AgrEvo USA Company Petition 97-336-01p for Determination of Nonregulated Status for Transgenic Glufosinate Tolerant Sugar Beet Transformation Event T120-7

Environmental Assessment and Finding of No Significant Impact

April 1998

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture, has prepared an environmental assessment in response to a petition (APHIS Number 97-336-01p) received from AgrEvo USA Company seeking a determination of non-regulated status for their genetically engineered glufosinate-ammonium (glufosinate) tolerant sugar beet designated as Transformation event T120-7 under APHIS regulations at 7 CFR Part 340. The plants have been engineered with a gene that confers resistance to the phosphinothricin herbicide, glufosinate. Based on the analysis documented in its environmental assessment, APHIS has reached a finding of no significant impact (FONSI) on the environment from the unconfined cultivation and agricultural use of event T120-7 and its progeny.

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I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 97-336-01p) from AgrEvo USA Company (AgrEvo) seeking a determination of non-regulated status for their transgenic glufosinate tolerant sugar beet designated as Transformation Event T120-7 (event T120-7). AgrEvo seeks a determination that event T120-7 and its progeny do not present a plant pest risk and, therefore, are no longer regulated articles under regulations at 7 CFR Part 340. Event T120-7 is sugar beet, Beta vulgaris ssp. vulgaris, containing a stably integrated gene which encodes the enzyme phosphinothricin-N-acetyltransferase (PAT). The PAT enzyme catalyzes the conversion of L-phosphinothricin, the active ingredient in the herbicide glufosinate-ammonium, to an inactive form, thereby conferring tolerance to the herbicide. The pat gene in event T120-7 is a synthetic version of the native gene isolated from Streptomyces viridochromogenes. The gene was introduced into sugar beet calli using disarmed Agrobacterium tumefaciens. Southern blot and polymerase chain reaction (PCR) analyses confirm that the incorporation has been limited to DNA sequences contained within the T-DNA borders and that

event T120-7 contains a single, stably integrated copy of the pat gene.

No differences in event T120-7 sugar beet compared to nontransformed counterpart beets as well as standard commercial sugar beet varieties growing in nearby fields were found in the agronomic characteristics, plant emergence and seedling vigor. Event T120-7 has also been field tested extensively in Canada, Western and Eastern Europe, and in the former Soviet Union. Field trial reports from these tests demonstrate that the transformed line did not exhibit weedy characteristics, and does not cause any harm to nontarget organisms or the general environment.

An environmental assessment (EA) was prepared prior to granting field test permits involving the event T120-7. The EA for the previous introductions of event T120-7 addressed plant pest risk issues relative to the conduct of field trials under physical and reproductive confinement. This EA specifically addresses the potential impacts of event T120-7 to the human environment through unrestricted use in agriculture. The U.S. Environmental Protection Agency (EPA) has the authority over the potential uses of the herbicide glufosinate ammonium (Basta , Ignite , Rely , Liberty , Harvest , and Finale) in conjunction with event T120-7 through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

APHIS has considered the information provided by AgrEvo in its petition as well as other scientific data, information, and comments received from the public relating to potential plant pest risk and related environmental impacts of event T120-7. An evaluation of the potential for significant impact to the human environment through the unconfined, agricultural use of event T120-7 resulted in a Finding of No Significant Impact (FONSI) by APHIS. This conclusion is based upon (1) the nature of the genetic modification; (2) the fact that sugar beet has weedy relatives with which it may interbreed in the United States and its territories but other herbicides exist to control such weeds if they become glufosinate-ammonium tolerant and (3) the fact that this modification will not increase the weediness potential of the sugar beets or negatively affect any nontarget or beneficial organisms. In conjunction with the FONSI, APHIS has made the determination that event T120-7 and its progeny do not pose a plant pest risk and are, therefore, determined to be no longer regulated articles according to 7 CFR 340. The determination document is in Appendix A.

II. INTRODUCTION

This EA examines potential environmental impacts from the unrestricted introduction of event T120-7. Event T120-7 and its progeny has been field tested under permits from APHIS in primary sugar beet growing regions of the USA since 1994. In total, 68 trials have been conducted under USDA authorization 94-054-06r, 94-347-01r; 96-052-02r; and 97-029-01r. AgrEvo based its petition, in part, on the data gathered from these trials. Field trial reports from these tests demonstrate no deleterious effects on plants, nontarget organisms, or the environment as a result of these field releases. All field trials were performed under physical and reproductive confinement. Further discussions of the biology of sugar beet, as well as of the genetic components of event T120-7, are found in the determination document (Appendix A). Because this information is included in Appendix A, it will not be described in detail in the body of this document.

Prior to issuing a permit for a field release, APHIS analyzes the potential impacts associated with the proposed introduction and prepares an environmental assessment that documents the environment analysis in accordance with regulations and guidelines implementing the National Environmental Policy Act (NEPA) of 1969, as amended (42 USC 4321 et seq.; 40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372). APHIS also evaluates cumulative impacts to the human environment from its determination of nonregulated status.

A genetically engineered organism is considered a regulated article if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest, or if there is reason to believe that it is a plant pest. The transgenic sugar beet plants described in the AgrEvo petition have been considered regulated articles because they contain certain noncoding regulatory sequences

(DNA) derived from known plant pathogens listed in 7 CFR Part 340.

III. PURPOSE AND NEED

The purpose of this EA is to ascertain whether the approval of a petition submitted to USDA/APHIS for the determination of nonregulated status of event T120-7 (that would allow their unconfined introduction into the environment) will present any plant pest risk or have any significant impact on the environment.

A petition was submitted to APHIS pursuant to regulations codified in 7 CFR Part 340 entitled "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests." The regulations govern the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. An organism is not subject to the regulatory requirements of 7 CFR Part 340 when it is demonstrated not to present a plant pest risk. Section 340.6 of the regulations, entitled "Petition Process for Determination of Nonregulated Status," provides that a person may petition the Agency to evaluate submitted data and to seek a determination that a particular regulated article does not present a plant pest risk and should no longer be regulated.

If the agency determines that the regulated article does not present a risk of introduction or dissemination of a plant pest, the petition would be approved for the unregulated introduction (importation, interstate movement, and release into the environment) of the articles or their progeny in question without any prior permit or notification from APHIS.

Effects associated with the potential uses of the herbicide glufosinate in conjunction with event T120-7 are outside the scope of the regulatory authority of APHIS. APHIS determination does not constitute authorization to use glufosinate on event T120-7. The EPA has authority over the use in the environment of pesticidal substances, including herbicides, under FIFRA; specifically, EPA has jurisdiction over registration of glufosinate for use on transgenic sugar beets as well as other transgenic and nontransgenic crops. EPA considers both human health and safety as well as nontarget effects of the herbicide and its breakdown products in making a decision on registration of a herbicide.

IV. ALTERNATIVES

In the course of preparing the environmental assessment for the AgrEvo petition, APHIS considered the following three alternatives: (1) deny the petition, so that event T120-7 would continue to be regulated under 7 CFR Part 340; (2) approve the petition, with geographical limitations; and/or (3) approve the petition so that event T120-7 would no longer be regulated when grown in the United States and its territories. Based on the biology of sugar beet, the nature of the genetic change, data and information presented by AgrEvo, scientific literature, and information and comment provided by the public, APHIS could find no basis for denying the petition (Alternative 1) or for imposing geographical limitations on the use of event T120-7 (Alternative 2).

V. POTENTIAL ENVIRONMENTAL IMPACTS

Potential impacts to be addressed in this EA are those that pertain to the use of event T120-7 in the absence of confinement.

Potential Impacts Based On Increased Weediness Of Event T120-7 Relative To Traditionally Bred Sugar beets

Almost all definitions of weediness stress as core attributes the undesirable nature of weeds from the point of view of humans; from this core, individual definitions differ in approach and emphasis (Baker, 1965; de Wet and Harlan, 1975; Muenscher, 1980). In further analysis of

weediness, Baker (1965) listed 12 common weed attributes, almost all pertaining to sexual and asexual reproduction, which can be used as an imperfect guide to the likelihood that a plant will behave as a weed. Keeler (1989) and Tiedje et al. (1989) have adapted and analyzed Baker's list to develop admittedly imperfect guides to the weediness potential of transgenic plants; both authors emphasize the importance of looking at the parent plant and the nature of the specific genetic changes.

The parent plant in this petition, Beta vulgaris L. ssp. vulgaris L., does not show any especially weedy characteristics. It is unlikely that as a result of cross-pollination descendants of crosses between transgenic and wild sugar beets would become part of breeding material or become established in any sugar beet ecological community (Lewellen 1998). In a review of the State Noxious-Weed Seed Requirements Recognized in the Administration of the Federal Seed Act, no reference was found regarding "wild" sugar beets or wild sugar beet relatives as either restricted or noxious weeds (Holm et al. 1979). This demonstrates that sugar beet does not have the necessary attributes which could allow it to become a serious weed problem in sugar beet growing areas.

Sugar beet is a biennial crop. The second season's crop produces seed. However, certain conditions such as low temperatures after planting and longer day length can cause the sugar beet to "bolt" or produce a seed stalk during the first growing season (Bell, 1946; Jaggard, Wickens, Webb and Scott, 1983; Durrant and Jaggard, 1988). These situations exist in Europe, especially England when growers seed too early in the spring. They also can occur in California where sugar beets are often seeded during the fall and winter months or when spring planted crops are overwintered. Bolters are a problem in the current planted crop because, although inflorescences (bolting stalk) may be cut off, the bolted plants contain more lignin in their roots and sugar yield could be reduced by 50% (Smith, 1987; Scott and Wilcockson, 1976; and Jaggard et al. 1983). While bolting can cause a problem in any given year it does not lead to any increase in weediness potential of sugar beet. Unwanted seed germination in sugar beet is controlled by various methods such as cutting at the base of the stalk, or treatment with non-selective herbicides.

Potential Impacts From Out crossing Of Event T120-7 to Wild Relatives

Wild species of sugar beets have been reported in the region surrounding the Mediterranean Sea and in the Caucasus Mountains of Russia and into Turkey and Iran. Wild species may also be found as far west as the Canary Islands (Doney, 1996; Cooke and Scott, 1993). Some relatively small wild populations of B. macrocarpa, Beta vulgaris L.ssp. maritima L. , and B. vulgaris L. ssp. vulgaris L. have become established in California due to the mild climate. The populations of Beta vulgaris L. ssp. vulgaris L., B. vulgaris L. ssp. maritima L. and B. macrocarpa probably developed from seed contaminants or from seed intentionally imported into California. No wild populations of Beta have been reported in the U.S. outside of California.

In 1928 Carsner, as referenced by McFarlane (1975), reported wild beet populations in Imperial, Santa Clara, Ventura, San Bernardino, Los Angeles, and Orange Counties of California. Carsner speculated that these beets were either B. vulgaris L. ssp. maritima L. or hybrids between B. vulgaris L. ssp. maritima L. and B. vulgaris L. ssp. vulgaris L. McFarlane, (1975) identified the wild beets in Imperial County as B. macrocarpa rather than B. vulgaris ssp. maritima. These populations have been established for many years and are not spreading. Beta macrocarpa is a species that occurs naturally in the Canary Islands and along the Mediterranean coastline. Seeds of B. macrocarpa may have been imported as contaminants in seed or in feed grain. McFarlane, (1975) reported the existence of numerous naturally occurring hybrids between plants of B. macrocarpa and B. vulgaris L. ssp. vulgaris L. in the Imperial Valley. .

Dahlberg and Brewbaker, (1948) referred to the population of B. vulgaris L. ssp. maritima L. in Santa Clara County as the "Milpitas wild beet". Seed brought in by the Franciscan Fathers when they established the Santa Clara and other missions in the late 1700's may be the source of these wild relatives. Sugar beets are no longer commercially grown in this area where these beets were found. Johnson and Burtch, (1958) describe sugar beets which evolved into annual

plants and became a weed problem in California. Recent surveys localize such populations in the Gilroy/Hollister area where sugar beet is grown.

Abe (1988) reported that B. vulgaris L. ssp. vulgaris L. and B. macrocarpa do not readily produce viable hybrids. Crosses with species outside the Beta type are made, with difficulty, using special plant breeding techniques. Due to the biennial nature of sugar beets the risk of gene transfer from transgenic sugar beets to weedy relatives is remote. Since bolting beets are uncommon except in fields or plots grown specifically for seed production, there is little opportunity for uncontrolled pollen flow due to adequate isolation distances. Even if gene transfer were to occur from event T120-7 to wild beets, other herbicides can be used to control such glufosinate-tolerant wild beets (Lewellen 1998 personal communication).

Potential Impact On Nontarget Organisms Including Beneficial Organisms Such As Bees And Earthworms

There is no reason to believe that deleterious effects or significant impacts on nontarget organisms, including beneficial organisms, would result from the cultivation of event T120-7. Glufosinate tolerant soybean that produce the same enzyme (PAT) are already commercialized and have proven safe and similar to their non-transgenic parents. The enzyme that confers glufosinate resistance in sugar beet is normally not present in sugar beets and is not known to have any toxic property. Field observations of event T120-7 revealed no negative effects on nontarget organisms. The lack of known toxicity for this enzyme suggests no potential for deleterious effects on beneficial organisms such as bees and earthworms. The high specificity of the enzyme for its substrates makes it unlikely that the introduced enzyme would metabolize endogenous substrates to produce compounds toxic to beneficial organisms. APHIS has not identified any other potential mechanisms for deleterious effects on beneficial organisms. In addition, there is no reason to believe that the presence of event T120-7 would harm any threatened or endangered species in the United States.

Consideration Of Potential Environmental Impacts Associated With The Cultivation Of Event T120-7 Outside the United States

APHIS has also considered potential environmental impacts outside the United States and its territories associated with the potential approval of event T120-7. Several factors contribute to the conclusion that there should be no impacts abroad from cultivation of this sugar beet line or its progeny.

Any international traffic in sugar beet would be fully subject to national and regional phytosanitary standards promulgated under the International Plant Protection Convention (IPPC). The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (105 countries as of October, 1996). The treaty, now administered by a Secretariat housed with the Food and Agriculture Organization in Rome, came into force on April 3, 1952, and establishes standards to facilitate the safe movement of plant materials across international boundaries. Plant biotechnology products are fully subject to national legislation and regulations, or regional standards and guidelines promulgated under the IPPC. The vast majority of IPPC signatories have promulgated, and are now administering, such legislation or guidelines. The IPPC has also led to the creation of Regional Plant Protection Organizations (RPPOs) to facilitate regional harmonization of phytosanitary standards.

Issues that may relate to commercialization of particular agricultural commodities produced through biotechnology are being addressed in international forums. APHIS has played a role in working toward harmonization of biosafety and biotechnology guidelines and regulations included within the RPPO for our region, the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the United States. NAPPO's Biotechnology Panel advises NAPPO on biotechnology issues as they relate to plant protection.

APHIS participates regularly in biotechnology policy discussions at forums sponsored by the

European Union and the Organization for Economic Cooperation and Development. In addition, APHIS periodically holds bilateral or quadrilateral discussions on biotechnology regulatory issues with other countries, most often Canada and Mexico. APHIS also acts as a consultant for the development of biotechnology guidelines and regulations, and has interacted with governments around the world in this manner. In the course of these wide-ranging studies and interactions, APHIS has not identified any impacts on the environment that might be relevant to the unconfined cultivation of event T120-7 sugar beet in the United States and its territories, or abroad.

Potential impacts on biodiversity.

Genetically engineered event T120-7 sugar beet is no more likely to become weed than lines developed by traditional breeding techniques. It is unlikely to increase the weediness potential of any other cultivated plant or native wild species with which it may interbreed. It will not harm threatened and endangered species and non-target organisms. Based on this analysis, APHIS concludes that there is no potential impact of event T120-7 on biodiversity.

Potential impacts on agricultural and cultivation practices.

Based on APHIS analysis, there is unlikely to be any significant adverse impact on agricultural practices associated with the use of this line. The introduction of event T120-7 in agriculture offers the opprtunity of no till cultivation of sugarbeet leading to decreased soil erosion and thereby soil sustainability.

Potential damage to raw or processed agricultural commodities.

An analysis of the components and processing characteristics of this line reveals no differences in any component that could have an indirect plant pest effect on any raw or processed plant commodity.

VI. CONCLUSIONS

In accordance with the requirements of NEPA, APHIS has considered the potential for significant impact on the environment of a proposed action, i.e, reaching the determination that event T120-7 have no potential to present a plant pest risk and should no longer be considered a regulated article under the regulations at 7 CFR Part 340. After careful analysis of the available information, APHIS concludes that its proposed action should not have a significant impact on the environment and that the proper alternative is to approve the petition so that event T120-7 would have a nonregulated status when grown in the United States and its territories. APHIS has identified no factors that would suggest any impact to the environment of the United States and its territories. While isolated environments, such as are found in Hawaii, Puerto Rico, or in territories or possessions of the United States, have fragile ecologies that have frequently been damaged through human intervention, APHIS has determined that in these environments event T120-7 will have impacts no different from traditional sugar beet varieties that are not subject to petition requirements under 7 CFR Part 340 before they enter agriculture. Sugar beet at present is not grown in Hawaii or Puerto Rico. This conclusion is based on factors discussed herein or in the determination included as appendix A, as well as the following factors:

1. Neither the glufosinate resistance gene nor its product or the regulatory sequences confer on event T120-7 or its progeny any plant pest characteristic. A pat gene that confers tolerance to the herbicide glufosinate has been inserted into a sugar beet chromosome in sugar beet lines. In nature, chromosomal genetic material from plants can only be transferred to another sexually compatible flowering plant by cross- pollination. Sexually compatible wild species of sugar beets in the United States and its territories are rare. Even if out crossing produced glufosinate-tolerant weeds, other herbicides are on the market to control them..

2. The gene that confers tolerance to the herbicide, glufosinate, will not provide event T120-7 or its progeny with any measurable selective advantage over nontransformed sugar beet plants in their ability to disseminate or to become established in the environment. There is no reason to believe that event T120-7 exhibit any increased weediness relative to that of traditional varieties or the unmodified parental lines.

3. The use of event T120-7 or its progeny in agriculture will not lead to an increase in weediness in any plant with which it can successfully interbreed.

4. There is no reason to believe that the use of event T120-7 or its progeny in agriculture will have a significant impact on any beneficial organisms in the environment or on any threatened or endangered species.

5. The use of event T120-7 or its progeny in agriculture will not cause damage to raw or processed agricultural commodities.

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