Monsanto Petition (11-188-01p) for Determination of Nonregulated status for MON 88302 (Herbicide-resistant Canola)

OECD Unique Identifier:

MON 883Ø2-9

Environmental Assessment

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TABLE OF CONTENTS PAGE

1. PURPOSE AND NEED 1

1.1 Background 1

1.2 Purpose of the Product 1

1.3 Coordinated Framework Review and Regulatory Review 2

1.3.1 USDA-APHIS 2

1.3.2 Environmental Protection Agency 3

1.3.3 Food and Drug Administration 3

1.4 Purpose and Need for This APHIS Action 4

1.5 Public Involvement 4

1.5.1 First Opportunity for Public Involvement 5

1.5.2 Second Opportunity for Public Involvement 5

1.6 Issues Considered 7

2. AFFECTED ENVIRONMENT 8

2.1 Agricultural Production of Canola 8

2.1.1 Canola Production in North America 8

2.1.2 Land use 10

2.1.3 Agricultural Production of Canola 11

2.1.4 Canola Seed Production 12

2.2 Physical Environment 12

2.2.1 Water Resources 12

2.2.2 Soil Quality 13

2.2.3 Air Quality 13

2.2.4 Climate Change 13

2.3 Biological Resources 14

2.3.1 Animal Communities 14

2.3.2 Plants Communities 14

2.3.3 Microorganisms 15

2.3.4 Biodiversity 17

2.4 Human Health 17

TABLE OF CONTENTS (Continued) PAGE

2.4.1 Consumer Health 17
2.4.2 Worker Health....................18
2.5 Animal Feed 19
2.6 Socioeconomics....................20
2.6.1 Domestic Canola Production 20
2.6.2 Organic Farming 21
2.6.3 Foreign Trade....................23
3. ALTERNATIVES....................24
3.1 No-Action Alternative: Continuation as a Regulated Article 24
3.2 Preferred Alternative: Determination That MON 88302 Canola Is No Longer a Regulated Article....................24
3.3 Alternatives Considered But Rejected from Further Consideration 25
3.3.1 Prohibit Any MON 88302 Canola from Being Released 25
3.3.2 Approve the Petition in Part....................25
3.3.3 Production/Geographical Restrictions to Isolate MON 88302 Canola from Non-GE Canola....................25
3.3.4 Requirement of Testing for MON 88302 Canola 26
3.3.5 Comparison of Alternatives 26
4. ENVIRONMENTAL CONSEQUENCES 35
4.1 Scope of Analysis....................35
4.2 Acreage and Area of Canola Production....................35
4.2.1 Agricultural Production of Canola....................37
4.2.2 Canola Seed Production....................50
4.2.3 Organic Canola Production....................51
4.3 Physical Environment....................52
4.3.1 Water Resources 52
4.3.2 Soil Quality 54
4.3.3 Air Quality 58
4.3.4 Climate Change....................59
4.4 Biological Resources....................61
4.4.1 Animal Communities....................61
4.4.2 Plant Communities....................62
4.4.3 Microorganisms 66

TABLE OF CONTENTS (Continued) PAGE

4.4.4 Biodiversity 68
4.5 Human Health 70
4.5.1 Consumer Health 70
4.5.2 Worker Health 71
4.6 Animal Feed 72
4.7 Socioeconomic Impacts 74
4.7.1 Domestic production of canola 74
4.7.2 Organic Market for Canola 76
4.7.3 Trade Economic Environment 77
5. CUMULATIVE IMPACTS 80
5.1 Assumptions Used for Cumulative Impacts Analysis 80
5.2 Past and Present Actions 81
5.3 Reasonably Foreseeable Actions 83
6. THREATENED AND ENDANGERED SPECIES 85
6.1 Potential Effects of Monsanto 88302 Canola on TES and Critical Habitat 87
6.1.1 Threatened and Endangered Plant Species and Critical Habitat 87
6.1.2 Threatened and Endangered Animal Species and Critical Habitat 88
6.2 Conclusion 89
7. CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS 90
7.1 Executive Orders with Domestic Implications 90
7.2 International Implications 91
7.3 Compliance with Clean Water Act and Clean Air Act 93
7.4 Impacts on Unique Characteristics of Geographic Areas 93
7.5 National Historic Preservation Act (NHPA) of 1966 as Amended 94
8. REFERENCES 96
9. LIST OF PREPARERS 112
APPENDIX A. APHIS THREATENED AND ENDANGERED SPECIES DECISION TREE FOR U.S. FISH AND WILDLIFE SERVICE CONSULTATIONS 113

LIST OF FIGURES

Figure 1. Canola Growing Regions of Canada and the U.S. 10
Figure 2. Major Canola-growing Region of North Dakota.. 11
Figure 3. U.S. Canola Oil Production, 1987-2009.. 36
Figure 4. Changes in Adoption of HR-Canola Varieties by Canadian Growers Since 1995 37
Figure 5. U.S./Canada Market Growth:Ten-year Projection of Herbicide-................................ 47
Figure 6. Distribution of Glyphosate-resistant Weeds in the U.S... 64
Figure 7. U.S. Canola Acreage: 1991-2012 75
Figure 8. U.S. Exports of Canola 2007-2012.. 78
Figure 9. Canola Seed Quantities in the U.S. 79

LIST OF TABLES

Table 1. Total U.S. Canola Acreage, 1991-2010 9
Table 2. Weed Species Detected in North Dakota Canola Production Fields 16
Table 3. Canola Acreage[1] Planted and Harvested in the U.S.: 2011-2012 21
Table 4. Summary of Issues of Potential Impacts and Consequences of Alternatives 27
Table 5. Guide to Timing of Canola Rotation Crops.. 40
Table 6. Herbicide Plant-back Restrictions for Canola 41
Table 7. Pesticide Seed Treatments Registered for Use on Canola 44
Table 8. Registered Herbicides Commonly Used on Canola in the U.S. 48
Table 9. Registered Herbicides for Herbicide-resistant Canola... 48
Table 10. Herbicide-resistant Weeds of 25 Canola-producing States 49
Table 11. Acreage of Herbicide-Resistant Canola Varieties Grown In North Dakota 52
Table 12. Herbicides and Application Methods[1] Used in North Dakota Canola......................... 63
Table 13. Canola Price/Hundred Weight and Value of U.S Production for 2009-2011.............. 75
Table 14. Harvest and Value of Sales from Certified Organic Canola Farms in 2008................ 77

ACRONYMS AND ABBREVIATIONS

a.i.	active ingredient
AIA	advanced informed agreement
AMPA	aminomethylphosphonic acid
AMS	Agricultural Marketing Service (within USDA)
AOSCA	American Organization of Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service (within USDA AMS)
BMP	Best Management Practice
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
CAA	Clean Air Act
CRLF	California Red-legged Frog
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
CWA	Clean Water Act
DNA	deoxyribonucleic acid
EA	environmental assessment
EIS	environmental impact statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act of 1973
ESU	Evolusionarily significant unit
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	food, feed, or processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FONSI	Finding of No Significant Impact

ACRONYMS AND ABBREVIATIONS

FQPA	Food Quality Protection Act
FR	Federal Register
FWS	Fish and Wildlife Service (of the U.S)
GE	genetically engineered
GHG	greenhouse gas
GR	glyphosate-resistant
GRAS	Generally recognized as safe
HED	Health Effects Division (of EPA)
HR	Herbicide Resistant
HRAC	Herbicide Resistance Action Committee
IPPC	International Plant Protection Convention
LMO	living modified organism
M	million
N_2O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act (of 1969 and subsequent amendments)
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOP	National Organic Program (of USDA AMS)
NRC	National Research Council
OFPA	Organic Foods Production Act
ODA	Oregon Department of Agriculture
PIP	Plant-incorporated protectants
PM	Particulate matter
POEA	Polyethoxylated tallow amine
NPS	non-point source (pollution)
PPA	Plant Protection Act
PPE	Personal Protective Equipment

ACRONYMS AND ABBREVIATIONS

ppm	parts per million
PPRA	Plant Pest Risk Assessment
RED	Registration Eligibility Decision
SDWA	Safe Drinking Water Act
SSA	Sole Source Aquifer
TES	threatened and endangered species
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USC	United States Code
WPS	Worker Protection Standard (for agricultural pesticides)

1. PURPOSE AND NEED

1.1 Background

Monsanto Company of St. Louis, MO (henceforth referred to as Monsanto) submitted petition 11-188-01p to the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services (BRS) in June 2011 (Monsanto, 2011). The purpose of the petition is to support a determination of nonregulated status for Canola event MON 88302 (henceforth referred to as MON 88302 Canola), which is resistant[1] to the herbicide, glyphosate. The MON 88302 Canola variety is currently regulated under Title 7 of the Code of Federal Regulations (7 CFR) part 340. Interstate movement and field trials of MON 88302 Canola have been conducted under permits issued or notifications acknowledged by APHIS since 2005. These field trials were conducted within selected canola-growing areas in the U.S., including California, Idaho, Minnesota, Montana, New Jersey, North Dakota, South Dakota, and Washington. Data resulting from these field trials are described in the MON 88302 Canola petition (Monsanto, 2011) and analyzed for plant pest risk in the USDA-APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2012b).

The petition stated that APHIS should not regulate MON 88302 Canola because it does not present a plant pest risk. If a determination of nonregulated status is made, it would include MON 88302 Canola, any progeny derived from crosses between MON 88302 Canola and conventional canola, and crosses of MON 88302 Canola with other biotechnology-derived canola lines that are no longer subject to the regulatory requirements of 7 CFR part 340 promulgated under the authority of the Plant Protection Act of 2000 (PPA).

1.2 Purpose of the Product

The current Roundup Ready canola product has restrictions in application rates and timing because of low expression of *cp4-epsps* in male reproductive tissue (USDA-APHIS, 2012b). MON 88302 allows for a wider period of application up to first flower instead of the 6-leaf growth stage. Label requirements applicable to glyphosate treatments made to the currently available, Monsanto, GE-(genetically-engineered) spring-canola cultivar (RT73) allow for only a single application of 0.39-0.56 lbs. of glyphosate a.i. (active ingredient) per acre up to the 6-leaf

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[1] *"Resistance"* to herbicides is defined by the Herbicide Resistance Action Committee (HRAC) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type (HRAC, 2013). Several technologies are available that can be used to develop herbicide resistance in plants including classical breeding, tissue culture, mutagenesis and genetic engineering. *"Tolerance"* is distinguished from resistance and defined by HRAC (2013) as the inherent ability of a plant to survive and reproduce following exposure to a herbicide treatment. This implies the circumstance in which there is no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. Throughout this EA (Environmental Assessment), APHIS has used the terms "resistance" and "tolerance" consistent with the definitions of the HRAC. It should be noted however, that different terms for the same concept may be used interchangeably in some instances. In its petition to USDA APHIS (Monsanto, "Petition for the Determination of Non-Regulated Status Fir Glyphosate-Tolerant Canola Mon 88302 ", ed. M. A. Wideman (Monsanto Company, 2011), vol. referenced the subject as, "Glyphosate-Tolerant Canola," and used the term "herbicide-tolerant" throughout it documentation to describe it. This terminology can be considered synonymous with "herbicide-resistant" (HR) used in this EA.

growth stage. This restriction is further limited to 0.39 lbs. a.i. after the 4-leaf stage. MON 88302 Canola is sufficiently resistant to tolerate higher glyphosate application rates equal to the maximum amount of a.i. currently approved for GR (glyphosate-resistant) corn and soybeans. This proposed maximum glyphosate application rate on MON 88302 is twice the currently labeled maximum application rate for RT73. Therefore, in contrast to existing GR-canola products on the market today, MON 88302 Canola will provide growers with an alternative GR variety that offers greater potential and flexibility in the weed-control strategy they select by allowing for glyphosate treatment to a wider range of developmental crop stages.

1.3 Coordinated Framework Review and Regulatory Review

Since 1986, the United States government has regulated GE organisms pursuant to Federal regulations published in the *Federal Register* entitled The Coordinated Framework for the Regulation of Biotechnology (51 FR 23302, 1986)(henceforth referred to here as the Coordinated Framework), and the policy statement for foods derived from new plant varieties (57 FR 22984, 1992). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). A summary of each role follows.

1.3.1 USDA-APHIS

APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code (USC) 7701–7772), regulate the introduction (i.e., importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340, when APHIS determines that it is unlikely to pose a plant pest risk. A GE 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 (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under 7 CFR 340, when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency for a determination that a particular regulated article is unlikely to pose a plant pest risk, and therefore, is no longer regulated under the plant pest provisions of the PPA or the regulations at 7 CFR 340. Under § 340.6(c)(4), the petitioner must provide information related to plant pest risk that the agency can use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

1.3.2 Environmental Protection Agency

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology. The EPA regulates plant-incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 USC 136 *et seq.*) and certain biological control organisms under the Toxic Substances Control Act (15 USC 53 *et seq*.). Before planting a crop containing a PIP, a company must seek an experimental use permit from EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 registration with EPA.

Under FIFRA (7 USC 136 *et seq.*), EPA regulates the use of pesticides, and requires registration of all pesticide products for all specific uses prior to distribution for sale. EPA examines: the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, EPA must determine through testing that the pesticide does not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may only be legally used in accordance with directions and restrictions on its label. The overall intent of the label is to provide clear directions for effective product performance, while minimizing risks to human health and the environment. The Food Quality Protection Act (FQPA) of 1996 amended FIFRA, enabling EPA to implement periodic registration review of pesticides to ensure they are meeting current scientific and regulatory standards of safety and continue to have no unreasonable adverse effects (US-EPA, 2011c).

EPA also sets tolerances (maximum residue levels) or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). A tolerance is the amount of pesticide residue that can remain on or in food for human consumption or animal feed. Before establishing a pesticide tolerance, EPA is required to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the FQPA. FDA enforces the pesticide tolerances set by EPA.

1.3.3 Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 USC 301 *et seq*.). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, on May 29, 1992 (57 FR 22984). Under this policy, FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

More recently (June 2006), FDA published recommendations in "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use" (US-FDA, 2006). This establishes voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

1.4 Purpose and Need for This APHIS Action

As noted in the previous section, any party can petition APHIS to seek a determination of nonregulated status for a GE organism that is regulated currently under 7 CFR 340. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as MON 88302 Canola. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism is unlikely to pose a plant pest risk. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS must respond to the petition from Monsanto requesting a determination of nonregulated status for MON 88302 Canola. APHIS has prepared this Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status of MON 88302 Canola. This action is consistent with regulations for the National Environmental Policy Act (NEPA) established by the Council of Environmental Quality (CEQ), and those of the USDA APHIS NEPA-implementing regulations and procedures (40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[2] that may result from a determination of nonregulated status for MON 88302 Canola.

1.5 Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a notice published in the *Federal Register*. On March 6, 2012, APHIS published a notice[3] in the *Federal Register* advising the public that APHIS is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms to allow for early public involvement in the process. As identified in this notice,

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[2]Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §1508.14).

[3]This notice can be accessed at: http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf

APHIS publishes two separate notices in the *Federal Register* for petitions for which APHIS prepares an EA. The first notice announces the availability of the petition, and the second notice announces the availability of the APHIS decisionmaking documents. As part of the new process, with each of the two notices published in the *Federal Register*, there is an opportunity for public involvement:

1.5.1 First Opportunity for Public Involvement

Once APHIS deems a petition complete, the petition is made available to the public for 60 days to provide an opportunity to comment on issues regarding the petition itself and give input that will be considered by the Agency as it develops its EA and PPRA. APHIS publishes a notice in the *Federal Register* to inform the public that APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice. This availability of the petition for public comment is announced in a *Federal Register* notice.

1.5.2 Second Opportunity for Public Involvement

Assuming an EA is sufficient, the PPRA and EA are developed, and a notice of their availability is published in a second *Federal Register* notice. This second notice follows one of two approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues:

<u>Approach 1: GE organisms that do not raise substantive new issues.</u>

This approach for public participation is used when APHIS decides, based on the review of the petition and an evaluation and analysis of comments received from the public during the 60-day comment period for the petition, that the GE organism does not involve new biological, cultural, or ecological issues because of the nature of the modification or the Agency's familiarity with the recipient organism. After developing its EA, finding of no significant impact (FONSI), and PPRA, APHIS publishes a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, FONSI, and PPRA for a 30-day public review period.

If no information is received that would warrant substantially changing the APHIS analysis or determination, the Agency's preliminary regulatory determination becomes effective upon public notification through an announcement on its website. No further *Federal Register* notices are published announcing the final regulatory determination.

<u>Approach 2: GE organisms that involve substantive new issues not previously reviewed by APHIS.</u> A second approach for public participation is used when APHIS determines that the petition for a determination of nonregulated status is for a GE organism that involves substantive new issues. This would include petitions for a recipient organism that has not previously been determined by APHIS to have nonregulated status, or when APHIS determines that gene modification(s) involves substantive biological, cultural, or ecological issues not previously analyzed by APHIS. Substantive issues are identified based on the Agency's review of the petition and its evaluation and analysis of comments received from the public during the 60-day comment period for the petition.

APHIS solicits comments on its draft EA and draft PPRA for 30 days, as announced in a *Federal Register* notice. APHIS reviews and evaluates comments and other relevant information, then revises the PPRA as necessary and prepares a final EA. Following preparation of these documents, APHIS approves or denies the petition, then announces its decision in the *Federal Register,* and provides notice of the availability of the final EA, PPRA, NEPA decision document, and regulatory determination.

More details about this expansion of opportunities for stakeholder review and comment are available in the *Federal Register* notice[4] published on March 6, 2012.

APHIS has determined that this EA will follow Approach 1. The issues considered in this EA were developed by reviewing the public concerns. They include public comments received in response to the *Federal Register* notice (77 F.R. 41357-8) announcing the availability of the petition (i.e., the first opportunity for public involvement previously described in this document). They also include issues noted in public comments submitted for other EAs of GE organisms, concerns described in lawsuits and those expressed by various stakeholders. These issues, including those regarding the agricultural production of canola using various production methods and the environmental and food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of MON 88302 Canola.

The public comment period for MON 88302 Canola petition closed on September 11, 2013. At its closing, the docket file contained a total of 4,670 public comments. These were screened and sorted into categories according to the subject matter addressed (e.g., air, water, soil impacts), and classified. Most comments expressed a general dislike of the use of GE organisms or were form letters sent to all of the dockets which were open at the time that this docket was open. The form letter expressed a concern that there were too many dockets published on the same day. It also referenced other open dockets and potential effects from the use of the subjects of those petitions. These issues are outside the scope of this EA. Substantive comments identified the following issues:

- Canola outcrossing with other mustards;
- Canola forming feral populations;
- Development of herbicide-resistant (HR) weeds;
- Use of herbicides on HR resistant crops;
- The fate of glyphosate in air and water;
- The effects of glyphosate use on biological organisms;
- The effect of glyphosate drift on outcrossing to weedy or wild relatives;
- Increase in plant pathogens or susceptibility to plant pathogens from the use of glyphosate;
- Concern that cross-pollination between GE and organic or crops for GE-sensitive markets will affect sales for growers of these crops;
- Concerns that MON 88302 Canola is not approved in all export markets.

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[4]This notice can be accessed at: http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf

APHIS evaluated these issues, provided citations and has included a discussion of them in this EA where appropriate.

1.6 Issues Considered

The list of resource areas considered in this EA were developed by APHIS through experience in considering public concerns and issues identified in public comments submitted for this petition and other EAs of GE organisms. The resource areas considered also address concerns described in previous and unrelated lawsuits, and issues for this or past petitions mentioned by various stakeholders. A summary of the resource areas considered in this EA follows:

Agricultural Production Considerations:

- Acreage and Areas of Canola Production
- Agronomic/Cropping Practices
- Canola Seed Production

Environmental Considerations:

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Microorganisms
- Biological Diversity

Human Health Considerations:

- Consumer Health
- Worker Safety

Livestock Health Considerations:

- Animal Feed/Livestock Health

Socioeconomic Considerations:

- Domestic Economic Environment
- Organic Canola Production
- Trade Economic Environment

2. AFFECTED ENVIRONMENT

This section includes a review of the prevailing conditions of the affected environment that might be impacted by canola production. Relevant environmental components include agricultural production area of canola, the physical environmental, biological resources, human health, animal feed, and socioeconomic resources.

2.1 Agricultural Production of Canola

The first commercial seed of this variety of rapeseed (*Brassica rapa*), which is referred to as "Oro," was released in 1966. The product from this cultivar had low animal palatability caused by high endogenous levels of glucosinolates, so it had limited use as meal for feed. Another *B. rapa* cultivar with lower glucosinolate levels was subsequently identified. The first low erucic acid, low glucosinolate cultivar, "Tower," was released for commercialization in 1974. In 1978, the Canola Council of Canada established a performance standard for these "double low" varieties, reserving the name "canola" to describe them. By definition, canola oil contains less than 2% erucic acid; the meal less than 3 mg/g of glucosinolates (Brown et al., 2008).

In January 1985, FDA granted canola oil GRAS (Generally Recognized as Safe) status for use in human foods. This promoted greatly increased sales and demand in the U.S. The FDA also allowed the qualified health claim, "healthy oil," for canola oil under which it is now widely marketed. Canola varieties have been available since 1989 (CCC, 2003), and canola is currently grown worldwide.

To date, traditional, non-GE plant breeding methods have been used to produce varieties of three *Brassica* species that meet the low eruic acid, low glucosinolate canola definition:

- *Brassica rapa*—common name: Polish canola;
- *Brassica napus*—common name: Argentine canola;
- *Brassica juncea*—common name: canola quality brown mustard.

In the U.S. three different types of canola are grown:

- Winter canola (planted in fall; harvested in spring) that requires vernalization (winter chilling to promote spring flowering);
- Winter canola that does not require vernalization;
- Spring canola (planted in the spring and harvested in the fall).

To achieve optimal production, it is recommended that winter canola be planted about six weeks before the first killing frost, which is defined as lower than 25°F (Atkinson et al., 2006). During winter, plants enter a dormant phase that is typically indicated by development of red/purple-colored leaves. Growth resumes in spring as temperatures reach 55-60°F (Atkinson et al., 2006).

2.1.1 Canola Production in North America

During 2001-2010, canola production in the U.S. averaged 1.2M (million) acres Table 1).

Table 1. Total U.S. Canola Acreage, 1991-2010

Year	Planted Acres (1,000 Acres)	Yield per Acre (lbs.)	Production (1,000 lbs.)
1991	155	1,300	191,100
1992	140	1,286	144,037
1993	199	1,350	252,450
1994	354	1,316	447,440
1995	446	1,278	548,447
1996	367	1,385	480,521
1997	671	1,237	780,710
1998	1,115	1,448	1,557,800
1999	1,076	1,306	1,363,680
2000	1,555	1,334	1,998,310
2001	1,494	1,374	1,998,515
2002	1,460	1,197	1,533,420
2003	1,082	1,416	1,512,250
2004	865	1,618	1,339,530
2005	1,159	1,419	1,580,985
2006	1,044	1,366	1,394,312
2007	1,176	1,238	1,430,734
2008	1,011	1,461	1,445,064
2009	827	1,811	1,474,130
2010	1,449	1,713	2,450,947
2011	1,072	1,475	1,538,010
2012	1,765	1,416	2,447,410
Source: USDA-NASS, 2010; USDA-NASS, 2012			

In North America, the primary canola-growing region is located in areas of the Great Plains characterized by high quality soil, but shorter, drier growing seasons than that preferred by most corn and soybean varieties. Most of this region is in the prairie provinces of Canada, but part of it extends into North Dakota (Figure 1).

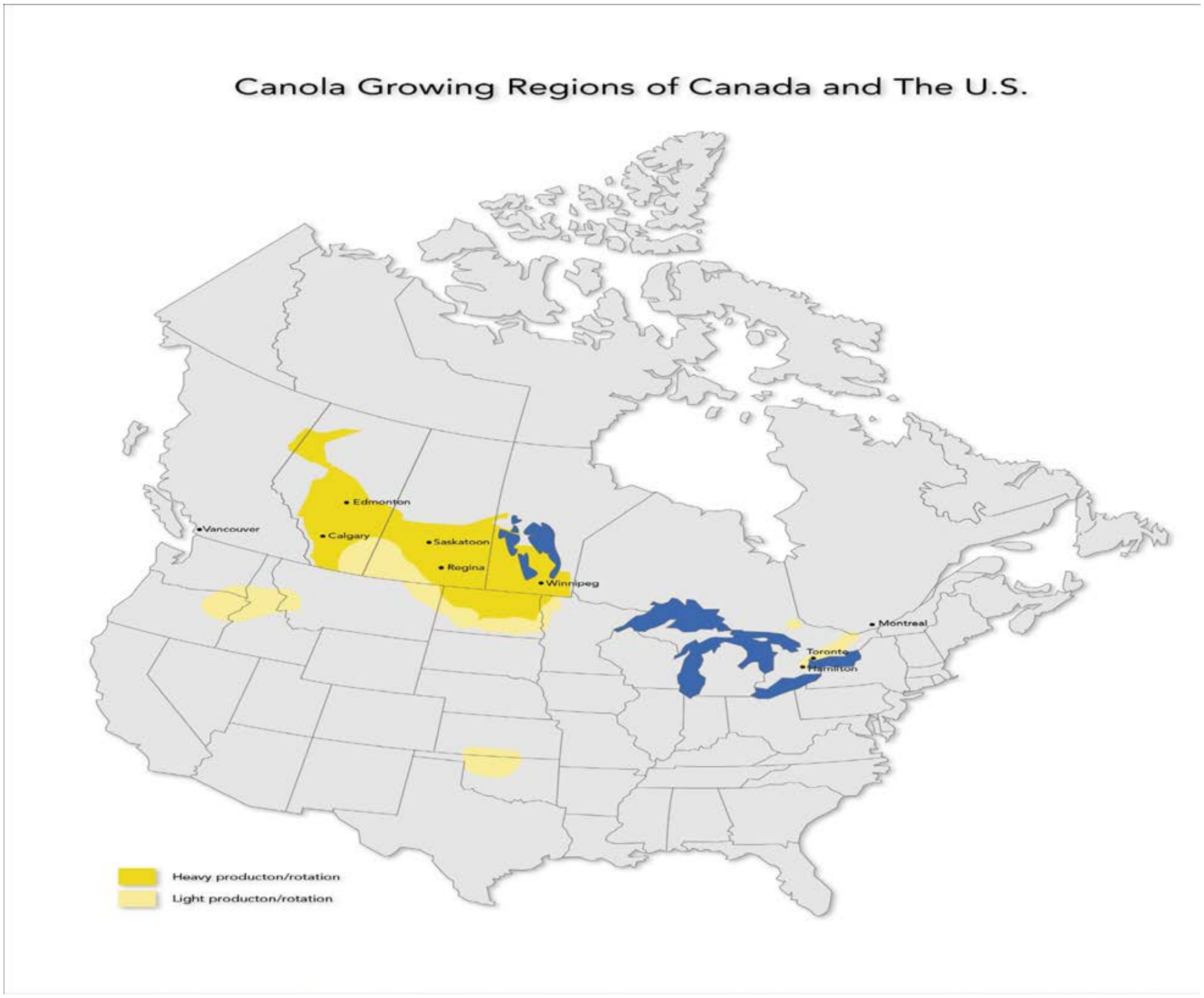


Figure 1. Canola Growing Regions of Canada and the U.S.
Most of the canola produced in North America is produced in Canada. Production in the U.S. is mainly in North Dakota where more than 90% of the U.S. canola crop is produced. Dark yellow shading delineates the region where canola is a major crop. Light yellow shading delineates canola-growing regions where canola is rotated with other crops, but is not a major crop of that region.

2.1.2 Land use

In the U.S., there are over 900M acres of farmland. About 1/3 of that land is harvested cropland. Harvested cropland includes field, vegetable, and forage crops. Canola is produced on approximately 0.04% of the harvested cropland in the U.S. It is a minor crop that is primarily grown in North Dakota. There are 22M acres of harvested cropland in North Dakota, but only slightly less than 5% of that is planted in canola, so it is not even one of the top five crops planted in that state. Cavalier County, North Dakota has more canola acreage than any other county in the U.S. In this county, canola is the second largest crop by acres according to the 2007 Census of Agriculture. Thirteen counties in North Dakota produce 75% of U.S. canola (Figure 2).

Figure 2. Major Canola-growing Region of North Dakota

Approximately ¾ of the U.S. canola crop is grown in thirteen counties (shaded) in ND. Note (cf. Figure 1) that these counties are conterminous within the primary North American canola-growing region, most of which is in western Canada.

2.1.3 Agricultural Production of Canola

Most canola grown in the U.S. is spring canola. It requires an average of 100-125 days from seeding to harvesting. Canola grows best in a temperature range of 54-86°F (12-30ºC). The optimal average temperature for maximum growth and development is 68°F (20ºC) (Brown et al., 2008).

Spring canola is planted in early spring (typically March) and is harvested in late summer or early autumn (usually September or October). In the U.S., it is grown primarily in states with a cooler climate (e.g., North Dakota, Minnesota).

Winter canola is typically planted in the Pacific Northwest, Midwest, and Great Plains. It requires vernalization to flower, so it needs to overwinter. Winter canola that is planted in the southeast region of the U.S. also overwinters, but does not require vernalization (Brown et al., 2008). Winter canola is typically planted in September and harvested in June or July. It is grown on fewer acres than spring canola, but can be grown in a broader range of environments, particularly where winters are mild.

2.1.4 Canola Seed Production

Favorable conditions for canola seed production include fertile soil, dry weather, access to irrigation, appropriate temperatures, and adequate distance from commercial canola production areas. Based on these constraints, most canola seed produced for sale for the North American market is produced in the summer in a small geographic area in southern Alberta, Canada and the northwestern U.S. Most of this is near Lethbridge, Alberta and there is a growing industry in the Maritime Provinces (Davison, 2005). Among U.S. areas, summer seed production occurs in the Columbia Basin in eastern Washington (Wohleb, 2009), the Grand Ronde Valley in Union County in northeastern Oregon (Wohleb, 2009). Canola seed may also be produced in other areas.

To meet the demand for seed and to minimize production risks, most seed companies have off-season seed production locations in the southwestern U.S. (Imperial Valley, California and Yuma Valley, Arizona (Nolte, No Date) and Chile (HITech Production, no date).

Based on an average canola seeding rate of five pounds per acre, approximately 7.5M pounds (3,400 metric tons) of canola seed is required to plant the approximately 1.5M-acre U.S. crop. With allowances for seed losses caused by weather, poor yields, quality issues, distribution excess, seed returns and replants, approximately 5,000 acres of commercial seed production are needed to supply sufficient seed to plant the entire U.S. canola acreage. Production of seed for winter canola to grow in the more southern areas of the U.S. is located in Kentucky and Virginia (MD-Cooperative-Extension-Service, 1991). These varieties are distinct from those grown in the northern U.S. and Canada, so are not the focus of much of the commercial seed industry.

2.2 Physical Environment

2.2.1 Water Resources

Surface water in rivers, streams, creeks, lakes, and reservoirs supports everyday life by providing water for drinking and other public uses, irrigation, and industry (USGS, 2011). In 2005, about 77% of the freshwater used in the U.S. was derived from surface water. Groundwater sources account for the remaining 23% (USGS, 2011).

A substantial amount of the U.S. water supply is used for agricultural purposes. It accounts for approximately 40% of water withdrawn from U.S. surface and groundwater sources. Most of this is for crop irrigation (CAST, 2009). Although the proportion of available freshwater used in agriculture varies widely among geographic areas, it is a major proportion of water use in all areas.

Agricultural NPS (non-point-source) pollution is the primary source of pollutants discharged into rivers and lakes. It is also a major contributor to groundwater contamination (US-EPA, 2005). Agricultural activities that cause NPS pollution include poorly located or managed animal feeding operations; overgrazing leading to soil erosion; too frequent and/or poorly timed plowing; improper, excessive, or poorly timed application of pesticides, irrigation water, or fertilizer. The pollutants that result from agricultural practices include sediment, nutrients, pathogens, pesticide residue, metals, and salts (US-EPA, 2005).

2.2.2 Soil Quality

The Soil Science Society of America defines soil as the unconsolidated mineral or organic material on the immediate surface of the Earth that serves as a natural medium for the growth of land plants (Soil-Science-Society-of-America, 2013).

Soil quality is the capacity of a specific kind of soil to sustain plant and animal productivity, maintain or enhance water and air quality, and support human health and habitation (USDA-NRCS, No Date). Several indicators used to measure soil quality include: soil organic matter, pH, water holding capacity, soil structure, microbial biomass and soil respiration (USDA-NRCS, No Date). A more detailed discussion of soil quality and health can be found on the National Resources Conservation Service Soils website (USDA-NRCS, 2013).

The northern Great Plains region of North America is recognized as having some of the world's most fertile soils, (Doran et al., 1996). However, the region is also subject to climatic extremes that include severe droughts, flash-flooding and intense summer heat and winter cold. For example, the all-time North Dakota record high temperature (121 $^{\circ}$F) and record low (-60°F) were set less than six months apart in 1936. Such climatic events can exacerbate crop production impacts on soil quality.

2.2.3 Air Quality

Dry air consists of about 78% nitrogen, 21% oxygen, 0.9% argon and 0.03% carbon dioxide. It also contains small amounts of water vapor and particulate matter. Air quality can affect the growth of plants in agricultural systems (Darley and Middleton, 1966) as well as human and animal health.

Agronomic practices used in agriculture affect air quality. Tillage exposes soil to wind erosion and utilizes motorized equipment that produces emissions. The use of (herbicide-resistant) HR crops has facilitated the adoption of conservation tillage (Towery and Werblow, 2010). Reduced tillage generates fewer particulates (dust), so potentially contributes to lower rates of wind erosion and release of soil particulates into the air, thus, benefitting air quality (Fawcett and Towery, 2002). Conservation tillage also minimizes the use of mechanized equipment that produces exhaust, so it reduces emissions.

2.2.4 Climate Change

Climate change represents a sustained, statistically significant change in average weather conditions over a broad region. EPA has identified CO_2, methane (CH_4), and nitrous oxide (N_2O) as the most important GHGs (greenhouse gases) contributing to climate change. While each of these occurs naturally in the atmosphere, human activity has been a major contributor to the increase their concentration since the beginning of the industrial revolution. The level of human-produced gases has been accelerating since the end of World War II, when industrial and consumer consumption expanded greatly. Since the advent of the industrial age, the increase in the concentration of some important GHGs are as follows: CO_2, 36%; CH_4, 148% and N_2O, 18% (US-EPA, 2011b).

Agriculture, including land-use changes for farming, is estimated to be responsible for 8% of all human-induced GHG emissions in the U.S. (Massey and Ulmer, 2010). Many agricultural activities affect air quality, including smoke from agricultural burning, machinery, and N_2O

emissions from the use of nitrogen fertilizer (Hoeft et al., 2000; Aneja et al., 2009; U.S. EPA, 2010b). Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (U.S. EPA, 2010b). Tillage contributes to GHG production because it releases CO_2 sequestered in soil and promotes oxidation of soil organic matter (Baker et al., 2005).

2.3 Biological Resources

This section provides a summary of the biological environment and includes an overview of animals, plants, microorganisms, and biodiversity associated with canola production. This summary provides the foundation to assess the potential impact to plant and animal communities..

2.3.1 Animal Communities

The affected environment for growing canola plants includes the managed agricultural fields plus adjacent areas that might be affected by agricultural operations. Mammals and birds, including migratory mammals and birds, may seasonally consume seeds from the planted fields, and invertebrates can feed on the plant and surrounding vegetation during the entire growing season.

Rodents and other small animals may inhabit canola fields, and the raptors, snakes and other animals that may prey on them are part of the affected environment. Deer may also browse in canola fields. Fish and other aquatic organisms in streams draining agricultural fields are also part of the affected environment.

The specific animals that are found in and around canola fields vary depending on field location and season of the year. Winter and spring canola fields may also attract different organisms because they are planted during different times of the year. Birds and small mammals may be associated with canola fields; geese and blackbirds for example, feed on canola (Boyles et al., 2012). Voles, squirrels, and deer mice may also be found in or around canola fields and may feed on canola seed (Bayne and Hobson, 1998). It is likely that predators (e.g., reptiles) of small mammals also use canola fields and surrounding areas as hunting grounds. If waterways are near canola fields, aquatic organisms such as fish and amphibians may be part of the animal community.

Invertebrates that feed on canola include cutworms, diamondback moths, flea and blister beetles, grasshoppers, true bugs, aphids, and armyworms (NDSU, 2011). Common pollinators attracted to canola include honey, bumble and leafcutter bees. Other local native pollinators may also visit fields when canola is flowering (Scott-Dupree et al., 2009)(Gavloski, 2012).

2.3.2 Plants Communities

Plant associations with canola production include within-field and outside-of-field communities. Within-field communities include canola as well as any weeds of canola that may be found in the field. Within-field communities can also include volunteers from crops that are rotated with canola and the weeds of those crops.

Out-of-field communities include plants in neighboring agricultural fields and native or naturalized species in the field margins and surrounding landscape. Some of the out-of-field plant communities can serve as sources of weeds in within-field communities.

Common weeds of canola include volunteers from rotation crops, for example wheat and barley (CCC, 2003; Harker et al., 2008). Table 2 identifies weeds that are found in canola fields in North Dakota, where most U.S. canola is grown. Weeds of the Brassicaceae family can contaminate the crop and reduce oil and meal quality (CFIA, 1994; OECD, 1997; CCC, 2003). They produce large numbers of seeds, some of which have prolonged dormancy that can cause a build-up of weed populations (CFIA, 1994; OECD, 1997; CCC, 2003).

Such closely related weeds of the Brassicaceae family include wild mustard (*Sinapis arvensis*), field pennycress (*Thlaspi arvense*), shepherd's purse (*Capsella bursa-pastoris*), ball mustard (*Neslia paniculata*), flixweed (*Descurainia sophia*), wormseed mustard (*Erysimum cheiranthoides*), hare's ear mustard (*Conringia orientalis*), and common peppergrass (*Lepidium densiflorum*) (CFIA, 1994; OECD, 1997; CCC, 2003). Other weeds include cleavers (*Galium aparine*), stork's bill (*Erodium circutarium*), and quackgrass (*Elytrigia repens) (CCC, 2003).*

Predominant weed species found in North Dakota canola fields during a survey in 2000 (Zollinger et al., 2003) are listed in Table 2.

A 1997 survey conducted in Montana indicated that kochia, wild buckwheat, Canada thistle, annual mustards, wild oats, and volunteer grain were the most prevalent weeds in canola (Petroff and Miller, 1999). Both the winter and summer complex of weeds occur in canola in Kentucky. Wild garlic bulblet, common chickweed, henbit, yellow rocket, Johnson grass and volunteer wheat can be found in canola. Volunteer corn, annual ryegrass and thistles have also been identified in Kentucky canola fields according to a 2010 survey (Johnson et al., 2010).

Canola can form feral populations and has been found along field margins, road sides, and other disturbed habitats (Crawley and Brown, 1995; Schafer et al., 2011). *B. napus* can also interact with certain plants through sexual reproduction. *B. napus* is predominantly self-pollinating. However, interplant (plants that are adjacent to each other) cross pollination occurs at a rate that ranges from 12%-55% with a mean of 30% (Beckie et al., 2003). Pollen of *B. napus* is heavy and sticky (OECD, 1997), and pollen movement is primarily by insects, such as honey bees (Thompson et al., 1999). Wind is a secondary cause of some pollen movement. Most (98.8%) of pollen travels less than twelve meters from its source (Scheffler et al., 1993). The low frequency of pollen dispersal over greater distances is attributable to pollinators (Thompson et al., 1999).

B. napus produces a large amount of pollen (OGTR, 2008) that can remain viable for 4-5 days under field conditions (Rantio-Lehtimäki, 1995). This, coupled with the potential for *B. napus* pollen movement, makes possible hybridization between *B. napus* and related sexually compatible species.

2.3.3 Microorganisms

Soil microorganisms affect soil structure formation, decomposition of organic matter, detoxification of natural and synthetic chemical compounds, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). The main factors affecting microbial population size and diversity include soil type and plant types present, which provide specific carbon and energy sources in soil, and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva et al., 2004). Plant roots, including those of canola (Rumberger and Marschner, 2003), release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere. Microbial diversity in the rhizosphere may be extensive and differs from the microbial community in the bulk soil (Garbeva et al., 2004).

Table 2. Weed Species Detected in North Dakota Canola Production Fields

Common Name	Scientific Name	Weed Frequency (%)[1]
Wild oat	*Avena fatua* L.	53
Kochia	*Kochia scoparia* (L.) Schrod.	53
Canada thistle	*Cirsium arvense* (L.) Scop.	42
Wild mustard	*Sinapis arvensis* (L.)	37
Perennial sowthistle	*Sonchus arvensis* L.	26
Volunteer cereals	*Hordeum vulgare* L., *Triticum aestivum* Desf., *Avena sativa* L.	16
Flixweed / Tansy mustard	*Descurainia sophia* (L.) Webb./ *Descurainia pinnata* (Walt.) Britt	6
Common lambsquarters	*Chenopodium album* L.	16
Quackgrass	*Elytrigia repens* (L.) Neyski.	11
Green foxtail	*Setaria viridis* (L.) Beauv.	11
Common ragweed	*Ambrosia artemisiifolia* L.	11
Common sunflower	*Helianthus annuus* L.	11
Wild buckwheat	*Polygonum convolvulus* L.	5
Pigweed species	*Amaranthus* species	5
Barnyardgrass	*Echinochloa crus-galli* (L.) Beauv	5
Common cocklebur	*Xanthium pensylvanicum* Wallr.	5
Field pennycress	*Thlaspi arvense* L.	5

[1]Weed frequency is the percentage of fields surveyed that contained the weed species in one or more sample quadrants.

2.3.4 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem. Biodiversity provides valuable genetic resources for crop improvement (Wilson, 1988b); (Harlan, 1975), and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). The loss of biodiversity results in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999).

The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management; 4) extent of isolation of the agroecosystem from natural vegetation (Southwood and Way, 1970).

Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas. Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvesting limit the diversity of plants and animals (Lovett et al., 2003).

Biodiversity can be maintained or reintroduced into agroecosystems through the use of woodlots, fencerows, hedgerows, and wetlands. Agronomic practices include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (e.g., compost, green manure, animal manure), hedgerows and windbreaks (Altieri, 1999).

2.4 Human Health

Humans interact with canola either as consumers of canola derived products or as workers who produce canola crops..

2.4.1 Consumer Health

Rapeseed is the traditional name for the oilseed crops in the mustard family, Brassicaceae. Rapeseed has been cultivated for thousands of years as a source of oil for cooking, lighting, and lubrication (Brown et al., 2008). In the 1940s, Canadian farmers cultivated rapeseed as a source of industrial lubricants, but as demand for industrial lubricants declined after World War II, two Canadian scientists bred *B. napus* to contain less erucic acid (a fatty acid that has been associated with heart disease) and more oleic acid (a fatty acid known to promote heart health), thereby improving the palatability of the oil and making it suitable for human consumption.

Any potential human health effects to consumers from glyphosate applied to GE HR canola are reviewed in the following section (Worker Health). Consumer health concerns about GE canola are primarily related to human consumption. The principal product derived from canola that is consumed by humans is vegetable oil. By volume, global canola oil consumption is third behind soybean and palm oil and second in the U.S.

According to the Organization for Economic Development (OECD, 2001) canola oil has one component, erucic acid, that is (as already noted here), associated with negative human health impacts. The compound is produced normally by rapeseed (OECD, 2001). Varieties that produce oil with less than 2% of this fatty acid are defined as canola, and canola oil is categorized as GRAS by FDA (21 CFR 184). The Codex Standard for Named Vegetable Oils (FAO, 2009) also specifies that canola oil cannot contain more than 2% erucic acid.

People may be exposed to residues from pesticides used to grow canola. EPA sets tolerances for each pesticide that can be used on canola. These specific tolerances can be found in 40 CFR part 180. The FFDCA mandates that before a pesticide can be used on a food crop, the EPA must establish a maximum residue level (tolerance). This is the maximum amount of pesticide residue that can remain on the crop or in foods processed from that crop (US-EPA, 2011h). The USDA has implemented the Pesticide Data Program (PDP) in order to collect data on pesticides residues on food (USDA-AMS, 2010b). The EPA uses PDP data to prepare pesticide dietary exposure assessments pursuant to the 1996 FQPA. Pesticide tolerances for glyphosate have been established for a wide variety of commodities, and are published in the *Federal Register*, 40 CFR §180.364, and the *Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities* (US-EPA, 2011d). The EPA tolerance for both canola seed and rapeseed is 20 ppm (parts per million).

Glyphosate is registered under a variety of trade names by several companies. There are currently over 400 active glyphosate products registered under FIFRA Section 3, and over 100 registered for use on terrestrial food crops (US-EPA, 2009b).

Glyphosate is a mild eye irritant (Toxicity Category III[5]), slight skin irritant (Toxicity Category IV), and is not a dermal sensitizer in guinea pigs. It has been found to have low toxicity via the oral, dermal, and inhalation routes (US-EPA, 2009c). Glyphosate is classified as neither a carcinogen nor a teratogen (US-EPA, 2009c). Based on toxicological considerations, the EPA HED (Health Effects Division) determined that the main metabolite of glyphosate, AMPA (aminomethylphosphonic acid), should not be regulated even though detectable levels sometimes occur in both foods for human consumption and animal feed (US-EPA, 2009c).

2.4.2 Worker Health

Field workers routinely exposed to canola through dermal contact or inhalation are subject to the same hazards that are encountered by workers exposed to other crops in similar situations.

All pesticides sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2011a). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered prior to November 1, 1984, such as glyphosate, must have a reregistration review every 15 years to ensure that they meet current standards (US-EPA, 2011a). Glyphosate was first registered in the U.S. in 1974. The most recent reregistration decision for glyphosate was issued in 1993 (US-EPA, 1993b; US-

[5] Category I indicates the highest degree of acute toxicity and Category IV the lowest.

EPA, 2009b; US-EPA, 2009a). It is currently under reregistration review, which began in July 2009 and is scheduled for completion in 2015 (US-EPA, 2009a).

The EPA published the Worker Protection Standard (WPS) pursuant to 40 CFR part 170 in 1992 for the purpose of reducing the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers (US-EPA, 2011i). The WPS offers protections to about 2.5M agricultural workers who work with pesticides at more than 600,000 agricultural workplaces (e.g., farms, forests, nurseries, greenhouses). The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment (PPE), restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.

Growers are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. For example, pesticide labels specify the appropriate worker safety practices that must be followed, including the necessary PPE to be worn by mixers, loaders, other handlers and applicators. These label restrictions are legally binding, and are enforced by the EPA and the states (FIFRA 7 USC 136j (a)(2)(G) Unlawful Acts). Therefore, glyphosate use on GE canola is expected to be consistent with the EPA-approved labels.

Various formulations of glyphosate contain surfactants such as polyethoxylated tallow amine at a level of up to approximately 20 percent (200 g/L). Tallow contains a variety of fatty acids (e.g., oleic, palmitic, stearic, myristic, and linoleic acids), as well as smaller amounts of cholesterol, arachidonic, elaidic, and vaccenic acids. While surfactants are typically classified as “inert” components in herbicides, they are not toxicologically inert and in many cases they are found to be more toxic than the herbicide itself (USDA-FS, 2003).

Allergies to *Brassica* spp. pollen are rare in the general population (Soutar, 1994), but a small group of workers who are intensively exposed to canola, such as plant breeders, may be at risk of developing an allergy to *B. napus* pollen (Fell et al., 1992).

2.5 Animal Feed

Canola can be grazed by livestock. It can also be made into hay or silage (North-Dakota-Extension-Service, 2008) although this is not a common practice. The meal that remains after crushing the seeds for oil can also be used as animal feed. Some animals find it less palatable than other oil seed crops. Most of canola meal in the United States is fed to cattle and pigs as part of a feed ration. It can also be used as feed for poultry, aquaculture, and specialty animals can also be fed canola meal as a high fiber protein source, but low palatability limits feeding rates (Ash, 2012c).

Regulatory control of feed manufacturers is similar to that for producers of food for direct human consumption. Under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE canola must comply with all applicable legal and regulatory requirements, which are designed to protect human health. To help ensure compliance, a voluntary consultation process with FDA may be implemented before feed containing GE-plant material is released into the market.

2.6 Socioeconomics

As part of an evaluation of impacts on the human environment, NEPA requires consideration of economic and social effects (40 CFR 1508.8), whether direct, indirect, or cumulative. However, under CEQ regulations (40 CFR 1508.14), ". . . economic or social effects are not intended by themselves to require preparation of an environmental impact statement."

The following socioeconomic factors are considered in this EA: the interaction of social and economic factors that affect agricultural production and products, including farm income and employment, crop production expenses, crop value and trade. The main focus of this assessment is the socioeconomic effect on the crop industry, including production, domestic and international trade, and crop producers.

2.6.1 Domestic Canola Production

In the U.S. 2010 growing season, canola was planted on approximately 1.5M acres. Production valued at $487M was 1.1M metric tons, which was 1.9% of the 60.6M metric tons produced worldwide (Boland and Brester, 2012).

Most U.S. canola production is located in the northern tier states contiguous with Canada. In 2011, North Dakota produced 1.3 billion pounds, with a total value of $297M. Oklahoma has become the second largest producer of canola in the U.S. Its 2011 harvest totaled 85M pounds valued at $20.5M (USDA-NASS, 2012b). Because it has a favorable profile for making cooking oil, biodiesel and feedstock, demand for canola is expected to remain high or increase. This continued strong demand is expected to promote future increases in canola acreage in the U.S. (Ehrensing, 2008; Minnesota Canola Council, 2009/2010).

Harvested acreage in Oregon (slightly less than 6,000 acres in 2012 (USDA-NASS, 2012c) is small in comparison to that for major canola-producing states (Table 3). However, planting canola in certain regions of the state is restricted because of its possible impact on specialty growers that produce seed crops for cabbage, broccoli, Brussels sprouts, and other commercially important varieties of *B. oleracea*. The concern is cross-pollination by canola.

As a countermeasure to protect seed crops, the Oregon Department of Agriculture (ODA) established a canola exclusion zone where growing canola is prohibited. There are also areas where canola can be grown, but the size of the field and isolation distances between fields is prescribed by ODA. On February 8, 2013, ODA published an administrative rule amending the "General Production Area/Protected Districts" in the Rapeseed Control Area (OAR 603-052-0860) (Oregon-Department-of-Agriculture, 2013). Under the rule, a rapeseed exclusion zone has been established in Oregon that encompasses most of the specialty seed production region of the state.

The administrative rule establishes a canola production exclusion zone in the Willamette Valley, which includes portions of Lane, Linn, Benton, Marion, Polk, Clackamas, Yamhill, Washington, Multnomah, and Columbia counties. The protected district will have two zones. The first is a fully protected zone of more than 1.9M acres that prohibits the growing of canola and contains the highest concentration of specialty seed growers in the valley. The second zone of about 1.7M acres, located outside the exclusion zone, allows canola production, but is limited to a maximum annual total of 2,500 acres. Producers desiring to grow canola are required to apply for a contract with ODA that contains specific requirements for managing the crop. The rule also establishes a minimum field size of 25 acres for canola. In general, ODA's rule limits how much canola can be grown in the Willamette Valley, where it can be grown, and requires management practices for production by controlling inadvertent spread of canola seed.

Table 3. Canola Acreage[1] Planted and Harvested in the U.S.: 2011-2012

State	Area planted		Area harvested	
	2011	**2012**	**2011**	**2012[2]**
Idaho	19.0	33.0	18.5	32.0
Minnesota	29.0	60.0	28.0	58.0
Montana	31.0	43.0	30.5	42.0
North Dakota	860.0	1,300.0	850.0	1,290.0
Oklahoma	100.0	150.0	85.0	130.0
Oregon	5.3	6.5	4.9	5.7
Washington	10.5	17.0	10.2	16.5
Other States[3]	16.7	22.0	15.9	18.9
United States	**1,071.5**	**1,631.5**	**1,043.0**	**1,593.1**

[1]Thousands of acres

[2]Estimate based on forecast data

[3]Other States include Colorado and Kansas

Source: (USDA-NASS, 2012c)

2.6.2 Organic Farming

In the U.S., only products produced using specific methods and certified under the USDA AMS National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010a). Organic certification is a process-based certification; not a certification of the end product. The certification process specifies and audits the methods and procedures by which the product is produced.

In accordance with NOP, each year an accredited organic certifying agent must review an operation. This must include a review of its organic system plan and record-keeping practices, and an on-site inspection of the production area(s). Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

Section 205.105 of the regulations identifies "Allowed and prohibited substances, methods, and ingredients in organic production and handling.

"To be sold or labeled as '100 percent organic,' 'organic,' or 'made with organic' (specified ingredients or food group(s))," the product must be produced and handled without the use of: . . . (e) Excluded methods . . . ."

Excluded methods identified at 7 CFR Section 205.2, are defined as follows:

> "A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture."

Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods (USDA-AMS, 2010a).

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops, so that the crops will flower at different times, and employing adequate isolation distances between organic and neighboring fields to minimize the chance for pollen exchange between fields (NCAT, 2003). Although the national organic standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the national organic standards (USDA-AMS, 2010a). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation if excluded methods were used and reasonable practices were implemented to avoid contact with products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2010a).

<u>Organic market and products</u>

The organic sector is rapidly growing both in the United States and the EU. Consumer purchases in these two regions made up 95% of estimated world retail sales of organic food products in 2003 (Dimitri and Oberholtzer, 2005). Annual manufacturer survey results (Organic Trade Association, 2011), indicated that estimated U.S. organic food sales for 2010 were $26.7 billion. This represented a 7.7 % growth rate from the previous year. The market sector experiencing the highest growth rate during 2010 was organic fruits and vegetables, which increased 11.8 % compared with 2009 sales. The market share for organic fruits and vegetables was 11% of all U.S. fruit and vegetable sales (Organic Trade Association, 2011). Organic products represented approximately 4% of total 2010 sales in the food and beverage sector (Organic Trade Association, 2011).

2.6.3 Foreign Trade

U.S. and global trade are greatly affected by the growth and stability of world markets, including changes in world population, economic growth, and income. Other factors affecting agricultural trade are global supplies and prices, changes in exchange rates, government support for agriculture, and trade protection policies.

U.S. farmers and agricultural firms rely heavily on export markets to sustain prices and revenues because productivity of U.S. agriculture increases faster than the demand for domestic food and fiber. U.S. food imports have increased with the corresponding increase in demand for greater diversity in the food supply. U.S. consumers benefit from imports because imports expand food variety. This also tends to stabilize year-round supplies of and prices for fresh fruits and vegetables.

Canola is a minor U.S. crop. The U.S. exports very little canola and the primary destination of that canola is Canadian crushing plants. The U.S. imports canola. Most of that comes from Canada to supplement domestic supplies used for crushing. As canola production has expanded over the past 20 years, global trade in canola seed and products has also increased. However, trade continues to be a smaller share of production than other major oilseeds. Trade in canola meal is limited because of the abundance of higher quality soybean meal and the high cost of transportation relative to the value of canola meal. Japan, Mexico, China, and the European Union (EU) are major importers of canola seed. The United States is the primary importer of canola oil and meal because of its proximity to Canada and the ease of cross-border trade (USDA-ERS, 2012b).

3. ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of MON 88302 Canola. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 88302 Canola is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2012b), APHIS has concluded that MON 88302 Canola is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 88302 Canola is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA.

Two alternatives are evaluated in this EA: (1) No-Action and (2) determination of nonregulated status of MON 88302 Canola. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

3.1 No-Action Alternative: Continuation as a Regulated Article

Under the No-action Alternative, APHIS would deny the petition. MON 88302 Canola and progeny derived from MON 88302 Canola would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of MON 88302 Canola and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS could choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MON 88302 Canola.

However, this alternative is not the Preferred Alternative because APHIS has concluded through a PPRA that MON 88302 Canola is unlikely to pose a plant pest risk (USDA-APHIS, 2012b). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

3.2 Preferred Alternative: Determination That MON 88302 Canola Is No Longer a Regulated Article

Under this alternative, MON 88302 Canola and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340 because MON 88302 Canola is unlikely to pose a plant pest risk (USDA-APHIS, 2012b). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 88302 Canola and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. Because the agency has concluded that MON 88302 Canola is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 88302 Canola is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to MON 88302 Canola and progeny derived from this event if the developer decides to commercialize MON 88302 Canola.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 88302 Canola. The agency evaluated these alternatives in accordance with its authority under the plant pest provisions of the PPA, and the regulations at 7 CFR part 340. This evaluation considered environmental safety, efficacy, and practicality to identify which alternatives would be further considered for MON 88302 Canola. Based on this evaluation, APHIS rejected several alternatives. These alternatives are described briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any MON 88302 Canola from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of MON 88302 Canola, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate because APHIS has concluded that MON 88302 Canola is unlikely to be a plant pest risk (USDA-APHIS, 2012b).

In enacting the PPA, Congress included findings in Section 402(4) that: “decisions affecting imports, exports, and interstate movement of products regulated under this title [i.e., the PPA] shall be based on sound science;”

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee established principles consistent with Executive Order 13563 to guide agencies in the development and implementation of policies for oversight of emerging technologies such as genetic engineering that included the following guidance:

“Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency; . . .”

Consistent with this guidance and based on the findings and scientific data evaluated for the PPRA (USDA-APHIS, 2012b), APHIS concluded that MON 88302 Canola is unlikely to pose a plant pest risk. Therefore, there is no basis in science for prohibiting the release of MON 88302 Canola.

3.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. APHIS has concluded that MON 88302 Canola is unlikely to pose a plant pest risk and it is the only line in the petition, so there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

3.3.3 Production/Geographical Restrictions to Isolate MON 88302 Canola from Non-GE Canola

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating MON 88302 Canola from non-GE canola production. However, because APHIS has concluded that MON 88302 Canola is unlikely to pose a plant pest risk (USDA-APHIS, 2012b), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of MON 88302 Canola based on the location of production of non-GE canola in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in the APHIS plant pest risk assessment for MON 88302 Canola, there are no geographic differences associated with any identifiable plant pest risks for MON 88302 Canola (USDA-APHIS, 2012b). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 88302 Canola does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with the APHIS statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340 and the biotechnology regulatory policies of the Coordinated Framework.

Based on the foregoing considerations, the imposition of isolation distances or geographic restrictions would not meet the APHIS purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. Individuals might choose on their own to geographically isolate their non-GE canola production systems from MON 88302 Canola or to use isolation distances and other management practices to minimize gene movement between canola fields. Information to assist growers in making informed management decisions for MON 88302 Canola is available from the American Organization of Seed Certifying Agencies (AOSCA, 2010).

3.3.4 Requirement of Testing for MON 88302 Canola

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. However, because MON 88302 Canola does not pose a plant pest risk (USDA-APHIS, 2012b), testing requirements are inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340 and the biotechnology regulatory policies of the Coordinated Framework. Therefore, for MON 88302 Canola such requirements would be inconsistent with the APHIS purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.3.5 Comparison of Alternatives

Table 4 includes a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 4 of this EA.

Table 4. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
Meets Purpose, Need and Objectives	**No**	**Yes**
Unlikely to Pose a Plant Pest Risk	Satisfied by regulated field trials.	Satisfied – plant pest risk assessment (USDA-APHIS, 2013b)
Management Practices		
Acreage and Areas of Canola Production	Since the 1999 introduction of herbicide-resistant canola in the U.S., production has fluctuated between 0.8-1.6M acres. Average U.S. canola acreage **is** about 1.1M acres. About 93% of it was located in North Dakota. Nearly all (99%) of the ND crop was herbicide resistant; 57% of that was glyphosate resistant.	No change from Alternative A
Agronomic Practices	Conservation tillage, which tends to provide a competitive advantage to canola production by promoting earlier crop emergence, has increased since the introduction of HR-canola varieties. In the northern U.S., use of tillage has declined from 89% to 35%; in some individual instances it remains useful in managing herbicide-resistant weeds. About half of growers rely on a 3-year rotation of canola, a small grain, and soybean. The remaining growers use a two-year rotation of canola/wheat.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa).

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
Canola Seed Production	Most seed production is in Alberta. In the U.S, seed production occurs in the Columbia Basin in eastern Washington, the Grand Ronde Valley in Union County in northeastern Oregon, and the San Luis Valley in south central Colorado. Most seed companies have off-season seed production locations in the southwestern U.S. About 5,000 acres of commercial seed production supply enough seed to plant the entire U.S. canola crop.	No change from the No-Action Alternative
Pesticide Use	EPA-approves uses of herbicides on canola. Specific treatment rates and crop stage restrictions apply to HR canola.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa).
Organic Canola Production	Certified organic production is an extremely small component of canola production conducted primarily in regions remote from major GE-canola-crop sites.	No change from No-action Alternative
Environment		
Soil Quality	Herbicide applications in conjunction with HR canola have promoted conservation	The approved in-crop glyphosate application rate for MON 88302 Canola will

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
	tillage, which preserves soil quality by reducing erosion. Growers currently use best management practices to address their specific needs in producing canola.	increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa), which do not have unacceptable impacts on soil quality.
Water Resources	The most important source of non-point source pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Glyphosate has a high affinity for binding with most types of soils, where it is degraded. This limits its mobility and transport into surface and groundwater.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa), which do not have unacceptable impacts on water resources.
Air Quality	Agricultural activities such as tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Applications may impact air quality from: drift; diffusion; volatilization of chemicals; exhaust emissions from motor vehicles and aircraft.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa), which do not have unacceptable impacts on air quality.
Climate Change	Agriculture-related activities are direct sources of greenhouse gases (e.g., exhaust from motorized	No change from No-action Alternative

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
	equipment) and indirect sources (e.g., soil disturbance from tillage, fertilizer production)	
Animal Communities	Invertebrates that feed on canola are typically considered pests and may be controlled by the use of insecticides or other production practices. Seed treatments are recommended to prevent flea beetle damage of young plants and foliar insecticide applications are recommended if damage reaches an economic threshold.	No change from No-action Alternative
Plant Communities	Plants growing in canola fields are considered weeds. Weeds can complete with growing canola plants for resources such as water, light, and soil nutrients. Young canola seedlings are very sensitive to early weed competition. Growers control weeds in and around fields using cultural, mechanical and chemical methods. Canola can form feral populations. Canola can hybridize with certain sexually compatible mustard plants.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa). the changes in the effects on plant communities associated with the preferred alternative would be minimal, and could have an overall positive effect on reducing weed resistance when compared to the No-action Alternative.

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
Soil Microorganisms	APHIS has previously examined potential impacts of glyphosate on microorganisms in soils of field under cultivation with HR crops, and has not found evidence linking applications of glyphosate to changes in soil microbial communities that have adverse effects on plants grown in those soils.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa), which do not have unacceptable impacts on microorganisms.
Biological Diversity	HR crops, such as canola, have been correlated with an increase in conservation tillage in U.S. crop production, which promotes biodiversity by allowing the establishment of other plants, and the accumulation of more plant residue that increases soil organic matter, food, and cover for wildlife. Effects of GE crops have been associated with positive impacts on biodiversity because of increased yields, fewer applications of less toxic pesticides, and facilitation of conservation tillage.	No change from No-action Alternative
Land Use	Canola is minor crop produced on approximately 0.04% of the harvested cropland in the U.S. Current trends influencing the acreage of canola planted annually are driven by market conditions (e.g., increased demand for US canola products and animal feed) and federal	No change from No-action Alternative

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
	policy.	
Human and Animal Health		
Risk to Human Health	Canola oil has one component (erucic acid) of human health significance because of its toxic properties. Varieties that produce oil with less than 2% of this fatty acid are defined as canola, and are generally regarded as safe by FDA. Residues, such as that that might arise from the CP4 EPSPS protein are removed during filtration. Workers that routinely handle glyphosate, may be exposed during spray operations. Because of low acute toxicity of glyphosate, absence of evidence of carcinogenicity and other toxicological concerns, occupational exposure data is not required for reregistration. However, EPA has classified some glyphosate formulations as eye and skin irritants. When used consistent with the label, pesticides present minimal risk to human health and safety.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa). Application at the higher rate does not pose any unacceptable risks to consumer health and worker safety when applied in accordance with the glyphosate registration label requirements approved by USEPA.
Risk to Animal Feed	Most canola cultivated in the U.S. is used to produce vegetable oil and animal feed. Canola-based animal feed is currently produced from GE-canola varieties that are no	No change from No-action Alternative

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
	longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. This includes HR-, GE-canola varieties.	
Socioeconomic		
Domestic Economic Environment	Farm income is positively impacted by currently available HR canola by reducing production costs or increasing revenues. GR canola generally has a positive impact on farm income due to cost savings from reduced fuel and pesticide use.	No change from No-action Alternative
Trade Economic Environment	Because the U.S. crushes more canola seed than it produces, the U.S. imports canola seed to meet the demand of the oil market. The U.S. exported 150-300 thousand metric tons of canola each year between 2007 and 2011. The majority of the canola exported went to Canada where it was processed. Foreign sales are mostly to Canadian crushing plants. The U.S. share of world production remains small, but is an increasingly important component of regional economies in the Northern Plains.	No change from No-action Alternative
Other Regulatory Approvals		

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
U.S.	FDA completed consultations.	No change from No-action Alternative. Satisfied: consultations with other agencies participating in the Coordinated Regulatory Framework completed.
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	No change from No-action Alternative:

4. ENVIRONMENTAL CONSEQUENCES

This analysis of potential consequences addresses the possible impact to the environment from the alternatives analyzed in this EA for MON 88302 Canola (i.e., No-Action or approving the petition for nonregulated status). These are described in detail throughout this section.

4.1 Scope of Analysis

For the purposes of this analysis, an impact was defined as any change (positive or negative) that alters the affected environment (described for each resource area in Section 2.0). Impacts may be categorized as direct, indirect, or cumulative. A direct impact is an effect that results solely from a proposed action without intermediate steps or processes. Examples include soil disturbance, air emissions, and water use. An indirect impact may be an effect that is related to but removed from a proposed action by an intermediate step or process. Examples include surface water quality changes resulting from soil erosion caused by increased tillage, and changes in worker safety impacts resulting from changes in herbicide use practices.

A cumulative effects analysis is also included for each environmental issue. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action, when added to other past, present, and possible future actions. If there are no direct or indirect impacts identified for a resource area, then there are no cumulative impacts. Cumulative impacts are reviewed in Section 5.

When it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Some impacts of this product and its cultivation will not differ between the alternatives. Although the preferred alternative would allow for new plantings of MON 88302 Canola anywhere in the U.S., APHIS will limit the environmental analysis to those areas that currently support canola production. To determine areas of canola production, APHIS used national agriculture statistics data (USDA-NASS, 2013) to identify the areas in which canola is grown.

4.2 Acreage and Area of Canola Production

<u>No-action Alternative: Acreage and Area of Canola Production</u>

Winter canola requiring vernalization is generally produced in the Pacific Northwest, southern Great Plains, and Midwest regions of the U.S. Winter canola not requiring vernalization is produced in the southeast region of the U.S. Spring canola is grown primarily in the northern Great Plains states including North Dakota, South Dakota, Minnesota, Montana, Idaho, and also in Washington. Winter and spring canola varieties may require different agronomic practices and can be affected by different insect pests and diseases. Growers consider climate as well as other factors when choosing which canola to plant (Brown et al., 2008). In a few areas, either crop may be grown. Winter canola has a higher yield potential than spring canola (Boyles et al., 2009), but can only be grown in areas with relatively mild winters.

According to the 2007 Census of agriculture, growers in 28 U.S. states planted canola. However, in 12 of these states, so few growers produced canola that NASS cannot report the data without violating the privacy of the individual growers. Of the remaining 16 states, five (Texas, Pennsylvania, Michigan, Nebraska, and California) each harvested less than 500 acres of canola. North Dakota produced about 93% of all the canola grown in the U.S.

In 2011, North Dakota farmers planted 860,000 acres of canola. In 2012, canola acreage in the U.S. for all purposes was estimated to be 1.6M acres ((Table 3). This is an increase of 0.6M acres from the previous year (USDA-NASS, 2012c).

Fluctuations in the geographic locations of production and total canola acreage are influenced by price, net return relative to other crops, and the availability of suitable varieties for the growing region. The overall demand for canola oil has increased since the 1980s. However the acreage dedicated to canola production in the U.S. does not meet U.S. demand for canola oil (Figure 3).

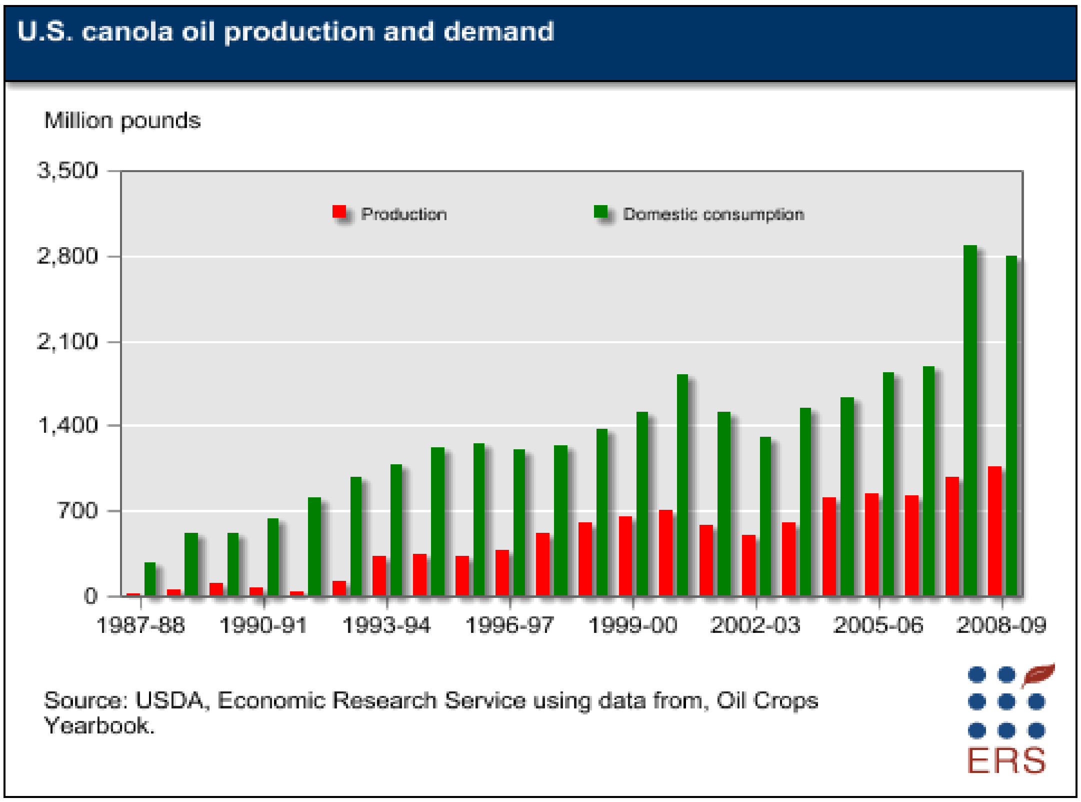
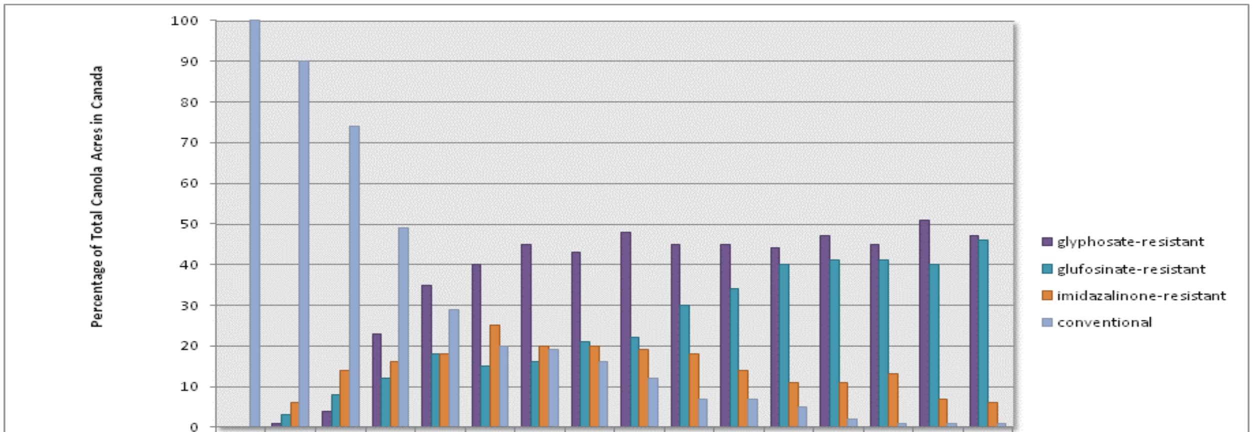


Figure 3. U.S. Canola Oil Production, 1987-2009

Production increased during the past two decades, but remains below U.S. demand.

By 2006, nearly all U.S. canola production was HR (Johnson et al., 2007). Commercially available canola varieties that are resistant to one of three different herbicides include: glyphosate, glufosinate and imidazolinone. The glyphosate- and glufosinate-resistant varieties were created using genetic engineering. Those resistant to imidazolinone were created using mutagenesis. In 2008, GE (glyphosate and glufosinate) HR canola was estimated to be 95% of the U.S. canola crop (Brookes and Barfoot, 2010). In 2006, 99% of the production in the principal U.S. canola-growing state of North Dakota was derived from HR-canola varieties, with GR varieties grown on 57% of that acreage. Glufosinate-resistant varieties were grown on 37% of the ND acreage and imidazolinone-resistant varieties were grown on 5% of the acreage in ND

(Johnson et al., 2007). In Minnesota, 78% of the acreage was planted in HR-canola varieties: 50% GR, 25% glufosinate-resistant, and 3% imidazolinone-resistant varieties (Johnson et al., 2007). A similar pattern for HR varieties adopted for planting in Canada has developed during the past two decades (Figure 4).



	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
glyphosate-resistant	0	1	4	23	35	40	45	43	48	45	45	44	47	45	51	47
glufosinate-resistant	0	3	8	12	18	15	16	21	22	30	34	40	41	41	40	46
imidazalinone-resistant	0	6	14	16	18	25	20	20	19	18	14	11	11	13	7	6
conventional	100	90	74	49	29	20	19	16	12	7	7	5	2	1	1	1

Figure 4. Changes in Adoption of HR-Canola Varieties by Canadian Growers Since 1995
Source: Canola Council of Canada, 2010a

<u>Preferred Alternative: Acreage and Area of Canola Production</u>

Approving the petition for nonregulated status is not likely to have any influence on the number of acres planted to canola in the U.S. As described in the No-action Alternative, the U.S. does not produce enough canola to meet the domestic demand for canola oil. Canola acreage is influenced by the demand for vegetable oil, the price of canola, and the price of other potential crops that could be planted on those same acres.

GR varieties are available for both winter and spring canola (Winfield, 2013). The approval of the petition for nonregulated status will not alter availability of currently marketed HR varieties. It may offer new choices in the marketplace if this trait is bred into commercial varieties that do not currently offer glyphosate resistance. Growers choose varieties by considering a number of characteristics, one of which is whether the variety is resistant to a particular herbicide. It is likely that canola acreage in the U.S. will continue to be planted predominantly with HR varieties.

4.2.1 Agricultural Production of Canola

<u>No Acton Alternative: Agricultural Production of Canola</u>

***Cropping Practices*.** Spring canola requires an average of 100-125 days from seeding to harvesting. Canola grows best in a temperature range of 54°-86°F (12-30ºC), with the optimal temperature for maximum growth and development being 68°F (20ºC) (Brown et al., 2008).

Spring canola is usually planted in March and harvested in September or October. In the U.S., most is grown in North Dakota (92% of production acreage), Minnesota, and the Pacific Northwest i.e., Idaho, Washington, and Montana) because optimal crop production occurs under a cool temperature regime.

Winter canola is planted in the Pacific Northwest, Midwest, and Great Plains, but requires vernalization (prolonged exposure to low temperatures) to flower, so it has to overwinter. Winter canola that is planted in the southeast region of the U.S. also overwinters, but does not require vernalization (Brown et al., 2008). Winter canola is typically planted in September and harvested in June or July. It is grown on fewer acres than spring canola, but can be grown in a broader range of environments if winters are mild.

The types of tillage utilized by growers include conservation tillage (no-till, ridge-till and mulch-till), reduced tillage, and intensive (i.e., conventional) tillage. Conventional tillage is associated with intensive plowing and less than 15% crop residue at the soil surface. Reduced tillage is associated with 15-30% crop residue. Conservation tillage, including no-till practices, is associated with at least 30% crop residue and substantially less soil erosion than other tillage methods (Sandretto and Payne, 2006). While tillage can increase soil erosion, which leads to reduced soil fertility and degraded water resources, it is an integral part of weed management (Duke and Powles, 2009a).

Conventional tillage is used for controlling weeds, reducing populations of overwintering insects, and controlling fungal outbreaks (MacRae et al., 2000; Brown et al., 2008; Duke and Powles, 2009b). It is most important for early seeding operations; it improves seed to soil contact and promotes rapid seedling development by warming the soil (Brown et al., 2008; Smyth et al., 2010a). Drawbacks to conventional tillage include soil moisture loss, increased soil compaction, loss of soil organic matter and increased vulnerability to wind and water erosion (Brown et al., 2008).

Survey information on tillage practices for Canada is described below. Similar survey information for the U.S. is incomplete. Nearly all canola production in Canada is situated in the western Prairie Provinces (Figure 1). Canola production practices used there (Smyth et al., 2010a) are similar to methods used in states such as North Dakota and Minnesota where most of the U.S. canola production occurs (Table 3). Therefore, the Canadian survey offers a comparable basis for analysis. These data indicated that for weed control, 77% of canola growers relied exclusively on herbicides, 28% used a combination of herbicide treatments and tillage, and 7% used only tillage (Smyth et al., 2010b).

Use of tillage has dropped considerably since 2000, when 89% of the growers reported using tillage as a form of weed control. Approximately a 5-fold increase in reliance on no-till or minimum till practices among western Canadian growers of HR canola was observed between 1999 and 2006 (Smyth et al., 2010a), a trend that is clearly correlated with increased adoption of HR canola (Duke and Powles, 2009b; Smyth et al., 2010a).

Despite the increasing flexibility in the ability to apply herbicides to control weeds, cultivation tillage continues to be used on some farms where HR canola is cultivated. This is most likely attributable to the cost of tillage, which is less expensive than herbicide control (Smyth et al., 2010b). In some areas of the U.S., individual growers confronted by GR weeds recently resorted to tillage to achieve adequate control (Duke and Powles, 2009a). In general, GE crops have reduced tillage from 89% to 35%, but as this report shows, in some individual instances, tillage is useful in managing HR weeds.

Rotational Practices. Crop rotation aids in the management of diseases, insects, and weeds and increases organic matter and soil fertility. It is recommended that spring canola follow cereal grains or fallow land in a rotation (Berglund et al., 2007), while winter canola is generally planted once every 2-3 years in a crop rotation with winter wheat (Schoonover, 2010). Successive planting of canola at the same location is not recommended because of increased risk from soil-borne fungal diseases such as *Alternaria*, blackleg, clubroot, and *Sclerotinia* (NDSU, 2005; Brown et al., 2008). Canola is also not recommended after pea, lentil, chickpea, soybean, sunflowers, and field or dry bean crops because they also increase the risk of soil-borne diseases such as *Sclerotinia*, *Rhizoctonia*, and *Fusarium* root rots (Brown et al., 2008).

In the northern U.S., approximately half of growers typically rely on a three-year rotation that includes canola, a small grain (generally wheat) and soybean. The remaining growers generally use a two-year rotation of canola and wheat. Canola is rarely rotated with corn.

Sclerotinia stem rot (*Sclerotinia sclerotiorum)* is a serious disease of canola that occurs worldwide (Luper et al., 2007). It caused an average state-wide yield loss of 13% in North Dakota and Minnesota from 1998-2007 with some fields suffering a 50% loss (Markell et al., 2009). Once the disease is established, the most important control is rotation with non-susceptible crops.

Blackleg disease (*Leptosphaeria maculans/biglobosa)* is also found worldwide. In North Dakota, it has reportedly caused yield losses surpassing 50% (Markell et al., 2009). Important control methods are rotation and disease-free, fungicide-treated seed (Luper et al., 2007).

Alternaria black spot is also found in all canola growing areas in the U.S. It tends to be a more prevalent problem in wetter years. Yield losses up to 20% or more have been reported if there is pod shatter (Brown et al., 2008). Control methods for *Alternaria* include rotation, sowing clean, disease-free seed, and controlling weeds. Clubroot is found in some areas with varying severity in the U.S. (MAFRI). In Quebec, heavily infested areas reportedly suffered a yield loss of 90% (Mendoza, 2009). Chemical control methods are not available for clubroot, so rotation with a non-brassacaceous crop is the only management alternative (MAFRI). Information about canola rotation with other crops that share diseases for the Great Plains can be found in Table 5.

Rotations are also used to help control weed populations that directly impact crop yields, and serve as reservoirs for pathogens (MacRae et al., 2000; NDSU, 2005). Many broad-leaf weeds, including wild mustard, pigweed, lambsquarters, marshelder, Canada thistle, and burdock are hosts of *Sclerotinia*, so it is critical to control these weed populations between rotations (NDSU, 2005). Preceding or following a canola planting in a rotation with another crop for which a different herbicide is used (e.g., a cereal rotation prior to planting canola to control broadleaf or perennial weeds) reducses problematic weed populations for the canola plantings (NDSU, 2005). Rotation of crops often allows for different herbicide control options depending on the herbicide-resistance traits available in that crop.

Table 5. Guide to Timing of Canola Rotation Crops

Crop	Number of Years Suggested Between Canola and Alternate Crop	Comments
Wheat Oats Barley	0	No diseases in common; can be grown the year before or after canola. Herbicide residue carryover can be a problem.
Corn Sorghum	0/1	No diseases in common; zero years where herbicide residue is not a concern and one year where atrazine is used on corn.
Potatoes Clover Field beans Cotton	1	Common diseases are *Rhizoctonia* and *Fusarium* root rots.
Alfalfa Soybeans	2	Common diseases are *Rhizoctonia* and *Fusarium* root rots and Sclerotinia stem rot.
Sunflowers	3	Common diseases are *Rhizoctonia* and *Fusarium* root rots and *Sclerotinia* stem rot.

Source: (Luper et al., 2007)

Injury to canola can be caused by herbicide residue. For example, this may result from treatment of a different crop previously planted at the same location as the canola crop. Some instances of persistent herbicide residue that required a 40-month interval before growing canola without risk of injury have been reported (NDSU, 2005; Brown et al., 2008). Therefore, the use of some herbicides on some crops can impose restrictions on the crop rotation systems that can be used at a given site. One advantage of GR crops is that glyphosate does not produce residue that must be managed with plant-back restrictions (Table 6). Therefore, GR canola is beneficial as a crop that broadens crop rotation options.

Canola produces glucosinolates in non-seed parts of the plant. These compounds are degraded in soil into products that are toxic to some species of insects, nematodes and fungi (Brown et al., 2008). The tap-root structure of canola plants promotes translocation of nutrients within the plant. This is important because it contributes to the release of nitrogen transported from deeper in the soil by post-harvest plant residue. It also increases the organic content of the soil for subsequent crops (Brown et al., 2008). Because canola is well adapted to regions where small grains are grown, it also provides growers with more options for other crops. This increases the potential for diversity of farm production and the reduction of market risks (Brown et al., 2008). GE canola has the same benefits as non-GE canola with respect to crop rotation.

Insecticide, Fungicide, and Fertilizer Use. Low soil fertility levels have a very serious impact on yield in canola production (Berglund et al., 2007). Nitrogen, phosphorous, potassium, and sulfur are applied in the spring before planting at application rates similar to those for small grain crops (NDSU, 2005; USDA-ERS, 2010). Sulfur requirements for canola are generally higher than for other crops and nitrogen is often limiting for the cultivation of winter canola (NDSU, 2005; Brown et al., 2008; USDA-ERS, 2010).

Table 6. Herbicide Plant-back Restrictions for Canola

Herbicide Common Name	Plant Back Restriction on Herbicide Label
Tralkoxydim	106 days
Carfentrazone	None
Metsulfuron	10 or 22 months
Triasulfuron	4 months
Imazamethabenz	15 months
Quizalofop	None
Atrazine	18 months
Difenzoquat	Next season
Pinoxaden	120 days
Flufenacet + Metributzin	12 months
Bentazon	None
Imazamox	26 months
Bromoxynil	30 days
Dicamba	120 days
Aminopyralid + Fluroxypyr	9 months
Clodinafop	30 days
Metolachlor	None
Pyraflufen	30 days

Herbicide Common Name	Plant Back Restriction on Herbicide Label
Flucarbazone	9 months
Tribenuron	60 days
Triallate	12 months
Chlorsulfuron	14-18 months
Chlorsulfuron	None
Paraquat	None
Thifensulfuron	45 days
Thifensulfuron	60 days
Diclofop	None
Pyrasulfotole + Bromoxynil	9 months
Diuron	12 months
Glufosinate	120 days
Linuron	12 months
Sulfosulfuron	22 months
MCPA	3 months
Propoxycarbazone	22 months
Propoxycarbazone + Mesosulfuron	12 months
Florasulam + MCPA	9 months
Mesosulfuron	10 months
Dimethenamid	None
Quinclurac	10 months
Prosulfuron	10 months
Sethoxydim	None

Herbicide Common Name	Plant Back Restriction on Herbicide Label
Pyroxulam	9 months
Pendimethalin	Next season
Fenoxyprop	None
Imazethapyr	40 months plus bioassay
Glyphosate	None
Clethodim	None
Metribuxin	12 months
Ethalfluralin	None
Sulfentrazone	24 months
Fluroxypyr	120 days
Clopyralid	None
Quinclurac	10 months
MCPB	None
Picloram	36 months or field bioassay
Trifluralin	None
2, 4-D	3 months

Based on (Brown et al., 2008)

Although some insect pests infest one type more than the other, spring and winter canola are impacted by the same species complex (Brown et al., 2008), so similar insecticide regimes can be used for both canola types. Insecticide products containing bifenthrin, deltamethrin, gamma cyhalothrin, lambda cyhalothrin, and methyl parathion as active ingredients are currently registered for canola in the U.S. (Brown et al., 2008). Seed treatments (with or without fungicides) are also registered for canola (Table 7). Cost-effective control of fungal diseases is usually achieved by using seed treatments that combine an insecticide and fungicide (Brown et al., 2008). Foliar fungicides are costly and used only in situations of extreme disease pressure or wet weather. Foliar fungicides include Endura and Ronilan EG for control of *Sclerotinia* and Quadris for blackleg (Brown et al., 2008). Planting disease-free certified seed and crop rotation are generally the most effective and economic means of controlling fungal diseases in canola (Boyles et al., 2009).

General Weed management. Growers control weeds because they reduce crop yield and quality by competition for water, nutrients, and sunlight. Decisions about weed management are among the most complex ones that growers must make because all options have advantages and disadvantages. Growers must manage simultaneously a wide array of broadleaf and grass weeds.

Table 7. Pesticide Seed Treatments Registered for Use on Canola

Seed treatment	Comments
Gaucho 600 (imidacloprid)	Provides seedling protection from aphids, flea beetles and wireworms when commercially applied.
Prosper 400	Contains a systemic chloronicotinyl insecticide (clothianidin) for flea beetle control, and three fungicides (thiram, carboxin, and metalaxyl) to help protect canola seedlings from seed rot damping off, seedling blight, and early season root rot caused by *Pythium*, *Rhizoctonia*, *Fusarium* and seed-borne *Alternaria* spp and blackleg.
Cruiser (thiamethoxam)	Systemic insecticide which belongs to a new subclass of neonicotinoids. Protects plants from a broad spectrum of seed, soil and foliar chewing and sucking insects.
Helix Xtra	Contains three fungicides (difenoconazole, mefenoxam and fludioxonil) and an insecticide (thiamethoxam), to protect canola seed against seed- and soil-borne diseases as well as flea beetles. Provides broad-spectrum protection against diseases such as seed rot, damping off, seedling blight, root rot and seed-borne blackleg.
Helix Lite	Contains three fungicides (difenoconazole, mefenoxam and fludioxonil) to protect canola seed against seed- and soil-borne diseases such as seed rot, damping off, seedling blight, root rot and seed-borne blackleg. Contains half the amount of thiamethoxam as Helix Xtra and is used for wireworm protection and where flea beetle pressure is low.

Source: (Brown et al., 2008)

In selecting a weed management strategy, growers choose the most economical means to control weeds that do not decrease the quality or quantity of the crop. Growers will often use a combination of weed management techniques including application of different herbicides to effectively control weeds in their fields. The strategy depends on the types of weeds, the level of infestation, the cropping system, the type of soil, cost, weather, time, and labor.

Once established, canola competes well with most weeds. Early weed control is critical however, because canola does not compete well with many weeds in its earliest developmental stages (NDSU, 2005; Harker et al., 2008). Studies of various HR varieties have shown that early herbicide application, before the 3- to 6-leaf stage, promotes yields (Martin et al., 2001; Harker et al., 2008).

As noted previously, another strategy to suppress weeds is crop selection in a rotation. For example, a wheat rotation prior to canola planting effectively manages Canada thistle because selective broadleaf herbicides that control perennial weeds can be applied to wheat (NDSU, 2005). One example is winter canola production in Oklahoma, where the crop is commonly rotated with wheat, sorghum, and corn to manage the problem weed complex of downy brome and Italian ryegrass (Luper et al., 2007).

There are three different types of HR-canola varieties currently available in the U.S. (Brown et al., 2008):

- conventionally derived imidazolinone-resistant (Clearfield);
- GE glyphosate-resistant (Roundup Ready);
- GE glufosinate-resistant (InVigor).

Most GE crops are insect resistant and/or HR. They were introduced commercially in 1996 (USDA-ERS, 2011). GE crops were quickly adopted because they provided growers with a highly profitable short-term term return on investment compared with conventional varieties (Scandizzo and Savastano, 2010). GE crops allow for production methods that are simpler and more flexible, so growers are able to reduce management time. This allows a single grower to increase income by expanding the crop acreage managed or performing non-farm work (Fernandez-Cornejo and Caswell, 2006). Growers also benefit from lower expenses attributable to a reduction in the need for pesticide applications. Collateral advantages include more opportunity to implement conservation practices and an overall reduction in environmental impacts of the crop production system.

Overuse of glyphosate has resulted in a negative impact because it has increased selection on resistant weeds in some field crops in the U.S. Growers with GR weeds in their fields may need to adopt alternative practices to help control them (Duke and Powles, 2009a). U.S. consumer concerns regarding GE crops have been widespread, but they have not been reflected in the marketplace (Fernandez-Cornejo and Caswell, 2006).

One analysis of the adoption of transgenic crop varieties globally (Brookes and Barfoot, 2010) indicated that the factors influencing adoption of HR- and insect-resistant crops included:

- Ease of use associated with broad-spectrum, post-emergent herbicides and the increased timeframe available to make spray applications;
- Reduction in damage to crops arising from the application of post-emergent herbicides;
- Ability to use alternative production technologies such as reduced or no-tillage practices;
- Time and fuel savings from the adoption of reduced/no-tillage and other agronomic practices as compared with those used in conventional cropping systems;
- Ease of weed control that promotes cleaner crops that reduce harvesting time and overall costs of harvesting, and result in higher product quality and value;
- Avoidance of potential damage from soil-incorporated residual herbicides in follow-on crops;
- Improved quality of family life arising from social benefits derived from time savings made from crop husbandry practices.

Since the commercial introduction of GR canola in 1999, production has fluctuated between 0.8-1.6M acres (Table 1). The stability of this range is indicated by the highest acreage years (1.6M) in 2000 and again recently in 2010. As described earlier, there was a substantial increase in the planting of HR varieties during the period 1999-2006 in the primary U.S production state of North Dakota from 25% to 99% (Johnson et al., 2007), but this was likely attributable to increased demand for canola-based products rather than availability of HR varieties. There is no indication that the introduction of GR varieties in 1999 substantially changed cultivation acreage of canola in the U.S. Furthermore, the planting of HR varieties is at or close to the maximum possible in the primary states of production (99% in North Dakota in 2006; 78% in Minnesota in 2006 (Johnson et al., 2007), which is similar to the trend in Canada (99% of Canadian canola acreage is planted in HR varieties (Figure 4). Therefore, the introduction of additional HR varieties, such as MON 88302 Canola, would not be expected to increase acreage and would likely be only a replacement for other HR varieties already being planted. The introduction of another GR variety to the marketplace would provide a market alternative and would not be expected to significantly change current canola acreage in the U.S.

As previously described, adoption of HR varieties is also high in Canada (Figure 4). Commercial adoption of HR-canola varieties in Canada has increased steadily since 1996, so that by 2010, 99% of Canada's 16.1M acres of canola were planted to either GE or non-GE HR varieties (Figure 4). Approximately 47% of Canada's HR-canola acres were planted with GR Roundup Ready® varieties, 46% were planted with glufosinate-resistant InVigor® varieties, and 6% were planted with imidazolinone-resistant Clearfield® varieties. These adoption rates demonstrate that producers are recognizing a substantial economic and environmental benefit from HR canola over non-HR varieties (Smyth et al., 2011).

An analysis of the long-term market for HR canola (USDA-APHIS, 2013c) indicates that glyphosate and glufosinate-resistant canola will remain popular with producers (Figure 5). It is not expected that producers will plant significant acreages of canola varieties with stacked resistance to glyphosate and glufosinate because of concerns about the need to control volunteer canola in crops rotated with canola. Inadequate weed control with imidazolinone-resistant canola is expected to limit demand for those varieties.

Herbicide Use and Weed Resistance. Compared to major crops such as corn, soybeans, and wheat, there are fewer herbicides available to canola growers. Registered herbicides for traditional canola are summarized in Table 8, and those for HR canola are listed in Table 9.

Crop pests respond to the repeated use of control tactics by evolving biological mechanisms to escape control. The first documented case of a weed developing resistance to an herbicide occurred in the mid-1960s (Ryan, 1970). During the 1970s, growers in North America and Europe began to recognize that one class of herbicides (triazines) that had successfully controlled many different weeds was no longer effective against certain populations of as many as 30 different weed species (Bandeen et al., 1982; LeBaron and McFarland, 1990). By 1990, weed scientists had evidence that at least 99 weed species contained individuals (biotypes) that had evolved resistance to one or more herbicides (Holt and LeBaron, 1990). Currently, more than 365 biotypes of HR weeds occur around the world (Weedscience.org, 2011).

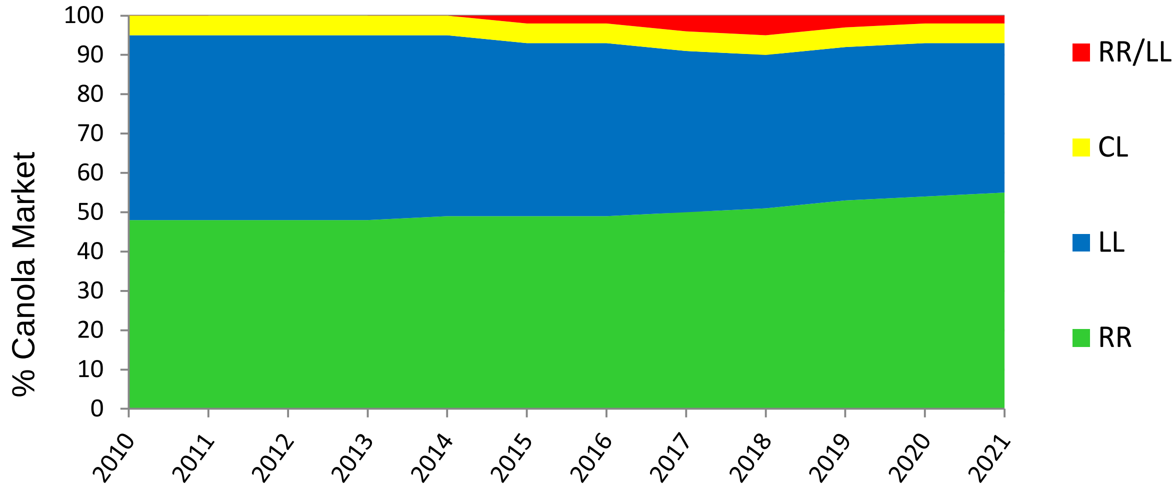


Figure 5. U.S./Canada Market Growth:Ten-year Projection of Herbicide-resistant Canola

RR/LL+CL = Roundup Ready x InVigor; CL = Clearfield; LL = InVigor; RR = Roundup Ready

Source: (USDA-APHIS, 2013a)

Only two GR weed species (common ragweed and kochia) are found in canola weed surveys in North Dakota (Table 2). All GR weed species, except *Poa annua* (annual bluegrass), are found in states reporting some canola crop acreage in 2007 (See Table 10).

Weeds with multiple herbicide resistance (glyphosate resistance plus resistance to at least one other herbicide class) have been reported in several states. A summary follows:

- glyphosate- and bipyridilium-resistant hairy fleabane in California;
- glyphosate- and ALS-resistant Palmer amaranth in Georgia and Mississippi;
- glyphosate- and ALS-resistant common waterhemp in Illinois;
- glyphosate- and ALS-resistant giant ragweed in Minnesota and Ohio;
- glyphosate- and ALS-resistant common ragweed and horseweed in Ohio;
- glyphosate-, PPO[6]-inhibitor- and ALS-resistant common waterhemp in Missouri;
- glyphosate- and glutamine synthase inhibitor-resistant Italian ryegrass in Oregon.

[6] Protoporphyrinogen oxidase

Table 8. Registered Herbicides Commonly Used on Canola in the U.S.

Herbicide	Application Method	Weeds Controlled
Assure II (quizalofop)	Foliar spray	Annual grasses and quackgrass
Poast (sethoxydim)	Foliar spray	Annual grasses
Select (clethodim)	Foliar spray	Annual grasses
Sonalan (ethalfluralin)	Preplant incorporated	Several annual broadleafs, foxtail, barnyard grass
Stinger (clopyralid)	Foliar spray	Canada thistle, perennial sowthistle, dandelion, curly dock, wild buck wheat, cocklebur, prickly lettuce, ragweed, chamomile, nightshade, and biennial wormwood
Treflan (trifluralin)	Preplant incorporated	Several annual broadleafs, foxtail, barnyard grass

Source: (USDA-APHIS, 2013a)

Table 9. Registered Herbicides for Herbicide-resistant Canola

Herbicide	Application Method	Weeds Controlled
Ignite (glufosinate) for InVigor varieties	Foliar spray	Annual broadleafs, annual grasses, when applied to early stages
Roundup (glyphosate) for RoundupReady varieties	Foliar spray	Most annual broadleafs and grasses
Beyond (imidazolinone) for Clearfield varieties	Foliar	Many annual broadleafs and grasses

Table 10. Herbicide-resistant Weeds of 25 Canola-producing States

Species Common Name	Resistant To One Or More Mode Of Action
Palmer Amaranth	Glycines
Italian Ryegrass	ACCase inhibitors, ALS inhibitors, Hlycines, Glycines ,
Johnson grass	Glycines
Hairy Fleabane	Bipyridiliums and Glycines
Smooth Crabgrass	Synthetic Auxins
Junglerice	Glycines
Barnyardgrass	ACCase inhibitors, Thiocarbamates and others, Synthetic
Late Watergrass	ACCase inhibitors, Thiocarbamates and others
Rigid Ryegrass	Glycines
Kochia	Photosystem II inhibitors, ALS inhibitors, Synthetic Auxins,
Wild Oat	ACCase inhibitors, Thiocarbamates, others, and Unknown
Common Waterhemp	ALS inhibitors, Photosystem II inhibitors , Glycines
Field Bindweed	Synthetic Auxins
Powell Amaranth	Photosystem II inhibitors , Ureas and amides
Redroot Pigweed	Photosystem II inhibitors , Ureas and amides
Horseweed	Glycines, Photosystem II inhibitors , Bipyridiliums, ALS
Wild Carrot	Synthetic Auxins
Common Purslane	Photosystem II inhibitors , Ureas and amides
Spiny Amaranth	Glycines
Goosegrass	Glycines, Dinitroanilines and others
Annual Bluegrass	Glycines
Common Ragweed	ALS inhibitors , Glycines, PPO inhibitors
Giant Ragweed	ALS inhibitors ,Glycines
Yellow Starthistle	Synthetic Auxins

Survey information on tillage practices for Canada follows. Similar survey information for the U.S. is limited or incomplete. The practices in the western provinces, where nearly all Canadian canola is produced (Smyth et al., 2010b), are virtually identical to U.S. cultivation methods in North Dakota, where most of the U.S. canola acreage is located (Table 3). The western Canada survey data indicate that for canola production, conventional tillage has become less expensive in recent years. For the period, 1999-2006, it was estimated that cultivation was less expensive than herbicide weed control options (Smyth et al., 2010b). When growers were asked about their weed control measures, 77% reported they use herbicides only, 28% said they use herbicides and tillage, and 7% said they used tillage only.

Use of tillage has declined considerably since 2000, when 89% of canola growers reported using this method of weed control. This is attributed to better weed control options that are possible with HR canola. Approximately a 5-fold increase in the use of no-till practices among western Canadian growers of HR canola was observed between 1999 and 2006 (Smyth et al., 2010b). This increase in the use of no-till or minimum-till practices is correlated with increased adoption of HR canola (Duke and Powles, 2009a; Smyth et al., 2010b).

In general, GE crops have reduced tillage from 89% to 35%, but in some instances tillage is necessary for effective control of HR weeds. Despite this ability to broadly apply herbicides to control weeds, cultivation tillage continues to be used on some farms cultivating HR canola. This is probably an effect of the lower cost of using tillage as compared with herbicide control (Smyth et al., 2010b). In some areas of the U.S., individual growers with GR weeds have recently resorted to tillage to control them (Duke and Powles, 2009a).

GE canola seeds average 30-40% more expensive than those for conventional varieties (Zollinger et al., 2008). Table 11 summarizes recent data (2008) by acreage planted for GE-, HR-canola types in North Dakota (Zollinger et al., 2008).

<u>Preferred Alternative: Agricultural Production of Canola</u>

As described in the No-action Alternative, agricultural practices are influenced by disease, insect and weed pressures. Approving the petition for nonregulated status would not change the effects of canola farming on agronomic practices used for disease and insect control. However, approval of MON 88302 Canola would allow greater latitude in the application of glyphosate in response to weed pressures. This would include making applications at twice the rate currently allowed for canola production because MON 88302 Canola is more resistant to glyphosate exposure than that of other HR-canola varieties now in production. It would also allow for making applications to canola crops in later stages of development. Canola varieties approved currently can only withstand glyphosate treatments until they reach the six-leaf stage of development. In contrast, stands of MON 88302 Canola can be treated until they reach the flowering stage. The net effect of the changes allowed for glyphosate applications to MON 88302 Canola is that the amount of a.i. would only increase to that permitted for use on other GR crops that are included among those used in rotation with canola.

4.2.2 Canola Seed Production

<u>No Acton Alternative: Canola Seed Production</u>

Under the No-Action Alternative, current canola seed production practices are not expected to change from continued regulation of MON 88302 Canola and its progeny under 7 CFR part 340 and the plant pest provisions of the PPA. MON 88302 Canola would be cultivated for seed in a limited area independent of any commercial seed production. Field tests (Monsanto, 2011) have determined that MON 88302 Canola is not significantly different from other canola cultivars, including non-GE- and other GE-canola varieties, all of which are currently planted in the primary canola-growing state of North Dakota (See Table 11). It is also expected that canola seed producers would continue to implement measures to preserve the identity of their seed varieties. No changes to canola seed production practices or locations would occur under the No-action Alternative.

Preferred Alternative: Canola Seed Production

Monsanto seed field trials have not demonstrated any agronomic or phenotypic differences between MON 88302 Canola and other GE-canola, control-group cultivars (Monsanto, 2011). Under the preferred alternative with nonregulated status, MON 88302 Canola would likely replace some other commercial, GR-canola cultivars on current production acres.

Based on the data provided by Monsanto for MON 88302 Canola, as well as previous experience with other GE-, HR-canola varieties that have been widely adopted by growers since their commercial availability in 1996, APHIS has concluded that the availability of MON 88302 Canola under the Preferred Alternative would not alter the agronomic practices, cultivation locations, seed production practices or quality characteristics of conventional and non-GE canola seed production (Monsanto, 2011). No change to seed production practices would be required if MON 88302 Canola were no longer regulated. The potential impacts to canola seed production associated with the Preferred Alternative would be the same as the No-action Alternative.

4.2.3 Organic Canola Production

No-action Alternative: Organic Canola Production

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2010a). However, certain markets or contracts may have defined thresholds (Non-GMO-Project, 2010).

Individuals, grower associations or other private or public entities can establish isolation distances and other management practices to minimize gene flow from GE canola to non-GE, organic-canola crops or other crops receptive to cross-pollination from GE canola, (e.g., countermeasures to protect seed crops of other cultivars of *Brassica* spp., established in Oregon (Oregon-Department-of-Agriculture, 2013).

Preferred Alternative: Organic Canola Production

Approving the petition for nonregulated status of MON 88302 Canola would not change the effects of canola farming on organic resources. Because most canola production currently uses HR-canola varieties, the introduction of an additional GR variety with the same potential for cross-pollination as existing non-regulated, GE-canola varieties will not have any effect on future canola production practices. Since the production practices do not change under the preferred alternative, when compared to the No-action Alternative, there would be no changes in the direct or indirect effects on organic canola production.

Table 11. Acreage of Herbicide-Resistant Canola Varieties Grown In North Dakota

District	HR-Canola Acres[1]	Resistant Variety					
		Glyphosate		Liberty		Clearfield[2]	
		Acres	% of Total	Acres	% of Total	Acres	% of Total
Northwest	223.0	126.1	56.6	95.7	42.9	1.2	0.5
West Central	78.0	60.0	76.9	17.1	21.9	ND[3]	ND
Central	34.5	11.7	34.0	18.7	54.2	3.7	10.8
East Central	4.5	3.2	71.7	1.3	28.3	ND	ND
Southwest	43.0	33.0	76.8	7.8	18.2	ND	ND
South Central	9.0	ND	ND	ND	ND	ND	ND
State Total	**910.0**	**507.0**	**55.7**	**355.6**	**39.1**	**17.4**	**1.9**

[1]in thousands of acres

[2]Clearfield is a variety with a trait developed by traditional plant breeding, so it is not a GE variety.

[3]No available data

Source (Zollinger et al., 2008).

4.3 Physical Environment

4.3.1 Water Resources

<u>No-action Alternative: Water Resources</u>

Canola cultivation may directly affect water resources through the use of local water sources for irrigation, or indirectly through associated management practices, including tillage and the use of agricultural inputs. The typical amount of water consumption during a growing season for successful canola production ranges up to 20 inches, depending on variety, management practices and the targeted yield (Hoeft et al., 2000). While normal climatic conditions may provide sufficient water to produce a crop, precipitation may vary across regions, so irrigation may be needed to supplement precipitation amounts.

In water, glyphosate is rapidly adsorbed onto suspended soil particles, and organic and mineral matter. It is degraded by microorganisms. Glyphosate residues in sediments underlying aerobic water have a half-life of seven days. In anaerobic aquatic sediment, its residual half-life is approximately 208 days (US-EPA, 2009e).

The fate of glyphosate and its metabolite, AMPA, on a watershed scale in three Mississippi River basin watersheds was compared to results for a watershed in France (Coupe et al., 2011). They found that 1% or less of glyphosate is transported to surface water, although their samples frequently detected both glyphosate and AMPA (Coupe et al., 2011). Variability was correlated to differences in source strength, rainfall runoff, and flow route. The study concluded the watersheds most at risk for transport of glyphosate have high application rates, rainfall events resulting in overland runoff, and flow routes unfiltered by soil.

The principal law governing pollution of the nation's water resources is the Federal Water Pollution Control Act of 1972, also known as the Clean Water Act (CWA) (US-EPA, 2011h). The CWA authorizes the establishment of water quality standards, permit requirements, and monitoring to establish a legal framework to protect and enhance domestic water quality. The EPA sets standards for water pollution abatement for all waters of the U.S. under the authority of this enabling legislation. In most cases, EPA extends to qualifying states the authority to issue and enforce permits. The CWA (33 USC 1251 *et seq*.) authorizes regulation of discharges of pollutants into the waters of the U.S. and the establishment of quality standards for surface waters. It is the principal U.S. legislation for safeguarding surface water, but it does not directly address groundwater or water quantity issues.

Surface water is an important natural resource used for many purposes, especially irrigation and public supply of drinking water and for everyday uses. The CWA authorizes a variety of regulatory and non-regulatory methods to:

- Reduce direct pollutant discharges into waterways;
- Finance municipal wastewater treatment facilities, and manage polluted runoff (US-EPA, 2008);
- Manage NPS, which results when runoff from rainfall, snowmelt, or irrigation moving over and through the ground accumulates natural and human-made pollutants that are ultimately transported into lakes, rivers, wetlands, coastal waters, and groundwater (US-EPA, 2011e).

Glyphosate has not been identified as the cause of impairment to any water bodies classified as such under Section 303(d) of the CWA (US-EPA, 2011f).

Tillage is an important tool for managing weeds in crop production systems (Givens et al., 2009). Therefore, alternative management systems that reduce tillage and conserve crop residue can produce many water quality benefits, such as less sediment and chemical runoff entering surface water, reduced pesticide residues in surface water, improved moisture content in soil, and reduced potential for flooding (Fawcett and Towery, 2002). The positive impacts of reduced tillage are attributable to the increased amount of plant residue on the soil surface, which serves as a physical barrier to erosion and runoff, allowing more time for water absorption into the soil (Locke et al., 2008). The positive correlation between tillage reduction and the cultivation of HR crops has been documented (Fawcett and Towery, 2002).

Glyphosate has a high affinity for binding with most types of soils, especially those with high organic content (Senseman, 2007). Because it is tightly bound to soil, transport to surface water by runoff from rain and irrigation occurs primarily by residue adsorbed on soil particles. This attribute also limits the mobility of glyphosate in soil and transport to groundwater.

Drinking water is protected under the Safe Drinking Water Act (SDWA) of 1974 (Public Law 93-523, 42 USC 300 *et seq*.). The SDWA is the main Federal law that ensures the quality of U.S. drinking water. Under the SDWA, the EPA sets national health-based standards for drinking water quality to protect against both naturally-occurring and man-made contaminants that may be found in drinking water. The EPA also oversees the states, localities, and water suppliers who implement those standards (US-EPA, 2011f). The Sole Source Aquifer (SSA) designation under the SDWA is used to protect drinking water supplies in areas with few or no alternative groundwater resources, where contamination would require an extremely expensive replacement (US-EPA, 2011g). The EPA defines SSA as an aquifer that supplies at least 50% of the drinking water consumed in the area overlying the aquifer. There are 77 designated SSAs in the U.S. and its territories (US-EPA, 2011g) .

The potential for glyphosate to move into groundwater or surface waters is considered low (US-EPA, 2009e). However, an exception to this observation has been reported for terrestrial applications made in close proximity to water bodies (WHO, 2005).

<u>Preferred Alternative: Water Resources</u>

With one exception, there would be no difference from the No-action Alternative for water resources from approving the petition for nonregulated status for MON 88302. Approval of the petition would make available a new canola variety that has a higher in-crop glyphosate application rate (i.e., the total amount that can be applied annually to a crop) than that of other currently available GR-canola varieties. The higher in-crop rate for MON 88302 Canola is however, less than or comparable to the in-crop rate currently allowed for GR sugar beets, alfalfa, corn, soybeans and cotton. Except for GR sugar beets, all of these are crops recommended in rotation with canola (Table 5), so fields used for GR canola plantings are already potentially subject to the higher in-crop glyphosate application rate. All of these GR crops cited here are no longer regulated by APHIS. As part of its decisionmaking process for these GR crops, APHIS prepared EAs (and/or EISs) and analyzed the potential effects on several different physical parameters, including water, that are associated with the higher glyphosate application rate now proposed for MON 88302 (USDA-APHIS, 2000; USDA-APHIS, 2004; USDA-APHIS, 2010b; USDA-APHIS, 2012a). EPA has also determined that use, in accordance with the labeling of currently registered pesticide products containing glyphosate, will not pose unreasonable risks or adverse effects on water and water use as well as soil, climate, and air quality. Based on these considerations, APHIS has concluded there would be no changes in the direct or indirect effects on water resources from the preferred alternative.

4.3.2 Soil Quality

<u>No-action Alternative: Soil Quality</u>

Terrestrial plant production of any kind has the potential to modify substrate soil quality wherever crops are cultivated. Since soil is characterized by layers distinguished from the initial parent material that result from additions, losses, transfers, and transformations of energy and matter, (USDA-NRCS, 1999), the intensity of disruption (e.g., depth and frequency of tillage) is a major factor determining the degree of impact. In addition to tillage, crops themselves impact soil quality because their root systems modify the soil environment and ultimately its ecology.

Methods to improve soil quality include: careful management of fertilizer and pesticide applications; use of cover crops to increase plant diversity and reduce exposure time of soil lacking cover vegetation to wind and rain; use of buffer strips, contour strips, wind breaks, and crop rotation to promote landscape diversity (USDA-NRCS, 2006b). Tillage is an important tool for managing weeds in crop production systems (Givens et al., 2009). Strategies for minimizing its use (i.e., no-till and conservation tillage) also complement some of the methods mentioned here for enhanced sustainability of soil exposed to intensive cropping, as well as other advantages. For example, tillage management tends to minimize soil compaction by reducing frequency of tilling, so in general**,** reduced tillage minimizes the loss of organic matter and protects the soil surface by leaving plant residue on the surface. However, for some soil types (e.g., heavy clay soils), reduced or no-till practices are unsuitable because they may increase compaction (USDA-NRCS, 1996). Conventional tillage may also be a better option for management of certain crop pests (USDA-NRCS, 2010).

Residue management is one of the most effective conservation methods to reduce wind and water soil erosion. It also benefits air and water quality, and wildlife (USDA-NRCS, 2006a). Reducing excessive tillage by conservation tillage minimizes loss of organic matter and protects the soil surface by leaving plant residue on the surface. Since canola grows best in medium textured, well-drained soils, surface placement of crop residue with conservation tillage improves soil physical, chemical, and biological properties compared with incorporation of residues with conventional tillage. Management that uses intensive tillage and leaves low amounts of crop residue on the surface increases loss soil organic matter (SOM). Intensive tillage turns the soil over, which buries most of the residue, stimulating microbial activity and increasing the rate of residue breakdown (USDA-NRCS, 1996). Residues left after conservation tillage increase organic matter and improve infiltration, soil stability and structure, and the soil-borne microbial community (Fawcett and Caruana, 2001; USDA-NRCS, 2006b).

Organic matter is a vital component in maintaining soil quality (USDA-NRCS, 1996) by:

- maintaining soil stability and structure;
- reducing potential for erosion;
- providing energy for microorganisms;
- improving infiltration and water-holding capacity;
- promoting nutrient cycles;
- metabolizing and detoxifying pesticides, other toxicants and naturally occurring toxins

- increasing cation exchange capacity[7]

Current canola cultivation impacts are caused primarily by tillage and harvesting equipment that tend to disturb and expose the top soil horizon. This makes the surface soil layer more susceptible to degradation from erosion by wind and runoff than soil that maintains a vegetated surface layer. Some of the most serious consequences of such soil degradation include decreased water retention, reduced accretion and sequestration of soil-borne carbon, and increased emission of GHGs (e.g., carbon dioxide and nitrous oxide (Lal and Bruce; U.S. EPA, 2010c)). Other potential negative impacts of degraded soil are indirect effects, such as reduced local surface water quality and the disruption of communities of organisms whose survival is contingent on that resource.

Fertilization may be used by canola growers. In general, canola requires 25% more nitrogen, and similar amounts of phosphorous and potassium compared to winter wheat, but canola requires slightly higher amounts of sulfur than wheat (Atkinson et al., 2006). Optimal soil pH for canola ranges from 5.8 to 6.2. Producers apply nitrogen, phosphorus, sulfur, and potassium in the spring before or at planting. Sulfur requirements are higher than for other crops. New crop varieties that are resistant to herbicides have helped to decrease the risk and effort associated with canola production (USDA-ERS 2012 yearbook; Atkinson et al., 2006).

The increased residue from conservation tillage increases in the top three inches of soil and protects the surface from erosion, while maintaining water-conducting pores. Soil aggregates in conservation tillage systems are more stable than those in conventional tillage because of the enhancing effects of products from SOM decomposition and the presence of soil microbial flora (e.g., bacteria and fungi). Hyphae (filamentous structures that are the predominant growth form of fungi) are especially effective in binding aggregates and soil particles together (USDA-NRCS, 1996). Although soil erosion rates in crop production are dependent on numerous local conditions such as soil texture and crop type, comparative studies contrasting conventional and no-till practices found that no-till practices were more effective in reducing erosion than conventional tillage (Montgomery, 2007). This reduction enables soil production to nearly replace soil losses from erosion. From 1982 through 2003, the estimated U.S. cropland erosion rate declined from 3.1 billion tons per year to 1.7 billion tons per year (USDA-NRCS, 2006a). This positive impact is partially attributable to effective weed control derived from herbicide applications that vastly reduce dependence on mechanical (tillage) methods (Carpenter et al., 2002).

Even in the absence of herbicide applications, conservation tillage tends to provide a competitive advantage to canola production by promoting earlier crop emergence (Bullied et al., 2003). The introduction of HR canola increases the effectiveness of weed control making conservation tillage a more feasible option (Fawcett and Towery, 2002).

Glyphosate is rapidly bound (adsorbed) to soil particles. Its adsorption rate in soil is minimally influenced by pH, organic matter content, and the ratio of clay, silt and sand composing a

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[7] Cation Exchange Capacity is the ability of soil anions (negatively charged clay, organic matter and inorganic minerals such as phosphate, sulfate, and nitrate) to adsorb and store soil cation nutrients (positively charged ions such as potassium, calcium and ammonium).

particular soil type. Soils high in phosphorus decrease adsorption, which increases its availability for plant uptake, microbial degradation, and leaching (Senseman, 2007), which increases its availability for plant uptake, microbial degradation, and leaching (Kremer and Means, 2009). However, because glyphosate tends to bind in most soils, this reduces its degradation rate. Since degradation is mediated by microbial action, the rate is also influenced by the species composition of microorganisms within the rhizosphere. The combined effect of these two important factors influencing degradation of glyphosate have been shown to result in an average half-life in soil of 47 days (Senseman, 2007) with a range of 2.4 to 160 days (US-EPA, 2009e).

Several reports indicate that glyphosate interacts with manganese by forming insoluble, stable complexes that either immobilize this element, or reduce plant uptake, preventing reduction in the plant and making it unavailable (Eker et al., 2006; Neumann et al., 2006; Ozturk et al., 2008; Cakmak et al., 2009; Huber, 2010). Huber (2010) and Cakmak (2009) also reported that glyphosate is a broad-spectrum chelate of several other nutrients (iron, calcium, magnesium, copper, iron, nickel and zinc). However, a clear consensus has not evolved among researchers studying the dynamics of these processes. Hartzler (2010), for example, agrees that glyphosate could immobilize essential elements temporarily, but does not believe that it specifically targets manganese or any other particular element. Instead, this interpretation indicates that it targets those cations[8] that are most prevalent in soil. Hartzler (2010) also reported that areas for which glyphosate interactions with manganese are described are limited to those with known soil manganese deficiencies. Camberato (2010) noted that manganese deficiency is not a new phenomenon and is also associated with high pH, low moisture, or high levels of organic matter. Regardless of the cause(s), its deficiency is recognizable and can be resolved through foliar application(s) of manganese fertilizers (Camberato et al., 2010).

Preferred Alternative: Soil Quality

With one exception, there would be no difference from the No-action Alternative for soil quality by approving the petition for nonregulated statusfor MON 88302. Approval of the petition would make available a new canola variety that has a higher in-crop glyphosate application rate than that of other currently available GR-canola varieties. The higher in-crop rate for MON 88302 Canola is however, less than or comparable to the in-crop rate currently allowed for GR sugar beets, alfalfa, corn, soybeans and cotton. Except for GR sugar beets, all of these are crops recommended in rotation with canola (Table 5), so fields used for GR canola plantings are already potentially subject to the higher in-crop glyphosate application rate. All of these GR crops cited here are no longer regulated by APHIS. As part of its decisionmaking process for these GR crops, APHIS prepared EAs (and/or EISs) and analyzed the potential effects on soil associated with the higher glyphosate application rate now proposed for MON 88302 (USDA-APHIS, 2000; USDA-APHIS, 2004; Rood, 2007; USDA-APHIS, 2010b) USDA-APHIS, 2012b. EPA has also determined that use in accordance with the labeling of currently registered pesticide products containing glyphosate will not pose unreasonable risks or adverse effect to soil, climate, air quality or water and water use. Based on these considerations, APHIS has

[8] A cation ion is an element with a positive charge (missing electrons) such as iron (Fe^{2+}), manganese (Mn^{2+}), calcium (Ca^{2+}), potassium (K^{+}) and sodium (Na^{+}).

concluded there would be no changes in the direct or indirect effects on soil quality from the preferred alternative.

4.3.3 Air Quality

No-action Alternative: Air Quality

The Clean Air Act (CAA) requires the maintenance of National Ambient Air Quality Standards (NAAQS). The NAAQS, developed by the EPA to protect public health, establishes limits for six criteria pollutants: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and coarse (inhalable) particulate matter (PM) greater than 2.5 micrometers and less than 10 micrometers in diameter (PM_{10}), and fine particles less than 2.5 micrometers in diameter ($PM_{2.5}$) The CAA requires states to achieve and maintain the NAAQS within their borders. Each state may adopt requirements stricter than those of the national standard and each is required by the EPA to develop a State Implementation Plan that contains strategies to achieve and maintain the national standard of air quality within the state. Areas that violate air quality standards are designated as non-attainment areas for the relevant pollutants, whereas areas that comply with air quality standards are designated as attainment areas. Primary sources of emissions associated with crop production include exhaust from motorized equipment such as tractors and irrigation equipment, soil particulates from tillage, wind-induced erosion, burning of fields, and spraying of herbicides and pesticides. Emissions contributing to GHGs associated with global warming are described in Subsection 4.3.4, Climate Change.

Pesticide and herbicide spraying introduce air quality impacts from drift and diffusion. Drift is defined by the EPA as "the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application" (US-EPA, 2000). Diffusion is gaseous transformation to the atmosphere (FOCUS, 2008). Factors affecting drift and diffusion include application equipment and method, weather conditions, topography, and the type of crop being sprayed (US-EPA, 2000). The EPA is currently evaluating new regulations for pesticide drift labeling and the identification of best management practices to control such drift (US-EPA, 2009d), as well as identifying scientific issues surrounding field volatility of conventional pesticides (US-EPA, 2010).

Chang et al. (2011) recently evaluated the occurrence and fate of glyphosate and its metabolite, AMPA, in the atmosphere and in rainfall in the Mississippi River basin. They found the frequency of glyphosate in the air was similar to that of other commonly applied herbicides, such as atrazine and metolachlor, but its incidence in rain was higher, primarily because of widespread use of glyphosate for crop production in the region (Chang et al., 2011). AMPA in air was sampled at a range of 0 to 1.0 as a fraction of glyphosate. Early in the application season it was lower, but increased as glyphosate degraded in soil to produce the metabolite. Its incidence in rain was similar. The study also investigated the source of glyphosate in the air and found most occurred from spray application rather than volatilization or transport from windborne soil. They concluded that up to 97% of glyphosate may be removed from the atmosphere by weekly rainfall greater than 30 millimeters (1.18 inches).

Other conservation practices, as required by the USDA to qualify for crop insurance and beneficial federal loans and programs (USDA-ERS, 2009), effectively reduce crop production impacts to air quality through the use of windbreaks, shelterbelts, reduced tillage, and cover crops that promote soil protection on highly erodible lands.

Preferred Alternative: Air Quality

Approving the petition for nonregulated status would not change the effects of canola farming on Air Quality. With one exception, there would be no difference from the No-action Alternative on air quality by approving the petition for nonregulated status for MON 88302. Approval of the petition would make available a new canola variety that has a higher in-crop glyphosate application rate (i.e., the total amount that can be applied annually to a crop) than that of other currently available GR-canola varieties. The higher in-crop rate for MON 88302 Canola is however, less than or comparable to the in-crop rate currently allowed for GR sugar beets, alfalfa, corn, soybeans and cotton. Except for GR sugar beets, all of these are crops recommended in rotation with canola (Table 5), so fields used for GR-canola plantings are already potentially subject to the higher in-crop glyphosate application rate. All of these GR crops cited here are no longer regulated by APHIS. As part of its decisionmaking process for these GR crops, APHIS prepared EAs (and/or EISs) and analyzed the potential effects on air quality associated with the higher glyphosate application rate now proposed for MON 88302 (USDA-APHIS, 2000; USDA-APHIS, 2004; USDA-APHIS, 2010b; USDA-APHIS, 2012a). EPA has also determined that use in accordance with the labeling of currently registered pesticide products containing glyphosate will not pose unreasonable risks or adverse effect to soil, climate, air quality or water and water use. Based on these considerations, APHIS has concluded there would be no changes in the direct or indirect effects on air quality from the preferred alternative.

4.3.4 Climate Change

No-action Alternative: Climate Change

Climate change represents a statistical change in global climate conditions, including shifts in the frequency of extreme weather, that may be measured across time and space (Cook et al., 2008; Karl et al., 2008). Agriculture is recognized as a direct (e.g, exhaust from equipment) and indirect (e.g, agricultural-related soil disturbance) source of GHG emissions (Rosenzweig and Parry, 1994; Dale, 1997; Fargione et al., 2008; Gutowski et al., 2008; Piñeiro et al., 2009; U.S. EPA, 2010a). GHGs, including CO_2, CH_4, and N_2O, function as retainers of solar radiation (Aneja et al., 2009). The U.S. agricultural sector is second only to energy production as a contributor to GHG emissions (U.S. EPA, 2010a).

U.S. agriculture may influence climate change through various facets of the production process (Horowitz and Gottlieb, 2010) and conversion of land to agriculture. CH_4 and N_2O are the primary GHGs emitted by agricultural activities. The major sources of GHG emissions associated with crop production are soil N_2O emissions, soil CO_2 and CH_4 fluxes, and CO_2 emissions associated with farm equipment operation (Adler et al., 2007). Over the 20-year period, 1990-2009, total emissions in the agriculture sector increased 8.7%. By 2009, 7% of total U.S. GHG emissions were attributed to agricultural sources (US-EPA, 2011b).

N_2O emissions from agriculture account for an estimated 69% of all U.S. N_2O emissions (US-EPA, 2011c). N_2O emissions are estimated at 69% of all U.S. N_2O emissions (US-EPA, 2011b). These are attributed to soil management activities including fertilizer application and cropping practices, so agriculture represents the largest source of this GHG.

Agricultural practices that produce CO_2 emissions include liming and the application of urea fertilization to agricultural soils. Emissions from intestinal (enteric) fermentation and manure management represent about 20% and 7% respectively of total CH_4 emissions from anthropogenic activities (US-EPA, 2011c). In 2009, the use of lime and urea fertilizers resulted in an 11% increase of CO_2 relative to 1990 emissions (US-EPA, 2011b). The agricultural sector also produces CO_2 emissions from fossil-fuel combustion by farm equipment as described previously in Subsection 2.2.4.

Soil-disturbing practices such as tillage can result in the release of sequestered organic carbon, which is produced by the remains of microorganisms (fungi, bacteria, etc.), in non-living organic matter and attached to inorganic minerals in the soil. Agriculture may also affect dynamic soil processes through tillage and other land management practices (Smith and Conen, 2004).

Conservation tillage strategies are associated with more stable and increased carbon sequestration resulting from a net reduction in carbon dioxide emissions (Lal and Bruce, 1999; West and Marland, 2002). Several reports indicate that the relationship between conservation tillage and increased carbon sequestration requires more study, as soil depth and seasonal sampling bias may inadvertently affect measurements (Angers et al., 1997; Potter et al., 1998; Wanniarachchi et al., 1999; West and Marland, 2002; Baker et al., 2007; Oorts et al., 2007). The relationship between different GHG emissions, such as carbon dioxide and nitrous oxide, can require modifications to models related to tillage strategies and global climate change (Gregorich et al., 2005). For example, increased nitrous oxide emissions as a result of conservation tillage strategies may offset any gains achieved through increased carbon sequestration.

As is also true of the relationship between conservation tillage strategies and carbon sequestration, a broad generalization regarding the impact of tillage on nitrous oxide emissions is difficult. Numerous factors influence soil nitrification cycles, including geographic location, soil structure, moisture, and farm-level management practices, including, but not limited to, those that relate to fertilizer and pesticide applications (Linn and Doran, 1984; Palma et al., 1997; MacKenzie et al., 1998; Campbell, 2003; Elmi et al., 2003; Gregorich et al., 2005; Grandy et al., 2006; Gregorich et al., 2006; Metay et al., 2007; Ball et al., 2008; Del Grosso et al., 2008; Farahbakhshazad et al., 2008; Halvorson et al., 2008; Philippe, 2008; Rochette et al., 2008; Almaraz et al., 2009; Poirier et al., 2009).

Baseline data for 1996-2004 for U.S. and Canadian canola production combined were used in one study (Brookes and Barfoot, 2004) to estimate impact on GHG emissions. Results indicated that CO_2 emissions declined by 94M kg from less fuel usage attributable to reduced tillage requirements. They also indicated that an additional 906M kg of CO_2 was sequestered by reducing soil tillage.

Preferred Alternative: Climate Change

Approving the petition for nonregulated status would not change the effects of canola farming on climate change. Because the majority of canola production uses HR-canola varieties, the introduction of an additional GR variety will have no effect on the production practices currently employed in canola. As described in the No-action Alternative, the effects of canola production on climate change result from the types of production practices used. Since the production practices do not change under the preferred alternative when compared to the No-action

Alternative, there are no changes in the direct or indirect effects on climate change from the preferred alternative when compared to the baseline (No-action Alternative).

4.4 Biological Resources

4.4.1 Animal Communities

No-action Alternative: Animal Communities

Invertebrates that feed on canola include pests. They may be controlled with insecticides or other management practices. Seed treatments are recommended to prevent flea beetle damage of young plants and foliar insecticide applications are recommended when population levels cause losses that exceed the cost of treatment, i.e., the economic threshold for damage (NDSU, 2011).

Vertebrate animals may consume canola plants or seed. Canola forage can have a protein content of 21-33% (Oplinger, 1989). It is about 40% oil, which can make it a high energy food source for some wildlife. Turkey and deer may graze on canola. Therefore it is not recommended for planting in fields where animal damage from these organisms occurs (Pennsylvania-State-University-Extension-Service, no date). Some State departments of fish and wildlife recommend planting canola as a fall or winter forage (Kentucky-Department-of-Fish-and-Wildlife-Resources, 2010). Canola seed is marketed as an attractant to wildlife (Elk-Mound-Seed-Company, No date).

About half of the canola planted is GR. Glyphosate is practically nontoxic to slightly toxic to birds, freshwater fish, marine and estuarine species, aquatic invertebrates and mammals and practically nontoxic to honey bees (which are used to assess effects on nontarget insects in general) (U.S. EPA, 1993). Glyphosate has a low octanol-water coefficient, indicating that it has a tendency to remain in the water phase rather than move from the water phase into fatty substances. Therefore, it is not expected to accumulate in fish or other animal tissues.

Preferred Alternative: Animal Communities

Compositional analyses were conducted to assess whether levels of key nutrients, toxicants and anti-nutrients in MON 88302 were equivalent to levels in the conventional control and commercial reference varieties. MON 88302 Canola is compositionally equivalent to other canola varieties currently available (Monsanto, 2011).

Based on the studies included in the petition, the physicochemical characteristics of the CP4 EPSPS protein expressed in MON 88302 Canola were determined and shown to be equivalent to those of an *Escherichia. coli*- (*E. coli*) produced CP4 EPSPS protein that has been used in CP4 EPSPS protein safety studies. An assessment of the potential of the CP4 EPSPS protein supports the conclusion that it does not pose any risk to animals. Another indicator of safety is that the strain of the donor organism (*Agrobacterium* sp. strain CP4) for the sequence encoding for CP4 EPSPS, is ubiquitous in the environment and is not commonly known to be an animal pathogen. Sequence analysis determined that CP4 EPSPS protein does not share amino acid sequence similarities with known allergens, gliadins, glueinins or protein toxins. The CP4 EPSPS protein is rapidly digested in simulated digestive fluids and demonstrates no oral toxicity in mice at the level tested. Therefore, the consumption of the CP4 EPSPS protein from MON 88302 Canola or its progeny is considered safe for animals.

Management practices associated with MON88302 canola are similar to those of currently available canola varieties. Therefore there are no changes in practices that would affect animal communities.

Based on the findings of these studies, APHIS has concluded that there are no changes in the effects on animal communities associated with the preferred alternative when compared to the No-action Alternative.

4.4.2 Plant Communities

No-action Alternative: Plant Communities

Plants that grow in canola fields are considered weeds by growers. Weeds can complete with growing canola plants for resources such as water, light, and soil nutrients. Young canola seedlings are very sensitive to early weed competition. Growers control weeds using cultural, mechanical and chemical methods. Once established, however, canola is a good competitor with most weeds.

Most canola grown in North America is HR. These varieties allow for over-the-top herbicide application of the post-emergent canola plants. The herbicide kills the nonresistant plants (weeds) but not the canola. There are currently three different types of HR canola (Brown et al., 2008). By 2006, 99% of the canola acreage in North Dakota was planted in an HR variety (see for varieties). In the same year, 78% of the Minnesota canola acreage was planted in HR varieties (Johnson et al., 2007). About 56% of the canola grown in ND was GR, 40% glufosinate-resistant, and 2% imidazolinone-resistant (Zollinger et al., 2008).

Some plants in or around canola fields are specifically targeted with weed management strategies that include the use of herbicides. Herbicide resistant weeds can be a problem in agricultural systems because frequent use of a particular herbicide can decrease its effectiveness. A summary of weeds that are resistant to herbicides in the 25 states that consistently produce canola appears in Table 10. Weeds of particular concern to canola growers include kochia and wild oat (see Table 2 for frequency of weeds in canola fields in North Dakota). Table 12 shows the herbicides currently used to control weeds in canola in North Dakota. Canola can be damaged or killed by residues of certain herbicides in the soil. Therefore, there are plant-back restrictions (Table 6) for many of the herbicides that are applied to control vegetation prior to canola planting, or are applied to previous rotational crops such as cereals. For example, canola cannot be planted for 40 months following application of imazethapyr unless the canola is an imidazolinone-resistant variety.

Insecticide, Fungicide, and Fertilizer Use. Low soil fertility levels have a very serious impact on yield in canola production (Berglund et al., 2007). Nitrogen, phosphorous, potassium, and sulfur are applied in the spring before planting at application rates similar to those for small grain crops (NDSU, 2005; USDA-ERS, 2010). Sulfur requirements for canola are generally higher than for other crops and nitrogen is often limiting for the cultivation of winter canola (NDSU, 2005; Brown et al., 2008; USDA-ERS, 2010).

Table 6A recent Canadian study assessed the environmental impact of HR canola (Smyth et al., 2011). It included a survey of nearly 600 canola farmers that queried them about their crop production experience in 2005-2006 and expected crop planting in 2007. Results indicated that annual herbicide use was reduced by nearly 1.3M kg. Tillage also declined on land used to grow HR canola, and an estimated 1M tons of carbon was either sequestered or no longer released, compared to what prevailed in 1995 (Smyth et al., 2011). In the northern U.S., it is likely that similar results could be expected from the production of HR canola. HR weeds, including weeds resistant to glyphosate, can be found in areas where canola is grown (see Figure 6.). In fields with GR weeds, growers may choose to grow glufosinate- or imidazolinone-resistant varieties. They may also choose to use cultural practices, or alternative herbicides. North Dakota publishes a weed management guide[9] that includes recommendations for weed management in canola.

Table 12. Herbicides and Application Methods[1] Used in North Dakota Canola Production

<table>
<tr><th rowspan="3">Herbicide</th><th rowspan="2">Acres treated[2]</th><th rowspan="2">Acres treated</th><th colspan="2">Number of Applications</th><th colspan="2">Operator/ Applicator</th></tr>
<tr><th>1</th><th>2</th><th>Farm</th><th>Custom</th></tr>
<tr><th>1000</th><th>%</th><th>%</th><th>%</th><th>%</th><th>%</th></tr>
<tr><td>Clethodium</td><td>123.6</td><td>13.6</td><td>100.0</td><td rowspan="2">0.6</td><td>89.0</td><td>11.0</td></tr>
<tr><td>Glufosinate-ammonium</td><td>354.3</td><td>38.9</td><td>99.4</td><td>90.2</td><td>9.8</td></tr>
<tr><td>Glyphosate</td><td>660.3</td><td>72.6</td><td>58.0</td><td>42.1</td><td>88.9</td><td>11.1</td></tr>
<tr><td>Imazamox</td><td>21.2</td><td>2.3</td><td>48.4</td><td>51.6</td><td>89.1</td><td>10.9</td></tr>
<tr><td>Quizalofop-p-ethyl</td><td>31.7</td><td>3.5</td><td>100.0</td><td>NA[3]</td><td>100.0</td><td>NA</td></tr>
<tr><td>Unknown or other herbicide</td><td>29.2</td><td>3.2</td><td>100.0</td><td>NA</td><td>100.0</td><td>NA</td></tr>
<tr><td>Total</td><td>1220.3</td><td>134.1</td><td>76.2</td><td>23.8</td><td>89.8</td><td>10.2</td></tr>
<tr><td colspan="7">[1]Pesticides applied as a tank-mixture were considered separately unless a commercial premix was used.
[2]Multiple applications to the same acre were reported as separate values. Acres treated can exceed 100% of the planted acres.
[3]Data not available</td></tr>
<tr><td colspan="7">Source: (Zollinger et al., 2008)</td></tr>
</table>

Feral populations of herbicide resistant canola, containing one or more herbicide resistant traits have been identified in areas where canola is commercially grown (Warwick et al., 2003; Schafer

[9] http://www.ag.ndsu.edu/weeds/weed-control-guides/nd-weed-control-guide-1

et al., 2011). Management of herbicide resistant canola is discussed in the PPRA (USDA-APHIS, 2012b).

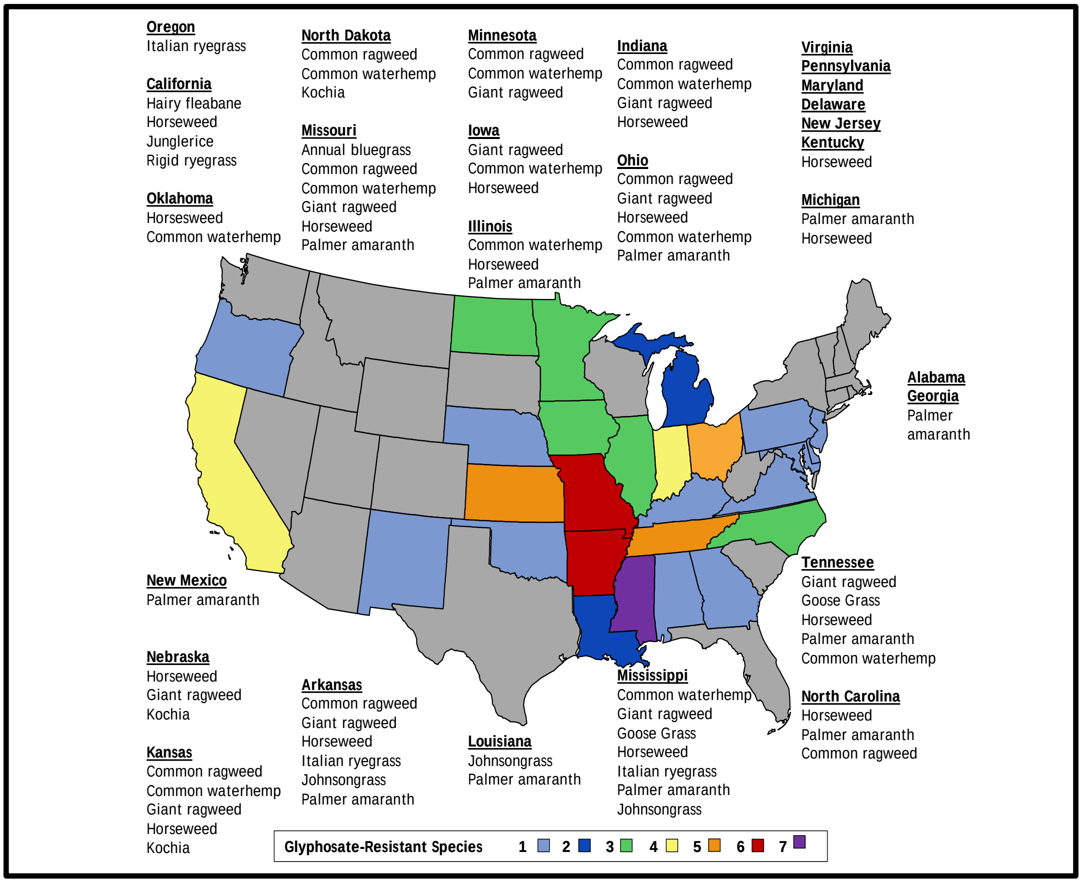

Figure 6. Distribution of Glyphosate-resistant Weeds in the U.S.
Source: (weedscience.org, 2013)

Glyphosate has a low vapor pressure, so volatilization from soils is not considered an important dissipation mechanism (US-EPA, 1993b). Drift beyond the target site can occur. One study has indicated that drift from glyphosate can provide a selective advantage to the backcross generation between GR, *B. rapa*, hybrid canola in a controlled environment. The study also indicated that drift could impact the flowers of *B. rapa* plants, decreasing the likelihood of cross-pollination between the GE crop and the non-GE weed (Londo et al., 2010). The authors conclude:

> In cases of early-flowering *B. rapa*, a delay in flowering phenology due to drift-level concentrations of glyphosate at a field boundary may encourage transgene flow by synchronizing flowering phenologies of both the crop and weed. However, later-flowering genotypes of *B. rapa* could also be desynchronized from *B. napus* flowering when exposed to

> glyphosate drift, reducing the potential for transgene gene flow (Londo et al., 2010).

The authors also indicated that additional study is needed to determine if these effects occur in the field.

Preferred Alternative: Plant Communities

Under the Preferred Alternative, as analyzed previously in Section 4.2.1, "Agricultural Production of Canola," approval of MON 88302 Canola would allow greater latitude in the application rate of glyphosate in response to weed pressures. This would include making applications at twice the rate currently allowed for other currently-approved varieties of GR canola. It would also allow for application of glyphosate at later developmental stages of canola crops until the onset of flowering.

APHIS has considered several offsetting concerns in analyzing these differences. The overarching one is that as part of its previous decisionmaking process for other GR crops (e.g., maize, soybeans, sugar beets), the Agency has prepared EAs (and/or EISs) and analyzed the potential effects of the higher glyphosate application rates now proposed for MON 88302 (USDA-APHIS, 2000; USDA-APHIS, 2004; Rood, 2007; USDA-APHIS, 2010b; USDA-APHIS, 2012a).

The maximum application rate approved for glyphosate has also been evaluated by the USEPA. Glyphosate is a non-selective herbicide with post-emergence activity on essentially all annual and perennial plants, and has the potential to impact nontarget plants as a result of runoff or spray drift (U.S. EPA, 1993). Regarding runoff, glyphosate binds strongly to agricultural soils and has low potential to move offsite dissolved in water (U.S. EPA, 1993). Moreover, glyphosate is not absorbed from agricultural soils by plants. During the re-registration process in 1993, additional data on terrestrial nontarget plants were requested by the U.S. EPA. These additional data were utilized in conjunction with an exposure assessment to further understand the potential risk to nontarget and threatened and endangered plants from the use of glyphosate herbicides in agriculture. Using the methodology described in a recent U.S. EPA effects determination for glyphosate (U.S. EPA, 2009b), it was determined that there is minimal risk to terrestrial plants that are not listed as threatened or endangered from glyphosate. Therefore, there is no evidence that effects on plant communities from MON 88302 Canola production will differ from those that occur in conjunction with other GR crops currently approved for production.

A second concern is that although the frequency is low, MON 88302 Canola crosses with other mustard species (USDA-APHIS, 2012b). However, this frequency is the same as that for other GE canola grown commercially. MON 88302 Canola reached first flowering later than the conventional control (61.1 vs. 56.2 days). However, the mean value of MON 88302 for days to first flowering was within the natural variability of the commercial reference varieties (45.9 – 67.5 days).. Therefore, the difference in days to first flower is unlikely to impact outcrossing to other sexually compatible mustard species. Just as alleles from currently available canola varieties can introgress into other sexually compatible, co-localized mustard plants, this is also likely to happen with MON 88302 Canola. The phenotypic, agronomic, and environmental interaction assessment of MON 88302 Canola was compared with the genetically similar conventional control. Observations were taken on plants not treated with glyphosate in order to evaluate only the impact of the introduced trait in MON 88302 Canola. Comparison to a range of commercial references established the range of natural variability for canola. Characteristics assessed included: seed dormancy and germination, pollen morphology, and plant phenotypic observations and environmental interaction evaluations conducted in the field. Commercial references grown concurrently were used to establish a range of natural variability for each assessed characteristic in canola. The phenotypic, agronomic, and environmental interaction assessment demonstrated that MON 88302 Canola is comparable to the conventional control (Monsanto, 2011). This is an additional indication that MON 88302 Canola is unlikely to have increased weediness or plant pest potential compared to conventional canola.

Seed dormancy and germination characterization indicated that MON 88302 seed had no changes in the dormancy or germination characteristics that could be indicative of increased plant weediness or pest potential of MON 88302. Furthermore, no visual differences in general pollen morphology were observed between MON 88302 and the conventional control, demonstrating that the introduction of the glyphosate-tolerance trait did not alter the overall morphology or pollen viability of MON 88302 compared to the conventional control (Monsanto, 2011).

The field evaluation of phenotypic, agronomic, and environmental characteristics of MON 88302 Canola also supports the conclusion that it is not likely to have increased weediness or plant pest potential or an altered environmental impact compared to conventional canola. Assessments included 12 phenotypic and agronomic characteristics, as well as observations for plant responses to abiotic stressors and plant-disease and plant-arthropod interactions. The observed phenotypic characteristics were comparable between MON 88302 Canola and the conventional control. Data show differences between MON 88302 Canola and the conventional control for early stand count, seedling vigor, seed maturity, lodging, plant height, visual rating for pod shattering, quantitative pod shattering, seed quality, yield, and final stand count. Therefore, no differences in hybridization effects are expected in the rate of introgression for MON 88302 Canola alleles into other sexually compatible mustards compared to that currently available GR-canola varieties.

Based on its analysis of the effects of these differences in the potential glyphosate-use patterns associated with MON 88302 Canola, APHIS has concluded that the changes in the effects on plant communities associated with the preferred alternative would be minimal, when compared to the No-action Alternative.

4.4.3 Microorganisms

No-action Alternative: Microorganisms

Soil microorganisms are important in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004). They may also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996).

The main factors affecting microbial population size and diversity include soil and plant type, and agricultural management practices (e.g., crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva et al., 2004). Plant roots, including those of canola, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere. GE plants potentially impact soil microbes directly from the transfer of introduced genetic material, exposure to expressed proteins through root exudation and crop residue incorporated into soil, or changes in agronomic practices used to produce crops. Indirect impacts may arise from changes in the amount and composition of residue from crops.

Gene transfer between microorganisms is common (Keese, 2008; McDaniel et al., 2010). However, biodegradation of plant materials tilled into soils generally results in fragmentation of DNA strands into small pieces (Lerat et al., 2007; Levy-Booth et al., 2008; Hart et al., 2009). The potential for protein conveying glyphosate resistance to remain functional in soils is remote because the protein degrades once it is released from cells, and then decays in soils (Australian Government, 2006). Studies of the impact of GE crops on soil microbial communities have indicated there have been minor to no non-target effects, but induced targeted alterations to the composition of the microbial community have usually resulted in the inhibition of plant pathogenic organisms (Kowalchuk et al., 2003).

Root exudates have been found to promote certain microbial populations, such as soybeans symbiotic relationship with nitrogen-fixing bacteria, and other free-living microbes that have co-evolved with plants that supply nutrients to and obtain food from their plant hosts (USDA-NRCS, 2004; Bais et al., 2006).

Crop rotation, irrigation, tillage, and agricultural chemicals such as fertilizers and pesticides affect microbial community structure and functions such as nutrient cycling, disease promotion or suppression, and presence in soil. An agronomic practice may be beneficial for one microorganism but detrimental to another. For example, the primary agents degrading glyphosate in soil and water are microorganisms feeding on the herbicide (Senseman, 2007). Reviews of studies investigating the impact of glyphosate on soil microorganisms found that numerous studies did not detect adverse effects under field use conditions, or found only minor effects that could not be separated from changes in habitat. Others reported effects at or near normal glyphosate use rates, but in most cases, the effects were temporary (Giesy et al., 2000). Some studies have implicated glyphosate as a cause for increases in the population and virulence of certain plant diseases, and for producing increased susceptibility to some diseases in GR-crop varieties (as reviewed in Johal and Huber, 2009). The authors suggest measures to minimize this potential that include using the minimum amount of glyphosate necessary for weed management, amending soils with micronutrients, detoxifying meristematic (i.e., growth) tissues by adding chelating agents to the soil, and detoxifying root exudates through the regular inoculation of nitrogen-fixing organisms (Johal and Huber, 2009).

APHIS has previously examined in detail the potential impacts of glyphosate on microorganisms in cultivation of GR alfalfa and sugar beets (USDA-APHIS, 2010a; USDA-APHIS, 2011). To date, there is no conclusive evidence linking applications of glyphosate to changes in soil microbial communities that have adverse effects on plants grown in those soils.

<u>Preferred Alternative: Microorganisms</u>

The Preferred Alternative is not expected to result in any new impacts to microbial communities when compared to the No-Action Alternative. After harvest, residue of MON 88302 Canola will remain at the site of cultivation. These crop residues will likely contain very small amounts of the novel CP4 EPSPS protein. This protein was developed by *Agrobaterium*-mediated transformation of canola hopocotyls (Monsanto, 2011). *Agrobacterium* sp. is a common soil-borne bacterium widespread in nature. Soils contain numerous organisms and enzymatic activity from decomposed organisms that degrade a wide array of molecules including proteins (Bastida et al., 2009). These processes would metabolize or sequester the CP4 EPSPS protein with no likely effect on the soil. Therefore, there should be no unique impacts on soil resulting from residue of MON 88302 Canola.

Approval of the petition would make available a new canola variety that has a higher in-crop glyphosate application rate (i.e., the total amount that can be applied annually to a crop) than that of other currently available GR-canola varieties. The higher in-crop rate for MON 88302 Canola is however, less than or comparable to the in-crop rate currently allowed for GR sugar beets, alfalfa, corn, soybeans and cotton. Except for GR sugar beets, all of these are crops recommended in rotation with canola (Table 5), so fields used for GR-canola plantings are already potentially subject to the higher in-crop glyphosate application rate. All the GR crops cited here are no longer regulated by APHIS. As part of its decisionmaking process for these GR crops, APHIS prepared EAs (and/or EISs) and analyzed the potential effects on microorganisms associated with the higher glyphosate application rate now proposed for MON 88302 (USDA-APHIS, 2000; USDA-APHIS, 2004; Rood, 2007; USDA-APHIS, 2010b; USDA-APHIS, 2012a). EPA has also determined that use in accordance with the labeling requirements of products containing glyphosate that are currently registered will not pose unreasonable risks or adverse effects to soil, including microorganisms, climate, air quality or water and water use. Based on these considerations, APHIS has concluded there would be no changes in the direct or indirect effects on microorganisms from the Preferred Alternative.

4.4.4 Biodiversity

No-action Alternative: Biodiversity

All plants, animals and microorganisms interacting in an ecosystem contribute to biodiversity (Wilson, 1988a; Wilson, 1988b). In agriculture, biodiversity contributes to critical functions such as pollination, genetic introgression, biological control, nutrient recycling, and other important processes. Significant impacts on any of these functions could require costly management (Altieri, 1999). Concerns regarding the potential impacts to biodiversity associated with the introduction of GE crops (and crops in general) include the loss of diversity, which can occur at the crop, farm, and/or landscape scale (Visser, 1998; Ammann, 2005; Carpenter, 2011).

At the farm scale, agronomic practices that can impact biodiversity include cropping practices (e.g., strip or contour cropping, crop rotation), soil conservation practices that maintain grass strips, windbreaks and shelterbelts, tillage, and the application of agrochemicals. Rotation of crops and strip contour cropping provides varied habitat that can benefit biodiversity. Establishment of soil-conserving grass and other vegetative borders stabilizes soil that maintains additional wildlife habitat. It also improves the quality of existing habitat (such as surface water quality) that contributes to biodiversity. Allowing unproductive field edges to become managed wildlife habitat promotes diversity in both plants and animal species (Sharpe, 2010).

Glyphosate effectively kills grass and broadleaf plants when applied at the recommended rates. At the farm scale, herbicide use in agricultural fields may impact biodiversity by decreasing weed populations or causing a shift in weed species present in the field. This may affect the species composition of insects, birds, and mammals that utilize these weeds. The quantity and type of herbicide use associated with HR canola, however, is dependent on many variables, including cropping systems, type and abundance of weeds, production practices, and individual grower decisions.

Use of HR crops, such as canola, has been correlated with an increase in conservation tillage in U.S. crop production (Givens et al., 2009). This promotes biodiversity by allowing the establishment of other plants between crop rows, and the accumulation of more plant residue that creates more soil organic matter, food, and cover for wildlife. In a review of literature that assessed the impacts of GE crops on biodiversity, Carpenter (2011) found a trend indicating that impacts to biodiversity have been positive because of increased yields, decreased applications of insecticides, use of less toxic herbicides, and facilitation of conservation tillage.

Crop production in general impacts biodiversity at the landscape scale because its establishment represents conversion of natural habitats to monocultures. Herbicide applications may negatively impact species that are dependent on the targeted weeds, which also reduces diversity. Potential impacts to landscape-scale diversity can be related to the effects of herbicides on non-target animal and plant species.

Assessments of the toxicity of glyphosate to animal species indicate a minimal risk to animals, but it is toxic to targeted plants and may affect non-targeted plants and animals through spray drift, volatilization (i.e., evaporation) and runoff. Inadvertent exposure may cause adverse effects that could lead to a decrease in biodiversity. However, glyphosate was found by the EPA to be only slightly toxic to birds, and practically nontoxic to fish, aquatic invertebrates and honeybees (US-EPA, 1993b).

The EPA is currently evaluating additional labeling requirements concerning best management practices (BMPs) for controlling pesticide spray drift. While herbicide use potentially affects biodiversity, the application of pesticides in accordance with registered uses and label instructions, and careful management of chemical spray drift, minimizes impacts.

In 2009, the EPA initiated reregistration of glyphosate and has identified additional data needs. Part of the risk assessment will include an acute avian oral toxicity study for passerine species. Some inert ingredients used as surfactants are more toxic than glyphosate to aquatic organisms. These will also be evaluated for acute toxicity to estuarine and marine mollusks, invertebrates, and fish (US-EPA, 2009b).

Preferred Alternative: Biodiversity

Under the Preferred Alternative, a determination of nonregulated status for MON 88302 Canola would provide growers with an additional GR variety. MON 88302 Canola is functionally the same as other GE- and non-GE-canola varieties with regard to agronomic and growth characteristics, growth form, reproductive trait, and utilization of resources. Because of these similarities, production practices will not change from those currently used for other GR-canola varieties. Therefore, a determination of nonregulated status for MON 88302 Canola is unlikely to have any direct effects on canola production practices, so there would be no change from the No-Action Alternative with regard to biodiversity.

Because MON 88302 Canola would only be another GR-canola option added to those currently available, it would not promote expansion of canola acreage. Therefore, there is no indication of a potential impact on biodiversity from increased habitat loss through conversion of natural landscape to cropland.

Based on the above information, APHIS has concluded that a determination of nonregulated status for MON 88302 Canola under the Preferred Alternative would not affect crop-, farm-, or landscape-scale biodiversity differently from that of the No-action Alternative.

4.5 Human Health

4.5.1 Consumer Health

No-action Alternative: Consumer Health

Human health concerns associated with GE crops include the potential toxicity of the introduced gene(s) and their products, such as the expression of new antigenic proteins, and/or altered levels of existing allergens (Malarkey, 2003; Dona, 2009). Consumer exposure to canola is almost exclusively from canola products—not the plant or plant parts. Nearly all consumer exposure is from canola oil and sometimes meal. Both canola meal and canola oil are classified as GRAS by FDA (21 CFR 184). All currently available GE-canola varieties have completed a consultation with FDA[10].

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. A food safety consultation, which found no safety concerns for MON 88302 Canola, was completed by the FDA (BNF No. 127) on April 23, 2012.

Under the No-Action Alternative, agricultural production of non-regulated GE and non-GE canola use EPA-registered pesticides for plant pest management of weeds, insects and other pests. The environmental risks of pesticide use are assessed by the EPA in the pesticide registration process. All pesticides are reevaluated regularly by the EPA to maintain and update their registration status under FIFRA.

The human health effects from exposure to glyphosate have been thoroughly evaluated by the EPA. The 1993 glyphosate RED (Registration Eligibility Decision) presents the data used by the EPA for chemical reregistration (US-EPA, 1993b). Glyphosate is classified as having low toxicity via the oral, dermal, and inhalation routes, and is not classified as a carcinogen or teratogen (US-EPA, 2009b; US-EPA, 2009c). Acute, subchronic, chronic, developmental, and reproductive studies to date indicate that glyphosate is not neurotoxic, although additional studies will occur as part of the current review process (US-EPA, 2009c). Based on additional toxicity tests, the EPA determined the main glyphosate metabolite, AMPA, does not require regulation (US-EPA, 2009c).The 1993 glyphosate RED presents the data used by the EPA for chemical reregistration (see US-EPA, 1993b).

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[10] See http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing for list of completed consultations.

A new review for reregistration began in July 2009. In conjunction with this process, EPA is currently conducting another comprehensive human health assessment for all uses of glyphosate and its salts (US-EPA, 2009b).

Pesticide tolerances for glyphosate on canola have been established (US-EPA, 2011d). Tolerances are the maximum residue concentrations allowable for pesticide that may remain on or in foods marketed in the U.S. These levels are established for every pesticide, based on its potential risks to human health. The EPA tolerance for glyphosate on both canola seed and rapeseed is 20 ppm.

Preferred Alternative: Consumer Health

The *cp4 epsps* gene is derived from a soil bacterium *Agrobacterium* sp. The physicochemical characteristics of the CP4 EPSPS protein expressed in MON 88302 Canola were determined and shown to be equivalent to those of an *E. coli*-produced CP4 EPSPS protein that has been used in CP4 EPSPS protein safety studies. An assessment of the allergenic potential of the CP4 EPSPS protein supports the conclusion that it does not pose any allergenic risk to humans or animals. Another indicator of safety is that the donor organism for the CP4 EPSPS coding sequence, *Agrobacterium* sp. strain CP4, is ubiquitous in the environment and is not commonly known to be a human or animal pathogen. Sequence analysis determined that CP4 EPSPS protein does not share amino acid sequence similarities with known allergens, gliadins, glueinins or protein toxins. The CP4 EPSPS protein is rapidly digested in simulated digestive fluids and demonstrates no oral toxicity in mice at the level tested. Therefore, the consumption of the CP4 EPSPS protein from MON 88302 Canola or its progeny is considered safe for humans and animals.

Under the FFDCA it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from GE canola must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although voluntary, until now all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food, meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. FDA evaluates the submission and responds to the developer by letter.

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. A food safety consultation, which found no safety concerns for MON 88302 Canola, was completed by the FDA (BNF No. 127) on April 23, 2012.

4.5.2 Worker Health

No-action Alternative: Worker Health

According to the NRC (National Research Council), adoption of GE crops has contributed to risk reduction associated with application of pesticides. This is attributed to a number of factors including reduced complexity and greater flexibility of farm management practices required for GE crops, which has allowed producers more opportunity to focus on worker safety (NRC, 2004). Both producers and farm workers experience reduced exposure to potentially harmful pesticides in GE-cropping systems because of the reduction in the amount of time required for applying pesticides, and the greater flexibility allowed in determining when pesticides are applied.

Agricultural workers that routinely handle herbicides, including glyphosate (mixers, loaders, and applicators), may be exposed during and after use. Because of the low acute toxicity of glyphosate, absence of evidence of carcinogenicity and other toxicological concerns, occupational exposure data is not required for reregistration (US-EPA, 1993b). However, the glyphosate RED does classify some end-use glyphosate products as eye and skin irritants and recommends PPE be worn by mixers, loaders, and applicators (US-EPA, 1993b). Because of the expected short-term dermal and inhalation exposures of occupational handlers and growers, no endpoints were identified by the EPA HED, so no occupational handler or occupational post-application assessments are required for reregistration (US-EPA, 2009c). Current EPA-approved labels for glyphosate include precautions and measures to protect human health. When used consistent with the label, pesticides present minimal risk to human health and safety.

Preferred Alternative: Worker Health

Approval of the petition would make available a new canola variety that has a higher in-crop glyphosate application rate than that of other currently available GR-canola varieties. The higher in-crop rate for MON 88302 Canola is however, less than or comparable to the in-crop rate currently allowed for GR sugar beets, alfalfa, corn, soybeans and cotton. All of these GR crops are no longer regulated by APHIS. As part of its decisionmaking process for these GR crops, APHIS prepared EAs (and/or EISs) and analyzed the potential risks to worker safety that might be associated with the higher glyphosate application rate now proposed for MON 88302 (USDA-APHIS, 2000; USDA-APHIS, 2004; USDA-APHIS, 2010b; USDA-APHIS, 2012a). EPA has also determined that use in accordance with the labeling of currently registered pesticide products containing glyphosate will not pose unreasonable risks to or adverse effect on workers who handle and apply pesticides. Based on these considerations, APHIS has concluded there would be no changes in the risks to worker safety from the Preferred Alternative.

4.6 Animal Feed

No-action Alternative: Animal Feed

Canola meal has a lower protein content (34-38%) than soybean meal (44-49%) and fewer key amino acids (Atkinson et al., 2006; Ash, 2012c). Therefore, canola meal is an economical protein source for animals that do not have high energy or lysine requirements (Ash, 2012c). The majority of canola meal in the United States is fed to cattle and swine as part of a feed ration. Poultry, aquaculture, and specialty animals can also be fed canola meal as a protein source, high in fiber content, at low palatability-limit feeding rates (Ash, 2012c). One disadvantage is its high level of sulfur (0.5% -1.3% on a 100% dry-matter basis), so the NRC recommends that total dietary sulfur not exceed 0.4% on a dry-matter basis. Another is that some producers have reported that cattle tend to develop scours, when fed canola hay or silage as the only source of roughage (Atkinson et al., 2006).

Regulatory control of feed production by the FFDCA is similar to that for food for direct human consumption; it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE canola must comply with all applicable legal and regulatory requirements, which are designed to protect human health. To help ensure compliance, a voluntary consultation process with FDA may be implemented before release of GE plants in animal feed into the market.

Most canola cultivated in the U.S. is grown mainly for vegetable oil and animal feed. Under the No-action Alternative, canola-based animal feed would be available from currently cultivated varieties (Kandel, 2011), including GE-canola varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. This includes HR-, GE-canola varieties.

<u>Preferred Alternative: Animal Feed</u>

The acreage of canola production is not expected to change under the Preferred Alternative. Therefore, the only possible difference between the No-action Alternative and the Preferred Alternative is safety of MON 88302 Canola. To establish the absence of any significant differences in safety from non-regulated HR canola, Monsanto initiated a consultation process with FDA for the commercial distribution of MON 88302 Canola and submitted a safety and nutritional assessment of food and feed derived from MON 88302 Canola to the FDA on March 23, 2011. Based on the safety and nutritional assessment Monsanto conducted, FDA accepted Monsanto's conclusion in a letter dated April 23, 2012. FDA stated:

> " food and feed derived from MON 88302 Canola are not materially different in composition, safety, and other relevant parameters from canola-derived food and feed currently on the market, and that the genetically engineered MON 88302 Canola does not raise issues that would require premarket review or approval by FDA. Based on the information Monsanto has presented to FDA, we have no further questions concerning food and feed derived from MON 88302 Canola at this time. However, as you are aware, it is Monsanto's continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements."

The introduced CP4 EPSPS proteins is unlikely to substantially affect the nutritional quality of canola meal derived from MON 88302 Canola. Previous GE canola demonstrated that it is not likely to have any significant impact on animal health and it has been approved by the three major federal regulatory agencies involved in regulating GE organisms: APHIS, the FDA, and US-EPA. There is no reason to suspect the new MON 88302 Canola would present a substantial risk to animal health. The CP4 EPSPS protein is equivalent to the protein expressed in commercial Roundup Ready crop products that are encoded by the *cp4 epsps* gene that confers tolerance to glyphosate-containing herbicides. Therefore, the quality of animal feed derived from MON 88302 Canola is unlikely to be substantially different than animal feed produced from current canola varieties. Therefore, APHIS concludes that impacts on animal feed from MON 88302 Canola if it is not regulated (i.e., the Preferred Alternative) would be the same as the No-action Alternative.

4.7 Socioeconomic Impacts

Canola agriculture can affect socioeconomic resources such as the domestic economy, international trade economy, and the social environment. This section describes key current issues within each of these topics.

4.7.1 Domestic production of canola

No-Action Alternative: Domestic Economic Environment

U.S. canola acreage increased during the period, 1990-2000. Since then, annual plantings have fluctuated between 0.8 and 1.8M acres. In 2012, canola production acreage exceeded that of all previous years for which data are available (Fig. 7). About 87% of U.S. canola production value comes from North Dakota. Idaho, Minnesota, Montana, and Oklahoma account for slightly less than 10%, and about 1% of the U.S. canola value is produced in Washington and Oregon. Slightly less than 2% of the production value is created in all the other canola-producing U.S. states (e.

Table 13). The current trend of increasing canola production value may be what is influencing the increase in acres planted.

Production costs are similar to wheat and may be estimated at $130 to $160 per acre, with harvest and marketing costs at $40 to $60 per acre (Boyles et al., 2012). Canola total expenses per acre, including both variable and fixed costs, would come to approximately $180. Presuming gross returns of $220 per acre, returns to land, capital and management would be approximately $40 per acre.

Increasing demand for oilseed along with the increase in price paid for canola may increase overall returns per acre for canola. However, increases in the cost of inputs such as fuel may offset the potential increase in gross income per acre.

The 2007 Census of Agriculture reported that 3,123 farms harvested canola, compared with 3,831farms in 2002 and 2,892 farms in 1997 (Ash, 2012b). As the number of farms declined between 2002 and 2007, the amount of harvested acreage remained about the same. The number of large farms over 1 thousand acres increased 23% while the number of farms under 100 acres declined 33%. This trend in increasing farm size is not specific to canola.

As described in section 2.6.1, some state governments have restrictions on growing canola in certain geographic areas. For example, Oregon has adopted a new rule establishing a zone where canola cultivation is restricted or prohibited. This rule applies to *Brassica* spp. (Oregon-Department-of-Agriculture, 2013).

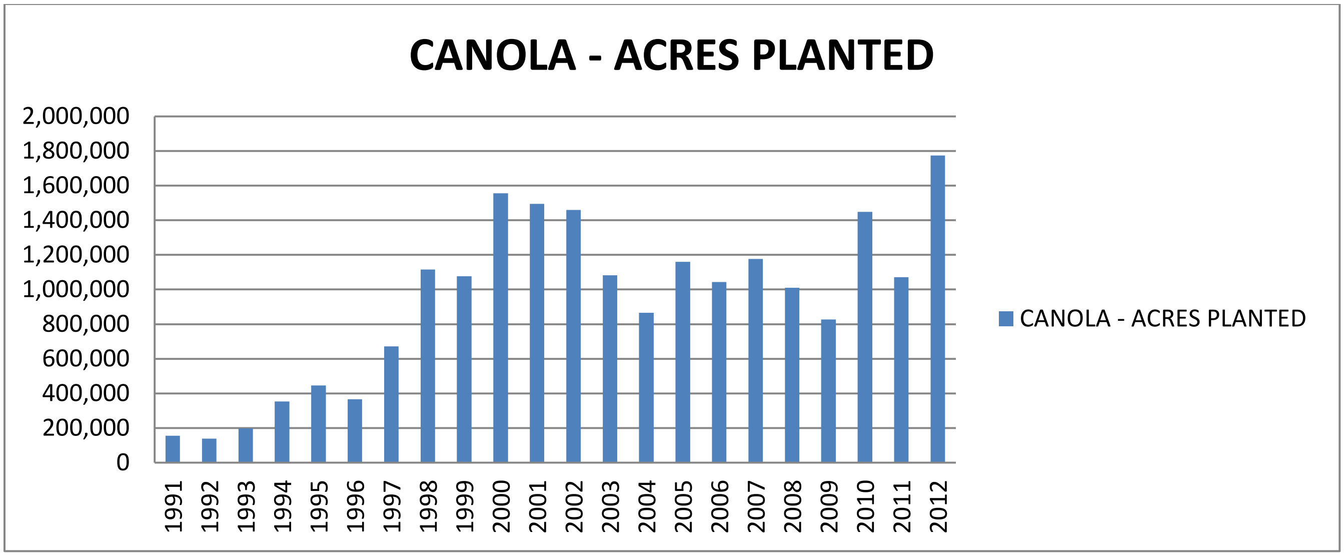

Figure 7. U.S. Canola Acreage: 1991-2012
Source: (USDA-NASS, 2012b)

Preferred alternative

Under the preferred alternative, MON 88302 Canola would likely be available to canola growers. The availability of MON 88302 Canola would be unlikely to influence the number of acres of canola planted. The trend toward increasing prices for canola and other oilseed crops is more likely to influence the number of acres planted. As discussed in section 4.2, most canola produced in the U.S. is HR. About half of this canola is GR. Assuming that MON 88302 Canola is priced competitively with other GE canola products, it is not likely to increase the proportion of GR canola planted. Therefore, the impact of the Preferred Alternative on domestic canola production will not differ from that of the No-action Alternative.

Table 13. Canola Price/Hundred Weight and Value of U.S Production for 2009-2011

State	[1]Price/hundred weight			[2]Value of Production			5 Years % Value
	2009	2010	2011	2009	2010	2011	
Idaho	14.00	18.70	20.00	3,451	6,193	7,770	1.6
Minnesota	NA[3]	20.90	24.10	NA	14,390	9,447	2.2
Montana	13.50	20.00	22.50	1,457	5,917	9,402	1.6

North Dakota	16.10	19.30	23.30	214,774	421,589	297,075	87.4
Oklahoma	19.00	17.30	24.10	9,139	15,501	20,485	4.2
Oregon	17.00	17.60	22.50	1,907	2,458	3,363	0.7
Washington[1]	NA	NA	22.60	NA	NA	4,380	0.4
Other U.S. States	18.10	17.80	23.60	8,204	5,505	5,631	1.8
United States	**16.20**	**19.30**	**23.30**	**238,932**	**471,553**	**357,553**	

[1]U.S. dollars (USD);
[2]In thousands of USD;
[3]Data not available

Source: (USDA-NASS, 2012b).

4.7.2 Organic Market for Canola

No-action Alternative

The 2008 Census of Agriculture provided the first data (Table 14) for U.S. organic canola. This indicated that there were approximately 232 acres of organic canola grown in four states, (Iowa, Michigan, New York, and Washington) (USDA-NASS, 2008a). The 2012 survey, reported that there were only two farms in Iowa and Wisconsin that harvested organic canola (USDA-NASS, 2012a). To avoid reporting data from individual farms, the only state specific data reported was 8.5 metric tons harvested in Washington with a value of $3,560 (Table 14).

From the available data, it appears that there are a limited number of organic canola growers, and they are located in areas that do not historically produce large amounts of canola. In the 2008 survey, the value of organic canola in the U.S. was about $93,000 or 0.03% of the total value of the canola crop in the same year. Some commenters who grow organic products have expressed concerns that cross-pollination between GE and organic varieties will affect the organic certification of their products (see comments APHIS-2012-0031-0055, APHIS-2012-0031-0056, APHIS-2012-0031-0058, APHIS-2012-0031-0062, APHIS-2012-0031-0069). Commenters have also expressed concerns that contracts for GE-free specialty markets can be difficult to meet if GE plants are grown in the area (see comment APHIS-2012-0031-0070).

Organic certification is process-based. Certifying agents validate the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Organic Foods Production Act of 1990 (OFPA). This is achieved through implementation of the NOP regulations established under authority of the OFPA.

These regulations prohibit the use of excluded methods, which include GE organisms, in organic operations. If all aspects of the organic production or handling process were followed correctly, then the presence of a detectable residue from a GE organism alone does not constitute a violation of this regulation. This policy was established in the NOP Regulation Preamble to the Final Rule (FR Vol. 65, No. 246, p. 80556), December 21, 2000.

Preferred Alternative

Availability of non-regulated MON 88302 Canola is not likely to influence the number of growers of organic canola, nor the number of acres planted to organic canola, so the value of organic canola should remain stable under the Preferred Alternative. The current commercial canola market is over 95% GE and the Preferred Alternative will not change that market share. Therefore, the approval of an additional GE variety is not likely to change the likelihood of cross pollination between GE and non-GE sexually compatible plants. The approval of the petition is also unlikely to change the geographic areas that produce either organic or GE canola.

4.7.3 Trade Economic Environment

No-action Alternative: Trade Economic Environment

Global canola production has increased rapidly during the past 40 years from the sixth to the second largest oil crop (second only to soybeans in the U.S.). Total U.S. exports have averaged slightly more than 224 thousand metric tons. Figure 8 shows the changes in export quantities between 2007 and 2011.

Table 14. Harvest and Value of Sales from Certified Organic Canola Farms in 2008

CANOLA, EDIBLE (POUNDS)	Harvested			Value of Sales	
	Farms	Acres	Quantity	Farms	Dollars
United States (2008 Survey)	**8**	**232**	**404,725**	**8**	**92,752**
Iowa	2	[1]NA	NA	2	NA
Michigan	1	NA	NA	1	NA
New York	2	NA	NA	2	NA
Washington	3	NA	18,610	3	3,560
United States (2012 Survey)	**2**	**NA**	**NA**	**2**	**NA**
Iowa	1	NA	NA	1	NA
Wisconsin	1	NA	NA	1	NA

[1]NA: Not available

(USDA-NASS, 2008b), (USDA-NASS, 2012a).

The U.S. exported 150-300 thousand metric tons of canola each year during the period, 2007-2011. Most U.S. canola exports go to Canada for processing in crushing plants although shipments to Mexico have been increasing (USDA-ERS, 2001). U.S. imports of canola oil continue to increase steadily from 0.5M metric tons in 2000 to 1.2M metric tons in 2010. The U.S. share of world production remains small, but is an increasingly important component of regional economies in the Northern Plains (Ash, 2012b). Over 90% of imported canola was sent to North Dakota, Minnesota, and Montana. Of this, less than 10% was used for seeding purpose and the rest went to crushing plants, primarily in North Dakota (U.S Grain Quality Control, 2008; Zollinger et al., 2008; USDA-ESMIS, 2012).

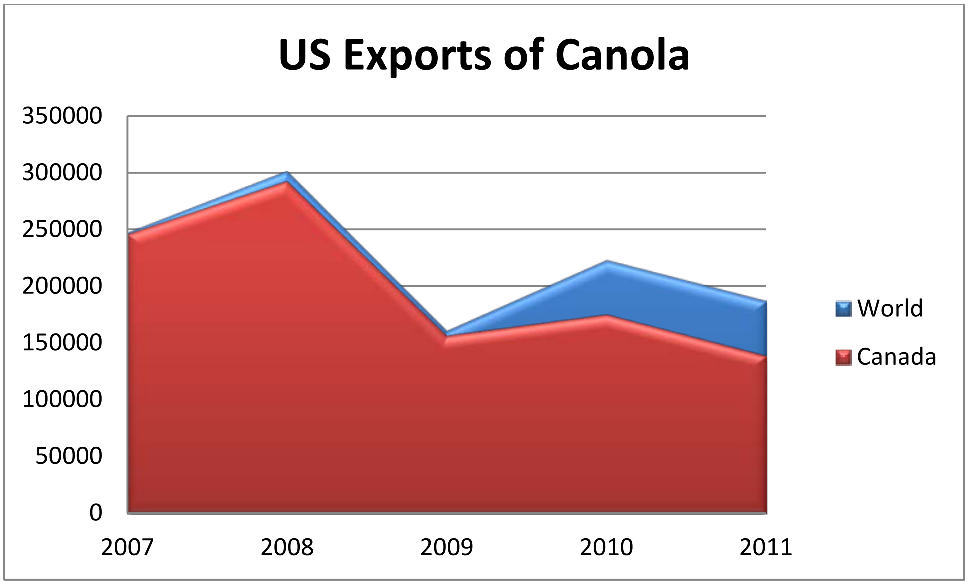

Figure 8. U.S. Exports of Canola 2007-2012

Because the U.S. crushes more canola seed than it produces, the U.S. imports canola seed to meet the demand of the oil market. Figure 9. shows a comparison of imports needed to offset the differential between U.S. production and demand.

Preferred Alternative: Trade Economic Environment

MON 88302 Canola is approved in Canada[11], which is the recipient of most US canola exports. Therefore, approving the petition for nonregulated statusis not likely to change either U.S. or international canola trade. Imports and exports are driven by demand for canola oil. Most canola varieties planted in both the U.S. and Canada are HR. MON 88302 Canola is only

11 http://active.inspection.gc.ca/scripts/database/pntvcn_submitdb.asp?lang=e&crops=1&company=all&trait=all&events=all

expected to replace some acreage planted with other GR varieties. Based on these determinations, APHIS concludes that the impact of selecting the Preferred Alternative will not differ from that of those currently associated with the No-action Alternative.

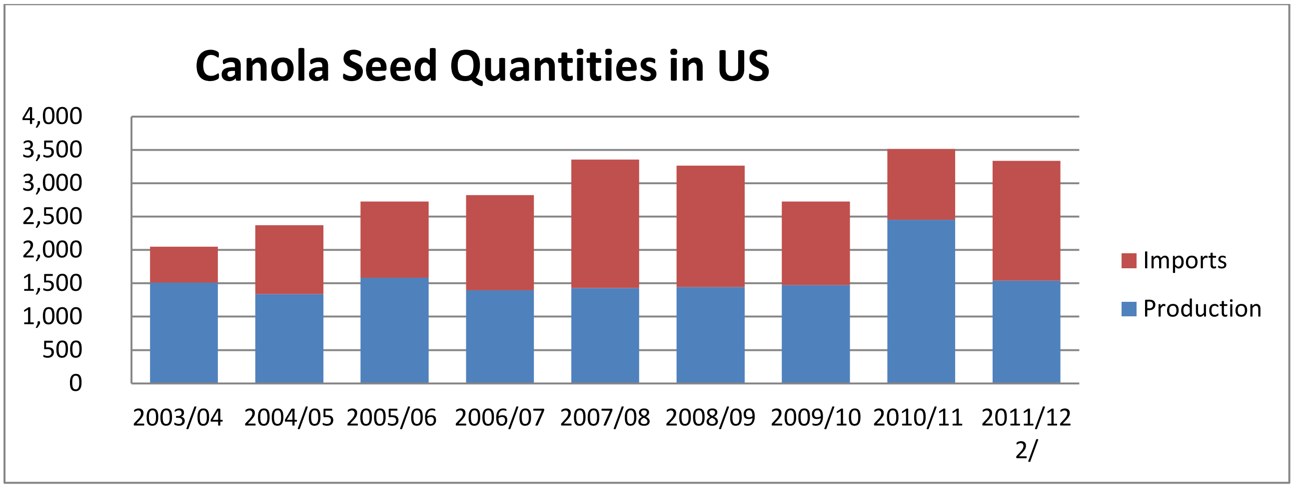

Figure 9. Canola Seed Quantities in the U.S.
Total domestic production and U.S. canola seed imports are shown in millions of pounds. Most seeds are crushed for oil. Crushing plants use imported seed to supplement the domestic supply when making canola oil. U.S. canola seed imports comprise 25-50% of all seed crushed annually for oil (Source:(USDA-ERS, 2012a).

5. CUMULATIVE IMPACTS

5.1 Assumptions Used for Cumulative Impacts Analysis

Cumulative effects have been analyzed for each environmental issue assessed in Section 4, Environmental Consequences. The cumulative effects analysis is focused on the incremental impacts of the Preferred Alternative taken in consideration with related activities including past, present, and reasonably foreseeable future actions. In this analysis, if there are no direct or indirect impacts identified for a resource area, then APHIS assumes there can be no cumulative impacts. Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential cumulative impacts.

APHIS considered the potential for MON 88302 Canola to extend the range of canola production and affect the conversion of land to agricultural purposes. Monsanto's studies demonstrate that MON 88302 Canola is similar in its growth habit, agronomic properties, disease susceptibility to other non-regulated varieties of GR-, and other GE and non-GE canola (Monsanto, 2011). This implies that its cultural requirements would neither differ from those of other canola nor change the areas in which canola is currently cultivated. As emphasized in Subsection 4.2, Acreage and Area of Canola Production, most canola cultivated in the U.S. is HR. If the petition is approved, MON 88302 Canola could replace other commercially available GR-canola varieties without requiring cultivation of new, natural lands. Therefore, land use changes associated with approving the petition for nonregulated status for MON 88302 Canola are not expected to be any different than those associated with the cultivation of other canola cultivars. Although the Preferred Alternative would allow for new plantings of MON 88302 Canola to occur anywhere in the U.S., APHIS focused its analysis of cumulative impacts on the areas in the U.S. that currently support canola production.

Potential, reasonably foreseeable cumulative effects were analyzed under the assumption that canola producers have used in the past, and would continue to use reasonable, commonly accepted BMPs suitable for the cropping system and varieties they choose. APHIS recognizes, however, that not all farmers will use such BMPs. Thus, this circumstance was also considered in the cumulative impacts analysis.

Monsanto submitted a request for amended labeling to the U.S. EPA in February 2011 for Registration Numbers 524-537 (Roundup WeatherMAX® Herbicide) and 524-549 (Roundup PowerMAX® Herbicide). The purpose of the request is to obtain a modification of the current use pattern for glyphosate on MON 88302 Canola. Although the amended labeling increases the rate of application and widens the application period relative to canola development, this use of glyphosate does not present any new environmental exposure consequences that have not been evaluated previously in conjunction with other Roundup Ready crops which have already been deemed acceptable by the U.S. EPA (US-EPA, 1993). The application rate increase proposed for MON 88302 Canola is the same as the approved maximum application rate allowed for GE corn and soybean varieties that are no longer regulated by APHIS. These application rates have been evaluated previously by the Agency (USDA-APHIS, 2000; USDA-APHIS, 2004; USDA-APHIS, 2010b; USDA-APHIS, 2012a) in other environmental assessments.

According to the petitioner (Monsanto, 2011), MON 88302 Canola could be combined with another commercially available HR variety in a stacked canola product, however, this is not a reasonably foreseeable future action (USDA, 2013a).

5.2 Past and Present Actions

In the preceding analysis, the potential impacts from approving the petition for nonregulated statusof MON 88302 Canola were assessed. The agronomic characteristics evaluated for MON 88302 Canola encompassed the entire life cycle of the canola plant and included germination, seedling emergence, growth habit, vegetative vigor, days to pollen shed, days to maturity, and yield parameters. The compositional analysis included the major constituents (carbohydrates, protein, fat, and ash), minerals, vitamins, amino acids, fatty acids, secondary metabolites, antinutrients, phytosterols, and nutritional impact. MON 88302 Canola is agronomically and compositionally similar to other GE- and non-GE-canola varieties (Monsanto, 2011; USDA-APHIS, 2013c). As a result, the potential impacts under the Preferred Alternative for all the resource areas analyzed are the same as those described for the No-action Alternative.

The Preferred Alternative is not expected to directly cause a measurable change in agricultural acreage or area devoted to conventional or GE-canola cultivation or canola grown for seed in the U.S. (see Subsections 4.2.1, Agricultural Production of Canola , and 4.2.2, Canola Seed Production). The majority of canola grown in the U.S. is GE and HR. Because MON 88302 Canola is another GR canola cultivar that is agronomically and compositionally similar to other commercially available GR-canola cultivars, and approximately 50% U.S. canola is GR, it is expected that MON 88302 Canola would replace other similar cultivars without expanding the acreage or area of canola production. Canola acreage may expand over time, but that expansion is driven by canola demand.

Based upon recent trends, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share (see Subsection 4.7.2, Organic Market for Canola). As described above, the majority of canola is GE and HR. Since 1994, seven GE-canola events or lines have been determined by APHIS to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA (USDA-APHIS, 2013c). U.S. organic canola production acreage is less than 500 acres. Because there are so few growers, more precise data are not publically available (see Table 14). Availability of another GE-, GR-canola variety, such as MON 88302 Canola under the Preferred Alternative, is not expected to impact the organic production of canola any differently than other GE varieties currently being grown.

Approving the petition for a determination of nonregulated status to MON 88302 Canola is not expected to result in changes to current canola cropping practices. Studies conducted by Monsanto demonstrate that, in terms of agronomic characteristics and cultivation practices, MON 88302 Canola is similar to other canola varieties currently grown (Monsanto, 2011), An independent analysis conducted by APHIS made the same conclusion (USDA-APHIS, 2013c). Therefore, no changes to current canola cropping practices such as tillage, crop rotation, or agricultural inputs associated with the adoption of MON 88302 Canola are expected (see Section 4.2).

Approving the petition for a determination of for MON 88302 Canola would have the same impacts to water, soil, air quality, and climate change as that of non-regulated, GR-canola varieties presently available. Agronomic practices that have the potential to impact soil, water and air quality, and climate change such as tillage, agricultural inputs (fertilizers and pesticides), and irrigation would not change because MON 88302 Canola is agronomically similar to other GR canola and other GE and non-GE canola. Other practices that benefit these resources, such as contouring, use of cover crops to limit the time soil is exposed to wind and rain, crop rotation, and windbreaks would also be the same. Because of its similarity to other non-regulated GR canola and the fact that half of the cultivated canola in the U.S. is GR, adoption of MON 88302 Canola is expected to replace other similar cultivars without changing the acreage or area of canola production that could impact water, soil, air quality, and climate change.

The impacts of the Preferred Alternative to animal and plants communities, microorganisms, and biodiversity would be no different than that experienced under the No-action Alternative. MON 88302 Canola is both agronomically and compositionally similar to other non-regulated, GR canola. Thus, it would not require any different agronomic practices to cultivate, and does not represent a safety or increased weediness risk different from other GR-canola varieties available currently. Availability of MON 88302 Canola would not impact the development of GR weeds or the trend to broaden weed management tactics to control HR weeds, because it is expected to replace other GR cultivars.

The potential impacts from the use of herbicides under the Preferred Alternative would be the same as those of the No-action Alternative. The methods of application for herbicides applied to MON 88302 Canola would not change from those already approved for other non-regulated, GR-canola cultivars. The approved rates of application would increase, however, the increase would not exceed the rate currently approved for other crops such as corn and soybeans. The total amount of the mix of herbicides that could be applied to MON 88302 Canola would be limited by the authorized EPA-registered uses and the total application amount allowed by law. Glyphosate and other pesticides are registered by the EPA under FIFRA and are reviewed and reregistered every 15 years to assess potential toxicity and environmental impact. Registration requires that a pesticide must not cause unreasonable human health or environmental risks. Pesticide residue tolerances for glyphosate and other herbicides and pesticides are listed in 40 CFR §180.364 and include acceptable concentrations for canola grain and forage. In addition, the safety precautions and EPA-labeled instructions for the application of pesticides would not change under the Preferred Alternative, ensuring continued human health and worker safety.

There are no differences in the potential for gene flow and weediness under the Preferred Action Alternative. Outcrossing and weediness are addressed in the PPRA (USDA-APHIS, 2013c) MON 88302 Canola is similar to other GR-canola varieties. The risk of gene flow and weediness of MON 88302 Canola is no greater than that of other non-regulated, GR-canola varieties.

Food and feed derived from GE canola must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release into the market to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food. MON 88302 Canola is expected to have no toxic effect to human health or livestock. Monsanto submitted a safety and nutritional assessment for food and feed derived from MON 88302 Canola and FDA accepted Monsanto's conclusion in a letter dated April 23, 2012. The FDA decision has been posted to the FDA website[12] for Final Biotechnology Consultations (BNF No. 127). The CP4 EPSPS protein is also expressed in soy and corn (see BNF 126). No change in food and feed safety is expected to occur under the Preferred Alternative.

Since MON 88302 Canola is GR, it would directly compete with the market share of other GR-canola varieties. Based on its similarity to other non-regulated, canola cultivars, MON 88302 Canola would likely replace other GR-canola cultivars without impacting canola acreage or production areas that may affect domestic markets. Since MON 88302 Canola is also agronomically and compositionally similar to other commercially available canola, there would be no changes to agronomic inputs or practices that may impact on-farm costs for canola producers or the domestic economic environment, including the organic canola market. MON 88302 Canola may provide better weed control than GR-canola varieties currently available. However, it will not affect the treatment of HR weeds any differently than current methods used to effect control, so associated costs of current production methods and herbicide resistant weed-related crop losses would not change. Therefore, no changes to the domestic economic environment are expected to occur under the Preferred Alternative.

MON 88302 Canola is also not expected to affect the seed, feed, or food trade any differently than other non-regulated, GR-canola varieties. Other countries already have access to GR-canola varieties and are important export competitors to U.S. canola trade. MON 88302 Canola is compositionally and agronomically similar to other GR cultivars in the marketplace. In summary, the potential cumulative effects regarding past and present actions combined with the Preferred Alternative have been analyzed, and no changes from the current baseline under the No-action Alternative would occur.

5.3 Reasonably Foreseeable Actions

APHIS is also currently considering a petition for nonregulated status of a different GR-canola variety, 73496 Canola. If APHIS approves that petition and MON 88302 Canola, there would potentially be two additional GR-canola varieties marketed to growers. These two new varieties would likely compete in the marketplace for a share of the GR-canola market. Factors such as the characteristics of the commercial varieties with which these events are bred, grower preferences, and price will determine how much of the market share these two new varieties replace. Therefore, the relative contribution of either of these events to total future canola production cannot be determined. However, neither is likely to shift the use away from other varieties that are resistant to herbicides with different modes of action, if growers are choosing those varieties for the resistance trait. If APHIS does not approve the petition for 73496 Canola, then these two events would not complete in the marketplace.

In 2012 the canola acreage planted was 65% greater than the canola acreage planted in the previous year. According to the NASS database, this was the most acreage planted with canola

[12] http://www.fda.gov/Food /Biotechnology/Submissions/ucm225108.htm

to date. Increased demand for oilseed (USDA-ERS, 2012b) and high canola prices (Ash, 2012a) may have influenced the expanded acreage.

There is also an increasing interest in winter canola production in areas where winter wheat is grown. For example, in Oklahoma the acreage planted to canola has increased almost 4-fold over the past four years (USDA-NASS, 2013). Canola is recommended as a rotation crop with winter wheat because the weed management options are different in the two crops (Boyles, 2009). Currently there are some varieties of winter canola that are resistant to glyphosate (Boyles, No date). APHIS was not able to identify information for the percent of winter canola acreage planted with GR varieties. If MON 88302 Canola is bred into winter canola varieties, it may be adopted in this developing market. The use of glyphosate on MON 88302 Canola would change compared to the use on currently available varieties, but would be similar to that used on other GR crops such as soybean and corn. While this higher rate could give better weed control in some situations, its overall effect on weed management in these winter canola growing areas will be minor.

In summary, the potential for impacts of MON 88302 Canola would not result in any changes to the resource areas when compared to the No A-action Alternative. No cumulative effects are expected from approving the petition for MON 88302 Canola, when taken in consideration of related activities, including past, present, and reasonably foreseeable future actions.

6. THREATENED AND ENDANGERED SPECIES

The Endangered Species Act (ESA) of 1973, as amended, is one of the most far-reaching wildlife conservation laws ever enacted by any nation. Congress passed the ESA to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the ESA is to conserve TES (threatened and endangered species) and their habitats as key components of America's heritage. To implement the ESA, the U.S. Fish & Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), other Federal, State, and local agencies, Tribes, non-governmental organizations, and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

A species is added to the list when it is determined by the USFWS/NMFS to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms;
- The natural or manmade factors affecting its survival.

Once an animal or plant is added to the list, protective measures apply to the species and its habitat. These measures include protection from adverse effects of federal activities.

Section 7 (a)(2) of the ESA requires that federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is "not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat." It is the responsibility of the federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or designated critical habitat. To facilitate their ESA consultation requirements, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination consistent with the PPA (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA regarding analyzing the effects of herbicide use associated with all GE crops on TES. As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on herbicide use associated with GE crops currently planted because EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under FIFRA. APHIS has no statutory authority to regulate the use of glyphosate or any other herbicide. Under its current Part 340 regulations, APHIS only has the authority to regulate MON 88302 Canola or any GE organism as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). APHIS has no regulatory jurisdiction over any other risks associated with

GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms.

After completing a plant pest risk analysis, if APHIS determines that MON 88302 Canola seeds, plants, or parts thereof do not pose a plant pest risk, then MON 88302 Canola would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that MON 88302 Canola is no longer regulated. As part of its EA analysis, APHIS is analyzing the potential effects of MON 88302 Canola on the environment including, as required by the ESA, any potential effects to TES and critical habitat. As part of this process, APHIS thoroughly reviews the GE product information and data related to the organism (usually a plant species, but may include other GE organisms). For each transgene/transgenic plant, APHIS considers the following:

- Biology and taxonomy of the crop plant and its sexually compatible relatives;
- Each transgene to characterize its structure and function, and the nature of the organism from which it was obtained;
- Location(s) of the new transgene and the quality and quantity of products (if any) derived from it;
- Agronomic performance of the plant including its disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Concentrations of any known plant toxins, if applicable;
- Sexual compatibility of the transgenic plant with any plant TES or plants serving as hosts of TES;
- Any other information relevant to the potential for an organism to pose a plant pest risk.

Consistent with this review process, APHIS has evaluated the potential effects that approval of a petition for nonregulated status for Monsanto 88302 Canola might have on Federally-listed and proposed TES, as well as designated and proposed critical habitat. Based upon the scope of this EA and production areas identified in Section 2 (Affected Environment) of this EA, APHIS obtained and reviewed the USFWS listed and proposed TES for each state where canola is grown commercially using the USFWS Environmental Conservation Online System[13]. Prior to obtaining this list, APHIS also considered the potential for Monsanto 88302 Canola to extend the range of canola production, and also the possibility that it would expand agricultural production into previously uncultivated natural habitat.

Comparison studies demonstrate that MON 88302 Canola is similar in its growth habit, agronomic properties, disease susceptibility, and composition to non-transgenic, control-group

[13] ECOS; as accessed 4/15/2011 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jspUS-FWS, Species Reports - Listings and Occurrences for Each State, 2011, Available: http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp, May 25 2011.

cultivars, other transgenic varieties of GR canola that are not regulated, and other GE- and non-GE canola (Monsanto, 2011; Pioneer, 2011). Since MON 88302 Canola will only replace other canola varieties currently cultivated, its introduction will not promote an expansion of canola acreage or result in extension of canola production into previously uncultivated natural habitat. Therefore, the issues discussed herein focus on the potential environmental consequences of approval of the petition for nonregulated status for MON 88302 Canola on TES and critical habitat in the areas where canola is currently grown.

APHIS focused its ESA effects analysis on the implications of exposure to the CP4 EPSPS protein in MON 88302 Canola, and the interaction between TES and the MON 88302 Canola plant, including potential for sexual compatibility and ability to serve as a host for TES. However, in furtherance of NEPA, APHIS also considered the potential impacts of the use of glyphosate herbicides to non-target organisms and the natural environment.

6.1 Potential Effects of Monsanto 88302 Canola on TES and Critical Habitat

USDA-APHIS, as described below, has evaluated the potential effects that approval of a petition for nonregulated status of MON 88302 Canola might have on Federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

6.1.1 Threatened and Endangered Plant Species and Critical Habitat

The agronomic data provided by Monsanto were used in the APHIS analysis of the weediness potential for MON 88302 Canola and potential to affect TES. Agronomic studies conducted by Monsanto tested the hypothesis that the weediness potential of MON 88302 Canola is unchanged with respect to conventional canola used in hybrid seed production. No differences were detected between MON 88302 Canola and conventional canola in growth, reproduction, or interactions with pests and diseases, other than the intended effect of tissue-specific herbicide resistance.

A review of the listed and proposed TES of plants indicates that none of them are classified in the same genus as that of the mustard varieties from which canola is derived (i.e., *Brassica rapa, B. napa, B. campestris or B. juncea).* The review also indicates that there are no listed or proposed TES of plants that are sexually compatible with *Brassica* spp., so transgenic canola will not cross-pollinate with any plant TES. Therefore, there is no evidence indicating that Monsanto 88302 Canola would directly affect any plant TES.

Monsanto has provided data in its petition indicating that compositionally, MON 88302 Canola is equivalent to other canola varieties currently grown. There are no toxins or allergens associated with this plant. The CP4 EPSPS protein is present in other crops proposed previously for nonregulated status, and subsequently evaluated by APHIS. There is no expectation that the protein or the plant will have any effect on TES of plants that may be exposed to Monsanto 88302 Canola.

In its PPRA, APHIS also evaluated MON 88302 Canola with particular emphasis on its weediness potential (USDA-APHIS, 2013b), and determined what effect, if any, that could have on designated critical habitat or habitat proposed for designation. Outcrossing and weediness are also addressed in the PPRA (USDA-AP(USDA-APHIS, 2013b), which demonstrated that MON

88302 Canola is similar to other GR-canola varieties. The risk of gene flow and weediness of MON 88302 Canola is no greater than that of other non-regulated, GR-canola varieties, nor is there any potential for GE canola to become invasive.

In conclusion, canola is neither sexually compatible with, nor does it serve as a host species for any listed species or species proposed for listing. Exposure to the MON 88302 Canola and the CP4 EPSPS protein will not affect any species, and MON 88302 Canola will not naturalize in critical habitat. APHIS has concluded that approval of a petition for nonregulated status for MON 88302 Canola, and its corresponding environmental release, will have no effect on listed plant species or species proposed for listing, and will not affect designated habitat or habitat proposed for designation.

6.1.2 Threatened and Endangered Animal Species and Critical Habitat

Monsanto has presented information on the food and feed safety of MON 88302 Canola, comparing the MON 88302 Canola variety with conventional varieties currently grown. There are no toxins or allegens associated with this plant, and the CP4 EPSPS protein is present in many crop plants (Monsanto, 2011). Compositionally, MON 87427 Corn was determined to be the same as conventional varieties. Compositional elements compared included moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients (Monsanto, 2011). Results presented by Monsanto show that the incorporation of the *cp4 epsps* gene and the attendant expression of the CP4 EPSPS protein in MON 88302 Canola does not result in any biologically-meaningful differences between MON 88302 Canola and the non-transgenic hybrid. Therefore, there is no expectation that exposure to the protein or the plant will have any effect on threatened and endangered animal species that may be exposed to MON 88302 Canola.

The FDA has concluded its review of Monsanto’s submittal of safety and nutritional data for MON 88302 Canola (FDA, 2012). Monsanto conducted safety evaluations based on Codex Alimentarius Commission procedures to assess any potential adverse effects to humans or animals resulting from environmental releases and consumption of MON 88302 Canola (Monsanto, 2011). These safety studies included evaluating protein structure and function, including homology searches of the amino acid sequences with comparison to all known allergens and toxins, an in vitro digestibility assay of the proteins, an acute oral toxicity feeding study in mice, and a feeding study in broiler chickens. MON 88302 Canola protein was previously determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and was degraded rapidly and completely in gastric fluid. (Monsanto, 2011). At this time, the FDA considers the consultation on MON 88302 Canola to be complete. A copy of the FDA consultation is available at the FDA website (Biotechnology Consultation Note to the File BNF No. 000127, April 23, 2012, MON 88302 Canola).

APHIS considered the possibility that MON 88302 Canola could serve as a host plant for TES. A review of the species list reveals that there are no members of the genus *Brassica* that serve as a host plant for any animal TES. Considering the compositional similarity between MON 88302 Canola and other varieties currently grown and the lack of toxicity and allergenicity of the CP4 EPSPS protein, APHIS has concluded that exposure and consumption of MON 88302 Canola would have no effect on threatened or endangered animal species.

6.2 Conclusion

After reviewing the possible effects of allowing the unregulated environmental release of MON 88302 Canola, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. Therefore, a detailed species by species analysis of effects is not necessary. APHIS also considered the potential effect of approval of a petition for nonregulated status of MON 88302 Canola on designated critical habitat or habitat proposed for designation, and could identify no differences from effects that would occur from the production of other canola varieties. Canola is neither sexually compatible with, nor serves as a host species for any listed TES or species proposed for listing.

Consumption of MON 88302 Canola by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Based on these factors, APHIS has concluded that approval of a petition of nonregulated status for MON 88302 Canola, and the corresponding environmental release of this canola variety will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS are not required.

7. CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

7.1 Executive Orders with Domestic Implications

The following executive orders require consideration of the potential impacts of the Federal action to various segments of the population.

- ***Executive Order (EO) 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"*** requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.
- ***EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"*** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

The No-action and Preferred Alternatives were analyzed with respect to EO 12898 and EO 13045. Neither alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children. Available mammalian toxicity data associated with the CP4 EPSPS protein establish the safety of MON 88302 Canola and its products to humans, including minorities, low-income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken with non-regulated MON 88302 Canola.

Human toxicity has also been thoroughly evaluated by the EPA in its development of pesticide labels for glyphosate (US-EPA, 1993b; US-EPA, 2009b; US-EPA, 2009c). Pesticide labels include use precautions and restrictions intended to protect workers and their families from exposures. APHIS assumes that growers will adhere to herbicide use precautions and restrictions. As discussed in Subsection 4.5, Human Health, the potential use of glyphosate on MON 88302 Canola at the proposed application rates would be no more than that currently approved for other non-regulated GR canola and found by the EPA not to have adverse impacts to human health when used in accordance with label instructions. It is expected that the EPA would monitor the use of MON 88302 Canola to determine impacts on agricultural practices, such as chemical use, as they have done previously for HR products.

Based on these factors, an extension of a determination of nonregulated status to MON 88302 Canola is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

The following executive order addresses Federal responsibilities regarding the introduction and effects of invasive species:

EO 1311 (US-NARA, 2010), “Invasive Species,” states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause.

Canola is not listed in the U.S. as a noxious weed species by the Federal government (USDA-NRCS, 2010), nor is it listed as an invasive species by major invasive plant data bases (University of Georgia and USDOI-NPS, 2009; GRN, 2012). While pollen-mediated gene transfer can occur, there are no differences in the potential for gene flow and weediness. Outcrossing and weediness are addressed in the PPRA (USDA-APHIS, 2012b) and MON 88302 Canola is similar to other GR-canola varieties. The risk of gene flow and weediness of MON 88302 Canola is no greater than that of other non-regulated, GR-canola varieties.

The following executive order requires the protection of migratory bird populations:

EO 13186 (US-NARA, 2010), “Responsibilities of Federal Agencies to Protect Migratory Birds,” states that federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

The environmental effects associated with glyphosate are summarized in the EPA RED for the herbicide (US-EPA, 1993b). Testing indicates that ecological toxicity of glyphosate is no more than slightly toxic to birds and does not exceed the EPA level of concern (US-EPA, 1993b). However, in accordance with new requirements under 40 CFR part 158, acute avian oral toxicity data for a passerine species (perching birds) is required for the current glyphosate registration review. Based on these factors, it is unlikely that a determination of nonregulated status for MON 88302 Canola would have a negative effect on migratory bird populations because its introduction would not alter current glyphosate-use patterns associated with the production of canola in the U.S.

7.2 International Implications

EO 12114 (US-NARA, 2010), “Environmental Effects Abroad of Major Federal Actions” requires federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken.

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of MON 88302 Canola. All 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 an APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of MON 88302 Canola subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards (IPPC, 2010) developed under the International Plant Protection Convention (IPPC). The purpose of the IPPC “is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for a pest risk analysis of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measures No. 11 (Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for GE organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The *Cartagena Protocol on Biosafety* is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which include those modified through biotechnology. The Protocol came into force on September 11, 2003, and 160 countries are Parties to it as of December 2010 (CBD, 2010). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol and the required documentation.

LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII, 2010). These data will be available to the Biosafety Clearinghouse.

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including those within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and those within the OECD. NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures No. 14: *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2009).

APHIS also participates in the *North American Biotechnology Initiative*, a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico, and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including Argentina, Brazil, Japan, China, and Korea.

7.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the potential changes in canola production associated with approving the petition for a determination of nonregulated status to MON 88302 Canola (see Subsection, 4.2, Agricultural Production of Canola) and determined that the cultivation of MON 88302 Canola would not lead to the increase in, or expand the area of, canola production that could impact water resources or air quality any differently than currently cultivated canola varieties. The herbicide resistance conferred by the genetic modification of MON 88302 Canola is not expected to result in any changes in water usage for cultivation compared to current canola production. As discussed in Subsections 4.3.1, Water Resources, and 4.3.3, Air Quality, there are no expected significant negative impacts to water resources or air quality from potential use of glyphosate or other pesticides associated with MON 88302 Canola production. Based on these analyses, APHIS concludes that an extension of a determination of nonregulated status to MON 88302 Canola would comply with the CWA and the CAA.

7.4 Impacts on Unique Characteristics of Geographic Areas

Approving the petition for a determination of nonregulated status to MON 88302 Canola is not expected to impact unique characteristics of geographic areas such as parklands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

Monsanto has presented results of agronomic field trials for MON 88302 Canola that demonstrate there are no differences in agronomic practices between MON 88302 Canola and currently available GR-canola varieties. The common agricultural practices that would be carried out in the cultivation of MON 88302 Canola are not expected to deviate from current practices, including the use of EPA-registered pesticides. The product is expected to be cultivated by growers on agricultural land currently suitable for production of canola, and is not anticipated to expand the cultivation of canola to new, natural areas.

The Preferred Alternative for MON 88302 Canola does not propose major ground disturbances or new physical destruction or damage to property, or any alterations of property, wildlife habitat, or landscapes. Likewise, no prescribed sale, lease, or transfer of ownership of any property is expected as a direct result of a determination of nonregulated status for MON 88302 Canola. This action would not convert land use to nonagricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 88302 Canola including the use of EPA-registered pesticides. The applicant's adherence to EPA-label-use restrictions for all pesticides is expected to mitigate potential impacts to the human environment.

With regard to pesticide use, approving the petition for a determination of nonregulated status for MON 88302 Canola is not likely to result in changes to the use of glyphosate on canola, including application timing and rates and annual maximum allowable applications. APHIS assumes that the grower will closely adhere to EPA-label-use restrictions for glyphosate.

Glyphosate was assessed by the EPA in 1993 and is currently under reregistration review scheduled for completion in 2015 (US-EPA, 2009a). Potential impacts to unique geographic areas have been considered by the EPA in its evaluation of glyphosate. In 1993, the EPA completed a reregistration analysis for glyphosate, which considered human health risk and ecological risks associated with potential exposure to glyphosate in multiple pathways (US-EPA, 1993b).

As a result of court orders and settlements, an endangered species assessment evaluating the potential impacts of the use of glyphosate on the federally threatened California red-legged frog (CRLF) is underway (US-EPA, 2009b). The EPA has requested initiation of formal consultation with the USFWS under Section 7 of the ESA to address the potential effects of glyphosate on the CRLF (US-EPA, 2009b). The EPA's formal consultation request for the CRLF was based on the potential for direct and indirect effects due to decreases in prey items, as well as potential impacts to habitat (See Section 6, Threatened and Endangered Species).

In 2004, the EPA made a "not likely to adversely affect" determination from the use of glyphosate on 11 evolusionarily significant units (ESUs) of salmon and steelhead in California and an ESU of salmon in southern Oregon (US-EPA, 2004) (see Section 6, Threatened and Endangered Species). Formal consultation with the NMFS was initiated by EPA on October 12, 2004 to fulfill a Consent Decree entered into between EPA and the Californians' for Alternatives to Toxics related to the potential effects of various pesticides used on plants and certain threatened and endangered salmon or steelhead species. While this consultation is ongoing, the EPA has allowed glyphosate to remain on the market, and it is approved for continued use in accordance with all label requirements. Submittals to this analysis can be found at the Regulations.gov website under docket designation EPA-HQ-OPP-2009-0361.

EPA plans to conduct a comprehensive ecological risk assessment, including an endangered species assessment, for all uses of glyphosate and its salts (US-EPA, 2009b). Assessments to determine impacts on unique geographic areas include:

- An ecological risk assessment to determine whether the use of glyphosate has "no effect" or "may affect" federally listed TES or their designated critical habitat;
- A spray drift buffer zone analysis to evaluate potential exposure reductions to non-target aquatic and terrestrial plants.

The information gathered during the ecological and endangered species risk assessment will be used by the EPA to make the registration review decision.

Based on these findings, including the assumption that label use restrictions are in place to protect unique geographic areas and that those label use restrictions are adhered to, approving the petition for a determination of nonregulated status to MON 88302 Canola is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

7.5 National Historic Preservation Act (NHPA) of 1966 as Amended

The NHPA of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties; 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

The APHIS proposed action of a determination of nonregulated status of MON 88302 Canola is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request. Thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

The APHIS Preferred Alternative would neither impact districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of nonregulated status of MON 88302 Canola.

The APHIS proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. These cultivation practices are already being conducted throughout the canola production regions. The cultivation of MON 88302 Canola is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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APPENDIX A. APHIS THREATENED AND ENDANGERED SPECIES DECISION TREE FOR U.S. FISH AND WILDLIFE SERVICE CONSULTATIONS

Decision Tree on Whether Section 7 Consultation with the U.S. Fish and Wildlife Service (USFWS) is Triggered for Petitions of Transgenic Plants

This decision tree document is based on the phenotypes (traits) that have been permitted for environmental releases under Animal and Plant Health Inspection Service (APHIS) oversight (for a list of approved notifications and environmental releases, visit Information Systems for Biotechnology). APHIS will re-evaluate and update this decision document as it receives new applications for environmental releases of new traits that are genetically engineered into plants.

BACKGROUND

For each transgene(s)/transgenic plant, the following information, data, and questions are addressed by APHIS, and the environmental analysis (e.g., environmental assessment [EA] or environmental impact statement [EIS]) for each petition will be publicly available. The APHIS review encompasses:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant); and
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species or a host of any threatened or endangered plant species.

The U.S. Food and Drug Administration (FDA) published a policy in 1992 on foods derived from new plant varieties, including those derived from transgenic plants (see http://www.fda.gov/food/biotechnology/default.htm). Under this policy, FDA considers its existing statutory authorities to be “fully adequate to ensure the safety of new ingredients and foods derived from new varieties of plants, regardless of the process by which such foods and ingredients are produced (U.S. FDA, 1992). Thus, genetically engineered foods must meet the same rigorous safety standards as are required of all other foods. Many of the food crops currently being developed using biotechnology do not contain substances that are significantly different from those already consumed by humans and so may be less likely to require pre-market approval. FDA expects developers to consult with the agency on safety and regulatory questions. A list of consultations is available at http://www.fda.gov/Food/Biotechnology/Submissions/default.htm. APHIS considers the status and conclusion of the FDA consultations in its EAs and EISs.

Below is the description of the APHIS review process to determine if consultation with USFWS is necessary. If the answer to any of the questions below is “yes,” APHIS contacts USFWS to determine if consultation is required.

1. Is the transgenic plant sexually compatible with a threatened or endangered plant[14] without human intervention?
2. Are naturally occurring plant toxins (toxicants) or allelochemicals increased over the normal concentration range in parental plant species?
3. Does the transgene product or its metabolites have any significant similarities to known toxins[15])?
4. Will the new phenotype(s) imparted to the transgenic plant allow the plant to be grown or employed in new habitats (e.g., outside the agro-ecosystem)[16]?
5. Does the pest resistance[17] gene act by one of the mechanisms listed below? If the answer is “yes,” then consultation with USFWS is NOT necessary.

A. The transgene acts only in one or more of the following ways:

i. As a structural barrier to either the attachment of the pest to the host, to penetration of the host by the pest, to the spread of the pest in the host plant (e.g., the production of lignin, callose, thickened cuticles);

ii. In the plant by inactivating or resisting toxins or other disease causing substances produced by the pest;

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[14] APHIS will provide USFWS a draft EA that addresses the impacts, if any, of gene movement to the threatened or endangered plant.

[15] Via a comparison of the amino acid sequence of the transgene’s protein with those found in the protein databases like PIR, Swiss-Port, and HIV amino acid databases.

[16] Such phenotypes might include tolerance to environmental stress such as drought, salt, frost, and aluminum or heavy metals.

[17] Pest resistance would include any toxin or allelochemical that prevents, destroys, repels, or mitigates a pest or affects any vertebrate or invertebrate animal, plant, or micro-organism.

iii. By creating a deficiency in the host of a component required for growth of the pest (such as with fungi and bacteria);

iv. By initiating, enhancing, or potentiating the endogenous host hypersensitive disease resistance response found in the plant; or

v. In an indirect manner that does not result in killing or interfering with normal growth, development, or behavior of the pest;

B. A pest derived transgene is expressed in the plant to confer resistance to that pest (such as with coat protein, replicase, and pathogen virulence genes).

For the biotechnologist:

Depending on the outcome of the decision tree, initial the appropriate decision below and incorporate its language into the EA or EIS. Retain a hard copy of this decision document in the petition's file.

___________ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS has reached a determination that the release following a determination of nonregulated status would have no effects on listed threatened or endangered species and consequently, a written concurrence or formal consultation with the U.S. Fish and Wildlife Service is not required for this EA or EIS.

___________ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of nonregulated status is not likely to adversely affect any listed threatened or endangered species and consequently obtained written concurrence from the U.S. Fish and Wildlife Service.

___________ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of nonregulated status is likely to adversely affect one or more listed threatened or endangered species and has initiated formal consultation with the U.S. Fish and Wildlife Service.