Notices

Federal Register
Vol. 67, No. 232
Tuesday, December 3, 2002

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 02–006–2]

Monsanto Co.; Extension of Determination of Nonregulated Status for Canola Genetically Engineered for Glyphosate Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to extend to one additional canola event our determination that a canola line developed by Monsanto Company, which has been genetically 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 decision is based on our evaluation of data submitted by Monsanto Company in its request for an extension of a determination of nonregulated status, an analysis of other scientific data, and a comment received from the public in response to a previous notice. This notice also announces the availability of our finding of no significant impact.

EFFECTIVE DATE: January 2, 2003.

ADDRESSES: You may read copies of the extension request, the environmental assessment and finding of no significant impact, and the comment received on an earlier notice of the availability of the environmental assessment in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. James White, Biotechnology Regulatory Services, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–5940. To obtain a copy of the extension request or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734–4885; e-mail: *Kay.Peterson@aphis.usda.gov*.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, "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," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

Background

On November 20, 2001, APHIS received a request for an extension of a determination of nonregulated status (APHIS No. 01–324–01p) from Monsanto Company (Monsanto) of St. Louis, MO, for a canola (*Brassica napus* L.) transformation event designated as glyphosate-tolerant canola event GT200 (GT200), which has been genetically engineered for tolerance to the herbicide glyphosate. Monsanto requested an extension of a determination of nonregulated status that was issued for Roundup Ready® canola line RT73, the antecedent organism, in response to APHIS petition number 98–216–01p (see 64 FR 5628–5629, Docket No. 98–089–2, published February 4, 1999). Based on the similarity of GT200 to the antecedent organism RT73, Monsanto requested a determination that glyphosate-tolerant canola event GT200 does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On February 28, 2002, APHIS published a notice in the **Federal Register** (67 FR 0247–0248, Docket No. 02–006–1) announcing that an environmental assessment (EA) for the Monsanto extension request had been prepared and was available for public comment. APHIS received one comment on the subject EA during the 30-day comment period, which ended April 1, 2002. The comment, which was from a consumer organization, urged denial of the subject extension request based on alleged deficiencies in the environmental assessments prepared for the antecedent organism and event GT200 canola. We have provided a response to this comment in an addendum to the finding of no significant impact (FONSI). The EA and FONSI are available from the person listed under FOR FURTHER INFORMATION CONTACT.

Analysis

Like the antecedent organism, canola event GT200 has been genetically engineered to express an enzyme, 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), from *Agrobacterium* sp. strain CP4, and the glyphosate oxidoreductase (GOX) gene/protein from *Ochrobactrum anthropi* strain LBAA, both of which impart tolerance to the herbicide glyphosate. The subject canola and the antecedent organism were produced through use of the *Agrobacterium tumefaciens* method to transform the parental canola variety Westar. Expression of the added genes in GT200 and the antecedent organism is controlled in part by gene sequences derived from the plant pathogen figwort mosaic virus.

Canola event GT200 and the antecedent organism were genetically engineered using the same

transformation method and contain the same enzymes that make the plants tolerant to the herbicide glyphosate. Accordingly, we have determined that canola event GT200 is similar to the antecedent organism in APHIS petition number 98–216–01p, and that canola event GT200 should no longer be regulated under the regulations in 7 CFR part 340.

The subject canola has been considered a regulated article under APHIS regulations in 7 CFR part 340 because it contains gene sequences derived from plant pathogens. However, GT200 has been approved for unconfined environmental release and food and feed use in Canada since 1997, with no subsequent reports of deleterious effects on plants, nontarget organisms, or the environment.

Determination

Based on an analysis of the data submitted by Monsanto and a review of other scientific data, APHIS has determined that canola event GT200: (1) Exhibits no plant pest characteristics; (2) is no more likely to become a weed than non-transformed traditional varieties; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not cause damage to raw or processed agricultural commodities; and (5) will not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture. Therefore, APHIS has concluded that canola event GT200 and any progeny derived from crosses with other canola varieties will be as safe to grow as canola that is not subject to regulation under 7 CFR part 340.

Because APHIS has determined that the subject canola event does not present a plant pest risk based on its similarity to the antecedent organism, Monsanto's canola event GT200 will no longer be considered a regulated article under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of the subject canola event or its progeny. However, importation of canola event GT200 and 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 EA was prepared to examine any potential environmental impacts associated with the proposed extension of a determination of nonregulated status. 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 FONSI with regard to the determination that Monsanto's canola event GT200 and events developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of Monsanto's extension request and the EA and FONSI are available upon request from the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Done in Washington, DC, this 26th day of November 2002.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 02–30514 Filed 12–2–02; 8:45 am]

BILLING CODE 3410–34–P

USDA/APHIS Decision on Monsanto Company Request (01-324-01p) Seeking an Extension of Determination of Nonregulated Status for Glyphosate Tolerant Canola Event GT200

Finding of No Significant Impact

September 2002

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has prepared an environmental assessment (EA) prior to approving an extension (APHIS Number 01-324-01p) of the determination of nonregulated status granted for petition 98-216-01p received from Monsanto Company under APHIS regulations at 7 CFR Part 340. The subject of extension request 01-324-01p is a glyphosate tolerant canola event GT200. Based on the analysis carried out in the EA, APHIS has reached a finding of no significant impact (FONSI) to the environment from its determination that event GT200 shall no longer be considered a regulated article. Before reaching this decision, APHIS requested and considered comments on the EA from the public. A response to the one comment received is included as an attachment to this FONSI statement.

Cindy Smith
Acting Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: OCT 08 2002

Trade and company names are used in this publication solely to provide specific information. Mention of a trade or company name does not constitute a warranty or an endorsement by the U.S. Department of Agriculture to the exclusion of other products or organizations not mentioned.

Registrations of pesticides are under constant review by the U.S. Environmental Protection Agency (EPA). Use only pesticides that bear the EPA registration number and carry the appropriate directions.

Attachment
Finding of No Significant Impact
Response to Comments
APHIS No. 01-324-01p

In response to a notice published in the *Federal Register* on February 28, 2002 (67 FR 9247–9248), APHIS received one comment on the environmental assessment (EA) prepared for APHIS no. 01-324-01p, a request for an extension of a determination of nonregulated status from Monsanto Company (Monsanto) for event GT200 canola. The comment, which was from a consumer organization, opposed the extension request based on alleged deficiencies in the EA for the extension request and the EA prepared for the antecedent organism, and on alleged deficiencies in APHIS' compliance with certain requirements of the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA). We have confined our response to the points made by the commenter that relate to plant pest or environmental risks posed by the subject extension of a determination of nonregulated status under the regulations in 7 CFR part 340.

We do not agree with the commenter's contention that APHIS' analysis of the impacts of the subject extension request is inadequate for an assessment of such impacts. The most recent National Academy of Sciences' (NAS) National Research Council (NRC) study, *Environmental Effects of Transgenic Plants* (NRC, 2002) reaffirmed the validity of APHIS' comparison of the risks posed by transgenic plants with the risks posed by conventionally-developed crops with similar traits (NRC, 2002, pp. 5, 7). The same NRC study also noted the need to "place potential impacts of transgenic crops within the context of environmental effects caused by other agricultural practices and technologies" (NRC, 2002, p. 3). The EA prepared for the antecedent organism in APHIS no. 98-216-01p reflects these perspectives and appropriately serves as the basis for our finding of no significant impact for event GT200 canola based on its similarity to the antecedent organism. Equally appropriately, the EA for APHIS no. 01-324-01p establishes this similarity and provides a brief summary of new information relevant to environmental impacts since the development of the original EA.

Specific deficiencies alleged by the commenter include deviations from standard NEPA formatting and terminology in the updated extension EA and inadequate substantive analyses in the environmental assessments of the impacts resulting from the marketing and commercialization of canola, including gene flow, herbicide use, and impacts on organic farmers. With regard to the EA formatting, though APHIS has already provided sections on purpose and need, alternatives, and references in the EA for the antecedent organism, we have added sections to the extension EA for the convenience of the reader. However, we do not agree with the commenter that there are substantive deficiencies in our analyses of the impacts of the issues related to marketing and commercialization. The problems noted by the commenter relating to gene flow and the development of herbicide resistance are not determined by or limited to the technology used to develop a new plant variety. APHIS does not regulate plant varieties, including canola, developed by conventional techniques, and the Federal government has a limited role in identity preservation and seed certification. In addition to the truth-in-labeling regulations under the Federal Seed Act (7 CFR part 201), the USDA's Agricultural

Marketing Service and Grain Inspection, Packers and Stockyards Administration published an Advance Notice of Proposed Rulemaking on November 30, 2000 in the *Federal Register* (65 FR 71272- 71273) concerning the possible further development of additional testing and standardization for seeds and commodities designed to differentiate products such as non-biotechnology-derived commodities. Federal, State, private, and international groups involved in seed certification all allow for some level of accidental, incidental, or adventitious presence of off-types even in the purest seed categories, such as foundation and breeder seed. With regard to the development of herbicide resistance, APHIS and the Environmental Protection Agency have established a working group (please see http://www.aphis.usda.gov/ppq/biotech/moul.html) to provide the public with information on ways to delay the development of herbicide resistant plants whether they occur via gene flow or natural selection.

APHIS has addressed the potential impacts of the subject canola event on organic farmers in the extension EA. In that EA we have made reference to the National Organic Program (NOP) administered by USDA's Agricultural Marketing Service, which considers that the presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation of the standards. (Please refer to the preamble of the NOP final rule at residue testing, changes requested but not made, (3) Threshold for Genetic Contamination for a discussion of "adventitious presence" in relation to organic production at website: http://www.ams.usda.gov/nop/nop2000/Final%20Rule/preamble/pre-residues.htm.) Further, the NOP requires that organic production operations have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances from adjoining land that is not under organic management. The organic system plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods.

Finally, the commenter alleges that APHIS has failed to consult with the Fish and Wildlife Service (FWS) on potential threats to endangered species of event GT200 canola. On the contrary, as explained in the extension EA, APHIS has discussed with FWS its approach to analyzing any potential threats from transgenic crop varieties to threatened and endangered species under the requirements of the ESA. In a meeting held July 28, 1999, APHIS and FWS reached a consensus that APHIS would use the decision tree approved by FWS to determine whether consultation with FWS would be required for a transgenic crop variety, a policy which APHIS has observed in the case of the subject extension request.

I. OVERVIEW

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), has prepared an environmental assessment (EA) in response to a request (APHIS number 01-324-01p) from Monsanto Company (Monsanto) for an extension of a previous determination of nonregulated status that APHIS issued for glyphosate tolerant canola event RT73 (the antecedent organism in APHIS number 98-216-01p). The Monsanto extension request claims that a new canola event, GT200, is similar to the antecedent organism and therefore does not present a plant pest risk, and should therefore no longer be a regulated article under regulations at 7 CFR Part 340.

Glyphosate-tolerant canola event GT200 expresses two stably integrated genes both of which provide tolerance to the herbicide glyphosate: the CP4 5-enolpyruvylshikimate-3-phosphate synthase (*EPSPS*) gene from *Agrobacterium* sp. strain CP4 and a modified glyphosate oxidoreductase (*GOX*) gene from the bacterium *Ochrobactrum anthropi* strain LBAA . The *EPSPS* gene encodes a glyphosate insensitive variant of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), an enzyme involved in the production of aromatic amino acids, that is normally inhibited by glyphosate; and the *GOX* gene encodes a glyphosate oxidoreductase enzyme that can break down glyphosate. The genes were introduced into canola via disarmed *Agrobacterium*-mediated transformation protocol. This is a well-characterized procedure that has been widely used for over a decade for introducing various genes directly into plant genomes. By disarming the *Agrobacterium* all phytopathogencity genes were removed. Some gene regulatory sequences were also derived from figwort mosaic caulimovirus but these sequences are not involved in pathogenicity.

There have been no field tests of Event GT200 in the United States. The Canadian government approved the use of this canola in food and feed and its unconfined release. This event has been commercially grown in Canada for several years and Monsanto has not reported to the Canadian Food Inspection Agency any deleterious effects on plants, nontarget organisms, threatened and endangered species, or the environment from the use of this canola. This extension request is to address the adventitious presence of this event in commercially available seeds sold in the U.S. until a Federal policy on this issue is developed. (Adventitious presence is the presence of events that have not been fully reviewed or approved by a regulatory agency and occurs in seeds and commodities as result of either cross-pollination or commingling of experimental seeds with commercial seed).

This assessment will describe in Section IV gene sequences inserted into the antecedent organism RT73, followed by a corresponding description of the regulated article GT200 in Section V. Section VI details the similarities and differences between the two canola events. Section VII contains information on environmental impacts.

The Food and Drug Administration (FDA) policy statement concerning regulation of products derived from new plant varieties, including those that are genetically

engineered, was published in the Federal Register on May 29, 1992, and appears at 57 FR 22984-23005. Monsanto initiated its consultation with FDA on glyphosate tolerant canola event GT200.

The Environmental Protection Agency (EPA) as part of its registration of glyphosate establishes tolerances for combined residues of glyphosate and its metabolite(s) for canola and other crop plants Federal Register: April 14, 1999 (Volume 64, Number 71, pages 18360-18367).

II. PURPOSE AND NEED

In compliance with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*) and the pursuant implementing regulations (40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372), APHIS has prepared this EA before making a determination on the status of GT200 canola as a regulated article under APHIS regulations. The developer of GT200 canola, Monsanto, submitted a petition requesting that APHIS make a determination that canola transformation event GT200, and any progeny derived from crosses of event GT200 with other nonregulated canola varieties, no longer be considered regulated articles under 7 CFR Part 340.

III. ALTERNATIVES

A. No Action: Continuation as a Regulated Article

Under the "no action" alternative, APHIS would come to a determination that GT200 canola and its progeny should continue to be regulated under 7 CFR Part 340. Permits or acknowledgment of notifications from APHIS would still be required for their introduction. APHIS would choose this alternative if there were insufficient evidence to demonstrate lack of plant pest risk from the unconfined cultivation of GT200 canola and its progeny.

B. Determination of Nonregulated Status

Under this alternative, GT200 canola and its progeny would no longer be considered regulated articles under 7 CFR Part 340. Permits or notifications to APHIS would no longer be required for introductions in the United States and its territories of GT200 canola or its progeny. A basis for this determination would be established, which would result in a Finding of No Significant Impact (FONSI) under NEPA. Unrestricted cultivation of the events would be permitted by APHIS. Such a determination, however, does not preclude any restriction on the cultivation of this canola that might be placed by other regulatory agencies also having authority.

C. Determination of Nonregulated Status, in Part

The regulations at 7 CFR Part 340.6 (d) (3) (i) state that APHIS may "approve the petition in whole or in part." There are two ways in which a petition might be approved in part:

Approval of some but not all of events requested in the petition. In some petitions, applicants request de-regulation of events derived from more that one independent transformation event. In these cases, supporting data must be supplied for each event. APHIS could approve certain events requested in the petition, but not others.

Approval of the petition with geographic restrictions. APHIS might determine that the regulated article poses no significant risk in certain geographic areas, but may pose a significant risk in others. In this case, APHIS may choose to approve the petition with a geographic limitation stipulating that the approved events could only be grown in certain geographic areas based on the identification of site-specific risks.

IV. THE ANTECEDENT ORGANISM, RT73

The antecedent organism was produced by transforming a parental event called Westar by using disarmed Agrobacterium vector system (plasmid PV-BNGT04). The transgenes present in RT73 are:

(a) right border sequence from disarmed *Agrobacterium tumefaciens*; (b) a modified 35S promoter from figwort mosaic virus; (c) the N-terminal chloroplast transit peptide sequences from the small subunit 1A of the ribulose-1,5-bisphosphate carboxylase (rbcS) gene from the plant *Arabidopsis thaliana*, which are designed to target the enzymes to the plant's chloroplasts; (d) a synthetic glyphosate oxidoreductase based on the gene from *Ochrobactrum anthropi* strain LBBA; (e) the 3' end of the pea rbcS E9 gene which provides the sites necessary for polyadenylation of the mRNA; (f) the 35S promoter from a modified figwort mosaic virus; (g) the N-terminal chloroplast transit peptide sequences from the small subunit 1A of the rbcS gene from the plant *Arabidopsis*; (h) the CP4 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene from *Agrobacterium* sp. strain CP4; (i) the 3' end of the pea rbcS E9 gene, and (j) the left border sequences from *A. tumefaciens*.

V. THE REGULATED ARTICLE, GT200

The regulated article, GT200, was produced by transforming a parental canola event called Westar by using disarmed Agrobacterium vector system (plasmid PV-BNGT03). The transgenes present are:

(a) right border sequence from disarmed *Agrobacterium tumefaciens*; (b) the 35S promoter from a modified figwort mosaic virus; (c) the N-terminal chloroplast transit

peptide sequences from the small subunit 1A of the ribulose-1,5-bisphosphate carboxylase (rbcS) gene from the plant *Arabidopsis*, which are designed to target the enzymes to the plant's chloroplasts; (d) a synthetic glyphosate oxidoreductase based on the gene from *Ochrobactrum anthropi* strain LBBA; (e) the 3' end of the pea rbcS E9 gene which provides the sites necessary for polyadenylation of the mRNA; (f) the 35S promoter from a modified figwort mosaic virus; (g) the N-terminal chloroplast transit peptide sequences from the small subunit 1A of the rbcS gene from the plant *Arabidopsis*; (h) the CP4 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene from *Agrobacterium* sp. strain CP4; (i) the 3' end of the pea rbcS E9 gene, and (j) the left border sequences from *A. tumefaciens*.

The sole difference between the RT73 and GT200 is that the glyphosate oxidoreductase genes in the latter differs by 5 base pairs resulting in a difference of 3 amino acids. In both cases, the enzymes catalyze the identical oxidative degradation of glyphosate.

VI. SIMILARITIES AND DIFFERENCES BETWEEN GT200 AND THE ANTECEDENT ORGANISM RT73.

Events RT73 and GT200 were produced by the transformation of canola *Brassica napus* Westar germplasm. Both events were a result of transformation using a disarmed *A. tumefaciens*. Both events display similar levels of tolerance to the herbicide glyphosate. The transformation has not impacted any of the key agronomic characteristics as the transformed events are similar to their non-transgenic counterparts including pollen production and viability, days to maturity, shattering, germination rates, seed dormancy, plant height, lodging, pest susceptibilities, and known toxicants (erucic acid, glucosinolates). Similarly, seed compositional characteristics (proximate analysis of percent protein, fat, ash moisture, fiber, carbohydrate, amino acids, fatty acids, total glucosinolates, chlorophyll, and sinapine) of the transformed events GT200 and the antecedent RT73 are similar to their transformed counter parts. Therefore, APHIS believes that there have been no significant unintended effects from tissue culture or transformation procedures with event GT200.

A comparison of sequences present in RT73 and GT200 reveals similarities and differences at the molecular level for the two events. Like RT73, GT200 was transformed using disarmed *A. tumefaciens* vector system. Both events involved the use of 35S promoter and terminator sequences from figwort mosaic virus and the *EPSPS and GOX* genes that confers tolerance to the herbicide glyphosate. The levels of protein expression are equivalent in both GT200 and the antecedent organism RT73.

Monsanto has submitted data to the FDA with regards to the food and feed uses of this product. The various parameters examined were percentage oil, protein, fibre and carbohydrates. The oil fraction was examined in detail for the specific fatty acid composition including the erucic acid levels, as well the level and composition of glucosinolate. For all the above parameters, all transgenic events were deemed substantially equivalent to the non-transgenic counterparts.

The only significant difference identified between the events GT200 and the antecedent RT73 at the molecular level is the presence of slightly modified glyphosate oxidoreductase enzyme.

VII. POTENTIAL ENVIRONMENTAL IMPACTS

The potential environmental impacts of alternatives A, B and C, as described above in section III are presented in this section.

Alternative A, Non Action.

In a decision to choose alternative A., no action, these plants would still require APHIS authorization to be planted. In this case measures would need to continue to be implemented to ensure physical and reproductive confinement of GT200 canola and any progeny derived from it.

If APHIS chooses Alternative A, then crop rotation and the numerous chemical herbicides will remain as options for weed control including use of glyphosate on RT 73 canola. APHIS envisions no significant adverse impacts over and above those associated with current practices.

Alternative B, Determination of Nonregulated Status.

A decision to choose alternative B, deregulation of GT200 canola, is addressed below. The unrestricted cultivation and distribution of GT200 canola is compared to that for other canola not subject to regulation by APHIS under 7 CFR Part 340.

This EA is tiered to the original EA of 98-216-01p in which the potential for impacts to the human environment through unrestricted use in agriculture of the antecedent organism have been addressed in detail.

Since the only difference between the antecedent and the new event GT200 is the presence of a slightly modified glyphosate oxidoreductase, no new EA is deemed necessary and no new significant environmental issues can be identified.

Organic farmers should not be impacted by the expected commercial use of this product since: (a) nontransgenic canola will likely still be sold and will be readily available to those who wish to plant it; (b) GT200 canola will be clearly labeled in its marketing as glyphosate resistant (i.e RoundUp Ready™) as it entails the use of the companion herbicide to reap any potential benefits, (c) USDA's National Organic Program (http://www.ams.usda.gov/nop/nop2000/Final%20Rule/nopfinal.pdf) requires that organic farmers plant certified (nonengineered) seed, and (d) the detection of the adventitious presence of event GT200 in organic canola is not precluded by the

USDA's National Organic Program if the producer can demonstrate that they purchased and planted certified (nonengineered) organic seed.

Since APHIS' approval of the original petition, there are no reports or data that suggest that the use of the events derived from RT73 has had any significant negative impact on nontarget organisms or threatened or endangered species. On July 28, 1999, APHIS met with the U.S. Fish and Wildlife Service (FWS) and FWS determined our assessments to be adequate for addressing the impact on threatened and endangered species.

Because the regulated article GT200 is substantially equivalent to the antecedent organism RT73, it does not present any new potential environmental impact issues other than those addressed in the EA associated with determination on petition number 98-216-01p (see appendix).

Alternative C, Approval of the Petition in Part

Approval of some but not all of events requested in the petition. The petition requested a determination of nonregulated status only for events derived from the one transformation event, designated as RT 73. Therefore, APHIS can consider only that one event for approval.

Approval of the petition with geographic restrictions. APHIS can identify no scientific issues to support geographic restrictions in planting RT 200 canola.

VIII. CONCLUSIONS

In accordance with the requirements of NEPA, APHIS has considered the potential for significant impact on the environment of the proposed action and has reached the following conclusions:

1. Neither the genes that result in accumulation of EPSPS and GOX, nor the EPSPS and GOX 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 EPSPS and GOX 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.

IX. REVIEWERS

Biotechnology Regulatory Services

Cindy Smith, Acting Deputy Administrator

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James L. White, Ph.D., Branch Chief (Preparer)

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Hanu Pappu, Ph.D., Biotechnologist

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Shirley P. Ingebritsen, M.A., Regulatory Analyst (Reviewer)

X. CONSULATIONS

Richard Sayer, Fish and Wildlife Service, Threatened and Endangered Species section, Dept. of the Interior

Phil MacDonald, Canadian Food Inspection Service, Plant Biosafety Office

Public Affairs section of Agricultural and Marketing Service (National Organic Program)

XI. AGENCY CONTACT

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APPENDICES: Environmental Assessment and Determination of Nonregulated Status for APHIS number 98-216-01p

Response to Monsanto Petition 98-216-01p for Determination of Nonregulated Status for Glyphosate-Tolerant Canola Line RT73

Environmental Assessment and Finding of No Significant Impact

January 1999

Finding of No Significant Impact

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture, has prepared an environmental assessment prior to issuing a determination in response to a petition (APHIS Number 98-216-01p) received from Monsanto Company regarding the status of glyphosate-tolerant canola line RT73 under APHIS regulations at 7 CFR Part 340. Canola line RT73 has been engineered to express a CP4 5-enolpyruvylshikimate-3-phosphate synthase (*EPSPS*) gene and a modified glyphosate oxidoreductase (*goxv247*) gene. The CP4 *EPSPS* gene encodes a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme and the *goxv247* gene encodes a glyphosate oxidoreductase (GOXv247) protein. These two proteins confer tolerance to the herbicide glyphosate in transgenic canola. Based upon the analysis documented in its environmental assessment, APHIS has reached a finding of no significant impact on the environment from its determination that glyphosate-tolerant canola line RT73 and its progeny shall no longer be regulated articles.

for Eileen T. Kolodka

Rebecca A. Bech, Assistant Director
Scientific Services
Biotechnology and Biological Analysis
Plant Protection and Quarantine
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: JAN 27 1999

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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 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.

VII. LITERATURE CITED

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APPENDIX A

RESPONSE TO MONSANTO PETITION 98-216-01p FOR DETERMINATION OF NONREGULATED STATUS FOR GLYPHOSATE-TOLERANT CANOLA LINE RT73

Prepared by
United States Department of Agriculture
Animal and Plant Health Inspection Service
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I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS) has determined, based on a review of scientific data and information that transformed glyphosate-tolerant canola line RT73 (*Brassica napus* L.) and all other lines bred or otherwise derived from this line by sexual or asexual reproduction, do not present a plant pest risk, and are therefore no longer considered regulated articles under 7 CFR Part 340. As a result of this determination, approval under those regulations will no longer be required from APHIS for planting, importation, or interstate movement of the above mentioned glyphosate-tolerant canola or its progeny. Exportation of this glyphosate-tolerant canola, and nursery stock or seeds capable of propagation will remain regulated according to the Foreign Quarantine Notice regulations at 7 CFR Part 319.

This determination has been made in response to a petition (98-216-01p) from Monsanto Company (Monsanto), St. Louis, Missouri, received August 4, 1998. The petition seeks a determination from APHIS that glyphosate-tolerant canola line RT73 and its progeny do not present a plant pest risk and should therefore no longer be considered regulated articles. On October 16, 1998, APHIS announced receipt of the Monsanto petition in the *Federal Register* (63 FR 55573-55574) and stated that the petition was available for public review. APHIS also indicated its role, as well as those of the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA), in regulation of glyphosate-tolerant canola, and food products derived from it. APHIS invited written comments on whether glyphosate-tolerant canola poses a plant pest risk, to be submitted on or before December 15, 1998. No comments were received.

Glyphosate-tolerant canola line RT73 expresses two stably integrated genes both of which provide tolerance to the herbicide glyphosate: the CP4 5-enolpyruvylshikimate-3-phosphate synthase (*EPSPS*) gene from *Agrobacterium* sp. strain CP4 and a modified glyphosate oxidoreductase (*goxv247*) gene from the bacterium *Ochrobactrum anthropi* strain LBAA. The gene CP4 *EPSPS* encodes a glyphosate insensitive variant of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), an enzyme involved in the production of aromatic amino acids, that is normally inhibited by glyphosate; and the *goxv247* gene encodes a glyphosate oxidoreductase (GOXv247) enzyme that can break down glyphosate. The genes were introduced into canola via an *Agrobacterium*-mediated transformation protocol. This is a well-characterized procedure that has been widely used for over a decade for introducing various genes of interest directly into plant genomes.

APHIS regulations at 7 CFR Part 340, 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 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 therefore 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 introduction of the regulated article (organisms) in question without permits or notifications under 7 CFR Part 340.

Glyphosate-tolerant canola line RT73 has been considered a "regulated article" because it contains noncoding DNA regulatory and coding sequences derived from the plant pathogens figwort mosaic virus, and *Agrobacterium* sp. CP4, respectively, and because *Agrobacterium tumefaciens* was used as a vector agent. As such, all field trials of glyphosate-tolerant canola line RT73 conducted in the U.S. were performed under conditions of physical and reproductive confinement as authorized by APHIS permits or notifications. Field tests have also been completed in Canada and Europe.

APHIS' determination that glyphosate-tolerant canola line RT73 will no longer be considered a regulated article under APHIS regulations at 7 CFR Part 340, is based on an analysis of field test data and other data provided to APHIS by Monsanto as well as other scientific information relating to the potential plant pest risk of glyphosate-tolerant canola. From our review, we have determined that glyphosate-tolerant canola line RT73: (1) exhibits no plant pathogenic properties; (2) is no more likely to become a weed than their non-engineered parental varieties; (3) is unlikely to increase the weediness potential of any other cultivated plant or native wild species with which they can breed; (4) will not cause damage to raw or processed agricultural commodities; and (5) is unlikely to harm other organisms, such as threatened or endangered species, or bees and earthworms that are beneficial to agriculture. APHIS has also concluded that there is a reasonable certainty that new progeny varieties bred from glyphosate-tolerant canola will not exhibit new plant pest properties, i.e., properties substantially different from any observed for the field tested glyphosate-tolerant canola, or those observed for canola in traditional breeding programs.

The potential environmental impacts associated with this determination have been examined 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. The Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) reached by APHIS for this determination are available from APHIS upon written request.

II. BACKGROUND

USDA Regulatory Authority. APHIS regulations, 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. A genetically engineered organism is deemed a regulated article either if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in § 340.2 of the regulations and is also a plant pest; if it is unclassified; or if APHIS has reason to believe that the genetically engineered organism presents a plant pest risk.

Prior to the introduction of a regulated article, a person is required under § 340.1 of the regulations to either (1) notify APHIS in accordance with § 340.3 or (2) obtain a permit in accordance with § 340.4. Introduction under notification (§ 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 § 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 and/or stipulated by APHIS, does not pose a plant pest risk.

The FPPA gives USDA authority to regulate plant pests and other articles to prevent direct or indirect injury, disease, or damage to plants, plant products, and crops. The PQA provides an additional level of protection by enabling USDA to regulate the importation and movement of nursery stock and other plants which may harbor injurious pests or diseases, and requires that they be grown under certain conditions after importation. For certain genetically engineered organisms, field testing may be required to verify that they exhibit the expected biological properties, and to demonstrate that although derived using components from plant pests, they do not possess plant pest characteristics.

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 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 may be granted. A petition may be granted in whole or in part.

Glyphosate-tolerant canola RT73 has been considered a "regulated article" because it contains noncoding DNA regulatory 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.

APHIS believes it prudent to provide assurance prior to commercialization that organisms developed using biological vectors from pathogenic sources, transforming material from pathogenic sources, or pathogens as vector agents, have been evaluated to assure that there is not a plant pest risk. Such assurance may aid the entry of new plant varieties into commerce or into breeding and development programs..

A certification that an organism does not present a plant pest risk means that there is reasonable certainty that the organism cannot directly or indirectly cause disease, injury, or damage either when grown in the field, or when stored, sold, or processed. This approach is considerably broader than a narrow definition of plant pest risk arising from microbial or animal pathogens, including insect pests. 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.

EPA and FDA regulatory authority. Glyphosate tolerant canola Line RT73 is currently subject to regulations administered by the EPA or the FDA regarding food and feed safety as described in the Environmental Assessment. FDA granted a finding of 'No Concern' for canola line RT73 in September 1995 following its consultation with Monsanto on food and feed safety for this transgenic canola; and EPA has granted a tolerance exemption for CP4 EPSPS and GOX. Monsanto is also seeking registration from the EPA for use of the commercial formulation of the glyphosate herbicide (Roundup) for over-the top application on "Roundup Ready" canola such as glyphosate tolerant canola Line RT73.

The decision by APHIS that glyphosate-tolerant canola is no longer a regulated article, is based in part on evidence provided by Monsanto concerning the biological properties of the glyphosate-tolerant canola, and its similarity to other varieties of canola grown using standard agricultural practices for commercial sale or private use. Glyphosate-tolerant canola has been field tested at 23 sites in the major canola growing states. Field trial reports from these tests show no deleterious effects on plants, nontarget organisms, or the environment as a result of these releases.

III. RATIONALE FOR DEVELOPING GLYPHOSATE TOLERANT CANOLA

Weed management is critical to maximize crop yield and obtain high-quality seed harvest free of weed seeds; but it is an expensive, labor intensive, and sometimes complicated operation. Glyphosate-tolerant canola will offer farmers a new option in controlling weeds. Often farmers use pre-emergent herbicides that will stop weeds seeds from germinating. However, this assumes that weeds will always be a problem in all parts of the field. With RT73 canola, farmers will have the option of applying herbicide after weeds have germinated and only in the areas of the field where there are

weeds. Applications in this manner may reduce the amount of pre-emergent herbicide used on canola. Glyphosate may also control certain weeds that are not effectively controlled by currently registered herbicides. Glyphosate is one of the most environmentally friendly herbicides.

IV. ANALYSIS OF THE PROPERTIES OF GLYPHOSATE-TOLERANT CANOLA

A brief description of the biology of canola and canola cultivation practices is expected to be helpful in specific environmental and biosafety issues applicable to glyphosate-tolerant canola. In addition, to reach its determination that glyphosate-tolerant canola does not present a plant pest risk, APHIS has analyzed basic information on the biology of canola but also data presented by Monsanto and scientific data on other topics relevant to a discussion of plant pest risk. Based on the data, APHIS has arrived at a series of conclusions regarding the properties of glyphosate-tolerant canola.

Biology and Cultivation of canola

Brassica napus L., is a mustard crop grown primarily for its seed which yields about forty percent oil and a high-protein animal feed. Varieties of *B. napus* are known by the common names of rapeseed, rape, oilseed rape, and canola.

Westar variety of canola (Klassen et al., 1987) was used for transformation. Since 1982, this variety has had a history of safe use in the commercial production and breeding of canola. Its pedigree has been published along with 6 year performance data (Klassen et al., 1987). It has been a standard, and has been used in the breeding of many registered varieties of canola.

Taxonomy of Rapeseed. *Brassica* is a genus within the plant family Brassicaceae (Cruciferae), which is commonly known as the mustard family. This family, of about 375 genera and 3200 species, includes species recognized as crops, condiments, ornamentals, and many weeds. *Brassica* contains about 100 species, including cabbage, cauliflower, broccoli, brussels sprouts, turnip, various mustards and weeds (Willis 1973). A diagrammatic representation of the genome relationship of some economically important Brassica species is given on pp. 11 of the petition for the readers of this document.

B. napus belongs to a group of six genetically related species (Röbbelen et al. 1989):

> *B. nigra* (Linnaeus) Koch, black mustard, a diploid species n=8, originally spread by trade over much of the Old World, and now spread as a weed throughout much of the New World, including virtually all of the United States.
>
> *B. oleracea* Linnaeus, cabbage, broccoli, brussels sprouts, cauliflower, kale, a

diploid species n=9, originally confined to the Mediterranean, but now widely grown in temperate gardens.

B. rapa Linnaeus (=*B. campestris* Linnaeus), field mustard, turnip, turnip rape, bird rape, a diploid species n=10, originally spread throughout much of Europe, Asia, northern India, and northern Africa, and now either grown as a vegetable or oil crop, or spread as an occasional weed in much of the United States.

B. carinata A. Braun, Abyssinian mustard, Ethiopian mustard, an allotetraploid species n=17, derived from *B. nigra* and *B. oleracea*, presumed to come from an ancient cross or crosses in northeast Africa, and occasionally grown in the United States as a novelty.

B. juncea (Linnaeus) Czerniakowska et Cosson, Indian mustard, brown mustard, mustard greens, an allotetraploid species n=18, derived from Old World crosses of *B. nigra* and *B. rapa*, and now grown for the leaves, or spread as an occasional weed in crops or waste places.

B. napus Linnaeus, the subject of this petition, an allotetraploid species n=19, derived from ancient crosses between *B. oleracea* and *B. campestris*, and now grown widely for its oil, and an occasional weed or volunteer in cultivated fields.

Sexual Reproduction and Inter-specific Crosses in Rapeseed.

B. napus produces an inflorescence of yellow, nectar-bearing flowers. The plants are capable of both self-fertilization and intra-specific cross-fertilization. Honeybees are the primary pollinators. Partial sexual compatibility exists with some related *Brassica* spp. and other closely related species outside the genus.

Rapeseed has unexceptional entomophilous flowers capable of both self- and cross-pollination. In cultivated fields, cross-pollination has been reported at about 35%, but varies depending on the availability of insect pollinators, cultivar, and weather. Downey and Bing (1990) reported outcrossing rates of 2.1, 1.1, and 0.6 percent for isolation plots located 46, 137, and 366 meters from a pollen source. Seed certification requires a reproductive isolation distance of 660 feet for the production of Foundation Seed for *B. napus*, and even greater distance (1320 feet) for self-incompatible species such as *B. rapa*. At these distances there is a tolerance of 0.05 percent offtypes, presumably derived from pollen contamination by sources beyond the specified distance (7 CFR Part 201.76).

Honey bees are the primary pollinators of rapeseed. Although a honeybee colony may collect nectar and pollen from many species, and potential foraging flights can be quite distant (to 10 km), several factors limit the potential for spread (Seeley, 1985) to those distances noted in the above paragraph. First, each individual honeybee forager almost

always collects nectar and pollen from a single plant species during a single visit. Second, given abundant flowers, such as in a cultivated field, individual honeybee foragers tend to collect nectar and pollen from flowers in the same or immediately adjacent plants. Third, honeybees are very sensitive to barometric pressure, and decrease foraging distances in response to impending adverse weather. Fourth, honeybees are subject to the pressures of energy economics, and do not forage at great distances from the nest when abundant nectar and pollen sources are close by, as in many agricultural settings.

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. The three allotetraploid species mentioned above undoubtedly arose from ancient natural crosses of diploid species, and therefore demonstrate the potential for gene movement among all these species. Bing (1991) reported the following crosses and attempted crosses of plants that may be outside cultivation or escapes from cultivation. Data reported are, in order, (1) cross performed (pistillate plant listed first, pollen plant listed second), (2) the number of hybrid seed per 100 pollinated buds, and (3) the results of co-cultivation.

> *Sinapis arvensis* x *B. napus*, no hybrid seeds, and no hybrids from field co-cultivation.
>
> *B. nigra* x *B. napus*, 0.1 hybrid seeds, and no hybrids from field co-cultivation.
>
> *B. rapa* x *B. napus*, 933.8 hybrid seeds, and 1.3% hybrids from field co-cultivation.
>
> *B. juncea* x *B. napus*, 401.9 hybrid seeds, 4.7% hybrids from field co-cultivation.

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; (2) *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).

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.

There is no published evidence for the existence of any mechanism, other than sexual crossing of compatible *Brassica* species, by which the introduced genetic sequences can be transferred to other organisms. Another mechanism by which *B. napus* can transfer

genetic material to sexually non-compatible plants is through "bridging." Bridging is defined as "a mating made between two incompatible or reproductively isolated species by first transferring the genetic material to an intermediate species that is sexually compatible with the two sexually incompatible species". Such a possibility of the "bridging" phenomenon may occur with *B. juncea* acting as the intermediate species. The occurrence of hybrids between *B. napus* and *B. juncea* is rare, and moreover, the hybrids do not persist long enough in the environment due to poor fertility, poor germination, and high seedling mortality, to serve as a bridge species. Furthermore, crosses between *B. juncea* and *B. nigra* are not fully compatible, and it follows that crosses between *B. napus* hybrids, and *B. nigra* would be even less compatible. Another genetic barrier for gene transfer is that it has to take place by chromosomal crossing over in the *B. napus* and *B. juncea* hybrid to be stably introduced into *B. nigra* (Scheffler and Dale, 1994).

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 with the exception of T-DNA of the Ti-plasmid of *Agrobacterium*. A certain amount of information can be found in the scientific literature (e.g., Carlson and Chelm, 1986; Wakabayashi et al., 1986) that provides a suggestion that transfer of genes from plants to microorganisms may have occurred over evolutionary time, i.e., in the eons since the various times of divergence between the kingdoms. Bryngelsson et al. (1988) have 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 would pose any plant pest risk. We conclude that concerns regarding DNA transfer from glyphosate-tolerant canola to microorganisms are, at best, highly speculative, and improbable, if not altogether impossible.

The risk of crosses between wild *B. rapa* x *B. napus* glyphosate-tolerant canola hybrids is lower than feral *B. napus* glyphosate-tolerant canola. Wild *B. rapa* x *B. napus* canola hybrids not only have much lower dormancy than the persistent wild *B. rapa* control, their dormancy level is lower than that of nontransgenic hybrid controls. This finding coupled with the reduced fertility of the inter-specific hybrids makes it very unlikely that populations of hybrids will persist. There is a small chance that the hybrids could backcross to wild *B. rapa* and thereby transfer the glyphosate-tolerant transgene to wild populations (Crawley et al. 1993). In Europe, *B. rapa* is a common weed in agricultural fields, and introgression of an herbicide resistance transgene from *B. napus* canola to wild *B. rapa* has been detected (Mikkelsen et al. 1996).

Neither the introduced genes, and their products, nor the added regulatory sequences controlling their expression presents a plant pest risk in glyphosate-tolerant canola

A disarmed *Agrobacterium tumefaciens* system was used to transfer the new genetic material into the parental Wester variety to produce glyphosate-tolerant canola Line RT73. This transformation system is well documented to transfer and stably integrate T-DNA containing genes of interest into a plant nuclear chromosome (White, 1989, Howard et a., 1990). Although the transformation process uses the plant pathogen, *A. tumefaciens* (the causal agent of a tumor-inducing, crown gall disease), the genes that cause crown gall disease are removed from the tumor-inducing (Ti)- plasmid, and therefore the transformed plant does not develop crown gall disease.

Sequences necessary for the expression of the desired trait were introduced between the left and right T-DNA borders from Ti-plasmids to create the chimeric plasmid vector PV-BNGT04. Monsanto provided molecular analyses which demonstrated that only a single copy of the T-DNA containing the genetic elements responsible for the glyphosate tolerant phenotype was inserted into the genomic DNA to produce Line RT73 and that plasmid backbone sequences, including *oriV* and a bacterial marker gene *aad* that confers streptomycin resistance, are <u>not</u> present. The inserted genetic material includes: (1) Two copies of the 35S promoter from a modified figwort mosaic virus (Gowda et al., 1989; Richins et al., 1987; Shepard et al., 1987) which drive expression of the inserted *goxv247* and *EPSPS* genes, (2) The N-terminal chloroplast transit peptide sequences from the small subunit 1A of the ribulose-1,5-bisphosphate carboxylase (rbcS) gene (Timko et al., 1988) and from the EPSPS gene (Klee et al., 1987), both from the plant *Arabidopsis*, which are designed to target the proteins encoded by the inserted *goxv247* and *EPSPS* genes, respectively, to the plant's chloroplasts; (3) The CP4 5-enolpyruvylshikimate-3-phosphate synthase (*EPSPS*) gene from *Agrobacterium* sp. strain CP4 (Padgette et al., 1996) and a modified glyphosate oxidoreductase (*goxv247*) gene from the bacterium *Ochrobactrum anthropi* strain LBAA (Barry et al., 1994; Woodward et al., 1994). The gene CP4 *EPSPS* encodes a glyphosate insensitive variant of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), an enzyme involved in the production of aromatic amino acids, that is normally inhibited by glyphosate; and the *goxv247* gene encodes a glyphosate oxidoreductase (GOXv247) enzyme that can break down glyphosate. (4) Two copies of the 3' end of the pea rbcS E9 gene which provides the sites necessary for polyadenylation of the mRNA for the inserted *goxv247* and *EPSPS* genes (Coruzzi et al., 1984; Morelli et al., 1985);

Data provided by Monsanto also demonstrated that *EPSPS* and *goxv247* genes are transmitted to offspring in a stable Mendelian manner.

Although some DNA sequences inserted into Line Rt73 were derived from known plant pests these sequences can not incite disease. Furthermore, during the transformation process, *Agrobacterium* were killed using an appropriate antibiotic; and no crown gall,

or figwort mosaic virus disease symptoms were observed in canola line RT73 by Monsanto under the field conditions. Furthermore, Monsanto provides evidence that expression of the introduced gene does not result in disease symptoms or the synthesis of products toxic to other organisms. Monsanto monitored glyphosate-tolerant canola field trials conducted from 1992-1993 at 22 locations in Canada and in 1996-1997 at 23 locations in the U.S. to verify the severity of any disease or insect infestation of the transgenic plants; and found that they did not differ significantly from that of the parental line.

Glyphosate-tolerant canola is neither a weed nor has any significant potential to become a weed, and does not transmit weedy characteristics to sexually compatible plants

Weediness can be broadly defined as any capacity for invasion of natural habitats. Many species of *Brassica* and related mustards are weeds or have weedy tendencies. *B. napus* is mentioned as an occasional weed, escape, or volunteer in cultivated fields (Munz 1968, Bailey 1949, Muenscher 1980). *B. juncea, B. nigra, B. rapa,* and *S. arvensis* (=*B. kaber*) to some degree are agricultural weeds, sometimes serious, in much of the United States (Gleason 1952; Slife et al. 1960; Reed 1970; Muenscher 1980).

B. napus is the only *Brassica* species naturalized in the United States, and is not considered to be a weed in the United States (Holm et al. 1979). Generally most crop plants are bred and carefully selected to express agriculturally useful traits, and therefore, they are not usually competitive in unmanaged or untended natural environments. In other words, they are not ecological fit to survive. Canola and other rapeseed are very well adapted for cultivation (fertilization, herbicide, and pesticide application), but not so for growth outside agricultural environments. Without favorable conditions, and intensive cultivation, domesticated types of *B. napus* cannot compete successfully with naturalized forms of *B. napus* in the United States. Naturalized types of *B. napus* are sporadically distributed in Canadian environments, whereas in the United Kingdom, they are widespread in the wild, although they have not been classified as weeds (Mitchell-Olds, 1992; Holm et al., 1991). Efforts are under way to confirm whether these widespread canola are self sustaining populations or are a result of repeated introductions (van der Meijden and de Vries, 1992). In any event, non-transgenic canola are not weeds, and the only question that arises is whether glyphosate-tolerant canola is a weed or has the potential to become a weed. From the experimental data submitted by Monsanto to directly address the question, it becomes very clear that agronomic and morphological characteristics observed on glyphosate-tolerant canola does not lead to suggest that glyphosate-tolerant canola is either a weed or has the potential to become a weed (Appendix 7 of the Petition: Weediness Potential Studies). Data for dormancy, germination, invasiveness, number of volunteers, seed production, pod shattering, overwintering capacity, and adaption to stress factors all demonstrate Line RT73 is equivalent to the nontransgenic parental Westar control. A slight delay in maturation for Line RT73 was considered to be within the natural variation expected for

the nontransformed Westar cultivar.

Transgenic canola with tolerance to glufosinate have been field tested to test the increased invasiveness under field conditions in the United Kingdom (Cherfas, 1991, Crawley, 1992; Crawley et al. 1993). The major conclusions of these studies are that transgenic canola is not any more aggressive than the nontransgenic canola, transgenic rapeseed do not invade undisturbed habitats, and they do not persist in the environment into which they were introduced any more than their parents did. More importantly, the reproductive rate of transgenic rapeseed was less than one in the presence of inter-specific competition in the uncultivated plots during the first year of the study, whereas in the cultivated plots the inter-specific competition was less than one in the second year of the study.

Glyphosate-tolerant canola will not cause damage to agricultural commodities

Canola, by definition is specifically bred to have extremely low levels of toxicants, although *B. napus* rapeseed and its close relatives are known to carry several toxicants (Bell, 1984; Busch et al. 1994; Cheeke, 1989). Canola varieties have very low levels (the range of about 6 to 16 micromole/g) of alkyl glucosinolates in the defatted meal.

The FDA granted its finding of 'No Concern' for canola line RT73 in September 1995. The two proteins CP4 EPSPS and GOXv247 do not pose any safety concern. These proteins are rapidly inactivated by stomach and intestinal fluids. Even if they were not, little harm is likely: enzymes of similar action are widely present in plants and are not associated with adverse effects. EPA has granted an exemption for the requirement of a tolerance for residues of these proteins.

Erucic acid is a monounsaturated fatty acid (22:1) normally produced in very high concentrations (20-60%) in rapeseed. Canola, by definition has less than 2% of erucic acid which is considered safe. Field production of crops that produce high levels of erucic acid for industrial purposes is not restricted or otherwise regulated in the United States. Erucic acid and glucosinolates are the only two toxicants known in rapeseed. Glyphosate-tolerant canola has been developed from low erucic acid and low glucosinolate canola varieties, and data provided by Monsanto demonstrates that canola line RT73 is well below regulatory specifications for their levels of erucic acid and glucosinolates. As such glyphosate-tolerant canola should not present any concerns as far as toxicological properties of glyphosate-tolerant canola.

Information provided by Monsanto regarding the components and processing characteristics of glyphosate-tolerant canola revealed no differences in any component that could have a direct or indirect plant pest effect on any processed commodity.

Glyphosate-tolerant canola will not have a negative impact 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.

Canola seed can remain in the soil profile and produce volunteer plants that may be considered weeds in subsequent crop rotations. If glyphosate-tolerant canola line RT73 volunteers occur in rotations with other glyphosate-tolerant crops currently on the market or on uncultivated land, glyphosate could not be used to manage it as a weed. Glyphosate-tolerant canola has been in commercial production in Canada since 1996, and Monsanto notes that control of glyphosate-tolerant canola volunteers has been achieved through the use of broadleaf herbicides like 2,4-D and sulfonylurea type herbicides either alone or in combination with glyphosate, depending on the crop. They note that normal crop and herbicide rotations have been effective in controlling such volunteers in commercial production. Because other canola varieties tolerant to herbicides with different modes of action (e.g. phosphinothricin) are also commercially available in the U.S. (as well as Canada), Monsanto is aware of the concern that there is a likelihood of canola volunteers possessing a combination of two different herbicide resistance genes via crossing and how such volunteers would be managed by growers. Mechanical means or appropriate alternative herbicides with different modes of action available for each of the major crops in a typical rotation could be used to manage such volunteers (See Table 9 of the petition). It is known that phosphinothricin is not employed to any significant degree for the control of canola volunteers. The Canadian Government has outlined the need for sound crop management practices for volunteer management and potential outcrossing concerns in its Document DD95-02 (Agriculture and Agri-Food Canada, 1995).

Glyphosate-tolerant canola will not be harmful to endangered or threatened species or beneficial organisms, including bees

There is no reason to believe that deleterious effects on beneficial organisms could result from the cultivation of glyphosate-tolerant canola. The proteins expressed in the transgenic canola plants are commonly encountered in nature, and therefore are normal parts of the diets of animals, humans and insects. Cabbage seedpod weevil (*Ceutorhynchis assimilis*) and other *Lygus* species are common pests of canola. These insects are not on the list of threatened and endangered species. Glyphosate-tolerant canola does not contain elevated level of toxic oils, and therefore, insects that may feed on glyphosate-tolerant canola will not be unduly affected in their ability to reproduce or function normally after feeding. Knowledge of the enzyme mode of action, and the lack of known toxicity for the newly expressed proteins suggest no potential for deleterious effects on beneficial organisms such as bees and earthworms. Results of trials in the United States and Canada do not reveal any noticeable adverse effects on beneficial organisms. APHIS has not identified any other potential mechanisms for deleterious

effects on beneficial organisms.

V. CONCLUSIONS

APHIS has determined that glyphosate-tolerant canola line RT73 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 the glyphosate-tolerant canola or its progeny. Importation of glyphosate-tolerant canola, and nursery stock or seeds capable of propagation, is still, however, subject to the restrictions found in the Foreign Quarantine Notice regulations at 7 CFR Part 319. This determination has been made based on an analysis which revealed that the glyphosate-tolerant canola line RT73: (1) exhibits no plant pathogenic properties; (2) is no more likely to become a weed than its non-engineered parental variety; (3) is unlikely to increase the weediness potential for any other cultivated plant or native wild species with which the organisms can interbreed; (4) will not cause damage to processed agricultural commodities; and (5) is unlikely to harm endangered or threatened species or other organisms, such as bees, that are beneficial to agriculture. APHIS has also concluded that there is a reasonable certainty that new progeny varieties bred from glyphosate-tolerant canola line RT73 will not exhibit new plant pest properties, i.e., properties substantially different from any observed for the field tested glyphosate-tolerant canola, or those observed for canola in traditional breeding programs.

for / Rebecca A. Bech, Assistant Director
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