Response to AgrEvo Petition 98-278-01p for Determination of Nonregulated Status for Canola Transformation Events MS8 and RF3 Genetically Engineered for Pollination Control and Tolerance to Glufosinate Herbicide

Finding of No Significant Impact

March 1999

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture, has prepared an environmental assessment prior to issuing a determination in response to a petition (APHIS Number 98-278-01p) received from AgrEvo USA Company regarding the status of canola transformation events MS8 and RF3 under APHIS regulations at 7 CFR Part 340. MS8 and RF3 canola are genetically engineered for male sterility and restoration of male fertility, respectively, and both transformation events are genetically engineered for tolerance to the herbicide glufosinate-ammonium. The purpose of this pollination control system is to enable the production of pure hybrid canola varieties.

APHIS has conducted an extensive review of the petition and supporting documentation, as well as other relevant scientific information. A thorough evaluation of the potential for significant impact to the human environment has brought APHIS to a Finding of No Significant Impact (FONSI). This conclusion is based on our analysis that MS8 and RF3 canola: (1) exhibit no plant pathogenic properties either as a result of the transformation process itself or from the insertion and expression of new genetic material conferring the herbicide tolerance and pollination control traits; (2) are no more likely to become weeds, or increase the weediness potential or effect biodiversity of sexually compatible relatives, any more than commercially available canola varieties; (3) will not cause damage to raw or processed agricultural commodities; (4) will not harm organisms beneficial to plants (e.g., bees and earthworms), or threatened or endangered species; (5) are unlikely to have any significant adverse impact on agricultural practices. APHIS has also concluded that there is a reasonable certainty that new progeny varieties bred from MS8 and/or RF3 will not exhibit new plant pest properties, i.e., properties substantially different from any observed for MS8 or RF3 canola, or those observed for traditionally bred canola.

In conjunction with the FONSI, APHIS has made the determination that MS8 and RF3 canola transformation events and progeny derived from either of these have no potential to pose a plant pest risk, and are, therefore, no longer regulated articles under regulations at 7 CFR part 340.

)))))))))))))))))))))) Sally L. McCammon Acting Assistant Director Scientific Services Plant Protection and Quarantine Animal and Plant Health Inspection Service U.S. Department of Agriculture Date:

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

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

ENVIRONMENTAL ASSESSMENT

TABLE OF CONTENTS

APPENDIX A: Determination: Response to AgrEvo Petition 98-278-01p for Determination of Nonregulated Status for Canola Transformation Events MS8 and RF3 Genetically Engineered for Pollination Control and Glufosinate Herbicide Tolerance I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 98-278-01p) from AgrEvo USA Company (AgrEvo) regarding canola transformation events MS8 and RF3. AgrEvo seeks a determination that these canola transformation events do not present a plant pest risk and should therefore no longer be regulated articles under regulations at 7 CFR Part 340.

The subject canola transformation events were genetically engineered for male sterility (MS8), restoration of male fertility (RF3), and tolerance to the herbicide glufosinate (both MS8 and RF3), to enable the production of pure hybrid canola varieties by the use of a pollination control system. The genes controlling pollination, barnase and barstar, were derived from the bacterium Bacillus amyloliquefaciens. The gene controlling glufosinate tolerance, bar, was derived from the bacterium Streptomyces hygroscopicus. These canola have been considered regulated articles because a plant pest, Agrobacterium, was used as a vector for the insertion of these genes into these canola and as a donor of certain sequences used to regulate expression of these genes.

Field trials of MS8 and RF3 canola and their progeny have been conducted under permits and notification acknowledged by APHIS according to regulations at 7 CFR Part 340. Performance standards and conditions for such field trials require that the regulated article and its offspring must not persist in the environment after completion of the test. This Environmental Assessment (EA) specifically addresses the potential for impacts to the human environment through use in agriculture of MS8 and RF3 canola or progeny derived from them following a determination of nonregulated status by APHIS under 7 CFR Part 340.

II. PROPOSED ACTION - Description and Statement of Purpose and Need.

APHIS Regulatory Authority for the Introduction of MS8 and RF3 Canola. The USDA/APHIS has recieved a petition (98-278-01p) submitted by AgrEvo for a determination of nonregulated status of MS8 and RF3 canola and their progeny. The purpose of this Environmental Assessment (EA) is to ascertain whether the proposed approval of this petition, which would allow for the unconfined introduction into the U.S. or its territories of these canola, would have a significant impact on the environment. This petition was submitted pursuant to regulations codified in 7 CFR Part 340. These regulations, 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" govern the introduction (importation, interstate movement, or release into the environment or any attempt thereat) of certain genetically engineered organisms and products.

MS8 and RF3 canola have been genetically engineered to express a bar gene derived from the bacterium Streptomyces hygroscopicus. The bar gene encodes the enzyme phosphinothricin-N-acetyltransferase (PAT) that confers tolerance to the post-emergence, broad-spectrum herbicide glufosinate-ammonium in MS8 and RF3 canola. In addition, MS8 and RF3 have been engineered with genes to control pollination and allow for the production of hybrids. MS8 has been engineered to express a ribonuclease encoded by the barnase gene derived from the bacterium Bacillus amyloliquefaciens. The ribonuclease blocks pollen development and results in male sterility in MS8 canola or progeny containing the gene. RF3 has been engineered to express a specific inhibitor of this ribonuclease encoded by the barstar gene, which is also derived from B. amyloliquefaciens. The ribonuclease inhibitor restores male fertility in plants containing the barnase gene. Thus male fertile canola plants such as RF3 that express the barstar gene can be used in controlled pollinations of male sterile canola plants such as MS8 that contain the barnase gene to produce hybrid progeny with restored male fertility. MS8 and RF3 canola have been considered "regulated articles" under 7 CFR Part 340 because the plant pathogen Agrobacterium tumefaciens was used as a transformation vector agent and as a source of noncoding sequences used to regulate the expression of inserted genes.

These canola have been extensively field tested in Canada, Europe, and the United States. Field testing in the U. S. has been conducted since 1997 only under conditions of physical and reproductive confinement as authorized by USDA permits (97-035-05r, 98-119-01r) and notifications (98-064-38n, 98-064-35n, 98-064-33n, 98-168-04n, 98-064-31n) according to APHIS regulations at 7 CFR Part 340. Prior to issuing a permit or notification for a field release, APHIS analyzes the potential impacts associated with the proposed introduction. AgrEvo has submitted field data reports for field tests conducted in the U.S. and data from the Canadian and European trials. These reports give information on the biological and agronomic characteristics of the plant, oil and seed quality, and any potential adverse effects on plants, nontarget organisms, or the environment associated with the field trial.

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 for determination of nonregulated status," provides that a person may petition the Agency to evaluate submitted data and determine whether a particular regulated article does not present a risk of introduction or dissemination of a plant pest. If a determination of nonregulated status is made, the petition would be granted, thereby allowing for unregulated introduction of the article in question. Permits and notifications under those regulations would then 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.

Prior to issuing a determination of nonregulated status, APHIS considers regulatory alternatives and evaluates the potential for significant impact to the human environment, in accordance with regulations and procedures implementing the National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 et seq.); 40 CFR Parts 1500-1508; 7 CFR Part 1b; 7 CFR Part 372.

Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) Regulatory Authority over MS8 and RF3 Canola. The FDA has authority to ensure the safety and wholesomeness of all food(s). The FDA policy statement concerning the

regulation of foods derived from new plant varieties, including genetically engineered plants, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Regulatory oversight for the safety of any food or feed products derived from MS8 and RF3 canola is under the jurisdiction of the FDA. FDA has granted a finding of 'No Concern' for the subject canola tranformation events in September, 1998, (please see the FDA Home Page at the following URL: (http://vm.cfsan.fda.gov/~lrd/biocon.html).

The EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, (7 U.S.C. 136 et seq.). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA, and the FDA enforces those tolerances. Full registration and tolerance establishment for use of glufosinate-ammonium herbicide Liberty7 on glufosinate-tolerant canola is pending with the EPA. The tolerance extension was announced by the EPA in the Federal Register on October 8, 1997 (62 FR 52544-52552) (please see the EPA Federal Register notice at the following URL: (http://www.epa.gov/docs/fedrgstr/EPA-PEST/1997/October/Day-08/p26537.htm).

III. ALTERNATIVES

In the course of preparing the environmental assessment for this petition, APHIS considered the following two alternatives: (1) deny the petition, so that MS8 and RF3 canola would continue to be regulated under 7 CFR Part 340; and (2) approve the petition, so that permits or notifications would no longer be required from APHIS under 7 CFR Part 340 for these canola tranformation events or progeny derived from them when introduced or grown in the United States and its territories.

IV. AFFECTED ENVIRONMENT AND POTENTIAL ENVIRONMENTAL IMPACTS

If APHIS denies the petition, MS8 and RF3 canola and progeny derived from either of these would continue to be regulated by APHIS under 7 CFR Part 340. Interstate movement, certain importations, and environmental releases of these canola could only be conducted under permits or notifications approved by APHIS that impose conditions of physical or reproductive confinement to prohibit persistence of these canola or their progeny in the environment. For example, to prevent out-crossing to sexually compatible species and persistence of any offspring, most canola field trials conducted under 7 CFR Part 340 require an isolation distance of 660 ft. from other commercial canola, control of sexually compatible wild or weedy relatives around the release site, strict harvesting measures, and post-harvest monitoring and termination treatments to control volunteers from the transgenic canola. AgrEvo would not be able to sell seed from these canola (or their progeny) to farmers for planting unless the farmers were able and willing to meet the conditions of the permit or notification. Farmers who grow canola for its oil and meal would find such conditions difficult, if not impossible, to meet. Denying the petition would have the effect of denying American farmers the benefit of hybrid canola seed that could be produced from MS8 and RF3 canola.

The remainder of this EA addresses potential environmental impacts from a determination that MS8 and RF3 canola or progeny derived from either of these should no longer be considered regulated articles under APHIS regulations at 7 CFR Part 340. These would be potential impacts that might be associated with cultivation and normal use in agriculture of MS8 and RF3 canola, and progeny derived from either of these, without APHIS imposed conditions of physical or

reproductive confinement from other sexually compatible plants. Additional technical information is included in the determination document appended to this EA (Appendix A.), and incorporated by reference. This includes further discussion of the biology, taxonomy, cultivation, and sexual reproduction and outcrossing potential of canola as well as of the genetic components inserted into MS8 and RF3 canola, and the analyses that lead APHIS to a conclusion that these canola have no potential to pose a plant pest risk.

Potential for the introduced genes, their products, and the added regulatory sequences controlling their expression to cause plant disease. MS8 and RF3 canola are considered regulated articles because the plant pathogen, A. tumefaciens (the causal agent of a tumor-inducing, crown gall disease), was used as a vector in the transformation process and as a donor for genetic material inserted into these plants. Because the genes that cause crown gall disease were removed from the tumor-inducing (Ti)- plasmid in A. tumefaciens, the transformed plants do not develop crown gall disease. Furthermore, initial transformed tissue was treated with an appropriate antibiotic to eliminate Agrobacterium; and no crown gall symptoms were reported in these canola by AgrEvo under field conditions. The specific DNA sequences from the plant pest Agrobacterium which were inserted into MS8 and RF3 canola cannot incite disease or result in the production of an infectious agent. Furthermore, AgrEvo provides evidence that expression of the introduced genes does not result in disease symptoms or an increase in susceptibility to diseases.

Potential impacts based on weediness potential of MS8 and RF3 canola relative to traditionally bred canola. Almost all definitions of weediness stress as core attributes the undesirable nature of weeds from the point of view of humans; from this core, individual definitions differ in approach and emphasis (Baker, 1965; de Wet and Harlan, 1975; Muenscher, 1980). In further analysis of weediness, Baker (1965) listed 12 common weed attributes 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 serious weed under conditions found in the United States. B. napus is listed as a weed in Weed Science Society of America (1992). The comprehensive world list of Holm et al. (1991) does not list it as a serious or principal weed anywhere in the world; they do, however, give two listings as a common weed: one in Finland and one in Kenya. B. napus is mentioned as an "occasional weed" by Munz (1968), and "sometimes escaped" by Bailey (1949). AgrEvo has submitted substantial evidence to indicate the lack of weedy nature of MS8 and RF3 canola and their hybrids, and for other glufosinate-tolerant canola transformation events under agricultural conditions. Field observations indicate that seed germination and dormancy, seed production, pest and disease resistance characteristics, time to flowering, and sensitivity to herbicides other than glufosinate-ammonium are the same for MS8/RF3 hybrids as for nontransgenic canola.

There is no reason to believe that the new traits engineered into MS8 and RF3 canola would by themselves, cause these canola to be more weedy. These genetic alterations do not result in characteristics commonly observed in many of the world's worst weeds (Baker, 1965). Other glufosinate-ammonium tolerant canola deregulated by APHIS exhibits no increased weediness potential (USDA, 1998). As previously noted, glufosinate tolerance is unlikely to increase weediness of 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. Consideration of supporting data on other glufosinate-tolerant canola also leads APHIS to believe that glufosinate tolerance will not lead to increased weediness. 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). Moreover, AgrEvo presents evidence that MS8 and RF3 canola are still susceptible to other herbicides that control related mustards (e.g. glyphosate, phenoxys, and sulfonylureas). The traits controlling pollination in MS8 and RF3 canola are not expected to increase the weediness potential of canola, and in fact male sterility would provide a competitive disadvantage.

Potential impacts from gene introgression from MS8 and RF3 canola into 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. An analysis of the potential for related species to hybridize with B. napus under field conditions (documented in Appendix A) has led APHIS to conclude that the potential would exist for transgene introgression from MS8 or RF3 or its hybrid to occur at a relatively low to moderate rate into B. rapa L. (=B. campestris L.), and at extremely low rates for B. juncea; B. adpressa , syn. Herschfeldia incana (hoary mustard); B. nigra; and R. raphanistrum (wild radish). All of these species are found in the major canola producing states of North Dakota, Minnesota, Montana, Idaho, Washington, and Georgia. Of these species, B. juncea, B. nigra, and B. rapa to some degree are agricultural weeds, sometimes serious, in much of the United States (Gleason, 1952; Slife et al., 1960; Reed, 1970; Muenscher, 1980). Reduced dormancy of B. rapa x B. napus hybrids relative to the persistent wild B. rapa, coupled with the reduced fertility of the inter-specific hybrid makes it very unlikely that populations of these hybrids will persist. There is a small chance that hybrids could backcross to wild B. rapa and thereby transfer the transgenes to wild populations (Crawley et al. 1993). Introgression into these other Brassica species and wild radish will be limited due to effects such as reduced fertility of the hybrids, triploidy, and chromosome incompatibilities, depending on the species.

Since MS8 and RF3 canola and their hybrids do not exhibit weedy characteristics or have any fitness advantage as a result of the transgenes, and due to the lack of selection pressure for these expressed traits outside of cultivation, transgene introgression into the sexually compatible relatives described above is unlikely to increase their weediness or impact their biodiversity anymore than would gene introgression from other canola cultivars currently available, including other nontransgenic, herbicide tolerant or cytoplasmic male sterile canola cultivars. The barnase and barstar genes would be expected to segregate independently of each other. Introgression of the barnase transgene in the absence of the barstar gene would most likely result in male sterility which would further limit gene introgression. In agricultural settings, introgression of the transgene conferring glufosinate tolerance into one of these weedy relatives may provide a competitive advantage if glufosinate is used for weed management; however, other herbicides or mechanical means can be used to successfully control such weeds.

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 on beneficial organisms could result from the cultivation of MS8 or RF3 canola or their hybrid. First the trait controlling male sterility affects only anther and pollen development; flower nectaries, which provide a source of nutrients for pollinators, develop normally, and the flowers do not show a greater tendency towards bud abortion. The RF3 plants and the hybrids have normal flower morphology, fertility, and attractiveness to insect pollinators. Normal insect activity was observed on all these plants. The new transgene proteins expressed in the transgenic canola plants were derived from common soil bacterium,

and ribonucleases and ribonuclease inhibitors are common in bacteria and plants. Therefore, the same or similar proteins are normal parts of the diets of animals, humans and insects. Other glufosinate tolerant canola transformation events have not been shown to be harmful to beneficial organisms or threatened and endangered species (USDA, 1998). Knowledge of the mode of action, and the lack of known toxicity for the newly expressed proteins suggest no potential for deleterious effects on beneficial organisms such as bees and earthworms. MS8 and RF3 canola and their hybrid do not contain elevated levels of toxic oils, and therefore, insects that may feed on these canola will not be unduly affected in their ability to reproduce or function normally after feeding. Results of trials in the United States, Canada, and Europe do not reveal any noticeable adverse effects on beneficial organisms. Common insects that feed on canola are not on the list of threatened and endangered species. APHIS concludes that the unconfined cultivation of MS8 and RF3 canola will not have deleterious effects, either directly or indirectly on organisms that are recognized as beneficial to agriculture or on threatened and endangered species.

Potential damage to processed agricultural commodities. The FDA has issued a finding of 'No Concern' for these canola transformation events in September 1998, and the use of these canola for food and feed purposes has also been granted by Canada. Erucic acid and glucosinolates are the only two toxicants known in rapeseed. MS8 and RF3 canola has been developed from low erucic acid and low glucosinolate canola varieties, and these transformation events were selected, in part, for normal oil and seed quality. AgrEvo confirmed that the erucic acid level was not higher than that expected for the canola variety from which MS8 and RF3 canola were developed. As such, MS8 and RF3 canola should not present any concerns as far as toxicological properties of canola. APHIS notes that Agriculture and Agri-Food Canada (1996) concludes that AgrEvo provided data which demonstrated that the nutritional composition of the whole seed, processed meal or oil derived from MS8, RF3, and their hybrid is substantially equivalent to conventional canola varieties. APHIS concludes that MS8, RF3 and their hybrid should not have a direct or indirect plant pest effect on any processed commodity.

Potential impacts on biodiversity. Our analysis determined that genetically engineered MS8 and RF3 canola and their progeny are no more likely to become weeds, or increase the weediness potential of any other cultivated plant or native wild species with which they can interbreed, any more than other commerical canola developed by traditional breeding techniques. They will not harm threatened and endangered species and non-target organisms, they are still attractive to pollinators, and the nutritional composition and toxicological properties of their seed products are within normal limits. APHIS therefore concludes that there unlikely to be a significant impact on biodiversity from the proposed action.

Potential impacts on agricultural and cultivation practices. APHIS has previously issued determinations of nonregulated status to other genetically-engineered glufosinate-tolerant canola (USDA, 1998) and corn engineered for male sterility (USDA, 1996) with similar genetic constructs as those used in MS8 and RF3 canola. APHIS is unaware of any adverse impacts on agricultural practices associated with the cultivation of these. Male-sterile oilseed rape plants are already used to some extent to develop hybrids. The pollination control system engineered into MS8 and RF3 canola, along with the glufosinate-tolerance trait, is expected to lead to a more efficient system for producing hybrid oilseed rape. F1 hybrids of canola are estimated to yield 20-25% more seeds and are more uniform than the best open-pollinated varieties.

Based on the APHIS analysis, there is unlikely to be any significant adverse impact on agricultural practices associated with the use of MS8 and RF3 canola. However, it is of concern that there is a likelihood of canola volunteers possessing a combination of two different herbicide resistance genes and how such volunteers

would be managed by growers. APHIS has deregulated other canola engineered for resistance to two different broad-spectrum post-emergent herbicides, glufosinate (USDA, 1998) and glyphosate (USDA, 1999). These canola are still sensitive to other herbicides, and information has been provided regarding the use in different crops of alternative herbicides which could be used to control Brassica volunteers or weeds should they obtain, through crossing, resistance to glufosinate and/or other herbicides with different modes of action.

Consideration of potential environmental impacts outside the United States associated with the proposed action. APHIS has also considered potential environmental impacts outside the United States and its territories associated with the proposed determination of nonregulated status of MS8 and RF3 canola, and progeny derived from them. This determination would allow for cultivation, interstate movement and importation into the United States and its territories without an APHIS permit or notification under 7 CFR Part 340. It does not, however, release the developer from its obligation to obtain any other necessary approvals for pesticide use on these canola or for their intentional movement in international trade. Canada is a major producer of canola, and they have already granted approval for environmental release, food and feed use of these canola. Approval to market MS8 and RF3 canola in the European Union (EU) has been requested, but is pending. 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 (106 countries as of 1999). 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 fora. APHIS has played a role in working toward harmonization of biosafety 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 fora sponsored by the EU 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, Mexico, and Argentina. 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. 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 studies and interactions, APHIS has not identified any significant impacts on the environment that might be relevant to MS8 and RF3 canola or follow from their unconfined cultivation in the United States and its territories, or abroad which could not be mitigated by reasonable agricultural practices. All the 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 the proposed determination.

V. 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. The introduced genes, and their products, and the added regulatory sequences controlling their expression do not confer upon MS8 and RF3 canola or their progeny any disease or plant pest characteristic.

2. MS8 and RF3 canola and their progeny do not exhibit increased weediness potential relative to other commerical canola. Furthermore, introgression of their transgenes into canola or its sexually compatible relatives should not increase their weediness or impact biodiversity any more than gene introgression from commercial canola cultivars.

3. The use of MS8 and RF3 canola or their progeny in agriculture will not cause damage to raw or processed agricultural commodities.

4. The use of MS8 and RF3 canola or their progeny in agriculture will not have a significant impact on any beneficial organisms in the environment, or on any threatened or endangered species.

5. The use of MS8 and RF3 canola or their progeny in agriculture is unlikely to have any significant adverse impact on agricultural practices.

VI. LITERATURE CITED

Agriculture and Agri-Food Canada. 1996. Determination of environmental safety of Plant Genetic Systems Inc.'s (PGS) novel hybridization system for rapeseed (Brassica napus L.). DD96-17-02. Plant Products Division. December 2, 1996.

Baker, H. G. 1965. Characteristics and Modes of Origin of Weeds. In: The Genetics of Colonizing Species. pp. 147-172. Baker, H. G., Stebbins, G. L. (eds.). Academic Press, New York and London.

Bailey, L. H. 1949. Manual of Cultivated Plants. Macmillan Publishing Company, New York. 1116 pp.

Crawley, M. J., Hails, R. S., Rees, M., Kohn, D., Buxton, J. 1993. Ecology of transgenic oilseed rape in natural habitats. Nature 363: 620-623.

de Wet, J. M. J., Harlan, J. R. 1975. Weeds and Domesticates: Evolution in the Man-Made Habitat. Economic Botany. 29:99-107.

Gleason, H. A. 1952. The New Britton and Brown Illustrated Flora of the Northeastern United States and Adjacent Canada. Vol 3. Hafner Press, New York. 595 pp.

Holm, L., Pancho, J. V., Herbarger, J. P., Plucknett, D. L. 1979. A Geographical Atlas of World Weeds. John Wiley and Sons, New York. 391 pp.

Keeler, K. 1989. Can genetically engineered crops become weeds? Bio/Technology 7:1134-1139.

Muenscher, W. C. 1980. Weeds. Second Edition. Cornell University Press, Ithaca and London. 586 pp.

Munz, P. A. 1968. A California Flora. University of California Press, Berkeley and Los Angeles. 1681 pp.

Office of Technology Assessment, United States Congress. 1988. New Developments in Biotechnology- 3. Field-Testing Engineered Organisms: Genetic and Ecological Issues. U.S. Government Printing Office, Washington, DC. 150 pp.

Reed, C. F. 1970. Selected Weeds of the United States. Agriculture Handbook No. 366. Agricultural Research Service, United States Department of Agriculture, Washington, D.C. 463 pp.

Slife, F. W. 1960. Weeds of the North Central States. Circular 718. University of Illinois Agricultural Experiment Station, Urbana, Illinois. 262 pp.

Tiedje, J. M., Colwell, R. K., Grossman, Y. L., Hodson, R. E., Lenski, R. E., Mack, R. N., Regal, P. J. 1989. The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations. Ecology 70:298-315.

United States Department of Agriculture. 1996. Environmental Assessment and Finding of No Significant Impact: Response to Plant Genetic Systems Petition 95-228-01p for Determination of Nonregulated Status for MS3 Corn.

United States Department of Agriculture. 1998. Environmental Assessment and Finding of No Significant Impact: Response to AgrEvo USA Company Petition 97-205-01p for Determination of Nonregulated Status for Glufosinate-ammonium Tolerant Canola Event T45.

United States Department of Agriculture. 1999. Environmental Assessment and Finding of No Significant Impact: Response to Monsanto Petition 98-216-01p for Determination of Nonregulated Status for Glyphosate-Tolerant Canola Line RT73.

Weed Science Society of America. 1992. Crop losses due to weeds in the United States. Weed Science Society of America, Champaign, Illinois.

VII. PREPARERS AND REVIEWERS

Scientific Services Rebecca A. Bech, Assistant Director Subhash Gupta, Ph.D., Biotechnologist (Reviewer) David S. Heron, Ph.D., Biotechnologist Karen E. Hokanson, Ph.D., Biotechnologist Susan M. Koehler, Ph.D., Biotechnologist (Preparer) James Lackey, Ph.D., Biological Safety Officer Craig R. Roseland, Ph.D., Biotechnologist Sivramiah Shantharam, Ph.D., Senior Operations Manager John Turner, Ph.D., Biotechnologist James L. White, Ph.D., Senior Operations Manager

Regulatory Coordination Michael Lidsky, J.D., Assistant Director Shirley P. Ingebritsen, M.A., Regulatory Analyst (Reviewer)

VIII. AGENCY CONTACT

Ms. Kay Peterson, Regulatory Analyst Scientific Services USDA, APHIS, PPQ 4700 River Road, Unit 147 Riverdale, MD 20737-1237 kay.peterson@usda.gov Phone: (301) 734-4885 Fax: (301) 734-8669