DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 01–101–2]

Aventis CropScience; Extension of Determination of Nonregulated Status for Canola Genetically Engineered for Glufosinate 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 event developed by Aventis CropScience, which has been genetically engineered for tolerance to the herbicide glufosinate, 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 Aventis CropScience 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: December 23, 2002.

ADDRESSES: You may read the extension request, the environmental assessment and finding of no significant impact, and the comment received 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) 734–5490. 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 July 25, 2001, APHIS received a request for an extension of a determination of nonregulated status (APHIS No. 01–206–02p) from Aventis CropScience (Aventis) of Research Triangle Park, NC, for a canola (*Brassica napus L.*) transformation event designated as Topas 19/2 (event Topas 19/2), which has been genetically engineered for tolerance to the herbicide glufosinate. Aventis requested an extension of a determination of nonregulated status issued previously for glufosinate-tolerant canola transformation event T45, the antecedent organism, in response to APHIS petition number 97–205–01p (see 63 FR 6703–6704, Docket No. 97–091–2, published February 10, 1998). Based on the similarity of canola event Topas 19/2 to the antecedent organism, Aventis requested a determination that glufosinate-tolerant canola event Topas 19/2 does not present a plant pest risk and, therefore, is not a regulated article under APHIS—regulations in 7 CFR part 340.

On March 1, 2002, APHIS published a notice in the **Federal Register** (67 FR 9431–9432, Docket No. 01–101–1) announcing that an environmental assessment (EA) for the Aventis extension request had been prepared and was available for public comment. APHIS received one comment on the subject EA during the designated comment period which ended April 1, 2002. We have provided a response to this comment as an attachment to our finding of no significant impact (FONSI). The EA and FONSI, including the attachment, are available from the person listed under **FOR FURTHER INFORMATION CONTACT.**

Analysis

Like the antecedent organism, canola event Topas 19/2 has been genetically engineered to contain a *pat* gene derived from *Streptomyces viridochromogenes*. The *pat* gene encodes the enzyme phosphinothricin-N-acetyltransferase (PAT), which confers tolerance to the herbicide glufosinate. The subject canola event and the antecedent organism were developed through use of the *Agrobacterium tumefaciens* method, and expression of the added genes in Topas 19/2 and the antecedent organism is controlled in part by gene sequences derived from the plant pathogen cauliflower mosaic virus. In summary, canola event Topas 19/2 and the antecedent organism contain the same genetic elements with the exception of the antibiotic resistance marker gene *nptII* in Topas 19/2, which was used as a transformant selection tool during the developmental process. The parental variety used to develop the antecedent organism was the *B. napus* var. AC EXCEL, while the *B. napus* cultivar Topas was used for transforming canola event Topas 19/2.

Canola event Topas 19/2 and the antecedent organism were genetically engineered using the same transformation method and contain the same enzyme that makes the plants tolerant to the herbicide glufosinate. Accordingly, we have determined that canola event Topas 19/2 is similar to the antecedent organism in APHIS petition number 97–205–01p, and, therefore, that canola event Topas 19/2 should no longer be regulated under the regulations in 7 CFR part 340.

The subject canola event has been considered a regulated article under APHIS' regulations in 7 CFR part 340 because it contains gene sequences derived from plant pathogens. However, canola event Topas 19/2 has been extensively field tested in Canada, and after having received the appropriate Canadian approvals, has been marketed commercially in Canada since 1995 with no reports of adverse effects on human health or the environment.

Determination

Based on an analysis of the data submitted by Aventis and a review of other scientific data, APHIS has determined that canola event Topas 19/2: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than the parental canola variety; (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

Topas 19/2 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, Aventis canola event Topas 19/2 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 Topas 19/2 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 extension of a determination of nonregulated status for the subject canola event. 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 Aventis' canola event Topas 19/2 and events developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the Aventis extension request and the EA and FONSI are available from the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Done in Washington, DC, this 19th day of November 2002.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 02–29755 Filed 11–21–02; 8:45 am]

BILLING CODE 3410–34–P

USDA/APHIS Decision on Aventis CropScience USA LP Request (01-206-02p) Seeking an Extension of Determination of Nonregulated Status for Glufosinate Tolerant Canola Event Topas 19/2

Finding of No Significant Impact

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 01-206-02p) of the determination of nonregulated status granted for petition 97-205-01p received from AgrEvo USA Company (now Aventis CropScience) under APHIS regulations at 7 CFR Part 340. The subject of extension request 01-206-02p is a glufosinate tolerant canola event Topas 19/2. 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 Topas 19/2 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: NOV 14 2002

Attachment
Finding of No Significant Impact
Response to Comments
APHIS No. 01-206-02p

In response to a notice published in the *Federal Register* on March 1, 2002 (67 FR 9431-9432), APHIS received one comment on the environmental assessment (EA) prepared for APHIS No. 01-206-02p, a request for an extension of a determination of nonregulated status from Aventis CropScience (Aventis) for canola event Topas 19/2. The comment, which was from a consumer/environmental organization, urged denial of the extension request based on alleged deficiencies in the EA for the extension request and the EA prepared for the antecedent organism, and in 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 any plant pest or environmental risks posed by the subject extension of a determination of nonregulated status.

We do not agree with the commenter's contention that APHIS' analysis of the impacts of the subject extension request are 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 basic validity of APHIS' comparison of the risks posed by transgenic plants with the risks posed by conventionally-developed crops with the same 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 petition No. 97-205-01p reflects these perspectives and appropriately serves as the basis for our finding of no significant impact for canola event Topas 19/2, based on its similarity to the antecedent organism. Equally appropriately, the EA for APHIS No. 01-206-02p establishes this similarity and provides a brief summary of new information relevant to environmental impacts since the development of the original EA. We would also reiterate the fact that the event that is the subject of the extension request has the appropriate clearances for food safety from the Food and Drug Administration, and for pesticide use from the Environmental Protection Agency.

Specific deficiencies cited by the commenter include deviations from standard NEPA formatting and terminology in the updated extension EA, and inadequate substantive analyses in the EA for the antecedent organisms of the impacts of gene flow, pesticide use, and impacts on organic farmers. With regard to the formatting of the extension EA, though APHIS has already provided sections on purpose and need, alternatives, and references in the EA for the antecedent organisms, we have added sections on purpose, need, alternatives and consultations for the convenience of the reader. However, we do not find inadequate our analysis 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 (AMS) and Grain Inspection, Packers and Stockyards Administration published a notice in the August 6, 2002, *Federal Register* (67 FR 50853-50854) announcing new programs to provide, among other things, standardization and quality assurance in biotechnology analysis to help improve the reliability of molecular testing. Federal, State, private and international groups involved in seed certification all allow for some level of accidental, incidental, or adventitious presence of all-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 AMS, 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.html). 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 any potential threats to endangered species of canola event Topas 19/2. On the contrary, as explained in the extension EA, APHIS discussed with FWS its approach to analyzing any potential threats from new crop varieties to threatened and endangered species. In a meeting held July 28, 1999, a consensus was reached that APHIS would use a decision tree to determine whether consultation with FWS would be required for a transgenic crop variety based on a series of criteria. APHIS observed this policy 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 01-206-02p) from Aventis CropScience USA LP (Aventis) for an extension of a previous determination of nonregulated status that APHIS issued for glufosinate tolerant canola event T45 (the antecedent organism in APHIS number 97-205-01p). The Aventis extension request claims that a new canola event, Topas 19/2, 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.

Canola event T45 was developed to allow the use of the herbicide glufosinate as a weed control option in canola. Glufosinate is a natural compound isolated from two species of Streptomyces fungi. It inhibits the activity of an enzyme, glutamine synthetase, which is necessary for the production of glutamine and for ammonia detoxification. The application of glufosinate leads to reduced glutamine and increased ammonia levels in the plant tissues. This causes photosynthesis to stop and the plant dies within a few days. The gene conferring tolerance to glufosinate was introduced via genetic engineering techniques. These techniques enabled the developer to express in the canola plants the phosphinothricin acetyl transferase (*pat*) gene. This gene, isolated from *Streptomyces viridochromogenes*, is referred to hereafter as *pat*. Because the pat enzyme produced by the *pat* gene chemically modifies the herbicide glufosinate to make it inactive, plants expressing this enzyme will be tolerant to this herbicide. The *pat* gene and the regulatory sequences controlling its expression were introduced by using a well-characterized disarmed *Agrobacterium*-mediated transformation and a well-established procedure that results in direct introduction of genes into plant genomes.

There have been no field tests of Event Topas 19/2 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 Aventis 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 potential adventitious presence of this event in commercially available seeds commercially sold in the U.S. (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 T45, followed by a corresponding description of the regulated article Topas 19/2 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. Aventis has successfully concluded its consultation with FDA on glufosinate tolerant canola event HCN92, derived from transformation event Topas 19/2.

The Environmental Protection Agency (EPA) as part of its registration of glufosinate establishes tolerances for combined residues of glufosinate and its metabolite(s) for canola and other crop plants (Federal Register: November 4, 1999, Volume 64, Number 213, pages 60112-60121).

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 Topas/19/2 canola as a regulated article under APHIS regulations. The developer of Topas/19/2 canola, Aventis, submitted a petition requesting that APHIS make a determination that canola transformation event Topas/19/2, and any progeny derived from crosses of event Topas/19/2 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 Topas/19/2 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 Topas/19/2 canola and its progeny.

B. Determination of Nonregulated Status

Under this alternative, Topas/19/2 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 Topas/19/2 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, T45

The antecedent organism event, T45, was produced by transforming a parental line called AC Excel by using disarmed *Agrobacterium* vector system. The fragment inserted into the plant contained the following sequences:

- 35 S promoter from cauliflower mosaic virus (Pietrzak at al., 1986)
- The gene encoding the phosphinothricin acetyl transferase which provides tolerance to glufosinate at the whole-plant level.
- Terminator and polyadenylation sequences of 35 S from cauliflower mosaic virus

V. THE REGULATED ARTICLE, Topas 19/2

Topas 19/2 was produced from a parental line Topas using disarmed *Agrobacterium* vector system. The following describes all DNA sequences inserted into the plant: Topas 19/2 contains 2 plant expression cassettes, one containing a single copy of the *pat* gene and the second one containing a single copy of the neomycin phosphotransferase gene (*npt* II) and respective regulatory sequences as follows:

The *pat* gene cassette (1) contains:

- 35S promoter sequences from cauliflower mosaic virus
- The gene encoding the phosphinothricin acetyl transferase (*pat*) from *Streptomyces viridochromogenes*
- Terminator and polyadenylation sequences of 35 S from cauliflower mosaic virus

The nptII Gene Cassette (2) contains:

- The Nopaline synthase (NOS) promoter sequences from *Agrobacterium tumefaciens*
- The Neomycin phosphotransferase II gene from *Escherichia coli*
- The Octapine synthase (OCS) terminator sequences from *Agrobacterium tumefaciens*

VI. SIMILARITIES AND DIFFERENCES BETWEEN Topas 19/2 AND THE ANTECEDENT ORGANISM T45.

Events T45 and Topas 19/2 were produced by the transformation of canola *Brassica napus* germplasm. Both events were a result of transformation using a disarmed *A. tumefaciens* in a cointegrative vector system. Both events display similar levels of tolerance to the herbicide glufosinate ammonium. The transformation has not impacted any of the key agronomic characteristics as the transformed events are similar to their non-transgenic counterparts including establishment, height, maturity, lodging, yield and disease susceptibility.

Similarly, seed compositional characteristics of the transformed events Topas 19/2 and the antecedent T45 are similar to their transformed counter parts. The FDA consultation has been favorably concluded with regards to the food and feed safety for both events. 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 equivalent to the non-transgenic counterparts.

A comparison of sequences present in T45 and Topas 19/2 reveals similarities and differences at the molecular level for the two events. Like T45, Topas 19/2 was

transformed using disarmed *A. tumefaciens* vector system. Both events involved the use of 35S promoter and terminator sequences from cauliflower mosaic virus and the *pat* gene that confers tolerance to the herbicide glufosinate ammonium. The *pat* gene is expressed and can be detected in green plant tissue in both events. The level of PAT protein expression is equivalent in both Topas 19/2 and the antecedent organism T45.

The only significant difference between the events Topas 19/2 and the antecedent T45 at the molecular level is the presence of *npt* II gene directed by the NOS promoter and OCS terminator sequences in Topas 19/2. The *npt* II gene is expressed and can be detected in green plant tissue.

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 Topas/19/2 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 glufosinate on T45 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 Topas/19/2 canola, is addressed below. The unrestricted cultivation and distribution of Topas/19/2 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 97-205-01p 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 Topas 19/2 is the presence of *npt* II gene (used for selection during the tissue culture process), no new EA is deemed necessary.

Event Topas 19/2 differs from the antecedent organism solely by the presence of *npt* II gene. *Npt* II is rapidly inactivated by stomach acid, is degraded by digestive enzymes (Fuchs et al., 1993), and is not glycosylated when produced in the transgenic tomato, oilseed rape, and cotton. In addition, enzymes such as APH(3')II are heat labile. Thus, APH(3')II does not possess any of the characteristics associated with allergenic proteins such as proteolytic stability, glycosylation, or heat stability (Taylor et al., 1987). In addition, protein and DNA sequence comparisons using sequences in four separate databases (GenBank, EMBL, PIR 29, and Swiss-Prot) showed that *npt* II does not have significant homology to any proteins listed as food allergens or toxins in these databases.

APHIS would like to note that NPTII has been approved for human consumption by FDA (Internet address http://vm.cfsan.fda.gov/~lrd/biotechm.html, see: Listing of final consultations under FDA's Biotechnology Policy). Likewise, government agencies in Canada, Japan, and the European Union have issued decisions that *npt*II is safe to be consumed by humans and animals.

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) Topas 19/2 canola will be clearly labeled in its marketing as glufosinate resistant (i.e Innovator™, Independence™) as it entails the use of the companion herbicide to reap any potential benefits, and (c) and the detection of the adventitious presence of event Topas 19/2 in organic canola is not precluded by the USDA's National Organic Program (http://www.ams.usda.gov/nop/nop2000/Final%20Rule/nopfinal.pdf) 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 Topas 19/2 has had any impact on nontarget organisms or threatened or endangered species. On July 28, 1999, APHIS met with the U.S. Fish and Wildlife Service and they determined our assessments to be adequate for addressing the impact of events derived from Topas 19/2 on threatened and endangered species. Therefore, APHIS concludes that there is no reason to believe that deleterious effects or significant impacts on nontarget organisms, including threatened and endangered species or beneficial organisms, would result from the expression of nptII. Data supports that this protein is not allergenic nor a toxin (see above).

Because the regulated article Topas 19/2 is agronomically similar to the antecedent organism T45, it does not present any new potential environmental impact issues other than those addressed in the EA associated with determination on petition number 97-205-01p.

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 Topas 19/2. 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 Topas 19/2 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. A gene that results in accumulation of PAT has been inserted into a canola chromosome in glufosinate tolerant canola. In nature, chromosomal genetic material from plants can only be transferred to another sexually compatible flowering plant by cross-pollination. Neither the gene that results in accumulation of PAT, nor the PAT itself, nor its associated regulatory sequences, confers on glufosinate tolerant canola or its progeny any plant pest characteristic.

2. In nature, the gene that results in accumulation of PAT will not provide glufosinate 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 glufosinate tolerant canola exhibits any increased weediness relative to that of the parental variety.

3. The use of glufosinate 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 glufosinate tolerant canola or its progeny in agriculture will not cause damage to raw or processed agricultural commodities.

5. The use of glufosinate 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. REFERENCES

Note: Appendices A and B provide additional citations which may be pertinent to this EA.

Fuchs, R. L. et al., "Safety Assessment of the Neomycin Phosphotransferase II (NPTII) Protein," Biotechnology, 11:1543-1547, 1993.

Pietrzak, M. et al. 1986. Expression in plants of two bacterial antibiotic resistance genes after protoplast transformation with a new plant expression vector. Nucleic Acids Res. 14:5857-5868.

Taylor, S. L. et al.,"Food Allergens: Structure and Immunologic Properties," Annals of Allergy, 59:93-99, 1987.

X. REVIEWERS

Biotechnology Regulatory Services

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XI. CONSULTATIONS

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Phil MacDonald, Canadian Food Inspection Service, Plant Biosafety Office

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XII. AGENCY CONTACT

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APPENDICES: Environmental Assessment and Determination of Nonregulated Status for APHIS number 97-205-01p

Response to AgrEvo Petition 97-205-01p for Determination of Nonregulated Status for Glufosinate Tolerant Canola

Environmental Assessment and Finding of No Significant Impact

January 1998

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 97-205-01p) received from AgrEvo USA Company regarding the status of glufosinate tolerant canola under APHIS regulations at 7 CFR Part 340. The plants, resulting from Transformation Event T45, have been engineered with a gene that results in accumulation of phosphinothricin-N-acetyltransferase (PAT), an enzyme that catalyzes the conversion of L-phosphinothricin to an inactive form, thereby conferring tolerance to the herbicide glufosinate. 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 certain lines of glufosinate tolerant canola shall no longer be regulated articles.

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TABLE OF CONTENTS

APPENDICES

I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 97-205-01p) from AgrEvo USA Company (AgrEvo) regarding glufosinate tolerant canola lines derived from Transformation Event T45 (T45). AgrEvo seeks a determination that these glufosinate tolerant canola lines (glufosinate tolerant canola) do not present a plant pest risk and should therefore no longer be regulated articles under regulations at 7 CFR Part 340. Glufosinate tolerant canola has been genetically engineered to express a gene that results in accumulation of phosphinothricin-N-acetyltransferase (PAT), an enzyme that catalyzes the conversion of L-phosphinothricin to an inactive form, thereby conferring tolerance to the herbicide glufosinate.

AgrEvo submitted its petition after the completion of field tests of glufosinate tolerant canola at 19 sites in the major growing States under permit 96-057-01r. Field tests have also been completed in Canada, Chile, Japan, the United Kingdom, and Australia. 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. These lines have received clearance for commercial use from Agriculture and Agri-Foods Canada (AAFC) and Health Canada.

An Environmental Assessment (EA) was prepared prior to granting each of the permits for a field trial using glufosinate tolerant canola. The EAs for the previous introductions of glufosinate 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 glufosinate tolerant canola.

APHIS has considered the information provided by AgrEvo in its petition as well as other scientific data relating to the potential plant pest risk of glufosinate tolerant canola. A thorough evaluation of the potential for significant impact to the human environment through the unconfined, agricultural use of glufosinate tolerant canola has brought APHIS to a Finding of No Significant Impact (FONSI). This conclusion is based upon (1) the purpose of the genetic modification; (2) the fact that this modification will not increase the weediness of canola or any sexually compatible plants; and (3) the fact that this modification will not negatively effect any nontarget organisms, including beneficials. In conjunction with the FONSI, APHIS has made the determination that certain glufosinate tolerant canola lines and their progeny have no potential to pose a plant pest risk, and are, therefore, no longer regulated articles. Our documentation of that determination is attached as Appendix A.

II. INTRODUCTION

This EA examines potential environmental impacts from the unrestricted introduction of glufosinate tolerant canola. Glufosinate tolerant canola has been extensively field tested in Canada, United States, Chile, Japan, United Kingdom, and Australia. During 1996, T45 canola was tested at 150 sites in Canada. In 1996, T45 canola was tested at 19 sites in the USA under permit 96-057-01r. In 1997, T45 canola was tested at 20 sites in the USA under permits 97-015-01r and 97-035-01r. The genetic material introduced into these lines has been discussed in detail in EAs prepared for field tests under the above permits. AgrEvo has presented field data reports for the USA release permits. AgrEvo has also presented data from the Canadian trials. These reports give information on plant height at crop maturity, yield, maturity dates, seed percent oil, seed protein, seed fatty acid composition, and seed glucosinolates. All these agronomic traits fall well within the range of the nontransformed species. The only significant consistent difference between glufosinate tolerant canola and the parent variety is the increase in the PAT enzyme that confers herbicide tolerance.

All 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 glufosinate tolerant canola are found in APHIS Determination of Nonregulated Status. Because this information is included as Appendix A, it will not be described in detail in the body of this document.

Prior to issuing a permit for a field release, APHIS analyzes the potential impacts associated with the proposed introduction, and prepares an environmental assessment which documents the analysis in accordance with regulations and guidelines 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 AgrEvo petition have been considered regulated articles because noncoding DNA regulatory sequences are derived from cauliflower mosaic virus, a plant pathogen, and because *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 glufosinate 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 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 Food and Drug Administration (FDA) has authority to ensure the safety and wholesomeness of all food(s). 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 glufosinate tolerant canola lines is under the jurisdiction of the FDA. AgrEvo has indicated that they are in consultation with the FDA.

The Environmental Protection Agency (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 insecticides, 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.

IV. ALTERNATIVES

In the course of preparing the environmental assessment for this petition, APHIS considered the following three alternatives: (1) deny the petition, so that glufosinate tolerant canola would continue to be regulated under 7 CFR Part 340; (2) approve the petition, with geographical limitations; and (3) approve the petition, so that permits would no longer be required from APHIS under 7 CFR Part 340 for glufosinate 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 AgrEvo, and scientific literature, APHIS could find no basis for denying the petition (Alternative 1), or for imposing geographical limitations on the use of glufosinate tolerant canola (Alternative 2).

V. AFFECTED ENVIRONMENT AND POTENTIAL ENVIRONMENTAL IMPACTS

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

Potential impacts based on increased weediness of glufosinate tolerant canola relative to traditionally bred canolas

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 not listed as a weed in Weed Science Society of America (1989). 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). AgrEvo has submitted substantial evidence to indicate the lack of weedy nature of transformed canolas under agricultural conditions. They have submitted data on germination, seed production, pest and disease resistance, response to salinity and stress, seed dormancy, and sensitivity to herbicides other than glufosinate, and other fitness characteristics. None of these characteristics show an increase in weediness potential.

The relevant introduced trait, glufosinate tolerance, is unlikely to increase weediness of this canola unless glufosinate 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 glufosinate tolerant canola (Tiedje et al., 1989; Office of Technology Assessment, 1988). AgrEvo data from field trials show no obvious increase in volunteers from seed, increase in seed dormancy, or other variation indicative of increased weediness. Moreover, AgrEvo presents evidence that glufosinate

tolerant canola is as readily controlled with non-glufosinate herbicides as the nontransformed canola.

Potential impacts from outcrossing of glufosinate 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 vigour and high sterility in the hybrids will generally mean that hybrids and their progeny will not survive in either an agicultural 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 glufosinate tolerance should not confer a competitive advantage in these species unless glufosinate 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 extrememly low levels, and as with members of the genus *Brassica*, it is unlikely that the gene that codes for glufosinate tolerance would confer a competitive advantage in these species unless glufosinate 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 glufosinate tolerant canola. Neither the PAT enzyme nor the gene that produces it is known to have any toxic properties.

Consideration of potential environmental impacts associated with the cultivation of glufosinate 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 glufosinate 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 impacts on the environment that might be relevant to glufosinate tolerant canola or follow from the unconfined cultivation of these canola lines in the United States and its territories, or abroad. 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 glufosinate tolerant canola lines are no more likely to become weeds than lines developed by traditional breeding techniques, are unlikely to increase the weediness potential of any other cultivated plant or native wild species with which these lines 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 these lines on biodiversity.

Potential impacts on agricultural and cultivation practices.

Based on APHIS analysis, there is unlikely to be any significant adverse impact on agricultural practices associated with the use of these lines.

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 glufosinate 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. A gene that results in accumulation of PAT has been inserted into a canola chromosome in glufosinate tolerant canola. In nature, chromosomal genetic material from plants can only be transferred to another sexually compatible flowering plant by cross-pollination. Neither the gene that results in accumulation of PAT, nor the PAT itself, nor its associated regulatory sequences, confers on glufosinate tolerant canola or its progeny any plant pest characteristic.

2. In nature, the gene that results in accumulation of PAT will not provide glufosinate 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 glufosinate tolerant canola exhibits any increased weediness relative to that of traditional varieties.

3. The use of glufosinate 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 glufosinate tolerant canola or its progeny in agriculture will not cause damage to raw or processed agricultural commodities.

5. The use of glufosinate tolerant canola or its progeny in agriculture will not have a significant impact on any beneficial organisms in the environment, or on any threatened or endangered species.

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RESPONSE TO AGREVO PETITION 97-205-01p FOR DETERMINATION OF NONREGULATED STATUS FOR GLUFOSINATE TOLERANT CANOLA

January 1998

Prepared by
United States Department of Agriculture
Animal and Plant Health Inspection Service
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TABLE OF CONTENTS

I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS) has determined, based on a review of scientific data and information that transformed glufosinate tolerant canola (*Brassica napus* L.) which is derived from Transformation Event T45, and all other lines bred or otherwise derived from this transformant by sexual or asexual reproduction involving Mendelian inheritance, do not present a plant pest risk, and are therefore no longer 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 glufosinate tolerant canola or its progeny. Importation of glufosinate tolerant canola mentioned above, and nursery stock or seeds capable of propagation are still subject to restrictions found in the Foreign Quarantine Notice regulations at 7 CFR Part 319. Variety registration and/or seed certification for individual glufosinate tolerant canola lines may involve future actions by the U.S. Plant Variety Protection Office and State Seed Certification officials.

The APHIS determination has been made in response to a petition from AgrEvo USA Company (AgrEvo), Wilmington, Delaware, dated July 18, 1997. The petition seeks a determination from APHIS that glufosinate tolerant canola and its progeny do not present a plant pest risk and are therefore no longer regulated articles. On September 30, 1997, APHIS announced receipt of the AgrEvo petition in the Federal Register (62 FR 51081-50982) 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 glufosinate tolerant canola, and food products derived from it. APHIS invited written comments on whether glufosinate tolerant canola poses a plant pest risk, to be submitted on or before December 1, 1997. No comments were received.

Glufosinate tolerant canola has been described by AgrEvo as any *B. napus* cultivar or progeny resulting from Transformation Event T45 (T45). T45 canola contains a stably integrated gene, *pat*, from *Streptomyces viridochromogenes*, which encodes phosphinothricin-N-acetyltransferase (PAT), with 35S promoter and terminator from cauliflower mosaic virus. The PAT enzyme catalyzes the conversion of L-phosphinothricin (PPT), the active ingredient in glufosinate-ammonium, to an inactive form, thereby conferring tolerance to the herbicide glufosinate.

APHIS regulations 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 not subject to the regulatory requirements of 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 that would allow for introduction of the regulated article (organisms) in question without permits or notifications under 7 CFR Part 340. In this instance, they are glufosinate tolerant canola.

Glufosinate tolerant canola has been considered a "regulated article" because it contain noncoding DNA regulatory sequences derived from cauliflower mosaic virus, a plant pathogen, and because *Agrobacterium tumefaciens* was used as a vector agent.

Field testing of glufosinate tolerant canola has been conducted with APHIS approval in 1996 and 1997. AgrEvo submitted its petition after the completion of field tests of glufosinate tolerant canola at 19 sites in the major growing states. All field trials were performed under conditions of physical and reproductive confinement. Field tests have also been completed in Canada, Chile, Japan, the United Kingdom, and Australia. Glufosinate tolerant canola has received clearance for commercial use from Agriculture and Agri-Foods Canada (AAFC) and Health Canada.

APHIS has determined that glufosinate tolerant canola identified in the petition does not present a plant pest risk, and therefore, will no longer be considered a regulated article under APHIS regulations at 7 CFR Part 340. The Agency decision is based on an analysis of data provided to APHIS by AgrEvo as well as other scientific data relating to the potential plant pest risk of glufosinate tolerant canola. AgrEvo provided both general and specific information and data from field testing of glufosinate tolerant canola. From our review, we have determined that glufosinate tolerant canola: (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 glufosinate tolerant canola will not exhibit new plant pest properties, i.e., properties substantially different from any observed for the field tested glufosinate 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 guidelines 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. An Environmental Assessment (EA) was prepared and a Finding of No Significant Impact (FONSI) was reached by APHIS for the determination that glufosinate tolerant canola is no longer a regulated article under its regulations at 7 CFR Part 340. The EA and FONSI are available from APHIS upon written request.

This document consists of two parts: (1) background information which provides the regulatory framework under which APHIS has regulated the field testing, interstate movement, and importation of glufosinate tolerant canola; and (2) analysis of the key factors relevant to the APHIS decision that glufosinate tolerant canola does not present a plant pest risk.

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.

Glufosinate tolerant canola has been considered a "regulated article" because it contain noncoding DNA regulatory sequences derived from cauliflower mosaic virus, a plant pathogen, and because *Agrobacterium tumefaciens* was used as a vector agent.

APHIS believes it prudent to provide assurance prior to commercialization that organisms, such as glufosinate tolerant canola developed in part from plant pest sequences, do not pose any potential plant pest risk. Such assurance may aid the entry of new plant varieties into commerce or into breeding and development programs. The decision by APHIS that glufosinate tolerant canola is no longer a regulated article is based in part on evidence provided by AgrEvo concerning the biological properties of the glufosinate tolerant canola, and its similarity to other varieties of canola grown using standard agricultural practices for commercial sale or private use. Glufosinate tolerant canola has been field tested at 19 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.

The fact that APHIS regulates genetically engineered organisms having plant pest components does not carry with it the presumption that the presence of part of a plant pest makes a whole plant pest or that plants or genes are pathogenic. The regulations are based on the premise that when plants are developed using biological vectors from pathogenic sources, transforming material from pathogenic sources, or pathogens are used as vector agents, that they should be evaluated to assure that there is not a plant pest risk. For each release permit application APHIS performs a review that allows a verification of the biology and procedures used; assesses the degree of uncertainty and familiarity; evaluate mitigating factors and agricultural practices of the crop in question and allows the identification of any predictable hazards. The overall aims of APHIS regulations in the Code of Federal Regulations at 7 CFR Part 340 are to allow for the safe testing of genetically engineered organisms under an appropriate level of oversight, and to enable any issues of potential or hypothetical risks to be addressed early enough in the development of the new organisms to allow for the safe use and application of biotechnology in agriculture.

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. In APHIS regulations at 7 CFR Part 340, a "plant pest" is defined as: "Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants."

Lack of plant pest risk may be arrived at when there is evidence that the plant under consideration: (1) exhibits no plant pathogenic properties; (2) is no more likely to become a weed than its non-engineered parental varieties; (3) is unlikely to increase the weediness potential for any other cultivated plant or native wild species with which the organism can interbreed; (4) does not cause damage to processed agricultural commodities; and (5) is unlikely to harm other organisms, such as bees, that are beneficial to agriculture. In addition, because the AgrEvo petition seeks a determination regarding glufosinate tolerant canola, it should be established that there is a reasonable certainty that any new glufosinate tolerant canola varieties bred from this glufosinate tolerant canola will exhibit plant pest properties not different from any observed for canola in traditional breeding programs or as seen in the development of glufosinate tolerant canola.

Oversight by Other Federal Agencies. The EPA regulates the use of pesticide chemicals, including herbicides, in the environment. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, (7 U.S.C. 136 et seq.), EPA has the authority to regulate the testing, sale, distribution, use, storage, and disposal of pesticides. Before a pesticide may be sold, distributed, or used in the United States, it must be registered under FIFRA Section 3. For a pesticide that is already registered, the use of the pesticide on a new crop plant (i.e., use on a crop for which the pesticide is not already registered) requires EPA approval of an amendment to the registration. In determining whether to approve the new use of the pesticide, EPA considers the possibility of adverse effects to human health and the environment from the new use. Under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended, (21 U.S.C. 201 et seq.), EPA also has responsibility for establishing tolerances for pesticide residues on food or feed.

The FFDCA provides FDA with authority to ensure the safety and wholesomeness of all food(s). 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 glufosinate tolerant canola is under the jurisdiction of the FDA. AgrEvo has indicated that they are in consultation with the FDA.

IV. ANALYSIS OF THE PROPERTIES OF GLUFOSINATE 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 glufosinate tolerant canola. In addition, to reach its determination that glufosinate tolerant canola does not present a plant pest risk, APHIS has analyzed basic information on the biology of canola but also data presented by AgrEvo 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 glufosinate 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.

Cultivar AC EXCEL, grown in western Canada was used for transformation. Recent interest in the crop has centered around cultivars that have low erucic acid, and thus contain desirable edible oils. Rapeseed oils have been used for lamp oils, soap making, plastics manufacturing, and high-temperature and tenacious high-erucic acid lubricating oils (Röbbelen et al. 1989; Weiss 1983). Other species of *Brassica* are also grown for rapeseed oil, but they are not the subject of this determination.

World production of rapeseed oil in 1987-1988 was 7.5 million metric tons, ranking it number three behind canola (15.4) and palm (11.7), and before sunflower (7.0), cottonseed (3.4), and peanut (2.8). China, India, Europe, and Canada are the top world producers. Current production in the United States is limited.

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).

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 glufosinate 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* glufosinate tolerant canola hybrids is lower than feral *B. napus* glufosinate 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 control. 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 glufosinate tolerant transgene to wild populations (Crawley et al. 1993).

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

The standard recombinant DNA technology to introduce the genes into plant cells (transformation) uses a recombinant plasmid (vector) molecule which is complex chimera of DNA sequences drawn from various organisms. Some of these organisms from which these DNA sequences are derived are known plant pests, and as such the transgenic crop plants or organisms become regulated articles under 7 CFR 340.

The introduction of the vector DNA does not present a plant pest risk in glufosinate tolerant canola identified in the present petition. The vector system used to transfer the *pat* gene into the canola nuclear genome, does not contain any disease causing sequences from the native tumor-inducing (Ti) plasmid system used by the plant pathogenic bacterium *Agrobacterium tumefaciens* for plant infection and gene transfer (Zambryski, 1988). Additionally, there are DNA sequences derived from cauliflower mosaic virus, a plant pathogen that is on the list of regulated articles in 7 CFR Part 340.

A. tumefaciens is the causal agent of a plant disease called crown gall, and *A. rhizogenes* causes hairy root disease. In glufosinate tolerant canola, none of the introduced coding regions or the regulatory sequences confer any plant pest risk. The vector system was used as a part of transformation method known as agro-infection that involves incubating the hypocotyl explants from 7 day old seedlings of canola with *A. tumefaciens* containing a binary vector to accomplish the stable gene transfer. AgrEvo states that the *pat* gene in glufosinate tolerant canola is transmitted through meiosis in a Mendelian fashion.

AgrEvo analyzed the physical structure of the integrated genetic material in glufosinate tolerant canola (See Figure 5 in the petition). Southern analyses demonstrate that there is a single copy of the *pat* gene, and that it is transmitted to offspring in a stable Mendelian manner.

Despite the presence of certain pathogen-derived sequences in the glufosinate tolerant canola genome, no crown gall, hairy root or CaMV disease symptoms were observed by AgrEvo under the field conditions. Furthermore, AgrEvo provides evidence that expression of the introduced gene does not result in disease symptoms or the synthesis of products toxic to other organisms. AgrEvo monitored the glufosinate tolerant canola field trials to verify that the severity of any disease or insect infestation of the transgenic plants and found that they did not differ from that of the parental line. No difference in disease and insect susceptibility was observed at the sites where glufosinate tolerant canola was tested.

Glufosinate tolerant canola is neither a weed nor have any significant potential to become a weed, and do 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 rapeseeds 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 canolas are self sustaining populations or are a result of repeated introductions (van der Meijden and de Vries, 1992). In any event, non-transgenic canolas are not weeds, and the only question that arises is whether glufosinate tolerant canola is a weed or have the potential to become a weed. From the experimental data submitted by AgrEvo to directly address the question, it becomes very clear that agronomic and morphological characteristics observed on glufosinate tolerant canola does not lead to suggest that glufosinate tolerant canola is either a weed or have the potential to become a weed (Table 13a, and 13b). None of the glufosinate tolerant canola showed increased seedling vigor, or overwintering ability.

Transgenic canola that are not glufosinate tolerant canola, 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 rapeseeds 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.

Weediness may be affected by seed dormancy and seed persistence. Field trials do not show any difference between the transgenic plants and nontransgenic plants.

Glufosinate 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 (30 micromole/g) of alkenyl glucosinolates in the defatted meal.

AgrEvo has been in direct consultation with the Food and Drug Administration to assure that glufosinate tolerant canola are safe for human and animal consumption. The PAT enzyme poses no safety concern. It is rapidly inactivated by stomach and intestinal fluids. Even if it were not, little harm is likely: enzymes of similar action are widely present in plants and are not associated with adverse effects.

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. Glufosinate tolerant canola has been developed from low erucic acid and low glucosinolate canola varieties, thus meeting the regulatory specifications for their levels. As such glufosinate tolerant canola should not present any concerns as far as toxicological properties of glufosinate tolerant canola.

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

Glufosinate 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 glufosinate tolerant canola. The PAT enzyme is commonly encountered in nature, and therefore it is a normal part 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. Glufosinate tolerant canola does not contain elevated level of toxic oils, and therefore,

insects that may feed on glufosinate 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 this protein 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 glufosinate tolerant canola will no longer be considered a regulated articles 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 glufosinate tolerant canola or its progeny. Importation of glufosinate 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 glufosinate tolerant canola: (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 glufosinate tolerant canola will not exhibit new plant pest properties, i.e., properties substantially different from any observed for the field tested glufosinate tolerant canola, or those observed for standard canola in traditional breeding programs.

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