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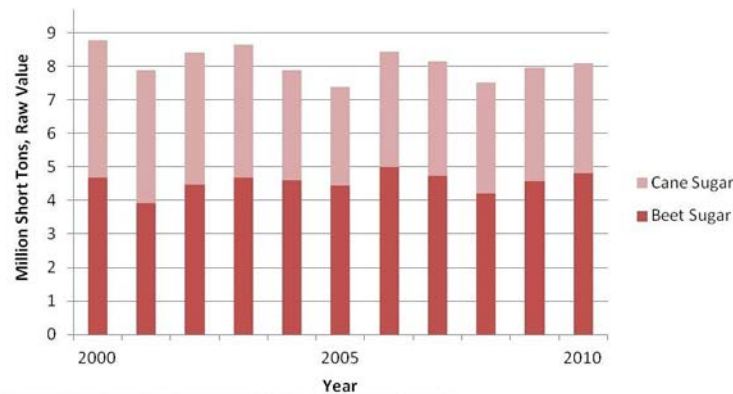
REGULATION OF GLYPHOSATE-RESISTANT SUGAR BEETS: CHALLENGES AND UNCERTAINTY

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The introduction of genetically modified (GM) seeds has had a major impact on U.S. agriculture. In the face of increased availability of biotechnology products, the structure of field crop production has changed significantly. This has led to the adjustment of both the manner in which crops are grown and the inputs used in production.

Figure 1: U.S. Sugar Production, 2000-2010



Source: ERS Sugar and Sweeteners Outlook, January 18, 2011

Sugar beets provide approximately 50% of domestic sugar production (Figure 1). In 2005, glyphosate-resistant sugar beets, also known as Roundup Ready sugar beets (RRSB) were introduced to the U.S. production system. By 2010, nearly 95% of sugar beets produced in the United States were grown from glyphosate resistant seed varieties (USDA APHIS, 2010). Once processed, sugar from genetically modified beets is indistinguishable from sugar from conventional production although there are sometimes distinctions made about source through labeling for final consumers, such as “pure cane sugar” or “Michigan Pioneer Sugar” (Bonnette, 2004).

Like other GM crops, introduction of RRSB has not been without controversy. Challenges to regulation of glyphosate-resistant sugar beets are on-going and have fostered increased uncertainty throughout the supply chain and policymaking process. The deregulation of RRSB has led to a legal dispute over the approval of the genetically modified crop. This ongoing dispute has increased uncertainty for the industry and sugar beet production as approval and use has been called into question. Ultimately, outcomes of this case will have implications for adjustments in U.S. sugar production and for the regulatory approval process for GM crops more broadly.

Regulatory Framework for Genetically Modified Crops

The National Environmental Policy Act (NEPA) was enacted in 1969 by the United States Congress in order control human interaction with the environment, and established requirements to determine potential harm to the

environment. The intent of NEPA is to mitigate negative environmental effects by analyzing potential outcomes before projects can be implemented (Bregman, 1999). NEPA established that the relevant government department must prepare a statement to outline “(i) the environmental impact of the proposed action, (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented, (iii) alternatives to the proposed action, (iv) the relationship between local short-term uses of man’s environment and the maintenance and enhancement of long-term productivity, and (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented” (NEPA, Section 102. 4332). Three agencies, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the United States Department of Agriculture (USDA) share responsibility for assessing environmental, health and safety impacts of agriculture biotechnology, though the scope of each agency has been criticized as poorly defined (Jackson and Villinski, 2002).

The five requirements of NEPA listed above are used as guidelines for the collection and analysis of new data that are compiled into an Environmental Impact Statement (EIS), which can take two years or more to complete. An Environmental Assessment (EA) uses less detailed evidence and can be completed in a shorter time period than an EIS. The results of an EA may be completed before an EIS and then may be used to determine the need for completion of an EIS (Bregman, 1999).

The Plant Protection Act of 2000 (PPA) was established to prevent negative environmental effects from the introduction of plant pests into the United States, including "organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests," (PPA).. The USDA and the Animal and Plant Health Inspection Service (APHIS) are assigned the duty of regulating such genetically altered plants. Thus, APHIS was the agency required to assess the implications of introducing RRSB under NEPA (Center for Food Safety, et al. v. Vilsack et al., 2009).

Glyphosate Resistant Sugar Beets

Under the PPA, commercial use of RRSB was restricted because of its classification as a regulated article (Center for Food Safety, et al. v. Vilsack et al., 2009). In 2003, APHIS was petitioned to deregulate RRSB under the premise that it should not be considered a plant pest (USDA APHIS, 2004). Deregulation of sugar beets would permit the production and sale of RRSB seed. Upon receipt of this request, APHIS completed an EA in order to evaluate whether RRSB should remain regulated, or be deregulated (Center for Food Safety, et al. v. Vilsack et al., 2009; USDA APHIS, 2004). An EA was then produced for public comment in 2004 (USDA APHIS, 2004).

Of the forty-four comments submitted to APHIS, three were opposed to the deregulation of RRSB. The following reasons were given in opposition to the deregulation of RRSB: “[a] sugar processor opposed the petition based on potential economic concerns; the biodynamic farmers generally opposed biotechnology, and the consumer group also opposed biotechnology and suggested that the EA was inadequate and an Environmental Impact Statement should be prepared,” (USDA APHIS, 2005, p.13007).

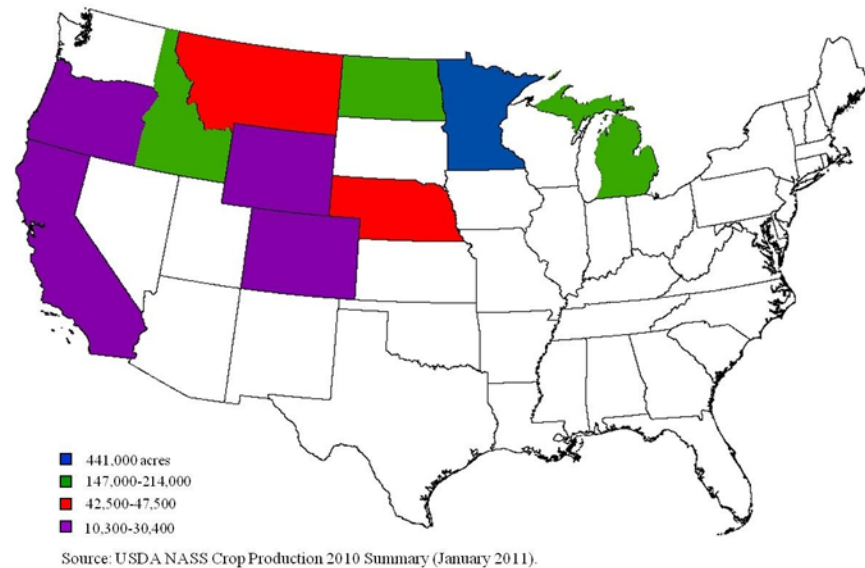
The completed EA concluded that RRSB “(1) Exhibits no plant pathogenic properties; (2) is no more likely to become weedy than the nontransgenic parental line or other cultivated sugar beet; (3) is unlikely to increase the weediness potential of any other cultivated or wild species with which it can interbreed; (4) will not cause damage to raw or processed agricultural commodities; (5) will not harm threatened or endangered species or organisms that are beneficial to agriculture; and (6) should not reduce the ability to control pests and weeds in sugar beet or other crops,” (USDA APHIS, 2005, p.13008). In addition, APHIS found that, because RRBS was not a plant pest and posed no more risk than its progenitor, it would have no economic impact. Citing these conclusions, APHIS determined that RRSB should no longer be termed a regulated article, and deregulated RRSB in 2005 (Center for Food Safety, et al. v. Vilsack et al., 2009; USDA APHIS, 2005).

The finding of no significant impact in the EA and resulting decision not to complete an EIS was questioned by opponents of RRSB. All prior crops produced through genetic modification—corn, soybeans, and cotton—had been approved after the completion of a full EIS rather than an EA. Of particular concern was the ability of RRSB to cross-pollinate with related crops during reproduction. Sugar beets are related to table beets and Swiss chard and are capable of interbreeding. If these vegetables are grown under organic conditions, interbreeding with RRSB would result in an otherwise organic crop with biotechnology traits.

Sugar beet seed production is a specialized operation and, particularly in biotech crops, has been concentrated among relatively few seed producers (Stiegert, Shi, and Chavas, 2010; Moschini, 2010). In addition, sugar beets are produced in temperate regions throughout the United States (Figure 2), while sugar beet seed production takes place

primarily in the Willamette Valley of Oregon, which is an area also known for the production of Swiss chard and table beets (Kockelmann and Meyer, 2006)

Figure 2: U.S. Sugar Beet Production



There is a one to two year lag between production of sugar beet seed and its use by sugar beet farmers. These lags make the planning process to meet demand for seed unusually complex (Jones, et al. 2003). Seed production can be accomplished through direct production methods or through transplanting of stecklings, young sugar beet plants (Kockelmann and Meyer, 2006). This seed is then purchased and planted by commercial beet growers in the spring and harvested in the fall for sugar without entering the seed production phase.

In 2008, the Center for Food Safety, Organic Seed Alliance, Sierra Club, and High Mowing Organic Seeds filed a complaint alleging that USDA and APHIS had not followed the necessary requirements in deregulating RRSB, thereby violating NEPA and PPA. Much of the dispute focused on the production of sugar beet seed, not sugar beets grown for sugar, because of the higher risk of pollen transfer to related crops grown in the same regions. A decision not to perform an EA or EIS may be overturned if the agency's decision was inappropriate given the provided evidence (Center for Food Safety, et al. v. Vilsack et al., 2009).

On September 21, 2009 Judge Jeffrey White of the United States District Court for the Northern District of California ruled that APHIS's decision to deregulate RRSB without an EIS was not valid, given the concerns regarding the potential environmental impacts (Center for Food Safety, et al. v. Vilsack et al., 2009). The court cited several reasons relating to the incompleteness of, or topics that were not addressed appropriately in the EA prepared by APHIS, including potential cross pollination. APHIS also did not examine the economic implications of the deregulation of RRSB. With this decision APHIS was then required to complete an EIS for RRSB (Center for Food Safety, et al. v. Vilsack et al., 2009).

On March 16, 2010 the court denied a motion for an injunction that attempted to disallow the use of RRSB in any production stages (USDA APHIS, 2011). Commercial sugar beet growers were permitted to plant RRSB for the 2010 growing season, but the court warned that the industry should be prepared to plant conventional seed in future growing seasons. An estimated \$1.5 billion could have been lost if producers were forced to switch to the limited conventional seed for the 2010 growing season (Voosen, 2010). On August 13, 2010 the court issued an order prohibiting the use of RRSB in future growing seasons, while allowing current plantings to remain in the ground (USDA APHIS, 2011).

Figure 3

Timeline of Regulatory Decisions on Roundup Ready Sugar Beets

March 17, 2005

Roundup Ready Sugar Beets (RRSB) are approved for use by APHIS.

January 23, 2008

Lawsuit filed against APHIS's decision to allow the use of RRSB.

September 21, 2009

U.S. District Court for Northern District of California rules that an EIS must be prepared because of incompleteness of EA.

March 16, 2010

Court denies plaintiff's attempt to prohibit use of RRSB in 2010 crop year.

August 9, 2010

A consideration for partial deregulation of RRSB is initiated.

August 13, 2010

Court returns RRSB to regulated status while APHIS completes an EIS.

August 2010

Industry parties apply for permits to produce sugar beet stecklings.

November 4, 2010

Public comment on an EA is solicited by APHIS to determine potential for partial deregulation of RRSB.

February 4, 2011

APHIS partially deregulates RRSB. Growers required to enter into an agreement with specified production requirements to prevent cross-pollination.

Source: Adapted from USDA-APHIS Roundup Ready Sugar Beet Case Timeline. Available at

http://www.aphis.usda.gov/biotechnology/sugarbeet_case.shtml

At the same time, APHIS began to consider, and in some cases approve, requests for permits that would allow future planting of glyphosate resistant stecklings to maintain a level of seed stock under limited conditions, including that the seeds could not be sold. APHIS also drafted an EA for partial deregulation of sugar beets that was posted for public comment. On February 4, 2011 APHIS announced that RRSB root crop production would be partially deregulated, again under a permit system, with the requirement that sugar beet growers follow strict guidelines regarding the control of stecklings. Issuance of these permits was challenged again and Judge White issued a preliminary injunction ordering the destruction of RRSB planted under these permits. On appeal, the Ninth Circuit Court of Appeals reversed this order on the grounds that the plaintiffs had not demonstrated that they were likely to suffer "irreparable harm" from the USDA's partial deregulation of RRSB. (USDA APHIS, 2011; Center for Food Safety v. Vilsack, 2011). Thus, resolution of this dispute will await the issuance of the EIS expected in 2012.

Regulatory Uncertainty and Its Implications

The on-going debate over future plantings of RRSB crops and seed has heightened uncertainty surrounding production decisions for the industry. In addition, challenges to decisions of a regulatory agency have implications for the introduction of biotech crops more generally as well as the oversight process. In the short run sugar beet producers were faced with three possibilities for the 2011 growing season: (1) glyphosate resistant seeds could not be planted and conventional seeds and inputs would be used to produce a sugar beet crop, (2) glyphosate resistant seeds could not be planted and conventional seeds and inputs are unavailable and no sugar beet crop would be produced, or (3) glyphosate resistant seeds could be planted under specific restrictions and permits. The consequences of scenarios on the sugar beet industry could have lasted beyond one season and could have changed the structure and viability of sugar beet production.

Under the scenario that RRSB would be regulated—not available for sugar beet producers—risk averse sugar processors, mainly grower cooperatives, attempted to secure conventional seed supplies as a hedge against a lack of sugar beets for their processing facilities. In addition to a likely shortfall in the availability of conventional seed, conventional chemicals were anticipated to be in short supply. Conversion to biotech practices was rapid and almost total in sugar beets—a specialty crop, so maintenance of conventional input supplies was likely to be less than it was in field crops, where a decline in input availability has been documented (Wolfenbarger, Owen, and Carriere, 2010). Beyond these inputs, some conventional sugar beet production relied on the use of migrant labor for weeding operations and a return to conventional

practices would have required a return to the use of labor in some areas. As the industry converted to RRSB, practices changed along with the technology. Efficiencies created by RRSB would be lost, and growers and processors could experience higher costs with conventional production. Repositioning the sugar beet industry for conventional production as a hedge against loss of RRSB seed might have proven costly, but could have been necessary to mitigate uncertainty over potential loss of access to RRSB options.

In some cases, it is likely that conventional seed and/or chemicals could be too costly to obtain or unavailable. In that scenario, growers would have been forced to eliminate sugar beets from their rotations as they shifted, at least

temporarily, to more profitable options. While growers might be expected to relatively easily convert plantings to another crop—within rotational constraints for a season, the impacts on the processing sector would likely be less reversible. Sugar beet processors would be missing the key input for sugar production, causing them to reduce or halt operations for at least the year that seed was unavailable. Even a temporary shortage could have long-term implications for sugar beet processors who typically operate with tight margins and very specific assets that are not easily converted to other uses.

Though the sugar beet industry could face uncertainty on this issue beyond the current growing season if future regulatory decisions are challenged in the courts, this episode demonstrates that regulatory uncertainty can also be created by a failure to follow statutory requirements. For example, the original APHIS decision was not to pursue an EIS in what must still be considered a sensitive policy area—the approval of GMO crops. This failure to produce an EIS on such an issue resulted in an inordinately lengthy series of legal challenges and complexities caused by the relatively long time lag necessary for sugar beet seed production. At the same time, when APHIS based its 2010 decision to partially deregulate RRBS production on a fully developed EIS, that decision withstood subsequent legal challenges. Consequently, one must ask whether the regulatory uncertainty created by the initial decision was foreseeable and would it have been avoided with a faithful execution of the statute as written? In considering the sources of future regulatory uncertainty, such questions must be asked.

In addition, the regulatory process itself is being challenged as it relates to the analysis and introduction of any future GM crops. As the Congressional Research Service has noted, the United States will soon be facing new issues related to GM crops—the introduction of corn products with industrial or pharmaceutical uses that pose new issues about cross-pollination, and the evolution of chemical resistant weeds—which will continue to pose serious questions about the approval of GM crops (Cowan and Alexander). In such an atmosphere, two things will very likely be true. First, it is now clear that the completion of an EIS is likely to be warranted when the introduction of genetically modified crops are considered. The GM approval process will have to follow the requirements established by NEPA or it will almost certainly encounter legal challenges to the use of those crops. Second, the importance of trust in a regulatory process, based on the faithful execution of that process is essential to the reduction of regulatory uncertainty. Attempts to bypass that process are likely to create, not reduce, regulatory uncertainty for input suppliers, farmers, processors and consumers.

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