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 *AMICI CURIAE* AGRICULTURAL AND COMMODITY TRADE ASSOCIATIONS IN SUPPORT OF PLAINTIFFS-APPELLANTS' MOTION FOR A PRELIMINARY INJUNCTION

(Amici and counsel listed on inside cover)

July 1, 2015

AMICI CURIAE

American Soybean Association
Corn Refiners Association
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives

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CORPORATE DISCLOSURE STATEMENT

Amici curiae – American Soybean Association, Corn Refiners Association, National Corn Growers Association, National Cotton Council, and National Council of Farmer Cooperatives – hereby disclose that they are non-governmental trade associations, are not owned in whole or in part by a parent corporation or a publicly traded company, and do not issue stock.

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INTEREST OF AMICI CURIAE[1]

Amici are national trade associations representing thousands of members who plant, grow, and process three of our nation's major row crops – corn, cotton, and soybeans. Covering the entire agricultural supply chain, from farmers and marketers to suppliers and refiners, *amici* have benefited substantially over the past two decades from modern biotechnology and the introduction of genetically engineered ("GE") crops. GE traits like herbicide- and insect-resistant plants have helped the agricultural industry enhance its ability to operate in a more efficient, profitable, and sustainable manner.

Amici have been following with great interest the food industry's challenge to the State of Vermont's Act 120 which, if upheld, will require certain food products, whether raw commodities or processed food, to be labeled as having been produced with genetic engineering. As key players upstream in the food supply chain, they have a vested interest in their continuing ability to produce and market GE crops. *Amici* include the following:

The American Soybean Association ("ASA") is the national trade association representing U.S. soybean farmers on domestic and international issues

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[1] No party or party's counsel authored this brief in whole or in part, and no party, party's counsel, or any other person, other than *amici* or their counsel, contributed money intended to fund the preparation or filing of this brief. On June 15, 2015, the parties filed a letter with the Court stipulating to the submission of *amicus* briefs without the need for individualized consent. Dkt. No. 43.

of importance to the soybean industry. ASA's work is made possible through the voluntary membership of approximately 22,000 farmers in 31 states. ASA also develops domestic and foreign markets for U.S. soybeans and soy products.

The Corn Refiners Association ("CRA") is the national association representing the U.S. corn refining (wet milling) industry. CRA and its predecessors have served this important segment of American agribusiness since 1913. Corn refiners manufacture sweeteners, ethanol, starch, bioproducts (made from natural, renewable raw materials), corn oil, and feed products from corn components such as starch, oil, protein, and fiber.

The National Council of Farmer Cooperatives ("NCFC") is a nationwide trade association founded in 1929 to represent America's farmer cooperatives. NCFC's membership includes approximately 60 regional marketing, supply, bargaining, and farm credit bank cooperatives, as well as state councils of cooperatives, from across the United States. NCFC members handle almost every type of agricultural commodity produced in the United States, market those commodities domestically and abroad, and furnish production supplies and credit to their individual and farmer cooperative members. NCFC constituent members represent nearly 3,000 farmer cooperatives across the United States, whose own members include a majority of our nation's more than two million farmers, ranchers, and growers. In addition, those farmer cooperatives provide jobs for approximately 180,000 Americans, many in rural areas. NCFC is the primary voice of the agricultural cooperative industry in this country.

The National Corn Growers Association ("NCGA"), which was founded in 1957, represents more than 42,000 dues-paying corn farmers nationwide and the interests of more than 300,000 growers who contribute through corn checkoff programs in their states. NCGA and its 48 affiliated state associations and checkoff organizations work together to create and increase opportunities for their members and their industry.

The National Cotton Council ("NCC") is the national organization of the U.S. cotton industry, representing producers, ginners, oilseed crushers, merchants, cooperatives, textile manufacturers, and cottonseed handlers and merchandisers in 18 States stretching from California to the Carolinas.

In adopting Act 120, the Vermont General Assembly briefly cites several environmental issues purportedly associated with GE crops without acknowledging the significant regulatory safeguards governing crop safety in this country.[2] Relevant to any debate over the use of GE crops are the extensive regulatory schemes implemented by the United States Department of Agriculture ("USDA") and the United States Environmental Protection Agency ("EPA"), which help ensure that GE crops, from seed development to harvest, do not pose any

[2] Vt. Acts & Resolves 120, §§ 1(4)(C)-(E) (2014).

unreasonable risks to the environment. Moreover, Act 120 seemingly ignores the substantial environmental benefits that biotechnology has delivered – *e.g.*, decreased pesticide and water use, reduced soil erosion, and a diminished carbon footprint – since GE crops were first commercialized in 1996.

Amici are well positioned to discuss these matters and to provide the Court with a broader perspective on the significant environmental and safety aspects of GE crops. Accordingly, *Amici* offer this brief in support of Plaintiffs-Appellants and their motion for a preliminary injunction.[3]

ARGUMENT

For farmers like John Reifsteck, GE crops have been a blessing. A third-generation farmer, he runs a successful grain operation in Illinois, planting GE corn and soybeans on 1,700 acres. Two decades ago, however, circumstances were much different. Weeds were choking-off his crops. Heavy tilling to control the weeds was eroding his land. His farm was looking less and less sustainable by the season. Biotechnology changed all that.

Mr. Reifsteck began planting GE crop varieties that are herbicide-resistant, allowing him to fight back against the weeds by applying a broad-spectrum

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[3] While this brief focuses on the regulatory programs carried out by USDA and EPA, we also note that the Food and Drug Administration ("FDA") regulates food safety, whether or not a food product is produced using genetic engineering. The FDA's evaluation focuses on safety issues associated with its intended use, not the method used to develop the product. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,310 (June 26, 1986).

herbicide without harming his crops. As the invading plants retreated, he drastically cut back on tilling his land, thus significantly reducing soil erosion. At the same time, Mr. Reifsteck introduced insect-resistant corn – a GE variety that produces its own protein that kills insects feeding on the plant – allowing him to virtually eliminate the spraying of conventional insecticides on his farm.

As Mr. Reifsteck turned to GE crops, he also acted in full compliance with regulatory safeguards. To protect against the emergence of pesticide-resistant insects, the federal government mandates the use of refuges – areas planted with non-GE varieties – to slow any potential resistance. In past seasons, Mr. Reifsteck planted about 20 percent of his corn with non-GE varieties. More recently, he has relied on "refuge in a bag" – a mixture of GE and non-GE seeds that are planted together, but which achieves the same stewardship goal as conventional refuges.[4]

A. GE Crops: Integral to U.S. and Global Agriculture

Mr. Reifsteck is not alone. Every farmer, whether planting GE crops or not, must navigate a seemingly endless number of challenges thrown at them by Mother Nature – drought, flooding, disease, and, of course, weeds and insects. Until the mid-1990s, farmers managed these risks, in part, by planting crops that had been modified through traditional breeding techniques to achieve a desired

[4] Telephone interview with John Reifsteck (June 25, 2015).

trait, like drought resistance in hybrid corn.[5] Conventional breeding techniques, however, proved to be time-consuming and unpredictable. With the advent of modern biotechnology, scientists have developed crop varieties with a range of traits on both an accelerated basis and with much more precision.[6]

As Mr. Reifsteck's experience shows, herbicide- and insect-resistant crops have afforded substantial benefits to both farmers and the environment. Virus- and disease-resistant crops also help maintain profitable yields in an industry where profit margins can be razor-thin. Moreover, crops can be modified to enhance their nutritional value, providing health benefits to the consumer while growing the farmer's bottom-line. For example, DuPont Pioneer recently developed a soybean that produces a particular oil – a high oleic oil – that will help food manufacturers and restaurants eliminate trans- and saturated fats.[7] And products currently in the

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[5] Crow, J.F., *90 Years Ago: The Beginning of Hybrid Maize*, 148 Genetics 923-28 (1998), *available at* http://www.genetics.org/content/148/3/923.short. All internet citations in this brief were last visited on June 30, 2015.

[6] CropLife International, Benefits of Biotechnology, *available at* https://croplife.org/plant-biotechnology/benefits-2/.

[7] *See* http://www.plenish.com. There are other examples. Golden Rice has been fortified through genetic engineering to contain beta-carotene. This crop is seen as a potential benefit to populations, particularly in developing countries, with high vitamin A deficiencies, which can lead to blindness and weakened immune systems. *See*, Tang, G. *et al.*, *Golden Rice is an effective source of vitamin A*, 89 Am. J. of Clinical Nutrition 6:1776-1783 (June 2009), *available at* http://ajcn.nutrition.org/content/89/6/1776.long. GE canola and soybeans are also being looked to for increases in dietary omega-3, which can promote health and disease prevention. Surette, M., *Dietary omega-3 PUFA and health: Stearidonic*

development pipeline will allow farmers to grow crops using less inputs and resources, like chemical fertilizers and limited fresh water supplies.

With such rapid growth, GE crops are integral to the continued economic vitality of the global agricultural sector. In 2013, 18 million farmers in 27 countries grew GE crops on 175 million hectares. More than 90 percent of those farmers operated small farms. GE crops – primarily corn, cotton, soybeans, and canola – offer farmers, including those in developing countries, the advantage of higher yields and lower production costs, and the benefits are considerable.[8] A recent meta-analysis of 147 studies found that, on average, GE crops increased farmer profits by 69 percent.[9]

Similar trends can be seen in the United States. As shown in the chart below, over 90 percent of the acreage currently planted for corn, cotton, and soybeans are of the GE variety.[10] These crops make up the vast majority of the 185 million acres planted with those commodities, covering the majority of states.

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acid-containing seed oils as effective and sustainable alternatives to traditional marine oils, 57 Molecular Nutrition and Food Research, 748-759 (2013).

[8] Fedoroff, N.V. *et al.*, *Agricultural Biotechnology – An Opportunity to Feed a World of Ten Billion*, 118 Penn State L. Rev. 4:859, at 868 (2014), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2542310.

[9] Klumper, W. *et al.*, *A Meta-Analysis of the Impacts of Genetically Modified Crops*, PloS One 9(11), at 4 (November 2014), *available at* http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0111629.

[10] USDA, National Agricultural Statistics Service, Quick Stats, *available at* http://quickstats.nass.usda.gov.

In 2014 alone, production value (GE and non-GE) reached almost $100 billion, with significant contributions to agriculture's positive trade balance as well.[11]

Commodity	2014 GE crop percentage	2014 total GE crop acreage	Number of states with 2014 plantings	2014 production value	2013-14 export quantities[12]
Corn	93%	~90 million acres	41	~52 billion dollars	47 million metric tons
Cotton	96%	~11 million acres	21	~5 billion dollars	9 million running bales (Upland)
Soybean	94%	~84 million acres	31	~40 billion dollars	48 million metric tons

B. Comprehensive Federal Regulation of GE Crops

Of course, as with any large-scale human endeavor, farming affects the environment. Soil erosion, pesticide use, and greenhouse gas emissions are issues that *all* farmers, not just those planting GE crops, must address. To minimize these impacts, the federal government has enacted extensive requirements, enforced by multiple agencies, aimed at promoting the safety of GE and non-GE crops alike.

Indeed, the federal government's regulatory approach is comprehensive. Seeking to "ensur[e] the safety of biotechnology research and products" and to help "assure reasonable safeguards for the public," the White House Office of Science and Technology Policy established in 1986 the "Coordinated Framework

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[11] *Id.*

[12] USDA, Foreign Agricultural Service, Export Sales Query System, *available at* http://apps.fas.usda.gov/esrquery/esrqg.aspx.

for Regulation of Biotechnology" ("Coordinated Framework").[13] Underlying this approach, which still governs today, is the recognition that existing laws as implemented by three agencies – FDA, USDA, and EPA – will adequately protect human health and the environment, from a GE plant's initial development to the final product on our supermarket shelves.[14] As noted in the policy's announcement, "[e]ach regulatory review will require that the safety . . . of a particular . . . product be satisfactorily demonstrated . . . prior to commercialization."[15]

1. USDA-APHIS

The Coordinated Framework's focus on safety is embodied throughout USDA's extensive regulatory program which restricts the introduction of genetically engineered products – sometimes called genetically modified organisms or "GMOs" – into the environment. Specifically, USDA's Animal and Plant Health Inspection Service ("APHIS") has authority under the Plant Protection Act ("PPA") to regulate organisms that have been modified through genetic engineering, and where APHIS determines or has reason to believe that it will pose a plant pest risk; that is, injury, damage, or disease to any crop or other

[13] 51 Fed. Reg. 23,302.

[14] *Id.* at 23,303.

[15] *Id.*

plant.[16] No such organism, called a "regulated article," may be released into the environment unless authorized by APHIS.[17] Only after it has been demonstrated that the GMO presents no greater plant pest risk than the unmodified version will that organism be granted "nonregulated status" and no longer be subject to any release restrictions under the PPA.[18]

In making these determinations, APHIS follows review procedures which feature numerous safeguards that protect agriculture and the surrounding environment from potential risks.

Pre-Market Review – When a developer proposes to introduce a GE crop into commerce, it must first proceed through one of several pre-market reviews conducted by APHIS. If the GMO might present a plant pest risk (*e.g.*, cross-pollination resulting in mortality of wild varieties), the developer must notify APHIS and either apply for a permit or complete a streamlined notification process.[19] These approvals are most often obtained by developers to conduct field

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[16] PPA, 7 U.S.C. §§ 7701-7772; 7 C.F.R. § 340.1; *see* USDA-APHIS, Coordinated Framework, *available at* http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology.

[17] 7 U.S.C. § 7711(a); 7 C.F.R. § 340.0(a).

[18] 7 U.S.C. § 7711(c); 7 C.F.R. § 340.6.

[19] 7 C.F.R. §§ 340.3 (notifications) (releases under the notification process are limited in duration and reserved for certain types of GMOs); 340.4 (permits). APHIS also provides State regulatory officials with an opportunity to comment on permit applications and notifications. 7 C.F.R. §§ 340.3(e); 340.4(b).

tests – *i.e.*, actual plantings on limited acreage – before commercialization. As discussed below, under either scenario, the developer must submit substantial information to APHIS and comply with significant restrictions or performance standards aimed at protecting the environment during the field test.

Moreover, when field tests and other data demonstrate that a GMO is unlikely to pose a plant pest risk, the developer must then submit a petition to APHIS prior to any release, accompanied by extensive supporting data, showing that further regulation is unwarranted.[20] Until recently, APHIS took on average almost three years to review such petitions. Even today, with improvements in the review process, two years can pass before approval.[21] As of September 2013, APHIS had received 145 petitions for nonregulated status and had granted 96. Corn, cotton, and soybean comprise most of those approved petitions.[22]

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[20] 7 C.F.R. § 340.6. Petitions for nonregulated status are also published in the *Federal Register* for public comment. 7 C.F.R. § 340.6(d)(2).

[21] USDA-APHIS, Biotechnology Regulatory Services ("BRS"), *Authorizations and Petition Improvement Process Update*, BRS Stakeholder Meeting Presentation, at 11 (November 19, 2014), *available at* http://www.aphis.usda.gov/biotechnology/downloads/Meetings/2014_sh_mtg/sh14_auth_petitions.pdf.

[22] USDA, Economic Research Service ("ERS"), *Genetically Engineered Crops in the United States*, at 7 (2014) ("USDA-ERS 2014 Report"), *available at* http://www.ers.usda.gov/publications/err-economic-research-report/err162.aspx. APHIS also maintains a website that tracks pending and completed determinations for non-regulated status. As of June 2015, the number of petitions granted by APHIS for nonregulated status was 115. USDA-APHIS, *Determinations of*

Risk-Based, Science-Based – The PPA makes clear that APHIS must base its decisions on an assessment of potential risk using "sound science."[23] Accordingly, APHIS scientists review comprehensive information regarding the GMO, such as research data, scientific literature, and results from field tests. This includes information regarding: (i) the characteristics of the GMO (*e.g.*, genetic makeup, the purpose of the introduced genetic material, and a description of its intended expression in the GE crop); (ii) significant differences between the modified and non-modified organisms; (iii) whether the GMO could cause plant disease or otherwise be toxic to other plants or animals feeding on the GE crop; and (iv) the potential for cross-pollination with non-regulated plants.[24]

Permit Conditions and Performance Standards – For "regulated articles," APHIS may impose extensive permit conditions or performance standards on GE crops to ensure their safe introduction and use. These include: (i) preventing potential cross-pollination with non-GE crops and other plants (*e.g.*, using fallow zones, border rows, and isolation distances); (ii) clearly demarcating planting areas used for GE crops (*e.g.*, flags, stakes, and markers) to minimize co-mingling with non-GE plants; (iii) keeping GMO containers separate and distinct from containers

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Nonregulated Status, *available at* http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml#not_reg.

[23] 7 U.S.C. § 7701(4).

[24] 7 C.F.R. §§ 340.3(b)-(d); 340.4(b); 340.6(b)-(c) (also requiring "information known to the petitioner which would be unfavorable to a petition").

of non-GE organisms; and (iv) disposing or destroying GE crops when they are no longer in use to prevent any further dissemination into the environment.[25]

Field Testing – Permitting and notification procedures also require the developer to conduct extensive field tests prior to commercialization, which can take years to complete.[26] These field tests are designed to evaluate numerous GE traits, such as herbicide tolerance, insect resistance, impacts on nutrition, and drought resistance.[27] The resulting data and analysis must be submitted to APHIS, including information regarding the GMO's impact on plants, other non-target organisms and the environment.[28] This information is then used by APHIS when deciding whether to grant a petition for nonregulated status.[29] Between 1996 and 2013, the number of releases granted by APHIS averaged roughly 800 per year.[30] Corn, soybean, and cotton represent the majority of those releases.

Inspections – APHIS and state regulatory officials are authorized to conduct targeted, on-site inspections and to review records to confirm compliance. The inspectors have access to not only the field sites themselves, but also equipment,

[25] 7 C.F.R. §§ 340.3(c); 340.4(f).

[26] USDA-ERS 2014 Report, *supra* note 22, at 4.

[27] *Id.* at 5-6.

[28] 7 C.F.R. §§ 340.3(d)(4); 340.4(f)(9).

[29] 7 C.F.R. § 340.6(c)(5).

[30] USDA-ERS 2014 Report, *supra* note 22, at 3.

related facilities, and seed storage.[31] According to a recent APHIS presentation, it conducted over 700 inspections in 2014 alone.[32]

Planting/Release Information – Developers must also submit to APHIS substantial information regarding the planting and release of GE crops, including the location of field sites and the number of acres to be planted.[33] This allows APHIS to evaluate applications for permits and notifications, assess risk, verify compliance through on-site inspections, and respond to any violations.

Notification of Unusual Occurrences – After APHIS allows a GMO to be released into the environment, it must be notified immediately of any "unusual occurrence." Examples include: (i) dispersal of a regulated material outside the approved planting area; (ii) unexpected impacts on non-GE crops or other non-target organisms; and (iii) GE characteristics that are substantially different than

[31] 7 C.F.R. §§ 340.3(d)(6); 340.4(d), (f)(5). USDA-APHIS, Compliance and Inspections, *available at* http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology. In cases of non-compliance, APHIS is authorized to require remedial or corrective actions, ranging from installing fencing to destruction of research crops. *Id.*; 7 U.S.C. § 7714(b); 7 C.F.R. § 340.4(f)(8).

[32] USDA-APHIS, BRS, *Biotechnology and USDA*, BRS Stakeholder Meeting Presentation, at 14 (November 19, 2014), *available at* http://www.aphis.usda.gov/biotechnology/downloads/Meetings/2014_sh_mtg/sh14_FY14_reflections.pdf.

[33] 7 C.F.R. §§ 340.3(d)(2); 340.4(b)(9).

those disclosed by the developer (*e.g.*, an unanticipated plant pest risk).[34] APHIS and the developer will then take any necessary remedial actions.

Additional Environmental Laws – APHIS also complies with other environmental laws when evaluating permit applications, which provide additional assurance of crop safety. For instance, under certain circumstances, APHIS considers broader impacts on human health and the environment by preparing an Environmental Assessment ("EA") and/or Environmental Impact Statement ("EIS") as required under the National Environmental Policy Act ("NEPA").[35] Moreover, APHIS requires applicants to submit information regarding potential effects of a GMO release on critical habitat of threatened or endangered species pursuant to the Endangered Species Act ("ESA").[36] Through these statutes, APHIS can further identify potential effects and avoid any impacts prior to an actual release (*e.g.*, by relocating a field test site to a less sensitive area).

[34] 7 C.F.R. §§ 340.3(d)(5), 340.4(f)(10). The PPA also provides for both criminal and civil penalties for any violations. 7 U.S.C. § 7734.

[35] 7 C.F.R. Part 372; *see also* USDA-APHIS, Environmental Documents, *available at* http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology. Both the EAs and EISs are subject to public comment through a notice published in the *Federal Register*. 7 C.F.R. § 372.8. All of the 115 determinations of nonregulated status listed on the APHIS website involved some form of NEPA review. *Determinations of Nonregulated Status*, *supra* note 22.

[36] 16 U.S.C. § 1536.

2. EPA

The Coordinated Framework's emphasis on safety is also manifested in EPA's regulation of pesticidal substances that are produced by a GE crop itself. Under the Federal Insecticide, Fungicide & Rodenticide Act ("FIFRA"), EPA is charged with ensuring that a given pesticide does not pose an unreasonable risk to human health or the environment.[37] This includes the regulation of any plant-incorporated protectant ("PIP"), which is defined as "a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such pesticidal substance."[38] The most common PIPs are Cry proteins from *Bacillus thuringiensis* ("*Bt*") bacteria that are genetically introduced into crops, including corn, cotton, and soybeans, and provide insecticidal resistance to various pests feeding on the plant.[39]

As with USDA's procedures, EPA has set forth an extensive review process designed to protect against any potential environmental risks of these GMOs.

Pre-Market Registration – FIFRA generally prohibits the sale and distribution of any unregistered pesticide.[40] Only those PIPs that complete a comprehensive pre-market registration and approval process may be introduced

[37] 7 U.S.C. § 136a(a); 40 C.F.R. § 152.1(a).

[38] 40 C.F.R. § 174.3.

[39] *See, e.g.*, 40 C.F.R. § 174.504.

[40] 7 U.S.C. § 136a(a); 40 C.F.R. § 152.15.

into the environment. As discussed below, developers must submit to EPA a detailed application containing information regarding the PIP, including laboratory and field testing results, as well as any data indicating potential adverse effects.[41] EPA then conducts a thorough review to determine whether there is any unreasonable risk to the environment or persons exposed to the PIP.[42] A new PIP registration typically takes about two years to complete (assuming no EPA extensions due to problems with an application, such as missing information).[43] As of November 2011, at least 40 PIPs had been registered.[44]

Science-Based and Data Driven – Developers seeking EPA approval of a PIP must submit substantial amounts of information to the agency covering a wide range of human health and environmental issues. This may include: (i) the PIP's physical and chemical properties; (ii) acute, subchronic, and chronic toxicity; (iii) developmental and reproductive toxicity; (iv) mutagenicity; (v) ecological (*e.g.*,

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[41] 7 U.S.C. § 136a(c); 40 C.F.R. §§ 152.42, .50, .107. EPA also publishes in the *Federal Register* notice of the pending application for public comment (including comment by other Federal agencies) for a new active ingredient or use pattern. 7 U.S.C. § 136a(c); 40 C.F.R. § 152.102.

[42] *Id.* EPA has exempted a limited number of PIPs from FIFRA compliance, such as where the genetic material that leads to the production of a pesticidal substance in a crop is from a sexually compatible plant. 40 C.F.R. § 174.25.

[43] EPA, *PRIA Fee Category Table – Biopesticides Division – PIP*, *available at* http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-pip.

[44] EPA, *Current & Previously Registered Section 3 PIP Registrations*, *available at* http://www.epa.gov/pesticides/biopesticides/pips/pip_list.htm (the site has not been updated since November 2011).

non-target animal and aquatic) effects; and (vi) environmental fate (*e.g.*, degradation and mobility studies).[45] EPA's reviews are based on "strict scientific standards and extensive input from academia, industry, other Federal agencies, and the public."[46] Past agency decisions regarding PIPs have also included peer reviews by the FIFRA Scientific Advisory Panel ("SAP"), a group of independent biologists, toxicologists, and other experts.[47] EPA seeks advice from the SAP on potential risks that a pesticide may "pose to wildlife, farm workers, pesticide applicators, non-target species, as well as insect resistance, and novel scientific issues surrounding new technologies."[48]

Field Testing – Registrations for PIPs are typically supported with data gathered by the developer during extensive field tests. Because this involves the introduction of a GE crop into the environment before a registration for commercialization has been approved, developers must obtain an Experimental

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45 7 U.S.C. § 136a(c); 40 C.F.R. Part 158, Subparts A-B, D, F-G, N.

46 EPA, *Plant Incorporated Protectants, available at* http://www.epa.gov/pesticides/biopesticides/pips/.

47 *Id.* While outside the scope of this brief, EPA also establishes tolerances and tolerance exemptions under the Food, Drug and Cosmetic Act ("FDCA") for residues of PIPs on food commodities. 21 U.S.C. § 346a. EPA must determine that there is a reasonable certainty of no harm based on aggregate exposures to the pesticide, including all anticipated dietary exposures. *Id.* Tolerances and tolerance exemptions for PIPs are reported at 40 C.F.R. § 174.500.

48 *PRIA Fee Category Table*, *supra* note 43, at n. 5. To date, SPA has convened approximately 18 meetings to discuss various issues regarding PIP registrations.

Use Permit ("EUP') from EPA.[49] Applications for an EUP must include information similar to that submitted for registrations, including the chemical and physical properties of the PIP, any prior testing or existing data regarding toxicity and effects on non-target animals and plants, and the location of the proposed testing and number of acres involved.[50] After field testing is completed, a developer must submit all of the resulting data to EPA, including any adverse effects from the use of or exposure to the PIP.[51]

***Use Restrictions and Labels* –** EPA must also approve a label for any pesticidal product. The label must include human and environmental hazard statements, as well as directions for use.[52] EPA is specifically authorized to impose any limitations or restrictions on use that the agency deems necessary to prevent any unreasonable adverse effects.[53] For instance, a typical PIP label will include a requirement that growers planting an insect-resistant crop must follow an Insect Resistance Management ("IRM") plan. IRMs typically require growers to create non-*Bt* refuges – areas planted with non-GE varieties – to slow the evolution

[49] 7 U.S.C. § 136c; 40 C.F.R. § 172.2. EPA allows limited exceptions to the EUP requirements, such as small-scale testing conducted on no more than ten acres.

[50] 40 C.F.R. § 172.4.

[51] 40 C.F.R. § 172.8. EPA is also authorized to inspect any EUP sites to determine compliance. *Id.*

[52] 40 C.F.R. Part 156.

[53] 40 C.F.R. § 156.10(i).

of *Bt*-resistant insects. As part of this program, developers must also require growers to sign stewardship agreements outlining the refuge requirements, educate growers regarding the IRM, monitor any change in insect resistance, and implement a remedial action plan in the event such resistance develops.[54]

As the foregoing discussion shows, GE crops are not subject to a mere cursory review or rubber stamp approval. Before the product ever reaches the American consumer, USDA and EPA will have expended countless hours, amounting to at least several years of regulatory scrutiny, determining that the GE crop is safe for the environment.

C. Environmental Benefits of GE Crops

Farmers are not the only ones who have benefited from GE crops; the environment has too. GE crops can mitigate agriculture's impact on the environment, through fewer pesticide applications, reductions in water usage, less soil erosion and runoff, and reduced greenhouse gas emissions.

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[54] EPA, Notice of Pesticide Registration and PIP Label, MON 89034 x TC1507 Insect-Protected Herbicide Tolerant Corn, EPA Reg. No. 524-585 (November 14, 2013), *available at* http://www3.epa.gov/pesticides/chem_search/ppls/000524-00585-20131114.pdf. EPA is also authorized to conduct inspections of any facilities where pesticides are being held for sale or distribution, while FIFRA sets forth civil and criminal penalties for non-compliance, 7 U.S.C. §§ 136g, 136l.

1. Less Insecticides

The substantial increase in *Bt* crop plantings has coincided with significant reductions in the use of conventional insecticides.[55] As noted above, *Bt* crops produce internally their own insecticidal proteins. The target pests, ranging from the European corn borer to the pink bollworm, die after ingesting plant parts that contain the protein. Accordingly, the need for traditional insecticide applications has fallen. For instance, USDA has reported that, between 1995 and 2010, the amount of insecticides applied by corn farms on a per-acre basis dropped from 0.21 pounds to 0.02 pounds, over a 10-fold decrease.[56] Similarly, *Bt* cotton has also contributed to the downward trend in insecticide use. Between 1996 and 2000, there were on average three applications per hectare to control various cotton pests. That number dropped to one application for 2006 to 2008.[57]

Fewer insecticides, moreover, is only half the story. *Bt* crops also remove more toxic and persistent insecticides from the environment through substitution

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[55] *See* Klumper, *supra* note 9, at 4 (finding a 39 percent reduction in the use of pesticides with GE crops, including conventional insecticides).

[56] USDA-ERS 2014 Report, *supra* note 22, at 23-24; *see also* National Research Council, *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States* ("NRC 2010 Report"), at 84-85 (2010), *available at* http://www.nap.edu/catalog/12804/impact-of-genetically-engineered-crops-on-farm-sustainability-in-the-united-states.

[57] International Cotton Advisory Committee, Expert Panel on Social, Environmental and Economic Performance of Cotton Production, *Factors Influencing the Use of Pesticides in Cotton in the U.S.*, at 4-5 (August 2010).

with a less hazardous alternative. *Bt* proteins are not hazardous to humans and are only toxic to a narrow range of insects.[58] *Bt* is also known to "show highly species-specific toxicity against certain insects and only a few insect species are affected by each of the proteins."[59] EPA has "concluded that *Bt* products will not pose unreasonable risks to human health or the environment."[60]

2. Reduced Herbicide Impact

While gauging the impact that herbicide-resistant ("HR") crops have had on levels of herbicide use is more complicated, overall there is good news here as well.[61] Many GE crops are engineered to be tolerant to certain herbicides, including glyphosate, the most commonly applied herbicide (often referred to by its trade name of Roundup®). Glyphosate is recognized to be "without substantial adverse effects on animals or on soil and water quality, unlike other classes of

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[58] Schrøder, M. *et al. A 90-day safety study of genetically modified rice expressing Cry1Ab protein (Bacillus thuringiensis toxin) in Wistar rats*, Food and Chemical Toxicology 45.3: 339-349, at 340 (2007).

[59] *Id.*

[60] *See* EPA, EPA's Regulation of Bacillus thuringiensis (Bt) Crops (2002), *available at* http://www.epa.gov/pesticides/biopesticides/pips/regofbtcrops.htm. As noted above, EPA has mandated the use of refuges and IRMs. *See* NRC 2010 Report, *supra* note 56, at 6 (finding that the "emergence of insect resistance to *Bt* crops has been low so far and of little economic or agronomic consequence").

[61] Whether HR crops decrease the application of herbicides depends on a variety of factors. For instance, a recent meta-analysis of 147 reports found that HR crops resulted in reduced herbicide use in some locations, but saw an increase in broad-spectrum herbicide use elsewhere. Klumper, *supra* note 9, at 4.

herbicides."[62] In particular, glyphosate is known to bind tightly to soil, which prevents and reduces its mobility in soil and groundwater.[63] Its environmental half-life is also relatively short due to biodegradation, meaning it does not persist in the environment for long.[64]

As a result, simply measuring how many pounds of glyphosate are applied per acre to HR crops can be misleading. A recent study regarding herbicide use on HR soybeans is illustrative. When the relatively lower toxicity and environmental persistency of glyphosate is taken into account, modeling conducted by USDA and EPA scientists indicates that the adjusted use levels of herbicides on GE soybeans were lower than the use levels of herbicides on conventional soybeans between 1996 and 2006.[65] As the USDA concluded just last year, "[b]ecause glyphosate is significantly less toxic and less persistent than traditional herbicides, the net impact

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[62] NRC 2010 Report, *supra* note 56, at 4; *see also id.* at 62 (Glyphosate "binds to soil rapidly (preventing leaching), it is biodegraded in soil bacteria, and it has a very low toxicity to mammals, birds, and fish. Glyphosate can be detected in the soil for a relatively short period of time compared to many other herbicides, but is essentially biologically unavailable.").

[63] EPA, Office of Ground Water and Drinking Water, Technical Factsheet on: Glyphosate, at 2, *available at* http://www.epa.gov/ogwdw/pdfs/factsheets/soc/tech/glyphosa.pdf.

[64] *Id.*

[65] Fernandez-Cornejo, J. *et al.*, *Conservation Tillage, Herbicide Use, and Genetically Engineered Crops in the United States: The Case of Soybeans*, 15 J. of Agrobiotechnology Mgt. and Econ. 231, at 237 (2012), *available at* http://www.agbioforum.org/v15n3/v15n3a01-fernandez-cornejo.htm.

of [HR] crop adoption is an improvement in environmental quality and a reduction in the health risks associated with herbicide use (even if there are slight increases in the total pounds of herbicide applied)."[66]

3. Less Soil Erosion: Low-Till and No-Till Practices

With the introduction of HR crops, a growing number of farmers are also adopting conservation tillage practices which offer substantial environmental benefits over conventional approaches. As any gardener knows, controlling weeds is critical. For farmers, weeds can quickly choke off a crop and reduce yield as the weeds compete for limited nutrients, water, and sunlight. Under conventional forms of weed control, farmers plow the soil several times throughout the year – in the fall to bury the crop residue, again before planting to destroy any weeds, and finally several times during the growing season to kill off yet even more weeds.

With conservation tillage, on the other hand, at least 30 percent of the residue remains, and in no-till farming the post-harvest residue is left completely undisturbed.[67] These low- and no-till practices are widely known to protect agricultural fields and the surrounding environment in a number of ways. In

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[66] USDA-ERS 2014 Report, *supra* note 22, at 24-25. While there is evidence of increasing glyphosate resistance in weeds, such issues are not unique to glyphosate in particular or GE crops in general. Farmers, whether they have adopted HR varieties or not, must adjust to herbicide resistance in weeds over time by employing an array of strategies and best management practices.

[67] NRC 2010 Report, *supra* note 56, at 63.

particular, conservation tillage guards against soil erosion by wind and rain, increases water retention in the soil, enhances soil quality, reduces runoff of sediment and pesticides, and limits agriculture's carbon footprint.[68] All of this is possible as HR crops allow weeds to be controlled with an over-the-top spray.

While the concepts underlying conservation tillage have been with us for a long time – American colonists recognized in the 18th century the value of using crop residues to minimize soil erosion[69] – there has been a noticeable shift to low-till or no-till practices since GE crops were commercialized. According to a recent USDA study, farmers using HR crops are more likely to employ conservation tillage than traditional methods. Because herbicides can be used to control weeds without harming nearby crops, it is much easier for farms to reduce, or in some cases, totally eliminate the need to plow under their fields.[70] The on-the-ground statistics are telling.

As of 1995, the year before the first GE crop was commercialized, about 63 million acres were under conservation tillage for corn, cotton, and soybeans. By

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[68] USDA-ERS 2014 Report, *supra* note 22, at 26-27.

[69] USDA, ERS, *Economic and Environmental Benefits and Costs of Conservation Tillage* ("USDA-ERS 1998 Report"), at 2 (February 1998), *available at* https://archive.org/details/economicsenviron00unit.

[70] USDA-ERS 2014 Report, *supra* note 22, at 27.

2004, in just eight short years, that number had jumped to 82 million acres.[71] As to each crop variety, 60 percent of HR soybean acreage was managed with conservation tillage in 1997, compared to 40 percent of non-HR plantings. By 2006, those numbers had spread to 86 percent and 36 percent, respectively. Similar trends are evident for cotton and corn. As of the mid-2000s, over 30 percent of acreage planted with HR cotton varieties was managed with conservation tilling, while conventional methods remained below 20 percent.[72] At the same time, 33 percent of HR corn varieties were in no-till systems, while only 19 percent of conventional corn was managed in that fashion.[73]

Increases in conservation tillage results in decreased soil erosion. Soil erosion is driven by two forces of nature – wind and rain – which under extreme conditions can result in desertification, as seen during the Dust Bowl of the 1930s.[74] Maintaining some level of crop residue on the surface of a field prevents rain drops from dislodging soil particles, which are susceptible to wind and

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[71] Conservation Technology Information Center, National Crop Residue Management Survey, *available at* http://www.ctic.purdue.edu/CRM/.

[72] USDA-ERS 2014 Report, *supra* note 22, at 27-28; *see also* Fernandez-Cornejo, *supra* note 65, at 237 (finding adoption of HR soybeans leads to a significant increase in the use of conservation tillage).

[73] USDA-ERS 2014 Report, *supra* note 65, at 27-28.

[74] Holland, J.M., *The environmental consequences of adopting conservation tillage in Europe: reviewing the evidence,* Agric., Ecosystems and Env't 103, at 1 (2004).

runoff.[75] For instance, scientists from USDA and the University of Missouri estimated that soil erosion is reduced by 50 percent where 30 percent of the field is covered with crop residue.[76] Soil loss is almost eliminated where no-till methods are employed.[77] The National Research Council ("NRC"), an organization within the National Academy of Sciences, also concluded in a 2010 study that "[c]orn and soybean are grown in regions where highly erodible land is common, and conversion to conservation tillage for these crops results in substantial reduction in soil loss and wind erosion."[78] It is no surprise, then, that as soil erosion is curbed, long-term agricultural productivity and sustainability is preserved.[79]

Less soil erosion also means improved soil quality through enhanced water retention and nutrient cycling.[80] The NRC, again in its 2010 study, noted:

> Leaving more crop residue on fields strengthens nutrient cycling and increases organic matter, a key component of soil quality. Soil organisms decompose plant residue, and this, in turn, cycles nutrients and improves soil structure. In general, soil organisms have greater

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[75] McCarthy, J. *et al.*, *Conservation Tillage and Residue Management to Reduce Soil Erosion*, University of Missouri (December 1993), *available at* http://extension.missouri.edu/p/G1650.

[76] *Id.*

[77] *Id.*

[78] NRC 2010 Report, *supra* note 56, at 68.

[79] USDA-ERS 1998 Report, *supra* note 69, at 31.

[80] NRC 2010 Report, *supra* note 56, at 68.

> abundance or biomass in no-till systems than in conventional tillage systems because soil is disturbed less.[81]

Conservation tillage also helps protect adjacent waterways and aquatic life by limiting the amount of various materials contained in runoff from agricultural fields. For instance, sedimentation can increase water temperatures and impact aquatic habitat. Fertilizers can lead to eutrophication – the excessive growth of algae and other vegetation due to nutrient loading – which lowers dissolved oxygen levels. And pesticides can enter waterways in runoff by either binding to sediments or moving in a dissolved form.[82] But conservation tillage mitigates these impacts by minimizing runoff. For instance, one study found that no-till and other conservation tillage practices cut nutrient loading up to 80 percent.[83] Similarly, a USDA study concluded that no-till practices curtail herbicide runoff by 30 percent when compared to conventional tillage methods.[84]

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[81] *Id.*; *see* Holland, *supra* note 74, at 13 (stating "[m]icrobial biomass, diversity and overall biological activity are generally considered to be higher in soils cultivated using [conservation tillage] techniques compared to those receiving deep cultivations").

[82] USDA-ERS 1998 Report, *supra* note 69, at 31-32; Holland, *supra* note 74, at 5.

[83] Andraski, B.J. *et al.*, *Phosphorus Losses in Runoff as Affected by Tillage,* Soil Sci. Soc. Am. J., Vol, 49, No. 6, 1523-1527, at 1526 (1985).

[84] USDA-ERS 1998 Report, *supra* note 69, at 33.

4. Climate Change and Reduced Greenhouse Gas Emissions

Looking forward, GE crops could potentially play a significant role in confronting climate change and cutting back on agriculture's carbon footprint. Specifically, herbicide- and insect-resistant crops help farmers substantially reduce their fuel consumption by limiting the number of tractor or equipment passes that are required to till a field or apply pesticides. Scientists at U.C. Berkeley, for example, concluded that "GE crop adoption reduces fuel consumption by 19% on average" when compared to non-GE plantings.[85]

With expanding low-till or no-till practices, moreover, GE crops can also improve carbon sequestration. As summarized in the U.C. Berkeley report:

> Undisturbed soils absorb carbon and convert it into organic matter in the ground. If left undisturbed for several years, the organic matter becomes a stable sink for carbon. . . . One report estimates that an acre of no-till land stores 0.64 metric tons more carbon each year than an acre of land in conventional tillage.[86]

5. Enhanced Global Food Production

Perhaps the most significant impact of GE crops, however, will be in feeding the world's citizens in the decades to come. The United Nations estimates that the

[85] Sexton, S. *et al.*, *Agricultural Biotechnology Can Help Mitigate Climate Change*, Agric. and Res. Econ. Update, vol. 14, no. 2, at 4 (Nov/Dec 2010), *available at* http://giannini.ucop.edu/media/are-update/files/articles/v14n2_1.pdf.

[86] *Id.* at 1.

global population will swell from 7.5 billion today to over 9 billion by 2050.[87] Yet we struggle to feed roughly one out of every nine individuals already alive.[88] Moreover, the amount of arable land continues to shrink due to urbanization, salinization, and desertification.[89] In the United States alone, which has more arable land than any other country, there has been an eight percent decline in the number of acres farmed over the last twenty years.[90]

Climate change will only exacerbate the problem. As temperatures rise and fresh water supplies dwindle, GE crops may hold the only promise of higher yields on less land or crops that can withstand extreme drought conditions.[91] Indeed, there could be a significant loss in productivity in the absence of GE varieties. One recent study found that, on average, GE crops have increased yields by 21 percent, with even higher yields in developing countries.[92] As such, GE crops will be an essential element in any efforts to enhance global food security while

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[87] U.N. Dep't of Econ. & Soc. Affairs, Population Div., No. ESA/P/WP.228, *World Population Prospects: The 2012 Revision, Highlights and Advance Tables*, at p. xv, Fig. 1 (2013), *available at* http://esa.un.org/unpd/wpp/Documentation/pdf/WPP2012_HIGHLIGHTS.pdf.

[88] Food and Agriculture Organization of the United Nations, *The State of Food Insecurity in the World*, at 8 (2015), *available at* http://www.fao.org/3/a-i4646e/index.html.

[89] Fedoroff, *supra* note 8, at 870.

[90] U.S. EPA, Land Use Overview, *available at* http://www.epa.gov/oecaagct/ag101/landuse.html.

[91] Fedoroff, *supra* note 8, at 871.

[92] Klumper, *supra* note 9, at 4.

minimizing environmental impacts. What is certain is that officials around the world, particularly in developing countries, will continue to look for biotechnology to alleviate growing pressures on agriculture and the environment.

CONCLUSION

Based on the foregoing, *amici* ask this Court to reverse the lower court's decision and grant Plaintiff-Appellants' motion for a preliminary injunction.

Respectfully submitted,

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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 6,999 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 prepared in Times New Roman 14-point font using Microsoft Word 2010.

/s/ Eric P. Gotting
Eric P. Gotting

CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2015, I caused the foregoing to be filed through this Court's CM/ECF appellate filer system, which will send a notice of electronic filing to all registered users.

/s/ Eric P. Gotting
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