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House Committee on Energy and Commerce; Subcommittee on Health
"A National Framework for the Review and Labeling of Biotechnology in Food"
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I want to thank the House Committee on Energy and Commerce and its Subcommittee on Health for having today's hearing and inviting me as a witness on behalf of the Center for Science in the Public Interest (CSPI). The issues surrounding the proper role of the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) in the oversight of genetically engineered (GE) crops and the labeling of foods made with or without ingredients from those crops are issues of obvious public concern that Congress needs to address. It is critical that the federal government ensure that all GE crops are safe and that whatever information is provided to consumers about foods and ingredients made from those crops be truthful, neutral, and non-misleading.

I am here today as the director of CSPI's Biotechnology Project. CSPI is a non-profit consumer organization, which was established 44 years ago. CSPI works primarily on food safety and nutrition and publishes our Nutrition Action Healthletter to educate consumers on issues surrounding diet and health. CSPI also advocates on behalf of consumers at federal agencies, Congress, and international organizations. Our activities are based on the best available science, which informs the positions we take and the messages we promote. CSPI does not receive any funding from industry or the federal government. That policy is important because it eliminates any real or perceived conflicts of interest when we

advocate for new government policies or corporate practices. Our funding primarily comes from individuals who subscribe to our newsletter or make individual contributions. We also receive some funding from independent philanthropic foundations.

CSPI addresses scientific concerns, government policies, and corporate practices pertaining to GE plants and animals that are released into the environment or that end up in our foods. The Biotechnology Project's goals are to:

- Educate policymakers, media, interested stakeholders, and the public about the benefits and risks associated with GE crops and animals;
- Advocate for strong, but not stifling, federal regulation that ensures safety to humans and the environment; and
- Provide expertise to help developing countries establish their own biosafety regulations and make science-based decisions about adopting GE crops.

CSPI has long advised consumers, journalists, and policymakers that foods and ingredients made from currently grown GE crops are safe to eat. That conclusion is consistent with similar conclusions made by numerous international and scientific bodies, including the FDA, the National Academy of Sciences, the Food and Agriculture Organization, and others. The current GE crops also have provided tremendous benefits to farmers and the environment in both the United States and around the world. However, actions by developers selling GE seeds and by farmers growing GE crops have led to the highly troublesome development of insects and weeds that are resistant to pesticides used by many farmers. GE crops could be used sustainably but instead they have been overused and misused, leading to disruption of the environment and opposition by consumers.

CSPI has advocated for improvements in current federal oversight to ensure safety to humans, animals, the environment, and agriculture. The three federal agencies that regulate GE crops are FDA, USDA, and the Environmental Protection Agency (EPA). While CSPI has identified problems or inadequacies with how each agency oversees GE crops and ensures their safe use, I will limit my testimony today to the federal government's oversight of food and feed safety issues, which are the primary responsibility of FDA and directly related to this hearing.

By way of background, FDA ensures the safety of foods under the Federal Food, Drug and Cosmetic Act (FFDCA). Under that law, FDA has established a "voluntary consultation" process whereby developers of GE seeds can provide FDA with safety data and their analysis of those data to show FDA that the GE crop is "substantially equivalent" to the conventional traditionally-bred counterparts. FDA set up that consultation process because it has held that GE crops are not "food additives," which undergo pre-market approval, but instead fall within the FFDCA's category of foods that are "generally recognized as safe." Neither FDA nor CSPI is aware of any commercially grown GE food crop that has not completed FDA's voluntary consultation process. When the FDA consultation process is completed for a particular GE crop, FDA responds to the seed developer by stating in a letter that FDA has "no further questions" about the developer's determination that the GE crop is substantially equivalent to its conventional counterpart. FDA never provides its own opinion or conclusion about the safety of that GE crop.

CSPI believes that FDA *should* determine the safety of all GE food crops before foods from those crops enter our food supply. FDA should review the safety data submitted by

the developer, conduct its own analysis of those data, and provide the developer and the public with its opinion of whether foods from that GE crop are safe to eat by humans and animals. That new regulatory process would further ensure safety of future crops and allay consumer concerns about biotechnology. It is also consistent with how most other countries ensure the food safety of GE crops. Therefore, CSPI has long advocated that Congress pass legislation that would require an FDA pre-market approval process for all GE food crops.

Congressman Pompeo's bill, H.R. 1599, only goes a small step toward what we believe should be the proper role for FDA to ensure the safety of GE crops and the foods made from them. Title I of H.R. 1599 would codify the current FDA voluntary consultation process and give FDA 180 days to respond with its "no further questions" letter to the seed developer or the marketer of foods made from a GE food crop. The standard that FDA would use to carry out the notification process is whether the GE crops is "as safe for humans and animals … as comparable marketed food," which is meant to be identical to the current "substantially equivalence" standard. If FDA does not send the required letter in the proposed time frame, FDA is automatically deemed to have "no further questions" about the notifier's own safety determination.

CSPI cannot endorse H. 1599, because it does not establish a mandatory pre-market approval process at FDA. Most importantly, H.R. 1599 does not require FDA to determine if the GE food crop meets the safety standard and provide its opinion on each particular GE crops' safety. In addition, it does not put the burden of proof on the notifier to satisfy FDA that the GE food crop or foods and ingredients made from that crop are safe before

marketing the GE crop. There is no automatic violation of the FFDCA if the GE crop, and food or ingredients from those crops, enter the food supply without an FDA finding that the GE crop is safe. Instead, H.R. 1599 does not alter the current law, which places the burden on FDA to show that the GE crop and foods made from it might be "adulterated" to get those potentially unsafe foods taken off the market.

Additional changes to H.R. 1599 are needed to establish an FDA oversight process that both ensures safety and gives consumers confidence that FDA is protecting the food supply from any unsafe GE crops. H.R. 1599 exempts GE crops where the "modification could not otherwise be obtained using conventional breeding techniques." That provision could be interpreted to exclude two GE crops that recently completed the FDA voluntary consultation process -- the GE non-browning apple and the GE non-bruising and low acrylamide potato -- because they conceivably could have been developed with non-GE methods, such as breeding or chemical mutagenesis.

Also, H.R. 1599 only covers GE crops intended for a food use. It would not require notification about GE food crops that produce pharmaceutical or industrial compounds, such as Syngenta's Enogen corn. That is a GE crop that has been engineered to produce an enzyme useful for corn ethanol production, but it could have serious quality impacts if mixed with corn used to produce certain food products.

Finally, H.R. 1599 does not establish a regulatory process that is transparent and participatory. FDA would not be required to provide the public with an opportunity to comment before it concludes its review. FDA would only need to make the notification public after the 180-day period has ended and it has issued a "no further questions" letter.

Therefore, H.R. 1599 does not establish the independent safety review that would give American consumers confidence that foods and ingredients from GE crops are safe to eat.

The recently announced "Amendment in the Nature of a Substitute to H.R. 1599" (Amendment), does not correct the major deficiencies identified above and does not grant FDA any new legal authority to ensure that GE food crops are safe. The Amendment no longer amends the FFDCA to make the current voluntary consultation process "mandatory." Instead, it amends the Plant Protection Act to state that a GE crop that has been granted "nonregulated" status under USDA regulations found at 7 CFR Part 340 cannot be marketed in interstate commerce until USDA has received from the developer the "no further questions" letter it received from FDA. FDA still would not need to make its own independent determination that the GE food crop meets the safety standard, and the Amendment does not provide FDA with the needed authority to prevent foods or ingredients from a GE crop from entering the food supply until the notifier satisfies FDA of their safety. Instead, GE food crops and ingredients from the notifier could continue to enter the food supply without FDA assuring the public of their safety.

The Amendment does mandate that all GE food crops and foods made from them must complete the FDA "no further questions" consultation process. However, foods and ingredients that came from GE food crops grown *outside* the United States are not subject to 7 CFR Part 340 and would not be subject to FDA enforcement if they did not complete the notification process.

Finally, as the Amendment is written, it is unclear whether GE plants that don't fall within USDA's regulations under 7 CFR Part 340 would need to complete the FDA

notification process. USDA has recently stated on numerous occasions that its Part 340 regulations do not apply to all GE crops but only those with potential "plant pest" concerns. GE food crops produced with the gene gun instead of agrobacterium as the method of transformation might not fall within USDA's oversight. Similarly, GE food crops that don't involve any DNA from known plant pests are outside of USDA's oversight.

H.R. 1599 and the Amendment provide USDA's Agricultural Marketing Service with new legal authority to establish a certification and labeling system for food manufacturers who wish to label foods that either contain or do not contain ingredients from GE food crops. CSPI supports the federal government's oversight of GE and non-GE labels to ensure they are truthful, neutral, and non-misleading. Today consumers confront numerous different label claims about foods that don't have ingredients from GE crops. There is no standard definition of what it means to be "non-GMO," no standard way to describe the claim in a neutral manner, and no way for the consumer to know if the claim is accurate (i.e., that they are actually buying a food whose ingredients did not come from a GE crop).

The proposed genetic engineering certification and labeling system proposed by H.R. 1599 and the Amendment would be a good step forward. It would require USDA to establish a non-GMO labeling system with uniform definitions and verified label claims. While CSPI believes there is no benefit to consumers from avoiding foods that contain ingredients from GE crops, CSPI understands that some consumers do want to buy such foods. The system that would be implemented at USDA if Congress passed H.R. 1559 would go a long way toward uniform labels with verifiable, non-misleading claims. Therefore, CSPI does endorse that portion of the legislation.