No. 09-475

In The Supreme Court of the United States

MONSANTO COMPANY, et al.,

Petitioners,

v.

GEERTSON SEED FARMS, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

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BRIEF FOR AMICI CURIAE UNION OF CONCERNED SCIENTISTS, CENTER FOR RESPONSIBLE GENETICS, DR. STEVEN R. RADOSEVICH, DR. PAUL E. ARRIOLA, DR. JOHN FAGAN, DR. E. ANN CLARK, DR. DON M. HUBER, AND CAROLINE COX IN SUPPORT OF GEERTSON RESPONDENTS

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INTEREST OF AMICI¹

Amicus curiae Union of Concerned Scientists ("UCS"), a leading science-based non-profit working for a healthy environment and a safer world, combines independent scientific research and citizen action to develop innovative, practical solutions and secure responsible changes in government policy, corporate practices, and consumer choices. What began as a collaboration between students and faculty members at the Massachusetts Institute of Technology in 1969 is now an alliance of more than 250,000 scientists and citizens. A major interest of UCS's Food and Environment Program is to strengthen the regulatory system that applies to products of agricultural biotechnology.

Amicus curiae Council for Responsible Genetics ("CRG") is a national non-profit organization with offices in Cambridge, Massachusetts and New York, New York. CRG was founded in 1983 to represent the public interest and foster public debate about the social, ethical and environmental implications of genetic technologies. CRG is dedicated to examining the best science, interpreting the results, assessing the implications, communicating them to a general

¹ Pursuant to Rule 37.6, counsel for *amici* state that no counsel for a party authored this brief in whole or in part, and that no person other than *amicus*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief. Petitioners and respondent have filed a letter of consent with the Clerk of the Court.

audience and creating lasting policy reform. CRG has investigated and reported on the commercial claims made about genetically modified crops and transgenic animals introduced into the food supply. CRG has questioned the compatibility of herbicide resistant plants and insect resistant crops with sustainable agriculture. CRG believes that all uses of genetically modified crops should meet rigorous safety testing and follow procedures of democratic participation by public stakeholder groups. CRG publishes a magazine, GeneWatch, that regularly includes articles by experts in the field on issues related to genetically engineered food.

Amicus curiae Steven R. Radosevich, Ph.D., is an Emeritus Professor at Oregon State University. Dr. Radosevich is a faculty member of the Department of Forest Ecosystems and Society and also an Adjunct Professor in the Departments of Crop Science, Environmental Sciences, and Philosophy. Dr. Radosevich's areas of expertise include Invasive Plant Species, Forest Ecology and Sustainable Forestry. He wrote the only textbook on the Ecology of Weeds and Invasive Plants, now in its third edition (Radesovich et al. 2007), and has been researching herbicide resistance since 1970. He received his M.S. and Ph.D. from Oregon State University and his B.S. from Washington State University.

Amicus curiae Paul E. Arriola, Ph.D., is a Professor of Biology at Elmhurst College in Elmhurst, Illinois. Dr. Arriola's areas of expertise include the population genetics and ecology of invasive plant species, with recent work addressing the consequences of the escape of engineered genes into wild/weedy plant populations. He received his Ph.D. in Botany (Plant Genetics) and B.S. in Biology from University of California, Riverside.

Amicus curiae John Fagan, Ph.D., is founder and Chief Scientific Officer of Global ID Group, which includes Genetic ID, a pioneer in the development of DNA tests to detect genetically modified organisms in food and agricultural products. Dr. Fagan formerly conducted biomedical research at the U.S. National Institutes of Health, studying molecular mechanisms of carcinogenesis. He holds a Ph.D. in Molecular Biology, Biochemistry, and Cell Biology from Cornell University.

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SUMMARY OF ARGUMENT

Genetically modified – or transgenic – crops pose substantial risks of harm to the human environment. The two most significant risks in this case are (1) the spread of unwanted transgenes to surrounding fields and wild plant populations and (2) the proliferation of herbicide-resistant weeds.² Both events are likely, and when either occurs, the resulting harm is effectively irreversible.

The district court found that these environmental risks were not adequately evaluated before Federal Respondents deregulated the transgenic crop Roundup Ready Alfalfa ("RRA") and, accordingly, it ordered further environmental review. To give effect to its liability ruling, the court fashioned an interim remedy that undid the premature deregulation by prohibiting new RRA planting pending completion of the requisite environmental risk analysis. That remedy comports with the general directive of the Administrative Procedure Act that courts "set aside"

² Because genetically modified crops do not exist in nature and are developed on an accelerated time scale never before seen in human history, they also may carry risks to consumers, as discussed briefly below. This brief focuses, however, on the two most significant environmental risks that lie at the heart of this case.

unlawful agency action, thereby restoring the status quo ante. 5 U.S.C. § 706(2); *Bowen v. Mass.*, 487 U.S. 879, 911 (1988) (noting that "[i]t seems perfectly clear" that upon finding an agency action unlawful, district court has "authority to grant the complete relief authorized by § 706").

Whether the remedy here is styled as a simple vacatur of the unlawful deregulation decision or as an affirmative injunction, its entry by the court was proper. The scientific literature fully supports interim restoration of the pre-decisional "no planting" regime until a proper environmental review is completed. While the likelihood of cross-contamination or the emergence of glyphosate-resistant weeds in any specific instance may appear small, the history of transgenic crops in the United States attests to one inescapable fact - in the aggregate, the collective risks from widespread use of RRA add up to a near certainty of irreparable harm. The district court's order setting aside the RRA deregulation action until those risks are adequately studied was, therefore, entirely consistent with its statutory and equitable authority.

ARGUMENT

RRA is a transgenic form of alfalfa (*Medicago* sativa ssp. sativa). It consists of a standard agricultural line of alfalfa that has been genetically modified, or transformed, by the insertion into its

genome of a foreign gene that conveys resistance to the herbicide glyphosate. Glyphosate is the active ingredient in the Roundup line of herbicides marketed by Monsanto. The transformation process used to create herbicide resistant crops is unlike the slow, steady process of traditional plant breeding that humans have practiced for millennia. Modern genetic engineering results in new plant gene combinations that have never occurred in nature, with attendant new risks to consumers, farmers, and the environment. The widespread use of RRA will bring with it certain predictable, serious risks of irreparable harm to farmers and to the public.

I. THE GENETIC CONSTRUCT THAT MAKES RRA HERBICIDE RESISTANT DOES NOT OCCUR IN NATURE AND THE PROCESS BY WHICH IT WAS CREATED IS TO-TALLY UNLIKE TRADITIONAL PLANT BREEDING.

A gene that scientists insert into another organism is called a "transgene," and organisms receiving the gene are "transgenic." The RRA genetic construct consists of fragments of DNA assembled together in the laboratory which do not occur together in nature. The main part of the RRA genetic construct – the coding region – consists of a gene from the soil bacterium Agrobacterium (Agrobacterium tumefaciens)³ that

³ U.S. patent #5633435

allows plants to grow even when treated with glyphosate. It is fused to gene fragments from petunia, pea, the laboratory model plant Arabidopsis, and the figwort mosaic virus.

The protein created by this RRA transgene does not affect potential yield.⁴ It does not increase a plant's rate of growth, final size, or nutrient content. The new protein serves only one function – it enables the plant to survive glyphosate treatment.

To transform alfalfa as described above, researchers rely on the same soil bacterium, Agrobacterium, that is the source of the RRA transgene coding region. Agrobacterium is a naturally occurring pathogen that induces cancer-like tumors in plants. Unlike bacteria that infect people, Agrobacterium inserts its own genes into (that is, it "transforms") individual cells of the host plant. In the wild, Agrobacterium genes cause the transformed cells to grow and divide uncontrollably and to produce a form of sugar that only Agrobacterium is able to use.

A major development in plant molecular biology came about with the discoveries that scientists can (1) replace Agrobacterium's tumor genes with any other gene sequence without affecting Agrobacterium's

 $^{^{\}scriptscriptstyle 4}$ See, e.g., Wendy Pline-Srnic Pest Manag. Sci. 61:225-234 (2005), at 228.

ability to insert these sequences into the host,⁵ and (2) induce Agrobacterium to infect a broad array of plant species under laboratory conditions.^{6,7,8,9,10} Following these discoveries, researchers began using Agrobacterium to transform plants with foreign genes in order to observe the effect these genes had on plant growth and development. Over the last two decades, scientists developed more sophisticated transformation methods that do not rely on Agrobacterium. These methods dominate genetics research today.

Three characteristics of the transformation process deserve emphasis. First, genetic engineering involving Agrobacterium and other transformation methods is a powerful technology that allows scientists, for the first time ever, to combine genetic

⁸ P. Chee et al., *Transformation of Soybean* (Glycine max) by *Infecting Germinating Seeds with* Agrobacterium tumefaciens. 91 Plant Physiol. 1212 (1989).

⁹ J. Gould et al., *Transformation* of Zea mays L. Using Agrobacterium tumefaciens and the Shoot Apex, 95 Plant Physiol. 426 (1991).

¹⁰ C. Loopstra et al., Agrobacterium-mediated DNA transfer in sugar pine, 15 Plant Mol. Biol. 1 (1990).

⁵ See, e.g., A. Müller et al., *High meiotic stability of a foreign gene introduced into tobacco by Agrobacterium-mediated transformation*, 207 Mol. Gen. Genet. 171 (1987).

⁶ N. Bechtold et al., *In planta Agrobacterium mediated gene transfer by infiltration of adult* Arabidopsis thaliana *plants*, 316 CR Acad. Sci. Paris 1194 (1993).

⁷ N. Bechtold and G. Pelletier, *In planta Agrobacteriummediated transformation of adult* Arabidopsis thaliana *plants by vacuum infiltration*, 82 Methods Mol. Biol. 259 (1998).

material from widely dissimilar and unrelated organisms – for example, bacterial genes with alfalfa genes or chicken genes with maize genes. In other words, scientists can produce combinations of genetic material that have never before occurred in nature.

Second, neither scientists nor the bacteria themselves can control where in the target plant genome the foreign gene will be inserted. Agrobacterium may insert its genes anywhere in native plant genes, thereby interrupting them or altering their function. One way to envision this process is to think of the genome as a book and of individual genes as the sentences that make up that book. Agrobacterium or scientists paste new sentences into the book randomly, without any regard for the words already there. In fact, researchers rely on this process when they want to interrupt plant genes at random to study the effects of the resulting damage.^{11,12,13}

Third, the process whereby Agrobacterium or scientists insert genes into the host plant genome can be unpredictable. Genes may be inserted multiple times, in multiple locations, as intact genes or as gene

¹¹ P. Krysan et al., *T-DNA as an Insertional Mutagen in Arabidopsis*, 11 Plant Cell 2283 (1999).

¹² M. Sussman et al., *The Arabidopsis Knockout Facility at the University of Wisconsin-Madison*, 124 Plant Physiol. 1465 (2000).

¹³ J. Alonso et al., *Genome-Wide Insertional Mutagenesis of* Arabidopsis thaliana, 301 Science 653 (2003).

fragments.^{14,15} Both academic researchers studying weeds¹⁶ and researchers at Monsanto's own facilities working with Roundup Ready transgenic crops¹⁷ have observed this phenomenon.

The new combinations of genetic material from unrelated organisms and the disruption of host genes during the transformation process present risks both to the environment and to human health. For consumers, in particular, changes in a crop's genome could increase the abundance of endogenous plant toxins or allergens, generate novel toxins, or decrease nutritional content.¹⁸ For these reasons, plant transformation as practiced on RRA creates a new

¹⁶ Id.

¹⁷ B. Palevitz, DNA Surprise: Monsanto discovers extra sequences in Roundup Ready soybean, 14 The Scientist 20 (2000).

¹⁸ As a result, when assessing the safety of transgenic crops such as RRA (and other transgenic crops already on the market), it is not sufficient to evaluate only the safety of the individual protein produced by the transgene itself. Instead, the potential for harm from the disruption of native plant genes during the plant transformation process should be evaluated.

¹⁴ M. Sussman et al., *The Arabidopsis Knockout Facility at the University of Wisconsin-Madison*, 124 Plant Physiol. 1465, 1466 (2000).

¹⁵ Salk Institute Genomic Analysis Laboratory Arabidopsis sequence indexed TDNA insertion project FAQ (http://signal. salk.edu/tdna_FAQs.html) (Last visited March 6, 2010) (reading, "[a]pproximately 50% of the lines contain a single insert [of foreign gene sequence], the other 50% of lines contain two or more inserts.")

transgenic plant whose safety and impact on people are unpredictable.

It is important to note that the transformation process for genetically modified crops is totally unlike traditional plant breeding. The latter process involves identifying similar, related plants with useful traits and crossing these plants to produce offspring with the best characteristics of both parents. Traditional breeding methods are responsible for significant improvements in myriad agronomically important traits (such as yield and pest resistance) in many crops over the past century. For example, in the last twenty years, the period during which transgenic crops were introduced, traditional breeding provided all but three to four percent of the 28 percent increase in maize yield.¹⁹

II. RRA IS LIKELY TO CONTAMINATE NEIGHBORING ALFALFA CROPS AND WILD ALFALFA POPULATIONS, CAUS-ING SIGNIFICANT PERMANENT HARM.

There is substantial evidence of human-designed genes contaminating conventional crops and wild relatives. The two major avenues of contamination are (1) pollen flow and (2) human error. Existing scientific

¹⁹ D. Gurian-Sherman, *Failure to Yield*, Union of Concerned Scientists 1, 3 (2009), http://www.ucsusa.org/food_and_agriculture/science_and_impacts/science/failure-to-yield.html (Last visited March 12, 2010).

studies demonstrate that RRA transgene contamination of alfalfa fields and wild alfalfa populations is likely to occur, difficult to undo, and costly for conventional and organic farmers.

A. Frequently Documented Transgene Movement Into Conventional Crops And Wild Relatives Demonstrates The Potential For Irreparable Harm.

Recent surveys document over 120 instances of transgene contamination since 1996.²⁰ These incidents have had a substantial impact on farmers, grain elevator operators, academic researchers, and consumers.

Contamination incidents are not limited to a single crop or region. Maize, rice, canola, tomatoes, and other crops have all been contaminated by transgenes. Transgene flow to other crops has occurred through cross-pollination of adjacent crops and wild plant populations, and perhaps most often, by simple human error. In many cases, the contamination occurred despite all parties following companyrecommended guidelines for the prevention of transgene

²⁰ See GeneWatch UK and Greenpeace International, GM Contamination Report 2005 – A review of cases of contamination, illegal planting and negative side effects of genetically modified organisms, 1, 6 (2005), available at http://www.greenpeace.org/ international/press/reports/gm-contamination-report (Last visited March 17, 2010); and GeneWatch UK and Greenpeace International, GM Contamination Register, available at http://www. gmcontaminationregister.org.

movement. It is likely that contamination incidents will continue at somewhat the same frequency.

Harms from transgene contamination vary by incident, but are often irreversible. When detected early enough, the harms consist largely of financial losses to farmers and seed companies. It is not uncommon, however, for contamination events to spread far beyond their initial scope before regulators detect them. In these cases, the impact is to a much broader swathe of the agricultural community than the guilty party can conceivably compensate. And the flow of transgenes into wild populations is effectively irreparable. The transgenes will continue to contaminate agriculture and the environment indefinitely.²¹

1. Widespread Contamination By Transgenic Starlink Maize Illustrates The Potential For Environmental Harm.

Aventis CropScience's release of StarLink maize is perhaps the best-known instance of transgenic crop contamination.²² StarLink transgenic maize harbors a

²¹ Reviewed in S. Smyth et al., Liabilities and economics of transgenic crops, 20 Nature Biotechnology 537, 539 (2002).

²² See, e.g., N. Harl, R. Ginder, C. Hurburgh and Iowa Attorney General S. Moline, *The StarLink Situation*, available at http://www.biotech-info.net/0010star.PDF (Last visited March 16, 2010); and Biotech Corn Tainted Vast Amounts. Company's *Report Expands Estimate*. Washington Post, March 18, (2001), summarized at Non-GM-farmers, http://www.non-gm-farmers. com/news_print.asp?ID=1168 (Last visited March 16, 2010).

transgene expressing a toxic protein meant to kill insects. In the late 1990s, regulators at the U.S. Environmental Protection Agency ("EPA"), following the advice of leading U.S. food allergists, identified the version of the toxic protein in StarLink as having a heightened risk for triggering allergic reactions compared to other versions. Consequently, the agency approved StarLink only for animal feed.²³

To effectuate regulatory restrictions, Aventis specified that the maize was not for human consumption or international trade²⁴ and placed contractual constraints on the use of StarLink maize not unlike those proposed by Monsanto to contain RRA.²⁵ Nevertheless, StarLink maize soon turned up in Taco Bell taco shells produced by Kraft Foods, prompting a massive recall.²⁶ Similar recalls occurred throughout the following months as more product contamination became clear.

It is not clear what the relative contributions of cross-pollination and inadvertent mixing of maize in

²³ N. Harl, R. Ginder, C. Hurburgh and Iowa Attorney General S. Moline, *The StarLink Situation*, available at http://www.biotech-info.net/0010star.PDF (Last visited March 16, 2010), at 2.

²⁴ Id., at 5.

 $^{^{25}}$ Id., at 5.

²⁶ A. Pollock, *Kraft Recalls Taco Shells with Bioengineered Corn*, N.Y. Times, September 23 (2000), at C1, available at http://www.nytimes.com/2000/09/23/business/kraft-recalls-taco-shells-with-bioengineered-corn.html?pagewanted=all (Last visited March 16, 2010).

grain elevators had in the movement of StarLink maize into human food channels. As one account explained, "[m]any [grain elevator operators] were unaware that any [transgenic maize line] had less than full domestic approval. This makes it likely that some corn containing StarLink . . . inadvertently entered elevators in those regions where it was grown in 1999. It is also possible that corn harvested adjacent to fields of StarLink corn could have been cross-pollinated."²⁷

What is clear, however, is that the StarLink contamination event was widespread and had significant impacts. *Half of Iowa's maize harvest tested as contaminated with StarLink*, making it unusable for human consumption or export. Nationwide, StarLink contaminated 4 percent of that year's maize crop.²⁸

The costs of this contamination event are huge but difficult to calculate. Aventis compensated farmers growing StarLink maize and maize grown within 660 feet of StarLink fields. The larger costs to grain companies and elevator operators of being stuck with contaminated mixed-maize stocks, and of cleaning their elevators, fell on the government. The

²⁷ N. Harl, R. Ginder, C. Hurburgh and Iowa Attorney General S. Moline, *The StarLink Situation*, available at http://www.biotech-info.net/0010star.PDF (Last visited March 16, 2010), at 6.

²⁸ Biotech Corn Tainted Vast Amounts. Company's Report Expands Estimate. Washington Post, March 18, 2001, summarized at http://www.non-gm-farmers.com/news_print.asp?ID=1168 (Last visited March 16, 2010).

U.S. Department of Agriculture ("USDA") paid up to \$20 million from a disaster relief fund to compensate seed companies for StarLink-contaminated planting seed, which had to be destroyed to prevent growers from inadvertently growing StarLink-contaminated corn.²⁹ A 2004 class-action settlement resulted in a payment of \$112 million to farmers whose crops were contaminated with StarLink maize.³⁰

According to the National Corn Growers Association, "[t]he StarLink dilemma was an unfortunate situation for all corn growers, not just those who used the StarLink product. Corn prices dropped significantly as a result of the situation and that impacted the entire industry."³¹ Furthermore, the settlement was "a step in the right direction, but *payments amount to little more than 'a drop in the bucket*' for farmers who experienced significant losses because of the StarLink disaster."³² Taco Bell franchisees won

²⁹ M. Kaufman, *The U.S. Will Buy Back Corn Seed; Firms to be Compensated for Batches Mixed With Biotech Variety*, Washington Post, March 8 (2001), archived at http://www.encyclopedia.com/doc/1P2-429720.html (Last visited March 16, 2010).

³⁰ U.S. Farmers to Get \$112 Million for GE Starlink Corn Contamination, GM WATCH daily, http://www.gmwatch.org. Available at http://www.organicconsumers.org/Corn/starlink.cfm (Last visited March 16, 2010).

³¹ Id.

³² Id. (emphasis added).

\$60 million to compensate for lost business.³³ But the biggest cost, to the reputation of the U.S. agricultural industry, was far greater; in the years following the StarLink incident, maize exports to Japan declined 44 percent and similar declines occurred in other export markets. A final report by industry consultants estimated that the final cost of the contamination event could be in the 'billions of dollars.'³⁴

2. Other Examples Of Pollen-Mediated Contamination Tell The Same Story.

Similar stories of other transgenic contamination in crops abound. In 2006, testing revealed that American rice had been extensively contaminated by an experimental herbicide-tolerant variety, known as LL601, that according to its developer, Bayer Crop-Science, had been discontinued in 2001. Investigators have never conclusively determined how and why LL601 genes showed up in commercial rice. But the impacts on rice producers were clear. They suffered \$200 million in direct and indirect losses from rejected, LL601-contaminated grain shipments and a consequent drop in rice prices contributed to a total

³³ Taco Bell Franchisees to get \$60 million. Reuters, June 8, 2001, available at http://www.gmfoodnews.com/re080601.txt (Last visited March 16, 2010).

³⁴ S. Laidlaw, *Starlink fallout could cost billions*, Toronto Star, January 9, 2001, available at http://www.gmfoodnews. com/ts090101.txt (Last visited March 16, 2010).

economic loss estimated at between \$741 million and \$1.285 billion.³⁵

Other reports have indicted pollen-mediated movement of herbicide resistance between canola fields,³⁶ from transgenic to wild populations of creeping bentgrass,³⁷ in wheat³⁸ and in corn.³⁹ John Fagan, founder of Fairfield, Iowa's Genetic ID, a company that screens for transgenic contamination, has explained that contamination happens "quite often."⁴⁰

Notably, all parties involved often "had followed isolation rules, but the genes [carried in pollen grains]

³⁵ Blue, E.N. (2007), "Risky Business," Neil Blue Consulting, for Greenpeace International, November 2007. http:// www.greenpeace.org/international/press/reports/risky-business.

³⁶ M. Rieger et al., *Herbicide Resistance Between Commercial Canola Fields*. 296 Science 2386 (2002).

³⁷ L. Watrud et al., Pollen-Mediated Movement of Creeping bentgrass – Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker. 101 Proc. Natl. Acad. Sci. 14533 (2004).

³⁸ Genetically Altered Wheat Flagged – Thailand Detects Shipment Not Cleared For Commercial Sales. Spokesman Review, October 14 (1999).

³⁹ I. Fürst, *Swiss soiled seed prompts tolerance question*, 17 Nature Biotechnology 629 (1999).

⁴⁰ K. Bett, *Mounting Evidence of Genetic Pollution from GE Crops – Growing Evidence of Widespread GMO Contamination*, Environmental Science and Technology, December 1 (1999), available at http://www.organicconsumers.org/ge/gepollution.cfm (Last visited March 17, 2010).

still moved into the [nontransgenic] foundation seed."⁴¹ By 2001, farmers routinely found transgenes "in corn that has been grown organically for ten to fifteen years," according to Arran Stephens, president of Nature's Path Foods, an organic grocer. "There's no wall high enough to keep that stuff contained."⁴²

3. Human Error Plays A Key And Inevitable Role In The Inadvertent Spread Of Transgenes.

Perhaps the greatest cause of transgene contamination is the "unscientific" phenomenon of simple human error. Fallible human beings mislabel bags, accidentally mix samples, take seeds from the wrong plant or put it in the wrong tube, confuse paperwork, miscommunicate with one another, and send seeds from the wrong stock. No one sets out to do these things, but they happen nonetheless.

Needless to say, no isolation practice, no agricultural precaution, and no reasonable degree of farmer diligence can protect against a seed company's simple mislabeling of transgenic seed as nontransgenic. In 1997, for example, Monsanto sold Roundup Ready canola that the government had not certified to be

⁴¹ S. Smyth et al., *Liabilities and economics of transgenic crops*, 20 Nature Biotechnology 537, 539 (2002).

⁴² B. Lilliston, *Farmers Fight to Save Organic Crops*, The Progressive, September 2001, available at http://www.progressive. org/0901/lil0901.html (Last visited March 17, 2010).

safe. Upon realizing its mistake, Monsanto recalled 60,000 bags of seed, enough to plant 600,000 acres with the unapproved seed.⁴³

The history is clear: Transgene contamination of conventional crops occurs often, despite farmers' efforts to comply with industry standards designed to protect against such events. It is expensive, particularly if not detected immediately. It can persist for years. And it harms exporting farmers' credibility beyond the immediate financial injury. Notwithstanding what seed companies like Monsanto say, the threshold of contamination that really matters is set internationally, as much by the marketplace as by foreign governments, not by any domestic standard of "reasonableness." As one affected farmer put it, "[t]he foreign buyers have flat out said they won't buy it. And I believe they won't."⁴⁴

4. Transgene Flow Into Nearby Wild Populations Is Also Common And Irreparable.

Transgenes often contaminate local wild populations as well. When wild plants are sufficiently closely related to the transgenic crop, they can interbreed

⁴³ The Western Producer, April 24, 1997.

⁴⁴ J. Gillis, *The Heartland Wrestles With Biotechnology*, Washington Post, April 22, 2003, at A01, available at http:// www.biotech-info.net/heartland.html (Last visited March 18, 2010).

to form viable offspring. Transgene crops can also interbreed with populations of conventional crop that have escaped from the farm ("feral" populations). The resulting hybrid plants will inherit half of their genes (including the transgene) from the crop species plant parent and half of their genes from the wild relative.

Researchers have reported numerous cases of transgenic crops interbreeding with wild relatives.⁴⁵ One study identified 65 crops species as capable of interbreeding with wild relatives, with another 100 species believed to be able to hybridize.⁴⁶ The actual number of species capable of hybridizing may be in the tens of thousands or higher.⁴⁷

In fact, gene flow from cultivated populations to wild relatives is well documented. It has been observed in sunflowers at multiple locations^{48,49} and in

⁴⁵ Reviewed in M. Bagavathiannan, and R. Van Acker (2009), The Biology and Ecology of Feral Alfalfa (Medicago sativa L.) and Its Implications for Novel Trait Confinement in North America, 28 Critical Reviews in Plant Sciences 69, 70 (2009).

⁴⁶ L. Rieseberg and J. Wendel, in *Hybrid Zones and the Evolutionary Process* (ed. R.G. Harrison, Oxford Univ. Press, New York) 70-109 (1993).

⁴⁷ C. Stewart Jr., et al., *Transgene Introgression from Genetically Modified Crops to their Wild Relatives*, 4 Nature Reviews Genetics 806 (2003).

⁴⁸ D. Arias and L. Rieseberg, *Gene flow between cultivated* and wild sunflowers. 89 Theor. Appl. Genet. 655 (1994).

⁴⁹ M. Ureta et al., *Gene flow among wild and cultivated* sunflower, Helianthus annuus in Argentina, 123 Agric. Ecosys. Environ. 343 (2008).

feral beet populations,⁵⁰ and the flow of multiple herbicide-resistance genes⁵¹ and other natural genes⁵² into feral canola populations is an ongoing problem. Triple herbicide-resistant canola has been detected in Canada, the result of crossing among three different single herbicide-tolerant varieties over several years.⁵³

One effect of these crosses is that the transgene, originally intended to protect the crop species from an herbicide intended to kill weeds, may now protect some of the very weeds that the herbicide was designed to kill. "[W]hen novel genes spread to freeliving plant populations, they have the potential to create or exacerbate weed problems."⁵⁴

Transgene movement into wild populations harms farmers by making their investments in herbicide

⁵² C. Devaux et al., Modelling and estimating pollen movement in oilseed rape (Brassica napus) at the landscape scale using genetic markers, 16 Mol. Ecol. 487 (2007).

⁵³ G. Steward, *A new breed of superweed*, The Toronto Globe and Mail, June 15, 2000, available at http://www.organic consumers.org/ge/superweed.cfm

⁵⁴ A. Snow, *Transgenic crops – why gene flow matters*, 20 Nature Biotechnology 542, 542 (2002).

⁵⁰ J. Arnaud et al., Evidence for gene flow via seed dispersal from crop to wild relatives in Beta vulgaris (Chenopodiaceae): consequences for the release of genetically modified crop species with weedy lineages, 270 Proc. Biol. Sci. 1565 (2003).

⁵¹ M. Aono et al., Detection of feral transgenic oilseed rape with multiple-herbicide resistance in Japan, 5 Environ. Biosafety Res. 77 (2006).

resistant crops useless, making their jobs more difficult, and making their products more costly to harvest. These harms ultimately are born not just by farmers but also by the population at large.

Wild relatives can cross-pollinate nontransgenic crops planted in their vicinity. "[Cross-pollination] from a crop to its wild relative is generally regarded as more difficult than from the wild relative to the crop."⁵⁵ Once a transgene gets into a wild population, this population will be a source of contamination to all fields within pollen's range for the indeterminate future.

As a consequence, the establishment of a transgene in a local population is effectively irreversible. Unlike contamination from a neighboring field of a transgenic crop, farmers cannot eliminate the source of contamination by plowing over the transgenic field. Wild plants often produce seeds that can lie dormant for years or even decades in so-called "seed banks" in the soil. Even if a farmer were willing and financially able to plow over every plant within miles of a plot, contaminated plants may still emerge from their seed banks for years to come. The impact of this contamination is that no farmer will be able to grow certifiably nontransgenic seeds from crops that can be cross-pollinated by contaminated wild relatives.

⁵⁵ C. Stewart Jr., et al., *Transgene Introgression from Genetically Modified Crops to their Wild Relatives*, 4 Nature Reviews Genetics 806, 809 (2003).

Although the individual chance of hybridization with a wild relative may be low in some cases, these numbers must be viewed in the context of the total number of chances that such an event will occur:

[C]ross-pollination between white rice and red rice [its wild relative] is rare, probably occurring less than 1 percent of the time. But multiply that by millions and millions of rice plants, they say – and then start using [herbicide], which by killing conventional red rice will allow the [herbicide]-resistant weed to dominate – and within a few years, huge expanses of the South could be infested with [herbicide]-resistant red rice. 'Anyone who works with rice and red rice knows it,' said Cynthia Sagers, a plant ecologist at the University of Arkansas. 'It's going to happen'.⁵⁶

B. RRA Transgene Contamination Of Adjacent Alfalfa Crops And Wild Populations Is Likely And Irreparable.

Petitioners' casual dismissal of these contamination risks for RRA are little more than wishful thinking. Their statistical argument is that because alfalfa is often grown as hay rather than to generate seed, the chance of transgene contamination is "2.5 in

⁵⁶ R. Weiss, *Biotech Rice Saga Yields Bushel of Questions* for Feds – USDA Approval Shortcut Emerges as Issue, Washington Post November 6, 2006, at 2, available at http://www. washingtonpost.com/wpdyn/content/article/2006/11/05/AR200611 0501092.html (Last visited March 16, 2010) (emphasis added).

one million."⁵⁷ This calculation is based on the critical assumption that farmers will not let hay grow past 10 percent flowering before harvesting⁵⁸ and that "[h]ay crops are harvested . . . before the flowers open and produce the pollen necessary for cross-pollination."⁵⁹ This assumption, however, does not stand up to scrutiny.

According to the University of Wisconsin Extension, an academic outreach program that provides alfalfa farmers with scientific advice on their farming practices:

The optimum yield and forage quality for milking dairy cows ranges from vegetative [absent all buds or flowers] to early bud on the first cutting to 10% flower on the second and third cuttings to full flower on a late-fall cutting. For animals with lower nutritional requirements, later stages [i.e., with more flowers] may be harvested.⁶⁰

In other words, growing alfalfa for hay does not preclude the plants from flowering. On the contrary, agriculture experts advise farmers to allow some plants to grow "to full flower" in order to maximize yield.

⁵⁷ Pet.App. 160a; Monsanto Petition for Certiorari, at 8.

⁵⁸ Pet.App. 128a-129a; Monsanto Petition for Certiorari, at 3.

⁵⁹ Monsanto Petition for Certiorari, at 4-5.

⁶⁰ D. Undersander et al., *Alfalfa germination and growth*, The learning store, University of Wisconsin Extension, available at http://www.learningstore.uwex.edu/pdf/A3681.PDF (Last visited March 15, 2010).

Petitioners' other key assumption - that alfalfa pollen grains are not dispersed by wind and are therefore unlikely to spread widely 61 – is equally suspect. Flowering RRA will release pollen that wild or domesticated honeybees or other wild insect pollinators may carry to adjacent fields. Researchers have documented occasional bee-mediated pollen transfer at distances of up to 4 kilometers (2.5 miles),⁶² regular transfer at distances of 1 kilometer (0.6 miles), and over 90 percent cross pollination at 250 meters (0.15 miles, or 275 yards).⁶³ The fact that alfalfa is a bee-pollinated forage crop does not preclude it from contaminating adjacent fields. If adjacent nontransgenic fields and RRA fields flower at the same time, the transgenic pollen can easily contaminate adjacent fields.

Moreover, even if Petitioners' calculation of transgene contamination were accurate, the chance of transgene contamination is not negligible. Farmers will plant up to 22 million acres with RRA.⁶⁴ A mature stand easily contains five plants per square foot or

⁶¹ Pet.App. 128a-129a; Monsanto Petition for Certiorari, at 3.

⁶² L. Teuber et al., Gene flow in alfalfa under honey bee (Apis mellifera) pollination, In Proceedings of the Joint Conference of the 39th North American Alfalfa Improvement Conference (NAAIC) and the 18th Trifolium Conference, Quebec City, Quebec, Canada (2004).

⁶³ P. Amand et al., *Risk of alfalfa transgene dissemination and scale-dependent effects*. 101 Theor. Appl. Genet. 107 (2000).

⁶⁴ Pet.App. 330a; Monsanto Petition for Certiotari, at 3.

218,000 per acre – that is, over 20 million plants on just 100 acres.⁶⁵ An event that occurs 2.5 times in a million ("almost a scientific impossibility" according to Petitioner)⁶⁶ becomes a fairly frequent occurrence when one has 22 million acres of chances.

The risk of transgene flow into wild, or "feral," alfalfa populations also is significant. Feral populations, as discussed above, create a number of problems for farmers. They readily cross with planted transgenic crops. They serve as a pollen source to contaminate nontransgenic crops, potentially over long distances. Most important, transgene contamination of feral populations is difficult if not impossible to undo.

RRA transgene is likely to move into feral alfalfa populations. Feral alfalfa populations occur along roadsides and other disturbed or unfarmed habitats throughout its planted range.^{67,68,69,70} A survey

⁶⁵ M. Rankin, *Alfalfa seeding rates: how much is too much,* University of Wisconsin Extension. http://www.uwex.edu/CES/ crops/AlfSeedingRate.htm. Chart showing at least 8 plants per acre.

⁶⁶ Monsanto Petition for Certiorari, at 17.

⁶⁷ F. Jenczewski et al., *Evidence for gene flow between wild* and cultivated Medicago sativa (*Leguminosae*) based on allozyme markers and quantitative traits. 86 American J. Bot. 677 (1999).

⁶⁸ S. Fitzpatrick et al., *Pollen-mediated gene flow in alfalfa: a three year summary of field research*. In: *Proceedings of 2003 Central Alfalfa Improvement Conference* (2003), available at http://www.foragegenetics.com/News.asp (Last visited March 18, 2010).

sponsored by Monsanto found feral alfalfa at more than 20 percent of almost 1,000 sites surveyed in five states and concluded that "[t]he proximity of feral populations to cultivated alfalfa suggests that gene flow will occur between these populations."⁷¹ An independent academic researcher studying feral alfalfa similarly concluded that "[h]igh ferality potential makes gene flow even more probable."⁷² Yet a third group listed alfalfa as a "Moderate Risk Crop" in terms of transgene flow to wild relatives, noting "if genes for herbicide tolerance were engineered into [alfalfa] crop populations they would probably

⁶⁹ D. Kendrick et al., Biogeographic survey of feral alfalfa populations in the U.S. during 2001 and 2002 as a component of an ecological risk assessment of Roundup Ready Alfalfa, In: Proceedings of North Central Weed Science Society Meeting, UT, USA (2005), available at http://www.a-c-s.confex.com/crops/ 2005am/techprogram/P7242.HTM (Last visited March 18, 2010).

⁷⁰ M. Bagavathiannan et al., *Feral nature of alfalfa: what role they could play in transgenic trait movement?* In: *Proceedings of Manitoba Agronomists' Conference*, The University of Manitoba, Winnipeg, MB, Canada (2006), available at http://www.umanitoba.ca/afs/agronomists_conf/proceedings/2006/bagavathiannan_feral_nature_of_alfalfa.pdf (Last visited March 18, 2010).

⁷¹ Supra n.69.

⁷² M. Bagavathiannan, and R. Van Acker (2009), *The Biology and Ecology of Feral Alfalfa* (Medicago sativa L.) and Its Implications for Novel Trait Confinement in North America, 28 Critical Reviews in Plant Sciences 69, 81 (2009).

introgress [move]" into their feral relatives' populations. 73

RRA transgene contamination is likely to harm adjacent farmers in three ways. First, if the farmer intended to harvest nontransgenic seed from that crop (for example, to maintain nontransgenic seed stocks for the following planting season), the seed and any hay grown from this seed will be irreparably contaminated with the transgene.

Second, even if farmers harvest the adjacent contaminated crops for hay without allowing the seeds harboring the transgenes to mature, a screen for transgenic contamination of the type used by, for example, European crop regulators or RRA-sensitive alfalfa buyers will detect the transgene and destroy the crop's nontransgenic value.

Third, if a transgene contamination event occurs, it is likely to go undetected for some period of time. If so, the contamination is likely to spread in later generations as the transgene is planted in fields commingled with nontransgenic alfalfa, much as it did in StarLink maize and LL601 rice contamination events. By the time a foreign regulator or buyer detects the contamination, the scale of the harm may be prohibitively large.

⁷³ C. Stewart Jr., et al., *Transgene Introgression from Genetically Modified Crops to their Wild Relatives*, 4 Nature Reviews Genetics 806, 811 (2003).

III. RRA WILL HASTEN THE EMERGENCE OF GLYPHOSATE-RESISTANT WEEDS.

Deregulation of RRA will likely exacerbate a rapidly growing threat to U.S. agriculture: the emergence of glyphosate-resistant ("GR") weed populations on millions of acres of cropland, described by a leading weed scientist as "a threat to global food production."⁷⁴

A. Selection Pressure Causes The Emergence Of Herbicide-Resistant Weeds.

Due to error in genome replication, a small amount of genetic variation is introduced with every new generation of a given organism. Most of these mutations are harmful or of no consequence to the individuals inheriting them. Occasionally, however, errors in DNA replication bring about changes that are beneficial. Usually these benefits only manifest in very limited circumstances. But under those circumstances, individuals harboring these beneficial heritable changes will rapidly out-compete others of their species. Such circumstances are said to "select" for the beneficial variant.

Glyphosate use selects for GR weeds, that is, it creates circumstances where, if a genetic variation conferring resistance to glyphosate does develop,

⁷⁴ S. Powles, *Gene amplification delivers glyphosate-resistant* weed evolution, Commentary, Proc. Natl. Acad. Sci. 107:955-56.

plants harboring the genetic variation will quickly out-compete other weeds, and the once-rare variant will become common.

Many farmers have embraced Round Ready ("RR") technology, which relies on the ability of glyphosate to kill weeds.⁷⁵ RR soybeans grow on 92 percent of the land cultivated for soy.⁷⁶ The figures are similar for other crops – 90 percent for RR cotton,⁷⁷ 60 percent for RR maize,⁷⁸ and 75 percent for RR canola.⁷⁹ Other farming nations that allow transgenic crops have similar adoption rates.⁸⁰ If the USDA approves RRA for general use, it is likely that farmers will adopt it on a large scale.

The EPA shows that agricultural use of glyphosate has risen dramatically since RR crops were introduced in 1996, increasing 140 percent from just 1997 to 2001, when it became the most widely used

⁷⁹ L. Gianessi, *Economic and herbicide use impacts of glyphosate-resistant crops*, 61 Pest Manag. Sci. 241 (2005).

⁸⁰ A. Cerdeira and S. Duke, *The Current Status and Environmental Impacts of Glyphosate-Resistant Crops: A Review*, 35 J. Environ. Qual. 1633, 1636 (2006).

⁷⁵ A. Cerdeira and S. Duke, *The Current Status and Environmental Impacts of Glyphosate-Resistant Crops: A Review*, 35 J. Environ. Qual. 1633, 1636 (2006).

⁷⁶ C. Benbrook, Impacts of Genetically Engineered Crops on Pesticide Use: The First Thirteen Years, The Organic Center, Nov. 2009, Suppl. Tables 2-4. http://www.organic-center.org/science. pest.php?action=view&report_ID=159.

⁷⁷ Id.

⁷⁸ Id.

herbicide in the U.S.⁸¹ And its use has doubled again since that time to reach 135 million pounds acid equivalents.⁸² USDA pesticide usage data reveal a similar trend. Since 1996, the intensity of glyphosate use (pounds/acre/year) has doubled on soybeans (2006) and tripled on cotton (2007).⁸³

Glyphosate is less environmentally harmful or toxic than many alternative herbicides.⁸⁴ As it is no longer under patent protection,⁸⁵ glyphosate's "cost has dropped dramatically."⁸⁶ Because of its broad activity and low environmental impact, glyphosate "is an ideal herbicide for use preplant, in fallow fields, and for spot or directed use to control an extensive

⁸¹ Environmental Protection Agency, *Pesticides Industry* Sales and Usage: 2000 and 2001 Market Estimates, Table 3.6 (2004).

⁸² Center for Food Safety, Comments on EPA's Registration Review of Glyphosate, Docket No. EPA-HQ-OPP-2009-0361 (2009), Figure 1, http://www.regulations.gov/search/Regs/home. html#documentDetail?R=0900006480a28745.

⁸³ Supra n. 76, Fig. 1.1, Table 4.1.

⁸⁴ F. Fishel et al., *Herbicides: How Toxic Are They?* University of Florida IFAS Extension document PI-133, at 3 (2009) accessible at http://www.edis.ifas.ufl.edu/pi170 (Last visited March 7, 2010).

⁸⁵ Monsanto's patent on the glyphosate molecule expired in September, 2000.

⁸⁶ S. Duke and S. Powles, *Glyphosate: a once-in-a-century herbicide*, 64 Pest Manag. Sci. 319, 319 (2008).

range of annual and perennial weeds."⁸⁷ It facilitates no-till farming, a practice that prevents erosion and reduces agricultural fossil fuel use.

All of these traditional uses of glyphosate are being put at risk by weed resistance due to the excessive "post-emergence" use of glyphosate with RR crop systems. Good agricultural practices recommend that farmers alternate the type of herbicide that they use by, for example, "burning down" their fields (*i.e.*, treating them with herbicide to clear all weeds in anticipation of planting a crop or to clear a field after harvest) with an herbicide other than glyphosate.⁸⁸ In practice, farmers often rely on glyphosate exclusively.⁸⁹ Monsanto has encouraged excessive use by wrongly assuring farmers that Roundup-only weed control with RR crops would not lead to weed resistance.⁹⁰

⁸⁷ S. Powles et al., *Evolved resistance to Glyphosate in rigid ryegrass* (Lolium rigidum) *in Australia*, 46 Weed Science 604, 604 (1998).

⁸⁸ S. Powles, *Evolved glyphosate-resistant weeds around the world: lessons to be learnt*, 64 Pest Manag. Sci. 360 (2008).

⁸⁹ USDA-NASS, Agricultural chemical use database (2008), Upland Cotton 2007 Report, http://www.pestmanagement.info/ nass/app_usage.cfm (Last visited March 18, 2010).

⁹⁰ B. Hartzler, *Two for the price of one*, Iowa State University, Dec. 17, 2004. Available at http://www.weeds.iastate. edu/mgmt/2004/twoforone.shtml.

A recent survey⁹¹ reports that 18 weed species have developed glyphosate resistance in at least 52 U.S. populations and 40 more worldwide. The survey reveals millions of acres of U.S. cropland infested with 10 resistant weeds species, with the majority expanding in scope.⁹² For example, GR Palmer amaranth (pigweed), first reported in one Georgia county in 2004, now infests several million acres in nine southern states, an extremely rapid spread that shows no signs of slowing.⁹³ Impacts for cotton farmers are severe as infestations can reduce yield by 50 percent^{94,95} and have resulted in the abandonment of thousands of acres of cotton land.⁹⁶

Since its discovery in Delaware in 2000, GR horseweed, which can reduce yields by 40-70 percent,

⁹⁴ A. Culpepper et al., *Glyphosate-resistant Palmer amaranth* (Amaranthus palmeri) *confirmed in Georgia.* 54 Weed Science 620 (2006).

⁹⁵ T. Gaines et al., *Gene amplification confers glyphosate resistance in* Amaranthus palmeri, 107 Proc. Natl. Acad. Sci. USA. 1029 (2010).

⁹⁶ E. Robinson, *Designing the perfect weed – Palmer amaranth*, Delta Farm Press, Dec. 24, 2008, http://deltafarmpress. com/cotton/palmer-amaranth-1226/.

⁹¹ Herbicide-resistant weeds, http://www.weedscience.org/ Summary/UspeciesMOA.asp?lstMOAID=12 (Last visited March 31, 2010).

⁹² Id.

⁹³ S. Culpepper and J. Kichler, University of Georgia Programs for Controlling Glyphosate-Resistant Palmer Amaranth in 2009 Cotton, University of Georgia Cooperative Extension, April 2009, http://mulch.cropsoil.uga.edu/weedsci/HomepageFiles/Palmer2009.pdf.

has infested up to 3.3 million acres in 16 states of the East, South, and Midwest.⁹⁷

GR giant ragweed, infesting six Midwestern states and Arkansas and Tennessee, is a particular problem in soybeans, where just three to four plants per square yard can reduce yields by as much as 70 percent.⁹⁸

Weed populations with multiple resistances to glyphosate and other herbicides are also on the rise, with six of eight identified since 2006.⁹⁹ Multipleherbicide-resistant weeds reduce farmers' weed control options, cost more to manage, and in some cases may mean literally 'uncontrollable' weeds.

Researchers point to a clear cause for this resistance: "[t]he widespread adoption of glyphosatetolerant (GT) crops, and subsequent glyphosate use, on a significant portion of the available agronomic cropland has provided a strong selection pressure for weeds that are not controlled by glyphosate."¹⁰⁰

⁹⁷ F. Laws, *Glyphosate-resistant weeds more burden to growers' pocketbooks*, Delta Farm Press, Nov. 27, 2006, http:// deltafarmpress.com/news/061127-glyphosate-weeds/.

⁹⁸ B. Johnson & M. Loux, *Glyphosate-resistant giant rag*weed confirmed in Indiana, Ohio, Purdue University press release, Dec. 21, 2006.

⁹⁹ Supra n.91.

¹⁰⁰ T. Webster and L. Sosnoskie, *Loss of Glyphosate Efficacy:* A Changing Weed Spectrum in Georgia Cotton. 58 Weed Science 73 (2010).

The solution researchers advocate is not the abolition of RR crop use. Quite the contrary, scientists argue for increased oversight so that glyphosate may be used for generations to come:

We are convinced that the unique features of glyphosate vitally necessitate its preservation for future harvests. Allowing glyphosateresistant weeds to evolve unchecked will have huge adverse effects on the future of weed management worldwide. We hope that actions can be galvanized to save the world's greatest herbicide for future generations and future harvests.¹⁰¹

B. Unregulated Adoption Of RRA Will Have A Disproportionate Impact On The Selection For Glyphosate-Resistant Weeds.

Unregulated RRA adoption will increase the selection pressure for glyphosate resistance in weeds in a few important ways. Contrary to Petitioners' claims, at present farmers often use little or no herbicide when growing alfalfa, in sharp contrast to herbicideheavy crops like maize, cotton and soybeans.^{102,103}

¹⁰¹ S. Duke and S. Powles, *Editorial – Glyphosate-Resistant* Weeds and Crops, 64 Pest Manag. Sci. 317 (2008).

¹⁰² Decl. of Charles M. Benbrook in Supp. of Pls.' Mot. For Summ. J., Case 3:06-cv-01075-CRB, at 4.

¹⁰³ USDA (1999), "Agricultural Chemical Usage: 1998 Field Crops Summary," USDA's National Agricultural Statistics Service, (Continued on following page)

Many farmers currently using no herbicide on alfalfa may adopt glyphosate with RRA, not in place of other herbicides but in place of companion cropping or other non-chemical means of weed control that do not select for glyphosate resistance. Based on EPA label rates, USDA determined that the maximum legally permissible amount of glyphosate that could be applied to RRA alone, given 90 percent adoption nationwide, was 142,761,960 pounds per year,¹⁰⁴ approximately the amount of glyphosate now used in all of American agriculture.¹⁰⁵ While alfalfa farmers would be unlikely to use so much, tens of millions of pounds of glyphosate could well be applied, with rates inevitably rising each year as resistant weeds proliferate, like they have for soybeans, cotton, and corn.

Another major risk from the unregulated adoption of RRA is the impact that it will have in the context of farmers' crop rotation strategies. "One of the most important ways to slow the development of resistance is to sequentially use different herbicides ... when different crops follow one another, are rotated, in a field over time."¹⁰⁶ In its 2004 petition for

May 1999, p. 9. Just 7% of alfalfa hay acres were treated with herbicides in 1998, the latest reliable data available.

¹⁰⁴ USDA APHIS, Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status. Draft Environmental Impact Statement, Nov. 2009, Appendix N at N17-N18.

¹⁰⁵ Supra n.82.

¹⁰⁶ Decl. of Doug Gurian-Sherman, For Perm. Inj., Case 3:06cv-01075-CRB, at 4.

nonregulated status, Monsanto identifies corn as a major rotation crop with alfalfa, and argues that low RR corn adoption (7 percent in 2002) lessens resistant weed concerns.¹⁰⁷ With 60 percent rather than 7 percent of America's most widely grown crop now RR, many more farmers would rely on glyphosate exclusively for weed control rather than alternating herbicides as they alternate crops. This change will create an unbroken, steady selection pressure for glyphosate resistance. The impact of this change will far exceed the simple quantitative increase in glypho-sate applied.¹⁰⁸

C. Weed Resistance Constitutes Irreparable Harm.

Five main points emerge from the facts in this section. First, even though genomic variants conveying glyphosate resistance are very rare, it is an observed fact that they emerge over time. The more heavily that U.S. farmers rely on glyphosate, the stronger the selection pressure will be to encourage the spread of GR weeds once they emerge. This selection pressure will disproportionately increase if RRA is approved for general use.

¹⁰⁷ Monsanto & Forage Genetics, Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (Medicago sativa L.): Events J101 and J163, April 16, 2004, pp. 302-303.

 $^{^{\}rm 108}$ Decl. of Doug Gurian-Sherman, For Perm. Inj., Case 3:06-cv-01075-CRB, at 5.

Second, the widespread emergence of GR weeds both reduces the efficacy of glyphosate and imposes substantial costs on farmers and U.S. agriculture in the form of reduced yields, increased production costs, greater soil erosion from increased weed tillage, and increased health and environmental harms associated with greater pesticide use.

Third, the emergence of GR weeds is preventable with appropriate agricultural practices. Specifically, scientifically-based stewardship regulations requiring that farmers diversify their weed control programs could substantially increase glyphosate's useful lifespan.

Fourth, although the emergence of GR weeds is preventable, the spread of glyphosate resistance over the course of a few generations within weed populations cannot be reversed once it has occurred.

Fifth, the parties suffering the greatest harm from GR weeds are the American farmer and, ultimately, the American consumer. Farmers rely on glyphosate because it is cheap, off patent, easy to apply, less harmful than most alternatives, and particularly conducive to no-till farming. Consequently, they can reduce their costs and pass some of these savings on to consumers. Because Petitioners no longer hold the exclusive patent to glyphosate, and their patents for many prominent RR crops are maturing, they have little incentive to protect the long-term efficacy of this herbicide. In sum, the widespread adoption of RRA will substantially increase the rate at which resistant weeds emerge. It is extremely likely that these resistant weeds will emerge without a policy born of USDA Animal Plant Health Inspection Service's serious consideration of the risks. Once GR weeds emerge, their harm will be irreparable. Ultimately, American farmers and consumers will bear the burden from the loss of this useful agricultural tool.

CONCLUSION

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For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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