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MANDATORY LABELING OF GENETICALLY MODIFIED FOOD

by

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INTRODUCTION

On July 19, 2016, legislation that would require the United States Department of Agriculture (USDA) to establish a nationwide standard for labeling bioengineered food and preempt states and local governments from requiring alternative labeling systems, was presented to President Barack Obama for his signature. Enactment of the legislation is likely to end one debate in Congress over the subject of genetically modified food labeling and Federal preemption over the subject, and begin a new debate within the USDA rule-making process and in the market.

Genetically modified organisms (GMOs) and the science describing how they work are complex and controversial subjects. This issue paper provides background on the history and science of the modification of plants to serve as food and the techniques used to develop new crop varieties. The paper then discusses the uses of genetically modified (GM) crops and the prevalence of those crops in the United States, and provides an overview of the current regulatory structure for GM crops within the U.S. Department of Agriculture, Environmental Protection Agency (EPA), and Food and Drug Administration (FDA). Finally, the paper summarizes various state laws that require the labeling of GM food, and the recently enrolled Federal legislation.

It should be noted that this paper deals generally with GM crops and not bioengineered animals for food. To the author's knowledge, only one genetically engineered animal (a salmon) has been approved in the United States. Thus, the law predominantly affects GM crop development, production, and sales, although there have been recent developments with bioengineered animals and the FDA has released relatively new guidance on the subject. As a result, crop predominance in the arena of GM food could change in the future.

GENETICALLY MODIFIED ORGANISMS

The History and Science of GMOs

Modification of plant species for useful purposes has been employed by civilizations for at least 10,000 years. The first methods of genetic modification were passive, by means of unconscious selection (as opposed to selective breeding). Early human civilizations relied on hunting and gathering. Plants that tended to be nontoxic, easy to harvest, and better tasting were consumed more frequently, and the seeds for those plants were more widely distributed through waste, compared to other plants that did not lend themselves to gathering and consumption. As plant cultivation began, unconscious selection likely continued to play a role. For example, wild wheats evolved brittle ears that shatter when disturbed, which allows their seeds to disburse and propagate.[i] Random mutations cause the wheat ears to remain intact when disturbed. Ancient farmers harvesting wheat would have unconsciously selected wheat plants with the mutation as their seeds were easier to harvest. Those seeds would have been used in the next crop, and the process would have repeated itself. Eventually, the selection process became conscious and early farmers selected plants for various traits. Early selection, conscious and unconscious, likely resulted in such crops as cereals, tomatoes, and carrots.[ii]

With Charles Darwin's development of the theory of evolution and Gregor Mendel's discovery of the rules of heredity in the mid- to late-1800s, a more nuanced understanding of genetics and plant breeding began to take shape. Subsequent developments in genetics were used to deliberately change the expression of certain traits in plants. Random mutations occur infrequently in nature, so techniques such as exposure to ionizing radiation or chemicals were used to accelerate mutagenesis (the process by which stable mutations occur) in plants. The

plants exposed to those techniques then were screened for useful traits and used for subsequent experimentation or breeding. These early techniques resulted in the development of several varieties of rice, wheat, and barley, as well as the Ruby Sweet grapefruit.[iii] Researchers also began culturing plant tissues in the early 1900s.[iv] A tissue culture allows researchers to grow, maintain, and manipulate cells and tissues in the laboratory. Through the first half of the 20th century, techniques were refined to the extent that, by the 1970s, single plant cells could be manipulated and then grown to create whole plants routinely.

The function of deoxyribonucleic acid (DNA) as a carrier of genetic information was known as early as the late-1920s. In 1953, Francis Crick and James Watson published the first articles describing DNA, for which they would win the 1962 Nobel Prize for medicine. In 1968, Robert Holley, Har Gobind Khorana, and Marshall Nirenberg were awarded the Nobel Prize in Physiology or Medicine for explaining the synthesis of proteins and deciphering the genetic code. The birth of genetic engineering, however, occurred in 1973 when a team of researchers published a paper describing the successful construction of a functional bacterial plasmid in vitro.[1] A plasmid is a small DNA structure that can replicate independently of a chromosome. Stanley Cohen, et al., used DNA-"cutting" enzymes called restriction endonucleases to cut gene sequences from separate plasmids, reassembled them, and inserted them into *Escherichia coli* (bacteria found in the environment and intestines of people and animals).[v] With this development, and the ability to manipulate single cells in vitro, it became possible to genetically engineer plants from individual cells.

Early genetic engineering of plants required the use of plant pathogens such as *Agrobacterium tumefaciens*, the causal organism for crown gall disease (a common plant disease that forms tumors or "galls" on the plant). As early as the 1940s, it was discovered that plant tumor cells retained tumor-like properties in the absence of *A. tumefaciens*.[vi] Researchers discovered in the 1970s that *A. tumefaciens* transfers DNA from a plasmid that contains tumor-causing genes into its host, causing a permanent genetic change in the host plant. Scientists developed the first genetically engineered plants by removing the disease-causing genes on the tumor-inducing plasmid and replacing them with other genes. Subsequent research has shown that most plants can be transformed using *Agrobacterium*-mediated transformation; however, its effectiveness varies depending on the plant.[vii]

Genetic engineering in plants from the 1980s into the 21st century has relied on four main technologies: recombinant DNA technology (combining DNA sequences through various sources and techniques, such as molecular cloning, to develop new DNA sequences), plant tissue culture, *Agrobacterium*-mediated transformation, and the gene gun. The gene gun (also known as microprojectile bombardment or biolistics) was developed in the mid-1980s as a means to transform plants resistant to *Agrobacterium*-mediated transformation.[viii] The technique involves accelerating microscopic particles (usually gold or tungsten) coated with many copies of the desired gene through a vacuum to pierce plant cells in a tissue culture for transformation.

More recent advances in molecular biology, biochemistry, and genetics have blurred the distinction between plant breeding and genetic engineering. Past efforts at plant breeding focused on selection of plants with the necessary physical characteristics without an examination of their genetic composition. Thus, plants had to be grown, sometimes for years, in order to determine

[1] "In vitro" means "in glass", and is used as a general term for a survey or procedure performed outside its normal biological context, for example, in a test tube or a Petri dish. This is contrasted with "in vivo" ("within the living") procedures, which occur within a living organism or within organisms in a natural setting.

whether the plants had the desired traits. With advances in molecular biology came the development of techniques that allowed breeders to screen for plants for desired genes through tissue cultures. Other current and future tools and techniques for genetic engineering include, for example, up- or down-regulation or silencing of genes to produce new traits, gene editing, synthetic chromosomes, and greater knowledge of specialized areas of molecular biology referred to as "-omics": genomics, proteomics, transcriptomics, metabolomics, and epigenomics (the studies of an organism's entire complement of genes, proteins, messenger ribonucleic acids (mRNAs), metabolites, and non-DNA compounds attached to or associated with DNA, respectively). All of these involve complex concepts of biochemistry and molecular biology, a detailed discussion of which is beyond the scope of this paper.

Use of GM Products

Researchers recognized early on that, given an understanding of the genes and pathways responsible, organisms could be engineered for a variety of biotic factors (of or relating to living or once-living organisms) and abiotic factors (nonliving physical or chemical elements), for such purposes as resistance to pathogens and tolerance to drought, respectively. Commercial genetic engineering of plants began in the 1980s. In 1988, a company received approval to field test a variety of tomato called the FLAVR SAVR, a tomato engineered for late ripening.[ix] By 1994, the FLAVR SAVR tomato would be the first crop grown for commercial sale. Monsanto received approval to field test soybeans resistant to glyphosate, an herbicide also sold by Monsanto under the name Roundup. Roundup Ready soybeans were first sold in the United States in 1996.[x]

Among the developed nations, the United States has the most permissive regulatory structure for GM research, introduction, and production. Accordingly, GM crops have achieved significant market penetration in U.S. crops. Of the 14 GM crops in global commercial production in 2015, 10 were grown in the United States.[xi] These included corn, soybeans, cotton, apples, alfalfa, papayas, potatoes, squash, canola, and sugar beets. In 2014, approximately half of U.S. cropland was planted with GM crops.[xii] The most commonly genetically engineered food crops are corn and soybeans. According to the USDA's National Agricultural Statistics Service, 88% of corn plantings and 93% of soybean plantings in 2012 were GE crops.[xiii] Most of these have been engineered for resistance to one or more herbicides, resistance to one or more insect pests, or some combination of these.

One of the most common traits engineered into present crops is insect resistance by a plant-incorporated protectant. Many organisms contain proteins or compounds that create a natural defense against insect pests. When the genes for the synthesis of these compounds or proteins are incorporated into the genome of a plant, the result is a variety of the plant that is capable of expressing the protein or chemical itself. This technology has been used to create a number of insect-resistant plants. One of the most common of these is a loose family of crops referred to as *Bt* crops. These crops, varieties of corn, potatoes, and cotton, express genes for the *Bt* toxin, a protein naturally synthesized by a bacterium, *Bacillus thuringiensis*. The *Bt* toxin, when consumed by a target organism, affects the gut cells and paralyzes the digestive system, causing starvation and death.[xiv] These proteins have been used in agriculture for over 50 years, and are used commonly in organic farming in the form of powders and sprays.[xv] Since the toxin must be eaten to be effective, *Bt* applied to the plant will not affect root or borer insects. When the genes for the toxin are incorporated into the genome of a crop plant, the toxin is expressed throughout the plant.

Crops in the research and development pipeline have been or could be engineered with a plethora of traits. One example is so-called golden rice, a variety of rice engineered to produce beta-carotene (a precursor for vitamin A).[xvi] Consumption of golden rice could be an effective means

of eliminating vitamin A deficiencies in regions where dietary vitamin A is unavailable. Another crop under development is a *Phytophthora infestans*-resistant potato. This species of fungus was the causal organism responsible for the Irish potato famine, and remains an economically significant pathogen of potatoes and tomatoes, costing approximately $6.0 billion per year.[xvii]

CURRENT REGULATION OF GM FOOD

Countries have developed diverse regulatory approaches to agricultural genetic engineering. These approaches have generally been categorized as promotional, permissive, precautionary, or preventative.[xviii] International regulation of GM food and the regulations of other nations are expansive topics beyond the scope of this paper; this work concerns only the laws and regulations of the United States and individual states.

The regulatory policy for GE crops in the United States was established in 1986 through the Coordinated Framework for the Regulation of Biotechnology (CFRB).[xix] The CFRB stated that products created through genetic engineering or other biotechnology would be regulated under the current law and in the manner applicable to similar products already regulated. As such, regulation of GMO crops is divided between the Environmental Protection Agency (pesticides), the Food and Drug Administration (GMOs in food, drugs, or biological products), and the U.S. Department of Agriculture (importation, planting, or transportation of plant GMOs and field testing of such products). A crop might be regulated by one or more of these agencies at any given point.

Environmental Protection Agency

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prohibits the sale or distribution of an unregistered pesticide.[xx] The EPA's jurisdiction under FIFRA covers a genetically engineered product, i.e., the engineered plant or substances produced by the plant, when the effect of product is pesticidal. Before a pesticide can sold or used, FIFRA requires the EPA to evaluate the pesticide for safety of human health and the environment; this requirement also applies to plant-incorporated protectants (PIPs).[xxi] These requirements typically involve studies assessing the risk to human health, nontarget organisms, and the environment, as well as an evaluation of the potential for gene flow or migration (the transfer of genes from one population to another) and the need for an insect resistance management plan. According to the EPA, 12 PIP products have been registered with the EPA since 1995.[xxii]

To address the unique circumstances posed by PIPs, the EPA promulgated "PIP rules". Under the rules, the EPA's authority to regulate PIPs extends to pesticidal substances produced and the genetic material needed to produce them.[xxiii] Under FIFRA, the EPA may exempt certain pesticides from tolerance requirements if there is a low probability of risk to the environment and human health. The EPA sets forth the criteria for an exemption from FIFRA for PIPs in 40 CFR § 174.21, but requires a person who produces a PIP for sale and obtains information regarding adverse effects on human health or the environment to submit the information to the EPA.[xxiv]

Food and Drug Administration

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA is charged with the regulation of human and animal food (other than meat, poultry, and eggs), drugs, and biological products for the protection of public health. The FFDCA allows the FDA to regulate food additives and prohibits the sale of misbranded or adulterated food.[xxv] A substance added to food can be categorized in one of two ways: as a "food additive", which requires FDA approval before it can be marketed, or as a substance "generally recognized as safe" (GRAS), which requires no FDA approval before

it can be marketed.[xxvi] Current FDA policy is to treat GM food as presumptively GRAS. However, where the product differs significantly in structure, function, or composition from substances currently found in food, preapproval by the FDA is needed.

While most GM food is treated as presumptively GRAS, the FDA encourages developers to consult with it before marketing a crop and to share information that demonstrates that the food is safe. During the process, the FDA usually takes the opportunity to determine the existence of any added substances that might require premarket approval. The Administration does not make safety findings, but does issue a final letter indicating that it has no more questions. According to the FDA, it had completed 171 consultations with developers through March 2016 and no GE product evaluated under this voluntary standard was marketed without the developer's addressing all outstanding safety questions.[xxvii] According to the National Academies of Science's Committee on Genetically Engineered Crops: Past Experiences and Future Prospects, developers view the FDA's consultation as a requirement before marketing commences.

United States Department of Agriculture

The USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for regulating field testing of certain microorganisms and genetically engineered plants and preventing the spread of plant pests and noxious weeds, as required under the Plant Protection Act. This includes prohibiting or restricting the importation, exportation, or movement in interstate commerce of any regulated article if necessary to prevent introduction of a plant pest or noxious weed into the United States.[xxviii]

Under this authority, APHIS requires notice or a permit before genetically engineered plants with plant pest sequences can be tested or released into the environment. Notification allows introduction of a genetically engineered plant without a permit, and is available for plants not classified as noxious weeds, provided various criteria are met.[xxix] If notification is not allowed, then a developer must apply for a permit in order to release the article into the environment for testing. The permit application requires the applicant to disclose information pertaining to the organism, including the donor and recipient organisms, the molecular biology of the altered system, and processes to prevent contamination or release into the environment. If the permit is granted, the plant is subject to requirements intended to prevent release and to allow the USDA to maintain oversight.

The regulations, specifically 7 CFR § 340.6, allow a party to submit to the USDA a petition for determination of nonregulated status, which removes the genetically engineered product from APHIS oversight. This is appropriate for plants that have been demonstrated not to pose a risk. Once a petition is received, it is published in the Federal Register for public comment. The petition must be approved or denied within 180 days of receipt.

MANDATORY GMO LABELING PROPOSALS

State Legislative Action

Until recently, state and local laws played a minor role in the regulation of GMOs. This was likely because of Federal field preemption doctrine, which precludes state regulation when Congress intends that comprehensive Federal regulation should occupy an entire field. There have been exceptions to this general trend. For example, California has prohibited specific genetically modified animals (e.g., the GloFish) from being bought or sold within the state.[xxx] In the last few

years, however, individual state legislatures have introduced legislation that would impose labeling requirements on GM food.

In 2015, according to the National Conference of State Legislatures, 29 states considered nearly 100 bills or resolutions related to genetically modified organisms. Most of these items were state legislature resolutions urging the use of scientific data, or "sound science", to inform national mandatory labeling requirements. Between the 2013-2014 and 2015-2016 legislative sessions, the Michigan Legislature has considered three such resolutions.[xxxi] House Resolution 193, introduced in 2013, urged the FDA to require that GM foods be labeled accordingly; it was not adopted. In 2015, the Michigan Senate adopted Senate Resolution 59, which urges Congress to pass legislation establishing a uniform and science-based label program for GM food. A similar resolution introduced in the Michigan House of Representatives, House Resolution 89, also was adopted. In addition, in other states, there have been several measures brought to the ballot, including California's failed Proposition 37 in 2012. If approved, Proposition 37 would have required GM food sold at retail to be labeled as genetically engineered.

Some states have passed more substantive laws. In 2013, Connecticut enacted an "Act Concerning the Labeling of Genetically-Engineered Food".[xxxii] The Connecticut law provides that certain food intended for human consumption and seed or seed stock that is intended to produce food for human consumption that is, in whole or in part, genetically engineered must be labeled as "Produced with Genetic Engineering". The law was later amended to exempt alcoholic beverages, nonalcoholic malt beverages, food that is not packaged for retail sale and is meant for immediate consumption or sold in a restaurant, farm products sold at a farmers' market or roadside stand, and food derived from an animal that was not genetically engineered but might have been fed with GM food, or treated with genetically engineered drugs.

In 2014, Maine enacted an "Act to Protect Maine Food Consumers' Right to Know About Genetically Engineered Food and Seed Stock", which contains provisions that are similar to the Connecticut law, including similar exemptions.[xxxiii] Specifically, any genetically engineered food offered for sale 18 months after the law's effective date must be accompanied by a disclosure that the food was produced with genetic engineering. Such food may not be described or identified as "natural".

The Maine and Connecticut laws contain language under which the provisions of the respective statutes will not be enforced unless certain conditions are satisfied. In the case of the Connecticut law, the law will be effective on October 1 following the date that the Commissioner of Consumer Protection recognizes that a) four other states, including one bordering Connecticut, enact similar mandatory GM food labeling laws, and b) the combined population of states located in the northeast region of the United States that have enacted such a law exceeds 20.0 million based on 2010 census figures. The Maine law will take effect 30 days after the Commissioner of Agriculture, Conservation and Forestry certifies that similar legislation has been adopted by at least five contiguous states, including Maine. If, by January 1, 2018, the contingency has not been met, the Act will be repealed that day.

Vermont also has enacted legislation relating to GM food labeling.[xxxiv] As of July 1, 2016, food offered for sale by a retailer that is entirely or partially produced with genetic engineering must be labeled accordingly. The food must be labeled with the words "produced with genetic engineering", unless it is a processed food that contains a product or products of genetic engineering. Under those circumstances, the food must be labeled as "partially produced with genetic engineering", "may be produced with genetic engineering", or "produced with genetic engineering". The law prohibits a food manufacturer from labeling a food product produced with

genetic engineering from including words or phrases on the packaging such as "natural", "all natural", or similar words that "would have a tendency to mislead a consumer". Although the Vermont law took effect on July 1, 2016, the Attorney General of Vermont has stated that because some packaged food has longer shelf life, improperly labeled food offered for sale in Vermont is presumed to have been packaged and distributed to retailers before the law's effective date, and will be permitted to remain on the shelves until January 1, 2017, unless there is evidence that the food was distributed on or after July 1, 2016.[xxxv]

Proponents of such requirements contend that most people believe that GM food is unsafe, and want food labeled. According to an August 2015 article published by the Pew Research Center, 57% of U.S. adults believe that GM food is generally unsafe, and nearly two-thirds would support a labeling requirement for GM food.[xxxvi] Supporters of labeling requirements argue that consumers have a right to know what is in their food, and assert that a consumer needs the information provided in a label in order to make an informed decision about the products he or she purchases. Furthermore, proponents contend that if GMOs in food are safe, then there is no harm in labeling them as GM food.

Labeling opponents generally perceive labeling initiatives as an effort to remove GM food from the market in favor of more expensive organic food. Critics of mandatory labeling laws contend that mandatory labels only intensify a misconception that GM food is dangerous when nearly all scientific evidence demonstrates that the presence of GMOs in food is not harmful. Moreover, GM food supporters point to the benefits that current GM food has to farmers and consumers and the benefits that future GM products could have. Opponents of mandatory labeling laws claim that if consumers wish to avoid GMOs, the USDA has an organic certification process that virtually guarantees that the food certified was not grown with GMOs.

Federal Legislation

With states moving to enact GM food labeling proposals, many suggested that Congress should pass a preemptory uniform GM food labeling law. This approach was prioritized after enactment of the Vermont GM food labeling law. The recently enrolled legislation to preempt state GMO labeling laws is S. 764.[xxxvii] The bill, which is said to represent a compromise between Senator Debbie Stabenow (D-MI) and Senate Agriculture Committee Chairman Pat Roberts (R-KS), would amend the Agricultural Marketing Act to establish a national bioengineered food disclosure standard. The bill would require the USDA to establish standards for labeling food packages containing bioengineered food. The label would need to have a *manufacturer-selected* disclosure in the form of a text, symbol, or electronic or digital link, but excluding internet website Uniform Resource Locators not embedded in the link. The bill also would preempt the establishment or enforcement of current and future state and local labeling requirements for bioengineered food in interstate commerce unless they were identical to the standard adopted by the USDA. The bill would apply to food subject to labeling requirements under the FFDCA and, under certain circumstances, the Federal Meat Inspection Act, the Poultry Inspection Act, or the Egg Products Inspection Act.

Supporters of this legislation contend that the bill is a bipartisan compromise to create a national standard for labeling GE food, instead of a patchwork of state programs and plans that could interfere with the nationwide marketing of food. The proponents note that there is broad consensus that GM food is safe and that any label should be accessible, while not so conspicuous as to create a "scarlet letter" for GM food. Critics of the legislation oppose it for three main reasons. Several groups oppose the legislation because it would allow disclosures in whatever form a manufacturer selected, including a quick response (QR) code. A QR code requires a machine (for

example, a smartphone) to be read. Thus, individuals without smartphones or other technology would be unable to read the disclosure. This, critics contend, would discriminate against the poor or those without the technology to read the label. Others oppose the bill because of its mandatory nature; the U.S. House of Representatives passed a different bill that would create a voluntary labeling program (the Safe and Accurate Food Labeling Act described below). Finally, there is opposition to the legislation based on federalism/states' rights grounds, namely, that individual states should be able to pass laws to protect their residents and guarantee their access to food information.

On July 19, 2016, S. 764 was presented to President Barack Obama, who is believed to support the legislation as is, and is expected to sign it. Once signed, the state laws described above will be preempted. The USDA will have two years from the date of enactment to establish the standards and complete the rule-making process, which will likely attract considerable lobbying efforts by affected businesses and interest groups. Because GM food labeling is a very contentious issue, S. 764 may not be the last word on the subject. A change in administration or knowledge about GM food safety could encourage subsequent legislative efforts. Accordingly, some of the other bills introduced during the 114th Congress are summarized below. These include proposals to enact the Safe and Accurate Food Labeling Act, the Genetically Engineered Food Right-to-Know Act, and the Biotechnology Food Labeling Uniformity Act.

The Safe and Accurate Food Labeling Act (H.R. 1599) would amend the FFDCA to require the FDA to continue its voluntary consultation process with GMO developers. The FDA could require a GM food to have a label informing consumers about material differences between a GM food and a comparable food if the disclosure were necessary to prevent a label from misleading consumers or to protect public health and safety; however, the use of GMOs in the production of the food would not, by itself, constitute a material difference.

The bill also would amend the Plant Protection Act to allow the sale of GM food if the FDA had determined that the food was safe. The FDA would have to share such a determination with the USDA, which would have to publish a list of GMO plants that could be sold as food. The bill would preempt state and local requirements for GM food.

Finally, the bill would amend the Agricultural Marketing Act to require the Agricultural Marketing Service to create a national genetically engineered food certification program. This voluntary program would be implemented through accredited certifying agents, which could certify whether a covered product was produced with genetic engineering. The bill specifies standards for labeling and certifying GM and non-GM food, and would prohibit the establishment or enforcement of a state or local labeling program, unless it was voluntary and met other requirements.

The Genetically Engineered Food Right-to-Know Act (H.R. 913) would amend the FFDCA to specify that a food would be misbranded if it had been genetically engineered or contained genetically engineered ingredients, unless that information was disclosed. The prohibition would not apply to food served in restaurants, medical food, packaged food with minimal (less than 0.9%) genetically engineered material, or food classified as genetically engineered only because its production used a genetically engineered vaccine, processing aid, or enzyme. The bill also would prohibit labeling food containing genetically engineered material as “natural", or with similar words. Other provisions of the bill relate to when a person would not be subject to penalties for misbranding genetically engineered food.

The Biotechnology Food Labeling Uniformity Act (S. 2621) would amend the FFDCA to require food that contained a GM ingredient to be labeled as genetically engineered, and to preempt state

and local labeling requirements. A food would be exempt from the labeling requirement if the GM ingredient accounted for less than 0.9% of the food's weight. A food also would not be subject to the proposed requirement solely because a genetically engineered vaccine was used at any point in the production of the food, or the food was produced using a processing aid or enzyme that was produced from a GMO.

CONCLUSION

With the passage and expected enactment of S. 764, Congress has given a clear signal that it intends to preempt the states with regard to labeling requirements for GM food. Since most states, including Michigan, do not have a GM food labeling law to preempt, the impact on those states in the immediate future will be minimal. Assuming the bill is enacted, it remains to be seen what will happen when the rule-making process begins, as parties opposed to and in favor of GMOs lobby to shape the development of the labeling standards.

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[i] Daniel Zohary, et al., *Domestication of Plants in the Old World*, 4th Edition, p. 30, 2012.
[ii] National Academy of Sciences Committee on Genetically Engineered Crops: Past Experiences and Future Prospects, *Genetically Engineered Crops: Experiences and Prospects*, p. 41, 2016.
[iii] *Genetically Engineered Crops: Experiences and Prospects*, p. 42; "Texas Grapefruit History", TexaSweet Citrus Marketing, Inc. website.
[iv] *Genetically Engineered Crops: Experiences and Prospects*, p. 44.
[v] Stanley Cohen, et al., "Construction of Biologically Functional Bacterial Plasmids *In Vitro*", *Proc. Nat. Acad. Sci. USA*, November 1973.
[vi] *Genetically Engineered Crops: Experiences and Prospects*, p. 44.
[vii] *Id*. at 45.
[viii] *Id*.
[ix] *Id*.
[x] *Id*.
[xi] *Genetically Engineered Crops: Experiences and Prospects*, p. 46.
[xii].Jorge Fernandez-Cornejo, et al., "Genetically Engineered Crops in the United States", Economic Research Report No. 162, USDA-Economic Research Service, p. 9, 2014.
[xiii] "Biotechnology Frequently Asked Questions (FAQs)", United States Department of Agriculture.
[xiv] "*Bacillus thuringiensis*", University of California San Diego website; "Bt Corn: Health and the Environment", Colorado State University Extension.
[xv] "*Bacillus thuringiensis*", University of California San Diego website.
[xvi] *Genetically Engineered Crops: Experiences and Prospects*, pp. 151, 289.
[xvii] Erica Goss, et al., "The Irish potato famine pathogen *Phytophthora infestans* originated in central Mexico rather than the Andes", *PNAS*, Vol. 11: 24, p.1 (2014).
[xviii] *Genetically Engineered Crops: Experiences and Prospects*, p. 56.
[xix] *Id*. at 310.
[xx] 7 U.S.C. § 136a.
[xxi] *Id*.; 40 CFR § 174.1
[xxii] "EPA's Regulation of Biotechnology for Use in Pest Management", U.S. Environmental Protection Agency.
[xxiii] 40 CFR § 174.3.
[xxiv] 40 CFR § 174.71.
[xxv] 21 U.S.C. § 331.
[xxvi] 21 U.S.C. §§ 321(s) and 348.
[xxvii] *Genetically Engineered Crops: Experiences and Prospects*, p. 313.
[xxviii] 7 U.S.C §§ 7711-7712.
[xxix] 7 CFR § 340.3.
[xxx] Kenneth Weiss, "State Takes Dim View of GloFish, Bans Sale", *Los Angeles Times*, 12-4-2003.

[xxxi] House Resolution 193 (2013). Michigan House of Representative and Senate Resolutions are available at the Michigan Legislature website: www.legislature.mi.gov.
[xxxii] Connecticut General Statutes § 21a-92c.
[xxxiii] Maine Revised Statutes, Title 22, §§ 2591-2596.
[xxxiv] Vermont Statutes, Title 9, §§ 3041-3048.
[xxxv] "GE Food Labeling Rule", Office of the Attorney General, Vermont.
[xxxvi] Monica Anderson, "Amid debate over labeling GM foods, most Americans believe they're unsafe", Pew Research Center, 8-11-2015.
[xxxvii] S. 764, and the other bills introduced in the 114th Congress summarized in this article are available on the Congressional website: www.congress.gov.