

engineered for tolerance to the herbicide glyphosate, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Monsanto Company and Dekalb Genetics Corporation in their petition for a determination of nonregulated status and an analysis of other scientific data. This notice also announces the availability of our written determination document and its associated environmental assessment and finding of no significant impact.

EFFECTIVE DATE: November 18, 1997.

ADDRESSES: The determination, an environmental assessment and finding of no significant impact, the petition, and any written comments received regarding the petition may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect those documents are asked to call in advance of visiting at (202) 690-2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Ray Dobert, Biotechnology Evaluation, BSS, PPQ, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-8365. To obtain a copy of the determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734-4885; e-mail: mkpeterson@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

On April 9, 1997, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 97-099-01p) from Monsanto Company of St. Louis, MO, and Dekalb Genetics Corporation of Mystic, CT (Monsanto/Dekalb), seeking a determination that a corn line designated as GA21, which has been genetically engineered for tolerance to the herbicide glyphosate, does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On August 13, 1997, APHIS published a notice in the *Federal Register* (62 FR 43311-43312, Docket No. 97-052-1) announcing that the Monsanto/Dekalb petition had been received and was available for public review. The notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject corn line and food

products derived from it. In the notice, APHIS solicited written comments from the public as to whether the subject corn line posed a plant pest risk. The comments were to have been received by APHIS on or before October 14, 1997. APHIS received no comments on the subject petition during the designated 60-day comment period.

Analysis

Corn line GA21 has been genetically engineered to contain a modified corn 5-enolpyruvylshikimate-3-phosphate-synthase (EPSPS) gene, which, when expressed in the plant, confers tolerance to the herbicide glyphosate. The modified corn EPSPS gene was introduced into the parental inbred corn line AT by the particle acceleration method, and its expression is controlled in part by the rice actin promoter and intron and the NOS 3' termination sequence derived from the plant pathogen *Agrobacterium tumefaciens*.

Corn line GA21 has been considered a regulated article under APHIS' regulations in 7 CFR part 340 because it contains gene sequences derived from a plant pathogen. However, evaluation of field data reports from field tests of the subject corn line conducted under APHIS notifications since 1994 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the subject corn plants' release into the environment.

Determination

Based on its analysis of the data submitted by Monsanto/Dekalb, and a review of other scientific data and field tests of the subject corn line, APHIS has determined that corn line GA21: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than corn developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not harm other organisms, including agriculturally beneficial organisms and threatened and endangered species; and (5) should not cause damage to raw or processed agricultural commodities. Therefore, APHIS has concluded that corn line GA21 and any progeny derived from hybrid crosses with nontransformed corn varieties will be just as safe to grow as traditionally bred corn lines that are not regulated under 7 CFR part 340.

The effect of this determination is that the Monsanto/Dekalb corn line designated as GA21 is no longer considered a regulated article under APHIS' regulations in 7 CFR part 340.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 97-052-2]

Monsanto Co. and Dekalb Genetics Corp.; Availability of Determination of Nonregulated Status for Genetically Engineered Corn Line

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that a corn line developed by Monsanto Company and Dekalb Genetics Corporation designated as GA21, which has been genetically

Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of corn line GA21 or its progeny. However, importation of the subject corn line or seeds capable of propagation is still subject to the restrictions found in APHIS' foreign quarantine notices in 7 CFR part 319.

National Environmental Policy Act

An environmental assessment (EA) has been prepared to examine the potential environmental impacts associated with this determination. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on that EA, APHIS has reached a finding of no significant impact (FONSI) with regard to its determination that the Monsanto/Dekalb corn line GA21 and lines developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and the FONSI are available upon request from the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Done in Washington, DC, this 28th day of November 1997.

Craig A. Reed,

Acting Administrator, Animal and Plant Health Inspection Service.

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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.

A handwritten signature in cursive script, reading "John H. Payne", written over a horizontal line.

John H. Payne, Ph.D.
Director

Biotechnology and Scientific Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date: NOV 18 1997

Keywords: corn; glyphosate tolerant; EPSPS

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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).

VII. REFERENCES

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

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APPENDIX A

**DETERMINATION OF NONREGULATED STATUS FOR
GLYPHOSATE-TOLERANT
CORN LINE GA21**

**Petitioners: Monsanto Company & Dekalb Genetics Corporation
Petition Number: 97-099-01p**

**United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Pest and Quarantine
Biotechnology and Scientific Services
Riverdale, Maryland**

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I. SUMMARY

APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act (FPPA), (7 U.S.C. 150aa-150jj) as amended, and the Plant Quarantine Act (PQA), (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. Section 340.6 of the regulations, entitled, "Petition 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.

On April 9, 1997, the Animal and Plant Health Inspection Service (APHIS) received a petition from the Monsanto Company (Monsanto) and Dekalb Genetics Corporation (Dekalb) requesting a determination that transgenic glyphosate tolerant corn line GA21 (hereafter referred to as line GA21) does not pose a plant pest risk and therefore, should no longer be considered a regulated article. On August 13, 1997, APHIS announced the receipt of the Monsanto/Dekalb petition in the *Federal Register* (62 FR 43311-43312, Docket No. 97-052-1), seeking comments from the public. The public comment period ended on October 14, 1997. In the *Federal Register* notice, APHIS indicated its role in the process of reviewing the Monsanto/Dekalb petition and the role of the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA).

The Animal and Plant Health Inspection Service (APHIS), on reviewing the Monsanto/Dekalb petition 97-099-01p, has concluded that the glyphosate tolerant corn line GA21 does not present any plant pest risk, and is, therefore, determined to no longer be considered a regulated article under its regulations at 7 CFR 340. As such, the applicant is no longer required to obtain a permit or notify APHIS for the unrestricted introduction and movement of corn line GA21 into the environment within the continental United States and its territories. Importation of corn line GA21 still will remain regulated according to Foreign Quarantine Notice regulations at 7 CFR 319.

The glyphosate-tolerant corn (*Zea mays*) line GA21 has been developed in an effort to provide corn producers with a novel weed control option. Corn line GA21 has been genetically engineered to contain a modified corn 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene, which when expressed in the plant, confers tolerance to the herbicide glyphosate (N-phosphonomethylglycine). The modified EPSPS protein is 99.3% identical to the EPSPS normally produced by corn plants. The introduced gene also has accompanying DNA regulatory sequences that modulate and direct its expression. The modified gene and its regulatory sequences were introduced into the inbred corn line (AT) via the particle bombardment technique that results in direct introduction of genes into the plant genome. The corn line GA21 is considered a regulated article because it contains regulatory sequences from the plant pest *Agrobacterium tumefaciens*.

APHIS has determined that corn line GA21 does not present a plant pest risk and will no longer be considered a regulated article, under APHIS regulations at 7 CFR Part 340. The Agency decision is based on an analysis of data provided to APHIS by Monsanto/Dekalb as well as other scientific data relating to the potential plant pest risk of corn line GA21. From our review, we have determined that this line: (1) exhibits no plant pathogenic properties; (2) is no more likely to become a weed than its non-engineered parental varieties; (3) is unlikely to increase the weediness potential for any other cultivated plant or native wild species with which it can interbreed; (4) is unlikely to harm organisms, such as bees and earthworms, that are beneficial to agriculture, or threatened and endangered species; and (5) will not cause damage to raw or processed agricultural commodities

The potential environmental impacts associated with this determination have been examined in accordance with regulations and guidelines implementing the National Environmental Policy Act of 1969, as amended (42 USC 4321 *et seq.*) and pursuant implementing regulations (40 CFR 1500-1508, 7 CFR Part 1b; 7 CFR Part 372). An Environmental Assessment (EA) was prepared and a Finding of no Significant Impact (FONSI) was reached by APHIS for the determination that corn line GA21 is no longer a regulated article under its regulations at 7 CFR Part 340. This decision does not release corn line GA21 from regulations administered by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) and the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (P.L. 104-179), (21 U.S.C. 301 *et seq.*).

The body of this document consists of two parts: (1) background information which provides the regulatory framework under which APHIS has regulated the field testing, interstate movement, and importation of the subject corn line, as well as a summary of comments provided to APHIS on its proposed action; and (2) analysis of the key factors relevant to APHIS' decision that corn line GA21 does not present a plant pest risk.

II. BACKGROUND

A. APHIS Regulatory Authority

APHIS regulations at 7 CFR 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act (FPPA), (7 U.S.C. 150aa-150jj) as amended, and the Plant Quarantine Act (PQA), (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. Under these regulations, a genetically engineered organism is deemed a regulated article if either 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 APHIS has reason to believe that the genetically engineered organism presents a plant pest risk. The FPPA gives the U.S. Department of Agriculture (USDA) the authority to regulate plant pests and other articles to prevent direct or

indirect injury, disease, or damage to plants and plant products. In addition, the PQA provides an additional level of protection by enabling USDA to regulate the importation and movement of nursery stock and other plants that may harbor injurious pests.

Before the introduction of a regulated article, a person is required under Section 340.0 of the regulations to either (1) notify APHIS in accordance with Section 340.3 or (2) obtain a permit in accordance with Section 340.4. Introduction under notification (Section 340.3) requires that the introduction meets specified eligibility criteria and performance standards. The eligibility criteria impose limitations on the types of genetic modifications that qualify for notification, and the performance standards impose limitations on how the introduction may be conducted. Under Section 340.4, a permit is granted for a field trial when APHIS has determined that the conduct of the field trial, under the conditions specified by the applicant or stipulated by APHIS, does not pose a plant pest risk.

An organism is not subject to the regulatory requirements of 7 CFR Part 340 when it is demonstrated to present no plant pest risk. Section 340.6 of the regulations, entitled "Petition 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 the agency determines that the regulated article does not present a risk of introduction or dissemination of a plant pest, the petition will be granted, thereby allowing for unregulated introduction of the article in question.

Corn line GA21 has been considered a "regulated article" under Part 340.0 of the regulations because certain noncoding regulatory sequences were derived from *Agrobacterium tumefaciens*, which is on the list of organisms in the regulation of widely recognized plant pathogens. APHIS believes it is prudent to provide assurance prior to commercialization that organisms, such as the subject corn line, that are developed in part from plant pest sequences, do not present any potential plant pest risk. Such assurance may aid the entry of new plant varieties into commerce or into breeding and development programs. The decision by APHIS that corn line GA21 is no longer a regulated article is based in part on evidence provided by Monsanto/Dekalb concerning the biological properties of this corn line and its similarity to other corn varieties grown using standard agricultural practices for commercial sale or private use.

The fact that APHIS regulates genetically engineered organisms having plant pest components does not carry with it the presumption that the presence of part of a plant pest makes a whole plant a pest or that the plants or genes are pathogenic (McCammon and Medley, 1990). APHIS' approach to plant pest risk is considerably broader than a narrow definition that encompasses only plant pathogens. Other traits, such as increased weediness, and harmful effects on beneficial organisms, such as earthworms and bees, are clearly subsumed within what is meant by direct or indirect plant pest risk. In APHIS' regulations at 7 CFR Part 340, a "plant pest" is defined as: "Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied

with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any - processed, manufactured, or other products of plants."

A determination that an organism does not present a plant pest risk can be made under this definition, especially when there is evidence that the plants under consideration: (1) exhibit no plant pathogenic properties; (2) are no more likely to become a weed than their non-engineered parental varieties; (3) are unlikely to increase the weediness potential for any other cultivated plant or native wild species with which the organism can interbreed; (4) do not cause damage to processed agricultural commodities; and (5) are unlikely to harm other organisms, such as bees, that are beneficial to agriculture, or threatened and endangered species. Evidence presented by Monsanto/Dekalb bears on all of these topics. In addition, because the Monsanto/Dekalb petition seeks a determination regarding corn line GA21, it should be established that there is a reasonable certainty that any new corn varieties bred with this line will not exhibit plant pest properties that are substantially different from any observed for corn in traditional breeding programs or as seen in the development of corn line GA21 already field tested.

B. EPA and FDA Regulatory Authority

Corn line GA21 is currently subject to regulations administered by the EPA and the FDA (described in Section II. of the Environmental Assessment) that require registration of pesticides prior to their distribution and sale and establishment of tolerances for pesticide residues in raw agricultural products. APHIS' decision on the regulatory status of the corn line GA21 under APHIS' regulations at 7 CFR 340, in no way releases this corn and its progeny from EPA and FDA regulatory oversight.

III. PUBLIC COMMENTS

APHIS received no comments on the Monsanto/Dekalb petition during the designated 60-day comment period that ended October 14, 1997.

IV. BIOLOGY AND CULTIVATION OF CORN

A brief discussion of corn biology follows in the next paragraph to help inform the subsequent analysis. This information is expanded in subsequent sections when it is relevant in addressing particular risk assessment issues.

Zea mays Linnaeus, known as maize throughout most of the world, and as corn in the United States, is a large, annual, monoecious grass, that is grown for human consumption, animal feed, silage, vegetable oil, sugar syrups, and other miscellaneous uses. Corn is grown commercially throughout the United States (Jewell, 1989). Corn has been cultivated since the

earliest historic times from Peru to central North America. Researchers believe that the domestication of *Z. mays* was centered in a region of Mexico near Mexico City (Galinat, 1988; Gould, 1968). *Zea* is a genus of the family Gramineae (the grass family) containing four described species: *Z. mays*, cultivated corn and teosinte; *Z. diploperennis*, diploperennial teosinte; *Z. luxurians*; and *Z. perennis*, a perennial teosinte. Of the four species of *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). The other species are occasional research subjects at university or experiment stations. *Z. perennis* is reported as established from James Island, South Carolina (Hitchcock and Chase 1951).

Annual teosinte (*Zea mays* subsp. *mexicana* Schrad) and corn are genetically compatible, and in areas of Mexico and Guatemala where they coexist, they have been reported to produce hybrids (Serratos et al., 1995). Indeed, corn was derived from teosinte, probably more than 8,000 years ago. During the transformation process of teosinte to cultivated corn, the latter gained several valuable agronomic traits that were not expressed in teosinte, but it lost the ability to survive in the wild. Cultivated corn and wild diploid and tetraploid members of *Zea* can be crossed to produce fertile F₁ hybrids. Nonetheless, in the wild, introgressive hybridization currently is limited, in part, by several factors including differences in flowering time, block inheritance, developmental morphology and timing of the reproductive structures, dissemination, and dormancy (Galinat, 1988), although research suggests introgression has occurred in the past (Doebley, 1990; Giddings et al., 1990). First-generation hybrids are less fit and show substantially reduced reproductive capacity which acts as a significant constraint on introgression. Seed from the F₁ hybrids does not disseminate well, and they do not produce seed of a quality that farmers find particularly useful for either human or animal consumption. Therefore, in spite of occasional gene flow over historical time, maize and teosinte have maintained separate identities in Mesoamerica for thousands of years, with modern corn being entirely dependent on human intervention for its persistence. During the transformation of cultivated corn from teosinte, corn gained several valuable agronomic traits, but lost the ability to survive in the wild. Although corn easily crosses with teosinte, teosinte is not present in the U. S. Corn Belt.

The closest known relative of *Zea* is *Tripsacum*, a genus of eleven species, widely distributed in North and South America (de Wet et al., 1981; Gould, 1968). Three species occur in the United States, two of which, *Tripsacum floridanum* (Florida Gamagrass) and *Tripsacum lanceolatum* (Mexican Gamagrass), are confined to the southernmost states of the United States. Only one, *Tripsacum dactyloides* (Eastern Gamagrass), has a distribution that includes the U.S. "corn belt" (Gould, 1968). *Tripsacum* differs from corn in many respects, including chromosome number ($n=9$), in contrast to *Zea* ($n=10$). All species of *Tripsacum* can cross with *Zea*, but only with difficulty and the resulting hybrids are sterile (Galinat, 1988). No cases of gene flow between corn and its wild relatives have been documented in the United States.

V. PLANT PEST RISK ASSESSMENT AND THE DETERMINATION

Based on information on the biology of corn, data presented by Monsanto/Dekalb and scientific data on other topics relevant to a discussion of plant pest risk, APHIS concluded the following regarding the properties of corn line GA21.

A. The Introduced Genes, Their Regulatory Sequences and Their Products in Corn Line GA21 do not Present a Plant Pest Risk.

The glyphosate-tolerant corn line GA21 was obtained by transforming a cell culture of the inbred corn line AT, by the method of particle bombardment, with a 3.4 Kb NotI restriction fragment from a plasmid designated pDPG434. This plasmid fragment contained the modified corn 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene along with regulatory sequences required for efficient gene expression. Transformed corn tissue was grown in the presence of glyphosate to select for cells with the modified-EPSPS gene.

The modified corn EPSPS gene was developed using in vitro mutagenesis of the cloned wild-type EPSPS from corn (Lebrun et al., 1991). In plants and microorganisms, EPSPS is involved in the biosynthesis of aromatic amino acids, vitamins, and many secondary metabolites. EPSPS is not present in animals (Steinrücken and Amrhein 1980). The enzyme EPSPS condenses phosphoenolpyruvic acid (PEP) and 3-phosphoshikimic acid (S3P) to 5-enolpyruvyl-3-phosphoshikimic acid. In unmodified corn lines, glyphosate inhibits EPSPS, a key enzyme in the shikimic acid pathway, disrupting protein synthesis which results in plant death. In vitro tests by the applicants demonstrated that the modified EPSPS is insensitive to glyphosate inhibition.

The modified EPSPS is 99.3% homologous to the wild-type corn EPSPS and provides tolerance to the herbicide glyphosate. The modified EPSPS was fused to a chloroplast transit peptide sequence that was based on sequences derived from corn and sunflower (*Helianthus annuus*) ribulose-1,5-bisphosphate carboxylase oxygenase (RuBisCo) (Lebrun et al., 1996). This transit peptide directs the modified EPSPS to the chloroplast, the normal site of aromatic amino acid biosynthesis and subcellular location of wild-type EPSPS. The fusion of the modified EPSPS with the chloroplast transit peptide results in an additional methionine at the N-terminal end of the EPSPS protein. A promoter and intron derived from the rice (*Oryza sativa*) actin 1 gene (McElroy et al., 1990) was used to direct and enhance the expression of the modified EPSPS gene in the plant. Promoters direct the production of the proteins to the cells where the gene product must be produced so the transgenic plants express the desired phenotype. A terminator sequence (NOS 3') from *Agrobacterium tumefaciens* is present to terminate transcription and direct polyadenylation (Fraleigh et al. 1983). Plasmid pDPG434 contains other selectable marker genes (*bla* for beta-lactamase and *lacZ* for beta-galactosidase) and an origin of replication (ColE1 or *ori*), all from *E. coli*, that facilitate the maintenance of the plasmid in *E. coli*. These genes were not included in the DNA fragment that was used to transform the parental corn line and evidence has been submitted that these sequences are not present in corn line GA21.

The plasmids were introduced in the corn tissue by particle gun method of transformation (Sanford, 1990, Gordon-Kamm et al., 1990), also referred to as the biolistic method. In this method plant tissues are bombarded with particles that are coated with DNA, with the result that particles are able to penetrate the cell wall and the cell membrane and deliver the DNA to the interior of the cell. Particles are typically tungsten or gold with a diameter of 0.2 to 4.0 microns. DNA introduced in this way generally has been shown to be incorporated into the nucleus (Hain et al. 1985).

Southern blot analysis was performed on DNA isolated from corn line GA21 using probes for the modified EPSPS gene, rice actin promoter, NOS 3' terminator, ColE1 origin of replication, and *bla*. The results indicated that corn line GA21 contains a single insertion event that contains two copies of the modified corn EPSPS gene cassette, and a third copy which was found to contain the rice actin promoter and the modified EPSPS sequence without the NOS 3' end. Analysis using the ColE1 and *bla* gene probes indicated that these genes were not present in corn line GA21.

Consistent with the Southern blot analysis, western blot analysis of protein submitted in the petition confirm that a single immunoreactive protein of the expected molecular weight (as predicted by the modified EPSPS gene sequence) is expressed in leaf tissue. Enzyme-linked immunosorbent assays (ELISA) were used to determine the levels of the expressed modified EPSPS in forage (leaf) and grain (seed) tissue. Since the endogenous and modified EPSPS are over 99% similar at the amino acid level, the ELISA assay used could not distinguish between these two proteins. Levels of EPSPS in non-transgenic control plants was below the limit of detection, and levels in corn line GA21 had a mean value of 119 $\mu\text{g/g}$ fresh weight in forage and 3.2 $\mu\text{g/g}$ in grain. The ELISA data were in agreement with the Western blot results which indicated that the expression of the modified EPSPS protein in line GA21 was at least one order of magnitude greater than that of the endogenous EPSPS in parental lines. Since EPSPS is widely prevalent in plants and microbes its presence is not associated with disease or injury in plants. Thus, this gene and the associated protein do not present a plant pest risk.

Monsanto/Dekalb has presented evidence in its petition that the modified EPSPS gene is stably integrated into the corn genome of corn line GA21. As integrated pieces of plant chromosomes, introduced foreign DNA is subject to the same rules governing chromosomal rearrangements and gene stability as other plants. Segregation data for six generations of line GA21 are consistent with molecular data indicating a single insertion site and simple Mendelian inheritance. The stability of the insert has been demonstrated through five generations of crossing and one generation of self pollination.

Despite the presence of certain pathogen-derived sequences from *A. tumefaciens* in the genome of corn line GA21, no crown gall disease symptoms were observed by Monsanto/Dekalb in this line during greenhouse or field studies. Furthermore, Monsanto/Dekalb provides evidence that expression of the introduced gene does not result in disease symptoms or the synthesis of products toxic to other organisms. Monsanto/Dekalb also has monitored field tests of corn line

GA21 to verify that the severity of any disease or insect infestation of the transgenic plants did not differ from that of the parental line. No difference in disease and insect susceptibility was observed at any field test site where the subject sublines were tested in the United States and Puerto Rico. Thus, the introduced regulatory sequences do not confer a plant pest risk.

There is no published evidence for the existence of any mechanism, other than sexual crossing of compatible *Zea* species, by which these genetic sequences can be transferred to other organisms. Comparative analyses of numerous gene sequences from microorganisms and plants have never, to our knowledge, yielded any published evidence of strong inter-kingdom gene homologies that would be indicative of recent or frequent gene exchanges between plants and microorganisms, except for *Agrobacterium*-mediated gene transfers. Movement of genes from plants to microorganisms may have occurred over evolutionary time (Carlson and Chelm, 1986; Wakabayashi et al., 1986; Doolittle et al, 1990). A single report (Bryngelsson et al., 1988) has suggested that plant DNA can be taken up by a parasitic fungus, but no evidence has ever been forthcoming that such DNA uptake has resulted in the frequent transfer of a functional DNA sequence. Even if a rare plant-to-microbe gene transfer were to take place, there is no reason to believe that such a transfer of any of the sequences in line GA21 would pose any plant pest risk. We conclude that concerns regarding DNA transfer from corn line GA21 to microorganisms are, at best, highly putative and speculative.

B. Corn Line GA21 has No Significant Potential To Become a Weed.

Most definitions of weediness stress the undesirable nature of weeds from the point of view of humans; individual definitions differ in approach and emphasis (Baker, 1965). Baker (1965) defines a plant as a weed if, in any specified geographical area, its populations grow entirely or predominantly in situations markedly disturbed by man (without, of course, being deliberately cultivated). He also described the ideal characteristics of weeds as including the following: discontinuous germination and long-lived seeds; rapid seedling growth; rapid growth to reproductive stage; long continuous seed production; self-compatibility, but not obligatory self-pollination or apomixis; if outcrossing, use of wind or an unspecialized pollinator; high seed number under favorable conditions; high germination rates, and seed production under a wide range of environmental conditions; high tolerance or plasticity of climatic and edaphic variation; special adaptations for dispersal; good competitiveness achieved through, for example, allelochemicals or choking growth; and, if perennial, then exhibiting vigorous vegetative reproduction, brittleness either at the lower nodes or of rhizomes or rootstocks, and having the ability to regenerate from severed rootstocks. Although Baker's characteristics have been criticized by some ecologists as nonpredictive, no more broadly accepted suite of characteristics has been defined by ecologists (Williamson, 1994). In our view, there is no formulation that is clearly superior at this time. 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. Cultivated corn lacks most of Baker's "weedy" characteristics (Keeler, 1989). Corn is not listed as a common, serious or principal weed or a weed of current or

potential importance in the United States or Canada in most weed literature (Holm et al., 1997; Muenscher, 1955; USDA, 1971; Weed Science Society of America, 1992). Corn appears as a volunteer in some fields and roadsides, but it never has been able to establish itself outside of cultivation (Gould, 1968).

Expression of the modified EPSPS protein in corn line GA21 will not likely provide a competitive advantage sufficient to cause it to be any more "weedy" than other corn cultivars. In agricultural settings, currently available herbicide tolerant corn plants are no more difficult to control (i.e., weedier) than non-tolerant plants. Techniques other than genetic engineering have been used to produce widely used corn varieties tolerant to the herbicides imidazolinone, sethoxydim and the sulfonyleurea class of herbicides. Even in the unlikely event of the movement of a glyphosate tolerance gene to other species (see below), glyphosate is not widely used on these plants as a control measure. If glyphosate-resistant plants did develop, many other methods of control would be readily available to eliminate these plants.

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 cultivars that are the result of traditional breeding. Corn line GA21 has retained the agronomic characteristics of the parental inbred corn line, AT. Monsanto/Dekalb has provided qualitative assessments regarding seedling emergence, seedling vigor, plant height, yield characteristics, tasseling, pollen and silk growing degree units, stay-green (a senescence rating), disease and pest susceptibilities, and several other tests. There is no reason to believe that the introduction of the modified EPSPS gene would have any effect on the reproductive biology of the corn line GA21, unless the insertion event interrupted a genetic locus critical for the normal reproductive function. 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 variety.

Based on this analysis, APHIS concludes that, with the exception of tolerance to glyphosate herbicide, corn line GA21 has agronomic traits similar to those of traditionally bred corn, and it does not exhibit traits that would cause increased weediness.

C. Corn Line GA21 Will Not Increase The Weediness Potential Of Any Other Plant With Which They Can Breed.

APHIS evaluated the potential for gene flow from corn line GA21 to other cultivated corn and wild relatives. Two potential impacts that might result from this sexual transfer of genes were evaluated: first, that the traits from corn line GA21 might cause free-living relatives to become "weedier", and second, that the transfer of genes might cause population changes that would lead to reduced genetic diversity.

The reproductive biology of corn and the distribution and sexual compatibility of its closest

relatives was discussed previously (section IV, of the Determination). While cultivated corn is sexually compatible with and has been shown to form fertile hybrids with teosinte in areas of Mexico and Guatemala where they co-exist, teosinte is not present in the U.S. While hybridization and introgression could occur in Mexico or Guatemala if transgenic corn were to cross with native teosinte, several factors in combination effectively reduce the probability of introgression. Corn and teosinte have maintained separate identities for hundreds of years in Mesoamerica, in spite of occasional introgression (Giddings et al., 1990). Other relatives of corn in the genus *Tripsacum* occur in the U.S., but hybrids with *Zea* are difficult to obtain and are often sterile or have greatly reduced fertility. Neither the weediness nor the survival of *Tripsacum*, therefore, will be affected by the cultivation of these transgenic corn plants because the transgenic variety poses no increased weediness itself and the two species are unlikely to successfully cross in nature. Furthermore, none of the sexually compatible relatives of corn in the U.S. are considered to be serious, principal, or common weeds in the U.S. (Holm et al., 1997); therefore it is unlikely that introgression of the modified EPSPS gene would have any impact on their populations as they would not be routinely subject to herbicide treatments.

Gene introgression into other corn cultivars via cross pollination is possible. If pollen from corn line GA21 were transferred to any receptive corn stigma within the period of pollen viability, cross-pollination would occur. This potential transfer becomes more unlikely as distance increases from the transgenic plants, and from a practical standpoint becomes increasingly unlikely at a distance much greater than the foundation seed isolation distance of 660 feet. In the U.S., farmers generally purchase hybrid corn seed for planting from a commercial source. If pollen of corn line GA21 were to fertilize the corn in a farmer's field, this corn will likely be harvested for products or other uses and would not likely be used as seed. Therefore, fertilization of nontransgenic corn by pollen from corn line GA21 grown for sale as food or feed should not result in dissemination of the trait to seed populations used for planting.

Should movement of genetic material take place to any receptive plants, and glyphosate resistance was transferred, no competitive advantage would be conferred because glyphosate is not used with these plants when they are found in non-agricultural areas. In agricultural areas such plants would be controlled by normal agronomic practices. 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 varieties produced by traditional breeding techniques.

D. Corn Line GA21 Is Not Harmful To Beneficial, Threatened or Endangered Organisms.

Consistent with its statutory authority and requirements under NEPA, APHIS evaluated the potential for corn line GA21 plants, plant products, and the modified EPSPS protein to have damaging or toxic effects directly or indirectly on nontarget organisms, particularly those that are recognized as beneficial to agriculture. APHIS also considered potential impacts on other nontarget pests, since such impacts could affect the potential for changes in agricultural practices.

There is no reason to believe that corn line GA21 will harm beneficial, threatened or endangered organisms. The enzyme and genetic material that confers glyphosate tolerance in corn line GA21 is 99.3% similar to that normally present in corn and is not known to have any toxic properties. EPSPS is an enzyme of the shikimate pathway for aromatic amino acid biosynthesis in plants and microorganisms, and is widely prevalent in the environment. Field observations of the subject corn line revealed no negative effects on nontarget organisms, suggesting that the modified EPSPS enzyme in corn line GA21 is not toxic to beneficial organisms. Knowledge of this enzyme's mode of action, and the lack of known toxicity for this protein suggest no potential for deleterious effects on beneficial organisms, such as bees and earthworms. The high specificity of EPSPS for its substrate makes it unlikely that the enzyme would metabolize endogenous substrates to produce any novel compounds toxic to beneficial organisms. The herbicide glyphosate is not metabolized any differently in corn line GA21 than in unmodified corn lines, and thus no new metabolites would be expected. APHIS has not identified any other potential mechanisms for deleterious effects on beneficial, threatened or endangered organisms.

E. Corn Line GA21 Will Not Adversely Impact 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. Biological diversity is the variety and variability among living organisms and the ecological complexes in which they occur (U.S Congress OTA, 1987). The glyphosate tolerance trait when present in corn line GA21 or in any other sexually compatible species would confer no competitive advantage in unmanaged environments, and thus is not expected to have an ecological impact. Based on this analysis, APHIS concludes that the potential impact on biodiversity of corn line GA21 line is equivalent to that of currently commercialized corn lines.

F. Corn Line GA21 Will Not Adversely Affect Agricultural Practices or Cause Damage To Raw Or Processed Agricultural Commodities.

The characteristics of corn line GA21 have no apparent attributes that could have an indirect plant pest effect on any raw or processed plant commodity. Although Monsanto/Dekalb did not provide detailed compositional analysis data in their petition, plants of corn line GA21 exhibited the typical agronomic characteristics of the parent corn during extensive testing in the laboratory, greenhouse and in the field. In APHIS' opinion, the components and processing characteristics of corn line GA21 should be no different from traditionally bred corn varieties and should not have an indirect plant pest effect on any processed plant commodity. In addition Monsanto/Dekalb has been in direct consultation with the Food and Drug Administration to assure that food and feed derived from this line are safe for human and animal consumption.

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 over 20 years of widespread use, only a single report of resistance to glyphosate (in annual ryegrass) has ever been reported (Pratley et al., 1996). 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 corn line GA21.

G. Consideration of Potential Environmental Impacts Associated with the Cultivation of Corn Line GA21 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.

Any international traffic in corn line GA21 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 through the United Nations Food and Agriculture Organization, 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 vast majority of IPPC signatories have promulgated, and are now administering, such legislation or guidelines. Mexico in particular has in place a regulatory process that would require a full evaluation of transgenic corn lines before they could be introduced into their environment. Our decision in no way prejudices regulatory action in any country. The IPPC has also led to the creation of regional plant protection organizations such as the North American Plant Protection Organization (NAPPO) whose member countries are the U.S., Canada, and Mexico. Our trading partners are kept informed of our regulatory decisions through NAPPO, and other fora. It should also be noted that all the existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new corn varieties internationally apply equally to the transgenic corn line covered by this analysis.

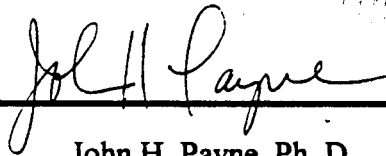
VI. CONCLUSION

APHIS has determined that corn line GA21 developed by Monsanto/Dekalb that have been field tested under APHIS authority will no longer be considered a regulated article under APHIS regulations at 7 CFR Part 340. Permits or notifications under those regulations will no longer be required from APHIS for field testing, importation, or interstate movement of corn line GA21 or its progeny. Importation of corn line GA21 or seeds capable of propagation are still, however, subject to the restrictions found in the Foreign Quarantine notice regulations at 7 CFR Part 319 just as applies to any other importation of corn seeds. This determination has been made based on data collected from these approved field trials, laboratory analyses and literature references presented herein which demonstrate that:

1. Neither the modified 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene, its product, nor the regulatory sequences confer on corn line GA21 or its progeny any plant pest characteristic. Although DNA from a pathogenic organism was used in its development, this corn line and plants derived from it are not infected by this organisms nor can this line incite disease in other plants.
2. The GA21 corn line is no more likely to become a weed than herbicide-tolerant corn which has been developed by traditional breeding techniques. Corn is not a weed, and there is no reason to believe that the introduced gene conferring tolerance to the herbicide glyphosate would enable corn to become a weed pest.
3. In nature, chromosomal genetic material from plants can only be transferred to another sexually compatible flowering plant by cross-pollination. Multiple factors ensure that gene introgression from corn line GA21 into wild plants in the United States and its territories is extremely unlikely. There are no significant populations of sexually compatible species of corn in the United States and its territories. Even in other regions, potential gene introgression from corn line GA21 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 lines.
4. There is no reason to believe that corn line GA21 will have a significant adverse impact on organisms beneficial to plants or agriculture, or other nontarget organisms, or will affect threatened or endangered species.
5. The use of corn line GA21 is unlikely to have any significant adverse impact on agricultural practices in the United States. The use of corn line GA21 or products derived from them will not cause damage to raw or processed agricultural commodities.

APHIS has also concluded that there may be new varieties bred from corn line GA21;

however, if such varieties are developed they are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for glyphosate tolerant corn already field tested, or those observed for corn lines developed from traditional breeding.



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Date: NOV 18 1997

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