

Monsanto/Dekalb Petition 97-099-01p for Determination of Nonregulated Status for Transgenic Glyphosate Tolerant Corn Line GA21

Environmental Assessment and Finding of No Significant Impact

November 1997

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture, has prepared an environmental assessment before issuing a determination of non-regulated status for a genetically engineered corn line designated GA21. This line has been engineered for tolerance to the herbicide glyphosate. APHIS received a petition (APHIS Number 97-099-01p) from the Monsanto Company (Monsanto) and Dekalb Genetics Corporation (Dekalb), regarding the status of this corn line as a regulated article under APHIS regulations at 7 CFR Part 340. APHIS has conducted an extensive review of the petition, supporting documentation, and other relevant scientific information. Based on the analysis documented in this environmental assessment, APHIS has reached a finding of no significant impact (FONSI) on the environment from the unconfined cultivation and agricultural use of the subject corn line 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 97-099-01p) from Monsanto Company (Monsanto) of St. Louis, MO and Dekalb Genetics Corporation (Dekalb) of Mystic, CT, (Monsanto/Dekalb) seeking a determination of non-regulated status for their glyphosate tolerant genetically engineered corn (*Zea mays*) line GA21, hereafter referred to as line GA21. The significant modification to GA21 corn plants relative to traditional corn varieties is that line GA21 corn has been modified to express a modified corn gene that provides tolerance to the herbicide glyphosate, the active ingredient in the herbicide Roundup .

Corn line GA21 is currently a regulated article under USDA regulations at 7 CFR Part 340. Interstate movements, importations, and field tests of line GA21 have been conducted under permits issued or notifications acknowledged by APHIS. Monsanto/Dekalb has petitioned APHIS for a determination that this corn line does not present a plant pest risk and, therefore, is no longer a regulated article under regulations at 7 CFR Part 340.

This EA specifically addresses the potential for impacts to the human environment through the use in agriculture of corn line GA21. It does not address the separate issue of the potential use of the herbicide glyphosate (Roundup) on this line or its progeny. The United States Environmental Protection Agency (EPA) has authority over the use in the environment of all pesticidal substances, including herbicides and insecticides, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

In accordance with APHIS procedures for implementing the National Environmental Policy Act, as amended (NEPA) (7 CFR Part 372), EAs were not prepared before granting permission for individual field trials because line GA21 met the eligibility criteria under the notification procedure and the trials met the performance standards (7 CFR Part 340.3). This EA addresses issues that are of relevance to the unconfined planting of corn line GA21, and APHIS concludes the following:

1. Line GA21 exhibits no plant pathogenic properties. Although DNA from a plant pathogenic organism was used in its development, GA21 corn plants are not infected by these organisms nor can these plants incite disease in other plants;
2. Line GA21 is no more likely to become a weed than other improved quality corn varieties which have been developed by traditional breeding techniques. Corn is not a weed in the U.S., and there is no reason to believe that the introduced genes would enable this corn line to become a weed pest;
3. Multiple factors ensure that gene introgression from the subject corn line into wild plants in the United States and its territories is extremely unlikely. Even in other regions, potential gene introgression from this corn line into wild relatives is not likely to increase the weediness potential of any resulting progeny nor adversely effect biodiversity or genetic diversity of related plants any more than would introgression from traditional corn varieties;
4. Line GA21 will not have a significant adverse impact on organisms beneficial to plants or agriculture, or other nontarget organisms, and will not affect threatened or endangered species; and

5. Line GA21 should not cause damage to raw or processed agricultural commodities or significantly affect agricultural practices.

Therefore, after a review of the available evidence, including that provided by Monsanto/Dekalb in its petition as well as other scientific data, APHIS believes that corn line GA21 will be just as safe to grow as traditionally-bred corn varieties not subject to regulation under 7 CFR Part 340. APHIS concludes that there will be no significant impact on the human environment if corn line GA21 and its progeny are no longer considered regulated articles under 7 CFR Part 340. The appended determination document (Appendix A) contains additional detailed analysis relevant to this decision.

II. BACKGROUND

Development of a glyphosate tolerant corn line. Monsanto/Dekalb has submitted a "Petition for Determination of Non-regulated Status" to the USDA, requesting a determination from APHIS that corn line GA21, and any progeny derived from crosses between this line and other nonregulated corn varieties, no longer be considered regulated articles under 7 CFR Part 340.

Glyphosate is a non-selective, broad-spectrum herbicide that kills plants by inhibiting an enzyme, 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) critical for the biosynthesis of aromatic amino acids, vitamins, and many secondary metabolites. Corn line GA21 has been genetically engineered to contain a modified corn EPSPS gene, which when expressed in the plant, confers tolerance to glyphosate. The expression of the modified EPSPS is controlled in part by the rice actin promoter and intron and the NOS 3' termination sequence derived from the plant pathogen *Agrobacterium tumefaciens*. The modified EPSPS gene was fused to a chloroplast transit peptide derived from corn and sunflower (*Helianthus annuus*) to allow subcellular targeting of EPSPS protein into the chloroplast. The genes were introduced into the parental inbred (AT) corn line via the particle bombardment technique that results in direct introduction of genes into the plant genome. The potential commercial use of these plants may offer farmers additional choices for the control of weeds.

Monsanto/Dekalb submitted its petition after numerous field tests of corn line GA21 in the United States and Puerto Rico. These field tests have been carried out at 10 sites under APHIS notifications 94-182-03N, 94-283-02N, 95-074-01N, 95-158-01N, 96-071-07N, 96-137-02N, 96-241-02N, and 96-278-02N. Field trial reports from these tests indicate that during field tests the transformed line had no deleterious effects on plants, did not exhibit weedy characteristics, and had no effect on nontarget organisms or the general environment. All field trials were performed under conditions of physical and reproductive confinement.

This EA examines potential environmental impacts from the unrestricted introduction of the subject line. Further discussions of the biology of corn, as well as of the genetic components of line GA21, are found in the determination document (Appendix A), and thus will not be described in detail in the body of this document.

APHIS Regulatory Authority. APHIS regulations under 7 CFR Part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act, (7 U.S.C. 150aa-150jj) as amended, and the Plant Quarantine Act, (7 U.S.C. 151-164a, 166-167) as amended, regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. An organism is no longer subject to the regulatory requirements of 7 CFR Part 340 when it is demonstrated not to present a plant pest risk. 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 corn line GA21 described in the Monsanto/Dekalb petition has been considered to be a regulated article because some noncoding DNA regulatory sequences were derived from the plant pathogen *Agrobacterium tumefaciens*.

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 determine that a particular regulated article does not present a plant pest risk and should no longer be regulated. If APHIS determines that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it is derived, the Agency can grant the petition in whole or in part. Therefore, APHIS permits or notifications would no longer be required for field testing, importation, or interstate movement of that article or its progeny. Normal agronomic practices with the subject line, e.g., cultivation, propagation, movement, and cross-breeding could also be conducted without further APHIS approval.

Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) Regulatory Authority. Effects associated with the potential uses of the herbicide glyphosate in conjunction with corn line GA21 are outside the scope of the regulatory authority of APHIS. An APHIS determination of non-regulated status does not constitute authorization to use glyphosate on the subject line. The EPA is responsible for the regulation of pesticides, including herbicides, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 et seq.). FIFRA requires that all pesticides, including herbicides, be registered for use on specific crops prior to distribution or sale. In cases in which the genetically modified plants allow for a new use of an herbicide or involve a different use pattern for the herbicide, the EPA must approve the new or different use. In making such an approval, the EPA considers potential adverse effects to human health and the environment from the use of the herbicide and its breakdown products. When the use of the herbicide on the genetically modified plant would result in an increase in the residues of the herbicide in a food or feed crop for which the herbicide is currently registered, or in new residues in a crop for which the herbicide is not currently registered, establishment of a new tolerance or a revision of the existing tolerance would be required. Residue tolerances for pesticides are established by the EPA under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.). The Food and Drug Administration (FDA) enforces tolerances set by the EPA under the FFDCA. Registration and a modified label for the herbicide Roundup for over-the-top use on glyphosate-tolerant corn (including line GA21) was approved on March 28, 1997 (62 FR 17723-17730).

The corn line GA21 is also subject to regulation by the Food and Drug Administration (FDA). FDA's policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992, and appears at 57 FR 22984-23005. FDA requests that firms provide a summary of their food (including animal feed) safety and nutritional assessment to the agency and discuss their results with agency scientists prior to commercial distribution. The applicant has stated that they are involved in ongoing consultations with the FDA.

III. PURPOSE AND NEED

APHIS has prepared this EA before making a determination on the status of corn line GA21 as a regulated article under APHIS regulations. The developers of this corn line, Monsanto Company and Dekalb Genetics Corporation, submitted a petition to APHIS requesting that APHIS make a determination that corn line GA21 no longer be considered a regulated article under 7 CFR Part 340.

This EA was prepared in compliance with the National Environmental Policy Act of 1969, as amended (NEPA) (42 USC 4321 et seq.) and the pursuant implementing regulations (40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372).

IV. ALTERNATIVES

A. No Action.

Under the Federal "no action" alternative, APHIS would not come to a determination that corn line GA21 is no longer a regulated article under the regulations at 7 CFR Part 340. Permits or acknowledgment of notifications from APHIS would still be required for introductions of corn line GA21. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from uncontained cultivation of corn line GA21.

B. Determination that corn line GA21 is no longer a regulated article.

Under this alternative, corn line GA21 would no longer be a regulated article under the regulations at 7 CFR Part 340. Permits or acknowledgment of notifications from APHIS would no longer be required for introductions of this corn line or its progeny. A basis for this determination would include a "Finding of No Significant Impact" under the National Environmental Policy Act of 1969, as amended (42 USC 4321 et seq.) and the pursuant implementing regulations (40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372).

V. POTENTIAL ENVIRONMENTAL IMPACTS

This EA addresses potential environmental impacts from a determination that corn line GA21 should no longer be considered to be a regulated article under APHIS regulations at 7 CFR Part 340. This EA considers the genotypic and phenotypic characteristics of corn line GA21 and the potential environmental impacts that might be associated with the unconfined cultivation of this line.

Additional technical information is included in the determination document appended to this EA, and incorporated by reference. This includes detailed discussions of the biology of corn, the genetic components used in the construction of corn line GA21, and the analyses that lead APHIS to conclude that this corn line has no potential to pose a plant pest risk.

A. Potential impacts based on increased weediness of the subject corn line relative to traditionally bred corn

Attributes considered essential for a plant to be categorized as a weed have been developed (Baker, 1965; de Wet and Harlan, 1975; Muenscher, 1980). Cultivated corn (*Zea mays* L.) possess few of the characteristics of plants that are successful weeds (e.g., it does not produce abundant, long-lived seed; it does not propagate vegetatively; it does not compete well with other plant species in the environment). In the United States, corn is not listed as a weed in the major weed references (Crockett 1977; Holm et al. 1979; Muenscher 1980; Weed Science Society of America, 1989), nor is it listed as a noxious weed species by the Federal Government (7 CFR Part 360). Corn is considered a highly inbred, well-characterized crop plant that is not persistent in undisturbed environments without human intervention. Although corn volunteers are not uncommon, they are easily controlled using herbicides or mechanical means. Furthermore, corn has been grown for centuries throughout the world without any reports that it is a serious weed pest.

The parent plant of corn line GA21 is an agricultural crop plant that exhibits no

weedy characteristics. The relevant introduced trait, glyphosate tolerance, is unlikely to increase weediness of corn line GA21. To increase weediness of the corn plant there would have to be selection pressure (Tiedje et al., 1989; Office of Technology Assessment, 1988). In agricultural settings, currently available herbicide tolerant corn plants are no more difficult to control (i.e., weedier) than nontolerant plants. There is no indication that the presence of a modified 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), will convert corn into a weed. This gene has no known involvement in plant disease or damage. In the United States, corn that is grown in rotation with soybeans may volunteer on occasion. Volunteers of line GA21 can be controlled using physical methods or with the use of other herbicides that are not based on glyphosate and which are registered for use on the crop, as appropriate.

APHIS considered data and observations provided in the petition on the agronomic performance and disease and insect susceptibility of corn line GA21 evaluated in field tests conducted from 1994 to 1996 in four U.S. states and Puerto Rico. No other attributes of corn line GA21 suggest that it may be any more "weedy" than the present corn lines that are the result of traditional breeding. Monsanto/Dekalb have presented information that corn line GA21 has retained the agronomic characteristics of the parental inbred corn line and differs only in its tolerance to glyphosate. The observations reported in the Monsanto/Dekalb application support APHIS' conclusion that corn line GA21 is no more likely to become a weed than any other currently used corn line.

B. Potential impacts from outcrossing of the subject corn line to wild relatives

A detailed description of the biology of corn (*Zea mays*) is included in the determination document (Appendix A). Only a brief summary relevant to the potential for gene flow from corn line GA21 to any wild relatives is provided here.

The species *Zea mays* is native to Mexico and Central America. In the genus *Zea* only *Z. mays* is common in the United States. It is known only from cultivation; it occasionally is spontaneous in abandoned fields or roadsides, but is incapable of sustained reproduction outside of cultivation (Gould 1968). Annual teosinte (*Zea mays* subsp. *mexicana*) is an ancient wild grass found in Mexico and Guatemala that is genetically compatible with corn (Serratos et al., 1995). In areas where the two species coexist they have been reported to produce hybrids (Wilkes, 1972; 1989). Introgressive hybridization in the wild is limited (Galinat, 1988), and rare hybrids show substantially reduced reproductive capacity (Giddings et al., 1990). Furthermore, although corn can produce hybrids with teosinte, teosinte is not present in the U. S. Corn Belt, thereby eliminating any risk of introgression. The closest relative to *Zea* is *Tripsacum*, a genus of eleven species, three of which occur in the United States (Gould, 1968). *Tripsacum* can cross with *Zea*, but only with difficulty and the resulting hybrids are often sterile (Galinat 1988).

Our analysis of the biology of cultivated herbicide-tolerant corn and its relatives leads us to predict that the environmental impacts of cultivation of corn line GA21 would be no different from such impacts attributable to similar varieties produced by traditional breeding techniques. Non-cultivated varieties of *Zea* sp. have coexisted and co-evolved in the Americas over millennia. Even if line GA21 were to be cultivated in agricultural regions around centers of *Zea* diversity, there is no reason to expect impacts from corn line GA21 to be significantly different from those arising from the cultivation of any other line of herbicide tolerant corn. Neither the weediness nor the survival of teosinte will be affected by the cultivation of corn line GA21, based on the facts that: the transgenic line poses no increased weediness itself; the two species are unlikely to successfully cross in nature; and the added traits would confer minimal selective advantage in the wild species habitat.

C. Potential impact on nontarget organisms including beneficial organisms such as bees and earthworms, and threatened or endangered organisms.

Consistent with its statutory authority and requirements under NEPA, APHIS evaluated the potential for corn line GA21 and plant products derived from this line to have damaging or toxic effects directly or indirectly on nontarget organisms. This includes those that are recognized as beneficial to agriculture and those that are recognized as threatened or endangered in the United States. APHIS also considered potential impacts on other "nontarget" pests, since such impacts could have an impact on the potential for changes in agricultural practices.

The Monsanto/Dekalb analysis of GA21 corn identified no toxic components that are present in concentrations significantly different from concentrations in nontransgenic corn. The genetic modification in corn line GA21 does not result in the production of novel proteins, enzymes, or metabolites in the plant that are known to have toxic properties. The production of a modified corn EPSPS in line GA21 should not be a concern since this protein is nearly (99.3%) identical to the endogenous corn EPSPS. EPSPS is an enzyme of the shikimate pathway for aromatic amino acid biosynthesis in plants and microorganisms, and is widely prevalent in the environment.

There is no reason to believe that deleterious effects or significant impacts on nontarget organisms, including beneficial organisms, would result from the cultivation of corn line GA21. Field observations of corn line GA21 revealed no negative effects on nontarget organisms, suggesting that the modified EPSPS protein in the tissues of this line is not toxic to organisms. The lack of known toxicity of EPSPS suggests no potential for deleterious effects on beneficial organisms such as bees and earthworms. The use of glyphosate herbicide in the cultivation of corn line GA21 or its offspring is regulated by the EPA under its existing regulations for the registration of pesticide use. EPA has considered the impacts on the environment, including effects on nontarget organisms in establishing residue tolerances for glyphosate on glyphosate-tolerant corn lines (EPA, 1997).

APHIS concludes that the unconfined growth of corn line GA21, and products derived from it, will have no deleterious effects on organisms recognized as beneficial to agriculture (e.g., earthworms, honey bees) or on other organisms, including any species recognized as threatened or endangered in the United States.

D. Potential Impacts on Biodiversity

As detailed in the sections above, we have concluded that corn line GA21 is no more likely to become a weed than other corn lines developed by traditional breeding techniques, is unlikely to increase the weediness potential of any other cultivated plant or native wild species with which this line can interbreed, and will not harm threatened and endangered species and non-target organisms. Based on this analysis, APHIS concludes that the potential impact on biodiversity of corn line GA21 is equivalent to that of currently commercialized corn lines.

E. Potential impacts on agricultural and cultivation practices or on processed agricultural commodities.

Consistent with its statutory authority which defines plant pests as those organisms which cause direct or indirect damage to plants and plant products, APHIS evaluated whether corn line GA21 might indirectly impact agricultural practices or harm plant products such as some agricultural commodities. APHIS considered the potential negative impacts associated with the cultivation of glyphosate-tolerant plants on current agricultural practices used for control of annual and perennial grasses and broad-leaved weeds. An issue considered is whether the introduction of

crops tolerant to glyphosate will result in a significant increase in the use of the herbicide, and thereby lead to the evolution of weeds which are resistant to glyphosate. The development of weeds resistant to glyphosate is unlikely given that plants are inherently intolerant to glyphosate due to its unique mode of action. In the unlikely event that glyphosate-tolerant weeds evolve, existing herbicides on the market, with a mode of action dissimilar to glyphosate, could be used. Based on its analysis, APHIS concludes that there is unlikely to be any significant adverse impact on agricultural practices associated with the use of the GA21 corn line.

In APHIS' opinion, characteristics of the GA21 corn line reveal no difference in any trait or characteristic that could have an indirect plant pest effect on any processed agricultural commodity.

F. Consideration of potential environmental impacts associated with the cultivation of glyphosate tolerant corn outside the United States

In accordance with Executive Order 12114, January 4, 1979, entitled "Environmental effects abroad of major federal actions," APHIS has also considered potential environmental impacts associated with the cultivation of corn line GA21 outside the United States and its territories.

Our analysis of the biology of corn leads to the conclusion that the cultivation of corn line GA21 either domestically or abroad would not have an adverse impact on the environment. In all analysis conducted, corn line GA21 displayed no significant differences from its parent line, except for its ability to withstand the application of the herbicide glyphosate.

Any international trade in corn line GA21 would be fully subject to national and regional phytosanitary standards promulgated under the International Plant Protection Convention (IPPC) of the Food Agricultural Organization. International traffic of GA21 corn 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, administered by a Secretariat housed with the United Nations Food and Agriculture Organization in Rome, came into force on April 3, 1952. It 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 IPPC has also led to the creation of Regional Plant Protection Organizations such as the North American Plant Protection Organization (NAPPO). Trading partners of the United States will be kept informed of USDA's regulatory decisions through NAPPO and other fora. Mexico possesses wild Zea populations and thus may be concerned with the potential for introgression of genes from domesticated Zea mays into these wild populations where such genes may have a negative impact. However, Mexico's regulatory process requires a full evaluation of transgenic plants before they can be introduced into their environment.

It should be noted that all the existing national and international regulatory authorities and phytosanitary protocols that currently apply to introductions of new corn varieties internationally will apply to GA21 corn.

VI. CONCLUSIONS

APHIS has reviewed the information provided by Monsanto/Dekalb in its petition as well as other scientific data in evaluating corn line GA21. After careful analysis of the available information, APHIS has identified no significant impact to the

environment from a determination that the subject line should no longer be considered a regulated article under the regulations at 7 CFR Part 340. Thus, the proper alternative is to approve the petition so that corn line GA21 would have a nonregulated status when grown in the United States and its territories.

From our review, we have determined that corn line GA21: (1) exhibits no plant pathogenic properties and cannot incite disease in other plants; (2) is no more likely to become a weed than non-engineered parental lines; (3) is unlikely to increase the weediness potential of any other cultivated plant or native wild species with which it can interbreed; (4) will not cause damage to raw or processed agricultural commodities or have any significant adverse impact on agricultural practices in the United States, and (5) is unlikely to harm organisms, such as bees and earthworms, that are beneficial to agriculture, or threatened and endangered species or adversely impact biodiversity. These conclusions are based on factors discussed herein and in the determination document included as Appendix A.

Therefore, APHIS concludes that corn line GA21 does not pose a plant pest risk. Furthermore, corn line GA21 will be just as safe to grow as traditional nontransgenic corn lines that are not subject to regulation under 7 CFR Part 340, and that there should be no significant impact on the human environment if corn line GA21 were no longer considered to be a regulated article under its regulations (7 CFR Part 340).

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X. APPENDIX A: Determination of 97-008-01p