

Agriculture (USDA), has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 98-216-01p) from Monsanto Company (Monsanto) regarding glyphosate-tolerant canola line RT73 (canola line RT73). Monsanto seeks a determination that canola line RT73 does not present a plant pest risk and should therefore no longer be a regulated article under regulations at 7 CFR Part 340.

Canola line RT73 has been engineered to express a CP4 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene from *Agrobacterium* sp. strain CP4 and a modified glyphosate oxidoreductase (goxv247) gene from *Ochrobactrum anthropi* LBAA. The gene EPSPS encodes a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme and goxv247 produces a glyphosate oxidoreductase (GOXv247) protein. The genes were introduced into canola via a *Agrobacterium*-mediated transformation protocol. The presence of these proteins in canola line RT73 confers tolerance to the herbicide glyphosate.

Field trials of Line RT73 have been conducted under permits and notification acknowledged by APHIS according to regulations at 7 CFR Part 340. Performance standards and conditions for such field trials require that the regulated article and its offspring must not persist in the environment after completion of the test. In accordance with APHIS procedures for implementing the National Environmental Policy Act (NEPA) (7 CFR Part 372), an Environmental Assessment (EA) was prepared prior to granting permits for field trials of glyphosate-tolerant canola. The EA for the previous introductions of glyphosate-tolerant canola addressed plant pest risk issues relative to the conduct of field trials under physical and reproductive confinement. This EA specifically addresses the potential for impacts to the human environment through use in agriculture of glyphosate-tolerant canola. Similarly, notifications were acknowledged based on the scientific review and the applicant's certification. The consultation process with the Food and Drug Administration (FDA) was completed in September, 1994.

Monsanto submitted a package to EPA in April 1998 for registration of glyphosate for over-the-top application on transgenic canola.

APHIS has considered the information provided by Monsanto in its petition as well as other scientific data relating to the potential plant pest risk of glyphosate-tolerant canola. A thorough evaluation of the potential for significant impact to the human environment through the unconfined, agricultural use of glyphosate-tolerant canola has brought APHIS to a Finding of No Significant Impact (FONSI). This conclusion is based upon:

1. Neither the genes that result in accumulation of CP4 EPSPS and GOXv247, nor the CP4 EPSPS and GOXv247 proteins, nor their associated regulatory sequences, confer on glyphosate-tolerant canola or its progeny any plant pest characteristic.
2. In nature, the gene that results in accumulation of CP4 EPSPS and GOXv247 proteins will not provide glyphosate-tolerant canola or its progeny with any measurable selective advantage over nontransformed canola plants in their ability to disseminate or to become established in the environment. There is no reason to believe that glyphosate-tolerant canola exhibits any increased weediness relative to that of traditional varieties.
3. The use of glyphosate-tolerant canola or its progeny in agriculture will not lead to an increase in weediness in any plant with which it can successfully interbreed.
4. The use of glyphosate-tolerant canola or its progeny in agriculture will not cause damage to raw or processed agricultural commodities.
5. The use of glyphosate-tolerant canola or its progeny in agriculture will not

have a significant impact on any beneficial organisms in the environment, or on any threatened or endangered species.

In conjunction with the FONSI, APHIS has made the determination that canola line RT73 and its progeny have no potential to pose a plant pest risk, and are, therefore, no longer regulated articles under regulations at 7CFR part 340.

II. INTRODUCTION

This EA examines potential environmental impacts from the unrestricted introduction of glyphosate-tolerant canola. Glyphosate-tolerant canola has been extensively field tested in Canada, Europe, and the United States. Monsanto has submitted field data reports for the U.S. release permits and notifications granted by APHIS. Monsanto has also submitted data from the Canadian trials. These reports give information on the biological and agronomic characteristics of the plant and the toxicant and compositional analysis of seeds and seed oil. All these traits fall well within the range of commercial varieties of canola. The only significant consistent difference between glyphosate-tolerant canola and the parental nontransformed variety is the increase in the CP4 EPSPS enzyme and GOXv247 protein that confer tolerance to glyphosate.

Testing in the U. S. has been conducted under USDA permits and notifications since 1995 (APHIS authorization numbers: 95-279-01r, 96-045-01r, 96-061-02r, 96-211-01r, 96-274-01r, 97-022-01r, 97-024-01r, 97-254-02n, 97-254-04n, 97-324-06n, and 97-309-03n). Field trial reports from these tests demonstrate no deleterious effects on plants, nontarget organisms, or the environment. Field trials in the United States were performed under conditions of physical and reproductive confinement. Further discussions of the biology of canola as well as of the genetic components of glyphosate-tolerant canola are found in the APHIS Determination of Nonregulated Status (Appendix A.).

Prior to issuing a permit or notification for a field release, APHIS analyzes the potential impacts associated with the proposed introduction in accordance with regulations and procedures implementing the National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 et seq.); 40 CFR Parts 1500-1508; 7 CFR Part 1b; 7 CFR Part 372. APHIS also evaluates the potential for significant impact to the human environment from its determination of nonregulated status.

A genetically engineered organism is considered a regulated article if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest, or if there is reason to believe that it is a plant pest. The transgenic canola plants described in the Monsanto petition have been considered regulated articles because they contain DNA sequences derived from the plant pathogens figwort mosaic virus and *Agrobacterium* sp. CP4 and because the plant pathogen *Agrobacterium tumefaciens* was used as a vector agent.

III. PURPOSE AND NEED

The purpose of this EA is to ascertain whether the approval of a petition submitted to USDA/APHIS for the determination of nonregulated status of glyphosate-tolerant canola, which will allow the unconfined introduction of the article, will have a significant impact on the environment. A petition was submitted to APHIS pursuant to regulations codified in 7 CFR Part 340 entitled "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests." The regulations govern the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. An organism is not subject to the regulatory requirements of 7 CFR Part 340 when it is demonstrated not to present a plant pest risk. Section 340.6 of the regulations, entitled "Petition Process for Determination of

Nonregulated Status," provides that a person may petition the Agency to evaluate submitted data and 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 would be granted, thereby allowing for unregulated introduction of the article in question. Permits and notifications under those regulations will no longer be required from APHIS for field testing, importation, or interstate movement of that article or its progeny. Normal agronomic practices with it, e.g., cultivation, propagation, movement, and cross-breeding could then be conducted without APHIS approval.

The FDA has authority to ensure the safety and wholesomeness of all food(s). The FDA policy statement concerning the regulation of foods derived from new plant varieties, including genetically engineered plants, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Regulatory oversight for the safety of any food or feed products derived from glyphosate-tolerant canola lines is under the jurisdiction of the FDA. FDA has granted a finding of 'No Concern' for canola line RT73 in September, 1994, (please see the FDA Home Page listed as below):

(<http://www.cfsan.fda.gov/~lrd/biocon.html>).

The EPA is responsible for the regulation of pesticides 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 prior to distribution or sale, unless exempt by EPA regulation. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA, and the FDA enforces the tolerances set by the EPA. A tolerance exemption for CP4 EPSPS was received on August 2, 1996 and for GOX on October 8, 1997 from the EPA (please see the EPA Federal Register notices):

(<http://www.epa.gov/docs/fedrgstr/EPA-PEST/1996/August/Day-02/pr-840DIR/pr-840.html>), (<http://www.epa.gov/fedrgstr/EPA-PEST/1997/October/Day-08/p26190.htm>) for respective proteins.

Monsanto submitted a package to EPA in April 1998 for registration for use of glyphosate for the over-the-top application on transgenic canola.

IV. ALTERNATIVES

In the course of preparing the environmental assessment for this petition, APHIS considered the following two alternatives: (1) deny the petition, so that glyphosate-tolerant canola would continue to be regulated under 7 CFR Part 340; and (2) approve the petition, so that permits would no longer be required from APHIS under 7 CFR Part 340 for glyphosate-tolerant canola when grown in the United States and its territories. Based on the biology of canola, the nature of the genetic change, data and information presented by Monsanto, and scientific literature, APHIS could not find any basis for denying the petition (Alternative 1).

V. POTENTIAL ENVIRONMENTAL IMPACTS

Potential impacts to be addressed in this EA are those that pertain to the use of glyphosate-tolerant canola in the absence of confinement.

Potential impacts based on increased weediness of glyphosate-tolerant canola relative to traditionally bred canola

Almost all definitions of weediness stress as core attributes the undesirable nature of weeds from the point of view of humans; from this core, individual definitions differ in approach and emphasis (Baker, 1965; de Wet and Harlan, 1975; Muenscher, 1980). In further analysis of weediness, Baker (1965) listed 12 common weed attributes, almost all pertaining to sexual and asexual reproduction, which can be used as an imperfect guide to the likelihood that a plant will behave as a weed. Keeler (1989) and Tiedje et al. (1989) have adapted and analyzed Baker's list to develop admittedly imperfect guides to the weediness potential of transgenic plants; both authors emphasize the importance of looking at the parent plant and the nature of the specific genetic changes.

Despite its ability to volunteer, escape from cultivated fields, and form temporary occasional populations, the parent plant in this petition, *Brassica napus*, is not a weed under conditions found in the United States. *B. napus* is listed as a weed in Weed Science Society of America (1992). The comprehensive world list of Holm et al. (1991) does not list it as a serious or principal weed anywhere in the world; they do, however, give two listings as a common weed: one in Finland and one in Kenya. *B. napus* is mentioned as an "occasional weed" by Munz (1968), and "sometimes escaped" by Bailey (1949). Monsanto has submitted substantial evidence to indicate the lack of weedy nature of transformed canolas under agricultural conditions. They have submitted data or information on germination, seed production, pest and disease resistance, response to abiotic factors (such as drought, heat, and frost), on salinity, seed dormancy, and sensitivity to herbicides other than glyphosate, and other fitness characteristics. None of these characteristics indicate an increase in weediness potential for canola line RT73.

The relevant introduced trait, glyphosate tolerance, is unlikely to increase weediness of this canola unless glyphosate is the only alternative for control of the plant. Such an alteration, because it does not confer any pest resistance or alter reproductive biology or change any physiology related to survival, does not confer a competitive advantage favoring the canola plants over unmodified varieties. To increase weediness of the canola plant there would have to be selection pressure on glyphosate-tolerant canola (Tiedje et al., 1989; Office of Technology Assessment, 1988). Monsanto data from field trials show no obvious increase in volunteers from seed, increase in seed dormancy, or other variation indicative of increased weediness. Moreover, Monsanto presents evidence that glyphosate-tolerant canola is as readily controlled with non-glyphosate herbicides as the nontransformed canola.

Potential impacts from outcrossing of glyphosate-tolerant canola to wild relatives

Whereas intra-specific crosses between *B. napus* cultivars occur readily, inter-specific crosses between *B. napus* and related species occur with varying degrees of success and are influenced greatly by the direction of the cross. Even where there is a possibility of hybridization between *B. napus* and a related species growing in the vicinity of a release, poor vigor and high sterility in the hybrids will generally mean that hybrids and their progeny will not survive in either an agricultural or natural habitat (Scheffler and Dale, 1994).

The potential of a gene movement, at very low level, from *B. napus* to other *Brassica* spp. such as *B. juncea* or *B. rapa*, will be subject to the availability of the target organism and the reduced fertility of the hybrids. *B. napus* can cross with *B. rapa* (under co-cultivation 1.3% hybrid seed was formed) and produce hybrids of much reduced fertility; *B. napus* can also cross at low frequency with *B. juncea* (under field co-cultivation 4.7% hybrid seed formed) and these hybrids can produce a small amount of seed and fertile progeny (Bing, 1991). The gene that codes for glyphosate tolerance should not confer a competitive advantage in these species unless glyphosate is used for control.

Gene movement is also possible to other members of the Brassicaceae, e.g. *Herschfeldia incana* (*Brassica adpressa*), and *Raphanus raphanistrum*. Gene movement is at extremely low levels, and as with members of the genus *Brassica*, it is unlikely that the gene that codes for glyphosate tolerance would confer a competitive advantage in these species unless glyphosate is used for control.

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

There is no reason to believe that deleterious effects or significant impacts on nontarget organisms, including beneficial organisms and endangered or threatened species, would result from the cultivation of glyphosate-tolerant canola. The CP4 EPSPS enzyme and GOXv247 protein encoded by EPSPS and *goxv247* genes respectively confer tolerance to the herbicide glyphosate in canola line RT73. Both proteins and the genes are not known to have any toxic properties.

Consideration of potential environmental impacts associated with the cultivation of glyphosate-tolerant canola outside the United States

APHIS has also considered potential environmental impacts outside the United States and its territories associated with the potential approval of this glyphosate-tolerant canola in the United States.

Several factors contribute to the conclusion that there should be no impacts abroad from cultivation of these canola lines or their progeny.

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

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

APHIS participates regularly in biotechnology policy discussions at forums sponsored by the European Union and the Organization for Economic Cooperation and Development. In addition, APHIS periodically holds bilateral or quadrilateral discussions on biotechnology regulatory issues with other countries, most often Canada and Mexico. APHIS also acts as a consultant for the development of biotechnology guidelines and regulations, and has interacted with governments around the world in this manner, including those in regions where canola originated or is cultivated in significant quantities (e.g., China, Japan, Korea, Association of South East Asian Nations member States, India, Pakistan, African States, and more). We have participated in numerous conferences intended to

enhance international cooperation on safety in biotechnology, and sponsored several workshops on safeguards for planned introductions of transgenic crops (crucifers, maize, wheat, potatoes, rice, tomatoes) most of which have included consideration of international biosafety issues.

In the course of these wide-ranging studies and interactions, APHIS has not identified any significant impacts on the environment that might be relevant to glyphosate-tolerant canola or follow from the unconfined cultivation of canola line RT73 in the United States and its territories, or abroad which could not be mitigated by reasonable agricultural practices. In addition to the assurance provided by the analysis leading APHIS to a finding of no significant impact for the introduction of this canola, it should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new canola cultivars internationally apply equally to those covered by this determination.

Potential impacts on biodiversity

Our analysis determined that genetically engineered glyphosate-tolerant canola line RT73 is no more likely to become weed than any line 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 there is no potential impact of this line on biodiversity.

Potential impacts on agricultural and cultivation practices.

Based on the APHIS analysis, there is unlikely to be any significant adverse impact on agricultural practices associated with the use of these lines. However, it is of concern that there is a likelihood of canola volunteers possessing a combination of two different herbicides resistance genes and how such volunteers would be managed by growers. It is known that glyphosate is not employed to any significant degree for the control of canola volunteers. This glyphosate-tolerant line has been in commercial production in Canada since 1996 and the Canadian Government has suggested the need for sound crop management practices for volunteer management control and potential outcrossing concerns in its Document DD95-02 (March 1995). Monsanto has provided information regarding the use of alternative herbicides which could be used to control Brassica volunteers or weed should they obtain, through crossing, resistance to glyphosate and/or other herbicides with different modes of action.

Potential damage to processed agricultural commodities.

An analysis of the components and processing characteristics of these lines reveal no differences in any component that could have an indirect plant pest effect on any processed plant commodity.

VI. CONCLUSIONS

In accordance with the requirements of NEPA, APHIS has considered the potential for significant impact on the environment of a proposed action, i.e, reaching the determination that glyphosate-tolerant canola has no potential to pose a plant pest risk and should no longer be considered a regulated article under the regulations at 7 CFR Part 340. After careful analysis of the available information, APHIS concludes that its proposed action will not have a significant impact on the environment, and that the proper alternative is to approve the petition. This conclusion is based on factors discussed herein or in the determination included as Appendix A, as well as the following conclusions:

1. Neither the genes that result in accumulation of CP4 EPSPS and GOXv247, nor the CP4 EPSPS and GOXv247 proteins, nor their associated regulatory sequences, confer on glyphosate-tolerant canola or its progeny any plant pest characteristic.
2. In nature, the gene that results in accumulation of CP4 EPSPS and GOXv247 proteins will not provide glyphosate-tolerant canola or its progeny with any measurable selective advantage over nontransformed canola plants in their ability to disseminate or to become established in the environment. There is no reason to believe that glyphosate-tolerant canola exhibits any increased weediness relative to that of traditional varieties.
3. The use of glyphosate-tolerant canola or its progeny in agriculture will not lead to an increase in weediness in any plant with which it can successfully interbreed.
4. The use of glyphosate-tolerant canola or its progeny in agriculture will not cause damage to raw or processed agricultural commodities.
5. The use of glyphosate-tolerant canola or its progeny in agriculture will not have a significant impact on any beneficial organisms in the environment, or on any threatened or endangered species.

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