, for example. The actual process of designing, compliance review, plate making, and lead-time for film would be 20-26 weeks. This would become even more complicated if additional states pass their own onerous regulations with different specific requirements.

After production, the distribution of most snack foods comes off, in most cases, a route truck with direct service to the grocery store. A state law such as Vermont's Act 120 will mandate a dual inventory for each SKU for every step along the distribution channel. The end result will be increased distribution costs and heightened opportunity for mistakes.

To be clear, the hardest hit by this will be the small, family-owned companies with just one plant or just a single line of production. Quite frankly, these costs could put some companies out of business and thereby increase consolidation in the industry by reducing the players to a few multi-category, multi-national players that can better take on the added cost of sourcing and segregating GMO and non-GMO crops. All of these changes will add final product costs to the consumer. The precise amount of added cost depends on each company's cost structure.

Sourcing Challenges

In order to avoid the need for duplicate labels in a state like Vermont, it is sometimes assumed that companies could simply remove the GMO ingredients from their products altogether. This is unrealistic because the availability of non-GMO crops is very limited. My understanding is that over 80 percent of the corn, cotton, and soybean crops in the U.S. are harvested from genetically engineered plants.[1] Snack food companies purchase a large majority of their ingredients derived from these plants.

For instance, the process for producing potato chips begins with developing a large network of growers for potatoes, contracting quantities in advance of plantings and harvests, and purchasing cooking oils such as cottonseed or soybean in advance to secure quantities and pricing. The same goes for other crops. One tortilla chip manufacturer told me that they would not have the opportunity to increase their contracts for non-GMO corn for a minimum of two years.

[1] United States Department of Agriculture Economic Research Service. "Recent Trends in GE Adoption". July 14, 2014. Retrieved from: http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx

Transitioning to GMO-free production could not happen overnight, or even by 2016, as is specified in Vermont's Act 120, for example.

Impact on Consumers and the Economy

On the other hand, manufacturers could also choose to end the distribution of their lines specifically in states that require mandatory GMO labeling. However, ceasing distribution isn't simple. Aside from limiting product options to consumers, there would be a ripple effect in the grocery industry. Retailers would need to be notified of the decision to stop selling in a state and manufacturers could run the risk of being fined if retailers do not comply.

Fewer players in the aisle could mean less incentive to keep quality high and prices low. Decreased promotion and distribution means fewer route sales people needed to deliver the product and job losses for some in the distribution chain, such as drivers, warehouse personnel, account executives, and field management. Fewer jobs could also lead to a decrease in tax revenue in a particular state.

Ultimately, a patchwork of state and local GMO labeling laws will hit consumers the hardest resulting in either increased costs at the grocery store or less availability of products on store shelves.

A recent study performed by economists at Cornell University concluded that mandatory GMO labeling laws would increase the cost of food by about $500 per family per year on average with some families bearing an increased cost of up to $1,500 per year[2]. These amounts don't include the regulatory costs the government will incur to actually implement the law that would likely be passed onto consumers in the form of taxes.

GMO-Free Options Already Exist

While we firmly believe the science shows that our GMO products are safe, SFA members support providing consumers with options in the marketplace. It is important to note that consumers can already choose to purchase non-GMO items and these options continue to expand. For over a decade both the United States Department of Agriculture's (USDA) National Organic Program and a non-profit organization, the Non-GMO Project have certified foods which are organic and non-GMO, respectively. A company cannot display a USDA Organic Seal or a Non-GMO Project Verified Seal without going through an intensive certification process. The Non-GMO Project alone has certified over 20,000 non-GMO products and this number continues to grow.

[2] Dyson School of Applied Economics and Management, Cornell University. "Costs of Labeling Genetically Modified Food Products in N.Y. State". May 2014. Retrieved from:http://dyson.cornell.edu/people/profiles/docs/LabelingNY.pdf

Many SFA members have already made the large investment required to gain these voluntary certifications that give our customers the freedom to choose between products that are produced, distributed, and marketed as Organic and non-GMO and labeled as such. Forcing companies to re-label more than 80 percent of their current products does nothing but add cost, confusion, and, ultimately, may limit the choices available to consumers.

Conclusion

SFA is concerned both about the burden state-level GMO labeling would put on interstate commerce, as well as the increased costs that could drive food companies out of business or increase food prices for consumers while potentially limiting their options in the marketplace.

SFA does not have a single member company that manufactures, distributes, and sells in just one state making a state labeling law incredibly complex to deal with. Multiply the challenges I've presented here for compliance in Vermont's Act 120 times 5, or 10, or even 25 states and you place an insurmountable burden on our food supply chain and add significant increased cost to our consumers.

For this reason, SFA supports the Safe and Accurate Food Labeling Act (H.R. 4432), a bill which eliminates the current proposed patchwork of state and local GMO labeling laws by creating one federal GMO standard which eliminates confusion, advances food safety, and provides much-needed consistency for manufacturers.

Again, thank you for your time and consideration of our views. I look forward to answering your questions.

Mr. PITTS. Chair thanks all of our witnesses for your testimony. I will begin the questioning. Recognize myself 5 minutes for that purpose.

Dr. Van Eenennaam, is there currently a lack of consensus about the validity of research and science behind the safety of foods and ingredients derived from genetically-engineered crops?

Ms. VAN EENENNAAM. Well, as I stated in my testimony, there is clear consensus among all of the leading scientific organizations throughout the world, and the meta-analysis of over 1,700 studies, about ⅓ of which are done by the public sector that do not have any industry funding, somewhere in that vicinity, have all come to the same conclusion that there are no unique risks posed by the use of this particular breeding method in the production of genetically-engineered crops.

Consensus doesn't mean unanimity, so there are scientists that you will hear that say that that is not true, but to your question earlier, it is as strong of a consensus, it is probably stronger than on global warming, it is 99 to 1, or something in that vicinity. And I think if you get consensus of all of the major scientific societies in the world, then that is a pretty strong consensus.

Mr. PITTS. The first generation of biotechnology products has brought tremendous benefits to farmers, as we have heard. What do you see as the potential for a consumer facing benefits of the next generation of biotechnology products?

Ms. VAN EENENNAAM. So certainly, and I might argue the consumer has had some benefit from the first generation also because of the decreased insecticide use associated with Bt crops, for example, has knock on benefits for the environment and the consumer, and also costs. But there are direct benefit traits being developed for consumers. For example, altered nutritional profiles of crops for improved human health, and particularly in developing nations, there are efforts to bio-fortify crops to improve the nutritional profile of staple crops of the world's poor to improve their nutrition. And so there is a huge interest amongst public sector scientists and also public-private partnerships to try to use this technology to improve foodstuffs and improve the nutritional composition of crops for both developed and developing countries.

Mr. PITTS. As a scientist, could you put in laymen's terms, you said this requires use of less pesticides. How does that occur, how do they make that occur?

Ms. VAN EENENNAAM. Well, for example, the insect-protected crops have a protein in them that basically targets Lepidoptera caterpillars so that when they eat the crop, they perish, but it is safe for humans. And so it basically enables farmers not to have to put insecticide on that crop. And so, for example, especially in the developing world, there has been a dramatic production in insecticides, over ½—they have doubled—decreased their insecticide use by over ½, and they have doubled their yields as a result of protecting the crops from the insects, and not having to use more dangerous insecticides to protect those crops. And so it is kind of breeding the crop to be protected from insects and, therefore, you can decrease your insecticide use.

And even in the U.S., it has decreased the use of insecticides on Bt corn over tenfold since the adoption of this technology.

Mr. PITTS. Thank you.

Mr. Faber, how would you describe or define natural?

Mr. FABER. Yes, that is a great question, Mr. Chairman. I think commonsense definition of natural for an ordinary consumer would not include genetically-modified ingredients. In fact, one of the major providers of the technology, Monsanto, itself does not define biotech traits to be something that should be described by natural. And I think you are getting it right at the heart of the matter, which is that consumers go to the store, they see an all-natural or natural disclosure, and roughly 60 percent, depending on its study, 58 percent, 64 percent in others, believe that that food is GMO-free.

What is important here is that we want consumers to be using their buying power to shape their lives and the world around them. If they are confused about what they are buying, they are not able to use their buying power to really make good, informed choices.

Mr. PITTS. Thank you.

Representative Webb, when would your law become effective? Is it effective now?

Ms. WEBB. We are involved in rulemaking now. Rules should be out July 2015 and in effect July 2016.

Mr. PITTS. All right. Ms. Forshee or Mr. Dempsey, how would this labeling requirement affect your snack food companies if they did not wish to comply?

Mr. DEMPSEY. Well, as I said, there are three options. They can reformulate, they could label, or they could cease sales within Vermont. And I think each individual company is going to have to make that decision based upon the number of businesses and SKUs that have to be relabeled.

Mr. PITTS. And finally, Ms. Forshee, has biotechnology impacted the way you farm, say, in the past decade?

Ms. FORSHEE. Well, I would say that we are able—with that kind of technology, we are able to use a practice of no-till which allows us to conserve moisture and not spray the crops nearly as much as—I mean there is a whole notion of—that farmers just dump pesticides and herbicides on their crops, but we don't. It is very costly to do that kind of an application, spray any kind of an application, and so we are very—what I want to say, we use GPS to do that so that there is just the right amount put on the crop and no more. And so the less we can do that, the more it is going to help our bottom dollar too for yield. So we have seen higher yields as well on our farm in the last 24 years——

Mr. PITTS. And with——

Ms. FORSHEE [continuing]. As a result of that.

Mr. PITTS. With no-till, less run-off—water run-off?

Ms. FORSHEE. That is correct. And also though the biotechnology traits in our crops, it all comes together as one.

Mr. PITTS. Thank you. My time has expired.

The chair recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. Faber and Representative Webb, you both believe that industry should be required to label all foods that contain GE ingredients, and you both also characterize such labeling requirements as

a modest disclosure or a simple request. And, Mr. Faber, you also state that food companies frequently change their labels to make new claims or to highlight new innovations. And I think an accurate summary of your position on this is that it simply is not a big deal for companies who use GE ingredients to label their products as such. Now, Mr. Dempsey, on the other hand, makes the argument that mandatory labeling for GE foods would dramatically increase the cost of the food because it would require manufacturers to segregate the food or use multiple labeling films, a number of things.

I guess in my view, on the one hand, if it is truly not that burdensome for industry to label their food, then why shouldn't they be required to do so. On the other hand, if the labeling requirement could result in higher food costs, maybe that is not a risk that we want to take.

So let me just ask you these questions in light of that. First, Mr. Faber or Representative Webb, can you elaborate on why you believe a mandatory labeling requirement is simple for industry, and how do you respond to the assertion by Mr. Dempsey and others in industry that complying with that requirement would be an elaborate and expensive prospect? Briefly if you can——

Mr. FABER. Right.

Mr. PALLONE [continuing]. Because I want to ask him a question too.

Mr. FABER. Absolutely. So very briefly, so we have heard reference from Mr. Pompeo and Mr. Butterfield to this $500 cost associated with food labeling. That study assumes two things, and one thing in particular is that disclosure would ultimately equal disparagement, that consumers would see a disclosure, they would stop eating food made with genetically-modified food ingredients, and that would cause costly supply change disruptions or force consumers to buy organic. What we know about how consumers use labels is they tend to look for certain attributes. You may look for fiber, I may look for calories. We tend not to read the whole package. We use that information to make particular decisions about our food choices. So the notion that American consumers are going to broadly reject foods with a modest, nonjudgmental disclosure I think is unfounded. We know that in part because we have labeling in 64 other countries, including countries like Brazil, where there has been a disclosure for—since 2001, and consumers more or less eat the way they have for the last 13 years. So I think we can all be confident that if we craft the disclosure in the right way, to your earlier point, Mr. Pallone, that we can give consumers information without rendering a judgment that ultimately leads to significant changes in buying behavior.

The other thing I will just quickly say again is that companies are already finding ways to make both non-GMO and GMO foods. We have segregation throughout the supply chain. We preserve identity of these grains throughout the supply chain, in part because the marketing needs, but also because of quality and allergen needs. So there is already an infrastructure in place that allows us to segregate non-GMO and GMO, and other kinds of grains and oils.

Mr. PALLONE. All right. I am going to go to Mr. Dempsey now because I want you to respond to those claims and specifically respond to the assertion that food companies are changing their labels so they can easily do this. What do you—how do you respond to what——

Mr. DEMPSEY. Well——

Mr. PALLONE [continuing]. Mr. Faber was saying?

Mr. DEMPSEY [continuing]. Certainly, food companies change their labels but not on a wholesale banner, and do all of them all at the same time. So you run into a big situation of X number of SKUs that have to be done all at the same time to comply with a law that goes into effect in 2016. Small businesses would be hit very hard because of that. They have historically been ones who change their labels very seldomly. And in central Pennsylvania, I can probably think of five or six companies that are using the same graphics, same bags that they have had for many years; the only changes, those being mandated by the FDA. So I think the real burden comes on the small family-owned, small operators who have SKUs that are genetically modified and have to label them, and rather than using what the market has now, and that is the option of a non-GMO or GMO-free certification, to notify and give consumers transparency, which gives the manufacturer the option of doing it.

Mr. FABER. Can I add just one quick thing?

Mr. PALLONE. Well, maybe I will ask Representative Webb, we have 40 seconds——

Ms. WEBB. Yes.

Mr. PALLONE [continuing]. If you want to say something.

Ms. WEBB. I would say that we are in rulemaking process now. We have manufacturers that are weighing in on how that label will be written. We are hoping that our labeling will be something that other states can use. The standards between Maine, Connecticut and Vermont, the legislation is similar. We are also a small state. We have 630,000 people in our entire state. People already drive to New Hampshire to avoid the sales tax, so if the industry chooses not to sell in Vermont, I am sure that we can get our Doritos over the state lines.

Mr. PALLONE. All right.

Mr. FABER. And I would like just to add, that not only do companies change their packaging all the time, the average lifespan of a label is about a year, we ask companies to change their disclosures. We ask them to change them for trans fat, we ask them to change them for allergen labeling, and we are about to ask them to change their labels as part of a refresh of the nutrition facts panel. So there are periods in the history of labeling where we ask companies to disclose a little bit more about what is in the food. This is the perfect time, since we are in the midst of an NFP rulemaking, to think about how can we make this disclosure in a way that is nonjudgmental.

Mr. PALLONE. Thank you.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Well, and I would have to say that from listening to the testimony today, that I am convinced we have to have a national policy. And we can argue, Representative Webb, about what that policy ought to be, and, Mr. Faber, we can argue about what that policy ought to be but I think it needs to be national. It may be relatively easy for Vermonters to cross the stateliness to get their Doritos, but I would have to submit that in parts of my district, and I represent the southwestern portion of Virginia, the Allegheny Highlands of Virginia, and Southside Virginia. It is a large district, it may be larger than Vermont, certainly has more people in it, but there are parts of that where, if you wanted to go and get some other product, you would have to drive several hours. There are other parts where you just walk across the street, and so if you had a grocer on one side of the street, and you looked at the labeling in that state and on Tennessee on State Street, and you said, I don't know about this genetic engineering, and you walk across the street, it might be the very same product but it might not have that label on in Virginia. So I am convinced we have to have a national label.

And just a few miles up the road from State Street, where you literally are on the main street of the town, and you are one state on one side and in another state on the other side of the street, is probably one of your members, Mr. Dempsey, Shearer Foods has a potato chip facility there and they obviously ship to a number of states from that Bristol, Virginia, plant.

Mr. DEMPSEY. That is correct.

Mr. GRIFFITH. And so that concerns me that they would have to have different labels for all the states that they operate in, but I am particular concerned about if we don't have a national policy, concerned that the consumer gets confused into what is it I am buying. Well, if I buy it in Virginia, it is a different product than what I am buying in Tennessee. I don't know whether you have any towns like that in Vermont that straddle the state line, but I have a number of them. Bristol, Virginia/Tennessee, Bluefield, Virginia/West Virginia, the Martinsville area has towns if you didn't know where you were, you would be out of Henry County and into North Carolina in a heartbeat traveling down 220. And so I think we have to be very, very concerned about that, and I do think it is important.

And then the other thing is your rulemaking process, I know your Attorney General is in charge of that, but what experience does Vermont have, Representative Webb, in food labeling? I mean is this something that they have done before in some kind of a large way, and what are they doing in that process to try to label these foods?

Ms. WEBB. Well, as I previously stated, we did make some changes to our maple syrup labeling.

Mr. PITTS. Can you poke your——

Ms. WEBB. I am not on?

Mr. PITTS. Yes.

Mr. GRIFFITH. Yes. You did say that about maple syrup, and what was the difference? I just assumed it was a parochial difference.

Ms. WEBB. Our labeling had been grade A, grade B. We chose to go with the standards that they are using in Quebec because they are a larger producer than our brave little state.

Mr. GRIFFITH. And grade A, grade B, what do they use in Quebec?

Ms. WEBB. Goodness. I am not——

Mr. GRIFFITH. Because I have to tell you the truth——

Ms. WEBB. Yes.

Mr. GRIFFITH [continuing]. My wife disagrees with me——

Ms. WEBB. Total difference.

Mr. GRIFFITH [continuing]. I can't tell the difference between A and B——

Ms. WEBB. Yes.

Mr. GRIFFITH [continuing]. So I always buy B because it is cheaper.

Ms. WEBB. Yes. I like B too.

Mr. GRIFFITH. Yes. But what is the Quebec standard so I will know what I am looking at when I go to——

Ms. WEBB. I——

Mr. GRIFFITH [continuing]. The store?

Ms. WEBB. I would have to look it up.

Mr. GRIFFITH. You would have to look it up. All right, I appreciate that. That was——

Ms. WEBB. We just recently——

Mr. GRIFFITH. That was not fair to ask you today anyway——

Ms. WEBB. Yes.

Mr. GRIFFITH [continuing]. I apologize. I do think it is complicated, and I would ask folks who are here today, or who are watching at home, if you have suggestions on how you might make some reasonable changes to Mr. Pompeo's Bill, he may or may not accept them, but I would ask that you submit those to the committee so that we can take a look at those changes because I am convinced we have to have a national standard. And I would like to know, if I am buying something that is labeled natural, and I do that on a fairly regular basis, I would like to know that there is something standard about it, and so I would like to see us move in that direction as well.

Mr. FABER. And, Mr. Griffith, we would be thrilled to work with you and with our colleagues in the food industry, and to craft a national disclosure that is mandatory, that works for the consumer, but that also works for food manufacturers who have to operate in 50 states, I think if people of goodwill could find a way to develop a disclosure that is truly nonjudgmental, and I would welcome the opportunity to do that.

Mr. GRIFFITH. Well, and I appreciate that. I will tell you that in thinking about this over the years, as you may have heard earlier, I do read labels fairly carefully——

Mr. FABER. Yes, I know.

Mr. GRIFFITH [continuing]. And I am convinced now that genetically-modified or genetically-engineered foods are so prevalent that we probably need to go the other way, and for those of us that may want to purchase something, that the labeling requirement ought to be on those who can certify that their food, in fact, does not have this product in it, as opposed to the reverse.

Mr. FABER. That is right. And you and I may agree or disagree about whether or not there are more herbicides or fewer herbicides, or—I think the bottom line here is that consumers want to be able to make those choices themselves. And it ultimately boils down not just to an issue of transparency, but an issue of trust. If we give parents, consumers the basic information, we should trust them to do their homework and make those choices for themselves.

Mr. GRIFFITH. I appreciate that.

And with that, Mr. Chairman, I see my time is up and yield back.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the gentlelady from California, Mrs. Capps, 5 minutes for questions.

Mrs. CAPPS. Thank you very much, Mr. Chairman. And to our witnesses, thank you for being at this hearing and your testimony.

I think we are finding ourselves in general agreement that a good federal standard for GE labeling is preferable to a confusing patchwork of state labeling rules, which it appears that we have today, but there still is disagreement about what exactly that standard should be. I want to be clear, I don't believe this is even a debate about whether or not GE foods are safe, it is a debate about whether or not consumers have the right to know what is in their food, and I think I am just echoing what some of you just have said. I firmly believe that consumers do have the right to make informed decisions about the food they eat, and I believe we pretty much all agree on this point.

Just to get it on the record, however, what about now a simple yes or no question so we can get this on the record. And I will start with Dr. Van Eenennaam, and right down the line, yes or no, do you think consumers should have the right to know what is in their food?

Ms. VAN EENENNAAM. I can't give you a yes-or-no answer to that.

Mrs. CAPPS. You can't say yes or no?

Ms. VAN EENENNAAM. No, because I don't think the labeling is about what is in the food, it is about the process used to make the food, and that is a really subtle difference.

Mrs. CAPPS. I hear you.

Ms. VAN EENENNAAM. So sugar from genetically-engineered sugar beet is the same as sugar from non-genetically-engineered sugar cane sugar.

Mrs. CAPPS. All right, I wanted to go faster than that, but we will give you——

Ms. VAN EENENNAAM. Well, I mean because I think we are not discussing about a label of what is in the food——

Mrs. CAPPS. But——

Ms. VAN EENENNAAM [continuing]. We are talking about a label of how it was produced.

Mrs. CAPPS. Well, I think that could be under the umbrella, but that, yes, we do need to do this and we also need to talk about how to do it and what should be in it. But I will just go right along.

Mr. FABER. Yes, of course consumers should have the right to know what is in their food.

Mrs. CAPPS. Yes.

Ms. WEBB. Absolutely.

Ms. FORSHEE. Yes.

Mr. DEMPSEY. It depends on how easy it is to give them the right to know. I think that is a too simple—a yes/no is too simple of a response.

Mrs. CAPPS. All right, I got an answer. Unfortunately, consumers currently do not have access to all the information they are looking for when it comes to GE foods, and consumers are often further confused, confused enough by not knowing what is in it, and then confused by what the information that they find on the packaging.

So I will now zero in on you, Mr. Faber. Why do you think there is currently so much consumer confusion when it comes to GE labels?

Mr. FABER. Well, consumers have been deluged with misleading claims for many, many years, especially claims like natural. They perceive those claims, natural, all-natural, to mean something that they don't. They perceive those claims to mean GMO-free, and they are using their buying power in a way that they think is improving the world around them, when it is actually not.

Mrs. CAPPS. And it is not. So you agree that the current voluntary system is not working?

Mr. FABER. And the voluntary system isn't serving consumers and codifying the voluntary system as H.R. 4432 would just continue to create more and more consumer confusion.

Mrs. CAPPS. That was my next question, so I can just let you underscore it again. One of the arguments in favor of H.R. 4432 is that it will reduce this confusion. You disagree?

Mr. FABER. We strongly disagree. I think if we lived in a world where consumers perfectly understood what natural, non-GMO, organic and other claims meant, then a voluntary system might make sense, but we don't live in that world.

Mrs. CAPPS. Right.

Mr. FABER. We live in a world where consumers are extraordinarily confused about what they are buying at the point of sale.

Mrs. CAPPS. Well, I think we would also agree that this is certainly a complicated topic, and any labeling system must be implemented carefully and in close consultation with the industry, actually with all the stakeholders, but the current system, I believe and I think there is some agreement here, is not working for consumers. So I am concerned that the bill we have before us, I guess I agree with you, Mr. Faber, that it just largely codifies the inadequate rules that we now have.

But I have 50 seconds left to ask you, and you agree that consumers are making decisions with their wallets, and they choose to avoid GE products, not because of food safety concerns, I want to bring up and let you respond to, but because of their environmental impact as well. So that is a further aspect, at least for many of my constituents. What are some of the environmental concerns that consumers are now having with the GE crops?

Mr. FABER. Thank you. Thank you, Mrs. Capps. There are many reasons that people want the right to know what is in their food. One is that the widespread adoption of GE corn and GE soybeans in the U.S. has increased the amount of herbicides that we use, and as those herbicides have become less effective due to weed re-

sistance, has forced farmers to turn to even more toxic herbicides like 2.4–D——

Mrs. CAPPS. I got you.

Mr. FABER [continuing]. Mentioned by Ms. Schakowsky earlier.

Mrs. CAPPS. And so, again, you think consumers should be able to take this kind of information into account as well when making food choices?

Mr. FABER. Consumers overwhelmingly tell you, tell us, tell consumer attitudes experts, they simply want to have that information so they can make those choices for themselves.

Mrs. CAPPS. Thank you very much.

I yield back.

Mr. PITTS. Chair thanks the gentlelady.

Now recognize the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman, I appreciate it so very much, and thank you for holding this hearing.

I have a couple of questions. Dr. Eenennaam, can you describe the current issue with Citrus Greening, affecting orange trees throughout the country? What is the role of GM technology in helping to fight this devastating disease?

Ms. VAN EENENNAAM. Well, Florida industry in particular is being hit by this particular disease, and as plant breeders looking for options as to how we might go about trying to solve the issue, and there are several land grant universities, I am aware of Florida and Texas and California, all looking at both conventional breeding if that is an option, but also genetic engineering options. And I think that is the power of the technology is you can bring in a gene from another species to enable those trees to be resistant to the Citrus Greening Disease, and that is really, I think, the opportunity that exists to utilize this technology to develop disease-resistant plants that are able to withstand devastating diseases like Citrus Greening Disease or Pierce's Disease. And I think many public sector scientists see this as a real opportunity to develop plants that are healthier, don't require any pesticidal inputs or anything, it is just basically breeding, to make those trees healthier and able to withstand that disease.

Mr. BILIRAKIS. Thank you very much.

Ms. VAN EENENNAAM. I think that is a really important—depending what the application of the genetically-engineered crop is depends on the environmental impacts. For example, the disease-resistant papaya doesn't require any inputs, and it enables those crops to grow. And so I think that you have to look at the application as to whether or not it has an increased or decreased effect on pesticide use. And it is application-specific and location-specific and country-specific.

Mr. BILIRAKIS. Thank you so much, doctor. And I am from the State of Florida, so I have a real interest.

Ms. Forshee, how much fuel does it take to plant and harvest your field? I know you talked about this a little bit, you alluded to it in your statement.

Ms. FORSHEE. How much what? I am——

Mr. BILIRAKIS. How much fuel does it take to plant and harvest your field?

Ms. FORSHEE. Well, I would say that—from planting to harvesting?

Mr. BILIRAKIS. Well, approximately.

Ms. FORSHEE. Right. I would say right now on my farm, we are not tilling the land. We are no-till farming. So we use fuel in our tractor when we plant the crop, which probably for a couple of hours of planting, you know, maybe like on an 80-acre farm would maybe consume about—I would say maybe ¼ of a tank of fuel to maybe ½ a tractor tank of fuel. So maybe 75 to 100 gallons there. And then we harvest the crop. I mean, you know, sometimes there does need to be an application if there is a weed problem, so I would say total, from planting to harvesting, maybe a couple hundred gallon, where before, if we were having to work the ground and, you know, really, you know, put strain on our tractors and equipment, it would double if not, you know, triple that fuel consumption.

Mr. BILIRAKIS. Thank you very much.

Ms. FORSHEE. Thank you.

Mr. BILIRAKIS. Thank you. Mr. Faber, if genetic modification were the only way to fight a particular disease, would the Environmental Working Group still oppose this type of technology?

Mr. FABER. Thank you for the question. We do not oppose genetic engineering, genetically-modified food ingredients. We think there are actually many promising applications of genetically-modified food ingredients. Dr. Van Eenennaam mentioned several of them. This isn't a question about the technology, this is a question of whether or not to require labeling; it is really a question of transparency, should people have this information to make their own choices for their own families. I am an optimist. I am optimistic that the promises that were made by the providers of this technology will ultimately be realized that will have traits that produce more nutritious food, that will see significant yield increases. All of those promises haven't yet been realized, but that is not what is at stake here in this question of whether or not to preempt Act 120, or whether or not to craft a national disclosure system. The real issue is should people have the right to decide for themselves, and does FDA have the authority now, I believe they do, to work with us to craft some kind of informative, fact-based, nonjudgmental disclosure on the back of the package.

Mr. BILIRAKIS. OK, thank you very much.

I yield back, Mr. Chairman.

Mr. PITTS. Chair thanks the gentleman.

The chair now recognizes Mr. Matheson 5 minutes for questions.

Mr. MATHESON. Thank you, Mr. Chairman.

Mr. Dempsey, in your industry when people manufacture, makes the product, perhaps someone else is a distributor, perhaps someone else is the grocery store owner, if you have a product that was supposed to be made for the state of Maine, and it accidently went by a truck to Vermont and got put on a shelf, and Vermont charges $1,000 a day fine, who is going to pay the fine out of the manufacturer, the distributor or the grocery store owner?

Mr. DEMPSEY. My understanding with the Vermont law the way it is currently crafted is the manufacturer is responsible for that on $1,000 a day per SKU.

Mr. MATHESON. Even if the distributor may be a separate third-party entity that——

Mr. DEMPSEY. Yes.

Mr. MATHESON [continuing]. Mistakenly went blunder?

Mr. DEMPSEY. Yes, in fact, the way I understand the law, the retailer is absolutely exempt from that fine.

Mr. MATHESON. Representative Webb, do you think that is a correct interpretation of the law?

Ms. WEBB. Is that to me? The retailer would be responsible if the product was an agricultural product such as corn that was——

Mr. MATHESON. I am talking about a pack of potato chips that got made some place else, and accidentally the distributor took it across state lines.

Ms. WEBB. I would have to check on that.

Mr. MATHESON. OK.

Ms. WEBB. I am happy to get back to you.

Mr. MATHESON. Seems to me in this hearing we are talking about this consumer right to know. I find it interesting, this is on an issue where everyone has acknowledged there is no health or safety risk here. I find this—it is the old clich AE1e, a solution in search of a problem. Now, we do have a problem with mislabeling where people say something is natural, and no one can decide what natural is. And I think that Mr. Pompeo's legislation rightly encourages the FDA to move forward on that issue, and give clarity that issue, and I think that is important. I think that is something we have consensus across the board here, but whether or not we should be doing labeling on a component of food that has no demonstrated health or safety risk, that is a tougher one for some of us to swallow, I think.

Mr. FABER. Mr. Matheson, could I?

Mr. MATHESON. No, I am going to ask you a question instead. I only have 5 minutes. You have indicated you think we should have a natural—national labeling system, but in addition to being a lobbyist for the Environmental Working Group, you are the executive director of Just Label It campaign.

Mr. FABER. That is correct.

Mr. MATHESON. And the Just Label It campaign has spent a lot of money in a lot of states pushing state-based initiatives to set up individual state systems. Do you want state systems or do you want a national system, and why are you encouraging this effort at the state level?

Mr. FABER. Yes, and as I testified—and thank you for the question, as I testified, we would greatly prefer a national solution. We believe that FDA has the authority to craft a national solution. FDA has used that authority to require disclosures unrelated to safety and health, to your earlier point. When food is unsafe in the United States, at least since 1906, we don't label it, we take it off the shelves.

Mr. MATHESON. We also make sure that——

Mr. FABER. But we——

Mr. MATHESON. But why are you pursuing it in each state? Tell me—what is the agenda here?

Mr. FABER. In the absence——

Mr. MATHESON. If I hear there is another agenda here——

Mr. FABER. There is no agenda here, except to——

Mr. MATHESON [continuing]. But pursuing it at the state level.

Mr. FABER [continuing]. Protect consumers. I wish that the Administration today would work with us to craft a national solution. In the absence of that leadership, we think it is appropriate for states to step in and help protect consumers from——

Mr. MATHESON. See, I appreciate that that is your statement. I tend to question the logic of that. I think if you want a national standard, going out and stirring things up in every state to do a patchwork system that everyone around here said is a bad idea——

Mr. FABER. Well——

Mr. MATHESON [continuing]. Doesn't make much sense to me.

Mr. FABER. Let——

Mr. MATHESON. I don't want to get in a debate with you, but I don't see the consistency in that, and I think there may be other agendas involved in terms of pursuing it at the state level.

Congress can help this as well if you want to engage Congress. This committee is holding hearings. I think we would have a conversation if there ought to be some national standard or not, and I welcome this hearing. I welcome Chairman Pitts scheduling this because I think this is an issue that deserves a lot of discussion, but there is another effort going on and, boy, a lot of effort and resources being spent in these different states on state ballot initiatives, and I question what the motivation is, and if that really gets us to where anybody in this room really wants to be, maybe some people want to be there with that patchwork of 50 stats, 50 different rules, or as Mr. Pompeo said, maybe we shouldn't limit it to states. It could be counties, it could be cities, it could be a lot more than 50. I think we ought to figure out what we are really trying to do here, and what the agendas are. And I think we ought to look for a national standard, at best, and I would suggest a national standard ought to be on science-based decision making about health and safety risks to consumers, to the integrity of our food supply chain, and that is what I encourage this—I think most people on a bipartisan basis would agree, that is the motivation for this committee in looking at this issue.

With that, Mr. Chairman, I will yield back the balance of my time.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentleman from Maryland, Mr. Sarbanes, 5 minutes for questions.

Mr. SARBANES. Thank you.

Mr. Faber, do you know if the Nutritional Fact Panel that is now required for products, did the FDA conclude that needed to be there for safety reasons, or was that something that the Congress just decided, in response to the demand they heard from the public, ought to be on products?

Mr. FABER. That is a terrific question. So the basis for the Nutrition Facts Panel was to try to promote nutrition and health.

Mr. SARBANES. Yes.

Mr. FABER. The NLEA clearly preempted states from changing the NFP, the Nutrition Facts Panel, from adding things to the ingredient line, or from regulating certain kinds of claims like health claims, but the NLEA was also carefully crafted to preserve for the

states other roles in food labeling, and states have already stepped into that role in many ways. And Mrs. Webb talked about this, whether it is grading butter and cheese in Wisconsin, or use-by and sell-by dates in 41 different states. I am not arguing for a patchwork quilt, but I think we should recognize that Congress, more than 20 years ago, explicitly recognized——

Mr. SARBANES. Yes.

Mr. FABER [continuing]. The longstanding role that states have played in food labeling, especially with regards to addressing consumer deception, and helping consumers understand what they are buying.

Mr. SARBANES. Mr. Dempsey, if the choice were between a situation where there were 50 different labeling regimes, or 1 uniform labeling requirement, but that requirement was that you had to indicate whether there was genetically-engineered ingredients included, which would be the better one from your standpoint?

Mr. DEMPSEY. We would want a federal standard that would place the FDA as a mandatory resource for determining what was genetically modified and what was not genetically modified, and we would want the labeling to be voluntary, similar to what we already have with organic. If someone wants an organic product, they go through an organic certification by the USDA, and we put organic on that. We do not put non-organic on the balance of the products. So it seems to me that forcing a mandatory labeling law onto products that are the predominant ones on the supermarket shelf goes against commonsense, and goes against convention and practice that we already have in the food industry.

Mr. SARBANES. Well, leaving this side of the debate about whether it makes commonsense or not, would it be preferable to having 50 different labeling——

Mr. DEMPSEY. Certainly preferable.

Mr. SARBANES. OK. Now, if there was such a label, could it be as simple as some would say, may contain genetically-engineered ingredients? And I don't know what the Vermont one says, but could you envision a national, Ms. Webb, standard that would essentially say something like that?

Ms. WEBB. We do allow for may——

Mr. SARBANES. Yes.

Ms. WEBB [continuing]. Contain.

Mr. SARBANES. Yes. Because as I am thinking about the disruption to the supply chain, it would seem to me that the burden, frankly, would end up being on those who want to be able to establish that their product is completely free of GE, to sort of police that supply chain. So just from a pricing standpoint, the genetically-engineered products, even if they had whatever extra cost you might attribute to that requirement added in, would end up being a lot less expensive potentially than the others. I am not asking a question, I am just kind of musing here about it.

So I guess what I am trying to sort out is, I don't think the public's reaction to knowing that something is genetically engineered is going to create some huge distortion in the current nature of demand out there. I think many will say, maybe genetically engineered, I get that. They will do price comparisons. They will look at fiber, they will look at other things and they will make a

decision on buying a product. And I am not also convinced that the industry can't handle the supply chain issues in a way that is significantly less expensive than the numbers that are being invoked, but it is a very complicated issue. I come from the perspective that there should be a right to know there, but within the context of that, I am ready to explore how industry can manage that right to know as efficiently and manageably as possible. Yes, you just want to——

Mr. DEMPSEY. It seems to me there is a right to know——

Mr. SARBANES. Yes.

Mr. DEMPSEY [continuing]. And the right to know is to look and shop for, as an organic shopper or a GMO shopper, for those seals that go through a certified and rigorous——

Mr. SARBANES. Yes.

Mr. DEMPSEY [continuing]. Certification process. That is the lack of transparency, if you ask me. It is also from our members' perspective gives a marketing advantage to it, and in most cases, these products are more expensive than the, if you will, conventional products that are on the shelf. So I mean there is information out there if the intelligent, educated consumer wants to find that product.

Mr. FABER. And unfortunately, consumers are looking at those claims, natural and organic, and many of them are getting it exactly backwards. They are thinking the natural claim that might be on a multigrain tortilla snack chip is the one that is GMO-free, and they look at the organic certification and they don't quite know what that means. And so that is why we think addressing the use of the word natural, and having a modest, nonjudgmental disclosure would help cure that consumer confusion. Consumers are extraordinarily busy, they are looking for a simple way to know what they are buying so they can use their buying power to shape the market.

Mr. SARBANES. Thank you.

I yield back.

Ms. WEBB. May I add also that in deference to Mr. Dempsey's concern for smaller businesses, the cost for a small business to go through the non-GMO project is prohibitive for them, which is why we were looking at the expense to go to the larger industry, rather than for people trying to get——

Mr. PITTS. Gentleman's time has expired.

Chair recognizes the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

Coming from Texas though, when you say it is a multigrain tortilla chip, you know, corn is corn, but I know my daughter keeps telling me multigrain chips are much better.

Mr. Dempsey, can you elaborate on how you feel the Vermont Act 120 would lead to a consolidation in the industry and many small businesses force to close, and also are the multi-category, multinational players the only companies that can currently have the capability to change their supply chain and bear these type of costs?

Mr. DEMPSEY. Smaller companies, the ones I would define as smaller companies, are companies with one plant, one line.

Mr. GREEN. Yes.

Mr. DEMPSEY. And as I said in my statements, closing those lines takes significant time out of the production process that would not be able to go right from non-GMO to GMO product. So then the companies have to decide whether they participate in the non-GMO labeling or the GMO labeling as it is in Vermont. They will have to make a decision on what products qualify to go into Vermont without labeling, and which ones don't. And a lot of those will determine both the distribution networks, some of those are DSD, some of those are warehouse, how do you leave open your, if you will, your company to fines if the wrong product gets into Vermont.

Mr. GREEN. OK. Mr. Faber, according to the non-GMO foods, the U.S. market perspective, GMO foods are expected to account for up to 40 percent of the market by 2017, representing a value of about $264 billion. You state that consumers deserve a choice of knowing what is in their food, but isn't the market already voluntarily moving in that direction?

Mr. FABER. Well, today, only about 3 percent of SKUs are certified as GMO-free by the non-GMO project, and so consumers are much likely today to see a natural claim on their multigrain tortilla chip——

Mr. GREEN. Yes.

Mr. FABER [continuing]. Than to see the little butterfly that means it has been a non-GMO certified multigrain tortilla chip. So consumers are much more likely today, and in the near future, to think that they are using their buying power to avoid GMOs, if that is what they choose to do, than they would if they are relying on that certification.

Mr. GREEN. Do you think there are any costs shifted to consumers due to the mandatory labeling laws and how they might change the operation of our food supply?

Mr. FABER. I don't believe that they will—even if we had a modest informational GMO disclosure tomorrow, that you would see dramatic change in buying behavior, and we know because we have GMO labeling in some form or another in 64 other countries, including countries where people eat more or less like us. Brazil is a great example where they have had a GMO disclosure since 2001, and where consumers have conferred a benefit to the GMO disclosure, and that is why they have not seen any significant change in buying behavior. So I am confident that if we had a GMO disclosure tomorrow, that the food industry would take all the money they have been spending to fight these ballot initiatives, which is now more than $100 million, and invest it into a topnotch consumer education campaign to persuade consumers that GMOs have all the benefits that we have heard about during this hearing.

Mr. GREEN. Well, and I guess that is my concern that, we heard from the FDA and, with their resources and, of course, we decide their resources to do the inspections, but there has been no proof that GMOs are actually bad to consume, and we also know, and I assume we will have testimony, but this is not the Ag Committee, but some of the GMOs have actually expanded our possibilities for food production, not only in our own country, because obviously we eat very well, but in parts of the world where starvation is an issue, whether it be the GMO rice product that you can, and those

have been shown that they they don't harm humans, but it does help the nutrition issues.

Mr. FABER. And as I said earlier, no one is arguing that farmers should be prohibited from planting GMOs, and GMO traits may indeed provide benefits to farmers or nutritional benefits someday. I think the real question here is whether or not people should be able to decide for themselves, and whether or not FDA has the authority to do so. As Mr. Waxman was talking about earlier, FDA has compelled disclosures simply because of consumer interest, and up until 1992, for the years between 1938 and 1992, understood that word material that we talked about earlier really to mean relevant. Was it information that a consumer would want to have in order to make an educated choice.

Mr. GREEN. Thank you for your patience, Mr. Chairman. I know I ran over time a little bit.

Mr. PITTS. Chair thanks the gentleman.

Now recognize Mr. Pompeo 5 minutes for questions.

Mr. POMPEO. Thank you, Mr. Chairman.

Ms. Forshee, thank you again for traveling out here to be here. You talked about the costs that would increase your small business to operate. I assume you wouldn't just eat those costs, you would attempt to pass them on as best you could to your customers?

Ms. FORSHEE. Yes, just like any small business. I think I left off the fact that we have one full-time hired man as well, so, not only do we farm, but farming is a business——

Mr. POMPEO. Yes.

Ms. FORSHEE [continuing]. And that is exactly right, that would have to be passed down.

Mr. POMPEO. I appreciate that. I have a lot of ground, I want to try and get some yes-or-no answers. We haven't been successful so far today. I am confident I will be the first to do so.

Earlier today, we had an FDA witness testify, a very senior FDA official testify. He said that GE foods in the U.S. marketplace today are safe as their conventional counterparts. We will start on my left, your right, and tell me if you agree, yes or no, with that statement.

Ms. VAN EENENNAAM. Yes.

Mr. FABER. I believe so.

Mr. POMPEO. That is a yes, for the record.

Ms. WEBB. Yes.

Mr. POMPEO. Just yes, yes.

Ms. FORSHEE. Yes.

Mr. DEMPSEY. Yes.

Mr. POMPEO. Yes. We have total unanimity. That is fantastic. That is one of the first times in this committee we have had that in my 4 years here, so that is all good news.

And, Mr. Faber, you were talking about misinformation out there. I can tell you you are part of the problem. Your organization is part of the problem. Mr. Matheson asked you about it. You say you don't want a patchwork. You have spent millions of dollars stirring up trouble to create just that patchwork of regulation, and you are continuing to do so today. I am confident that the phones are ringing in my office as a result of your efforts to stir up this very challenge. And so I would just urge you to work to get to the

right place. This piece of legislation requires the FDA to define natural, the very thing that you spent so much time in your testimony speaking to. So I am with you.

Mr. FABER. Yes.

Mr. PALLONE. I want that to occur. But when you put up things and you call this piece of legislation the dark act, saying we are denying consumers the right to know, there is nothing in this legislation that denies any consumer any capacity to know precisely what it is they are eating. If any willing provider deems it appropriate, and finds customer demand to provide information to their customers about the nature of that product, no one's right to know is being impinged today, nor would it be if this bill became law.

So as you are out there working to defeat this legislation, I hope you will be honest in the way you talk to America about this because it is very important that folks have the right to know. This Bill would never impinge on that. So I am sure today you will go out and issue something that says that this is not the dark act. I look forward to reading that on my Web site.

Mr. Dempsey, you were talking about this. One to 10 on a scale, how does this impact the businesses that you represent if we fail to get this law put into place and a patchwork of rules becomes the norm in America?

Mr. DEMPSEY. Ten being the most difficult scenario?

Mr. POMPEO. Sure.

Mr. DEMPSEY. Ten for sure.

Mr. POMPEO. And so if it is a 10, what is it for the smallest businesses in America?

Mr. DEMPSEY. Multiply that times 10.

Mr. POMPEO. Thank you.

Ms. Webb, how many FDA-level quality scientists are employed by the state of Vermont today that are reviewing these sets of food rules?

Ms. WEBB. I have no idea.

Mr. POMPEO. So you——

Ms. WEBB. We are not trying to compete with the FDA or be the FDA.

Mr. POMPEO. So are there any folks that are experts in food safety applied today by the state of Vermont that is trying to put forth a set of rules that I promise you the citizens you represent think have something to do with food safety?

Ms. WEBB. I would have to get back to you on that.

Mr. POMPEO. You don't know. I would appreciate you getting back with the committee and answering that question.

I want to come back to choice, Ms. Forshee, and this really comes to you. You are both the producer and the consumer. Today, if you decided, for whatever reason, because you had some personal preference with respect to non-GMO foods, do you think you could walk into a store somewhere, I guess not near you, 20 miles, but somewhere in Kansas and find that set of products on the shelves, or if you didn't, contact the providers of those foods and say I want you to label that? Do you think you could pull that off?

Ms. FORSHEE. No. I mean——

Mr. POMPEO. Yes.

Ms. FORSHEE [continuing]. I don't believe so.

Mr. POMPEO. Yes.
Ms. FORSHEE. I really don't.
Mr. POMPEO. Yes.
Ms. FORSHEE. I mean I feel that it is safe——
Mr. POMPEO. Yes.
Ms. FORSHEE [continuing]. And that is what I care about is knowing that it is safe, but no.
Mr. POMPEO. I appreciate that.
Mr. Chairman, I yield back.
Mr. PITTS. All right, the chair thanks the gentleman.
That concludes the questions of the members present. I am sure we will have follow-up questions. We will send them to you in writing. We ask that you please respond promptly.
And members will have 10 business days to submit questions for the records. That means they should submit their questions by the close of business on Monday, December 29.
Thank you very much for your testimony, for your willingness to come today, in a very important and informative hearing.
Without objection, the subcommittee is adjourned.
[Whereupon, at 1:13 p.m., the subcommittee was adjourned.]
[Material submitted for inclusion in the record follows:]

Corn Refiners Association
Statement
Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients
Subcommittee on Health
Committee on Energy & Commerce
U.S. House of Representatives
Wednesday, December 10, 2014

Thank you for the opportunity to provide the views of the Corn Refiners Association. Each year, our members purchase and process between 15% and 20% of America's corn supply to make over 1000 products, principally food ingredients. Corn based food ingredients are used in the formulation of 40% to 70% of consumer retail food products.

As strategic partners of the National Corn Growers Association, the Corn Refiners Association supports the development of efficiency enhancing production practices and technologies for American agriculture, including responsible use of biotechnology. We rely on the production of America's farmers and support policies that seek successful, profitable corn producers. The adoption of biotechnology enhanced crops has provided farmers with opportunities to reduce use of pesticides and increase yields, resulting in environmental and agronomic benefits to society.

We respectfully submit that a fundamental question for Congress is whether consumer interest in biotechnology labeling laws for foods should be addressed in various ways by various states or whether a uniform food labeling approach should be taken for all foods sold in the United States. We urge enactment of a uniform, national food labeling approach, which consumers would find more understandable and consistent wherever they purchase food. A uniform approach would also help keep food more affordable..

Using corn ingredients in food to illustrate, permit us to explain why a state by state food labeling approach regarding use of biotechnology would be far more expensive than a uniform national approach. Of course, most corn in the U.S. now is produced with biotechnology.

It is difficult to convey the variety and scale of the American food supply. For example, in an average supermarket, refined corn ingredients can be found on thousands of labels. Many of the products consumers enjoy daily get their start with corn: jams, jellies, sauces, marinades, cereals, condiments, canned fruits and vegetables, baked goods, meat products like bologna and hot dogs, yogurts, snack items, cough drops, toothpaste, paper, cosmetics and soap to name a few. Refined corn ingredients that are minor ingredients generally impart characteristics that we often take for granted, such as:

- Enabling foods to maintain improved textural characteristics during freezing, thawing, and heating.
- Improving bioavailability of vitamins and shelf life of certain flavors.
- Enhancing texture and moisture in items such as protein bars, meal replacement drinks, and dried soups.
- Providing sweetness, as well as thickening, texture, clarity, and sheen in food applications such as cereal bars, ice cream, salad dressings, and canned fruits.

- Imparting tart flavor in confectionery and beverages and serve as a preservative in many food products.

The Corn Refiners Association has periodically conducted a survey to determine how many items in a typical grocery store contain refined corn. Based on a survey conducted in 1999 and updated for current market conditions, we estimate more than 4,500 items in a typical grocery store contain refined corn ingredients. Many contain multiple ingredients from corn.

Of course, corn is just one example of an important crop that is used widely in the food supply. It provides an example of the large reach and cost that mandatory labeling of biotechnology enhanced crops could have on the marketplace and the consumer.

Recently, economists from Cornell University, with support to that institution from the Gates Foundation, conducted a study of costs potentially arising from enactment of New York's proposal to require labeling of foods containing ingredients produced with biotechnology. The Cornell economists calculated the midpoint annual increase in costs to a family of 4 to be $224 and a billion dollars to the state. These calculations assumed 10% of consumers switched to organic products and 40% switched to non-biotech labeled products. This scenario created a dual food production system in which new labeling costs were passed on throughout the entire food production chain and ultimately borne by consumers.

The Cornell economists found that costs would increase significantly as the threshold is lowered for allowed presence of foods produced through biotechnology in unlabeled products. A zero threshold for foods produced through biotechnology may not be possible, as found by experience from marketing to the European Union and from FDA allergen control requirements. Independent of the degree of consumer adoption of non-labeled foods, mandatory labeling of foods produced through biotechnology would have a very significant impact on the farming communities, the entire food production sector, and consumer food costs. Our low cost and efficient food production system based on economy of scale would be fragmented.

From our experience with corn products, permit us to describe how increased costs of mandatory labeling would ripple through the food production system:

- Farmers - Lost yield and increased pesticide and fuel use; field and equipment needing segregation; increased labor and man hours needed for cleanouts to insure labeling compliance, crop segregation and identity preservation is required, which reduces scale. Producing both labeled and non-labeled products requires duplicate equipment dedicated to biotech and non-biotech farm production and/or causes time consuming extensive cleanouts. Harvest storage bins, country elevators, transport vehicles and processing systems must be dedicated and maintained separately. Additionally, crop fields must be managed to avoid cross contamination, a problem for corn farmers due to pollen drift. Increased buffer zones lowers acreage efficiency, and lawsuits can arise from contamination. Farm income will suffer.

- Corn Processors- Identity testing of raw materials would result in hundreds of thousands of dollars additional costs per facility per year, and similar to corn producers issues of minimizing cross contamination and maintaining scale would raise costs. Due to the high cost of preventing cross contamination in large continuous flow production facilities, at least some dedicated facilities would likely be required. Such facilities would likely encounter increased sourcing costs for dedicated non-biotechnology facilities. A typical corn refining facility receives several hundred

trucks of corn a day and a 100 rail car unit train every few days. Processing a thousand tons of corn per day while ensuring against contamination for unlabeled products would be a daunting task.

- Food Processors- A separate label would have to be designed for each unique state imposing food biotechnology labeling requirements, with a separate ingredient compliance program incorporating the unique requirements of each state labeling program. So, for each state labeling requirement, the suppliers of the typical grocery store would be required to maintain a separate label inventory, and ingredient labeling compliance program (with contracting, recordkeeping, and testing verification) for approximately 4,500 food products, simply because of the corn ingredients in those products.

- Warehouses and Retail Stores – Major food distribution centers are key to the efficiency of the food distribution system. These facilities typically handle thousands of food product SKU's. Each new state mandatory labeling requirement would almost double the number of SKU's in each of those facilities, with associated cost increases for recordkeeping and reduced efficiencies of scale.

- Consumers – It is absurd to suggest that these increased costs would not be passed on to ultimate consumers. Food costs would increase, with the difficulty in bearing that cost falling hardest on low income consumers. Likely variation in various state labeling programs would result in consumer confusion about precisely what the labeling means. Therefore, consumers would bear increased food costs without clear understanding of what the mandatory labeling means.

- State government – State by state mandatory labeling programs means that enforcement costs would fall far more heavily on state agencies than with a uniform national labeling program where a single enforcement action would have national effect. Further, the labeling of possible allergens or for compositional enhancements created by biotechnology is already required under FDA labeling law and thus would add to enforcement costs.

We realize that some may question our assertion that various state mandatory labeling requirements should be assumed to be unique. Given the great potential for variation in scope of definitions of foods subject to biotechnology labeling requirements, definitions of biotechnology uses subject to labeling requirements and issues regarding tolerances without triggering labeling requirements, we assert that this is a reasonable assumption. Moreover, we note that at the time of the enactment of the recent mandatory menu labeling amendments to the Federal Food, Drug, and Cosmetic Act, there were almost 30 state and local menu labeling requirements for standard menu items of chain restaurants. No two of those requirements were identical.

Accordingly, we respectfully urge enactment of a nationally uniform labeling program for foods produced through biotechnology and commend for your consideration H.R. 4432, sponsored by Representatives Pompeo, Butterfield, Matheson, Blackburn and Whitfield. We appreciate your consideration of our comments.

Congress of the United States
Washington, DC 20515

January 9, 2015

Dr. Alison L. Van Eenennaam
Cooperative Extension Specialist
Animal Genomics and Biotechnology
University of California Davis
One Shields Avenue
Davis, CA 95616

Dear Dr. Van Eenennaam:

Thank you for appearing before the Subcommittee on Health on Wednesday, December 10, 2014, to testify at the hearing entitled "Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients."

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these requests with a transmittal letter by the close of business on Monday, January 26, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: Frank Pallone, Ranking Member, Subcommittee on Health

Attachment

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

ONE SHIELDS AVENUE
DAVIS, CALIFORNIA 95616-8521
TELEPHONE: (530) 752-7946
EMAIL: alvaneenennaam@ucdavis.edu

Friday January 23, 2015

Dear Congressman Morgan Griffith,

I am pleased to provide you and other members of the Committee with my thoughts, suggestions and feedback to your question from the December 10th, 2014 House Energy and Commerce Health Subcommittee hearing entitled "Examining FDA's Role in the Regulation of Genetically Modified Ingredients."

"Please provide your thoughts, suggestions, and feedback on Mr. Pompeo's Bill, H. R. 4432 from the 113th Congress"

I appreciate that Congress is beginning to conduct a serious conversation about the use of genetic engineering (GE) as a powerful and valuable breeding method in the development of agricultural crops. I think the hearing was very helpful in dispelling the unfounded food safety concerns that have been raised about genetically engineered foods since no member raised safety as a concern as it relates to labeling of food derived from GE crops, and all panelists unanimously agreed that there were no safety questions associated with food derived from the GE crops that have been commercialized to date. Likewise, not one lawmaker on the subcommittee stated clear opposition to the inclusion of GE crops in the food supply.

SAFETY

As I stated in my testimony, this absence of safety concerns agrees with the overwhelming scientific consensus about the safety of food produced from the commercialized GE crop varieties and the abundance of public and private data that supports that consensus. To date, no material differences in composition or safety of commercialized GE crops have been identified that would justify a MANDATORY label based on the GE nature of the food derived from GE crops and, by extension, the Food and Drug Administration (FDA) does not support such process-based mandatory labeling.

The FDA does require labels on products that demonstrably pose novel hazards that might affect safety or have significant unexpected differences in composition, irrespective of the breeding method used to produce that product. These are material facts. In contrast, breeding methods that create no material difference in products require no special labeling. Although the food safety of GE crops, and ingredients derived from them, has been reviewed by the FDA prior to introduction of all new GE varieties commercialized to date, some have expressed concerns that GE crops are inherently less safe than those produced by other plant-breeding techniques. Their major safety contention is that the process of GE per se can produce unintended changes resulting in long-term adverse consequences.

The FDA has stated that it has no basis for finding that GE foods "differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding". Therefore, since GE breeding methods create no material difference in products, no label is required for GE foods. In the two decades since this initial finding, the FDA has not encountered any evidence or data that have caused it to change its position despite having reviewed regulatory packages on well over one hundred GE events.

If the use of GE in one specific application resulted in a product that differed significantly from its conventional counterpart, the FDA could require labeling for those specific qualities. For instance, since high omega-3 and high oleic vegetable oils differ significantly in composition from their conventional counterparts, the FDA could require that these oils be labeled—not because they were produced using GE, but because there is a material difference in the oil products.

The FDA would also require labeling for potential allergenicity if the food contained a novel allergen that a consumer would not expect to be present in a specific type of food. As an example, if a peanut protein was inserted into a tomato, the product would need to be labeled to warn individuals allergic to peanuts that the GE tomato may present an allergenic risk unless the developer could demonstrate that there was no allergy risk from that peanut gene. To date, no GE products have required such a specific label. It should be noted that the FDA allows voluntary process-based labeling as long as it is not false or misleading.

CONSUMER CHOICE

In 2001, the FDA put out a draft guidance that set forth requirements for industry as to acceptable language for voluntary labels on products not containing any GE ingredients. The guidance stated that it is not possible to demonstrate a zero level of GE ingredients and therefore prohibits claims that a food is GE "free." It also advised that "a label statement that expresses or implies that a food is superior (e.g., safer or of higher quality) because it is not GE would be misleading" given the lack of evidence that GE foods are materially different than non-GE foods. It was also considered that it would be misleading to label a food or ingredient as being non-GE, when in fact no commercialized GE varieties of that food or ingredient exist on the market.

Indeed, in recent years, a large number of food products indicating the absence of GE ingredients through non-GE or organic labels have also been offered in the U.S. market. Food manufacturers and retailers have voluntarily labeled such products, and often third-party organizations have certified the accuracy of the claims and labels. More than 14,800 food products and 800 brands are reported to have been certified as meeting the Non-GMO Project standard alone. Another option consumers have is to buy organic products, because the use of GE is not allowed in certified organic production systems. Additionally, some manufacturers are doubly verifying their certified organic products with the Non-GMO Project Verified and other non-GMO certification programs. Altogether, these voluntary measures provide consumers with non-GE choices in the U.S. marketplace at commercially achievable standards.

FOOD PRICES

Mandatory labeling of all foods that might contain ingredients from GE crops would increase U.S. food costs. Opponents of mandatory GE labeling schemes have argued that they would be very costly and that their costs would be paid by all consumers, including those who do not wish to avoid GE. Proponents have argued that the implied costs would be minimal. Indeed, a handful of studies have sketched out the potential costs of the mandatory labeling initiatives in California and Washington. The results have varied from more than $1 billion per year to a few thousands of dollars.

The widely differing calculations in the estimated costs of the proposed mandatory labeling schemes are explained by fundamentally different conjectures about the responses of key players in the food supply chain and the changes they could bring about in the U.S. food market. Much depends on how food manufacturers, food retailers, and other food merchants would choose to act if mandatory GE labeling

was put in place. On the one hand, they could choose to maintain the current composition of their products, placing GE labels on them when necessary. On the other hand, they could choose to change the composition of their products in order to avoid the use of GE labels. The reactions of food manufacturers and retailers could be shaped by expectations of negative consumer response toward GE labels, targeting of their products by political activists, exploitation of GE labels by competitors, and concern that a mandated label might be mistakenly interpreted by consumers to confer a food safety warning. If manufacturers choose to maintain their products and place labels on them, the cost impact of mandatory labeling would be the relatively minor cost of the ink to print new labels and the more significant costs associated with tracking and monitoring to ensure compliance. If manufacturers choose to substitute GE ingredients with non-GE ones to avoid labels, the cost impact of mandatory labeling would be substantial and associated with new product formulation and sourcing non-GE ingredients.

Changing the composition of foods sold in the market today in order to avoid the use of GE labels would involve the replacement of GE ingredients with others derived from commodities that have not yet been genetically engineered (e.g., wheat or rice) or with non-GE and organic ingredients. Such changes are both difficult to implement and costly. Changes in ingredients may alter the final product as it is not always possible to achieve identical appearance and functionality when reformulating and redeveloping a product using alternative ingredients (e.g. changing from corn starch to tapioca or potato starch)[1]. Moreover, non-GE ingredients will tend to be more expensive and may have more uncertain and inconsistent supplies. The added costs of avoiding mandatory GE labels are therefore more or less the same as those incurred by products voluntarily labeled non-GE, as described above. In effect then, appraisal of the added costs for mandatory labeling involves (1) an estimation of the share of the food market that might become non-GE, and (2) an estimation of the costs that would be incurred to procure non-GE ingredients and reformulate products.

If a significant share of the prepared and ready-to-eat foods sold in supermarkets today were to require non-GE ingredients, the demand for certified non-GE and organic products would increase well beyond its current levels. The markets of non-GE and organic food ingredients are, in effect, specialty markets, and as such they can exhibit noticeable price jumps even under modest changes in their demand and supply conditions. Hence, under expanded markets and increased demand conditions, price premiums for such ingredients could well exceed their current levels.

It is worth noting, that while mandatory GE labeling is often assumed to enable consumer choice, mandatory GE labeling laws in other countries have had the opposite effect in that they resulted in the virtual disappearance of any labeled GE product from the shelves, thereby decreasing choice and increasing price for those consumers unconcerned about GE food. In the European Union, Greenpeace and other anti-GE organizations quickly launched negative campaigns targeting GE-labeled products and publicized supermarkets or food brands carrying GE labels. In response, retailers decided not to stock

[1] Processed foods often contain a number of ingredients that are derived from different commodities like corn, soybean, canola, and sugar beets. Ensuring that all ingredients used in any given processed product come from non-GE commodities would complicate their supply chains. For example, peanut butter might contain sugar from GE sugar beets, molasses from GE corn, and vegetable oils from GE canola and corn varieties. If food manufacturers were to reformulate such products, they would have to ensure that all individual ingredients were certified non-GE. Many highly processed ingredients and oils contain no detectable traces of their GE origin (e.g. no GE DNA or protein is present in oil meaning there is no way to test for its presence) which further complicates certification of non-GE ingredients.

brands with GE labels to avoid the risk of losing sales because of such campaigns and boycotts, and food processors avoided using GE ingredients to decrease their risk of loss in market share.

It is unclear how much U.S. consumers are willing to pay for mandatory GE labeling; although if a mandatory GE labeling law was enacted there will be little choice but to pay the resulting costs. At the beginning of the decade, 77% of the public indicated that it would not be willing to pay more than $50 per year per household for GE labeling, with 44% of respondents not willing to pay anything extra for GE labeling. Furthermore, analysis of the failed CA, OR and WA mandatory labeling of GE food initiatives indicate that the concern about potential food price increases figured prominently in their defeats.

Over time, food prices would rise at some level to cover the costs of any mandatory GE labeling regime in the U.S. market. An important question then is who would be most affected by such price hikes? So far, state initiatives have called for mandatory GE labeling of foods bought at the grocery store and consumed at home but do not generally require the same for foods consumed in restaurants, cafeterias, catered events, schools, and the like. They also invariably exclude all organic foods from mandatory GE labeling, irrespective of where they are consumed or their potential GE content. Given these exemptions and the proposed rules on what foods would actually need the GE labels, the proposed mandatory labeling schemes will likely have a greater impact on low-income households.

In summary:

- Current federal (FDA) labeling authority is federal and already requires labels on products that demonstrably pose novel hazards such as new potential allergens.
- All domesticated crops and animals have been genetically modified in ways that some may consider "unnatural"; there is no science-based reason to single out foods derived from crops that have been developed using GE as a breeding method for mandatory process-based labeling. Wide-ranging evidence shows that GE technology is equally safe to conventional breeding.
- Mandatory labeling based on breeding method abandons the traditional U.S. practice of providing for non-safety related consumer food preferences through voluntary product differentiation and labeling (i.e. marketing and promotion of products with specific attributes or produced using a certain production or breeding method e.g. Kosher; Organic; Grass-Fed; Humanely Raised, Heirloom.
- Mandatory GE labeling would increase U.S. food costs. The size of this increase would depend on choices made in the marketplace by suppliers, marketers and consumers; and what products are included in labeling requirements. If, as in other places, sellers move to non-GE offerings in response to mandatory labeling to avoid negative campaigns by political activist groups, food costs could rise significantly and these increased costs would exact a greater burden on low-income families.

I would encourage you to read the Council for Agricultural Science and Technology (CAST) Issue Paper Number 54 entitled "**The Potential Impacts of Mandatory Labeling for Genetically Engineered Food in the United States**", which was released in April of 2014 to further explore the science-based food safety, legal and potential economic implications of mandatory labeling of foods derived from crops that were developed using genetic engineering in the United States.

Sincerely,

Alison Van Eenennaam

Alison Van Eenennaam, Ph.D.

Congress of the United States
Washington, DC 20515

January 9, 2015

Mr. Scott Faber
Vice President of Government Affairs
Environmental Working Group
1436 U Street, N.W., Suite 100
Washington, D.C. 20009

Dear Mr. Faber:

Thank you for appearing before the Subcommittee on Health on Wednesday, December 10, 2014, to testify at the hearing entitled "Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients."

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these requests with a transmittal letter by the close of business on Monday, January 26, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: Frank Pallone, Ranking Member, Subcommittee on Health

Attachment

January 26, 20015

Adrianna Simonelli
Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Ms. Simonelli:

Thank you for the opportunity to respond to Mr. Griffith's Question for the Record on H.R. 4432.

Consumers simply want the right to know about the presence of genetically modified food ingredients in their food. What's more, misleading claims have led to many consumers to incorrectly believe that "natural" foods are GMO free.

Rather than require a simple disclosure regarding the presence of genetically modified food ingredients and prohibit "natural" claims on such foods, H.R. 4432 would keep consumers in the dark by preempting state GMO labeling laws, narrowing FDA's authority to craft a *mandatory* GMO labeling solution, and by codifying the current *voluntary* GMO labeling system that has fueled consumer confusion.

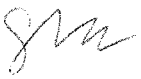
Instead, Congress should prohibit the use of "natural" claims on foods with genetically modified food ingredients, subject genetically modified food ingredients to more rigorous safety testing, and should enact H.R. 1699, which requires a GMO disclosure on food with genetically modified food ingredients.

There are many reasons consumers want to know about the presence of GMOs in their food. Rather than boosting yields or nutritional benefits, GMO crops have so far only succeeded in boosting herbicide applications. What's more, genetically modified food ingredients are not subject to same safety reviews typically required of pesticides or many food additives. H.R. 4432 fails to address longstanding flaws in FDA safety reviews that contribute to consumer uncertainty and concern about those ingredients What is needed, in addition to federally mandated labeling for genetically engineered ingredients in food, is a robust, modern safety review system for GMO crops that will ensure protection of public health and the environment.

When I testified, in response to a question, that I believed that genetically modified food ingredients were not harmful to eat, I was sharing my personal belief that consuming food containing genetically modified food ingredients would not cause the sort of immediate harm caused by adulterated food contaminated with pathogens. By any definition, a technology that significantly increased the use of herbicides and forced farmers to turn to more toxic herbicides is harmful to people and the environment.

Regardless of the reason, consumers should have the right to know what they are eating and feeding their families.

Sincerely,



Scott Faber

Congress of the United States
Washington, DC 20515

January 9, 2015

Representative Kathryn L. Webb
Assistant Majority Leader
Vermont House of Representatives
1611 Harbor Road
Shelburne, VT 05482

Dear Representative Webb:

Thank you for appearing before the Subcommittee on Health on Wednesday, December 10, 2014, to testify at the hearing entitled "Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Monday, January 26, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: Frank Pallone, Ranking Member, Subcommittee on Health

Attachments

January 22, 2015

Adrianna Simonelli
Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515
Adrianna.Simonelli@mail.house.gov

Re: Responses to January 9, 2015 Additional Questions for the Record

Responses to the Honorable Renee Ellmers:

1. **If transparency in what people are eating is the motivating factor for the enactment of Act 120 as you state, what is the justification for exempting such a wide swath of food actually consumed in the state, such as restaurant food or what is consumed in convenience stores?**
    a. **Furthermore, how are consumers being given more information with a label saying the food is or may be genetically engineered if the label does not specify which ingredients in that product may have been the result of genetic modification? Or does the state believe an entire food product is genetically engineered?**

Response to 1: Act 120 requires labeling on the vast majority of foods sold in grocery stores, as well as packaged foods in convenience stores. The law provides consumers with information that is currently unavailable at the point of sale—when they are deciding what food products to purchase. While the Act includes some limited exemptions, each serves a purpose. For instance, the restaurant exemption takes into account the impracticability of requiring labeling in the restaurant environment, just as the federal Nutrition Labeling and Education Act similarly exempts certain restaurants from its mandatory nutritional labeling regime.

Response to a: Consumers who wish to avoid genetically engineered foods, whether for health, environmental, religious, or other reasons, benefit from knowing that a product was produced or may have been produced with genetic engineering, regardless of the specific ingredient that was produced with genetic engineering.

Responses to the Honorable Michael Pompeo:

1. **What is the name of the entity that is reviewing GMO standards in Vermont?**

Response: Though I am not sure what is meant by "reviewing GMO standards in Vermont," the Vermont Attorney General's Office is the entity that is engaging in the rulemaking process to implement Act 120 and will approve third-party organizations that verify for a producer that a food is not produced with genetic engineering.

Responses to the Honorable Morgan Griffith:

1. **Please provide your thoughts, suggestions, and feedback on Mr. Pompeo's bill, H.R. 4432 from the 113th Congress.**

Response: Please see my attached December 10, 2014 testimony in opposition of H.R. 4432.

Congress of the United States
Washington, DC 20515

January 9, 2015

Ms. Stacey Forshee
Fifth District Director
Kansas Farm Bureau
2627 KFB Plaza
Manhattan, KS 66503

Dear Ms. Forshee:

Thank you for appearing before the Subcommittee on Health on Wednesday, December 10, 2014, to testify at the hearing entitled "Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Monday, January 26, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: Frank Pallone, Ranking Member, Subcommittee on Health

Attachments

Stacey Forshee

Owner/Operator of Forshee Farms LLC in Kansas

House Committee on Energy and Commerce; Subcommittee on Health

Hearing entitled "Examining FDA's Role in Regulation of Genetically Modified Food Ingredients"

December 10, 2014

Questions for the Record Responses

The Honorable Renee Ellmers

1. **Ms. Forshee, you mention in your testimony how the choice of adopting biotechnology has brought economic and environmental benefits to your farm operation. Do you think all these mandatory labeling proposals out there not based on any kind of safety finding are a way to restrict the planting choices you make on your farm?**

Yes, labeling laws are a way to restrict what we grow and how we farm, directly and indirectly.

The Honorable Morgan Griffith

1. **Please provide your thoughts, suggestion, and feedback on Mr. Pompeo's bill, H.R. 4432 from the 113th Congress.**

We need a federal solution that lets consumers make informed decisions rather than a patchwork of state and local laws that are confusing and not uniform. H.R. 4432 is a common-sense bill that helps protect against consumer confusion.

The bill offers consistency and safety for consumers and strengthens federal oversight to help us move beyond confusing, state-by-state labeling laws that needlessly undermine consumer confidence in the safe U.S. food supply.

Not only do inconsistent labeling laws confuse consumers, they also threaten to harm state economies and wreak havoc on farm businesses like mine. H.R. 4432 ensures that the flow of interstate commerce continues uninterrupted and allows farmers across the U.S. to continue to contribute to the nation's economy by growing safe, nourishing food in the most efficient, cost-effective way while protecting our limited natural resources.

Congress of the United States
Washington, DC 20515

January 9, 2015

Mr. Tom Dempsey
Chief Executive Officer
Snack Food Association
1600 Wilson Boulevard, Suite 650
Arlington, VA 22209

Dear Mr. Dempsey:

Thank you for appearing before the Subcommittee on Health on Wednesday, December 10, 2014, to testify at the hearing entitled "Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients."

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these requests with a transmittal letter by the close of business on Monday, January 26, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: Frank Pallone, Ranking Member, Subcommittee on Health

Attachment

Questions for the Record - Tom Dempsey, Snack Food Association
Submitted January 26, 2015

Rep. Morgan Griffith:

Please provide your thoughts, suggestions, and feedback on Mr. Pompeo's bill, HR 4432 from the 113th Congress.

First, I would like to again thank the Subcommittee for providing a forum for a balanced review of one of the most critical issues facing the food industry today, the labeling of genetically modified organisms (GMOs).

My past role as president of one of the largest privately owned snack brands in the United States provides me with firsthand experience about what mandatory GMO labeling would mean for the food industry. It would impact nearly every aspect of SFA members' business, upping costs by requiring increased product inventory, added complexity for packaging and distribution processes, and extensive new regulatory and training requirements.

SFA does not have a single member company that manufactures, distributes, and sells in just one state, which makes complying with a patchwork of state labeling laws such as Vermont's incredibly complex. As I mentioned during my testimony, the hardest hit by these new burdens would be the small, family-owned companies with just one plant or just a single line of production. Quite frankly, these costs could put some companies out of business and thereby increase consolidation in the industry.

A patchwork of mandatory labeling laws would also confuse consumers and add unnecessary costs at the grocery store. Additionally, some food manufacturers may be forced to end the distribution of their products in states that require mandatory GMO labeling. This would have a ripple effect across the distribution chain, impacting drivers, warehouse personnel, account executives, and field management. And while consumers in some states, such as Vermont, may have the option to cross state lines to shop for goods if products were pulled from grocery shelves, as you correctly pointed out during the hearing that is simply not feasible for everyone.

For all of these reasons, I would also like to thank Rep. Pompeo for his leadership in crafting legislation that represents a dramatic step in the right direction to address the problems with mandatory GMO labeling. SFA's members appreciate that H.R. 4432 balances the desire of some consumers for an additional label with the recognition that mandatory labels should be reserved for safety and nutrition concerns. This is especially important given that all of the panelists at the Subcommittee's hearing agreed that the safety of GMO products is not a concern. The safety of GMOs is backed by FDA, USDA, EPA and 20 years of experience in the field.

While we firmly believe the science shows that GMO products are safe, SFA members are dedicated to providing consumers with options in the marketplace. We agree with you that a national standard for GMO labeling– rather than a state-by-state patchwork of arbitrary rules – is the best approach. While the potential to confuse consumers about the safety of a product with a mandatory GMO label is too great, we would appreciate the opportunity to continue the conversation about a structured voluntary labeling system. We believe that a voluntary labeling program similar to that used by USDA's National Organic Program is the best way to create a meaningful label that will help consumers make educated choices.

We also believe that the term "natural" needs FDA attention and a formal definition. Our manufacturers continue to be subject to numerous lawsuits as it relates to labeling our products as "natural". This definition should not be left up to the courts. Regardless of a legal decision, the litigation process is costly and time consuming and ultimately will drive up product costs for consumers.

Again, thank you for your consideration of our views. We hope this lays the groundwork for a federal solution to the threat of a costly and confusing patchwork of state labeling rules. SFA would be happy to be a resource should you have any additional questions.

Sincerely,

Tom Dempsey
Snack Food Association
President and CEO

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