



ONE SHIELDS AVENUE  
DAVIS, CALIFORNIA 95616.8521  
TELEPHONE: (530) 752.7946  
EMAIL: [alvaneennaam@ucdavis.edu](mailto:alvaneennaam@ucdavis.edu)

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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 10<sup>th</sup>, 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 113<sup>th</sup> 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)<sup>1</sup>. 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

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<sup>1</sup> 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, Ph.D.