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 (marketed under the name of 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 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 deregulating the item. 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. For both GE alfalfa and sugar beets, APHIS issued a "finding of no significant impacts" (FONSI), in June 2005 and March 2005, respectively.

Lawsuits subsequently challenged the adequacy of the EAs as the basis of the FONSI. The courts agreed that APHIS should have prepared an environmental impact statement (EIS) for both deregulation decisions. APHIS was directed by the court to complete an EIS on the effects of deregulating both of the GE varieties.

The court in the GE alfalfa case halted planting of the genetically modified seed after May 3, 2007, 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.

The court in the GE sugar beet case did not formally prohibit planting sugar beet, but it voided APHIS's deregulation decision in August 2010. This decision undoes the five-year-old approval of GE sugar beet, from which nearly half of U.S. sugar is derived. APHIS announced on September 1, 2010, that the agency is evaluating a request to partially deregulate GE sugar beets, which would permit planting and harvesting sugar beets under certain restrictions. APHIS issued four permits authorizing seedling production that would not allow flowering or transplanting without additional authorization. In December, a judge ordered those seedlings pulled from the ground, holding that APHIS had violated NEPA in issuing the permits. This ruling was put on hold by the Ninth Circuit.

APHIS anticipates that the draft EIS for sugar beet will be publicly available May 2011, and the final EIS in May 2012. A draft EIS for alfalfa was released to the public on December 14, 2009. The final EIS is scheduled for publication in fall 2010, when APHIS also will announce its decision on deregulating the GE alfalfa.

The cases of GE alfalfa and sugar beet highlight continuing policy questions about the adequacy of APHIS's deregulation protocol, particularly regarding the environmental review process. In their suits against APHIS, plaintiff lawyers 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 beet). APHIS currently is in the process of issuing a final rule on its revision of regulations regarding the importation, interstate movement, and environmental release of GE organisms.

Contents

Contacts

Plant Biotechnology Regulation and Oversight

The basic federal guidance for regulating biotechnology products is the Coordinated Framework for Regulation of Biotechnology (51 *Fed. Reg.* 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- 22915.

[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 impacts," 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 beet). APHIS conducted EAs of the GE plants to assess the impacts of growing them on a commercial scale. APHIS issued FONSIs for GE alfalfa in June 2005 and for GE sugar beet in March 2005.

Both of these EA FONSIs were challenged in separate lawsuits. The courts found that APHIS's environmental assessments were inadequate to support issuing FONSIs. 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 submitted a petition to APHIS in 2004 requesting non-regulated status for 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 prepare an EIS on the implications of the deregulation. As noted above, APHIS can produce an EA to determine whether an EIS is necessary. APHIS took the latter course, publishing a draft EA and soliciting public comments on whether GE alfalfa should be deregulated. On June 27, 2005, following review of those comments, APHIS announced in the *Federal Register* its decision to issue a FONSI and deregulate GE alfalfa.[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. Because the EA is a more limited assessment of the environmental impact, the decision to issue a FONSI rather than conduct an EIS opened APHIS to legal challenge. This challenge (litigation discussed below) resulted in the courts directing APHIS to conduct 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). Document accessible at http://www.aphis.usda.gov/brs/fedregister/BRS_20050627a.pdf.

The EA was deemed inadequate for a FONSI by the court for several reasons. Not only could GE alfalfa have environmental implications for domestic producers that were not addressed, it also could have economic effects on farmers who sell to export markets. Japan and South Korea, America's most important alfalfa export customers, warned that they would discontinue imports of U.S. alfalfa if a GE variety were grown in this country. U.S. alfalfa exports total nearly $480 million per year, with about 75% going to Japan. This potential effect resulting from deregulation was an action that, as defined by the National Environmental Protection Act, had the potential of "significantly affecting the quality of the human environment."[11] It was deemed to have been inadequately addressed in the EA, and thus the EA was inadequate for issuing the FONSI.

On December 14, 2009, following litigation (discussed below), APHIS announced that its draft EIS concerning GE alfalfa was available for public comment.[12] The comment period, which was extended, ended March 3, 2010. The final EIS, which will address the nearly 135,000 comments received, is expected to be published in fall 2010.

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.[13] Following a similar regulatory path to that of GE alfalfa, GE sugar beets were deregulated in 2005 and approved to be grown 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 a 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.[14] Like the GE alfalfa decision, the FONSI for GE sugar beets was based on an EA. 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 FONSI, similar to that of GE alfalfa,

[11] 42 U.S.C. § 4332(2)(C).

[12] The draft EIS may be downloaded at APHIS's website: http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa_deis.pdf. 75 *Federal Register* 1585 (Jan. 12, 2010).

[13] 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.

[14] 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.

APHIS subsequently published a notice in the *Federal Register* of its intent to prepare an EIS and the proposed scope of the study.[15]

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

- management practices for organic sugar beet, conventional sugar beet, and glyphosate-tolerant sugar beet;
- production levels of organic and conventional sugar beet, Swiss chard, and table beet by region, state, and county;
- potential impacts of glyphosate-tolerant sugar beet cultivation on livestock production systems;
- potential impact of glyphosate-tolerant sugar beet on food and feed;
- differences in weediness traits of conventional vs. glyphosate-tolerant sugar beet;
- occurrences of common and serious weeds found in organic, conventional, and glyphosate-tolerant sugar beet;
- management practices for controlling organic, conventional, and glyphosate-tolerant sugar beet; 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 are 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."[16]

[15] 75 *Federal Register* 29969 (May 28, 2010).

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

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."[17] 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's organic statute 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."[18] 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).[19] An EIS requires the most scrutiny and the most public input. While an EA also requires a review of 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.[20]

GE Alfalfa Litigation

APHIS prepared EAs for the deregulating determinations for both alfalfa and sugar beet. Separate judges found that the environmental reviews were inadequate.[21] 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.[22] 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.[23] Also, the

[17] 42 U.S.C. § 4332(2)(C).

[18] 42 U.S.C. § 4332(2)(A).

[19] 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.

[20] 40 C.F.R. § 1508.4.

[21] Geertson Seed Farms v. Johanns, No. C 06-01075, 2007 U.S. Dist. LEXIS 14533 (N.D. Cal. Feb. 13, 2007) (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. Sept. 21, 2009) (sugar beet).

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

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

court found APHIS's argument unsubstantiated that alfalfa grown for forage[24] 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.[25]

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."[26]

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 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.[27] 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.[28]

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,[29] 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.

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

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

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

[27] 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).

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

[29] 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.

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.[30] 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.[31]

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.[32] 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 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

[30] 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).

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

[32] *Id.* at 2758.

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.[33]

The dissenting opinion of the 7-1 decision[34] 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.[35] The dissent stated that an injunction was appropriate here where "the environmental threat is novel."[36] 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.

With the Supreme Court's decision that the injunction should not have been imposed, the question now before APHIS is whether GE alfalfa can be grown under conditions of partial deregulation—that is, can some of the requirements for growing GE alfalfa under regulated conditions be modified? As of late August 2010, APHIS has not announced any decision with regard to partially deregulating GE alfalfa.

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.[37] 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 those statutory mandates. The letter to Secretary Vilsack asserts that the broad regulatory authority

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

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

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

[36] *Id.* at 2768.

[37] 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.

provided APHIS has been "ignored in order to justify deregulation of a biotech crop that has limited utility to anyone except the manufacturer."[38] The letter further asserts 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).[39] 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, argues that APHIS could issue an interim permit to allow planting of GE alfalfa in fall 2010. The letter cites 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."

GE Sugar Beet Litigation

The district court that reviewed GE sugar beet 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.[40] It found that deregulation could result in significant environmental impacts. The court focused on the risk of gene transmission not only on non-GE sugar beet, but also on related crops such as Swiss chard and table beet. 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 beet. 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 beet.[41] The plaintiffs had waited to try to enjoin planting sugar beet until five years after it was deregulated. According to the court, in the five years between when GE sugar beet was deregulated and an injunction was sought, GE sugar beet became the industry standard, with over 95% of all sugar beet planted being GE.[42] 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.[43] 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 beet after August 13, 2010. The court stated that APHIS's failure to act after the September

[38] This refers to Section 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.

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

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

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

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

[43] Center for Food Safety v. Vilsack, No. C 08-00484 (N.D. Cal. Aug. 13, 2010).

2009 decision (holding that GE sugar beet 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 enough to warrant retaining regulated status for a GE item will have to be determined on a case-by-case basis.

The federal court ruling vacating the original deregulation order does 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 does the decision prevent APHIS from considering a partial deregulation order that could permit growers to plant GE sugar beets under certain regulatory restrictions. The court's decision does not apply to GE sugar beet root and seed crops planted before August 13, 2010.

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.[44] 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.[45] The Ninth Circuit issued an emergency stay, delaying the effective date of the order.[46] Appeals have been filed as well.

Some have argued that because the order does not direct destruction of the seedlings, there are still some options for the growers. However, as noted by the court, the permits do not allow transplanting. While the court does not expressly require killing the seedlings after they are uprooted, it holds that continued growth of the sugar beet seedlings could cause an irreparable environmental harm that the order intends to stop.[47] Growers could be violating both a court order and their APHIS permits if they try to keep the seedlings alive.

APHIS is also evaluating a request to partially deregulate GE sugar beets. The agency is working on an EA to allow future seed and root crop plantings under a combination of permits, administrative orders, or other regulatory measures. The decision regarding a partial deregulation

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

[45] Center for Food Safety v. Vilsack, No. 3:10-cv-04038-JSW (N.D. Cal. Nov. 30, 2010).

[46] Center for Food Safety v. Vilsack, Nos. 10-17719, 10-17722 (9th Cir. Dec. 6, 2010).

[47] Center for Food Safety v. Vilsack, No. 3:10-cv-04038-JSW, at 10 (N.D. Cal. Nov. 30, 2010) (stating that the plaintiffs established that the seedlings posed potential irreparable damage to the environment).

is expected before the end of the year. There will be an opportunity for public comment on any environmental analysis developed to assess the impact of a partial deregulation. In its announcement, APHIS stated that regulatory measures would include mitigating restrictions consistent with those proposed by the federal court as interim measures while APHIS completes the EIS.[48]

Proposals for Plant Biotechnology Regulatory and Legislative Changes

The cases of GE alfalfa and GE sugar beet 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 beet 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 importation, interstate movement, and environmental release of certain GE organisms.[49] A subsequent issue-focused 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

[48] "USDA Announces Next Steps on Sugar Beets," USDA News Release 0437.10, September 1, 2010. Accessible at http://usda.gov/wps/portal/usda/usdahome.

[49] 73 *Federal Register* 60009 (Oct. 9, 2008). Document access at http://frwebgate1.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=DZom2U/2/2/0&WAISaction=retrieve.

GE organism, or based on the possibility of unknown risks as a plant pest or noxious weed when insufficient information is available.[50] 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.[51] 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 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. While legislative activity has been relatively subdued in the 111th Congress, recent hearings have focused on the relationship between the adoption of various GE varieties and the evolution of herbicide resistance in weeds.[52] Other biotechnology-related legislation in the 111th Congress includes the

[50] 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.

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

[52] 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-
(continued...)

Genetically Engineered Safety Act of 2010 (H.R. 5578), which would prohibit 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 establish various protections for farmers and ranchers that may potentially suffer economic harm from genetically engineered seeds, plants, or animals. Neither of these bills, however, specifically addresses how NEPA is used by APHIS in its regulatory process. A third bill, the Genetically Engineered Food Right to Know Act (H.R. 5577) would amend 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.

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