

GMO Crop Regulations: From the Farm to the Shelves

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Introduction

Over the past several decades, concern over the labeling structure of genetically modified (GM) crops has frustrated a large portion of Americans. This frustration is a response to scientific questions regarding the crops' impacts on consumer health and the agricultural industry. Even in light of last year's Stanford metadata analysis stating that organic/non-GM crops offer no discernible nutritional benefit,¹ consumers still note a strong desire to have GM crops labeled.² However, this continued demand has led to little regulatory change at farm and consumer levels.³ Both areas are rife with confusion as executive agencies are forced to use older laws to regulate new technology.⁴

General Concerns over GM Crops

Genetically modified crops—transgenic crops produced by the introduction of foreign DNA into conventional crops—were originally designed to create a variety of agricultural benefits.⁵ These benefits range from increased yields to pesticide resistance.⁶ Critics are concerned that GM crops limit biodiversity and that pesticide resistance may not have led to lower pesticide usage rates.⁷

In 2013, the United States will produce 90% of its cotton, 93% of its soybeans, and 90%

¹ Crystal Smith-Spangler et al., *Are Organic Foods Safer or Healthier Than Conventional Alternatives?: A Systematic Review*, 157 ANNALS INTERNAL MED. 348, 348–66 (2012).

² Lauren Zeichner, *Product vs. Process: Two Labeling Regimes for Genetically Engineered Foods and How They Relate to Consumer Preference*, 27 ENVIRONS ENVTL. L. & POL'Y J. 467, 485 (2004).

³ See Michelle T. Friedland, *You Call That Organic?--the USDA's Misleading Food Regulations*, 13 N.Y.U. ENVTL. L.J. 379, 440 (2005).

⁴ See Rebecca Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16-SPG KAN. J.L. & PUB. POL'Y 393, 406 (2007).

⁵ *Id.* at 404.

⁶ *Id.*

⁷ *Id.*

of its corn from GM seed.⁸ This is a major increase from 2000, when 61% of cotton, 54% of soybeans, and 25% of corn were grown from GM seed.⁹ These crops demonstrate the U.S. trend toward greater reliance on GM crops.¹⁰ This is in sharp contrast to U.S. consumers' concerns about whether GM crops are safe for consumption.¹¹ A Pew Research poll from 2007 found that 34% of Americans believe that GM crops are safe for human consumption, but 29% believe that they are not.¹² These GM consumption concerns are based on conflicting evidence of the nutritional benefits, as well as the large-scale use of pesticides on food crops.¹³ Although specific data has not shown clear evidence of harm based on GM crop consumption, there is concern that the studies to date have not been systematic enough to identify potential dangers.¹⁴ A National Research Council report stated that the "absence of evidence of an effect is not evidence of absence of an effect" and further noted that the assumption of GM safety was nonscientific due to the lack of monitoring.¹⁵

Regulatory Structure

Modern U.S. regulation of GM crops derives from the Coordinated Framework for Regulation of Biotechnology (Framework), which was developed by the Reagan Administration's Office of Science and Technology Policy (O.S.T.P.) in 1986.¹⁶ The Framework

⁸ *Genetically Engineered Varieties of Corn, Upland Cotton, and Soybeans, by State and for the United States, 2000-13*, USDA ECON. RESEARCH SERV., <http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx> (last updated July 8, 2013).

⁹ *Id.*

¹⁰ *See id.*

¹¹ Bratspies, *supra* note 4, at 423.

¹² Memorandum from Mellman Group to Pew Initiative on Food and Biotechnology, *Public Sentiment about Genetically Modified Food* (2007), available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Public_Opinion/Food_and_Biotechnology/2006summary.pdf.

¹³ *Id.*

¹⁴ Maria R. Lee-Muramoto, *Reforming the "Uncoordinated" Framework for Regulation of Biotechnology*, 17 DRAKE J. AGRIC. L. 311, 324–25 (2012).

¹⁵ *Id.* (citing Board On Agric. & Natural Res., Nat'l Research Council, *Environment Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, 19 (2002)).

¹⁶ Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

was created in response to early GM tests designed to limit ice crystallization within plants.¹⁷ The Framework was drafted to achieve “balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry.”¹⁸ As a result, the O.S.T.P. decided that a “mosaic” of existing laws should regulate GM crops.¹⁹ O.S.T.P. found that without enacting any new regulations specific to biotechnology, existing statutes could regulate this new industry.²⁰ Therefore, all oversight of GM crops is based on expansions of 1986 executive branch regulations.²¹

The major premise underlying regulation of GM crops under existing law is that GM crops should be held to the same standards as their conventional equivalents.²² This concept of “substantial equivalence” creates a dichotomy, as it requires these agencies to act as regulators and, especially in the case of the USDA, promoters of the product.²³

The Framework also assumes that “[b]y the time a genetically engineered product is ready for commercialization, it will have undergone substantial review and testing during the research phase, and thus information regarding its safety should be available.”²⁴ Therefore, because of “substantial equivalence,” the regulatory agencies cannot look at the process of producing the crop, but can only ensure that the GM crop’s end product matches its conventional crop equivalent.²⁵ This makes the GM crop industry the sole party responsible for ensuring that the process of GM crop manipulation is safe.²⁶ In order for a regulatory agency to prove that a

¹⁷ Dorothy Du, *Rethinking Risks: Should Socioeconomic and Ethical Considerations Be Incorporated into the Regulation of Genetically Modified Crops?*, 26 HARV. J.L. & TECH. 375, 377 (2012).

¹⁸ Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303.

¹⁹ *Id.* at 23,406.

²⁰ *Id.*

²¹ Du, *supra* note 17, at 379.

²² Lee-Muramoto, *supra* note 14, at 320.

²³ Bratspies, *supra* note 4, at 406 (noting that the USDA’s mission is to develop new markets for U.S. agriculture).

²⁴ Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,304.

²⁵ Bratspies, *supra* note 4, at 406–07.

²⁶ *Id.* at 406.

GM crop is dangerous, it needs to prove that it is not substantially similar to its conventional counterpart and thus is unsafe.²⁷

Food and Drug Administration

The Food and Drug Administration (FDA), through the Federal Food Drug and Cosmetics Act, regulates agriculture through its ability to identify and remove “adulterated” foods.²⁸ “Adulterated” food is any food that “bears or contains any poisonous or deleterious substance which may render it injurious to health.”²⁹ However, GM crops are considered “substantially equivalent” to their conventional counterparts and therefore if their conventional counterpart is not considered “adulterated,” they fall into the category of Generally Regarded as Safe (G.R.A.S.).³⁰ A voluntary process between the FDA and a GM crop developer establishes substantial equivalence.³¹ GM crops are simply recognized as variants of the current crops with no different safety concerns.³² Considering the voluntary nature of the process to establish substantial equivalence and G.R.A.S., there is concern that there is little impetus for the industry to fully investigate GM crops’ safety issues.³³

In 2001, the FDA attempted to change the rules for G.R.A.S. determination by requiring manufacturers to submit preliminary data prior to crop commercialization.³⁴ However, the incoming Bush administration requested that all pending rules be removed from the Federal Register prior to the completion of the commenting process.³⁵

²⁷ *Id.* at 406.

²⁸ Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 342 (2005).

²⁹ Bratspies, *supra* note 4, at 408 (citing Federal Food Drug and Cosmetics Act, 21 U.S.C. § 342(a)(1) (2000)).

³⁰ Lee-Muramoto, *supra* note 14, at 320.

³¹ *Id.*

³² Bratspies, *supra* note 4, at 408.

³³ *Id.*

³⁴ *Id.* at 409.

³⁵ Memorandum for the Heads and Acting Heads of Executive Departments and Agencies (January 26, 2001), available at <http://www.whitehouse.gov/sites/default/files/omb/memoranda/m01-09.pdf> (directing that regulations

Environmental Protection Agency

Under the Federal Insecticide, Fungicide, and Rodenticide Act (F.I.F.R.A.), the Environmental Protection Agency (EPA) sets and regulates the tolerances of pesticides on all crops.³⁶ Currently, GM crops are primarily designed to increase yields through pesticide resistance or internal creation of their own pesticides.³⁷ Therefore, the EPA has the responsibility to regulate any GM crop that secretes “plant incorporated pesticides” (P.I.P.s).³⁸ The industry applicant provides the data used to evaluate these crops to the EPA.³⁹ Similar to FDA regulations for voluntary establishment of substantial equivalence, this creates a potential conflict of interest.⁴⁰ The EPA oversees pesticide and herbicide use, but it does not evaluate herbicide resistant crops.⁴¹

United States Department of Agriculture

The United States Department of Agriculture (USDA) regulation of GM crops is based on the Plant Protection Act (P.P.A.). The P.P.A. provides for the evaluation of new food crops for potential risks to local environments or commerce.⁴² However, the USDA is also bound by substantial equivalence and therefore must look at GM crops in the same manner as conventional crops.⁴³ Once any crop, including a GM crop, finishes field-testing, it is approved for commercial use.⁴⁴ Furthermore, the USDA is prohibited from looking at cross-pollination issues

sent to the Office of the Federal Register, but not yet published, be withdrawn, and that regulations already published but not yet in effect be postponed).

³⁶ *Id.*

³⁷ Bratspies, *supra* note 4, at 411.

³⁸ *Id.*

³⁹ Maria Gabriela Balboa, *Legal Framework to Secure the Benefits While Controlling the Risks of Genetically Modified Foods: A Comparison of the Cartagena Protocol and Three National Approaches*, 31 TEMP. J. SCI. TECH. & ENVTL. L. 255, 268 (2012).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Bratspies, *supra* note 4, at 411.

⁴³ *Id.*

⁴⁴ *Id.* at 412.

with local crops, and therefore, the possible harms from the spread of GM traits.⁴⁵ This lack of pollination drift oversight has caused serious problems to organic farmers.⁴⁶ Estimated U.S. contamination damages of organic corn have been reported at \$90,000,000 per year.⁴⁷

Additionally, the USDA is responsible for the National Organic Program (N.O.P.), instituted in 1990 to certify organic farming practices.⁴⁸ In 1997, the USDA initial N.O.P. practices intended to allow GM crops among the acceptable “organic” practices.⁴⁹ After over 275,000 comments, primarily negative, the USDA decided not to deem GM crop use as an acceptable “organic” process.⁵⁰

General Concerns Regarding the Genetically Modified Industry

Because GM crops are overseen by three separate agencies, some issues are overlooked as each agency feels that it falls into a different agency’s purview.⁵¹ These concerns range from inadequate regulation to prevent cross-pollination, to the spread of undesirable genetic traits from GM non-food crops.⁵²

Current methods to avoid cross contamination in the United States consist of buffer areas between GM and conventional crops.⁵³ In 2003, approximately 20% of farms growing GM crops failed to comply with buffer restrictions; therefore leading to high a probability of cross-

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ Lee-Muramoto, *supra* note 14, at 319 (citing K.L. Hewlett & G.S.E. Azeez, *The Economic Impacts of GM Contamination Incidents on the Organic Sector* (2008), available at http://orgprints.org/12027/1/The_Economic_Impacts_of_GM_Contamination_Incidents_on_the_Organic_Sector.pdf).

⁴⁸ Donald T. Hornstein, *The Road Also Taken: Lessons from Organic Agriculture for Market- and Risk-Based Regulation*, 56 DUKE L.J. 1541, 1552 (2007).

⁴⁹ *Id.*

⁵⁰ *Id.* at 1553.

⁵¹ Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2172 (2004).

⁵² *Id.*

⁵³ Bratspies, *supra* note 4, at 414.

pollination.⁵⁴ Because of practices such as this, it is virtually impossible to assure that any U.S. corn or soybean is 100% non-GM.⁵⁵

Another major concern is that only the USDA regulates non-food GM crops, which do not produce their own pesticides.⁵⁶ The USDA has limited knowledge about these crops, which are typically designed to produce pharmaceutical or industrial chemicals.⁵⁷ However, the USDA testing is still limited to whether the crops have a negative impact on their local environment as pest plants.⁵⁸ No testing is required regarding cross-pollination with food crops.⁵⁹

An additional concern is that since 1999, the fifty largest GM product producers have spent over \$572,000,000 in campaign donations and lobby expenditures in a field where the status quo is very accommodating of their needs.⁶⁰ As current regulation tends to favor the industry, changes to the Framework are unlikely.⁶¹

International Concerns

Current tensions in agricultural trade between the European Union (EU) and the United States are likely caused by fundamentally different regulatory systems used to determine the safety of GM crops.⁶² In the EU, GM crops require individual risk assessments before they begin commercial production.⁶³ These risk assessments are tied to the process of a crop's creation (i.e. genetic modification) as opposed to similarity to conventional counterparts.⁶⁴ This leads to the fact that by definition, GM crops in the EU cannot be labeled as "substantially similar" to pass

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.* at 413.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ Lee-Muramoto, *supra* note 14, at 364.

⁶¹ *See id.*

⁶² *Id.* at 333.

⁶³ Balboa, *supra* note 39, at 257.

⁶⁴ Lee-Muramoto, *supra* note 14, at 334.

the risk assessment.⁶⁵

The United States filed a complaint with the World Trade Organization (WTO) regarding the EU's refusal to accept U.S. crop shipments due to the EU moratorium on GM crop approval.⁶⁶ The United States claimed that the EU did not have any data to support their denial based on health concerns, and further claimed that the EU's requirement to exclude U.S. crops was an "undue delay" on trade.⁶⁷ The WTO eventually ruled that the EU was wrong solely on procedural grounds and did not comment on the scientific evidence on the safety of GM crops.⁶⁸ Therefore, no real progress has been made on the issue of GM crop trade between the EU and United States, and as a result, the EU has passed a zero tolerance threshold for unapproved GM crops, which virtually ensured that U.S. grains could not be imported to the EU.⁶⁹

In addition to the EU approach, the Cartagena Protocol is a modern attempt to create an international regulatory structure for general biotechnology.⁷⁰ The Cartagena Protocol allows nations to share information on previous risk assessments of GM technologies.⁷¹ Additionally it requires that nations disclose the GM crops in potential exports.⁷² Unfortunately, the Cartagena Protocol, although recognized in 132 countries, has not been approved in several of the world's largest agricultural exporters including the United States, Argentina, Australia, and Canada.⁷³ Therefore, the Cartagena Protocol's attempt to regulate GM crops worldwide has been severely impaired.⁷⁴

⁶⁵ *Id.*

⁶⁶ *Id.* at 335

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ Balboa, *supra* note 39, at 263.

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

Product Labeling

Even with the majority of Americans supporting GM labeling, the FDA does not require any labels to distinguish GM foods from non-GM foods.⁷⁵ Additionally, the FDA originally ruled that voluntary labels such as “GM-free” would “misbrand” the product, a violation of Federal Food, Drug, and Cosmetic Act.⁷⁶ Because GM crops are considered G.R.A.S., any labeling that leads to the inference that GM crops are dangerous is considered misleading.⁷⁷ Concerns over “misbranding” were also based on the lack of a clear definition of the degree of genetic manipulation required for a crop to be considered GM.⁷⁸ However, with no labeling to differentiate GM and non-GM foods, consumers had lost the opportunity to opt out of buying GM crops and thereby slow the changes in food products.⁷⁹ In 2001, the FDA and USDA reconsidered and allowed for the possibility of voluntary “GM-free” labeling based on the allowance of “fair trade” labeling.⁸⁰ However, through this voluntary process, individuals are not necessarily able to easily distinguish which products do not contain GM crops.⁸¹

Organic or Natural

Organic labeling began in the 1970s and was state controlled until 1990.⁸² The Organic Foods Production Act passed by Congress in 1990 created a certification program for organic production.⁸³ It took the USDA seven years initially to propose standards, including one heavily contested suggestion that GM crops were not prohibited in organic production.⁸⁴ This provision

⁷⁵ Du, *supra* note 17, at 383.

⁷⁶ *Id.* at 385.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.* at 384.

⁸⁰ *Id.* at 385.

⁸¹ *Id.* at 386.

⁸² Friedland, *supra* note 3, at 382.

⁸³ *Id.*

⁸⁴ *Id.* at 383.

was stripped from the final standards.⁸⁵ In 2002, the USDA’s “organic” production standards were adopted after several revisions.⁸⁶ Originally, “organic” labeling avoided GM crops, as GM crops did not meet the standards for organic certification.⁸⁷ However, “organic” products do not require testing to ensure that there are no traces of GM residues from cross-pollination.⁸⁸ Even with testing, there are no EPA tolerance levels for GM residue that could be used when defining whether a product is organic.⁸⁹ Therefore, “organic” labels indicate any product where GM crops are not intentionally used.⁹⁰

Additionally, organic certification is primarily handled by private certifying agents who are paid and overseen by organic producers and processors.⁹¹ Neither the USDA nor any other governmental organization takes part in the certification of “organic” production.⁹² Certification is founded on an “organic” production plan, which meets N.O.P. standards and an annual visit, by the certifying agent to ensure adherence to the approved plan.⁹³ Therefore, the certifying agent lacks the comprehensive oversight to prevent problems related to GM crops.⁹⁴

Furthermore, the FDA has refused to explicitly define the term “natural” leading to legal challenges of its definition.⁹⁵ There are several cases pending throughout the country where the primary issue is what constitutes “natural.”⁹⁶ The current interpretation is that “all natural” is a “mere product description[]” and therefore asserts no claim that the product is free from GM

⁸⁵ *Id.*

⁸⁶ *Id.* at 384.

⁸⁷ Du, *supra* note 17, at 386.

⁸⁸ Friedland, *supra* note 3, at 391.

⁸⁹ Du, *supra* note 17, at 386.

⁹⁰ *Id.*

⁹¹ Friedland, *supra* note 3, at 390.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ Nicole M. Civita & Susan A. Schneider, *2012 Developments in Food Law and Policy*, 18 DRAKE J. AGRIC. L. 39, 70 (2013).

⁹⁶ See *In re Tropicana Orange Juice Mktg. & Sales Practices Litig.*, 867 F.Supp.2d 1341 (M.D. Fla. 2012) (looking at the use of “natural” in Tropicana marketing).

crops.⁹⁷

Proposed changes

The federal government handles almost all regulation of GM crops; however, a few states have recently tried to institute state labeling standards.⁹⁸ California's Proposition 37 was designed to create statewide GM labeling standards.⁹⁹ Products using GM crops would have been "misbranded" if they did not explicitly state that they included "genetically engineered" materials either on the front or back of the container.¹⁰⁰ Additionally, GM foods would never be allowed to market themselves as "natural" products.¹⁰¹ This bill enjoyed early support but did not pass because of a well-financed ad campaign by the food industry.¹⁰²

Washington state initiative I-355 is based on Proposition 37.¹⁰³ It includes standards for labeling products as "genetically engineered," but does not restrict GM crops from using the "natural" label.¹⁰⁴ Initiative I-522 should be on Washington ballots soon.¹⁰⁵

Conclusion

Current federal regulation of GM crops is based on the Coordinated Framework for Regulation of Biotechnology and the other laws existing in 1986. The age and piecemeal nature of these regulations is concerning based on the modern nature of this industry. Additionally, these laws do not meet the desires of consumer's for greater clarity regarding labeling of GM crop products. However, due to pressures by the agricultural industry, little change is likely to occur.

⁹⁷ Littlehale v. Hain Celestial Group, Inc., No. C 11-6342 PJH, 2012 WL 5458400, at *1 (N.D. Cal. Jul. 2, 2012).

⁹⁸ Civita, *supra* note 95, at 48.

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 48–49.

¹⁰¹ *Id.* at 49.

¹⁰² *Id.* at 48.

¹⁰³ *Id.* at 50.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*