15-1504-cv

IN THE

United States Court of Appeals for the Second Circuit

GROCERY MANUFACTURERS ASSOCIATION, SNACK FOOD ASSOCIATION, INTERNATIONAL DAIRY FOODS ASSOCIATION, and NATIONAL ASSOCIATION OF MANUFACTURERS,

Plaintiffs-Appellants,

v.

WILLIAM H. SORRELL, in his official capacity as the Attorney General of Vermont; PETER SHUMLIN, in his official capacity as Governor of Vermont; JAMES B. REARDON, in his official capacity as Commissioner of the Vermont Department of Finance and Management; and HARRY L. CHEN, in his official capacity as the Commissioner of the Vermont Department of Health,

Defendants-Appellees.

On Appeal from the
United States District Court for the District of Vermont
Case No. 1:14-cv-117-cr (Hon. Christina Reiss)

BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF PLAINTIFFS-APPELLANTS AND IN SUPPORT OF REVERSAL

(counsel listed on inside cover)

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Amicus curiae Biotechnology Industry Organization hereby discloses that it is a nongovernmental trade association, is not owned in whole or in part by a parent corporation or a publicly traded company, and does not issue stock.

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INTEREST OF AMICUS CURIAE[1]

Biotechnology Industry Organization ("BIO") is the world's largest biotechnology trade association, whose members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO's members include corporate entities (from entrepreneurial start-ups to Fortune 500 multi-nationals), academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. Through its Food and Agriculture Section, BIO has taken the lead in promoting the safety and benefits of genetically engineered ("GE") crops developed through agricultural biotechnology. BIO advocates for scientific regulatory approaches for these crops both domestically and abroad, while also supporting the concurrent cultivation of conventionally bred and organic crops.

Plaintiffs-Appellants (the Associations) seek reversal of the District Court's order denying their motion to preliminarily enjoin Act 120, a Vermont law

[1] This brief was not authored in whole, or in part, by counsel for a party; no party and no party's counsel contributed money intended to fund the preparation or submission of the brief; and no person, other than BIO, its members, or its counsel, contributed money intended to fund the preparation or submission of the brief. *See* Local Rule 29.1(b). All parties to this appeal have consented to the filing of this brief. *See* Fed. R. App. P. 29(a).

requiring the labeling of certain foods produced in whole or in part through genetic engineering. Pursuant to Federal Rule of Appellate Procedure 29(a), BIO respectfully submits this brief as *amicus curiae* in support of the Associations.

BIO and its members have a strong interest in this appeal. BIO's members have devoted countless hours of research and many millions of dollars to exploring innovative technologies and processes for the development of biotechnology-derived or GE crops. BIO's members and staff are intimately familiar with the comprehensive regulatory regime governing the development and use of GE crops, and with the established scientific consensus that such crops are as safe to grow and eat as non-GE crops. The Vermont legislature's purported factual findings and reasons offered in support of Act 120 are inconsistent with that consensus. As *amicus curiae*, BIO will provide insight into the highly specialized legal and factual context in which biotechnology products are developed, tested, and commercialized, which insight will aid this Court in evaluating the issues presented on appeal and the practical impacts of the parties' positions.

INTRODUCTION AND SUMMARY OF ARGUMENT

In May 2014, the Vermont legislature passed Act 120, a law that requires the labeling of certain foods "offered for retail sale in Vermont" after July 1, 2016, that are "produced entirely or in part from genetic engineering" and sets forth the labeling requirements for those products. 9 Vt. Stat. Ann. §§ 3043(a), (b). The

law also prohibits such foods from being labeled as "natural," "naturally made," "naturally grown," "all natural," or "any words of similar import that would have the tendency to mislead a consumer." *Id.* § 3043(c). The law contains many exemptions, which mean that its labeling requirements and prohibitions apply to some but not all foods "produced entirely or in part from genetic engineering." *See id.* § 3044(1)-(8). In connection with its enactment of Act 120, the Vermont General Assembly detailed a number of "Findings," including the statements that "[t]here is a lack of consensus regarding the validity of the research and science surrounding the safety of [GE] foods" and that genetically engineered foods "potentially pose risks to health, safety, agriculture, and the environment." 2014 Vt. Acts & Resolves 120, §§ 1(2)(D), 1(4).

These "Findings" by state legislators ignore the overwhelming global scientific consensus on the safety of foods derived from GE crops, which are subject to a rigorous, multiyear regulatory review process before being cleared for commercialization. To BIO's knowledge, every GE crop on the market today was thoroughly evaluated by multiple federal agencies as part of this scientific review process. This process is nonpartisan and objective—dozens of GE crops have cleared review since the 1990s. *See generally* USDA Animal and Plant Health Inspection Service, *Petitions for Determination of Nonregulated Status, available at* http://goo.gl/poyuHm (last visited June 24, 2015) (listing all GE plants that have

cleared USDA regulatory review and have been deregulated, along with pending petitions for deregulation); FDA, *Biotechnology Consultations on Food from GE Plant Varieties*, http://goo.gl/L24Pji (last visited June 25, 2015) (listing all completed FDA biotechnology consultations on GE foods evaluated under FDA's 1992 Statement of Policy, discussed below). Not only have GE crops been deemed safe by expert federal agencies, but numerous other governmental and nongovernmental agencies in the U.S. and around the world have reached the same conclusion, including the U.S. National Academy of Sciences, the World Health Organization, the American Medical Association, the European Commission, the British Medical Association, and the Union of the German Academies of Science and Humanities. This is a major reason why Vermont's Act 120 fails First Amendment scrutiny: the Act is flatly inconsistent with the U.S. and global scientific consensus.

This brief provides background on the science of plant breeding and reviews the widespread use and acceptance of genetic engineering as an established element of U.S. agriculture and the many benefits of GE crops. The brief then describes the comprehensive and robust regulatory framework that the federal government has established to ensure that GE crops are as safe to grow and eat as non-GE crops; the federal government's commitment to a science-based regulatory

approach for GE crops as embodied in international treaty obligations; and the global scientific consensus establishing the safety of GE crops.

ARGUMENT

I. The Science of Plant Breeding and Biotechnology and Its Benefits

Plant evolution and all plant breeding are based on the interplay and unique combinations of genes among plants. This biological certainty has existed since the dawn of time. It was the ability to harness this activity that allowed humans to cultivate crops and develop agriculture millennia ago. Modern genetic engineering reflects an extension and refinement of this age-old and naturally occurring phenomenon. Advancements in agricultural biotechnology and the proliferation of GE crops have led to remarkable benefits for consumers, growers, and the environment.

A. Genetic Engineering Is a Natural Progression in the Science of Plant Breeding.

Genetic engineering, including recombinant DNA technology, is widely considered to be the next logical step in a natural progression in plant breeding techniques that have been developed over time and, in particular, over the past century. Crop scientists and other members of the scientific community overwhelmingly agree that there is nothing inherent in modern biotechnology techniques, including genetic engineering, that distinguishes the potential risks of GE plants from those of non-GE plants. Indeed, a report issued in 1989 by the

National Research Council (NRC) of the National Academy of Sciences explored the basic biological principles that underlie the various means of altering the genetic makeup of organisms and found that "no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes."[2]

The Food and Agriculture Organization (FAO) and the World Health Organization (WHO) similarly found, in a 1991 Joint Consultation report, that "genetic modification of organisms by means of current technologies represents the latest point reached in a continuum of development rather than a unique branch of science."[3] The report concludes:

> Biotechnology has a long history of use in food production and processing. It represents a continuum embracing both traditional breeding techniques and the latest techniques based on molecular biology. The newer biotechnological techniques, in particular, open up very great possibilities of rapidly improving the quantity and quality of food available. The use of these techniques does not result in food which is inherently less safe than that produced by conventional ones.

Id. § 7.1.

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[2] Committee on Scientific Evaluation of the Introduction of Genetically Modified Microorganisms and Plants into the Environment, National Research Council, *Field testing genetically modified organisms: Framework for decisions* 14 (1989), *available at* http://goo.gl/n2xI8B.

[3] WHO, *Strategies for assessing the safety of foods produced by biotechnology*: *Report of the Joint FAO/WHO Consultation* § 6.2 (1991), *available at* http://goo.gl/I2HFP5.

Likewise, the Institute of Food Technologists, a seventy-year old international non-profit organization and world leader in food science, has concluded that foods derived using recombinant DNA technology are merely "the latest step in a 10,000-year sequence of human intervention in the genetic improvement of food."[4] The late Nobel Prize-winner Norman Borlaug wrote that genetic engineering of plants complements, rather than replaces, traditional breeding "to identify desirable genes from remotely related taxonomic groups and transfer these genes more quickly and precisely into high-yield, high-quality crop varieties."[5] The textbook "Breeding Field Crops," long recognized as the standard work in its field, expresses a similar view, emphasizing that all plants—not just those derived through biotechnology—are the result of genetic manipulation:

> Biotechnology in its most simplistic sense is the genetic modification of living organisms. Hence, all crop varieties grown today have had their DNA manipulated in some form or another. . . . Traditional plant breeding procedures are based on *manipulation of genes and chromosomes through sexual reproduction* in whole plants. . . . Today, biotechnology has developed the genomic tools for supplementing traditional plant breeding procedures *by extending genetic manipulations beyond the level of sexual reproduction*.[6]

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[4] Institute of Food Technologists, *IFT Expert Report on Biotechnology and Foods*, 54 Food Technology 124, 124 (2000).

[5] Norman E. Borlaug, *Ending World Hunger: The promise of biotechnology and the threat of antiscience zealotry*, 124 Plant Physiology 487, 489 (2000), *available at* http://goo.gl/w3lqKF.

[6] David Allen Sleper & John Milton Poehlman, *Breeding Field Crops* 115 (2006).

The U.S. Food and Drug Administration ("FDA") has commented in a policy statement on the similarity among various traditional and modern plant breeding methods and concluded that genetic engineering techniques "are more precise" and actually "increase the potential for safe, better-characterized, and more predictable foods."[7]

Modern biotechnology techniques allow plant scientists, for the first time, to directly observe and record the genetic contents of plants and to manipulate them with greater specificity and certainty than ever before. That those changes can be traced in this manner for the first time, however, does not mean that genetic changes in plants are occurring for the first time. Rather, such changes, some significant, occur naturally and constantly. In modern agriculture, plant scientists are actively working to encourage and direct these changes in order to improve plant health, sustainability, and nutrition. In reviewing the place of genetic engineering in the context of several thousand years of genetic modification of food crops, Professor C. S. Prakash concludes that: "When compared to the gross genetic alterations using wide-species hybridization or the use of mutagenic

[7] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,986 (May 29, 1992). *See also* USDA National Agricultural Library, *A Focus on Agriculture Biotechnology* (2005), https://goo.gl/UBnkFo; *infra* Section II.C (discussing the global scientific consensus surrounding modern genetic engineering and GE crops).

irradiation, direct introduction of one or a few genes into crops [using biotechnology] results in subtle and less disruptive changes that are relatively specific and predictable."[8]

B. Plants Improved Through Biotechnology Are Highly Beneficial and Widely Prevalent in U.S. Agriculture.

Plant products on the market today created through biotechnology have brought significant benefits to farmers, consumers, and the environment. Some of the commercially available biotechnology-derived crops and their traits include:

- High oleic soybeans, providing improved cooking oils and processed foods with lower levels of saturated fat and trans-fatty acids;
- Corn and cotton protected against harmful insects, reducing the need to spray conventional pesticides;
- Herbicide-resistant crops, enhancing farmers' ability to control weeds and reducing reliance on mechanical plowing, thereby reducing fuel use, soil erosion and degradation, and greenhouse gas emissions;
- Drought-resistant corn; and
- Squash and papayas resistant to harmful viruses.

[8] Channapatna S. Prakash, *The Genetically Modified Crop Debate in the Context of Agricultural Evolution*, 126 Plant Physiology 8, 11 (2001), *available at* http://goo.gl/K06fej. Professor Prakash is a Professor of Plant Genetics, Biotechnology and Genomics at Tuskegee University, Alabama, and past member of the USDA Advisory Committee on Agricultural Biotechnology.

Benefits of future biotechnology products include crops with improved nutritional value and plants used for production of second-generation biofuels and other bio-based products.

Crops improved through biotechnology have been widely accepted by food growers, marketers, and consumers. Indeed, as of 2014, GE varieties comprise 96% of all cotton cultivated in the U.S., 94% of all soybeans, and 93% of all corn.[9] Globally, a record 448 million acres of GE crops were grown in 2014, the 19th year of commercialization of GE crops (1996-2014), when growth continued after a remarkable 18 consecutive years of increases.[10] Global hectarage of GE crops increased more than 100-fold from 1.7 million hectares in 1996 to 181.5 million hectares in 2014, making GE crops the fastest adopted crop technology in recent history.[11] GE crops were planted in the Americas (*e.g.*, Canada, U.S., Mexico, Brazil, Argentina and Chile); Asia (*e.g.*, India, China, Pakistan and the Philippines); Africa (*e.g.*, South Africa, Burkina Faso, and Sudan); Australia; and Europe (*e.g.*, Spain, Portugal, and the Czech Republic).[12]

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[9] USDA Economic Research Service, *Adoption of Genetically Engineered Crops in the U.S.*, http://goo.gl/mHd9zL (last visited June 24, 2015).

[10] International Service for the Acquisition of Agri-Biotech Applications (ISAAA), Executive Summary, *Global Status of Commercialized Biotech/GM Crops: 2014*, *available at* http://goo.gl/cmFxP5.

[11] *Id.*

[12] *Id.*

According to the International Service for the Acquisition of Agri-Biotech Applications ("ISAAA") at Cornell University, of the 28 countries that planted GE crops in 2014, 20 were developing and 8 were industrialized countries.[13] More than half the world's population, 60% or approximately 4 billion people, live in the 28 countries planting GE crops.[14] In 2014, 18 million farmers grew biotechnology-derived crops—notably, over 90%, or over 16.5 million, were small resource-poor farmers in developing countries.[15] And ISAAA has identified a number of major sustainability benefits flowing from the adoption of GE crops, including (1) contributing to food security and self-sufficiency by increasing productivity and economic benefits sustainably at the farmer level; (2) conserving biodiversity by increasing productivity; (3) contributing to the alleviation of poverty and hunger by contributing to incomes of resource-poor farmers; (4) reducing agriculture's environmental footprint; and (5) helping to mitigate climate change and reducing greenhouse gases by decreasing carbon dioxide emissions and increasing conservation tillage.[16] With the world's population set to reach 9.6 billion by

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[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*; *see also* Graham Brooks & Peter Barfoot, PG Economics Ltd, UK, *GM crops: global socio-economic and environmental impacts 1996-2012* (2014), *available at* http://goo.gl/8n5gIw.

2050, improving sustainability while increasing production is a key goal for global agriculture.[17]

II. The U.S. Regulatory Framework

A. The Federal Government's Coordinated Regulatory Framework Assures the Safety of GE Crops.

Recognizing biotechnology's "tremendous potential," the White House Office of Science and Technology Policy created what is known as the Coordinated Framework in 1986 to provide a "coordinated and sensible regulatory review process" governing biotechnology in the United States. 49 Fed. Reg. 50,856, 50,856-67 (Dec. 31, 1984) (proposed policy); 51 Fed. Reg. 23,302 (June 26, 1986) (final policy). The Coordinated Framework is founded on three federal statutes, under which three federal agencies—the United States Department of Agriculture ("USDA"), FDA, and the Environmental Protection Agency ("EPA")—each exercise scientific judgment within their area of expertise. This comprehensive statutory and regulatory regime establishes a uniform approach to GE crops that ensures regulatory decisions are "based upon the best available science." 49 Fed. Reg. at 50,857. The typical GE crop requires years of field testing and scientific analysis to clear the required regulatory hurdles. For those

[17] *See, e.g.*, United Nations, Department of Economic and Social Affairs, *World Population Prospects*: *The 2012 Revision* (June 2013), *available at* http://goo.gl/EdWkQl.

GE crops that successfully complete these federal scientific reviews, the crop is deemed the same as its non-GE counterpart for federal regulatory purposes.

B. USDA Regulation

USDA's Animal and Plant Health Inspection Service ("APHIS") regulates GE crops pursuant to its authority to regulate plant pests under the Plant Protection Act ("PPA").[18] The PPA, like the rest of the Coordinated Framework, emphasizes that regulatory decisions must "be based on sound science." 7 U.S.C. § 7701(4). In implementing the PPA[19], APHIS promulgated a regulatory scheme at 7 C.F.R. Part 340 governing the introduction in the U.S. of genetically engineered organisms and other plant products that are derived from known or suspected plant pests.[20] To BIO's knowledge, every GE crop marketed in the U.S. has cleared that APHIS regulatory process.

Under the PPA's implementing regulations, "regulated articles" are prohibited from being imported, moved in interstate commerce, or introduced into

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[18] USDA's authority to regulate plant pests also extends to non-GE plant pests, which are regulated under 7 C.F.R. Part 330.

[19] The regulations were promulgated under the authority of two predecessor statutes to the PPA, the Federal Plant Pest Act and the Plant Quarantine Act, both of which were superseded by the PPA in 2000. *See* 52 Fed. Reg. 22,892, 22,892-93 (June 16, 1987) and 7 U.S.C. § 7758.

[20] *See* 7 C.F.R. § 340.1 (definition of "regulated article). For a detailed video overview of APHIS's regulatory regime for GE crops, *see* APHIS, USDA, *Regulation of Biotechnology*, http://www.youtube.com/watch?v=ytzwXOaIvqQ (Apr. 8, 2014).

the environment without express approval from APHIS. 7 C.F.R. §§ 340.0(a), 340.1. New GE crops are generally treated as "regulated article[s]" because, for regulatory purposes, they are presumed to be "plant pests" until APHIS determines that the specific GE crop is unlikely to pose a "greater plant pest risk" than its non-GE counterpart. *Id.* § 340.6(c)(4). To conduct its assessment, APHIS must analyze data from federally authorized field trials of the new GE crop and perform an extensive scientific review of the plant, including its genetic structure and plant pest potential. *Id.*

To provide APHIS with the data it needs, Part 340 establishes a detailed regulatory regime for conducting field trials. *Id.* §§ 340.3-.4. In authorizing a field trial, APHIS reviews, approves, modifies, or enhances the field trial procedures and safeguards as appropriate for the particular type of crop.[21] Approved field trials are subject to ongoing inspections by USDA inspectors, 7 C.F.R. §§ 340.3(d)(6), 340.4(d), and APHIS requires a series of reports regarding the trials, *id.* §§ 340.3(d)(4), 340.4(f)(9).[22] If information from the field trials and other sources indicates that the GE crop variety poses no greater plant pest risks than its

[21] *See, e.g.*, APHIS, USDA, *Minimum Separation Distances to be used for Confined Field Tests of Certain Genetically Engineered Plants* (2013), *available at* http://goo.gl/cTNCKh.

[22] Detailed information on field trial requirements, including isolation distances, volunteer monitoring and other requirements, is available at APHIS, USDA, *Compliance and Inspections*, http://goo.gl/Ci81ak (last modified Jan. 20, 2015).

non-GE counterpart, an individual may petition APHIS for a determination of nonregulated status. 7 C.F.R. § 340.6(a). APHIS publishes preliminary draft determinations and considers public comments before reaching a final scientific conclusion. APHIS's decision to grant such a petition represents a regulatory determination that the GE crop may be used in the United States in the same way as its non-GE counterpart, including for commercial purposes.

APHIS's expertise in regulating GE crops is extensive. Between 1987 and 2012, APHIS reviewed more than 38,000 proposals for the importation, interstate movement, or field testing of regulated articles, including many proposals for GE corn, cotton, soy, and other food or feed crops.[23] To date, APHIS has exercised its authority under the PPA and granted non-regulated status to 115 GE crops, with additional reviews currently pending.[24]

C. FDA Regulation

In coordination with USDA's review, the FDA has broad authority under the Federal Food, Drug, and Cosmetic Act ("FFDCA") to regulate the safety of GE-derived food and food ingredients, including animal feed. 21 U.S.C. § 301 *et seq.* FDA regulates GE crops "[u]sing a science-based approach" to ensure that "foods

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[23] *See* 3 L. of Envl. Prot. § 19:27, at 193 (2014).

[24] *See generally* APHIS, USDA, *Petitions for Determination of Nonregulated Status*, *available at* http://goo.gl/poyuHm (last visited June 24, 2015).

and ingredients made from genetically engineered plants . . . are safe to eat."[25] The agency has developed a premarket consultation process to assess whether foods derived from new GE crops are substantially equivalent to foods developed through traditional plant breeding. *See* Statement of Policy: Foods Derived From New Plant Varieties ("1992 Policy"), 57 Fed. Reg. 22,984, 22,985-86 (May 29, 1992) (explaining that GE crops are not inherently more dangerous than conventionally bred crops and that FDA's regulatory approach to foods from GE plant varieties is identical in principle to that applied to foods from non-GE plants).

The FDA summarized its 1992 Policy as follows:

> The regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use of the food (or its components). The method by which the food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods were used.

Id. at 22,984-85.

Thus, FDA's analysis of foods from GE plants includes consideration of whether the foods differ in toxicants, nutrient concentrations, or allergenicity. *Id.* at 22,986-88. To date, FDA has completed 166 safety consultations on foods from

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[25] FDA, Dept of Health & Human Servs., *FDA's Role in Regulating Safety of GE Foods*, http://www.fda.gov/forconsumers/ consumerupdates/ucm352067.htm (last updated May 9, 2014).

GE crops.[26] Although the FDA process is not mandatory, all GE food and feed derived from GE crops currenly on the market in the U.S., to BIO's knowledge, have cleared this FDA review.[27]

Among its many regulatory responsibilities with respect to the food supply, FDA is responsible for ensuring the accuracy of the food label. Food is deemed to be "misbranded" if "its labeling is false or misleading in any particular." 21 U.S.C. § 343(a)(1). FDA has consistently held that "the use, or absence of use, of bioengineering in the production of a food is not a fact that is material either with respect to consequences resulting from the use of the food or due to representations on the labeling." 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001).

Even after conducting an extensive public outreach campaign over a seven-year period and receiving thousands of comments requesting mandatory disclosure

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[26] *See* FDA, *Biotechnology Consultations on Food from GE Plant Varieties*, http://goo.gl/L24Pji (last visited June 25, 2015).

[27] *See* APHIS, USDA, *Engagement on APHIS Biotech Regulations, The Coordinated Framework,* http://goo.gl/NMTAlj (last visited June 30, 2015); *see also* Testimony of Michael M. Landa, Director, Center for Food Safety & Applied Nutrition, U.S. Food & Drug Administration (FDA), before U.S. House of Representatives, Committee on Energy and Commerce, Health Subcommittee (Dec. 10, 2014), at 10, *available at* http://goo.gl/O8F3aF ("Landa Testimony") ("The fact that participation in the process is voluntary should not mislead individuals to believe that the process does not provide for a rigorous food safety evaluation. . . . FDA considers a consultation to be complete only after all safety and other legal issues have been resolved. The premarket consultation process is working well and protects public health by helping FDA ensure that firms are making market-entry decisions in compliance with the law.").

of the fact that a food was bioengineered, the FDA in 2001 reaffirmed its decision to not require special labeling of all bioengineered foods, stating that it "is still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under [FFDCA]." 66 Fed. Reg. 4840. Rather, FDA has consistently held that the "labeling requirements that apply to foods in general also apply to foods produced using biotechnology." *Id.* at 4839; *see also* Landa Testimony at 2 ("[FDA's] 1992 [policy] statement and its scientific underpinnings still reflect FDA's current thinking about foods derived from GE plants and, based on our evaluations, we are confident that the GE foods in the U.S. marketplace today are as safe as their conventional counterparts.").

Notwithstanding FDA's extensive experience with GE foods under the FFDCA, Vermont legislators rejected FDA's policies, and the scientific assessments underlying those policies, when the state legislature enacted Act 120.

D. EPA Regulation

In further coordination with USDA and FDA, EPA regulates the use of pesticides in conjunction with GE crops in three ways pursuant to its authority under the FFDCA and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq*. First, before a pesticide may be used on any food crop (GE or non-GE), EPA specifies the amount of pesticidal residue (called

a "tolerance") that may legally remain in or on foods under the FFDCA. *See* 21 U.S.C. § 346a. Second, under FIFRA, EPA must approve any pesticide before it may be marketed or used on any crop (GE or non-GE, food or not) in the U.S. *See* 7 U.S.C. §§ 136a(c)(5), 136j(a)(1). Third, for certain GE crops that have been genetically modified to produce so-called "Plant-Incorporated Protectants" ("PIPs") to protect the plants from insect pests without the need for traditional pesticide applications, EPA regulates the PIPs as pesticides under FIFRA and FFDCA. *See* 66 Fed. Reg. 37,772 (July 19, 2001); *see generally* 40 C.F.R. pt. 174.

In short, all three agencies work together under the Coordinated Framework to ensure that the potential impacts of growing GE plants are subject to a thorough science-based assessment prior to commercialization. Notwithstanding the intensive governmental, academic, and commercial oversight these plants have received since 1986, not a single instance of actual harm to health, safety, or the environment has been ever been confirmed for any GE crop, whether in development or following completion of the U.S. regulatory process.

III. International Treaty Obligations Regarding GE Crops

The federal government's commitment to a science-based regulatory approach for GE crops extends beyond domestic law. In 1994, the United States, along with 123 other countries, entered into the World Trade Organization's ("WTO's") Agreement on the Application of Sanitary and Phytosanitary Measures

(the "SPS Agreement").[28] In so doing, the United States promised the international community that any U.S. law or regulation—national or local—enacted "to protect animal or plant life or health . . . from risks arising from the . . . spread of pests, diseases, disease-carrying organisms or disease-causing organisms" or "to protect human or animal life or health . . . from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs" would be "*based on scientific principles*" and would not be "maintained without *sufficient scientific evidence*." SPS Agreement, art. 2.2 & annex A (emphasis added); *see id.*, art. 13.

The United States takes this obligation seriously. For example, after the European Communities (EC) refused to approve new GE crops for use throughout the European Union from 1999–2003, the United States brought a successful challenge before the WTO.[29] The United States alleged, and the WTO panel agreed, that the EC's *de facto* moratorium on GE crops violated the EC's obligations under the SPS Agreement—obligations that match our own.[30] When the EC defended the moratorium based in part on the "precautionary principle," the

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[28] *Available at* http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

[29] Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DR293/R 1 (Sept. 29, 2006), *available at* https://goo.gl/n20S1w.

[30] *Id.*

United States responded that the EC's statements about "the purported risks of biotechnology" were "fundamentally misleading."[31] The United States explained:

> The safety of biotech products has been confirmed by scientific reports issued under the auspices of renowned international institutions, such as the [United Nations Food and Agriculture Organization (FAO)] and [United Nations World Health Organization (WHO)], seven national and international academies of science, and the Organization for Economic Co-operation and Development, as well as independent scientists in the United States, Africa and Europe.[32]

The scientific advisory bodies of the European Union, it added, "have also confirmed the conclusion that, for both food and environmental risks, plants produced through modern biotechnology do not present new or novel risks."[33] In light of these studies, the United States concluded that the "notion of precaution" could not justify an across-the-board moratorium on new GE crops.[34]

IV. The Global Scientific Consensus Surrounding GE Crops

In addition to being deemed safe by expert federal agencies, multiple other governmental and non-governmental organizations worldwide have reached the same conclusions concerning the safety of GE crops. The consensus surrounding the safety of GE crops is truly overwhelming. For example:

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[31] *Id.* at 99.

[32] *Id.* at 29.

[33] *Id.* at 100.

[34] *Id.* at 101.

- [E]very other respected organization [in addition to the EU] that has examined the evidence has come to the same conclusion: consuming foods containing ingredients derived from GM crops is no riskier than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques. . . . GM crops are the most extensively tested crops ever added to our food supply." American Association for the Advancement of Science, *Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods* (Oct. 20, 2012), *available at* http://goo.gl/82vY0A.

- "[N]o effects on human health have been shown as a result of the consumption of [G.M.] foods by the general population in the countries where they have been approved." WHO, *Frequently asked questions on genetically modified foods* (May 2014), *available at* http://goo.gl/5L9k1K (last visited June 24, 2015).

- "Foods derived from GM crops have been consumed by hundreds of millions of people across the world for more than 15 years with no reported ill effects (or legal cases related to human health) despite many of the consumers coming from that most litigious of countries, the USA." Suzie Key et al., *Genetically Modified Plants and Human Health*, 101 J. of the Royal Soc. of Med. 290, 292-93 (2008), *available at* http://goo.gl/h7JAUD.

- "[N]o adverse health effects attributed to genetic engineering have been documented in the human population." National Academy of Sciences ("NAS") Report, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* 8 (2004), *available at* http://goo.gl/4PlC2u.

- In 2000, the National Research Council confirmed the NAS's conclusion, outlined in a 1987 NAS white paper, *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues*, *available at* http://goo.gl/yqoL2a, that GE crops are as safe to grow as non-GE crops and, further, found no evidence that GE crops are unsafe to eat, National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation* 5–6, 8 (2000), *available at* http://goo.gl/it9bfk, a finding repeatedly reaffirmed by the FDA. *See* Landa Testimony at 14 ("[W]e are confident that GE foods in the U.S. marketplace today are as safe as their conventional counterparts."); Agric., Rural Dev., FDA, and Related

Agencies Appropriations for 2015: Hearing Before the Subcomm. on Agric., Rural Dev., FDA, and Related Agencies of the H. Comm. on Appropriations, 113th Cong. 936 (2014) (statement of Dr. Margaret Hamburg, Comm'r, FDA), *available at* http://goo.gl/K2o7R1 ("very credible scientific organizations . . . have looked hard at this issue over a long period of time," and FDA "ha[s] not seen evidence of safety risks associated with genetically modified foods").

- "[F]ood derived from GM plants approved in the EU and the USA poses no risk greater than those from the corresponding 'conventional' food. On the contrary, in some cases food from GM plants appears to be superior with respect to health." Union of the German Academies of Science and Humanities, Commission Green Biotechnology, InterAcademy Panel Initiative on Genetically Modified Organisms, Group of the International Workshop Berlin 2006, *Are there health hazards for the consumer from eating genetically modified food*? 1, *available at* http://goo.gl/5z5CtN.

- "If we look at evidence from [more than] 15 years of growing and consuming GMO foods globally, then there is no substantiated case of any adverse impact on human health, animal health or environmental health, so that's pretty robust evidence, and I would be confident in saying that there is no more risk in eating GMO food than eating conventionally farmed food." Anne Glover, Chief Scientific Adviser, European Commission, *GE Food Poses No Risk*, Crop Biotech Update (Aug. 3, 2012), *available at* http://goo.gl/eCLypB.

These statements are supported by an abundance of scientific research, including a significant compilation funded by the European Union involving over 130 research projects, conducted over a 25-year period by more than 500 independent research

groups.[35] "Indeed, the science is quite clear: crop improvement by the modern molecular techniques of biotechnology is safe."[36]

CONCLUSION

For the foregoing reasons, and for the reasons stated in Plaintiffs-Appellants' Brief, the order of the District Court should be reversed.

Respectfully submitted,

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[35] Joanne Wendel & Jon Entine, Genetic Literacy Project, *With 2000+ global studies affirming safety, GM foods among most analyzed subjects in science* (Oct. 8, 2013), http://goo.gl/VC4o2E; *see also* Genetic Engineering & Risk Analysis (GENERA) Database, http://genera.biofortified.org/viewall.php; European Commission, *A Decade of EU-Funded GMO Research, 2001-2010*, *available at* http://goo.gl/Y3Q3bp.

[36] *Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods* (Oct. 20, 2012), *available at* http://goo.gl/82vY0A.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I hereby certify that this Brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and 32(a)(7)(B) because the Brief contains 5,516 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

I further certify that this Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because the Brief has been has been prepared in Times New Roman 14-point font using Microsoft Word 2010.

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