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The Legal Basics of Genetically Modified Organisms and Organic Food Regulation

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Introduction

On July 1, 2016, a Vermont state law mandated labeling of food sold in Vermont that contains genetically modified ingredients. With this deadline looming, debate about the need for and content of a national GMO labeling law intensified. On July 14, 2016, the House of Representatives passed S.764 creating a framework to establish a National Bioengineered Food Standard. After it becomes effective, the law will immediately preempt the law of Vermont and all other state law "relating to the labeling or disclosure of whether food is bioengineered or was developed or produced using bioengineering." In the context of this ongoing debate, this chapter provides an introduction to the legal basics that govern the regulation of food containing GMOs and food that does not contain GMOs, a/k/a, organic food.

Genetically Modified Organisms (GMO) Regulation

Federal Regulation of GMOs

Federal regulation of "Genetically Modified Organisms" or "GMOs" is the most intensely debated issue in agriculture law today. Although the *status quo* will change in the future with respect to the labeling of bioengineered food, at the federal level GMOs will continue to be regulated pursuant to health, safety, and environmental legislation governing conventional products.

At the national level, GMOs are regulated in the United States under the Coordinated Framework for Regulation of Biotechnology, published in 1986, with a focus on the nature of the products rather than the process in which they are produced. The document concluded that foods made with genetic engineering techniques are not fundamentally different from conventional foods in terms of overall composition, so there was no need for legislation specifically dealing with GMO foods. Ultimately, the document established that regulation should focus on the nature of the final food product rather than the process by which the food product is made.

Several federal agencies play important regulatory roles within the Coordinated Framework for Regulation of Biotechnology. Plant GMOs are

regulated by the US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) under the Plant Protection Act (PPA).[1] GMOs in food, drugs, and biological products are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA)[2] and the Public Health Service Act.[3] GMO pesticides and microorganisms are regulated by the Environmental Protection Agency (EPA) pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)[4] and the Toxic Substances Control Act (TSCA).[5] The form of federal regulation varies depending on the type of GMO involved.

Legally, in the United States, there is little difference between how GMOs are treated and how other hybrid crops are treated. Farmers have been practicing hybridization since the beginning of the agriculture era, and modern methods were developed in the mid-nineteenth century. Hybrid foods result from cross-breeding plants under controlled pollination to produce a hybrid plant with desirable characteristics of both organisms that were crossed. GMOs result from cross-breeding at the genetic level.

Government regulation of genetically modified (GM) food is not as straightforward as protecting the food supply from contamination. Numerous parties have a stake in influencing the regulatory policies of GM technologies, from consumers and non-governmental organizations (NGOs) to farmers' associations and biotechnology companies. Within the dialogue of competing interests, scientific studies contribute to the regulatory process by assessing the potential impacts of the foods on human and environmental health.

The new federal GMO labeling bill passed by both the House of Representatives and the Senate will establish national standards for GMO labeling. However, the law is not self-implementing. Under the law the U.S. Department of Agriculture (USDA) has two years to establish a national bioengineered disclosure standard, and procedures and requirements relating thereto. So the labeling requirement will not go into effect until

[1] Plant Protection Act (PPA), Pub. L. No. 106-224, 114 Stat. 438.
[2] See 21 U.S.C.A. §§ 301 et seq.
[3] See 42 U.S.C.A. §§ 201 et seq.
[4] See 7 U.S.C.A. §§ 136 et seq.
[5] Toxic Substances Control Act (TSCA), Pub. L. No. 94-469, 90 Stat. 2003.

USDA publishes a final rule containing the standard. Nevertheless, the preemption of state GMO labeling laws such as the Vermont law will be immediately preempted.

The new law is an amendment of the Agricultural Marketing Act of 1946, 7 U.S.C. 1621, *et seq*. It applies to products regulated as foods subject to the FFDCA, as well as meat, egg and poultry products regulated by the USDA, but only if the primary ingredient in the food would be subject to FFDCA labeling requirements. The law does not apply to "food served in a restaurant or similar retail establishment" or to "very small food manufacturers."

The new law will require disclosure that a food product is bioengineered, which means that it:

(A) contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and

(B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.

Importantly, the law limits the scope of its application to animals by providing that food derived from an animal shall not be considered "bioengineered food" solely because the animal consumed feed produced from, containing or consisting of a bioengineered substance. On the other hand and somewhat confusingly, the law provides that a food is not conclusively deemed non-GMO solely because the food is not subject to the disclosure standard. Moreover, it remains unclear whether refined products like soy oil, sugar from beets, high fructose corn syrup and other ingredients sourced from GM crops, but which do not contain genetically modified DNA, proteins or the like will considered bioengineered or not.

Finally, the new law does *not* require an actual labeling statement with a disclosure and GM information is not required to be on the label or package of the food product itself. Instead, a QR or SQUARE code on the label package, scannable by a smartphone, will be required. For small manufacturers, the standard is to allow for placing the information on an internet site or making it available by telephone.

State Regulation of GMOs

Prior to passage of the new federal law, several states had sought to distinguish foods based on the process by which foods are produced. In other words, some states sought to distinguish hybrid foods that result from hybridization on the genetic level—GMOs—from foods that result from hybridization on the non-genetic level. Three states enacted state laws that attempted to expressly define GMOs: Connecticut, Maine and Vermont.

In 2014, Connecticut became the first state to pass a law defining GMOs.[6] Connecticut defined the process of "genetic engineering" in the context of GMOs as:

> …a process by which a food or food ingredient that is produced from an organism or organisms in which the genetic material has been changed through the application of: (A) In vitro nucleic acid techniques, including recombinant DNA (deoxyribonucleic acid) techniques and the direct injection of nucleic acid into cells or organelles; or (B) fusion of cells, including protoplast fusion, or hybridization techniques that overcome natural physiological, reproductive or recombination barriers, where the donor cells or protoplasts do not fall within the same taxonomic group, in a way that does not occur by natural multiplication or natural recombination.

The law defined "organism" as "any biological entity capable of replication, reproduction or transferring genetic material."

Similarly, Maine defined "genetic engineering" as "the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injection of nucleic acid into cells or organelles, or the fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection."[7]

[6] Conn. Gen. Stat. Ann. § 21a-92c (2015).
[7] Me. Rev. Stat. Ann. tit. 22, § 2593 (2015).

Neither the Connecticut GMO statute nor the Maine GMO statute ever became effective. Rather, by their own terms, the statutes were only to become effective if and when a critical mass of additional states in the Northeast enact similar laws or lawmakers in Connecticut or Maine took additional action to activate these laws.

In contrast, Vermont's GMO statute—known as "Act 120"— became effective on July 1, 2016.[8] In adopting Act 120, the Vermont legislature incorporated the same definitions of "genetic engineering" and "organism" contained in the Connecticut statute. Mandatory GMO labeling—such as Act 120—raises several legal and political issues, such as:

- When and how can government force businesses to make statements they do not want to make or prohibit them from making statements they *do* want to make? (Put another way, do US companies have First Amendment rights to use labels of their choice?)
- In today's complicated economy, which level of government—state or federal—is best equipped to regulate food labels within constitutional limits?

The drive by Vermont and other northeastern states to distinguish hybridization on the genetic level from hybridization on the non-genetic level is, to a large degree, the result of the increased prevalence of GMOs in the food supply and the general tendency of law and regulation to change in response to changes in the subject matter being regulated. In the United States, farmers have been planting increasing amounts of GM crops since GM seeds first became available in 1996. Yet, what counts as a "GMO" remains largely subjective. The attempt by states to expressly define GMOs and distinguish GMOs from other hybridization processes is highly controversial.

Act 120 was controversial because the law was broad, reached food grown and produced beyond Vermont's borders, and imposed daily monetary penalties of $1,000 for each and every violation of the law. Unless exempted under Act 120, Vermont's GMO labeling requirement applied to *all* food sold in Vermont, not just to Vermont retailers who sold food in the

[8] Vt. Stat. Ann. tit. 9, § 304 (2015).

state. US food manufacturers cannot control where their food is ultimately sold. Thus, food manufacturers may have had to change their ingredients or label *all* food they sell in the United States, except food the Vermont law exempts, which includes home-state staples maple syrup and cheese as well as beef, poultry, and eggs. Indeed, after prior attempts to pass a federal labeling law failed , major diversified agribusiness companies such as ConAgra, General Mills, Kellogg's, and Mars announced that they would begin labeling all their products in anticipation of Act 120 becoming effective and triggering a need to comply with Vermont law.

GM Techniques

In 1973, the idea of recombinant DNA or "rDNA" was developed by biochemists Herbert Boyer and Stanley Cohen. Boyer and Cohen reported the construction of functional organisms that combined and replicated genetic information from different species. Their experiments dramatically demonstrated the potential impact of DNA recombinant engineering on agriculture, as well as medicine and pharmacology. These techniques have been developed to increase resistance to insects, make crops tolerant to herbicides, delay ripening, and increase yield and for other reasons. In 1994 the FDA approved the first genetically engineered product for commercial sale, the delayed-ripening Flavr Savr tomato.

A number of recombinant engineering techniques exist for the production of GMOs. The two most commonly employed are the bacterium *Agrobacterium tumefaciens*, which is naturally able to transfer DNA to plants, and the "gene gun," which shoots microscopic particles coated with DNA into the plant cell. Generally, individual plant cells are targeted and these are regenerated into whole GM plants using tissue culture techniques.

Genetic engineering techniques vary by the type of crop being modified. For example, for corn and soybeans, seeds are modified at the genetic level to increase resistance tolerance of herbicides that combat weeds growing about the crops. For tomatoes, scientists modified a gene that triggered ripening and consequently increased shelf-life. Likewise, scientists recently introduced genetic modification in apples to inhibit browning and in potatoes to inhibit bruising. Cotton is modified with short sequences of genes that produce a protein that acts as an insecticide.

US Agencies and Their Roles in Regulating GMOs

The FDA is responsible for regulating the safety of GM crops that are eaten by humans or animals. According to a policy established in 1992, FDA considers most GM crops as "substantially equivalent" to non-GM crops. In such cases, GM crops are designated as "Generally Recognized as Safe" under the FFDCA, and do not require pre-market approval. If, however, the insertion of a transgene into a food product results in the expression of foreign proteins that differ significantly in structure, function, or quality from natural plant proteins and are potentially harmful to human health, FDA reserves the authority to apply more stringent provisions of FFDCA that require pre-market approval of food additives, whether or not they are the products of biotechnology.

In 1997, FDA established a voluntary consultation process with GM crop developers to review the determination of "substantial equivalence" before the crop is marketed, such as assessing the toxicity and allergenicity of the gene product and the plant itself. If the data in the food-safety assessment are satisfactory, FDA notifies the developer that marketing of the crop may proceed.

The USDA is the federal regulatory agency that monitors and regulates the use of biotechnology for agricultural purposes. USDA reviews data generated from field trials to determine whether a product or crop would have the potential to become a plant pest or cause any detrimental effects on the environment. Genetically engineered herbicide-tolerant crops are subject to USDA's jurisdiction, a pesticide subject to US EPA's jurisdiction. Instead, herbicide-tolerant crops are engineered to produce proteins that are resistant to a specific herbicide sprayed on them. An example of this is glyphosate-tolerant soybean, corn, and canola.

Within USDA, APHIS regulates the movement, importation, and field testing of genetically engineered organisms through permitting and notification procedures. APHIS regulates the planting, importation, or transportation of GM plants pursuant to its authority under the PPA, 7 U.S.C. § 7701-7786,[9] which authorizes the Secretary of Agriculture to "prohibit or restrict the importation, entry, exportation, or movement in

[9] 7 U.S.C.A. §§ 7701 to 7786.

interstate commerce of any plant, plant product [etc.] if the Secretary determines [it] is necessary to prevent the introduction ... of a plant pest or noxious weed within the United States."[10] By regulation, APHIS classifies most GM plants as plant pests or potential plant pests and as "regulated articles."[11] Under the PPA, a regulated article must receive prior approval from APHIS before it is introduced.[12]

APHIS grants authorization to use GM plants in three ways: through a notification process, a permitting process, or a determination of non-regulated status.

Notification Procedure

The notification procedure is available to plants that are not classified as noxious weeds, or weeds in the release area, if certain criteria and performance standards are met. The criteria include that the plant must be a species that APHIS has determined may be safely introduced; the genetic material must be stably integrated; the expression of the genetic material must not result in plant disease; etc. The performance standards govern shipment, storage, planting, and testing, and are intended to prevent the plant from being released from containment. When the applicant sends a notification, APHIS will respond within a prescribed time with an acknowledgement or a denial. If the notification is denied, the applicant may apply for a permit.[13]

Permit Procedure

The permit procedure requires an applicant to submit information concerning, among other things, the donor organism, the recipient organism, the composition of the regulated article; the expression of altered genetic material in the regulated article and the molecular biology of the system used to produce the article; the locality where the donor and recipient organisms and the regulated article were developed; the purpose of the regulated article; the quantity to be introduced; processes to prevent

[10] 7 U.S.C.A. § 7712(a) (2015).
[11] 7 C.F.R. § 340.1 (2015).
[12] 7 U.S.C.A. § 7711(a) (2015).
[13] 7 C.F.R. § 340.3 (2015).

release; the intended destination, use, and distribution; and the final disposition of the regulated article. If APHIS grants the permit, it is subject to conditions designed to ensure both that the regulated article remains contained and that APHIS can maintain regulatory oversight. Failure to comply with the conditions can result in withdrawal of the permit.[14]

Determination of Non-Regulated Status

GM plants that have been tested and have been shown not to pose a risk may be eligible for a determination of non-regulated status. A petition for determination of non-regulated status must include detailed biological information on the regulated article and the recipient organism, published and unpublished scientific studies, data from field tests, and other information designed to assist APHIS in determining whether the plant constitutes a pest. Upon receipt of a petition, APHIS publishes a notice in the Federal Register and allows sixty days for public comment. APHIS has 180 days to approve in whole or part or deny the petition.[15]

The US EPA regulates biopesticides, including Bt toxins, under FIFRA. If a crop is genetically engineered to carry a gene for a Bt toxin, EPA requires the developer to verify that the toxin is safe for the environment and conduct a food-safety analysis to ensure that the foreign protein is not allergenic.

State lawmakers across the country introduced 101 bills addressing genetically modified organisms in 2015 legislative. Thirteen of the bills were enacted. Overall, the bills related to labeling, agriculture, and the use of sound science in regulating GMOs. Of the thirteen that were enacted, nine urge science-based data to be used in future GMO regulation, four relate to food labeling standards, and two concern other matters. States enacting GMO legislation were Alabama, Connecticut, Idaho, Indiana, Maine, Michigan, Mississippi, North Dakota, Pennsylvania, Tennessee, and Texas.

[14] 7 C.F.R. § 340.4 (2015).
[15] 8 C.F.R. § 340.6 (2015).

GMO Litigation in the United States

In the United States, allegations of direct violations of GMO regulations are unusual. In one of the rare cases involving alleged violation of GMO regulation, a federal court in California ruled, for the first time ever, that the USDA failed to abide by federal environmental laws when it approved a genetically engineered crop without conducting a full Environment Impact Statement (EIS). However, in 2013, in *Monsanto Co. v. Geertson Seed Farms*, the United States Supreme Court reversed the decision and held that the district court abused its discretion in permanently enjoining farmers from planting Roundup Ready Alfalfa (RRA) seeds anywhere in the United States until APHIS complied with the National Environmental Policy Act (NEPA) and conducted an environmental impact statement (EIS).[16]

In March of 2016, several NGOs filed a lawsuit in the US District Court for the Northern District of California seeking to overturn the FDA's approval for sale and consumption of a genetically modified salmon. The NGOs alleged the FDA's regulation of such technology under the FDCA—regulating genetic modifications under provisions covering animal drugs—goes beyond the scope of the law.[17]

Lawsuits brought by private parties alleging false or misleading labeling of food that contains genetically modified ingredients are increasing. Claims of regulatory violations are still very rare, but can present significant potential liability in private litigation. For example, numerous corn farmers have brought lawsuits against GM seed supplier Syngenta and alleged that Syngenta deliberately misrepresented that two varieties of its GM corn would be approved by China. In November of 2013, China discovered the unapproved genetic modification of corn in export shipments to China. In response, China stopped importing *all* corn from the United States. Farmers who did not grow Syngenta's GM corn claim in the lawsuits that Syngenta's actions caused the price of all corn on the market to decrease and caused them significant economic damage.

[16] *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 130 S. Ct. 2743, 177 L. Ed. 2d 461 (2010).
[17] Jacob Bunge, *Lawsuit Challenges FDA's Right to Approve Genetically Modified Animals*, The Wall Street Journal (March 31, 2016).

Attorneys should keep their clients informed of developing GMO regulations via electronic alerts and white papers. Even though allegations of direct non-compliance with rules and regulations governing GMOs are rare, representations about whether or not products contain GMOs and the distribution of products that contain GMOs are closely scrutinized by enterprising litigation lawyers.

International Regulation of GMOs

Compared to the United States, the European Union (EU) imposes strict regulations on GM foods. The European Commission, the executive cabinet of the EU, established its general policy for GM food regulation in 2002. The EU treats all GMOs as "new food," which must be evaluated on a case-by-case basis by the European Food Safety Authority. GMOs in Europe are regulated pursuant to the extremely conservative "precautionary principle," which holds that in the absence of near-certainty about the safety of an action, the burden to prove an absence of harm falls on those parties proposing the action. Even when the European Food Safety Authority approves GMOs, food labels must expressly identify the ingredients as genetically modified.

In addition, even when the EU approves GMOs, individual countries can and often do ban commercial sale of GM food products. EU legislation passed in 2015 allows individual countries greater freedom in disapproving GM foods; specifically, the countries' approval decisions can be based on factors beyond health risks. Previously, justification for countries' bans of GMOs was limited to scientific data showing the risk of GMOs to human or environmental health. Member states can now ban GMOs based on considerations such as socioeconomic policy and cultural traditions of land use. In October of 2015, nineteen European countries notified the EU of their intention to "opt out" of growing GM crops in all or parts of their territories, effectively banning the growing of GM crops in these countries. The EU's resistance to GM crops has been controversial and led to disputes before the World Trade Organization (WTO).

Below is a summary of the regulatory approach to GMOs of several countries in the EU, Asia, and South America.

Argentina

Argentina is the third largest grower of biotech crops in the world, after the United States and Brazil. GMOs are regulated in Argentina under the Law on Seeds and Phytogenetic Creations and the Law on the Promotion of the Development and Production of Modern Biotechnology, and under administrative regulations issued by the Secretary of Agriculture, Livestock, Fisheries and Food. Argentina has not ratified the Cartagena Protocol on Biosafety.

Belgium

Belgium is considered to have an intermediate level of restrictions on GMOs, although public opinion tends to generally be hostile to GMOs. Most of Belgium's regulation of GMOs is directly or indirectly derived from European regulations. Overall, regulation of GMOs in Belgium is mostly focused on authorization requirements prior to their production, use, or distribution; on mandatory technical requirements to limit the potential release of GMOs into non-GMO fields; and on information and transparency measures.

Brazil

In Brazil, GMOs are governed by a law that defines the concept of a GMO and sets rules for the laboratories that work with them. Additionally, it establishes authorization procedures for GMO research, and establishes rules for the production and marketing of GMOs, restrictions on their release into the environment, regimes for their cultivation, requirements for reporting their release, inspections and monitoring of GMO research activities and their commercial release, implementing authorities and authorizing procedures for their release, and restrictions on GMOs in foodstuffs. Finally, it provides for the punishment of administrative violations and criminal offenses.

Canada

Canada regulates products derived from biotechnology processes as part of its existing regulatory framework for "novel products." The focus is on the

traits expressed in the products and not on the method used to introduce those traits. The Canadian Food Inspection Agency is responsible for regulating GM plants and approving GM feed for animals. Health Canada is mandated to assess the safety of foods for human consumption, including GMOs in foodstuffs, and for authorizing them to be sold in Canada. Advertising or labeling the presence of GMOs in particular food is voluntary unless there is a health or safety concern.

China

In China, restrictions on GMOs are primarily provided by the agricultural GMO regulations enacted by the State Council in 2001 and relevant administrative rules. The agricultural GMO regulations regulate not only crops, but also animals, microorganisms, and products derived from these sources. The testing, production, and marketing of GMOs in China are subject to government approval. Foreign companies that export GMOs to China, including GMOs as raw materials, must apply to the Ministry of Agriculture and obtain GMO Safety Certificates.

Egypt

Egypt takes a permissive approach to GMOs, and its public policy does not oppose growing, importing, and exporting genetically modified crops. Egyptian activists have voiced their rejection of this policy. Egyptian laws do not contain restrictions on researching, producing, or marketing genetically modified crops and food products. The country also has no restrictions on releasing genetically modified organisms into the environment. A draft law on biosafety was not approved by the Egyptian Parliament.

England and Wales

The growth and sale of GMOs are permitted in England and Wales, subject to an intensive authorization process that occurs primarily at the EU level. Most legislation in England and Wales that applies to GMOs is implementing legislation for EU law. The general attitude in England is averse to GMO products; however, a slight shift in attitude toward GMO

products has recently been reported, and the UK government's policy indicates a more receptive attitude toward these products.

France

The production and sale of certain GMOs are legal in France, but are subject to very restrictive rules. French legislation supplements the broader framework of EU regulation with national rules that provide additional restrictions, particularly focused on the potential release of GMOs in the environment, and on labeling requirements for GMO products. As a result of both public hostility to GMOs and these legal restrictions, there are currently no GMO crops grown in France, even though France imports substantial amounts of GMOs from abroad.

Germany

Germany discourages the cultivation of GM crops to the extent possible within the already stringent EU legislation on GMOs. Germany imposes strict liability for accidental contamination with GMOs, and has tough and methodically enforced controls over the release of GMOs.

Israel

Israeli law permits the development and growth of GMOs for research purposes in accordance with requirements established by subsidiary legislation. Although GMO growth is not permitted for commercial purposes, GMO products may be imported, sold, and used in the production of food and pharmaceuticals in Israel. Israel's religious *kashrut* authority has determined that the use of GM ingredients in food does not affect its kosher status because GMOs are only used in "microscopic" proportions. To date, legislation specifically regulating the labeling of GM components in food does not appear to have been passed.

Italy

As a member of the EU, Italy has been implementing European directives concerning GMOs over the last two decades, but at a rather reluctant pace.

In fact, as reflected by GMO legislation in Italy, Italian public opinion has shifted from a decidedly general opposition to the introduction of GMOs into a more recent open acceptance of them. The Italian Constitutional Court has ruled that the national government is constrained from encroaching on the power of regional governments to establish their own regimes on GMOs. As a consequence, some regions have enacted slightly more permissive regimes than others.

Japan

Japan enacted the Cartagena Act in 2003 to implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Although it is legal to plant GM crops in Japan if certain procedures are followed, no commercial planting of GM crops (aside from ornamental flowers) is occurring in Japan at this time, mainly because the general public is skeptical about the safety of GM crops. Nevertheless, Japan is one of the largest importers of GM foods, though labeling is required if GM crops are used in food in certain cases.

Lebanon

Although Lebanon ratified the Convention on Biological Diversity in 1994 and the Cartagena Protocol in 2008, it has not yet adopted policies dealing with GMOs. While there are some existing laws that are indirectly relevant to this subject matter, it is fair to say that no comprehensive legal regime on this issue exists at this time.

Mexico

Mexico's Law on Biosecurity of Genetically Modified Organisms is a federal law that provides rules concerning GMOs, and is aimed at preventing, avoiding, or reducing the risks that these activities may cause. The GMO law provides that violations of its provisions or its regulations are punishable with civil penalties. Mexico's Federal Criminal Code provides that an individual who, in contravention of applicable law, commercializes, transports, stores, or releases into the environment a GMO that negatively alters or may alter the components, structure, or functioning of natural ecosystems is punishable with imprisonment of one to nine years and a fine.

Netherlands

Although the Netherlands was the first EU Member State to have legal coexistence guidelines on genetically engineered crops, commercial production of GM crops has not yet taken place. While the government and the agriculture sector take a pragmatic approach toward the import and use of GM products, public opinion is divided as to whether GM foods pose health risks. Activities involving GMOs are for research purposes in laboratories or field trials, and are tightly regulated, in particular through EU Directives made applicable in the Netherlands. Prior risk assessment and subsequent monitoring and reporting are necessary for all GMO-related activities. Criminal penalties and administrative sanctions may be applied to violations of licensing requirements.

New Zealand

The importation, development, testing, and release of GMOs are strictly regulated in New Zealand. Such activities must be approved by the Environmental Protection Authority, which is required to take into account environmental, economic, social, cultural, and public health considerations. GM techniques have been approved for use in research involving both plants and animals, subject to various controls. There are currently no GM commercial crops, though imported food and ingredients derived from GMOs must be approved by a food safety authority and clearly labeled on packaging before sale. Criminal and civil penalties may be applied in relation to breaches of the legislation, and offenders may be ordered to mitigate or remedy any adverse effect on people or the environment.

Norway

Norway is one of the most restrictive importers of GM products and does not produce GMOs. As Norway is only part of the European Economic Area and not a full EU Member, it is not bound by EU directives but generally implements EU directives nonetheless. There are several EU-approved GMOs that are specifically illegal in Norway. Following a recent regime shift in Norway it is yet unclear whether Norway's position on GMOs might change.

Russian Federation

Cultivation of transgenic plants for commercial use is not allowed in the Russian Federation. However, several types of GM food and feed lines that have passed the procedure of state registration and control are allowed to be imported, processed, and used for food or feed production. Research on genetically engineered animals is not supported by the government. Russia recently adopted an approval procedure for release of GMOs into the environment, which brings the country closer to possible cultivation of GM plants. Currently, eighteen GM food lines and fourteen GM feed lines are approved and registered in Russia.

South Africa

The primary legislation in South Africa dealing with GMOs, including their contained use, trial release, commercial release, and import and export, is the Genetically Modified Organisms Act of 1997 (GMO Act)[18] and its subsidiary legislation. The GMO Act places various restrictions on the research, production, and marketing of GMOs, including requiring permits, risk assessments, notification to the public, registration, and demonstrated safety to the environment. The GMO Act imposes civil liability on people who conduct GMO-related activities for damage they cause and criminalizes various acts, including violations of its provisions or refusing to cooperate with the regulatory bodies.

South Korea

South Korea signed the Cartagena Protocol on Biosafety in 2000 and enacted implementing legislation the following year. Importing, cultivating, researching, and developing GMOs are permitted, as long as applicable procedures are observed. Even though more and more research on GMOs is being performed, people are still concerned. As yet, there has been no authorized GMO cultivation within Korea. Restrictions on GM food include a safety assessment in addition to a risk assessment and approval procedure. Sellers of GM food must follow labeling requirements.

[18] Genetically Modified Organisms Act of 1997 (GMO Act), Law No. 15 of 1997 (S. Afr.).

Sweden

Swedes, both consumers and producers, are very conscious of GMOs. GMO use is limited and almost exclusively used in animal fodder products. The use of GMOs in food is a sensitive topic that generates strong public opinion. A majority of Swedes consider it important that their milk is GMO free, and dairy farmers therefore avoid GMOs in their fodder. Sweden, as a EU Member, has adopted a case-by-case analysis for each GMO. One GM potato for industrial use has been approved for cultivation in Sweden, but currently no GMOs are being produced.

International GMO Litigation

Anti-GMO Litigation

India's Supreme Court is expected to rule soon on a petition to bar GM-crop cultivation. Fears that India's government relied too heavily on biotech companies to research safety and that GM plants would mix with wild versions prompted nutritionist Aruna Rodrigues to seek out independent scientists and compile data to challenge the government over its handling of GM crops.

In 2005, Rodrigues filed a petition with India's Supreme Court seeking a moratorium on GMO field trials, arguing that such crops would damage the nutritional qualities of the food. The court accepted her petition, which is still winding its way through India's judicial system.

If the Supreme Court opens the door to the cultivation of GM crops in addition to cotton, which is widely cultivated in India, sales of GM seeds likely will grow again. India's food-security concerns may lead it to soften its stance, seed industry officials say. The country is a big importer of edible oil and lentils—protein sources for many mired in poverty—and has high child-malnutrition rates. GMO proponents say biotech seeds would increase production of protein-rich crops on India's mostly small farms, which the United Nations numbers at 138 million.

Trade Dispute Litigation

In 2003, the United States formally complained to the WTO that the EU system of approval of GM products was so slow that it amounted to a moratorium in violation of international trade laws. In addition, the United States, Canada, and Argentina complained about "safeguard measures" taken by several EU states to prohibit the importation and marketing of GM products.

The complaint listed several provisions of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) that were seen to be relevant.[19] A WTO panel found that the EU had indeed imposed a *de facto* moratorium on most of the biotech product applications pending at the time of the complaint. The panel found that the moratorium was not covered under the SPS Agreement as an action taken on the basis of a risk assessment and that the approval process itself had not been completed without "undue delay" as required.

In addition, the member state safeguards were not justified as a temporary restriction necessitated by the lack of sufficient evidence, and had not been implemented on the basis of a valid risk assessment. The panel report was adopted in November 2006. The EU subsequently moved several products through the approval process.

However, although the panel clarified the obligation of governments to move applications at a reasonable pace through approval processes, it did not settle some of the more fundamental GMO-related issues. The panel report did not address the question as to whether GM and non-GM products are considered "like products" under the WTO rules. Nor did the panel report clarify whether existing EU GMO regulations themselves were consistent with the obligations under binding WTO agreements. And the panel avoided any statements that might indicate whether GMOs are safe. Moreover, other trade-related GMO issues have emerged since the ruling regarding requirements for segregation of GM and non-GM crops, the tolerance levels for "adventitious presence" of GM materials, and the costs of testing for traces of GMOs.

[19] Agreement on Sanitary and Phytosanitary Measures,https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm (1996).

A series of 2012 meetings and workshops of the Council of the European Union ended with no solution toward the settlement required under the WTO judgment made six years earlier. Despite efforts from Hungary and Denmark (in particular) to develop compromise language and break a deadlock against GM imports, the Council concluded that "a political agreement on the GMO dossier is not possible."

Future GMO-driven trade disputes are likely to arise before the WTO. Given the EU's 2015 empowerment of its members to ban GMOs on non-scientific bases and the willingness of many of those members to do so, future conflict with US GMO interests is inevitable.

Organic Food Regulation

Federal Regulation of Organic Food

The organic movement began in the early 1900s in response to a shift toward synthetic nitrogen-based fertilizers and synthetic pesticides. In December of 2000, the USDA promulgated its first National Organic Program Final Rule (NOP). The NOP received over 40,000 comments and went into effect in October of 2002.

Organic agriculture is regulated in the United States under the Organic Foods Production Act of 1990 (OFPA), 7 USC. § 6501, *et seq.*, and the NOP regulations promulgated thereunder at 7 C.F.R. Part 205.[20] Pursuant to this law, the National Organic Standards Board (NOSB) has defined "organic agriculture" as "an ecological production management system that promotes and enhances biodiversity, biological cycles and soil biological activity. It is based on minimal use of off-farm inputs and on management practices that restore, maintain and enhance ecological harmony."[21]

The NOSB advises the US Secretary of Agriculture with developing standards for organic production and other aspects of implementing the OFPA and the NOP, including advice about whether or not substances should be allowed or prohibited in organic production. The NOSB is a

[20] Organic Foods Production Act of 1990 (OFPA), 7 U.S.C.A. §§ 6501 *et seq.;* C.F.R. Pt. 205.
[21] 7 C.F.R. § 205.2 (2015).

fifteen-member advisory board comprised of organic community and stakeholder representatives. The NOSB must review every substance on the National List of Allowed and Prohibited Substances every five years to determine whether each substance continues to meet all required criteria. This is referred to as the "sunset" review.

State Regulation of Organic Food

The OFPA created national standards from a patchwork of state laws and regulations. However, the OFPA does not completely preempt state regulation of organic food production. States may and still do have their own organic programs provided the programs are approved by the NOP. For example, California has its own organic program under the California Organic Products Act of 2003.[22] The California law incorporates by reference federal regulations under the OFPA. Additionally, the California law grants authority to the California Secretary of the Department of Food to bring actions to enforce the law and collect civil penalties for violations.

Organic Techniques

Organic farming techniques are defined as much by what they do not utilize—synthetic fertilizers and pesticides—as by the techniques organic farmers do employ, which are not unique to organic farming. Some of the techniques that organic farmers utilize are as follows:

Biological Fertilizers

Organic farmers maintain the health of their soil by using manure or compost and other organic material. Biological fertilizers, like compost, release nutrients slowly, build up organic soil matter, and increase the capacity of soil to retain moisture.

[22] Cal. Health & Safety Code §§ 110810 *et seq.* (2015).

Beneficial Insects

Some organic farmers introduce beneficial insects such as ladybugs, soldier beetles, green lacewings, big-eyed bugs, and beneficial nematodes that eat harmful insects.

Crop Rotation

Organic farmers often do not grow the same crop on the same field year after year. Crop rotation naturally replenishes the soil because different plants demand different nutrients from the soil. By rotating crops, soil is given time to replenish nutrients.

Buffers

Organic farmers designate the edges of their land as buffer zones. This means the land is managed in accord with organic practices, but the crops grown on them are not sold as organic because some plants in the buffer may have been exposed to genetically engineered crops or chemicals used in conventional agriculture, but barred from use in organic farming.

Cover Crops

Cover crops such as clover, rye, and wheat are planted between growing seasons to help replenish the soil with nutrients and prevent soil erosion. They also help maintain populations of beneficial insects. Cover crops can control weeds by smothering and shading them and out-competing them for nutrients.

Certification as "100 Percent Organic"

Initial and Annual Compliance Inspections

Farmers seeking to have their farms certified as "100 percent organic" must submit to an initial pre-certification inspection as well as annual compliance inspections, which frequently are unannounced or unscheduled. Farmers are required to grant access to the inspectors at any time to retain their

certification status. Additionally, if any suspicions arise about adherence to the national standards, inspectors may test products or the ground during pre- and post-harvest time periods.

The purpose of organic inspections is to confirm that an organic operation meets the NOP standards and regulations at the time of certification and every year thereafter, as long as it remains certified. Inspectors do this by confirming that what an organic farmer states in an application, called an Organic System Plan (OSP), is what the farmer is doing in practice.

Best practices for preparing for a "100 percent organic" certification inspection are as follows:

- Review the sections of the National Organic Standards that are relevant to the operations.
- Review any communications from the certifier that have been received in the past year.
- Review the Organic Systems Plan for the operations.
- Assemble relevant records including records relating to crop production, field history, field activity, input purchases, sales, soil management, pest management, manure management (if operations include animals), and labels and labeling.

The producer or handler chooses a certifier and requests an application packet. USDA accredited certification agencies (ACAs or certifiers) are listed on the NOP website. All USDA-accredited certifiers—whether private (non-profit or for-profit) or governmental—certify to the same USDA National Organic Standards. Some certifiers, however, are better recognized in the organic industry/marketplace.

While certification is important, not all small businesses must become certified. Any producer or business that sells less than $5,000 in organic food or products is not required to obtain certification. Furthermore, companies that only handle products and do not repackage them are not required to be certified. This includes businesses that prepare ready-to-eat items on premises or simply use the word "organic" on an information panel.

Attaining and Maintaining 100 Percent Organic Certification

Applicants for USDA certification must submit several pieces of information including: the type of organization to be certified; history of substances and chemicals used on the land during the last three years; the kinds and categories of organic products being grown, raised or produced; and the OSP, which details the practices used, record-keeping system, and methods used. Businesses applying for certification must keep post-certification records for up to five years, with detailed information about the production, harvest, and handling of organic products.

Enforcement of NOP Requirements

USDA-accredited certifying agents and the public submit hundreds of complaints of alleged regulatory violations to the NOP each year. If the violation is confirmed, these investigations often result in:

- Product label changes
- Uncertified farms and businesses becoming certified organic
- Enforcement actions

Depending on the severity of the violation, punishments can include financial penalties up to $11,000 per violation and/or suspension or revocation of the farm or business' organic certificate. A suspended or revoked operation cannot sell, label, or represent its products as organic. Once the suspended operation meets any specified waiting period and can demonstrate full compliance with the USDA organic regulations, it can request that the NOP reinstate its organic certificate.

In 2010, the USDA Office of the Inspector General (OIG) found that enforcement of the NOP rules was lacking: "We found that NOP officials need to improve their enforcement of program regulations and their resolution of complaints ... NOP officials did not have adequate procedures or a system for tracking the receipt, review, and disposition of complaints and any subsequent enforcement actions."[23]

[23] USDA OIG, *Oversight of the National Organic Program,* Audit Report 01601-03-Hy (March 2010).

The OIG Report included fourteen recommendations, all of which were agreed to by the NOP. Despite this apparent commitment to increased enforcement, in FY 2013, the NOP still imposed only eighteen civil penalties, totaling $78,500, for willful violations of the USDA organic food regulations. At the same time, however, the NOP reported working with the USDA Office of Inspector General and Department of Justice on several high-profile criminal enforcement cases.

Since 2013, criminal prosecutions indicate the maturation of the organic food regulatory program and the exponential growth of the industry. As in other industries that undergo rapid expansion, the lure of increased profits creates incentives for bad actors to engage in fraud. The recent use of criminal prosecutions may signal a new enforcement strategy for the USDA, as it struggles to address increasing complaints and violations of organic standards with limited resources. Criminal prosecutions generally receive significant press attention and have a strong deterrent effect, which could make them a powerful tool for ensuring the integrity of organic food labels. Two of those high-profile cases involved the sale of fraudulent fertilizers—labeled as "organic," but in fact containing prohibited synthetic ingredients.

Private tort lawsuits also play an important role in enforcing NOP requirements. In 2015, the California Supreme Court held in *Quesada v. Herb Thyme Farms, Inc.* that the OFPA does not preempt claims against allegedly intentional misrepresentation of organic food status.[24] According to the Supreme Court, the OFPA only preempts state law on matters related to organic certification, not private actions against alleged misuse of the "organic" label.

In *Herb Thyme Farms*, the plaintiff alleged that Herb Thyme Farms mixed products from its conventional farms with products of its certified organic farm and sold the mixtures under a "Fresh Organic" label. In other words, the plaintiff claimed the defendant marketed non-organic products as

[24] *Quesada v. Herb Thyme Farms, Inc.*, 62 Cal. 4th 298, 195 Cal. Rptr. 3d 505, 361 P.3d 868 (2015). *Compare In re Aurora Dairy Corp. Organic Milk Marketing and Sales Practices Litigation*, 621 F.3d 781, 796, 67 A.L.R. Fed. 2d 631 (8th Cir. 2010) (affirming district court's dismissal of the class plaintiffs' claims under Colorado consumer protection laws for purportedly mislabeling milk as "organic" because those claims were impliedly preempted by OFPA).

organic, not that the defendant's organic farm failed to comply with organic requirements. The Supreme Court found the plaintiff could state a claim under California consumer fraud law.

According to the Supreme Court, state consumer fraud lawsuits further the purpose of the law; they promote avoiding consumer deception, build consumer trust in a standard definition of "organic," and protect legitimate organic producers from unfair competition. The Supreme Court reasoned if it found preemption it "would render organic labeling uniquely immune from suits for deception because of legislation Congress passed, in part, to prevent food from being deliberately mislabelled as 'organic.'"[25] Consequently, the Supreme Court concluded that the OFPA could not be interpreted, under the doctrine of preemption, "as shielding from suit the precise misconduct [the OFPA] sought to eradicate."[26]

Comparison of GM Agriculture v. Organic Agriculture

US Data and Global Data

About 75 percent of US food contains GM ingredients. The most frequently genetically engineered crops are soybeans, corn, cotton, and sugar beets. In 2015, 92 percent of corn, 94 percent of soybeans, and 94 percent of cotton grown in the United States contained GM ingredients. Other agricultural products that frequently include GM ingredients are milk and canola oil. In other words, to date, most successful genetic modification of food has incurred at the commodity input level, not at the consumer level in the grocery store.

A 2016 Purdue University study found that without GMOs, global consumers would pay somewhere between $14 and $24 billion more per year for food. While many countries around the world have imposed significant restrictions or outright bans on GMOs, farmers in India have embraced genetically engineered cotton, which comprises about 97 percent of all cotton grown in India. Still, globally, GM seed sales appear to be slowing. Sales grew 4.7 percent to $21 billion in 2014, compared with 8.7

[25] *Quesada v. Herb Thyme Farms, Inc.*, 62 Cal. 4th 298, 195 Cal. Rptr. 3d 505, 361 P.3d 868 (2015).
[26] *Quesada*, 62 Cal. 4th at 321.

percent growth in 2013 and average annual growth of 21 percent from 2007 through 2012, according to research firm PhillipsMcDougall Ltd.

In contrast, the market for organically grown food is growing more quickly by almost every measure. According to USDA estimates, total certified organic crop acreage increased from 638,500 acres in 1995 to 3,084,989 acres by 2011. But those organic acres still comprised only 0.83 percent of total crop area of 370.7 million acres in 2011 according to the USDA. Total organic acreage has increased about 138 percent from when the USDA's NOP began in 2002 to 2011. Wheat had the most certified organic area of any major crop with 344,644 acres, equal to 0.63 percent of total wheat area in 2011. Next was corn with 234,470 acres, equal to 0.26 percent of total corn area, followed by soybeans with 132,411 acres, equal to 0.17 percent of total soybean area.

USDA does not have official statistics on US organic retail sales, but information is available from industry sources. US sales of organic products were an estimated $28.4 billion in 2012—over 4 percent of total food sales—and will reach an estimated $35 billion in 2014, according to the *Nutrition Business Journal*. Fresh fruits and vegetables have been the top selling category of organically grown food since the organic food industry started retailing products over three decades ago, and they are still outselling other food categories, according to the *Nutrition Business Journal*. Produce accounted for 43 percent of US organic food sales in 2012, followed by dairy (15 percent), packaged/prepared foods (11 percent), beverages (11 percent), bread/grains (9 percent), snack foods (5 percent), meat/fish/poultry (3 percent), and condiments (3 percent).

In 2013, the global organic food market was estimated to be $72 billion dollars. According to all sources, the United States is the largest market for organic food products in the world, followed by Germany, France, and China. A total of 106.5 million acres was dedicated to organic farming at the end of 2013. In Oceania, organic land increased by 42 percent, which was mainly due to rangeland areas shifting to organic production in Australia. Australia is the country with the largest organic agricultural area (42.5 million acres, with 97 percent of that area used as grazing), followed by Argentina (7.9 million acres) and the United States (5.43 million acres).

Consumer Opinions

GMO Public Opinion: Why Doesn't the Public Believe the Science?

Consumer opinions of GMOs are difficult to gauge reliably because actual consumer behavior appears to contradict survey data. In 2001, the Public Acceptance of Agricultural Biotechnologies conducted focus group studies and found respondents expressed a rather ambivalent attitude toward GMOs. Respondents did not reject or accept GMOs out of hand, and distinguished between different types of GMOs. In 2003, surveys in the United Kingdom found only 13 percent of consumers said they actively avoid GM foods, while 74 percent were not sufficiently concerned to actively avoid GMOs.

In a series of polls conducted over five years, from 2001 to 2006, researchers found that public understanding of biotechnology was relatively low, and that consumers were relatively unaware of the extent to which their foods included genetically modified ingredients. Support for the introduction of GM foods into the food supply held steady at 26 to 27 percent of respondents in favor over that time period, while opposition to the introduction of GMOs fell from 58 to 46 percent over the period.

In 2015, the Pew Research Center reported that a majority of the general public (57 percent) said that GM foods are generally unsafe to eat, while 37 percent said such foods are safe. By contrast, 88 percent of scientists belonging to the American Association for the Advancement of Science found GM foods are generally safe.

Clearly, to the extent the public opinion has negative opinions of GMOs, it appears that the opinions may be a proxy for a broader ambivalence and distrust of science in general. Public opinion on GMOs has been fairly steady during the twenty-first century despite scientific advancement in genetics because surveys show the public is slow to change its opinions even when provided with new information. For example, a 2015 University of Florida Institute of Food and Agricultural Sciences survey showed that before survey participants received information about GMOs, 32 percent believed GM foods were safe to eat, 32 percent were not sure, and 36 percent did not believe GM foods were safe to eat. After they received new

scientific information, about 45 percent believed genetically modified foods were safe to eat, but 43 percent were not swayed by the information.

The GMO industry has responded to negative opinions by publishing editorials in newspapers and undertaking other efforts through blogs and social media to educate the public about the reliability of the science underlying GMOs. For example, in April of 2015, Chipotle Mexican Grill announced that it would take steps to minimize the amount of GMOs in the food its restaurants serve with a goal of becoming completely GMO-free. In response, the senior director of the National Cattlemen's Beef Association published a blog post that noted "the reaction from major media outlets including [National Public Radio] and the *Washington Post* was not favorable." Indeed, the *Washington Post* editorial page called Chipotle's GMO-free announcement a "gimmick."

Attorneys can join with the GMO industry to make sure the public is made aware of the most current scientific findings regarding GMOs. Attorneys also can assist the GMO industry in seeking approvals for new GMO foods from government regulators so that the public can have confidence that food containing GMOs has been scrutinized and deemed safe and healthy. Finally, attorneys can assist the GMO industry in crafting a common sense labeling policy for foods containing GM ingredients.

Public Opinion of Organic Food

Generally, US citizens have positive opinions of organic food. According to a 2014 report, a little less than half of US citizens, 45 percent, actively try to include organic foods in their diets, while 15 percent actively avoid them. More than a third, 38 percent, say they "don't think either way" about organic foods. In the United States, inclusion of organic foods is highest in the West (54 percent) and lowest in the East (39 percent). US citizens who report living in a big or small city are more likely to eat organic foods than those who describe their location as a town or rural area, 50 percent versus 37 percent, respectively, while those who live in suburban areas fall between these two groups. The growing availability of organic food is fueled by studies showing that organic buyers are spending more per shopping trip and are shopping more frequently than those who never purchase organic.

The level of awareness and concern for the food we are eating is higher than it has ever been and shows in changing attitudes and in changing habits, too. The popularity of organic food appears to be growing. Sales of fresh prepared foods have grown nearly 30 percent since 2009, while sales of center-of-store packaged goods have started to fall. General Mills has announced it will drop all artificial colors and flavors from its cereals. Perdue, Tyson, and Foster Farm have begun to limit the use of antibiotics in their chicken. Kraft declared it was dropping artificial dyes from its macaroni and cheese. Hershey's will begin to move away from ingredients such as the emulsifier polyglycerol polyricinoleate to "simple and easy-to-understand ingredients" like "fresh milk from local farms, roasted California almonds, cocoa beans and sugar."

In March of 2016, General Mills announced it expects to have 250,000 organic acres by 2019, a year ahead of its previous goal. General Mills has increased the organic acreage it supports by 120 percent since 2009, making it the second largest buyer of organic fruits and vegetables and the third largest natural and organic food maker in the United States.

When answering clients' questions about organic foods, advocates of organic food take into account a definition of healthy that goes beyond nutrient content. It is important for organic food advocates to discuss the whole situation about organics, not just nutrients. Attorneys can assist organic food growers in certifying their crops with the USDA.

Comparing the Benefits and Challenges of GM and Organic Agricultural Production

GMO Benefits and Challenges

With global population expected to grow to more than 9 billion people in 2050 and 11 billion people by 2100, Purdue University President Mitch Daniels says GMOs are the best hope for the future. "If we are going to feed a hungry world, we need them," said Daniels. "Therefore, it's not just anti-scientific, it's inhumane, it's callous, and it's heartless. For rich people to say, like Marie Antoinette, you know, 'find something else to eat.'" Daniels said Purdue is leading the world in making food more abundant, safer, and even more environmentally friendly. He hopes their example will lead to more knowledge and general acceptance of GMOs.

Daniels' views are supported by a March, 19, 2015 article in the peer-reviewed journal *Cell* by Stephen P. Long, Amy Marshall-Colon, and Xin-Ghuang Zhu.[27] In *Meeting the Global Food Demand of the Future by Engineering Crop Photosynthesis and Yield Potential*, the authors stated:

> Nothing is more important to human health and well-being than an adequate supply of food in terms of nutrition and calories. Although a significant proportion of the global population has suffered malnutrition over the last 50 years, it has been the result of failures in access to food, not in its global production. Indeed, over this period, we have seen surpluses of the major crops, which make shortages a very distant concern for most of the population. The most important primary foodstuffs, in terms of millions of metric tons (Mt) produced in 2013, were maize (1,018 Mt), paddy rice (746 Mt), wheat (713 Mt), and soybean (276 Mt) (Food and Agriculture Organization of the United Nations, 2015). These four crops account for about two thirds of calories consumed globally (Ray et al., 2013). Moreover, the average global yield per unit area of land (t/ha) for each of these crops has more than doubled since 1960, as illustrated for rice and wheat (Figure 1). So why bother worrying about food security now? One reason is that these global surpluses in staple crops have influenced the progressive decline in spending on plant science research and crop improvement, evident at the global level (Beintema and Elliott, 2009). However, this shift in funding may be myopic in the face of current global population and food consumption trends. Notably, the global population is expected to increase from just over 7 billion today to 9.5 billion by 2050, a 35% increase (USCB, 2015). An increasing proportion of the population will be urban, resulting in diets shifting increasingly from staples to processed foods, fortified with more meat and dairy products, which require

[27] Stephen P. Long, Amy Marshall-Colon and Xin-Ghuang Zhu, *Meeting the Global Food Demand of the Future by Engineering Crop Photosynthesis and Yield Potential*, Cell (March 19, 2015), *available at:*http://www.cell.com/cell/fulltext/S0092-8674(15)00306-2.

> large amounts of primary foodstuffs to produce. For example, 10 kg of feed is required to produce 1 kg live cattle (Smil, 2000). Thus, an increase in urban population will result in an increased demand for high-quality animal products, requiring an increase in crop production that is substantially faster than that estimated based solely on the projected population growth. This trend is expected to continue, and it is predicted that the world will need 85% more primary foodstuffs by 2050, relative to 2013.
>
> So is our current rate of increase in crop yields sufficient to meet this rising demand? It doesn't seem to be the case. If current rates of crop yield improvement per hectare are simply maintained into the future, supply will fall seriously below demand by 2050.

Consistent with the findings of the authors of the *Cell* article, some documented benefits of genetically modified agriculture are as follows:

Shrinking Our Environmental Footprint

- GMOs enable farmers to be better stewards of the environment, allowing farmers large and small to grow more crops on less land while using fewer pesticides and less water.
- In the United States, the adoption of GM crops resulted in pesticide use reduction of 46.4 million pounds in 2003. Globally, GM crops have reduced pesticide spraying (1996-2011) by 9 percent, or 975 million pounds.

Lowering the Price of Food

Because they require fewer pesticides, land, and water, GMOs help keep food production costs down, resulting in lower prices for consumers. GM technology helps reduce the price of crops used for food, such as corn, soybeans, and sugar beets, by as much as 15 to 30 percent. Mercaris, a market data researcher, found that 2013 prices for non-GM corn averaged 51 cents per bushel higher than GM corn.

Alleviating World Hunger and Malnutrition

- GMOs have helped feed more than 300 million Americans and a global population of 7 billion—of which 1 in 8 suffers from hunger and malnutrition.
- Experts predict that by 2050 the world will need 70 percent more agricultural production to keep pace with population growth—utilizing GM crops that increase productivity while reducing land, water, and pesticide use will be critical to this achievement.

The benefits of GMO use are measured in both increased farm income in the form of sales of greater yields, and in reduced cost in the form of reduced application of pesticides and insecticides. There are three factors that contribute to benefits from GM crops. First, GM crops contribute to food production increases and thus improve the availability of food at global and local levels. Second, GM crops affect food safety and food quality. Third, GM crops influence the economic and social situation of farmers, thus improving or worsening their economic access to food. This latter aspect is of particular importance, given that an estimated 50 percent of all undernourished people worldwide are small-scale farmers in developing countries.

In regard to the first pathway, GM technologies make food crops higher yielding and more robust to biotic and abiotic stresses. This stabilizes and increases food supplies, which is important against the background of increasing food demand, climate change, and land and water scarcity. In 2012, 420 million acres—around 12 percent of the global arable land—were planted with GM crops, such as soybean, corn, cotton, and canola, but most of these crops were not grown primarily for direct food use. While agricultural commodity prices would be higher without the productivity gains from GM technology, impacts on food availability could be bigger if more GM crops were commercialized.

Concerning the second factor, crops with new traits can be associated with food safety risks, which have to be assessed and managed case by case. But such risks are not specific to GM crops. Long-term research confirms that GM technology is not *per se* more risky than conventional plant breeding

technologies. On the other hand, GM technology can help to breed food crops with higher contents of micronutrients; a case in point is Golden Rice with provitamin A in the grain. Such GM crops have not yet been commercialized. Projections show that they could reduce nutritional deficiencies among the poor, entailing sizeable positive health effects.

The third factor relates to GM crop use by smallholder farmers in developing countries. Half of the global GM crop area is located in developing countries, but much of this refers to large farms in countries of South America. One notable exception is *Bacillus thuringiensis* (Bt) cotton, which is grown by around 15 million smallholders in India, China, Pakistan, and a few other developing countries. Bt cotton provides resistance to important insect pests, especially cotton bollworms. Several studies have shown that Bt cotton adoption reduces chemical pesticide use and increases yields in farmers' fields. There are also a few studies that have shown that these benefits are associated with increases in farm household income and living standards. Higher incomes are generally expected to cause increases in food consumption in poor farm households.

Public perception of GM foods is the biggest challenge facing the GMO industry. Public opinion on GMO issues tends to be highly polarized. Proponents of GM foods who seek to educate the public about the science underlying GMOs face an uphill battle. In addition, the extreme polarization of the GMO issue makes it difficult for lawmakers and regulators to reach a consensus approach to labeling that is acceptable to farmers and other agricultural producers. These challenges are essentially the same for all types of GMO products and in all regions.

The biggest factor driving the challenges facing GMOs is the wide gap between the public and scientists on science-related topics. As stated above, the Pew Research Center has found a majority of the general public (57 percent) believe GM foods are generally unsafe to eat, while 88 percent of scientists belonging to the American Association for the Advancement of Science found GMO foods to be generally safe. Overcoming public ambivalence toward the scientific evidence supporting the use of GMOs is critical if the world is to fight and overcome hunger in the future.

Organic Food Benefits and Challenges

Subjective personal taste and choice about the types of food a person wants to eat are the factors that contribute the most to the benefits of organic foods. Organic food consumers strongly believe that organic food tastes better than non-organic food. Organic food is often sold locally, which increases freshness and may result in better tasting food than food that has been processed, frozen, shipped, and transported across long distances.

Competitive pricing is the biggest challenge facing the organic food market. Organic foods are relatively high priced. For example, according to *The Wall Street Journal*, when Ben & Jerry's Homemade, Inc., which is part of Unilever PLC, decided to remove GMO from its ice cream, it took about three years and the new products averaged 11 percent higher in price.

The important implication of relatively high price premiums for organic foods in general, and organic fruits and vegetables in particular, is that they are simply too expensive for the majority of consumers. Even those consumers who identify themselves in surveys as potentially interested in organic foods often do not actually purchase organic products because conventionally produced food is less expensive. All countries with relatively large consumption of organic foods possess high levels of per capita income. In broad terms, organic foods tend to be luxury items in the sense that their consumption is highest in countries with high per capita incomes.

Lower organic yields and more volatility in organic supply are likely causes for the relatively large price premiums for fresh organic food. Seasonality in production presents a serious hurdle to reducing organic price premiums, particularly for highly perishable fresh fruit and vegetables. Globally, for all but a select few, relative prices of organic and conventional food items are the most important consideration in buying food. While many surveys have found that consumers are willing to pay more for organic foods, actual behavior belies their responses. Economic experiments and limited retail evidence suggest that increase in organic purchases resulting from lower price premiums at retail are substantial, although when price premiums are as high as 200 percent, small reductions in those premiums have little detectable effect. Reductions of retail price premiums in conjunction with augmented signage and promotion have greater effects than price

reductions alone. Future growth in demand for organic products will hinge on how much organic price premiums can be reduced.

Competitive Trends in Agriculture: GMO Foods vs. Organic Foods

From niche players to large enterprises, companies are rushing to meet consumers' increasing demand to know more about what is in their food, where it came from, and how it was produced**.** New "smart labels" are putting more nutrition information on packages and eventually could showcase where a company buys its ingredients. Some websites now feature names and profiles of farmers who grow wheat and oats for cereals.

Technology and consumer demand for transparency are driving these trends. Three of the most important competitive trends in agriculture today are:

1. The relative nutritional value of organic food compared to food that contains GMOs;
2. Consumer response to labeling food containing GM ingredients; and
3. The definition of "natural" foods.

Relative Nutritional Value of Organic Food vs. GM Food

Whether organic food possesses greater nutritional value than conventionally grown food is controversial. A 2012 Stanford University meta-analysis of 237 studies of organic produce, meats, and dairy foods concluded that organic foods are no more nutritious than their conventional counterparts. Still, many advocates for and consumers of organic foods contend that organics are more nutritious. Beyond the issue of nutrition, studies have found that organic food is higher in certain antioxidants and lower in pesticide residues than conventional counterparts.

Consumer Response to Labeling Food Containing GMOs

GMO suppliers fear that mandatory GMO labeling will scare consumers away from foods that contain genetically modified ingredients. The Grocery Manufacturers Association has warned that if labeling is required,

consumers will turn away from GM foods in droves, meaning farmers who grow GM crops—the bulk of which are corn and soy—will suffer and food costs will increase.

In a blog in March of 2016, Lorraine Merrill, commissioner of the New Hampshire Department of Agriculture, Markets & Food, said: "Mandatory labeling of foods derived from biotechnology will create a 'skull and crossbones effect' on our safe and affordable food supply which will generate or exacerbate fears of advanced genetic techniques... If consumers and food manufacturers migrate to more GMO-free products, food costs will go up."

The Definition of "Natural"

As the organic food industry has grown, the importance of defining the term "natural" has grown. However, to date, the US FDA has not defined "natural" despite opportunities—and even an invitation from a federal court—to do so. In 1991, the FDA adopted an "informal policy," which states that "natural" means that "nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there." The policy carries only the weight of an advisory opinion; it does not establish a legal requirement.

On its website, the FDA has provided the following explanation of the meaning of "natural" food labels:

> From a food science perspective, it is difficult to define a food product that is "natural" because the food has probably been processed and is no longer the product of the earth. That said, the FDA has not developed a definition for use of the term natural or its derivatives. However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.[28]

When companies advertise food that contains synthetic substances as "natural," the FDA has taken action. In 2011, the FDA issued a warning

[28] FDA, "What is the meaning of 'natural' on the label of food?" *available at:* http://www.fda.gov/aboutfda/transparency/basics/ucm214868.htm.

letter to Alexia Foods regarding its use of a "natural claim." The FDA indicated that the "natural" on Alexia's Roasted Red Potatoes & Baby Portabella Mushrooms was false and misleading and constituted misbranding because the product contained disodium dihydrogen pyrophosphate, a synthetic preservative. In May 2012, a class action lawsuit alleging that a variety of Alexia's frozen potato products were falsely labeled as "all-natural" piggy-backed on the warning letter. The suit was settled for $3.2 million in July 2013.

The majority of food labeling lawsuits, at least one hundred filed since 2011, have alleged misleading use of the "natural" claim. For example, in 2013, plaintiffs obtained a $9 million settlement with PepsiCo over claims that Naked Juice products were deceptively advertised and labeled as "all natural" and "non-GMO" when its products actually contained ingredients from GM crops. Also in 2013, Barbara's Bakery paid $4 million to settle claims that the company mislabeled its cereal and snack products as "all natural" when they actually contained GM ingredients.

In light of cases like these, the FDA's repeated reluctance to establish a definition or enforceable standard for the term "natural" was challenged by several judges, who decided in 2013 that the FDA, not the courts, should decide this issue. The order in *Cox v. Gruma Corporation* referred the issue of GMOs and labeling of "natural" foods to the FDA for the first time.[29] In providing the FDA with an opportunity to address the question, the court recognized that "[t]he FDA has regulatory authority over food labeling," the FDCA "establishes a uniform federal scheme of food regulation to ensure that food is labeled in a manner that does not mislead customers," and food labeling "requires the FDA's expertise and uniformity in administration."[30]

However, on January 16, 2014, the FDA responded to the court and declined the opportunity to address the definition of "natural." In doing so, the FDA noted that amending its "natural" policy required fulfilling the process of formal rulemaking and that the policy could not be changed "in the context of litigation between private parties."

[29] *Cox v. Gruma Corporation*, 2013 WL 3828800 (N.D. Cal. 2013).
[30] *Cox v. Gruma Corporation*, 2013 WL 3828800 at*1 (N.D. Cal. 2013).

In November of 2015, the FDA issued a request for public comment on the following three questions:

1. Is it appropriate to define the term "natural?"
2. If so, how should the FDA define "natural?"
3. How should the FDA determine appropriate use of the term "natural" on food labels?

In March of 2016, the United States Court of Appeals for the Ninth Circuit indicated it is willing to wait for the FDA to determine the meaning of the term "natural." In *Kane v. Chobani, LLC*, the Ninth Circuit reversed the dismissal of plaintiff's class action and remanded the action with instructions for the district court to enter a stay under the primary jurisdiction doctrine.[31] This doctrine allows the judicial branch to defer ruling on an issue that should be decided in the first instance by an executive agency with relevant expertise. In this case, the Ninth Circuit recognized that questions regarding proper use of the term "natural" on food products "implicated technical and policy questions" that should be addressed by the FDA. The Ninth Circuit noted that because the FDA has recently expressed its intent to issue updated guidance on the term "natural," a stay would not cause indefinite delay and would further the court's interest in judicial efficiency. This decision could have repercussions for a number of pending lawsuits regarding the use of the term "natural" on labels.

Conclusion

Food law is a surprisingly emotional area of the law. Farmers, processers, and consumers increasingly tend to have passionate feelings about food, where food comes from, and how food is produced. The days when the consuming public was ambivalent about the process of food production and distribution are increasingly confined to the past. Attorneys need to be prepared to handle the emotional issues raised in this area as well as the legal and scientific issues.

For information on GMOs, the peer-reviewed literature is best, and the gold standard is reproducible studies that align to form a scientific

[31] *Kane v. Chobani, LLC*, 2016 WL 1161782 (9th Cir. 2016).

consensus. These works can be found in the GENERA database at www.biofortified.org. Alternatively, quality papers can be found on Google Scholar. PubMed only lists papers that come from journals that meet certain quality criteria.

For organic foods, the National Organic Program Handbook is the bible of organic certification. The goal of the NOP Handbook is to provide those who own, manage, or certify organic operations with guidance and instructions that can assist them in complying with the USDA organic regulations. It is important to note that the NOP Handbook is non-binding and any citation issued needs to reference the USDA organic regulations.

In addition, timely information on both GMOs and organic foods can be found on Twitter at such accounts as @FarmBureau (American Farm Bureau), @nataglaw (National Ag Law Center), and @brownfield (Brownfield Ag News).

GM technologies are not going anywhere. Florida orange growers are looking to genetic technology to help them battle citrus greening disease. Bananas, another at-risk monoculture, may also need a GM fix to keep them on supermarket shelves. Others see a bright future for drought-resistant GM crops as farmers around the world grapple with climate change. Additional consumer-facing GMOs are on the horizon. Canada has emerged as a leader in the field. Summerland, B.C.'s Okanagan Specialty Fruits last year received approval from Health Canada and the Canadian Food Inspection Agency to grow and sell the world's first non-browning genetically modified apples in this country after figuring out how to "turn off" the gene that makes the flesh discolor. Similarly, Massachusetts-based AquaBounty received approval from the FDA for the world's first genetically modified fish. The AquaAdvantage salmon is a farm-raised Atlantic salmon imbued with growth hormone genes from a Chinook salmon and an ocean pout. The changes allow it to grow much more quickly—a potential boon for the aquaculture industry.

In contrast to the mixed messages that are emanating from the GMO market, the market for organic food appears to be growing robustly. According to a recently published TechSci Research report, Global Organic Food Market Forecast & Opportunities, the global organic food market is

projected to register a compound annual growth rate of over 16 percent during 2015 to 2020. Growth in the market can be attributed to growing consumer awareness about food production and increasing awareness with regard to the freshness benefits of organic food. Other factors driving organic food sales across the globe include increasing income levels, improving standard of living, and government initiatives aimed at encouraging widespread adoption of organic products.

Attorneys can be prepared to advise clients on labeling requirements and options after the USDA develops the National Bioengineered Food Standard. In theory, the organic food market may grow even more quickly after the labeling of GMO ingredients commences under the National Bioengineered Food Standard. However, given the large percentage of the public that is ambivalent about GMOs, the growing body of science that indicates consuming GMOs is safe, and the fact that labeling is unlikely to dramatically increase the relative cost of GM food vis-à-vis organic food, only time will tell if the new will be a boon to the organic food market.

Key Takeaways

- Respond to negative publicity by educating the public, especially focusing on the reliability of the science underlying GMOs. Take advantage of social media and blogs, as well as publishing editorials in newspapers. Assist clients in making the public aware of the most current scientific findings regarding GMOs.
- Assist the GMO industry in seeking approvals for new GMO foods to ensure public confidence in the safety and healthiness of food containing GMOs. Especially, assist the GMO industry and the USDA in crafting a common sense labeling policy under the National Bioengineered Food Standard for foods containing GMO ingredients.
- Prepare for an uphill battle when educating the public on the science behind GMOs. Public opinion on GMO issues tends to be highly polarized. This polarization makes reaching a consensus on the labeling issue difficult for lawmakers and regulators. Prepare your strategy to deal with the 2015 Pew Research Center report on public perceptions of GMOs: 57 percent of the general public believe GMO foods are generally unsafe to eat, while 88 percent of

scientists belonging to the American Association for the Advancement of Science believe GMO foods are generally safe.

- When dealing with GMOs exported overseas, be prepared for much stricter regulations from the EU, as compared to the United States. Resulting from public concern regarding the food safety crises of the 1990s and its tradition of risk-averse regulation, the EU's precautionary principle became the central tenet for GMO food regulation: since potential risks of GMO foods are not completely known, regulatory decisions err on the side of caution and require a high burden of proof for product safety. All GMO foods are regulated because they are made with processes different from those used to produce conventional foods. There is no standard policy because 2105 EU legislation allows individual countries greater freedom in disapproving GMO foods. Therefore, countries' approval decisions can be based on factors beyond health risks, where previously bans required scientific data showing the risk to human or environmental health from GMOs. Now considerations can be socioeconomic policy and cultural traditions of land use.
- Pay attention to the development of new federal GMO regulations from the USDA and be prepared to advise clients on labeling requirements and options.
- Keep in mind that definitions of healthy can go beyond nutrient content. When advocating for organic foods, focus on discussing the whole situation about organics, not just nutrients. Attorneys can assist organic food growers in certifying their crops with the US Department of Agriculture.

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