

Section by Section Summary of Discussion Draft

Overview

This legislation would create a uniform, national program governing the premarket review and labeling of genetically engineered foods. First, it would require the Food and Drug Administration (FDA) to conduct a safety review of all new plant varieties used for genetically engineered food before those foods are introduced into commerce. Second, the legislation would create a new legal framework, subject to FDA oversight, governing the use of label claims regarding either the absence of, or use of, genetically engineered food or food ingredients. The legislation would also require FDA to develop Federal definition for “natural” claims on product labels. Given this new legal framework, states would be precluded from imposing any requirements that are not identical to these Federal requirements.

TITLE I – Bioengineered Food

Section 101. Definitions.

The term “bioengineered food” is defined to mean a food developed through recombinant deoxyribonucleic acid (DNA) technology. A food is not a bioengineered food solely because it was produced with a bioengineered processing aid or enzyme. The terms “bioengineering” or “bioengineered” are defined to mean the process described above as applied to food.

Section 102. Notification Program for Preclearance of Bioengineered Food that is a Plant or Derived from a Plant.

This provision would add a new section to the Federal Food, Drug, and Cosmetic Act (FFDCA) creating a mandatory premarket notification program for bioengineered foods. It would require that a developer of a plant-based bioengineered food submit a premarket notification to the FDA before marketing the food, explaining the developer’s basis for determining the bioengineered food was as safe as a comparable traditional food. Premarket notification must be submitted 120 days before bioengineered food is delivered into the marketplace. Those bioengineered foods that were approved through the voluntary consultation process prior to this legislation being enacted would be grandfathered in. The bill would also provide for informal consultations with the Secretary prior to submitting a premarketed notification. The mandatory consultation process would be as follows: within 30 days, FDA would be required to issue a preliminary response in writing to notify the developer that 1) the notification is complete and has been filed or 2) the notification is incomplete and specify the additional information required prior to filing. The FDA would have 90 days to review the notification and state whether the agency objects to the developer’s determination. The FDA also would have the option to extend the review period by 90 days, not more than once. The developer would have the option to withdraw the notification at any time prior to a determination by FDA. If FDA responds it has no objections, the developer may market the food.

As part of the review process, FDA may specify any special labeling the agency believes is necessary to protect health and safety or to prevent the label of the bioengineered food from being false or misleading, based on any material difference between the bioengineered food and the comparable traditional food. The use of bioengineering does not, by itself, constitute a material difference.

The premarket notification and the agency's response would be made publicly available. The Secretary may issue any regulations or guidance that may be necessary to implement this program. The provisions of this section would apply 30 days after enactment, regardless of whether regulations and guidance have been issued. These procedures would largely codify a preexisting voluntary consultation process currently used by FDA.

Section 103. Labeling of Whether Food is Bioengineered

This section would create a new Federal legal framework for labeling related to bioengineered foods. It would allow manufacturers to voluntarily make claims about the absence of bioengineered ingredients if the manufacturer has in place a traceability program to ensure bioengineered food is not commingled with the non-bioengineered food at any stage of production from farm to retail, while making allowances for unavoidable, inadvertent cross contact with bioengineered foods. The claim could be made on dairy products derived from cows and other milk-producing animals that consumed feed or a feed ingredient or received a drug or biological product that was developed through biotechnology and has been authorized for such use by the Secretary. The claim may also be made on a food produced with a bioengineered processing aid or enzyme. To avoid misleading consumers, claims regarding bioengineering would not be permitted to state or imply that a food is more or less safe solely because of the use or absence of bioengineered food. The provision would also authorize FDA to develop regulations for the voluntary labeling of the presence of bioengineered ingredients in food products. As under the mandatory notification program, FDA would have the authority to mandate special labeling to address any material difference that could affect health and safety or cause consumer deception. The regulations under this section shall not prevent a person from a) disclosing voluntarily on the labeling of bioengineered food the manner in which the food has been modified to express traits or characteristics that differ from its comparable marketed food or 2) from disclosing in advertisements, on the Internet, in response to consumer inquiries, or on other communications that a food is or contains an ingredient derived through the use of biotechnology.

Section 104. Preemption.

Consistent with other labeling sections in this FFDCA, this section would preempt any state labeling laws that are not identical to the Federal program.

Title II – Natural Foods

Section 201. Labeling of Natural Foods

This section would direct FDA to develop a federal definition of the term “natural” for use on food packaging. This definition would apply to those foods labeled “100% natural,” “naturally grown,” “all natural,” “contains ‘no artificial ingredients,’” “nothing artificial,” and other terms identified/defined by the Secretary.

Section 202. Regulations

Within 12 months of the date of enactment of the legislation, the Secretary would issue proposed regulations to implement this section and a final rule would be issued within 36 months.

Section 203. Preemption

Consistent with other labeling sections in this FFDCA, this section would preempt any state definitions of the term “natural” that are not identical to the Federal definition.

Ensuring Safe and Affordable Food for American Families

The American food industry has led the world in healthy and plentiful food production for generations. Over the last two decades, the food industry has used genetically modified (GM) technology to produce more nutritious food at lower cost for consumers across the country. GM technology improves crops and reduces the use of chemicals, while lowering costs for the American people by as much as 30%. Today, up to 80% of the nation's food products include GM ingredients.

The American food industry is committed to providing consumers with choices to fit their tastes, dietary preferences and requirements and budgets, as well as with important information to help make those choices. The U.S. Food and Drug Administration (FDA) currently sets national standards for food labeling based on sound science and extensive review. Some groups are attempting to create a system of conflicting state-based labeling requirements for GM foods, which would create confusion, reduce choices and increase costs for consumers.

When it comes to genetically modified food ingredients, the food and beverage industry is;

- 1) Committed to providing consumers with an abundant supply of safe, nutritious and affordable food.
- 2) Committed to the use of safe agricultural biotechnology that helps feed billions of people in the U.S. and around the globe, while preserving our natural resources.
- 3) Committed to an open dialogue with consumers about GM technology that will advance their knowledge, understanding and support of the technology.
- 4) Committed to responsible nationwide public policies that will protect consumers and facilitate informed consumer choices by providing them a single, federal framework for regulating the use and labeling of genetically modified food ingredients.

Healthier Foods at Lower Cost

For nearly twenty years, farmers and food manufacturers have used GM technology to add desirable traits from one plant to another, without introducing anything unnatural or using chemicals. As a result crops are more plentiful and potentially more nutritious.

Today nearly 80% of the food we eat is produced with GM ingredients, lowering costs for consumers up to 30%. These technological advances allow farmers and food and beverage companies to continue to provide consumers with safe, cost-effective and high quality food choices.

According to the U.S. Food and Drug Administration (FDA), and a number of US regulatory agencies that study and monitor food safety, GM foods and ingredients are safe and pose no health risks. Numerous scientific bodies and health groups, such as the World Health

Organization, the American Medical Association and the National Academy of Science, have concluded that food and beverages containing GM ingredients are materially no different than foods without them.

Protecting Consumers' Health and Safety: Building on the Strong Foundation

Consumers should be armed with the information they need to make their own food choices. That's why the U.S. Food and Drug Administration (FDA) currently provides a comprehensive federal framework for food labeling that uses sound science to give consumers the best information about the safety, composition and nutritional aspects of food products. This labeling policy has served consumers well by providing them with straightforward and meaningful information to make safe and healthful food choices.

Currently, FDA does not require foods to be labeled as having been produced with GM technology because it has found that there is no health risk associated with GM foods or any material difference between GM and non-GM foods at all. However, over the past several years, some groups have put forward ballot initiatives and legislation to require special labels for products containing these ingredients. Last year, California voters rejected a ballot measure (Proposition 37) that would have imposed a mandatory label. Voters in Washington will consider a similar measure this year, and efforts are underway to put a labeling measure on the ballot in Oregon in 2014. Connecticut recently passed labeling legislation, and efforts are being considered in neighboring states.

These state-based labeling initiatives – which only mislead consumers into thinking foods produced using GM technology pose a health risk or are different than what's been on their shelves for the last 20 years – would create an unnecessary state patchwork of conflicting labeling requirements which would snarl inter-state commerce and create confusion, reduce choices and increase costs for consumers.

Bolstering Consumer Confidence in the Food Supply by Establishing a New, Single Federal Framework for Regulating the Use and Labeling of GM Technology

To establish a responsible federal policy framework that will protect consumers and facilitate informed consumer choices, as well as guard against a costly, unnecessary and inefficient state-by-state system, federal legislation is needed that will provide for a series of regulatory measures that will allow farmers, processors, food and beverage manufacturers and everyone in between to use GM technology to produce safe, abundant and affordable food.

Specifically, legislation is needed that would address the following principles:

- **Mandate FDA Safety Reviews:** Ensure consumers are protected by requiring the U.S. Food and Drug Administration (FDA) to conduct a pre-market safety review of all new GM technology to guarantee they are safe for use in food. This will be done through FDA mandatory consultations in the existing USDA framework

- **Require Federal GMO Labeling for Safety:** Directs FDA to mandate a label on any product that contains ingredients derived from genetically engineered plants if those ingredients present any health or safety risks
- **Create a National Standard for Voluntary Labels:** The legislation should direct the FDA to mandate labels on products containing a GMO ingredient only if it is determined that the ingredient presents a health or safety risk.
 - In addition, the legislation should direct FDA to develop a new, uniform national framework to support voluntary “GMO-Free” labeling. FDA would develop a certification and verification process to support this requirement, which would also apply to any companies that want to voluntarily label their products for the presence of GM ingredients.

This action will ensure consumers have consistent information that will allow them to make informed decisions when they shop, and it will prevent confusion that can be caused by conflicting state standards.

- **Increase Transparency:** Increase transparency and avoid consumer confusion by creating a consistent federal definition for “natural” claims on product labels.
- **Prevent Consumer Confusion:** Prevent consumer confusion that would be caused by conflicting state standards, and better protect consumers by creating a new uniform national legal framework. This will ensure consumers receive consistent information based on sound science by precluding states from imposing any labeling requirements that are not identical to Federal requirements standards.