No. 12-15052

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY, et al. Plaintiffs-Appellants.

v.

THOMAS J. VILSACK, et al., **Defendants-Appellees**

and

FORAGE GENETICS, et al. Intervenor Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA Case No. 3:11-cv-01310 SC

BRIEF OF AMICI CURIAE CROPP COOPERATIVE, ANNIE'S INC., CLIF BAR & COMPANY, LUNDBERG FAMILY FARMS, NATIONAL COOPERATIVE GROCERS' ASSOCIATION, NATIONAL ORGANIC COALITION, NATURE'S PATH FOODS, INC., ORGANIC SEED ALLIANCE, ORGANIC TRADE ASSOCIATION, STONYFIELD FARM, INC., UNITED NATURAL FOODS, INC. IN SUPPORT OF PLAINTIFFS-APPELLANTS SEEKING REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, *amici curiae* state the following:

CROPP Cooperative states that it is a farmer-owned cooperative incorporated under Chapter 185 of the Wisconsin Statutes, has no parent corporation, and no publicly-held corporation owns 10% or more of its stock.

Annie's, Inc. states that it is a public company listed on the NYSE, with a majority stake held by affiliates of Solera Capital, LLC.

Clif Bar & Company states that it is a privately-held California corporation, has no parent corporation, and no publicly-held corporation owns 10% or more of its stock.

Lundberg Family Farms states that it is a privately-held California corporation, has no parent corporation, and no publicly-held corporation owns 10% or more of its stock.

National Cooperative Grocers' Association states that it is a retailer-owned cooperative incorporated as a 308B in the State of Minnesota, has no parent corporations, and no publicly-held corporation owns 10% or more of its stock.

National Organic Coalition states that it is a project of the Rural Advancement Fund International ("RAFI"), a 501(c)(3) non-profit corporation, that RAFI has no parent corporation, and that no publicly held corporation owns

more than 10% of RAFI's stock.

Nature's Path Foods, Inc. states that it is a family-owned business, has no

parent corporation, and no publicly-held corporation owns 10% or more of its

stock.

Organic Seed Alliance states that it is incorporated as a 501(c)(3) non-profit

organization in the state of Washington, has no parent corporation, and no

publicly-held corporation owns 10% or more of its stock.

Organic Trade Association states that it is a 501(c)(6) non-profit corporation,

has no parent corporation, and no publicly-held corporation owns 10% or more of

its stock.

Stonyfield Farm, Inc. states that it is a privately-held corporation, and that it

has a parent company, Group Danone (a publicly-traded company), which owns

86% of its stock.

United Natural Foods, Inc. states that it is a for-profit corporation trading on

the NASDAQ exchange, has no parent corporation, and that no publicly-held

corporation owns 10% or more of its stock.

Dated: April 23, 2012

Respectfully submitted,

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Counsel for Amici Curiae Cropp Cooperative, et al.

INTERESTS OF THE AMICI CURIAE

Amici are commercial and public-interest members of the organic food industry as well as participants in the market for conventional, non-genetically engineered foods. They grow organic grains, fruits, or vegetables; own organic livestock; sell organic products or conventional, non-genetically engineered products; or are organizations dedicated to the integrity of the organic label. Amici have a strong interest in presenting their concerns regarding the unrestricted use of Defendant-Intervenor Monsanto's genetically-engineered ("GE") alfalfa product lines J101 and J163 (collectively, Roundup® Ready Alfalfa or "RRA"), because such use affects their ability to choose to produce or sell organic or conventional products.

Amicus CROPP Cooperative ("CROPP"), the nation's largest farmer-owner cooperative, markets certified organic products under the Organic Valley® and Organic Prairie® brands. CROPP's membership includes over 1600 certified organic dairy farmers, beef and pork producers, and feed crop growers located in 34 states, all of whom rely on the availability of certified organic alfalfa.

Transgenic contamination of organic alfalfa crops by RRA will cause CROPP's

¹ Pursuant to Rule 29(c)(5) of the Federal Rules of Appellate Procedure, *amici* state that (a) no party's counsel authored the brief in whole or in part; (b) no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and (c) no person—other than *amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief.

members to face a significant decline in the marketability of their products and a significant increase in production costs.

Amicus Annie's, Inc. is a leading natural and organic food company based in Berkeley, CA, with net sales of \$117 million in fiscal 2011. Annie's offers consumers more than 125 products that are present in over 25,000 retail locations in the United States and Canada. Annie's is concerned by the introduction of RRA because customers expect certified organic foods to be completely free of genetically modified ingredients, and that confidence could be eroded by the introduction of RRA.

Amicus Clif Bar & Company is the leading maker of organic energy bars and healthy snacks in North America. Clif Bar & Company is committed to protecting the integrity of the organic supply chain, from the farmer to the consumer, and its business depends on the availability of certified organic products.

Amicus Lundberg Family Farms is a leading producer of organic rice and organic rice products in North America. Lundberg Family Farms is committed to protecting the integrity of the organic supply chain, from the farmer to the consumer. Its business depends on the availability of certified organic rice and other organic ingredients.

Amicus National Cooperative Grocers' Association ("NCGA") is a business services cooperative for retail food co-ops located throughout the United States. It

represents 125 food co-ops operating over 160 stores in 35 states with combined annual sales of over \$1.4 billion. NCGA supports consumers' right to have access to organic foods free from GE contamination and believes that RRA stands not only to compromise that right but also the integrity of the organic label.

Amicus National Organic Coalition ("NOC") is a national alliance of farmer and rancher associations, environmentalists, consumer and food safety groups, and progressive industry members involved in organic agriculture and in upholding the integrity of the organic label. NOC believes the integrity of the organic label and the ability of its members to meet consumer expectations and foster organic markets are dependent upon the exclusion of GE products, ingredients, and methods from organic products.

Amicus Nature's Path Foods, Inc. is North America's largest certified organic breakfast cereal manufacturer. Nature's Path is affected by organic consumer opinion, and believes consumer demand for its products will be impacted should organic alfalfa become contaminated by RRA.

Amicus Organic Seed Alliance ("OSA") is a nonprofit organization with a mission to advance the ethical development and stewardship of the genetic resources of agricultural seed. OSA accomplishes its mission through research, education, and advocacy with organic farmers and other agricultural professionals.

Amicus Organic Trade Association ("OTA") is the membership-based

business association for organic agriculture and products in North America, representing over 6,500 organic businesses across 49 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA believes that its members' livelihoods will be harmed by the release of GE alfalfa into the environment.

Amicus Stonyfield Farm, Inc. is the largest organic yogurt manufacturer in the world, and the third largest yogurt brand in the U.S. Stonyfield Farm purchases certified organic milk from the member farmers of amicus CROPP Cooperative, and fears that the economic viability of its business will be in peril if supplies of organic alfalfa become contaminated by RRA.

Amicus United Natural Foods, Inc. ("UNFI") is the nation's leading distributor of natural, certified organic, and specialty foods, with sales of nearly \$4 billion annually in the United States. UNFI operates 20 distribution centers serving 17,000 retail locations, and fears that its ability to meet market demand for products reliably free of GE organisms is at risk from the introduction of RRA.

SUMMARY OF ARGUMENT

Defendants' decision to allow the unregulated use of RRA will result in the transgenic contamination of organic alfalfa, an essential feed for the multi-billion-dollar organic food industry. The term "transgenic contamination" refers to the

unintended transfer of genetic material from GE crops to non-GE crops. RRA contains a transgene whose only purpose is to allow engineered plants to grow even when exposed to the herbicide glyphosate, the active ingredient in Monsanto's Roundup herbicide.

Based on historic examples of contamination, there is a risk that the RRA transgene will be transferred from RRA to organic, conventional, and feral alfalfa. These contamination incidents have caused billions of dollars of damage to growers and sellers of organic and other non-GE products. Organic farmers have lost the price premium they could previously charge for their products and exporters have lost foreign markets in GE-sensitive countries. In some cases, the contamination has been so widespread that it has eliminated farmers' ability to choose to grow or sell organic products while simultaneously eliminating consumers' ability to choose organic products. Even when contamination has not been so widespread, growers of non-GE crops have faced the financial and technical burdens of avoiding and detecting contamination before it can spread.

Defendants' unrestricted deregulation of RRA will almost certainly cause similar economic damage and loss of consumer choice here. Viable pathways for contamination exist and that Defendant-Intervenors' contractual or voluntary management practices will not prevent contamination. In fact, some contamination has already occurred during field trials, even with RRA being planted only on

limited acreage.

Transgenic contamination of alfalfa, once it occurs, will have devastating consequences for the organic and conventional (non-GE) food industry. Producers and sellers of organic dairy products, including *amici*, rely on the availability of organic alfalfa hay as feed for their livestock to meet USDA organic standards. Even without a loss of certification, they face market rejection, both domestically and overseas, because consumers of organic products demand GE-free foods and because many countries reject GE food products altogether.

As explained in Plaintiffs-Appellants' brief, Defendants have the authority to grant the deregulation petition only in part, imposing geographic restrictions and isolation distances. Defendants' authority to partially deregulate GE crops has repeatedly been recognized by Defendants themselves, as well as by the courts—most prominently by the Supreme Court in the precursor to this case, *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2760-61 (2010). Such measures would substantially reduce the risk of widespread transgenic contamination and would require that the producers and growers of RRA share the burden of avoiding contamination.

Defendants trumpet the ideal of so-called "coexistence" between GE and non-GE agriculture in the United States. If this ideal is not to prove a mirage, they must ensure that organic and conventional farmers can continue to grow crops free

of transgenic contamination from GE crops. Defendants' position in this litigation that they do not have the authority to order a partial deregulation of RRA, should it prevail, would destroy any hope of coexistence. To preserve the organic and conventional farming and consumers' freedom of choice, the district court's decision must be reversed.

ARGUMENT

I. DEFENDANTS' ACTIONS WILL LEAD TO THE TRANSGENIC CONTAMINATION OF ORGANIC ALFALFA.

History has shown that whenever GE crops are approved for general use, the GE transgenes in those crops eventually escape into non-GE crop populations.

Such transgenic contamination can occur in various ways and has produced several well-documented examples of widespread economic harm. Transgenic contamination is virtually certain to occur again with RRA now that Defendants have approved it for unrestricted use. Indeed, as the record shows, contamination has already started to occur.

A. <u>Transgenic Contamination is Ubiquitous and Occurs through in Various Ways.</u>

Transgenes from genetically-engineered crops have repeatedly contaminated conventional and organic crops. There have been at least 326 occurrences of transgenic contamination since 1996.² As a U.S. Government Accountability

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² See Greenpeace Int'l, GM Contamination Report 2007 – Annual Review of Cases of Contamination, Illegal Planting and Negative Side Effects of Genetically

Office ("GAO") report concluded: "Unauthorized releases of GE crops into food, animal feed, or the environment beyond farm fields have occurred, and it is likely that such incidents will occur again."3

Transgenic contamination can and does occur in a variety of ways.⁴ For example, pollen from GE crops can fertilize non-GE plants, in some cases even when those plants are miles away. ER0327-30; ER0335-38; ER0372-74; ER0380-81. Various farming practices can also result in contamination, including seed mixing, improper seed cleaning of machinery, and spillage during transport. ER0372-73; ER0380. Finally, human errors at any stage of the crop production process can lead to contamination. Id.

Three examples demonstrate the ease with which transgenes can enter organic or conventional crops. First, in 1995, Monsanto's strain of glyphosateresistant canola, known as GT-73 or Roundup Ready canola, was approved for use in Canada. After only two seasons of commercial planting, plants containing the

Modified Organisms 10 (2008) [AR 10-00009956]. (Citations beginning "AR" refer to documents available in the administrative record.)

³ GAO, Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring 1 (2008) (emphasis added) [AR 10-00009617].

⁴ *Id.* at 15 (identifying cases of contamination caused by cross-pollination, commingling of GE- and non-GE crops after harvest, misidentified seed, and uncontrolled volunteer plants).

glyphosate-resistance transgene were found in non-GE fields.⁵ One study of non-GE canola seedlots found that 32 of 33 samples were contaminated with GE transgenes.⁶ This example is particularly relevant because canola is agronomically similar to alfalfa: both are bee-pollinated, hardy crops with many volunteer plants and significant feral populations.⁷

Second, Aventis CropScience's StarLink maize, which includes a transgene for a toxic protein that is intended to kill insects, illegally entered the human food supply in 1999. Because of concerns about allergic reactions, StarLink maize was not approved for human consumption, but only for growth as an animal feed.

⁵ Michelle Marvier & Rene C. Van Acker, *Can Crop Transgenes Be Kept on a Leash?*, 3 Frontiers Ecology & Env't 93, 94 (2005) [AR 10-00013714].

⁶ See Lyle F. Friesen, et al., Evidence of Contamination of Pedigreed Canola (Brassica napus) Seedlots in Western Canada with Genetically Engineered Herbicide Resistance Traits, 95 AGRONOMY J. 1342, 1345 (2003) [AR 10-00008236]; Mary A. Reiger, et al., Pollen-Mediated Movement of Herbicide Resistance Between Commercial Canola Fields, 296 SCIENCE 2386 (2002) [AR 10-00020160].

⁷ If anything, contamination is even more likely in alfalfa. *See* Muthukumar V. Bagavathiannan, et al., *Commercialization of Perennial GE Crops: Looming Challenges for Regulatory Frameworks*, 24 J. AGRIC. ENV'TL ETHICS 227, 232 (2011) (identifying risk of gene flow in alfalfa as "high" and in canola as "medium-high"); ER0375-89. GE canola has more recently caused transgenic contamination in the United States. In 2010, scientists who tested feral canola plants in North Dakota found that 80% of the plants they tested contained GE transgenes. *See* Meredith Schafer, et al., *The Establishment of Genetically Engineered Canola Populations in the U.S.*, 6 Pub. Lib. Sci. ONE e25736 (2011), available at

http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.002573; Andrew Pollack, *Canola, Pushed by Genetics, Moves into Uncharted Territories*, N.Y. TIMES, Aug. 10, 2010, at D3.

ER0373. Aventis placed limits on the use of StarLink maize similar to those that Monsanto uses for RRA.⁸ ER0417. Despite these precautions, 430 million bushels of corn, more than 4 percent of the 1999 harvest, were found to contain the StarLink transgene.⁹ The transgene was found in taco shells, corn bread, and polenta—nearly 300 food products in all.¹⁰ The cause or causes of this contamination episode are not fully understood, but could have involved inadvertent mixing of maize in grain elevators or cross-pollination of conventional corn from fields near those in which StarLink maize was grown. ER0372-73.

Third, in August 2006, the USDA announced that it had discovered that GE transgenes from Bayer AG's Liberty Link rice had contaminated the U.S. long-grain rice supply.¹¹ Within five days of the announcement, the European Union—

⁸ Julie Vorman, *EPA Unlikely To Again OK Biocrop for Animal Feed Only*, REUTERS, Oct. 26, 2000 ("The EPA approval required Aventis to carefully label each bag of StarLink seed, spell out the restrictions in legal documents given to farmers and take other steps to ensure StarLink did not enter the human food supply.").

⁹ Marc Kaufman, *Biotech Grain Is in 430 Million Bushels of Corn, Firm Says*, WASH. POST, Mar. 18, 2001, at A9.

¹⁰ Anthony Shadid, *Bioengineered Corn More Prevalent than Thought*, BOSTON GLOBE, May 17, 2001, at C2; Marc Kaufman, *Biotech Corn Found In Variety of Foods*, WASH. POST, Apr. 24, 2001, at A3.

¹¹ Press Release, United States Department of Agriculture, Release No. 0306.06: Investigation of Regulated Rice in Commercial Rice Samples (Aug. 18, 2006), available at

 $http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true\&contentid=2\\006/08/0306.xml.$

which had previously imported more than 5% of all U.S. long-grain rice—announced that it would no longer accept long-grain rice from the U.S. unless the rice was tested and certified as free of GE transgenes. In 2007, rice farmers throughout the southern U.S. faced a severe shortage of uncontaminated rice seed.

As indicated above, these were not isolated incidents. Herbicide-resistance genes have also contaminated non-GE crops of corn, ¹⁴ creeping bentgrass, ¹⁵ and flax. ¹⁶ As the authors of a review of the scientific literature concluded, "the movement of transgenes beyond their intended destinations is a virtual certainty." ¹⁷

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¹² Press Release, European Commission, *Commission Requires Certification of US Rice Exports to Stop Unauthorised GMO Entering the EU*, Aug. 23, 2006, *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/1120.

¹³ David Bennett, *GM Rice Contamination Leads to Proposed Class Action*, DELTA FARM PRESS, Mar. 25, 2007, at 6.

¹⁴ Rex Dalton, *Modified Genes Spread to Local Maize*, 456 NATURE 149, 149 (2008) (contamination in Mexico); Ingeborg Fürst, *Swiss Soiled Seed Prompts Tolerance Question*, 17 NATURE BIOTECHNOLOGY 629 (1999) (contamination in Switzerland).

¹⁵ Lidia S. Watrud, et al., Evidence for Landscape-level, Pollen-mediated Gene Flow from Genetically Modified Creeping Bentgrass with CP4 EPSPS as a Marker, 101 PROC. NAT'L ACAD. SCI. 14,533 (2004).

¹⁶ ER0484; Martin Mittlestaedt, Who Contaminated Canada's Crops? Prairie Whodunit Has Flax Farmers Baffled, GLOBE & MAIL (TORONTO), Oct. 28, 2009, at A1.

¹⁷ Marvier & Van Acker, *supra* note 5, at 94; *see* ER0361 ("Seeds of traditional varieties of corn, soybeans, and canola are pervasively contaminated with low levels of DNA sequences derived from transgenic varieties.").

B. <u>Transgenic Contamination of Alfalfa is Likely to Occur, and in Fact Has Already Begun.</u>

Transgenic contamination is not only a general threat. Instead, alfalfa has several characteristics that make transgenic contamination especially likely in this crop. The district court itself recognized that APHIS has "acknowledged that full deregulation could lead to transgenic contamination." ER0008. In fact, some contamination has already occurred.

There are several mechanisms for transgenic contamination of alfalfa. ER0380-82. First, pollen from flowers on RRA plants will fertilize non-GE alfalfa in other fields. ER0380-81. Alfalfa is bee-pollinated, and researchers have documented some transfer of pollen by bees between fields up to 2.5 miles apart, regular transfer at 0.6 miles, and over 90% cross-pollination at 275 yards. ER0641; ER0320-26; ER0327-34; ER0335-38. Therefore, if adjacent fields with RRA and non-GE alfalfa flower during the same time period, the RRA plants will likely pollinate the non-GE ones.

In addition, even if commercial RRA fields do not directly contaminate non-GE alfalfa fields, feral alfalfa can still be a conduit through which contamination

pollen source.") [hereinafter "Alfalfa I"].

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¹⁸ P.C. St. Amand, et al., *Risk of Alfalfa Transgene Dissemination and Scale-Dependent Effects*, 101 THEOR. APP. GENET. 107 (2000) [AR 10-00021778]; *see Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624 at *5 (N.D. Cal. Feb. 13, 2007) ("Alfalfa seeds are pollinated by bees and, as a result, there is a realistic potential for contamination from seed fields to nearby seed fields; indeed, APHIS admits that insects pollinate alfalfa up to two miles from the

occurs. Feral alfalfa populations are common in areas in which alfalfa is commercially grown. ER0327-34.¹⁹ As APHIS recognized in the Final Environmental Impact Statement ("FEIS"), "[i]f feral alfalfa grows between fields of [glyphosate-tolerant ("GT")] alfalfa and non-GT alfalfa, then it could provide a corridor for gene flow, or a strip of growth that can serve as a reservoir for the GT gene, between these fields." ER0587. One scientific study found that 83% of feral alfalfa populations within two miles of RRA seed fields tested positive for the RR trait after only two years of RRA production. ER0335. Moreover, feral alfalfa could also serve "as a stepping stone for pollinators that would be more likely to travel between flowers that are closer together than between distant fields." ER0587. As a result, "feral alfalfa populations will obstruct the coexistence of IRRA] with conventional alfalfa."

¹⁹ Muthukumar V. Bagavathiannan, et al., *Occurrence of Alfalfa* (Medicago sativa L.) *Populations Along Roadsides in Southern Manitoba, Canada and their Potential Role in Intraspecific Gene Flow*, 20 Transgenic Res. 397 (2011); Muthukumar V. Bagavathiannan & Rene C. Van Acker, *The Biology and Ecology of Feral Alfalfa* (Medicago sativa L.) *and Its Implications for Novel Trait Confinement in North America*, 28 Critical Rev. Plant Sci. 69 (2009) [AR10-00001313] [hereinafter Bagavathiannan & Van Acker, *Biology and Ecology of Feral Alfalfa*]; Muthukumar V. Bagavathiannan & Rene C. Van Acker, *The Feral Nature of Alfalfa and Implications for the Co-Existence of Genetically Modified (GM) and Non-GM Alfalfa* [AR10-00001332].

²⁰ Bagavathiannan & Van Acker, *Biology and Ecology of Feral Alfalfa*, *supra* note 19, at 82 [AR10-00001326]. In addition, accidental seed mixing can occur for a variety of reasons, including the failure to clean machinery properly and spillage. ER0380.

One need not hypothesize about the possibility of contamination *because it has already happened*. *See Geertson Seed Farms v. Johanns*, 570 F.3d 1130, 1137 (9th Cir. 2010) ("[T]he court found that genetic contamination had already occurred, and it had occurred while Monsanto and Forage Genetics had contractual obligations in place."), *rev'd on other grounds by Monsanto v. Geertson Seed Farms*, 130 S. Ct. 2743 (2010). APHIS allowed limited plantings of RRA while it was assessing the impacts of deregulation. These plantings resulted in significant contamination. For example, Cal/West Seeds found that more than 12 percent of seed lots tested in California in 2009 demonstrated the adventitious presence of the RRA transgene, up from 3 percent in 2008. ER0343; ER0642. Similarly, farmers reported in 2006 that 11 of 16 fields tested in Montana, Wyoming, and Idaho contained detectable levels of transgenes. ER0641; ER 0394; ER0447.

In addition, there is no record support for supposing that Defendant-Intervenors' proposed contractual measures will be effective in mitigating the risk of transgenic contamination.²¹ In particular, there is no evidence that Defendant-Intervenors will monitor, let alone effectively enforce these measures, or that they have done so with other Roundup Ready crops, for which such contractual measures are standard practice. *See* ER0379 (citing study finding that 20% of corn

²¹ Defendant-Intervenor Monsanto requires anyone who purchases a bag of GE seed to sign a "Monsanto Technology/Stewardship Agreement." *See* Monsanto, TUG 2012: U.S. Technology Use Guide 4 (2011), *available at* http://www.monsanto.com/SiteCollectionDocuments/Technology-Use-Guide.pdf.

growers did not follow stewardship agreement requirements); ER0360-62 (finding pervasive contamination in corn, soybean, and canola despite industry practices). Moreover, one of the key measures relied upon—that RRA growers will harvest their hay before 10% of the plants bloom (thus in theory avoiding pollen flow)—is undermined by evidence in the record that 18% of alfalfa growers harvested their crop later than that time.²²

In sum, widespread transgenic contamination of conventional and organic alfalfa by RRA is almost certain to occur. As a leading researcher on transgenic contamination summarized it in his comments:

[O]ur research made plain . . . that the confinement of novel traits in commercially produced alfalfa would be very difficult because of alfalfa's outcrossing nature, the fact that it is insect pollinated, its perennial nature, its excellent capability as a feral species and the ubiquity of feral alfalfa populations in alfalfa production regions. As such, the mitigation of any harm that may result from the escape of traits from . . . [RRA] will be very challenging if not impossible. ²³

II. THE TRANSGENIC CONTAMINATION OF ORGANIC ALFALFA WILL CAUSE SIGNIFICANT ECONOMIC HARM TO THE ORGANIC FOOD INDUSTRY AND LIMIT CONSUMERS' ABILITY TO CHOOSE WHAT KIND OF FOOD TO BUY.

The organic food industry is a large and rapidly-growing segment of the nation's agricultural economy. Overall sales of certified organic food and

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²² See FEIS, App. V at V-32 [AR3-00011717]; see also ER0330.

²³ AR 3-00009150-51 (comments of Dr. R.C. Van Acker on FEIS). Citations beginning "APHIS-2007-0044" refer to documents available in the regulatory docket for the deregulation decision available at www.regulations.gov.

beverages approached \$28 billion in 2010, the most recent year for which data are available—more than triple the total in 2002.²⁴ Organic products now account for 11.6% of all fruit and vegetable sales and 5.7% of all dairy product sales.²⁵

Organic dairy farming is an integral part of this thriving industry. ER0405. Organic dairy sales reached approximately \$3.9 billion in 2010.²⁶ Between 2000 and 2008, annual sales grew at an average rate of more than 23 percent per year.²⁷ *Amicus* CROPP Cooperative, which sells certified organic milk under the brand name Organic Valley®, had more than \$690 million in total sales in 2011.²⁸

As a result of the greater costs required to satisfy organic certification standards, farmers, food processors, and retailers receive a price premium for certified organic products. For example, alfalfa growers garner about an 18-20% premium for certified organic alfalfa compared conventional alfalfa. ER0426. Similarly, according to Agricultural Marketing Service reports, in March 2012, the average price for a gallon of organic whole milk was \$4.02, compared to \$3.63 for non-organic whole milk.²⁹

²⁴ See Organic Trade Ass'n, 2011 Organic Industry Survey, at 5 (2011).

²⁵ *Id.* at 13.

²⁶ *Id.* at 31.

²⁷ *Id*.

²⁸ CROPP Cooperative, 2011 Annual Report, at 13 (2012), *available at* http://www.organicvalley.coop/fileadmin/pdf/CROPP_Annual_Report_11.pdf.

²⁹ See USDA AMS, Whole Milk Monthly Reports – 2012,

If widespread RRA alfalfa contamination occurs, the costs to amici could be catastrophic. Prior contamination incidents have had devastating economic consequences. First, the transgenic contamination of canola in Canada, described above, destroyed European demand for organic canola from western Canada. ER0385; ER0394. Canola crops and oil from western Canada can no longer be marketed as organic or non-GE. ER0385; ER0394. Second, in response to contamination by StarLink maize, the USDA announced that it would pay seed companies up to \$20 million to compensate them for having to destroy StarLinkcontaminated seed,³⁰ and Aventis eventually paid about \$120 million to settle lawsuits arising from the incident.³¹ One analysis found that the StarLink contamination episode cost U.S. corn growers approximately \$500 million. ER0417. Third, the contamination of conventional rice Bayer AG's Liberty Link transgene caused even greater economic harm, ER0417-18, ER0428; a spokesperson for a rice industry trade group described it as "the most significant

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5096547; USDA AMS, Organic Whole Milk Monthly Reports – 2012, http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5096549; *see also* APHIS-2007-0044-11487 (comments of *amicus* CROPP Cooperative on DEIS) ("In 2006, the average price received by our farmers for a hundred pounds of milk (cwt) was \$27.48, compared to a conventional average price of \$12.66 (a difference of \$14.82)."); *see generally* ER0487-89.

³⁰ Marc Kaufman, *U.S. Will Buy Back Corn Seed*, WASH. POST, Mar. 8, 2001, at A3.

³¹ Marc Gunther, *Attack of the Mutant Rice*, FORTUNE, July 9, 2007, at 74.

event in the history of the U.S. rice industry."³² Bayer eventually agreed to pay \$750 million to approximately 11,000 U.S. rice farmers.³³

The costs here will also be devastating. Organic alfalfa farmers will struggle to meet USDA organic standards. Organic dairies will struggle to find an adequate supply of organic feed to provide their livestock. Even if they manage to satisfy regulatory standards, they will still face market rejection, both at home and abroad, because consumers expect organic products to be GE-free.

To be marketed or sold as certified organic, alfalfa hay must be grown according to standards established by the USDA's National Organic Program ("NOP") pursuant to the Organic Foods Production Act of 1990, 7 U.S.C. §§ 6501-6523. NOP regulations prohibit producers of certified organic foods from using

³² Lisa Shumaker, US GMO Rice Caused \$1.2 bln in Damages—Greenpeace, Reuters News, Nov. 6, 2007.

³³ Ian Berry, *Bayer to Pay Rice Farmers for Gene Contamination*, WALL ST. J., July 1, 2011, *available at* http://online.wsj.com/article/SB10001424052702304450604576420330493480082 .html.

Other contamination episodes have resulted in similar costs. For example, when Canadian flax was found to be contaminated with the Triffid transgene, the European Union "slammed the doors on further imports of flaxseed from Canada, threatening a lucrative \$320-million annual market for farmers. [P]rices for flax . . . plunged by \$2 to \$3 a bushel from around \$11 before reports of the contamination." Mittlestaedt, *supra* note 16, at A1. U.S. corn exporters are estimated to lose approximately \$300 million per year in exports because of the European Union's rejection of GE corn. Pew Initiative on Food & BIOTECHNOLOGY, U.S. v. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD 3-4 (2005).

"excluded methods," 7 C.F.R. § 205.105(e), which are defined to include "methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes," *id.* § 205.2. The organic standard does not tolerate transgenic contamination.

Organic dairies rely on a regular supply of organic alfalfa hay. ER0490; ER0498. Although organic livestock must spend at least 120 days per year on pasture, ³⁴ organic alfalfa is an essential feed during other parts of the year. All organic livestock operations, including organic dairies, must use 100% organic feed; there is no *de minimus* exception. *Id.* § 205.237(a). Under these standards, contamination of organic alfalfa with the RRA transgene will render the alfalfa ineligible for organic certification and will eliminate that alfalfa as a permissible feed for organic livestock. As a result, organic dairy farmers will lose the organic premium they currently receive for their products, a loss that one analysis values at \$225 million per year. ER0432.

Aside from these regulatory requirements, consumers of organic products—as noted above—expect these products to be free of GE material. ER0387; ER0392-93; ER0405-06. The prohibition on the use of GE seeds in the organic standard was itself the result of massive public opposition to a proposed rule that

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³⁴ See U.S. Dep't of Agriculture, National Organic Program, Access to Pasture (Livestock), 75 Fed. Reg. 7154 (Feb. 17, 2010).

would have permitted their use.³⁵ Further, thousands of people people, including more than 53,000 Organic Consumers Association members, submitted comments to APHIS expressing their concerns about contamination of organic alfalfa and stating that they avoid foods that contain, or are produced by, genetically-modified organisms. APHIS-2007-0044-12880. Surveys indicate that up to 76% of consumers who buy organic expect these products to be free of GE materials. ER0392. As Judge Breyer observed in *Alfalfa I*, "to many farmers and consumers . . . organic means not genetically engineered, even if the farmer did not intend for his crop to be so engineered." *Alfalfa I*, 2007 WL 518624, at *7. As a result, "[t]he organic industry risks losing its credibility and markets if the USDA allows GE material to make its way into organic products." ER0392.

Export markets are, if anything, more sensitive to the presence of genetically-engineered material in food. Alfalfa is exported either as seed or as hay. Saudi Arabia, the most impotant destination for the \$80 million alfalfa seed export market, has zero tolerance for transgenic contamination. ER0638; ER0456. S&W Seed Co., a major exporter, reports that "over 60% of our seed sales are to countries that have **zero tolerance** for GMO seed." ER0453; *see* ER0428. 93% of

³⁵ U.S. Dep't of Agriculture, National Organic Program, 65 Fed. Reg. 13,512, 13,514 (proposed rule Mar. 13, 2000) ("275,603 commenters on the first proposal nearly universally opposed the use of [GE] technology in organic production systems. Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods.").

the \$171 million alfalfa hay export market is to countries that are GE-sensitive. ER0428; *see* ER0473-74; ER0475-80. APHIS has recognized that "[t]here is evidence that Japan could decrease its imports of non-GT alfalfa hay from the United States with GT alfalfa deregulation." ER0639. In sum, if alfalfa hay and seed cannot be certified as GE-free, exporters face rejection by foreign markets, resulting in massive economic losses. ER0458-65. One study estimates the total loss at \$197 million per year. ER0432.

Even the *risk* of contamination of organic alfalfa with the RRA transgene will cause significant economic harm to organic dairy farmers. *See Monsanto*, 130 S. Ct. at 2755 (finding that alfalfa farmers had standing based on their need to take measures to avoid contamination and to test for contamination). Farmers who do not want their alfalfa to be contaminated by RRA will need to create buffer zones around their fields and monitor and test their crops for contamination.³⁶ Because APHIS has deregulated RRA without any restrictions, the financial burden of avoiding contamination falls entirely on non-GE farmers.³⁷ ER0396; ER0483. APHIS itself acknowledges that "[p]roducers of organic and non GE alfalfa may incur costs to create additional buffer zones or to implement testing protocols,"

³⁶ See Erik Stokstad, Can Biotech and Organic Farmers Get Along?, 332 SCIENCE 166, 167 (2011) ("Organic farmers bear the costs of preventing gene flow into their crops, which they do by planting buffer strips, for example, and testing for transgenes.").

³⁷ See id.

ER0545, and that these costs could slow the growth of the organic market, ER0616.

The costs to organic farmers of these measures will be substantial. It costs approximately \$180 per sample to test alfalfa seeds for the presence of the glyphosate-resistance gene. ER0431. Companies like CROPP, which pool milk from many suppliers, will need to ensure that every farmer tests alfalfa on a regular basis to ensure that it is not contaminated. The combined cost of testing all organic alfalfa and of testing all conventional alfalfa exports to GE-sensitive countries is estimated to be approximately \$8 million per year. ER0431. A major U.S. seed company has informed its customers that "[i]t is becoming clear that [the RRA transgene] . . . can easily spread and that we are going to have to take extraordinary measures when producing foundation seed and commercial seed for GMO sensitive markets." ER0343.

More fundamentally, the defendants' unrestricted deregulation of RRA harms amici and other organic farmers, retailers, and consumers by eliminating their ability to choose to grow, sell, or consume non-genetically engineered foods. See Alfalfa I, 2007 WL 518624 at *9 ("For those farmers who choose to

³⁸ These harms to organic agriculture are also environmental harms. Organic agriculture is associated with reduced pesticide and fertilizer use, better soil quality, and increased biodiversity. Indeed, organic production is defined as a system that integrates "cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity." 7

grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop."). Moreover, this form of contamination is not like chemical pollution, which can be cleaned up after a spill: "Once the gene transmission occurs and a farmer's seed crop is contaminated with the Roundup Ready gene, there is no way for the farmer to remove the gene from the crop or control its further spread." Id. at *5. Depriving consumers of the ability to choose between GE and non-GE alfalfa, beef, or dairy products will result in permanent changes in the structure of the markets for these products and prevent fair competition between GE and non-GE products. These results are contrary to the purposes of the Plant Protection Act, which include the protection of all agriculture (not just GE varieties), as well as the environment and economy, see 7 U.S.C. § 7701, as well as with USDA's avowed goal of "coexistence" of GE and non-GE agriculture. ER0554, ER0559.

III. PARTIAL DEREGULATION OF ROUNDUP-READY ALFALFA WOULD REDUCE THE HARM TO AMICI.

As explained above, the unrestricted deregulation of RRA will cause significant economic harm to organic and conventional agriculture and compromise consumer choice. The most direct way to avoid these harms would be for Defendants to refuse to deregulate RRA at all. If, however, deregulation must

C.F.R. § 205.2.

occur, then the imposition of conditions pursuant to a partial deregulation would reduce the harm to *amici*.

As appellants demonstrate, APHIS has the authority under the Plant Protection Act, 7 U.S.C. §§ 7701-7772, to grant only a partial deregulation of RRA. Appellant Br. at 14-35. Such a partial deregulation could restrict cultivation of RRA to certain parts of the country, as well as impose conditions on the manner in which RRA is planted or harvested, such as mandatory buffer zones between RRA fields and fields planted with non-genetically engineered alfalfa or a mandatory requirement that RRA be harvested before flowering. *See* ER0558-63.

APHIS itself included in its FEIS, as one of the "preferred alternatives," a detailed set of geographic restrictions, isolation distances, and other use restrictions that it concluded would reduce the risk of contamination. ER0558-63. The agency asserted that these measures would satisfy its "purpose and need" of "promoting coexistence" between GE- and non-GE agriculture. ER0559. Various courts, most significantly the Supreme Court in an earlier round of this litigation, have recognized Defendants' authority to impose such conditions.³⁹ Even Defendant-

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³⁹ See Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743, 2760-61 (2010); Center for Food Safety v. Vilsack, No. C 08-00484 JSW, 2009 WL 3047227, at *8 n.3 (N.D. Cal. Sept. 21, 2009) (observing that APHIS "could have partially deregulated Roundup Ready sugar beets, by approving the petition but imposing geographic limitations"); Alfalfa I, at *1 (stating that APHIS had the authority to "approve the petition with a geographic limitation on where the genetically engineered alfalfa could be grown").

Intervenor Forage Genetics analyzed the benefits of such measures and requested that they be imposed on an interim basis pending completion of the FEIS. ER0666-80.

Both types of restrictions would reduce the harm to amici. First, as APHIS found in the FEIS, such restrictions would reduce the risk of transgenic contamination, thereby decreasing the likelihood of a catastrophic collapse of the supply of GE-free alfalfa. ER0588; see also APHIS-2007-0044-8841 (comments of Muthukumar Bagavathiannan and Dr. Rene Van Acker), at 1 ("It is possible that strict adherence to stewardship practices, including the management of feral populations, can reduce the adventitious presence of GM traits and may facilitate the co-existence of GM and non-GM alfalfa."). As a result, as APHIS recognized, partial deregulation might reduce the risk of rejection of U.S. alfalfa by export markets. See ER0616 ("Increased rejection of GT alfalfa seed in foreign markets would possibly not impact U.S. exports if conventional seed marketing is able to convey the added safeguard generated by the segregation of conventional seed production from GT hay."); see also ER0452-55; ER0466-68. Partial deregulation would also help preserve the multi-billion-dollar domestic market in organic dairy products, which, as explained above, faces collapse if widespread transgenic contamination occurs.

Second, these restrictions would more equitably share the financial burden

of preventing contamination among all producers, rather than placing it entirely on the shoulders of organic and conventional (non-GE) farmers. In the FEIS, APHIS itself acknowledges that organic farmers' "[a]dditional stewardship costs are less likely under the Isolation/Geographic Restriction Alternative because GT alfalfa and non-GT alfalfa seed growing areas would be isolated from each other." ER0616.

CONCLUSION

Defendants' decision creates great economic risks for the fastest-growing sector of the agricultural economy. No other agency has the authority to address these harms; if the district court's constricted view of Defendants' legal authority is allowed to stand, *amici* will be left without further legal recourse. Defendants can and must act to share the burden of preventing transgenic contamination equitably among all participants in the agricultural economy.

For the foregoing reasons, *amici* respectfully request that the judgment of the district court be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(A)

Pursuant to Fed. R. App. P. 32(a)(7)(C) and Ninth Circuit Rule 32-1, this brief is proportionately spaced, has typeface of 14 points Times New Roman and contains 6,137 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). The word processing software used to prepare this brief was Microsoft Word 2007.

/s/ Shaun A. Goho

CERTIFICATE OF SERVICE

I hereby certify that on April 23, 2012, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: April 23, 2012	/s/
•	Shaun A. Goho