Deregulating Genetically Engineered Alfalfa and Sugar Beets: Legal and Administrative Responses

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Summary

Monsanto Corporation, the developer of herbicide-tolerant varieties of genetically engineered (GE) alfalfa and sugar beet (called Roundup Ready alfalfa and Roundup Ready sugar beet), petitioned USDA's Animal and Plant Health Inspection Service (APHIS) for deregulation of the items. Deregulation of GE plants is the final step in the commercialization process. Monsanto filed a petition for deregulation of its GE alfalfa in 2004, and for GE sugar beets in 2005.

As part of the deregulation process, APHIS conducts an environmental review under the National Environmental Policy Act (NEPA) to determine whether any significant environmental impacts will result from deregulation. APHIS conducted a limited review, known as an environmental assessment (EA), of the GE plants to assess the impacts of growing them on a commercial scale. APHIS issued a "finding of no significant impact" (FONSI) for GE alfalfa and GE sugar beets.

Lawsuits subsequently challenged the adequacy of the EAs in separate actions. Both courts held that APHIS should have prepared a more analytically thorough environmental impact statement (EIS) for the deregulation decisions. Separately, the courts directed APHIS to complete an EIS on the effects of deregulating GE alfalfa and GE sugar beets.

The court in the GE alfalfa case halted planting of the genetically modified seed, and nullified the deregulation. The injunction was appealed to the U.S. Supreme Court, which held that the injunction was too broad and that the court should have considered partial deregulation. The Supreme Court did not discuss the appropriateness of the environmental review. In the meantime, APHIS completed the environmental review directed by the lower court, releasing a final EIS for GE alfalfa on December 16, 2010. On January 27, 2011, Secretary Vilsack announced that APHIS was granting GE alfalfa full deregulation. On January 5, 2012, a federal district court rejected claims that the deregulation violated the law.

The court in the GE sugar beet case did not formally prohibit planting sugar beets, but it voided APHIS's deregulation decision in August 2010, undoing the five-year-old approval of GE sugar beets, from which nearly half of U.S. sugar is derived. APHIS issued four permits authorizing seedling production that would not allow flowering or transplanting without additional authorization. In November 2010, a judge ordered those seedlings pulled from the ground, holding that APHIS had violated NEPA in issuing the permits. The Ninth Circuit temporarily halted that decision in December 2010, ultimately holding in February 2011 that the seedlings did not have to be removed.

APHIS announced on February 4, 2011, that the agency would partially deregulate GE sugar beet *root* crop production, but would continue full regulation for sugar beet *seed* crop production while the EIS was prepared. The final EIS for GE sugar beets was published June 1, 2012. On July 20, 2012, APHIS issued its determination of non-regulated status for GE sugar beets. Provisions to amend APHIS's regulatory procedures under the Plant Protection Act have been introduced in the House farm bill (H.R. 6083) and in the House Agriculture appropriations bill (H.R. 5973).

The cases of GE alfalfa and sugar beets highlight continuing policy questions about the adequacy of APHIS's deregulation protocol, particularly regarding the environmental review process. In their suits against APHIS, plaintiffs cited the EAs' failure to assess the impact on non-GE alfalfa growers (particularly those who export to Japan, Korea, and Taiwan) and on producers of commercial table beet and chard seeds (species that can cross-pollinate with GE sugar beets).

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Plant Biotechnology Regulation and Oversight

The basic federal guidance for regulating biotechnology products is the Coordinated Framework for Regulation of Biotechnology (51 *Federal Register* 23302), published in 1986 by the White House Office of Science and Technology Policy (OSTP). A key regulatory principle is that genetically engineered (GE) products should continue to be regulated according to their characteristics and unique features, not their production method—that is, not on the basis of their creation through biotechnology. The framework provides a regulatory approach intended to ensure the safety of biotechnology research and products, using existing statutory authority and previous agency experience with traditional breeding techniques. The three lead agencies are U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA) at the Department of Health and Human Services, and the Environmental Protection Agency (EPA).

APHIS regulates the importation, interstate movement, and field testing of GE plants and organisms that are or might be plant pests under the Plant Protection Act of 2000 (PPA; 7 U.S.C. §§7701 *et seq.*).[1] Because the Coordinated Framework for Regulation of Biotechnology regulates GE plants under existing authorities, APHIS's guiding statutory authority under the PPA became the vehicle by which APHIS regulated plants that had been genetically modified to produce novel proteins, such as those conferring herbicide tolerance and pest resistance.[2] GE plants that are or might be plant pests are considered "regulated articles" under APHIS regulations (7 C.F.R. §§340-340.9). APHIS authorization must be obtained prior to import, interstate movement, or environmental release, including field testing.

In the 1986 Framework document, USDA published proposed rules under the PPA that would allow it to regulate outdoor uses of transgenic plants. These regulations were finalized in June 1987 in essentially the same form as the proposed rules.[3] Technically, the PPA regulations do not cover all genetically engineered plants. The regulations cover only those plants engineered to contain DNA sequences from certain genera containing species that were considered to be potential plant pests. The regulations included a broad list of such genera; and this had the practical effect of causing most transgenic plants to be captured by the regulations.[4]

A "regulated" plant cannot be introduced into the environment unless its developer obtains APHIS authorization through either the permit process or the notification process. Permits impose restrictions on movement and planting to prevent escape of plant material that may pose a pest

[1] APHIS also regulates animal biologics (i.e., viruses, serums, toxins for animal vaccines) under the Virus, Serum, and Toxins Act (21 U.S.C. §§151 *et seq*.).

[2] The Plant Protection Act of 2000 (P.L. 106-224) consolidates all or part of 10 existing USDA plant health laws into one comprehensive law, including the authority to regulate plants, plant products, certain biological control organisms, noxious weeds, and plant pests. The Plant Quarantine Act, the Federal Pest Act, and the Federal Noxious Weed Act are among the 10 statutes the new act replaces. The PPA expands the definition of noxious weed from the definition in the Federal Noxious Weed Act, which included only weeds that were of foreign origin, new to the United States, or not widely prevalent in the United States. The PPA now defines a noxious weed as a weed that could harm agriculture, public health, navigation, irrigation, natural resources, or the environment. Under the PPA, noxious weeds are regulated similarly to plant pests.

[3] 52 *Federal Register* 22892 (June 16, 1987).

[4] The genus *Agrobacterium* was on the APHIS list of regulated items. In practice, DNA sequences from *Agrobacterium tumefaciens* were almost universally used in GE procedures. The presence of *A. tumefaciens* DNA in the resulting plant would often be enough to subject the GE plant to regulation under the PPA.

risk. Developers follow APHIS guidance on testing and movements to ensure that the plant will not damage agriculture, human health, or the environment, including the human environment. Most GE crops have been developed under the notification option, an expedited procedure that is less rigorous than permitting.[5] Notification can be used in lieu of permitting when the plant species is not considered a noxious weed (or a weed in the release area) and other APHIS standards are met.

After a GE variety is approved for release into the environment on a trial basis, the developer of the GE seed typically petitions APHIS for "deregulated status" of the particular GE "event" that has been initially approved. This is the last step to full-scale commercialization of the GE plant. Once the GE plant is deregulated, it is no longer subject to APHIS regulation under 7 C.F.R. Part 340. A significant step in this deregulation process involves an assessment of the plant's environmental impact, including impacts on the human environment. The National Environmental Policy Act (NEPA) requires federal agencies to prepare a detailed environmental impact statement (EIS) for all "major Federal actions significantly affecting the quality of the human environment."[6] The "human environment" includes socioeconomic impacts that might arise from the major federal action. If an agency is unsure of the significance of any environmental impacts, it may prepare an environmental assessment (EA), which is a limited review. Based on the conclusions of that review, the agency can decide an EIS is needed because of the impacts found, or it may issue a "finding of no significant impact," known as a FONSI.

Monsanto Corporation, the developer of herbicide-tolerant varieties of GE alfalfa and sugar beet (marketed under the name of Roundup Ready alfalfa and Roundup Ready sugar beet), petitioned APHIS for deregulation of these items in 2004 (for GE alfalfa) and 2005 (for GE sugar beets). APHIS conducted EAs of the GE plants to assess the impacts of growing them on a commercial scale. APHIS issued EA-FONSIs for GE alfalfa in June 2005 and for GE sugar beets in March 2005.

Both of these EA FONSIs were challenged in separate lawsuits. The courts found that APHIS's environmental assessments were inadequate. These two cases are discussed in detail below (see "Legal Challenges of APHIS Environmental Assessments and Injunctions").

Monsanto's GE Alfalfa

Alfalfa is the fourth-largest crop grown in the United States, with nearly 23 million acres of alfalfa harvested annually. It is a perennial that can be planted in the spring and fall, and a typical field may be harvested three or four times a year. The crop can remain productive for several years and is often rotated with other crops because it improves the soil's nitrogen content. While nearly all states grow some alfalfa, most alfalfa acreage is in the West and Midwest, including California, South Dakota, Wisconsin, Idaho, Iowa, and Minnesota. Most alfalfa is grown for hay or forage for livestock, primarily for dairy cattle, beef cattle, and horses. A portion of the crop also is grown for seed, mostly in the western United States.

[5] Introducing into the environment a so-called bio-pharm plant (i.e., those GE plants that have been engineered to express a pharmaceutically active compound) is authorized under the APHIS permit process rather than the notification process.

[6] 42 U.S.C. §4332(2)(C).

Weed management in alfalfa fields is a long-standing concern for alfalfa producers. One of Monsanto's GE innovations is the development of plant varieties that are tolerant of the broad-spectrum herbicide glyphosate, marketed under Monsanto's Roundup trademark.[7] Roundup Ready (RR) soybeans, cotton, canola, and corn are widely planted varieties that express this genetically engineered trait. With Monsanto's development of GE alfalfa—the first perennial to be genetically engineered—a grower can apply a glyphosate-based herbicide to the field after weeds have germinated and not harm the growing alfalfa plant. Concerns about increasing weed-tolerance stemming from the widespread use of glyphosate on GE varieties, and questions about the toxicity of glyphosate, continue to be raised.[8]

As noted above, APHIS regulates the release into the environment of "organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests."[9] These "regulated articles" are field-tested subject to APHIS's performance standards governing releases into the environment. APHIS authorized field trials for GE alfalfa in 1998. Monsanto subsequently submitted protocols to APHIS that included a 900-foot buffer zone between the GE alfalfa and non-GE alfalfa, and confinement of flowering plants in cages so that pollinators (e.g., bees) could not get access. The protocols also required that GE alfalfa be destroyed when the field trials ended, that plant residue be disked into the soil, and that the fields be labeled and monitored for one growing season. From 1999 to 2005, APHIS authorized 297 field trials for GE alfalfa.

Following nearly eight years of field trials, Monsanto and Forage Genetics International submitted a petition to APHIS in May 2003 requesting deregulated status of two lines of GE alfalfa under the Plant Protection Act.

APHIS Decision to Deregulate GE Alfalfa

Deregulating a GE item is a "major federal action" and, as such, NEPA requires APHIS to review the environmental implications of the deregulation, preparing either an EA or an EIS. As noted above, an EA can be used to determine whether an EIS is necessary. But APHIS found an EIS was not required by the circumstances. On June 27, 2005, following review of public comments on the draft EA, APHIS announced in the *Federal Register* its decision to deregulate GE alfalfa and issued a FONSI.[10] APHIS essentially concluded that GE alfalfa exhibited no plant pathogenic properties that could have environmental impacts, and, consequently, that an EIS was not required. The EA is a more limited assessment of the environmental impacts of an action, and the decision to issue a FONSI rather than conduct an EIS led to a legal challenge. This challenge (litigation discussed below) resulted in a court directing APHIS to prepare an EIS.

[7] Plants are genetically engineered to be glyphosate-tolerant by inserting into the plant genome a gene coding for the expression of a particular enzyme. The gene comes from a common soil bacterium, *Agrobacterium*, and is introduced into the plant by a procedure widely used over the past 20 years.

[8] The evolution of herbicide-resistant weeds has been well-documented. The widespread adoption of glyphosate-tolerant GE varieties is a significant factor in the development of the herbicide resistance. On July 28, 2010, the House Committee on Oversight and Government Reform's Domestic Policy Oversight Subcommittee held hearings entitled "Are 'Superweeds' an Outgrowth of USDA Biotech Policy?" on the emergence of herbicide-resistant weeds, with particular focus on glyphosate-resistant weeds.

[9] 7 C.F.R. §340(a)(2).

[10] 70 *Federal Register* 36917 (June 27, 2005).

On December 14, 2009, following litigation (discussed below), APHIS announced that its draft EIS concerning GE alfalfa was available for public comment. The comment period, which was extended, ended March 3, 2010. The final EIS, which addresses the 244,000 comments received on the draft EIS, was published on December 16, 2010.[11] The final EIS examined three possible outcomes: (1) complete deregulation, (2) continuing the plant's regulated status, and (3) partial regulation with geographic restrictions and isolation distances on production of GE alfalfa seed and, in some locations, hay production.[12]

On January 27, 2011, Secretary Vilsack announced that APHIS was granting GE alfalfa full deregulation.[13] The stated basis of the decision was that GE alfalfa posed no greater plant pest risk than other conventional alfalfa varieties. APHIS concluded that any option other than full deregulation was inconsistent with their regulatory authority under the Plant Protection Act. In the EIS, APHIS identified both the complete deregulation and the partial/conditional deregulation as preferred alternatives.[14] While the decision to deregulate means that APHIS has no further regulatory control over the planting, distribution, or other actions related to GE alfalfa, growers continue to be subject to any contract restrictions imposed by Monsanto's technology use agreement. Those non-regulatory restrictions include managing hay to prevent seed production, harvesting at or before 10% bloom in areas where seed is produced, and prohibitions on use in wildlife feed plots. Growers who raise alfalfa for seed would be required to follow Forage Genetics International Best Practices.

Representatives of national agricultural commodity associations (e.g., American Farm Bureau Federation, National Cotton Council, USA Rice Federation) sent a letter to the Administration's Office of Science and Technology Policy on January 5, 2011, opposing the partial deregulation, arguing that such a decision would be a significant departure from the 1986 *Coordinated Framework for Regulation of Biotechnology.*[15] The letter also expressed concern that a partial deregulation could have impacts on current trade agreements. At a forum on January 20, 2010, convened by the House Agriculture Committee, Members queried Secretary Vilsack about the partial deregulation option, and indicated their support for full deregulation.

The Center for Food Safety (CFS), one of the original plaintiffs, criticized APHIS's decision and vowed to continue its legal challenge to deregulating GE alfalfa. In an open letter to Secretary Vilsack, CFS claimed that the Final EIS was still deficient in its assessment of the impacts of GE alfalfa, noting among other alleged deficiencies, not properly assessing liability and oversight, the impact of increased herbicide use, and the harm from herbicide-resistant weeds.[16]

[11] The Final EIS is available at http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf.

[12] The draft EIS considered only two alternatives: (1) continuing to regulate GE alfalfa, or (2) complete deregulation.

[13] USDA News Release No. 0035.11, *USDA Announces Decision to Fully Deregulate Roundup Ready Alfalfa* (January 27, 2011). 76 *Federal Register* 5780 (February 2, 2011).

[14] EIS, Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status, Executive Summary p. iii (December 2010).

[15] A copy of the letter is available at http://www.soygrowers.com/members/dw2/weekly/LL11/pdf/RRAlfalfaltr010511.pdf.

[16] Copy of the letter is available at http://www.centerforfoodsafety.org/wp-content/uploads/2011/01/Open-Letter-CFS-to-Vilsack-FINAL-1-24-10-with-CC-list.pdf.

Monsanto's GE Sugar Beets

Weed management is a significant problem for sugar beet growers as well. Monsanto's GE sugar beet was initially poised for introduction in 2000, but because large sugar-using food companies (e.g., Hershey, Mars) were worried about consumer acceptance of GE-derived sugar, growers were reluctant to plant them. Approximately five years later, most sugar processors were less concerned about consumer resistance, while growers were eager to plant the herbicide-tolerant varieties.[17] Following a similar regulatory path to that of GE alfalfa, APHIS deregulated GE sugar beets in 2005, approving them for food and feed.

Sugar beets account for about half of the national overall sugar production. GE sugar beets have been widely commercialized in the United States since they were first planted in 2008/2009 in the western United States. In the 2009/2010 crop year, GE varieties accounted for about 95% of the 1.185 million acres of sugar beets planted nationally, up from about 60% in 2008/2009. Sugar beets are grown in 11 states, in five regions of the United States. Two of these regions are east of the Mississippi River, while the other three are in the Great Plains and far West. GE sugar beets have been approved for feed, food, and cultivation in Canada and Japan. GE sugar beets have also been approved for feed and food use—but not cultivation—in the European Union, Mexico, South Korea, Australia, New Zealand, Colombia, Russia, China, Singapore, and the Philippines.

APHIS issued an EA-FONSI for the cultivation and agricultural use of a Monsanto/KWS SAAT AG-developed variety of glyphosate-tolerant (Roundup Ready) sugar beet (designated as Event H7-1) in March 2005.[18] The determination meant that GE beets were no longer a regulated article under 7 C.F.R. Part 340. Following a court challenge (discussed below) of the EA-FONSI, similar to that of GE alfalfa, APHIS subsequently published a notice in the *Federal Register* of its intent to prepare an EIS and the proposed scope of the study.[19]

In the notice of APHIS's intent to prepare an EIS, APHIS listed several potential issues that would be addressed in the EIS. These included

- management practices for organic sugar beets, conventional sugar beets, and glyphosate-tolerant sugar beets;
- production levels for organic and conventional sugar beets, Swiss chard, and table beets by region, state, and county;
- potential impacts of glyphosate-tolerant sugar beet cultivation on livestock production systems;
- potential impact of glyphosate-tolerant sugar beets on food and feed;
- differences in weediness traits of conventional vs. glyphosate-tolerant sugar beets;

[17] The actual sugar derived from GE sugar beets contains none of the engineered protein that confers herbicide-tolerance—that is, the sugar from GE-beets is chemically indistinguishable from that derived from non-GE sugar beets.

[18] Monsanto Company and KWS SAAT AG Petition 03-323-01p for Determination of Nonregulated Status for Roundup-Ready Sugar Beet Event H7-1. USDA/APHIS Environmental Assessment and Finding of No Significant Impact, February 2005. Document available at http://www.aphis.usda.gov/brs/aphisdocs2/04_11001p_com.pdf.

[19] 75 *Federal Register* 29969 (May 28, 2010).

- occurrences of common and serious weeds found in organic, conventional, and glyphosate-tolerant sugar beets;
- management practices for controlling organic, conventional, and glyphosate-tolerant sugar beets; and
- cumulative impact on the development of glyphosate-resistant weeds.

Sugar beet seed is grown primarily in Oregon's Willamette Valley, which is also an important seed-growing area for crops closely related to sugar beets, such as Swiss chard and table beets. GE sugar beets are wind-pollinated and would likely cross-pollinate the related crops being grown in the same area. The GE beets could also cross-pollinate non-GE beets, but because most sugar beets are now GE beets, this may not be as significant an issue as the potential contamination of non-GE alfalfa by GE alfalfa. Biological contamination of table beets and Swiss chard seed, especially organic table beet and chard seed, could represent a significant economic impact for organic farmers, who could face major market losses if their crops were contaminated by a GE variety. In the September 21, 2009, order requiring APHIS to prepare an EIS (discussed below), the court emphasized that "the potential elimination of a farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food, is an action that potentially eliminates or reduces the availability of a particular plant and has a significant effect on the human environment."[20]

Legal Challenges of APHIS Environmental Assessments and Injunctions

National Environmental Policy Act (NEPA): Overview

NEPA requires that federal agencies evaluate the environmental consequences of "major federal actions significantly affecting the quality of the human environment."[21] Under NEPA, the environmental review must consider the environmental impact of the proposed action, any adverse environmental effects that cannot be avoided should the proposal be implemented, and alternatives to the proposed action. Analysis of environmental impacts "affecting the quality of the human environment" can also include socioeconomic impacts. NEPA requires that environmental analyses use an interdisciplinary approach "which will insure the integrated use of the natural and social sciences and the environmental design arts in planning and in decisionmaking."[22] NEPA also established the Council on Environmental Quality (CEQ), a White House office that establishes NEPA regulations for all agencies to follow. In addition to the general NEPA regulations, each agency prepares its own regulations or guidelines on how to follow NEPA.

Environmental reviews can take three forms: an EIS, an EA, or a categorical exclusion (CE).[23] An EIS requires the most scrutiny and the most public input. While an EA also requires a review of

[20] Center for Food Safety v. Vilsack, No. C 08-00484, 2009 U.S. Dist. LEXIS 86343 (N.D. Cal. September 21, 2009).

[21] 42 U.S.C. §4332(2)(C).

[22] 42 U.S.C. §4332(2)(A).

[23] A categorical exclusion occurs when an agency has determined that a type of action typically has no significant impacts, and therefore, no review is required. See 40 C.F.R. §1508.4.

the impacts and alternatives, its review is more limited: it is designed to determine whether there are significant impacts from a proposed action that would require an EIS, rather than to analyze those impacts fully. A CE is used when an agency has determined in advance that a type of action, individually or cumulatively, has no significant impacts on the environment.[24]

GE Alfalfa Litigation

APHIS prepared EAs for the deregulating determinations for both alfalfa and sugar beets. Separate judges found that the environmental reviews were inadequate.[25] Both initial NEPA decisions were by the federal District Court for the Northern District of California. The alfalfa case was decided first, and the court found that APHIS, in preparing the EA-FONSI, had failed to take a hard look at the environmental consequences. The court said there was no supporting material in the EA for the conclusion that gene transmission from the GE alfalfa was highly unlikely to occur.[26] Despite APHIS's finding of no significant impact, the court found evidence that there might be a significant environmental impact. Specifically, the court noted that APHIS had found that gene transmission would occur on some scale, but failed to explore measures that could prevent or reduce such contamination.[27] Also, the court found APHIS's argument unsubstantiated that alfalfa grown for forage[28] was never harvested after seed maturity.

Another reason the environmental review was inadequate, according to the court, was because it failed to consider cumulative impacts as required under NEPA. In this case, that meant APHIS should have evaluated the cumulative impact of deregulating multiple GE crops that are designed to be resistant to a particular herbicide. The plaintiffs argued that twice as much herbicide would be used on those GE crops, possibly causing pollution but also leading to herbicide-resistant weeds. The court agreed that these environmental effects had not been considered, not just for alfalfa, but in the larger context of the other modified seed, such as soybean and corn.[29]

The district court rejected APHIS's argument that any harm from GE alfalfa would be economic and outside the scope of NEPA. Economic effects could include the loss of revenue for alfalfa export if the crops were contaminated. The court held that any economic harm was a direct result of the changed physical environment—unintentional genetically modified alfalfa. Because economic harm was an interrelated and a direct effect, it was appropriate to review under NEPA. The court noted that a NEPA review was intended to consider all impacts to avoid "undesirable and unintended consequences."[30]

When courts hold that an EA is inadequate, one course of action is to direct the agency to prepare an adequate EA as a way of remedying the NEPA defects. Instead, this court directed APHIS to

[24] 40 C.F.R. §1508.4.

[25] Geertson Seed Farms v. Johanns, No. C 06-01075, 2007 U.S. Dist. LEXIS 14533 (N.D. Cal. February 13, 2007) (*Geertson Seed Farms*) (alfalfa), *aff'd*, 570 F.3d 1130 (9th Cir. 2009), *rev'd sub nom*. Monsanto Co v. Geertson Seed Farms, 127 S. Ct. 2743 (2010); Center for Food Safety v. Vilsack, No. C 08-00484, 2009 U.S. Dist. LEXIS 86343 (N.D. Cal. September 21, 2009) (sugar beet).

[26] *Geertson Seed Farms*, at *21.

[27] *Geertson Seed Farms*, at *18-19.

[28] Alfalfa grown for forage typically is harvested before seeds form.

[29] *Geertson Seed Farms*, at *30-31.

[30] 42 U.S.C. §4331(b)(3). *Geertson Seed Farms*, at *25-26.

prepare an EIS, finding that there were substantial questions regarding the environmental impact of the GE alfalfa deregulation.

Additionally, the court halted planting of any GE alfalfa after March 30, 2007, and prohibited the sale of GE seed.[31] The court stated that this was not a drastic remedy because it still allowed regular alfalfa to be sold and planted. The injunction only returned GE alfalfa to its regulated status. APHIS had proposed various restrictions that would permit planting GE alfalfa while APHIS prepared the EIS: mandatory isolation distances between GE alfalfa and conventional and organic seed production fields; mandatory harvesting conditions; handling requirements; and a prohibition on the use of GE alfalfa for livestock grazing or in mixed grass pastures. The court rejected the alternatives, finding that APHIS would be conducting an abbreviated environmental review of those options before the court without having to follow NEPA.[32]

The plaintiffs wanted a complete ban on GE alfalfa. But because they did not seek a preliminary injunction prior to the court's decision and some growers had planted GE alfalfa,[33] which was commercially available for planting in June 2005, the court held that growers who had already planted GE alfalfa would not be required to remove the plants.

Supreme Court Decision

The decision of the lower court to enjoin planting GE alfalfa was appealed, although the findings of an inadequate NEPA review were not. (APHIS was preparing an EIS.) The Ninth Circuit Court of Appeals affirmed the lower court determination that the injunction was appropriate under the circumstances.[34] The Supreme Court disagreed, holding that the scope of the injunction was too broad—the district court had overstepped its authority in preventing APHIS from designing a different way of regulating GE alfalfa and from preventing any planting or harvesting of the product.[35]

Courts must consider four factors when determining whether an injunction is an appropriate remedy: (1) availability of another remedy, such as money damages; (2) irreparable injury if the injunction is not granted; (3) balance of harms; and (4) the public interest. The Supreme Court said that none of these factors supported issuing the injunction.[36] The Court described the lower court's ruling as doing three things: vacating the deregulation decision; prohibiting new deregulation while the EIS was being prepared; and preventing planting and sale of GE alfalfa. The first factor was not being challenged. The Court said that the injunction was inappropriate based on the remaining two parts.

The Supreme Court said that the lower court could only restrict the deregulation that was in front of it and not a different regulatory scheme, and accordingly, the injunction went too far. One

[31] Geertson Farms, Inc. v. Johanns, No. 06-01075, 2007 WL 776146 (N.D. Cal. March 12, 2007) (preliminary injunction); Geertson Farms, Inc. v. Johanns, 2007 WL 1302981 (N.D. Cal. May 3, 2007) (permanent injunction).

[32] Geertson Farms, Inc. v. Johanns, 2007 WL 1302981, *5 (N.D. Cal. May 3, 2007).

[33] Approximately 5,500 growers across 263,000 acres were estimated to have planted GE alfalfa grown before the injunction. *Ag Biotech Reporter*, vol. 3, no.2, January 25, 2010.

[34] Geertson Seed Farms v. Johanns, 570 F.3d 1130 (9th Cir. 2009), *rev'd sub nom*. Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010).

[35] Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010).

[36] *Id.* at 2758.

reason the Court rejected the injunction was that it was premature. APHIS had not yet acted to deregulate again or in a different way, and so there could be no finding of irreparable injury, according to the Court. The Court referred to *partial deregulation*, using the term to mean where APHIS would impose some restrictions on planting and harvesting, similar to those brought to the district court's attention at the time of the injunction hearing. The Court said the injunction was harsh because there was no need to enjoin partial deregulation—the administrative process for partial deregulation would be available for challenge just as it had been for full deregulation. The courts could review the harms when partial deregulation was completed. By preventing APHIS from acting to deregulate partially, the injunction had prevented the possibility that APHIS would sufficiently restrict the use of GE alfalfa such that no genetic transmission would occur.

The Court rejected the injunction on new planting of GE alfalfa on the same basis. If a partial deregulation decision had been allowed, planting may have been acceptable under those conditions. But because the lower courts rejected APHIS's offers of partial deregulation, modified planting could not be considered in the deregulation process. Additionally, the Court noted that since injunctive relief is a "drastic remedy," which should be used only when necessary, different relief could have been tailored to avoid the injunction. A partial deregulation would allow a more limited remedy.

Essentially, the Supreme Court holding contemplates the possibility that instead of preparing (or in addition to preparing) an EIS for full deregulation of GE alfalfa, as required by the district court, APHIS could conduct a separate, partial deregulation process. The partial deregulation could impose conditions on planting and harvesting. When concluded, some restrictions would still be in place, even though growers could plant GE alfalfa. Presumably, that partial deregulation would still undergo a NEPA review. The Court suggested it could be subject to a NEPA challenge.[37]

The dissenting opinion of the 7-1 decision[38] disputed the authority of the Court in this case over the issue of partial deregulation, which, Justice Stevens said in his dissent, had never been raised or argued before either the district court or the court of appeals on its way to the Supreme Court.[39] The dissent stated that an injunction was appropriate here where "the environmental threat is novel."[40] Justice Stevens noted that halting deregulation did not prevent the use of alfalfa, it just prevented the deregulated use of GE alfalfa. Accordingly, vacating the deregulation decision put regulated use of GE alfalfa back in place, and was not as drastic a step as painted by the majority. Additionally, the dissenting opinion addressed the environmental impacts of GE alfalfa, finding that the balance of harms supported the injunction. The dissent said that the majority opinion did not dispute the factual findings of the district court that GE alfalfa can and has genetically modified other crops and that genetic contamination could harm the U.S. export market for alfalfa.

[37] Monsanto Co. v. Geertson Seed Farms, at 2760.

[38] Justice Breyer abstained, as his brother was the judge for the District Court for the Northern District of California who issued the injunction.

[39] Monsanto Co. v. Geertson Seed Farms, at 2765.

[40] *Id.* at 2768.

Alfalfa Litigation Challenging the 2011 Deregulation

Following an EIS, APHIS announced it was fully deregulating GE alfalfa. The Center for Food Safety, the plaintiff that successfully challenged the EA as inadequate, brought suit arguing that the final EIS is deficient, and that APHIS violated the Plant Protection Act when it claimed it could not deregulate this crop.[41] The district court held that APHIS had complied with the law.[42] The decision is being appealed. Oral arguments were held October 24, 2012.[43]

Congressional Response to the GE Alfalfa Court Decision

Senator Leahy and Representative DeFazio sent a letter to Secretary of Agriculture Tom Vilsack opposing the APHIS FONSI and urging the Secretary to keep GE alfalfa a regulated item.[44] The Members cited evidence from Cal/West Seeds, a major alfalfa seed exporter, that a reported 30% of 10 seed stock lots had tested positive for GE alfalfa from the two years when GE alfalfa was grown prior to the injunction. The letter also cited Dairyland Seed Company, another major alfalfa seed producer and exporter, which reported contamination of 11-16 sites at distances of up to 1.5 miles, considerably farther than the 900-foot isolation distances APHIS recommends. The threat of losses to export markets in Japan, Korea, and Taiwan, the potential damage to organic dairy producers, and the potential development of herbicide-tolerant weeds were also cited as reasons to retain regulated status for GE alfalfa. The letter states that these concerns were minimized and/or dismissed by APHIS in its issuance of a FONSI.

Section 10210 of the enacted 2008 farm bill (P.L. 110-246) provides APHIS with added authority to ensure that the GE contamination was minimized or prevented. APHIS has yet to adopt these statutory mandates. The letter to Secretary Vilsack asserted that the broad regulatory authority provided APHIS has been "ignored in order to justify deregulation of a biotech crop that has limited utility to anyone except the manufacturer."[45] The letter further asserted that "there is significant concern that the risks to alfalfa producers and U.S. agriculture are too great and benefits too few to allow deregulation."

Representatives Jenkins, Herger, and Courtney also sent a letter to Secretary Vilsack (co-signed by 75 Members).[46] Their letter requested that APHIS partially deregulate GE alfalfa while the final EIS is being completed. The Members' letter, while recognizing that the Supreme Court decision does not actually give growers permission to plant GE alfalfa, argued that APHIS could issue an interim permit to allow planting of GE alfalfa in fall 2010. The letter cited the Supreme Court ruling that the decision to enjoin further planting was "a drastic and extraordinary remedy, which should not be granted as a matter of course," and that a "permanent injunction is not now needed to guard against any present or imminent risk of likely irreparable harm."

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[41] Center for Food Safety v. Vilsack, CV-11-1310-EDL (N.D. Cal. *complaint filed* March 18, 2011).

[42] Center for Food Safety v. Vilsack, 844 F. Supp. 2d 1006 (N.D. Cal. 2012).

[43] Center for Food Safety v. Vilsack, No. 12-15052 (9th Cir. Oct. 24, 2012).

[44] The letter was co-signed by 49 House Members and five other Senators. A copy of the letter may be accessed at http://leahy.senate.gov/imo/media/doc/AlfalfaLetter.pdf.

[45] This refers to §10204 of the 2008 farm bill (P.L. 110-246), which directs the Secretary to take action on each issue identified in the document *Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework,* October 2007.

[46] The text of the letter is at http://www.agrimarketing.com/show_story.php?id=61598.

On January 20, 2011, the House Committee on Agriculture held a forum, with Secretary Vilsack as a witness, on the options available to the Secretary regarding GE alfalfa. The Secretary had previously raised the issue of the option to partially deregulate as a means of promoting "coexistence" among GE alfalfa growers, organic growers, and conventional alfalfa growers. A partial deregulation was one of three options considered in the final EIS. Members of the committee queried Secretary Vilsack on his authority under the Plant Protection Act to do anything but fully deregulate GE alfalfa because APHIS had determined that GE alfalfa was not a plant pest as defined by the Plant Protection Act.

GE Sugar Beet Litigation

The district court that reviewed GE sugar beets used the same reasoning as the district court in the GE alfalfa case and reached the same conclusion: APHIS should have prepared an EIS for its deregulation determination.[47] It found that deregulation could result in significant environmental impacts. The court focused on the risk of gene transmission not only for non-GE sugar beets, but also for related crops such as Swiss chard and table beets. However, the GE sugar beet court did not examine whether deregulation would lead to herbicide-resistant weeds, stating that APHIS's failure to consider gene transmission was enough to find that the EA violated NEPA.

Unlike in the alfalfa decision, no injunction was granted regarding sugar beets. In its September 2009 decision, the court found that the balance of harms and the public interest weighed in favor of allowing continued deregulation of GE sugar beets.[48] The plaintiffs had waited to try to enjoin planting sugar beets until five years after they were deregulated. According to the court, in the five years between when GE sugar beets were deregulated and an injunction was sought, GE sugar beets became the industry standard, with over 95% of all sugar beets planted being GE.[49] Not enough non-GE seed would be available were an injunction to issue. Therefore, the court found that the plaintiffs' delay in seeking an injunction and the harm that would result if it were granted weighed in favor of denying the injunction.

In August 2010, the court revisited the issue of whether to issue an injunction.[50] While the court did not issue an injunction, it vacated the deregulation decision of APHIS. By not issuing an injunction, the court avoided the "drastic remedy" the Supreme Court criticized in the GE alfalfa decision. However, the practical effect is that this decision halted unregulated planting of GE sugar beets after August 13, 2010. The court stated that APHIS's failure to act after the September 2009 decision (holding that GE sugar beets posed a serious environmental harm) suggested that the agency considered the environmental review a "mere formality." APHIS could have used that time to conduct an environmental review based on its request for a nine-month delay, according to the court, and then vacating the deregulation would not have been necessary.

As it stands, the court precedent is that GE crops may pose an environmental harm by genetically modifying other crops. The economic impacts of the genetic contamination have been found to be direct effects that are properly considered under NEPA. Whether or not such harm is significant

[47] Center for Food Safety v. Vilsack, No. C 08-00484, 2009 U.S. Dist. LEXIS 86343 (N.D. Cal. September 21, 2009) (sugar beet).

[48] Center for Food Safety v. Schafer, No. C 08-00484, 2010 U.S. Dist. LEXIS 35808 (N.D. Cal. March 16, 2010).

[49] *Id.* at *11-12.

[50] Center for Food Safety v. Vilsack, 734 F. Supp. 2d 948 (N.D. Cal. 2010).

enough to warrant retaining regulated status for other GE items will have to be determined on a case-by-case basis.

The federal court ruling vacating the original deregulation order did not restrict growers' ability to harvest sugar beets planted before August 13, 2010, or that of processors to convert existing GE sugar beets to sugar and sell the product. Neither did the decision prevent APHIS from considering a partial deregulation order that could permit growers to plant GE sugar beets under certain regulatory restrictions.

APHIS announced on September 1, 2010, that it was issuing permits to sugar beet seed producers to authorize seedling production in fall 2010. The permits would prohibit seedling flowering or transplanting without additional approval. The Center for Food Safety filed suit to stop the permits and force removal of the seedlings. APHIS had issued the permits under a categorical exclusion (CE) under NEPA, which meant the agency had found no significant impacts would result from planting the seeds. The plaintiffs argued that the CE violated NEPA, and the court agreed.[51] The court found that the seedlings had no independent utility unless they were allowed to continue to grow, but APHIS had not looked at the environmental consequences of the entire life cycle. By isolating the permits to plant seedlings, without considering the future of the plants (such as transplanting or flowering), APHIS improperly segmented the environmental review, according to the court. In December, the court ordered the seedlings uprooted.[52] The Ninth Circuit issued an emergency stay, delaying the effective date of the order,[53] ultimately holding that the order went too far.[54]

The Ninth Circuit found that based on the biennial growth pattern of sugar beets, in which the root develops in the first year and seeds develop only in the second year, there was no showing of likely injury from genetic contamination. The permitted sugar beet crops would be completely harvested after the first year, well before development of pollen.

On November 4, 2010, APHIS published its draft EA on partially deregulating GE sugar beets—Event H7-1—for seed and crop production.[55] A final EA-FONSI was issued on February 4, 2011, when the agency announced that it would partially deregulate GE sugar beet *root* crop production, but not *seed* crop production.[56] GE sugar beet seed would remain fully regulated. The partial deregulation of GE sugar beet root crop production was an interim measure effective through December 31, 2012, while APHIS completed the EIS.

The Center for Food Safety filed suit in the Northern District of California arguing that the EA is contrary to law.[57] Other plaintiffs in that suit include Organic Seed Alliance, Sierra Club, and High Mowing Organic Seed. The suit claims there are significant environmental effects due to increased use of herbicide on GE crops and questions whether sugar beet seed production can be

[51] Center for Food Safety v. Vilsack, No. 3:10-cv-04038-JSW (N.D. Cal. September 28, 2010) (holding that the plaintiffs had a likelihood of winning the case).

[52] Center for Food Safety v. Vilsack, No. 3:10-cv-04038-JSW, 2010 U.S. Dist. LEXIS 141390 (N.D. Cal. November 30, 2010).

[53] Center for Food Safety v. Vilsack, No. 10-17719 (9th Cir. December 6, 2010).

[54] Center for Food Safety v. Vilsack, 636 F.3d 116 (9th Cir. February 25, 2011).

[55] 75 *Federal Register* 67945 (November 4, 2010).

[56] 76 *Federal Register* 6759 (February 8, 2011).

[57] Center for Food Safety v. Vilsack, No. 3:11-cv-00831-JSW (N.D. Cal. *complaint filed* February 23, 2011).

predicted and controlled. It also claims the EA is procedurally flawed because it was issued after the 2010 seedlings were growing. This case was transferred to the D.C. District Court upon a motion by APHIS.[58]

The American Crystal Sugar Company, which grows about half of U.S. sugar beets, and other sugar processors filed suit in the D.C. District Court to eliminate the interim conditions put on both sugar beet root crop and sugar beet seed crop by APHIS.[59] The plaintiffs seek the alternative remedy of a court declaration that the EA is legally sufficient, which could block a NEPA challenge by other parties. These two cases were consolidated.[60] In light of the July 2012 regulatory decision, the court held that the case was moot, rejecting the Center for Food Safety's claim that APHIS might again issue partial deregulation for other GE crops without complying with NEPA.[61]

Proposals for Plant Biotechnology Regulatory and Legislative Changes

The cases of GE alfalfa and GE sugar beets highlight the regulatory complexities of such biological innovations, especially as they pertain to commercialization of these GE varieties through the APHIS process of deregulation. While initial deregulation of herbicide-tolerant and pest-resistant GE corn, soybeans, and cotton varieties led to widespread adoption of these plants over the past 15 years, new GE plant innovations are raising new concerns about the adequacy of the APHIS biotechnology regulatory regime. For example, current development of GE varieties of corn that will express industrial chemicals and pharmaceuticals raises concerns about their potential to cross-pollinate with corn meant for human consumption. Both GE alfalfa and GE sugar beets show the potential for such cross-pollination and its attendant environmental impacts. With development of GE plants that express industrial chemicals, the issue may take on even greater environmental significance. Another environmental concern has arisen as acreage of herbicide-tolerant GE varieties has increased: herbicide-resistant weeds (mainly glyphosate-tolerant varieties) have also evolved. The plant biotechnology industry is responding to such weed resistance with development of new "stacked" GE varieties, ones combining tolerance to several different herbicides within a single seed. Such innovations may raise further concerns about the adequacy of the existing regulatory structure.

Proposed APHIS Revisions

In July 2007, APHIS published a draft EIS as part of the evaluation of its regulatory structure. In October 2008, APHIS proposed a revision of its regulations regarding the import, interstate movement, and environmental release of certain GE organisms.[62] A subsequent issue-focused

[58] Center for Food Safety v. Vilsack, No. 3:11-CV-00831 (N.D. Cal. March 17, 2011). Upon transfer, that case became Center for Food Safety v. Vilsack, No. 1:11-cv-00586 (D.D.C. 2011).

[59] Grant v. Vilsack, No. 1:11-cv-00308-JDB (D.D.C. *complaint filed* February 7, 2011).

[60] Grant v. Vilsack, No. 1:11-cv-00308 (D.D.C. April 12, 2011).

[61] Grant v. Vilsack, No. 1:11-cv-00308 (D.D.C. September 25, 2012).

[62] 73 *Federal Register* 60009 (October 9, 2008). Document access at http://frwebgate1.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=DZom2U/2/2/0&WAISaction=retrieve.

meeting on the proposed rule changes was held on April 29-30, 2009. The public comment period initially was to end on November 24, 2008, but was extended to June 29, 2009. The final rule has not yet been published. These proposed revisions are the first since the regulations were established in 1987. Under current regulations, a GE organism is a regulated article if it is a plant pest or there is reason to believe it might become a plant pest. In the notification of the proposed regulation revisions, APHIS stated that technological advances have led to the possibility of developing GE organisms that do not fit within the plant pest definition, but still might cause environmental or other physical harm by the definition of a plant pest under the Plant Protection Act. According to APHIS, the new regulations would subject a GE organism to oversight based on known plant pest and noxious weed risks of the parent organisms, or based on the traits of the GE organism, or based on the possibility of unknown risks as a plant pest or noxious weed when insufficient information is available.[63] The proposed regulations also include regulating GE seedlings, tubers, cuttings, bulbs, and spores.

APHIS further proposes to reorganize the regulations for permit applications and evaluation procedures by discontinuing its notification procedure, while retaining the permitting procedure. The proposed regulations would also establish a new petition procedure for APHIS to approve a new conditional exemption from the permit requirements, which is currently done by amending regulations.

For environmental releases, APHIS proposes a permitting system based on two primary risk-related factors: (1) the ability of the unmodified recipient plant species to persist in the wild, and (2) the potential of the GE trait to cause harm based on the plant pest and noxious weed definitions. With respect to the persistence factor, APHIS proposes grouping plant species into four risk categories based on the risk of persistence of the plant or its progeny in the environment without human intervention. Four similar risk categories are also proposed for potential harm caused by the GE trait. Other proposed regulatory changes include remediation authorities for failure to comply with regulations, and agency response to low-level presence (LLP) of regulated plant materials in commercial seeds or grain that may be used for food or feed.

Reactions to the proposed revisions were mixed, and were, in part, the reason APHIS extended the original comment period and held public meetings on some of the more controversial proposed changes (e.g., scope of the regulatory changes, incorporation of the Plant Protection Act's noxious weed authority into APHIS's regulatory authority, revision of the permit process, and environmental release of GE crops that produce pharmaceutical and industrial compounds). In their comments on the proposed rule changes, biotechnology industry representatives and nongovernmental organizations expressed opposition to the expansion of APHIS authority to regulate GE organisms if they posed a risk as a plant pest or noxious weed. The industry representatives also took issue with the proposal to take a voluntary approach to GE regulation, arguing that it could have a significant impact on international trade.[64] The Center for Food Safety (CFS) denounced the proposal, stating that "these proposed regulations may set in motion a process that would put many GE crops completely beyond the bounds of regulation." CFS said that its biggest concern is that the proposed rules remove established criteria in determining the very scope of regulation. In March 2009, more than 80 advocacy groups signed a letter urging

[63] Only a small fraction of weeds are considered to be noxious weeds. APHIS currently lists 98 aquatic, terrestrial, or parasitic plant taxa as noxious weeds.

[64] "Industry, NGOs, Strongly Oppose Proposed USDA Biotech Regulation," *Inside U.S. Trade*, October 17, 2008.

Secretary of Agriculture Tom Vilsack to halt approving GE crops until the agency changes its regulatory approach to biotechnology.

Legislative Activity

Congress has generally supported development in plant biotechnology. An early step by the House Agriculture Committee indicated the 112th Congress would continue that trend. At a forum on January 20, 2011, convened by the House Agriculture Committee, Members queried Secretary Vilsack about partial deregulation and indicated their support for full deregulation.

While legislative activity was relatively subdued in the 111th Congress, hearings focused on the relationship between the adoption of various GE varieties and the evolution of herbicide resistance in weeds.[65] Other biotechnology-related legislation in the 111th Congress included the Genetically Engineered Safety Act of 2010 (H.R. 5578), which would have prohibited the open-air cultivation of GE pharmaceutical and industrial crops, and the use of common human food or animal feed as the host plant for a GE pharmaceutical or industrial chemical. Another bill, the Genetically Engineered Technology Farmer Protection Act (H.R. 5579), would have established various protections for farmers and ranchers that may potentially suffer economic harm from genetically engineered seeds, plants, or animals. A third bill, the Genetically Engineered Food Right to Know Act (H.R. 5577), would have amended the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly.

Partly in response to the cases of GE alfalfa and sugar beets, Congress has made legislative proposals that would streamline APHIS review process for GE plants. Provisions to amend APHIS's regulatory procedures under the Plant Protection Act have been introduced in the House farm bill (H.R. 6083) and in the House Agriculture appropriations bill (H.R. 5973).

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[65] On July 28, 2010, the House Committee on Oversight and Government Reform's Domestic Policy Oversight Subcommittee held hearings on the emergence of herbicide-resistant weeds, with particular focus on glyphosate-resistant weeds.