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RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

June 16, 2015

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing entitled "A National Framework for the Review and Labeling of Biotechnology in Food"

The Subcommittee on Health will hold a hearing on Thursday, June 18, at 10:00 a.m. in room 2123 of the Rayburn House Office Building, entitled "A National Framework for the Review and Labeling of Biotechnology in Food."

I. BACKGROUND

The hearing will cover some of the same issues that were taken up by the subcommittee on December 10, 2014, at an oversight and legislative hearing, entitled "Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients." Additionally, at this hearing the subcommittee will discuss an amendment in the nature of a substitute (AINS) to H.R. 1599, the Safe and Accurate Food Labeling Act, introduced by Rep. Mike Pompeo (R-KS) and Rep. G.K. Butterfield (D-NC). A prior version of this legislative measure bearing the same title and numbered as H.R. 4432 was introduced in the 113th Congress, and aspects of that bill were discussed in detail at the December 10th hearing.

This hearing memorandum provides an overview of the regulation of genetically engineered (GE) plants and food and feed from those plants, and of H.R. 1599 and the AINS. For a more detailed discussion of genetic engineering and regulatory oversight of GE plants and their foods, see the December 9, 2014, subcommittee memorandum.

II. WHAT IS GENETIC ENGINEERING?

Genetic engineering, also called bioengineering, employs recombinant DNA (rDNA) technology and other molecular biology techniques to produce biological products or to modify characteristics of plants, animals, or microbes by making changes in the DNA (or in the case of

some viruses, the RNA) of the organism. For example, through the use of various "cutting" and "pasting" enzymes, one can cut out DNA segments from one organism and paste (or "recombine") them into the genome of another organism. When successful, the recipient (recombinant) organism will then have new characteristics provided by the new genes brought in on the introduced DNA segment. Genetic modification is a term often loosely used to refer to genetic engineering, even though selecting for new traits through traditional plant and animal breeding are also forms of genetic modification --- albeit through less direct means.

III. USE OF GENETIC ENGINEERING IN FOOD AND AGRICULTURE

According to United States Department of Agriculture (USDA), 90 percent of corn, 94 percent of soy beans, 96 percent of cotton plants and 95 percent of sugar beets grown in the U.S. are genetically engineered.[1] The most common genetic modifications are to make the plants resistant to certain caterpillars[2] and/or to enable them to tolerate one or more herbicides. Most GE plants are grown as commodity crops and are used for animal feed, ingredients in processed foods, cooking oil, and industrial uses. For instance, less than one percent of corn grown in the U.S. is sweet corn, the type typically sold for eating as corn on the cob, and apparently little of that is genetically engineered.[3] One well-cited example of a GE food that is primarily consumed by humans is papaya. Some 80 percent of papaya grown in Hawaii is genetically engineered to be resistant to the ring spot virus.[4]

IV. REGULATORY OVERSIGHT OF GENETICALLY ENGINEERED PLANTS AND FOOD FROM SUCH PLANTS

A. FDA and EPA Testing and Review

[1] United States Department of Agriculture, *Adoption of Genetically Engineered Crops in the U.S.* (2014) (online at http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx); United States Department of Agriculture, *Sugar & Sweeteners* (2014) (online at http://www.ers.usda.gov/topics/crops/sugar-sweeteners/background.aspx).

[2] This is accomplished by introduction of genes from the soil bacterium *Bacillus thuringiensis* (Bt) which encode a protein that is toxic to certain types of caterpillars; the Bt bacteria are also registered as pesticides with EPA, one of the few pesticides allowed in organic farming. *See, e.g.,* University of California San Diego, *Bacillus thuringiensis* (online at http://www.bt.ucsd.edu/).

[3] Sonya Lunder, Environmental Working Group, *Most Corn on the Cob Isn't GMO* (Apr. 28, 2014) (online at http://www.ewg.org/enviroblog/2014/04/corn).

[4] Amy Harmor, The New York Times, *A Lonely Quest for Facts on Genetically Modified Crops* (Jan. 4, 2014) (online at http://www.nytimes.com/2014/01/05/us/on-hawaii-a-lonely-quest-for-facts-about-gmos.html?_r=1).

Since 1996,[5] GE plants intended for food or feed use have undergone a voluntary consultation process at FDA to determine whether food and feed derived from the plants pose any safety or regulatory issues different from those posed by foods and feeds from comparable non-GE plants. If the plant has not been engineered to contain a pesticide, this consists primarily of determining whether the newly introduced protein(s) in food from the plant are allergens or toxins, whether the levels of native toxins and anti-nutrients in food from the plant are within normal ranges, and whether the levels of significant native nutrients in food from the plant are within normal ranges. If the plant was engineered to contain a pesticide, the Environmental Protection Agency (EPA) does the food safety evaluation of the pesticide (referred to as a plant incorporated protectant, or PIP) through its mandatory pesticide registration process,[6] while FDA does all other aspects of the food safety evaluation.

If FDA finds that there are significant differences between food from the GE plant and food from a non-GE counterpart, it may require the food to be labeled to indicate how it is different from what consumers would expect. However, any such labeling would be limited to the "material" difference in the food, and would not include how such difference was created (i.e., FDA would not require that the food be labeled as GE).

At the end of the consultation process, if the FDA finds no scientific or regulatory issues warranting further investigation, it issues a letter to the company saying it has no further safety or regulatory questions about food and feed from the crop.

B. USDA Testing and Review

USDA's Animal and Plant Health Inspection Service (APHIS) conducts a regulatory process to determine whether a plant that is engineered using a segment of DNA from a plant pest poses a plant pest risk, and thus should be deemed a "regulated article." If APHIS determines that the plant does not pose such risk, APHIS issues a regulation stating that the plant is not a regulated article, and can be distributed and grown like any other agricultural plant. Before issuing that regulation, APHIS also conducts a review of any potential adverse environmental impacts that use of such plant might cause, consistent with requirements of the National Environmental Policy Act.

Finally, for those who want to avoid GE foods altogether, USDA's Agricultural Marketing Service (AMS) administers the National Organic Program, under which it certifies

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[5] FDA, *Consultation Procedures under FDA's 1992 Statement of Policy - Foods Derived from New Plant Varieties* (June 1996, revised October 1997) (online at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm096126.htm).

[6] EPA, *EPA's Regulation of Biotechnology for Use in Pest Management* (May 2014) (online at http://www.epa.gov/pesticides/biopesticides/reg_of_biotech/eparegofbiotech.htm); and EPA, *Plant Incorporated Protectants* (Jan. 2013) (online at http://www.epa.gov/pesticides/biopesticides/pips/index.htm).

foods as organic if they meet specified criteria. Their criteria for organic foods includes the non-use of genetically modified organisms.[7]

V. RIGHT TO KNOW GE LABELING

Advocates in favor of mandatory "right to know" labeling have petitioned FDA to require such labeling, arguing that the agency should consider as material information any "change in food at the atomic, molecular, or genetic level that a significant share of consumers would find relevant to their purchasing decisions."[8] They are also working on state referenda that would impose mandatory labeling requirements within individual states.

Labeling initiatives have been on the ballot in California, Washington, Oregon, and Colorado, but all have failed. Additionally, three states have passed right to know legislation, Maine, Connecticut, and Vermont. The Maine and Connecticut laws do not go into effect unless surrounding states pass comparable legislation. Vermont's labeling law goes into effect in July 2016, if it survives legal challenge.[9]

There are many arguments for and against such right-to-know initiatives:

- Proponents of mandatory labeling argue that consumers have a right to know what is in their food.
    - Opponents argue that those who want to avoid GE foods can buy foods labeled as organic or non-GE, and that a GE label would provide little information because some 75 percent-80 percent of packaged multi-ingredient foods would have to be labeled, except for those already labeled as organic or non-GE.

- Proponents argue that most polls show over 90 percent of consumers want GE labeling.
    - Opponents argue that polling can be misleading, and that when consumers are asked what information they want on a label, very few mention information about genetic engineering.

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[7] United States Department of Agriculture, *National Organic Program* (2013) (online at http://www.ams.usda.gov/AMSv1.0/NOPOrganicStandards).

[8] *See, e.g.*, Center for Food Safety, CFS Legal Petition to Label GE Foods (online at http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/the-cfs-legal-petition-to-label-genetically-engineered-foods#).

[9] Food Safety News, *Judge: Vermont's GMO-Labeling Law and Industry Lawsuit Can Both Proceed* (April 29, 2015) (online at http://www.foodsafetynews.com/2015/04/judge-vermonts-plans-for-gmo-labeling-law-and-industry-lawsuit-can-both-proceed/#.VX7cNPlVijs).

- Proponents argue that mandatory GE labeling would cost very little, just the cost of paper and ink.
    - Opponents argue that it would lead to a shift in use of GE crops and would require channeling and segregation of GE and non-GE crops, with significant added costs to farmers and food manufacturers.

VI. H.R.1599, THE SAFE AND ACCURATE FOOD LABELING ACT OF 2015

H.R. 1599 covers food from bioengineered organisms. It defines bioengineered organisms as plants modified using recombinant DNA techniques, in which the modification could not have been achieved through conventional breeding techniques.

The bill would convert FDA's voluntary consultation process into a mandatory notification process, with newly specified procedures and deadlines. Most notably, 180 days after FDA responded to a notifier that the notification submission was complete, the product could go on the market unless FDA sent a written response to the notifier identifying why FDA determined that the notification submission did not support the notifier's claim that the food was as safe as comparable non-bioengineered food. It would require FDA to list all completed notifications on its website (something FDA already does).

The bill also would amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to prohibit voluntary labeling that stated or implied that the use or non-use of bioengineering made a food safer, and would prohibit states and local governments from imposing any additional restrictions on sales, distribution, or marketing of bioengineered plants or their foods and from requiring labeling pertaining to whether a food contained ingredients from bioengineered plants.

It would require that a voluntary labeling claim that a food was not made using bioengineering may only be made if the food's ingredients were subject to supply chain process controls aimed at keeping them separate from bioengineered plants and materials. It states that the inadvertent presence of bioengineered material in a food does not preclude the food from being labelled as non-bioengineered. FDA must promulgate regulations specifying the maximum permissible level of such inadvertently present bioengineered material in a food labeled as non-bioengineered. It also states that eggs and dairy products from animals fed with bioengineered feed or treated with bioengineered drugs are not precluded from being labeled as non-bioengineered.

The bill also would require FDA to issue, within two years of the bill's enactment, a final regulation defining the term "natural."

VII. AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 1599

The AINS uses the term "GE plant" rather than "bioengineered organism." It does not make any changes to the existing FDA voluntary consultation process. However, it effectively turns it into a mandatory program by making it a prohibited act under the Plant Protection Act to market a GE plant, or food from a GE plant, unless USDA has received documentation that the food had successfully completed the FDA consultation process. It would require USDA to

maintain a website registry containing all submissions to USDA and FDA for GE plants found to be non-regulated articles, and the USDA and FDA findings regarding those submissions.

The AINS retains H.R. 1599's restrictions and prohibitions regarding GE food labeling, but would require USDA to promulgate regulations to establish conditions under which a food can be labeled as made with or without the use of genetic engineering. It does not state, however, that eggs and dairy from animals fed with GE food or treated with GE drugs may be labeled as non-GE. The AINS retains the USDA non-GE food certification program.

The bill does not require FDA or USDA to define the term "natural."

VIII. WITNESSES

Todd W. Daloz, JD
Assistant Attorney General
Office of the Vermont Attorney General

Gregory Jaffe, JD
Biotechnology Project Director
Center for Science in the Public Interest

Rick Blagden
President and Chief Executive Officer
Council of Supply Chain Management Professionals

John Reifsteck
Chairman of the Board and President
GROWMARK, Inc.

L. Val Giddings, Ph.D.
Senior Fellow
Information Technology & Innovation Foundation