Bayer CropScience LP Petition (16-235-01p) for Extension of Determination of Non-regulated Status for Male Sterile, Glufosinate-Ammonium Resistant MS11 Canola (*Brassica napus*)

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Final Environmental Assessment

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ACRONYMS AND ABBREVIATIONS

2,4-D	2,4-Dichlrophenoxyacetic acid
ACCase	Acetyl CoA caboxylase
a.i.	Active ingredient
APHIS	Animal and Plant Health Inspection Service
Bar	Bialaphos resistance gene that occurs naturally in *Streptomyces hygroscopicus* and encodes for the phosphinothricin-N-acetyltransferase (PAT) enzyme
CAA	Clean Air Act
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (U.S.)
CH_4	Methane
CO	Carbon monoxide
CO_2	Carbon dioxide
CO_2eq	Carbon dioxide (CO_2) equivalent
CWA	Clean Water Act
EA	Environmental Assessment
EFSA	European Food Safety Agency
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ELISA	Enzyme-linked immunosorbent assay
ESA	Endangered Species Act
EU	European Union
F1	First generation
F2	Second generation
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FONSI	Finding of No Significant Impact
FQPA	Food Quality Protection Act
FR	Federal Register
FSMA	Food Safety Modernization Act
FWS	U.S. Fish and Wildlife Service
GE	Genetically engineered
GHG	Greenhouse gas
GMO	Genetically modified organism
GRAS	Generally Recognized As Safe
HR	Herbicide resistant
HEAR	High erucic acid rapeseed
HRW	Herbicide Resistant Weeds
IPM	Integrated pest management

ACRONYMS AND ABBREVIATIONS

IWM	Integrated weed management
K	Potassium
Kg	Kilogram
lb	Pound (avoir.)
LEAR	Low erucic acid rapeseed
LLP	Low level presence
LLOQ	Lower limit of quantitation
m^2	Square meters
MCPA	2-methyl-4-chlorophenoxyacetic acid
MOA	Mode of action
N	Nitrogen
N_2O	Nitrous oxide
NAAQS	National Ambient Air Quality Standards
NMFS	National Marine Fisheries Service
ng/ml	Nanogram per milliliter
NASS	National Agricultural Statistics Service
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NNI	Neonicotinoid insecticide
NO_2	Nitrogen dioxide
NOx	Nitrogen oxides
NOP	National Organic Program
NPS	Non-point source (pollution)
ODA	Oregon Department of Agriculture
OECD	Organization for Economic Cooperation and Development
O_3	Ozone
P	Phosphorus
OSHA	Occupational Safety and Health Administration
PAT	The enzyme phosphinothricin N-acetyltransferase or phosphinothricin acetyltransferase
Pb	Lead
PDP	Pesticide Data Program
PM	Particulate matter
P_2O_5	Phosphorus pentoxide (fertilizer)
PPA	Plant Protection Act
PPRA	Plant pest risk assessment
PPRSA	Plant pest risk similarity assessment
PPA	Plant Protection Act
RFS	Renewable fuel standard
RFS2	Second renewable fuel standard

Acronyms and Abbreviations

S	Sulfur
SIP	State implementation plan
SU	Sulfonylurea-type active ingredients
SO_2	Sulfur dioxide
SO_x	Sulfur oxides
t	Ton
T&E	Threatened & Endangered
TSCA	Toxic Substances Control Act
U.S.	United States and its territories and possessions
USDA	U.S. Department of Agriculture
USC	U.S. Code
USFWS	U.S. Fish & Wildlife Service
USGS	U.S. Geological Survey
WHO	World Health Organization
WPS	Worker protection standards
WSSA	Weed Science Society of America

1 PURPOSE AND NEED

1.1 Background

Bayer CropScience LP, Research Triangle Park, N.C. (referred to as Bayer in this document) submitted a petition (16-235-01p) to the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) in September 2016, requesting that an APHIS determination of non-regulated status for InVigor® Hybrid Canola MS8 and RF3, made by APHIS in 1999 (64 FR 61, March 31, 1999, p.15337), be extended to genetically engineered (GE) MS11 canola. Bayer has requested that APHIS extend non-regulated status to MS11 canola based on its similarity to MS8 canola; both MS11 and MS8 canola have been genetically engineered for male sterility and resistance[1] to the herbicide active ingredient, glufosinate-ammonium. MS11 canola is currently regulated under Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340). Interstate movements and field trials of MS11 canola have been conducted under permits issued or notifications acknowledged by APHIS since 2014. The field trials were conducted in diverse growing regions across the United States, with most conducted in North Dakota and Washington.

APHIS regulations at 7 CFR § 340.6(e) enable petitioners to request that the Agency extend a determination of non-regulated status to a GE organism regulated under 7 CFR part 340 based on its similarity to a GE organism APHIS previously evaluated and determined was not subject to 7 CFR part 340. APHIS requires that such extension requests include sufficient information to allow the Agency to assess the similarity of the regulated organism and its non-GE antecedent(s) with the antecedent GE organism(s) that are not regulated by APHIS.

As part of its consideration of Bayer's extension request APHIS conducted a Plant Pest Risk Similarity Assessment (PPRSA) (USDA-APHIS 2016). This Environmental Assessment (EA) has also been prepared to respond to the requirements of the National Environmental Policy Act (NEPA). APHIS conducts these analyses prior to making a decision on whether or not to extend non-regulated status to MS11 canola.

1.2 Petitioners Intended Use of MS11 Canola

The purpose of MS11 canola is to eventually replace the current MS8 canola line that is used as breeding stock in the production of GE herbicide-resistant (HR) canola crop seed. The current breeding stock incorporates two GE canola lines. The first is a male sterile canola line (MS8), which is conferred by a dominant barnase gene that produces male sterility. The second is a canola line that restores fertility via a dominant barstar gene (RF3), which reinstates male fertility in MS8 and RF3 canola hybrid seed. Both the MS8 and RF3 canola lines have been genetically engineered to contain the bar gene that encodes for the production of the enzyme phosphinothricin N-acetyltransferase (PAT), which confers resistance to the herbicide active ingredient glufosinate-ammonium. Bayer's GE HR canola hybrid seed is currently produced by crossbreeding MS8 and RF3 canola (denoted as MS8 × RF3), which results in fertile,

[1] "Resistance" to herbicides is defined by the Weed Science Society of America (WSSA) as the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type. In a plant, resistance may be naturally occurring, induced by such techniques as genetic engineering, or by tissue culture or mutagenesis. "Tolerance" is distinguished from resistance and defined by WSSA as the inherent ability of a plant to survive and reproduce following exposure to an herbicide. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. In its request to APHIS, Bayer references MS11 canola as herbicide "tolerant" and used the terms "tolerance" and "tolerant" throughout its documentation to describe MS11 canola. In this EA, APHIS has used the term "resistance" when referring to MS11 canola to be consistent with the WSSA definition. For the purposes of this EA, Bayer's use of the term "herbicide-tolerant" can be considered synonymous with "herbicide-resistant" (HR), as used in this EA.

glufosinate-ammonium resistant crop seed. It is anticipated that MS8 will be gradually phased out and replaced by MS11 canola during the next ten years.

Like MS8 canola, MS11 is male sterile and glufosinate-ammonium resistant. The only difference between MS11 and MS8 canola is that MS11 also contains the barstar gene that results in low level expression of the barstar protein. This protein is also expressed by the RF3 canola line. The barstar gene in the MS11 canola line is intended to improve transformation efficiency; it has no effect on the male sterile or HR phenotype of MS11. MS11 canola exhibits the same phenotype as MS8: Male sterility conferred by the expression of the barnase protein in tapetum cells (cells found within the male flower parts [stamen] of plants), and glufosinate-ammonium resistance conferred by the bar gene and expression of PAT in green plant tissues.

There is no difference between the intended purpose and rational for the use of MS11 and MS8 canola, the subject of petitions 16-235-01p and 98-278-01p, respectively. GE MS11 canola will be used for the same purposes as MS8 canola, to produce glufosinate-ammonium resistant canola crop seed. Crops derived from MS11 canola hybrid seed will be used for the production of canola oil and canola meal, the latter of which is primarily used for animal feed.

1.3 The Coordinated Framework and Regulation of Biotechnology Products

Since 1986, the U.S. government has regulated GE organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology[2] (referred to in this document as the Coordinated Framework).

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 U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA). A summary of each role follows.

1.3.1 USDA-APHIS

APHIS has authority to regulate plant pests under the Plant Protection Act (PPA) of 2000 as amended. APHIS regulations at 7 CFR part 340 (7 U.S. Code (U.S.C.) 7701–7772) govern the introduction (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 part 340 when APHIS

[2] See https://www.whitehouse.gov/blog/2016/09/16/building-30-years-experience-prepare-future-biotechnology

has reason to believe that the GE organism may be a plant pest or APHIS does not have sufficient information to determine if the GE organism is unlikely to pose a plant pest risk.

1.3.2 Environmental Protection Agency

The EPA regulates the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology, termed plant incorporated protectants (PIPs). The EPA regulates pesticides, including PIPs, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) and certain biological control organisms under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53 *et seq*.).

Under FIFRA, the EPA requires registration of a pesticide for a specific use prior to distribution or sale of the pesticide for a proposed use pattern. The 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; and storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, the EPA must determine through testing that the pesticide will not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. The EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling. 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 of 1996 amended FIFRA, enabling the 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 2015d).

Before planting a crop containing a PIP, a company must seek an experimental use permit from the EPA. When assessing the potential risks of genetically engineered PIPs, the EPA requires extensive studies examining numerous factors, such as risks to human health, non-target organisms and the environment, potential for gene flow, and the need for insect resistance management plans.

The EPA also sets tolerances for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 *et seq*.). The EPA is required, before establishing a pesticide tolerance, to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the Food Quality Protection Act of 1996. The FDA enforces the pesticide tolerances set by the EPA.

1.3.3 Food and Drug Administration

The FDA regulates GE organisms under the authority of the FFDCA. The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, in the *Federal Register* on May 29, 1992.[3] Under this policy, the FDA implements a voluntary consultation process to ensure that human food and animal food safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of food derived from GE plants. This voluntary consultation process provides a way for developers to receive assistance from the FDA in complying with their obligations under federal food safety laws prior to marketing.

In June 2006, the 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) for establishing voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants.

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[3] Available at U.S. FDA: Statement of Policy - Foods Derived from New Plant Varieties; http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm

Early food safety evaluations help ensure 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 the FDA, but the information may be used later in the biotechnology consultation.

1.4 Purpose and Need for APHIS Action

Under the authority of the plant pest provisions of the PPA and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. Any party can petition APHIS for a determination of non-regulated status for a GE organism that is regulated under 7 CFR part 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 MS11 canola. When a petition for non-regulated status is submitted, APHIS must determine the potential plant pest risk a GE organism may pose. The petitioner is required to provide information under 7 CFR § 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. Pursuant to the PPA and 7 CFR part 340 APHIS must respond to Bayer's petition request for an extension of non-regulated status to MS11 canola by issuing a determination of regulatory status.

For actions such as determinations of non-regulated status and extensions of non-regulated status, APHIS prepares environmental documentation as part of its obligations under NEPA and APHIS NEPA implementing regulations at 7 CFR part 372. Whenever possible, APHIS will use existing EAs or Environmental Impact Statements (EISs) for Agency determinations on the antecedent organism(s). In some cases, only new Findings of No Significant Impact (FONSIs) will be required. In other cases, a new EA is required to combine the analysis from multiple environmental documents when there are multiple antecedents. There are some situations, as is the case for this petition, which require a new EA be written to update relevant information from previous environmental documents. Due to the time that elapsed since issuance of the prior FONSI for MS8 and RF3 canola (1999), APHIS has prepared this EA to consider the potential environmental effects of an Agency determination of non-regulated status for MS11 canola, consistent with the Council of Environmental Quality's (CEQ) NEPA regulations (40 CFR parts 1500-1508) and the USDA and APHIS NEPA-implementing regulations and procedures (7 CFR part 1b, and 7 CFR part 372). This EA has been prepared to evaluate potential impacts on the human environment (40 CFR § 1508.14) that may result from an extension of non-regulated status to MS11 canola.

1.5 Public Involvement

APHIS routinely seeks public comment on EAs prepared as part of the Agency's response to petitions seeking a determination of non-regulated 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 in the *Federal Register* to advise the public of changes to the way it solicits public comment when considering petitions for determinations of non-regulated status for GE organisms to allow for early public involvement in the process.[4] A summary of current practices follows.

1.5.1 First Opportunity for Public Involvement

Once APHIS deems a petition complete, the petition is made available for public comment for 60 days, providing the public an opportunity to raise issues regarding the petition itself and give input for consideration by the Agency as it develops its EA and Plant Pest Risk Assessment (PPRA). APHIS publishes a notice in the *Federal Register* to inform the public that APHIS will accept written comments

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

regarding a petition for a determination of non-regulated status for a period of 60 days from the date of the notice.

1.5.2 Second Opportunity for Public Involvement

Assuming an EA is sufficient, the EA and PPRA 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 non-regulated status raises substantive new issues:

Approach 1: For GE organisms that do not raise substantive new issues

This approach for public participation is followed when APHIS decides, based on the review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that raises no substantive new issues, such as gene modifications that do not raise new biological, cultural, or ecological issues due to the nature of the modification or APHIS' familiarity with the recipient organism. Under this approach, APHIS will publish a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, preliminary PPRA and preliminary FONSI for a 30-day public review period.

If no substantive information is received that would warrant substantial changes to APHIS' analysis or determination, APHIS' preliminary regulatory determination will become effective upon public notification through an announcement on its website. No further *Federal Register* notice will be published announcing the final regulatory determination.

Approach 2. For GE organisms that raise substantive new issues not previously reviewed by APHIS

A second approach for public participation will be used when APHIS determines that the petition for a determination of non-regulated status raises substantive new issues such as a recipient organism that has not previously been determined by APHIS to have non-regulated status or when APHIS determines that gene modifications raise substantive biological, cultural, or ecological issues not previously analyzed by APHIS. APHIS reviews the petition, analyzes and evaluates comments received from the public during the 60-day comment period on the petition to determine if substantive issues have been identified.

APHIS solicits comments on its EA and preliminary PPRA for 30 days through a *Federal Register* notice. APHIS reviews and evaluates comments and other relevant information, after which it may revise the PPRA and EA, as necessary. Following the preparation of these final documents, APHIS either approves or denies the petition request, announcing in the *Federal Register* the availability of APHIS' final PPRA, EA, FONSI (as appropriate), and regulatory status determination for the GE organism.

1.5.3 Public Involvement for Extensions of Prior APHIS Regulatory Decisions

APHIS practices are different for public participation in Agency decisions that extend the scope of a previous (initial) determination of non-regulated status to GE organisms similar to the subject of the initial determination. In such instances, the previously published original petition remains the petition of reference for public review. A notice of the petition for extension is not published in the *Federal Register*; instead, the petition for extension is made available on APHIS' website.[5] If the PPRSA concludes that the GE organism(s) subject of the extension request is unlikely to pose a plant pest risk, and the prior NEPA analysis is applicable (e.g., EA), a preliminary FONSI is prepared. These documents and the Agency's preliminary regulatory status determination are made available for a 30-day public review and comment

[5] USDA-APHIS: Petitions for Determination of Non-regulated Status: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

period. After the comment period, if no substantive information is received that would warrant substantial changes to APHIS' analysis, a final FONSI and regulatory status determination are issued, and posted on the APHIS web site. This is a final decision; no further action is taken.

If a new EA is prepared for an extension request, the new EA is also made available for public review and comment. A new EA may be prepared if the body of scientific literature on the GE organism has expanded since the initial EA and FONSI were prepared, or too much time has elapsed between the initial petition's NEPA analysis and petition for extension request. In instances where a new EA is prepared, APHIS will publish a notice in the *Federal Register* announcing its preliminary PPRSA, EA, preliminary FONSI, and preliminary regulatory status determination for a 30-day public review and comment period. APHIS reviews and evaluates comments and other relevant information, after which it may revise the preliminary PPRSA, EA, preliminary FONSI, and preliminary regulatory status determination, as warranted. If no substantive information is received that would require changes to the analyses presented in these documents, no changes to these analyses or the Agency's preliminary regulatory status determination is made. Following preparation of the final documents, APHIS will either approve or deny the petition, announcing in the *Federal Register* the availability of APHIS' final PPRSA, EA, FONSI (as appropriate), and regulatory status decision document.

1.5.4 Public Involvement for Petition 16-235-01p

APHIS conducted an EA for the prior petition (98-278-01p) and issued a FONSI for its determination of non-regulated for MS8 and RF3 canola in 1999. APHIS has considered the NEPA documentation for petition 98-278-01p, and, due to the time that has elapsed since the prior EA and FONSI were issued, has conducted a new EA for Bayer's MS11 canola petition (16-235-01p). APHIS has prepared this new EA to consider the potential environmental impacts of an agency determination of non-regulated status for MS11 canola. Consequently, public involvement for petition 16-235-01p and this EA followed the procedure described above, when a new EA is prepared for an extension request.

On April 12, 2017, APHIS announced in the *Federal Register* it was making available its EA, preliminary regulatory determination, preliminary FONSI, and preliminary PPRSA for a 30 day public review and comment period (82 FR No. 69, April 12, 2017, pp. 17625-17626). On May 10, 2017, APHIS announced in the *Federal Register* that the comment period would be extended to May 30, 2017 (82 FR, No. 89, May 10, 2017, p. 21790). At the end of the comment period APHIS had received 5 comments. APHIS evaluated all comments received and determined that no new information was presented in the comments that required changes to the EA, PPRSA, or the Agency's preliminary regulatory status determination. Hence, APHIS prepared a final EA, FONSI, and PPRSA, and has issued a final decision to extend non-regulated status to MS11 canola. All of these documents are available to the public on the APHIS-BRS website (Petition 16-235-01p).[6] All comment received on the draft EA remain available for public review at www.regulations.gov, Docket ID: APHIS-2017-0015.[7] APHIS provides a more detailed response to comments in the last section of the FONSI tiered to this EA.

1.5.5 Scope of Analysis in this EA

APHIS developed a list of topics for consideration in this EA based on issues identified in the EA for InVigor® Hybrid Canola MS8 and RF3 (USDA-APHIS 1998), public comments submitted for this and other EAs and EISs evaluating petitions for non-regulated status, the scientific literature on agricultural

[6] USDA-APHIS-BRS, Petitions for Determination of Nonregulated Status: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

[7] https://www.regulations.gov/docket?D=APHIS-2017-0015

biotechnology, and issues identified by APHIS specific to wild and cultivated *Brassica* species. The following topics were identified as relevant to the scope of analysis in this EA (40 CFR § 1508.25).

Agricultural Production

- Acreage and Areas of Canola Production
- Agronomic Practices and Inputs

Physical Environment

- Soils
- Water Resources
- Air Quality
- Climate Change

Biological Resources

- Soil Biota
- Animal Communities
- Plant Communities
- Herbicide-Resistant Weeds
- Gene Flow and Weediness
- Biodiversity

Human Health

- Consumer Health and Worker Safety

Animal Health

- Animal Feed/Livestock Health

Socioeconomic Considerations

- Domestic Economic Environment
- International Trade

In addition to possible direct and indirect impacts on the topic areas listed above, potential cumulative impacts relative to these topics were also considered, as well as potential impacts on threatened and endangered species (TES). The EA also examines and ensure adherence of the proposed action to Executive Orders, and environmental laws and regulations to which the action may be subject.

2 ALTERNATIVES

Two alternatives are evaluated in this EA: (1) No Action, which would result in the continuation of Bayer's MS11 canola as a regulated article; and (2) extension of non-regulated status for MS11 canola.

2.1 No Action Alternative: Continuation as a Regulated Article

One of the alternatives that must be considered by APHIS is a "No Action Alternative," pursuant to CEQ regulations at 40 CFR part 1502.14. Under the No Action Alternative, APHIS would deny the petition. MS11 canola and progeny derived from MS11 canola would continue to be regulated articles under 7 CFR part 340. Authorizations by APHIS would continue to be required for introductions of MS11 canola and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MS11 canola.

This alternative is not the Preferred Alternative because APHIS conducted a PPRSA and determined that MS11 canola is unlikely to pose a plant pest risk (USDA-APHIS 2016). Choosing this alternative would not satisfy the purpose and need of responding appropriately to Bayer's petition (16-235-01p) and issuing a determination of regulatory status for MS11 canola, as required by 7 CFR part 340.

2.2 Preferred Alternative: Determination of Non-regulated Status for MS11 Canola

Under the Preferred Alternative, MS11 canola and progeny derived from it would no longer be regulated articles under the regulations at 7 CFR part 340. APHIS would no longer require authorizations for introductions of MS11 canola. Under this alternative, growers may have future access to MS11 canola and progeny derived from it if the developer decides to commercialize MS11 canola.

Because APHIS conducted a science-based preliminary PPRSA for MS11 canola that concluded MS11 is unlikely to pose a plant pest risk (USDA-APHIS 2016), this alternative best meets the purpose and need to respond appropriately to the petition for non-regulated status pursuant to the requirements in 7 CFR part 340 and the Agency's authority under the plant pest provisions of the PPA. Because the Agency concluded that MS11 canola is unlikely to poise a plant pest risk, a determination of non-regulated status for MS11 canola is a response that is consistent with the plant pest provisions of the PPA, 7 CFR part 340, and the biotechnology regulatory policies described for the Coordinated Framework.

2.3 Alternatives Considered but Dismissed from Detailed Analysis

APHIS evaluated several other alternatives for consideration in the EA in light of the Agency's statutory authority under the PPA and APHIS implementing regulations at 7 CFR part 340, but dismissed these alternatives for consideration in the EA. The alternatives considered are summarized below along with the reasons for dismissal from detailed analysis.

2.3.1 Prohibit the Release of MS11 Canola

APHIS considered prohibiting the environmental release of MS11 canola, including denying permits for field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MS11 canola is unlikely to pose a plant pest risk (USDA-APHIS 2016).

In enacting the Plant Protection Act (PPA) of 2000, Congress included findings that:

“decisions affecting imports, exports, and interstate movement of products regulated under [the PPA] shall be based on sound science;…” (7 U.S. C. §7701(4)) and that “The Secretary’s determination on the petition shall be based on sound science” (7 U.S.C. § 7711(3)(c)).

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies, such as genetic engineering, at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

“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”

MS8 canola is no longer regulated by APHIS. It has been in commercial production for over 10 years. Over this time, APHIS is not aware of MS8 canola being a plant pest or presenting a plant pest risk. In addition, MS11 canola has been field tested under APHIS permits. Based on the preliminary PPRSA for MS11 canola (USDA-APHIS 2016), experience with MS8 canola, MS11 field tests, and additional scientific information, APHIS concluded that MS11 canola is unlikely to pose a plant pest risk. Accordingly, there is no scientific or legal basis for prohibiting the release of MS11 canola. Consequently, an alternative that would prohibit the environmental release of MS11 was dismissed.

2.3.2 Approve the Request for Extension 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 non-regulated 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 previously concluded that MS8 and RF3 canola lines should no longer be regulated. APHIS has also concluded that MS11 canola is unlikely to pose a plant pest risk (USDA-APHIS 2016). Hence, it would be inconsistent with APHIS statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340 to consider approval of the petition only in part. Consequently, this alternative was dismissed from detailed analysis in this EA.

2.3.3 Isolation of MS11 Canola and Non-GE Canola Production Systems or Geographic Restriction

In the past, APHIS has received public comments expressing concerns regarding gene movement between GE and non-GE plants. APHIS considered requiring isolation distances for separation of MS11 canola from non-GE canola production. APHIS also considered geographically restricting the production of MS11 canola based on the location of production of non-GE canola in organic production systems or production systems for GE-sensitive markets. However, because APHIS has concluded that MS11 canola is unlikely to pose a plant pest risk (USDA-APHIS 2016), prescribing isolation distances or geographic restrictions on production would be inconsistent with APHIS’ statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340. In addition, the imposition of isolation distances or geographic restrictions would not meet APHIS’ purpose and need to respond appropriately to the request for extension of non-regulated status based on the requirements in 7 CFR part 340 and the Agency’s authority under the PPA. Consequently, this alternative was dismissed. While APHIS is not restricting the planting of MS11 canola, this does not prevent individuals from voluntarily choosing to isolate or geographically restrict their non-GE canola production systems from MS11 canola or to use other management practices to minimize gene movement between canola fields.

2.3.4 Requirements to Test for MS11 Canola

During comment periods for other petitions for non-regulated status, certain commenters requested that the USDA require and provide testing for the presence of GE material in non-GE production systems. Because there are no federal regulations describing standardized testing criteria or quantitative thresholds for GE material in non-GE cropping systems or crop products, nationwide testing and monitoring would be extremely difficult to implement. Additionally, because MS11 canola is unlikely to pose a plant pest risk (USDA-APHIS 2016), the imposition of any type of testing requirements for MS11 canola would be inconsistent with the PPA, 7 CFR part 340, and federal regulatory policies embodied in the Coordinated Framework. Consequently, this alternative was dismissed from detailed analysis.

2.4 Comparison of the Alternatives Considered

Table 2-1 presents a summary of the environmental consequences associated with the No Action Alternative and Preferred Alternative that are evaluated in this EA. Detailed analysis of the affected environment is discussed in Chapter 3, and potential impacts of the alternatives considered discussed in Chapters 4 through 7.

Table 2-1. Summary of Potential Impacts for the Alternatives Considered

Analysis	No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest	Preferred Alternative: Extension of Non-regulated Status to MS11 Canola
Meets Purpose and Need	No	Yes
Unlikely to pose a plant pest risk	Addressed by the use of regulated field trials.	Determined by the plant pest risk similarity assessment (USDA-APHIS 2016).
Agricultural Production		
Acreage and Areas of Canola Production	Denial of the petition would have no effect on the location or acreage of canola production. There may be fluctuations in production areas and acreage relative to market demand for canola products.	Extension of non-regulated status to MS11 canola, and the eventual replacement of MS8 with MS11 canola, is not expected to alter the location or acreage of canola production.
Agronomic Practices and Inputs	Agronomic practices or inputs used in canola crop production would remain unchanged.	Because MS11 canola is phenotypically and agronomically similar to currently cultivated MS8 canola, agronomic practices and inputs would be the same.
Physical Environment		
Soils	Agronomic practices, inputs, or other factors that impact soils would be unaffected by denial of the petition. Growers will continue or adopt management practices, such as crop rotation, tillage, and pest and weed management strategies that maximize crop yield, avoid the development of herbicide resistance, preserve soil quality, and avoid erosion. Growers may experience more efficient weed control using HR canola over non HR varieties. This may reduce the need for certain weed control practices such as tillage. A reduction in tillage may reduce soil erosion in some areas.	Because MS11 canola is phenotypically similar to currently cultivated MS8 canola, and agronomic management practices and inputs are the same for both MS11 and MS8 canola, potential impacts to soils would be unchanged.

Table 2-1. Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest**	**Preferred Alternative: Extension of Non-regulated Status to MS11 Canola**
Water Resources	Agronomic practices and inputs, such as irrigation needs and pesticide use, or other factors that may impact water resources would be unaffected. Soil erosion and runoff are a significant form of non-point source (NPS) water pollution. This NPS can introduce sediments, fertilizer, pesticides, and other types of pollution into aquatic ecosystems. It is expected that growers will continue or adopt management practices to mitigate erosion, run-off, and other adverse impacts on water quality. Growers may experience more efficient weed control using HR canola over non HR varieties. This may reduce the need for certain weed control practices such as tillage. A reduction in tillage may reduce erosion in some areas. The EPA regulates pesticides applied to GE HR canola and determines whether pesticides, including those that contain glufosinate, pose an unacceptable risk to non-target organisms, including aquatic organisms.	Because MS11 canola is phenotypically and agronomically similar to currently cultivated MS8 canola, an extension of non-regulated status to MS11 canola is not expected to alter potential impacts on water resources.
Air Quality	Emission sources and the level of emissions associated with canola production would be unaffected by denial of the petition.	Potential impacts on air quality would be the same as under the No Action Alternative.
Biological Resources		
Soil Biota	Potential impacts on soil biota would be unaffected by denial of the petition. The EPA regulates pesticides applied to GE HR canola and determines whether pesticides pose an unacceptable risk to soil biota.	Commercial production of MS11 canola and MS11 hybrid crops is unlikely to affect soil biota any differently than cropping systems based on MS8 hybrid canola.
Animal Communities	Potential impacts on animal communities would be unaffected by denial of the petition. Canola fields can contain several animal species. Some species (such as insect crop pests) may need to be controlled using a range of tools. These tools may be deployed within integrated pest management strategies. The EPA regulates pesticides and determines whether they pose an unacceptable risk to animal communities. It is violation of federal law to use a pesticide in a manner that is not in strict accordance with the instructions on its EPA-approved label.	Potential impacts on animal communities would the same as that under the No Action Alternative.

Table 2-1. Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest**	**Preferred Alternative: Extension of Non-regulated Status to MS11 Canola**
Plant Communities	Potential impacts on plant communities would be unaffected by denial of the petition. Plants (other than crop plants) in canola fields are considered weeds as they can impact crop yield and quality. Weeds are managed using a range of tools, including mechanical control methods such as tillage and herbicides. Growers may be able to more efficiently control weeds when they use HR canola varieties compared to when they use non-HR varieties. This may reduce the need for certain weed control practices such as tillage and the use of additional herbicides. The EPA regulates and determines how pesticides can be used. EPA pesticide use requirements are intended to be protective of non-target plant communities and other plants, such as those in adjacent fields.	Potential impacts on plant communities would the same as that for the No Action Alternative.
Herbicide Resistant Weeds	The over-reliance on a weed control method, such as using a single herbicide, can impose a selection pressure on weed communities adjacent to or within production systems. Over time, this can lead to the development of weed populations that are resistant to that control method. Although the use of glufosinate could result in development of resistant weed populations, there are several strategies that greatly reduce the chances that this will occur. The EPA issued updated guidance for glufosinate resistance management in 2016. This is supported by technical information from the Weed Science Society of America (WSSA), information developed and disseminated by the USDA, universities, and others. It is violation of federal law to use a pesticide in a manner that is not in strict accordance with the instructions on its EPA-approved label. It is expected that herbicides registered for use on canola will be used per EPA requirements, within an overall strategy that reduces the development and spread of glufosinate resistant weed populations.	Because the agronomic management practices used in cultivation of MS11 canola are the same as those currently used in cultivation of MS8 canola, an extension of non-regulated status to MS11 canola is not expected to increase the propensity for, or the rate or extent of development of, glufosinate resistant weed populations.

Table 2-1. Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest**	**Preferred Alternative: Extension of Non-regulated Status to MS11 Canola**
Gene Flow and Weediness	Pollen may flow from GE HR canola to sexually-compatible wild relatives i.e., *Brassica* spp. The progeny of this gene flow (e.g., seeds) could spread populations to other areas and lead to the establishment of additional feral hybrid populations. Because of the general ecological requirements of *Brassica* spp., the establishment of feral hybrid populations is more likely in sites that are subject to frequent disturbances. Pollen dispersal is most likely to areas 300 feet or less from pollen sources. Rarely, outcrosses may occur at distances up to 2 miles away. APHIS recognizes interspecific and intraspecific hybridization will occur, although probably at a low frequencies. Gene flow is most likely to occur among *B. napus* crops grown in adjacent areas, and *B. napus* crops and wild relative *B. rapa* species.	An extension of non-regulated status for MS11 canola would not be expected to increase or decrease the risk for gene flow to wild relative species as compared MS8 canola. Likewise, the risk for occurrence and persistence of feral canola hybrids and volunteers would not be expected to be any different. Based on the PPRSA, APHIS concluded that is unlikely that gene introgression from MS11 event to other organism with which it can interbreed will increase their weediness (USDA-APHIS 2016). Consequently, the Preferred Alternative is not expected to substantially differ from the No Action Alternative in regard to the potential environmental impacts associated with gene flow and weediness.
Biodiversity	Under the No Action Alternative, MS11 canola and its progeny would continue to be regulated by APHIS under 7 CFR part 340, and it could be grown in field trial settings under permit or notification. Because of the relatively small acreages and short periods required for field trials compared to that of commercial-scale crop seed production, it is unlikely that MS11 field trials would impact biodiversity.	Because MS11 canola is phenotypically and agronomically similar to currently cultivated MS8 canola, potential impacts on biodiversity would be the same as under the No Action Alternative.
Human and Animal Health		
Human Health	The FDA regulates food and feed safety and, in 1998, consulted with AgrEvo (acquired by Bayer CropScience in 2001) on MS8 and RF3 canola. The bar, barnase, and barstar genes and their expression products have been evaluated by the FDA, naturally occur in soils worldwide, and present negligible risk to human health. MS8 canola has been on the commercial market for over a decade. The EPA regulates use of glufosinate. The EPA concluded on glufosinate registration review that the current tolerances are accurate and protective of human health. The EPA pesticide registration review for glufosinate includes the development of use	An extension of non-regulated status for MS11 canola would present negligible risk to human health, to include worker safety. MS11 canola is phenotypically and agronomically similar to currently cultivated MS8 canola, which has been used for production canola oil and canola meal in the United States for more than a decade. An extension of non-regulated status would not be expected to have any effect on glufosinate use, EPA regulation of glufosinate, or worker protection standards.

Table 2-1. Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest**	**Preferred Alternative: Extension of Non-regulated Status to MS11 Canola**
	restrictions that, when followed, have been determined to be protective of worker health. It is violation of federal law to use a pesticide in a manner that is not in strict accordance with the instructions on its label.	
Animal Health and Welfare	The FDA consulted with AgrEvo on MS8 and RF3 canola and had no concerns regarding feed derived from these canola cultivars. Under the No Action Alternative, MS11 canola will remain a regulated article, will not be available as an animal feed, and current canola based feed for livestock will remain unchanged.	The PAT, barstar, and barnase proteins present negligible risk to animals. Extension of non-regulated status to MS11 canola would not result in any novel exposure of livestock to these proteins, given they are currently present in commercial GE HR canola used for production of canola meal, as well as in soils. Under both the Preferred and No Action Alternative animal health and welfare would be expected to be supported by canola based feed, to include canola meal derived from MS8 canola hybrids and MS11 canola hybrids.
Socioeconomic Effects		
Domestic Economic Environment	MS11 canola would continue to be regulated by APHIS and would not be used for commercial purposes. MS8 canola hybrids would continue to be cultivated, relative to grower preference for this GE HR canola variety. Accordingly, there would be no impact on the U.S. domestic canola oil, meal, or biodiesel markets on a decision to deny the extension request. Production of organic canola is currently limited; any increase will be commensurate with market demand for organic canola oil, and perhaps organic canola meal for feed. Certified organic foods are produced according to federal standards set by the USDA National Organic Program. Under these standards, the use of GE crops is prohibited in products labelled “organic”.	It is expected that MS11 canola would, over time, supplant MS8 canola. While there could be some efficiencies gained in the production of MS11 hybrid crop seed compared to the current MS8 based cropping systems, the potential domestic economic impacts associated with the introduction of MS11 canola into commerce would not be different than those currently observed for MS8 hybrid canola.
International Trade	MS8 canola hybrid seed would be exported subject to market demand. There would be no impacts on trade under the No Action Alternative.	U.S. canola imports and exports would be unaffected by an extension of non-regulated status to MS11 canola. Bayer will seek international regulatory approvals in Australia and Canada.
Cumulative Impacts		
Agriculture, Physical and Biological Resources, Public Health, Socioeconomic	No significant cumulative impacts on agronomic practices and inputs, the acreage and areas of canola production, the physical environment and biological	There are no reasonably foreseeable adverse cumulative effects on any aspect of the human environment that would derive from MS11 canola, or any hybrid progeny

Table 2-1. Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest**	**Preferred Alternative: Extension of Non-regulated Status to MS11 Canola**
	resources, development of pest and weed resistance, gene flow and weediness, human and animal health, domestic markets, or international trade were identified.	derived from it (e.g., insect and disease resistant canola). It is highly unlikely an extension of non-regulated status for MS11 canola would contribute to any adverse cumulative impacts.
Climate Change	All agricultural cropping systems, to include canola, contribute to climate change. A cumulative impact associated with canola production is its contribution to global greenhouse gas emissions, such as N_2O and CO_2. Based on current data, GE HR canola has in part contributed to reductions in GHG emissions from canola cropping systems over the last two decades. These contributions to N_2O and CO_2 emissions reductions, relative to canola production in the 1990s and prior decades, would be expected to continue.	Unchanged from No Action Alternative
Coordinated Framework Review		
U.S. Regulatory Agencies	Voluntary consultation with the FDA and changes to the EPA registration of glufosinate based herbicides would be unnecessary.	Bayer may undergo voluntary consultation with the FDA on the food and feed safety and MS11 canola and hybrids derived from it. The EPA will determine the uses of herbicides that contain glufosinate on MS11 canola.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Fully compliant	Fully compliant

3 AFFECTED ENVIRONMENT

This chapter provides a discussion of the current conditions of those aspects of the human environment potentially impacted by an extension of non-regulated status to MS11 canola. For the purposes of this EA, those aspects of the human environment are: canola production practices, the physical environment, biological resources, public health, animal feed, and socioeconomic issues.

3.1 Overview of Canola Production and Uses

3.1.1 Rapeseed and Canola Cultivars

The plant common names "rapeseed" and "canola" are often used interchangeably. However, canola and rapeseed are two different crops. Both plants belong to the same family, the *Brassicaceae* (formerly *Cruciferae*), commonly called the "mustard family" (Al-Shehbaz 2001). In addition to rapeseed and canola, several economically important crops are also in the *Brassicaceae* family. For example, mustard greens, kale, turnips, and cabbage are plants in the *Brassicaceae* family (Al-Shehbaz 2001). The *Brassicaceae*, also contains plants considered to be weeds and/or wildflowers.

Taxonomic experts offer a range of opinions, although the genus *Brassica* is typically divided into about 19 species (USDA-NRCS 2016; ITS 2017). While rapeseed and canola are of the same genus and species, i.e., *Brassica napus* L., they are distinct cultivars. The oil that they produce contains different compounds, as described in the following section. The taxonomic relationship and common names used for these plants is summarized in Table 3-1. Rapeseed is the traditional name for oilseed crops in the *Brassicaceae*. Rapeseed may also be referred to as rape, oilseed rape, rapa, and rappi, as well as canola in some cases (USDA-NRCS 2016). The crop plant subject of petition 16-235-01p and this EA is *B. napus* subsp. *napus* (canola).

Table 3-1. The Scientific Names and Corresponding Common Names for Several Species in the Genus *Brassica*.

Scientific Name	Common Name
Brassica napus L.	rapeseed, rape, rape, oilseed rape, rapa, rappi
Brassica napus L. subsp. *napus*	Argentine canola, canola, colza, oilseed rape, and rape
Brassica napus L. subsp. *napus* forma *napus*	Swede rape, winter rape
Brassica napus L. subsp. *napus* forma *annua*	annual rape, summer rape
Brassica napus L. subsp. *rapifera*	rutabaga, Swedish turnip

Source: (Wiersema and León 2013)

Various historic uses of rapeseed oil have been reported, such as for food, lamp oil, and as a steam engine lubricant due to its cold weather tolerance (Shahidi 1990). History suggests rapeseed was cultivated in India well over 2000 years ago, spreading to China and Japan around 1000 years ago, with cultivation in Europe beginning around the 13th century (OECD 2012). In North America, cultivation of canola for vegetable oil and animal feed began in Canada in the 1950s, with significant U.S. production beginning the 1990s.

3.1.2 Canola

Canola is a particular variety of *Brassica* derived from the traditional (i.e., non-GE) breeding of *Brassica napus*, *B. rapa*, and *B. juncea*. This was done to reduce the levels of two types of undesirable natural compounds that can occur in *Brassica* spp., erucic acid and glucosinolates. Erucic acid is a nutritionally undesirable fatty acid. This type of compound is sometimes called an "anti-nutrient." Seed oil from early rapeseed cultivars contained 20% to 50% erucic acid. Studies of rapeseed during the 1950s to the 1970s in several animal species indicate that erucic acid was one of a number of fatty acids that are poorly metabolized by animals (Sauer and Kramer 1983). If fed in large quantities, they were associated with heart disease (myocardial lipidosis) (Sauer and Kramer 1983). In addition, most *Brassicaceae* produce sulphur-containing compounds called glucosinolates. These are also undesirable in animal feeds.[8] While there are about 250 forms of glucosinolates that are produced by plants in 16 families of the order Brassicales, only about 20 glucosinolates are commonly found in *Brassica.* spp. (OECD 2012). A single *Brassica* species will often contain about four types of glucosinolates, although some may contain as many as 15 different glucosinolates. Glucosinolates occur in varying amounts in all tissues of the plant, and are one of the sources of the distinct flavor of many brassicaceous vegetables (e.g., cabbage, kale, collards) and the spicy/hot component of mustards (OECD 2012). High levels of glucosinolates can lower the value of rapeseed meal as animal feed, as many animals find the taste of glucosinolates unpleasant, leading to a reduced feed intake (Khajali and Slominski 2012). Very high levels of glucosinolates in animal feed have also been associated with reduced growth rates in livestock and poultry (EFSA 2008; Khajali and Slominski 2012).

Historically, rapeseed was not widely used as a food or animal feed crop in North America because of the levels of erucic acid and glucosinolates (Lin et al. 2013; CFIA 2016). Research findings indicated the nutritional value of rapeseed oil could be substantially improved if the erucic acid and glucosinolate levels could be reduced (Sauer and Kramer 1983; Lin et al. 2013; CFIA 2016). The recommended target concentration for erucic acid as a fraction of total fatty acid content is < 5% (OECD 2012). During the 1960s, plant breeders using traditional breeding, began developing low-erucic acid *B. napus*, *B. rapa*, and *B. juncea* varieties that also had low glucosinolate content (Lin et al. 2013; CFIA 2016). In 1978, the Western Canadian Oilseed Crushers Association registered low-erucic acid (LEAR) varieties with the name "canola," which is a portmanteau of CANadian Oilseed. *B. napus*, *B. rapa*, and *B. juncea* varieties that are commonly referred to as “0-rapeseed,” or “low-rapeseed.” Those varieties that are both low in erucic acid and glucosinolates are called “00-rapeseed” or “double-low rapeseed.” The latter is the most common variety used worldwide today in production of canola oil for human consumption, and canola meal for animal feed. The term “canola” is used to indicate a 00-rapeseed variety. The present definition of canola is an oil that must contain less than 2% erucic acid and the solid component of the seed must contain less than 30 micromoles per gram of any one or any mixture of 3-butenyl glucosinolate, 4-pentenyl glucosinolate, 2-hydroxy-3 butenyl glucosinolate, and 2-hydroxy-4-pentenyl glucosinolate per gram of air-dry, oil free solid. This standard is approximately 18 micromoles per gram of seed on an air-dry basis.[9]

The FDA classified canola oil produced from LEAR varieties as Generally Recognized as Safe (GRAS) on January 1, 1985 (US-FDA 1985). Canola grade oil is derived from two species of *Brassica*; *B. rapa* and *B. napus*. In North America, rapeseed refers to rapeseed oil used for industrial purposes. Canola, refers to edible canola grown for oil and meal. In other parts of the world, the term “rapeseed” may be used when referring to canola. In this EA, the term rapeseed will be used interchangeably when referencing global statistics and other information, consistent with the use of “rapeseed” outside of North America.

3.1.2.1 Canola Oil

Food use

Canola oil is the third largest source of vegetable oil in the world after soybean and palm oil (USDA-ERS 2016c). In the United States, canola oil is used in frying and baking applications, and is an ingredient in salad dressings, margarine, and a variety of other food products. Canola oil appeals to certain consumers,

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[8] It is not glucosinolates themselves that are directly undesirable in animal feeds. It is some of the breakdown products that are produced by the enzymatic action of a group of enzymes called β-thioglucosidases (myrosinases).

[9] International Consultative Group of Research on Rapeseed: http://gcirc.org/fileadmin/documents/Bulletins/B20/B20%2018Glucosinolate%20Levels.pdf

because it is low in saturated fat, a good source of monounsaturated fats, and is free of artificial trans-fats. More recently, high-oleic canola varieties have been developed that are used in commercial high-temperature frying applications to replace partially hydrogenated oils (Huth et al. 2015).

Industrial Use

Generally, "industrial rapeseed" refers to high-erucic acid rapeseed (HEAR) oil, which has a erucic acid content of at least 45% in the seed oil. A small amount of HEAR oil is produced in the United States, and used for a variety of purposes ranging from lubricants, hydraulic fluids, and penetrating oils to fuel, soap stock, and paints. HEAR oil is biodegradable and is used in applications requiring high heat stability where the risk of oil leaking into waterways or ground water is significant (USDA-ERS 2016b). In the United States, HEAR is grown under contract and is not introduced to the regular grain handling system (USDA-ERS 2016c).

Canola and rapeseed oil are also used for biodiesel production. In the United States, canola oil contribution to biodiesel production increased from 246 million pounds in 2011 to approximately 1 billion pounds in 2014, declining to 745 million pounds in 2015. It was the second largest biodiesel resource during 2011 and 2012, and the third and fourth largest biodiesel source in 2014 and 2015, respectively (EIA 2016). Biodiesel demand in the United States is driven primarily by the renewable fuel standards (RFS) (Schwab et al. 2016), which were created by Congress in an effort to reduce greenhouse gas (GHG) emissions, expand the United States renewable fuels resources, reduce reliance on imported oil, and reduce air pollution.

Unlike the United States, the majority of European cars and trucks run on diesel fuel, and in Europe, rapeseed is the most common plant stock for biodiesel production (Carré and Pouzet 2014). Currently, about 68% of European biodiesel production is derived from rapeseed, 15% from soybean and 6% from palm oil (EBIA 2017). With increasing biofuel mandates, industrial use of rapeseed oil has increased rapidly in the EU from 4.2 million metric tons in 2000 to 10.2 million in 2015 (IndexMundi 2017).

3.1.2.2 Canola Meal

Canola meal is used extensively for animal feed and is second only to soybean meal as a source of protein meal. Canola meal has a lower protein content than soybean meal (34-38% versus 44-49%). Consequently, it is used as feed for animals that do not have high energy or lysine (a type of essential amino acid) requirements. Canola meal is primarily used in feed for cattle, swine, and poultry (USDA-ERS 2016c).

3.2 Acreage and Areas of Canola Production

3.2.1 Global Production

Global canola/rapeseed [10] production has grown rapidly over the past 40 years, rising from the sixth to the second largest oilseed crop in the world (Figure 3-1). For production cycle 2015/16,[11] global rapeseed production was 68.4 million metric tons, following soybeans at 312.7 million metric tons (USDA-FAS 2016).

[10] Canola is called rapeseed in many countries, hence usage of the word rapeseed when referring to global markets. The word canola is used in the United States, Canada, and Australia.

[11] For oilseeds, the marketing year commences April 1 for Japan, July 1 for the European Union and New Zealand, August 1 for Canada and October 1 for Australia. The U.S. marketing year begins June 1 for canola (rapeseed), and September 1 for soybeans and sunflower seed.

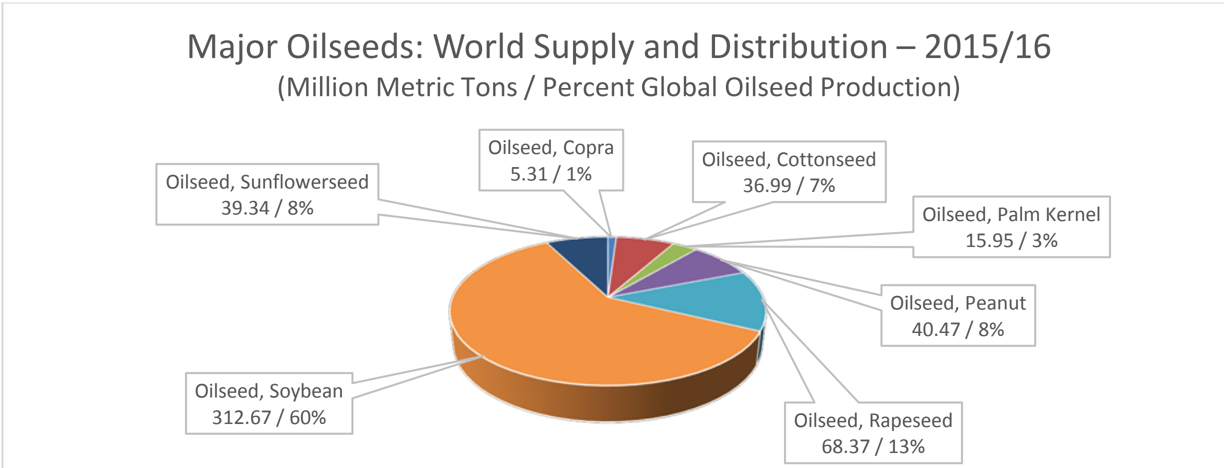

Figure 3-1. Global Oilseed Production by source - 2105/16
Source: (USDA-FAS 2016)
Note: Rapeseed in reference to global production includes canola

The majority of production occurs in the European Union (EU), China, and Canada (Figure 3-2). Commensurate with canola seed production, canola oil was the third most commonly produced vegetable oil in 2015/16 at 27.6 million metric tons, and accounted for approximately 15% of global vegetable oil production (USDA-FAS 2016). Canola meal is currently the second largest source of feed meal after soybean meal. In 2015/16, global production of canola meal was 39.5 million metric tons, which accounted for about 11% of all protein meals (Table 3-2). U.S. canola production is relatively small compared with global output. In 2015/16 U.S. canola seed production was 1.3 million metric tons, which was about 2% of the global supply (USDA-FAS 2016).

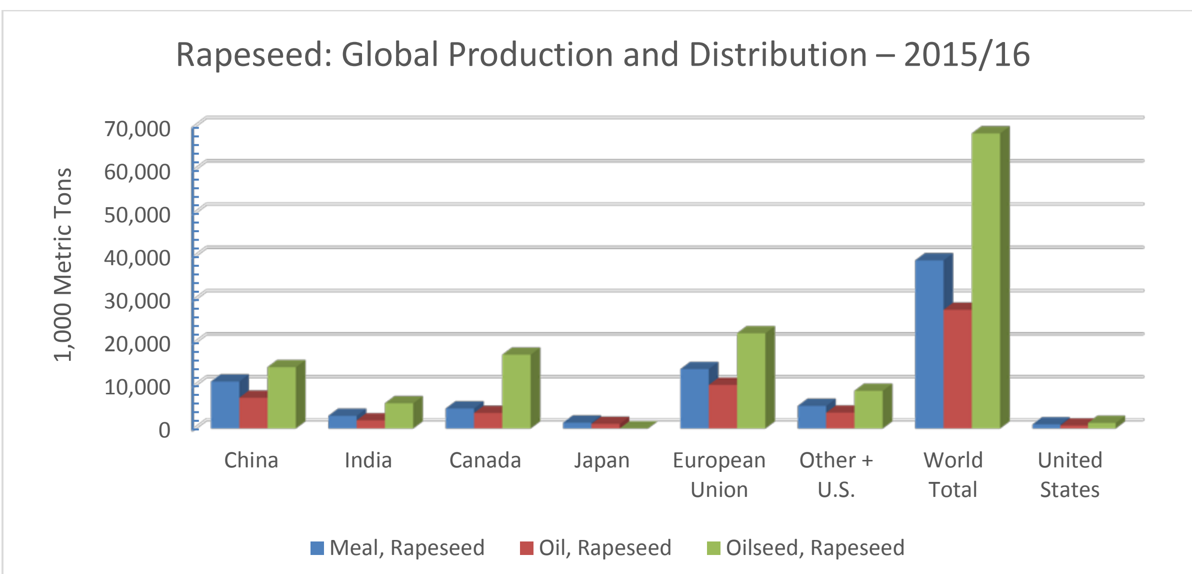

Figure 3-2. Global Production of Rapeseed – 2015/16
Source: (USDA-FAS 2016)
Note: Rapeseed in reference to global production includes canola

Table 3-2. Rapeseed and Products: World Supply and Distribution – 2015/16			
	Meal	**Oil**	**Oilseed**
		Thousand Metric Tons	
China	10,950	7,176	14,300
India	2,953	1,900	5,880
Canada	4,665	3,625	17,200
Japan	1,360	1,075	3
European Union	13,851	10,157	22,199
Other + United States	5,270	3,698	8,785
World Total	39,049	27,631	68,367
United States	971	703	1,304

Source: (USDA-FAS 2016)

3.2.2 U.S. Production: Conventional, GE, and Organic Canola

The FDA extended GRAS status to 00-rapseed in 1985 (US-FDA 1985). This was followed by an increase in U.S. production. While the U.S. share of global canola production remains small, demand has increased. This may be due in part to possible dietary attributes: For example, canola oil has relatively low concentrations of cholesterol and saturated fats, and contains relatively high concentrations of monounsaturated fats compared to other vegetable oils. By 2012, there were 3,995 canola farms in 34 states, totaling about 1.7 million acres (USDA-NASS 2014). While canola is produced in many states, approximately 90% of U.S. production occurs in North Dakota. Primary canola producing states are listed in Table 3-3. Canola produces a bright yellow flower, and it is considered to be an attractive aspect of the agricultural landscape by many people. The optimal temperature for canola growth and development is between 54° F and 86° F; canola production is concentrated in the northern plains.

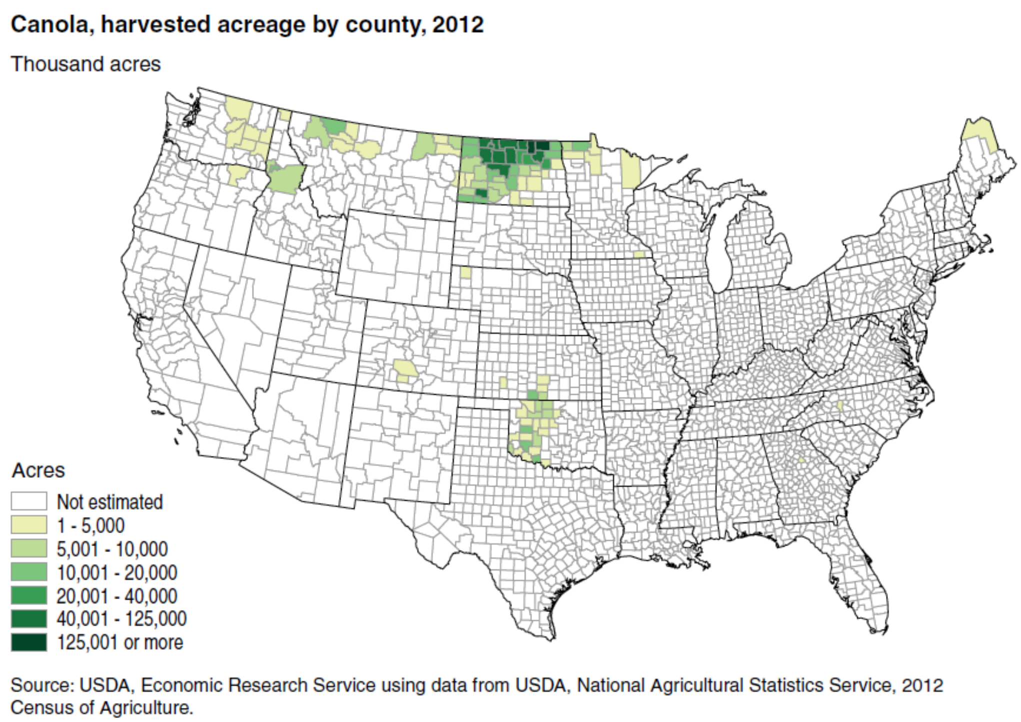

Figure 3-3. Primary Areas of Canola Production in the Conterminous United States – 2012

Table 3-3. U.S. Canola Area Planted, Harvested, and Production – 2015			
State	**Area planted**	**Area harvested**	**Production**
	(1,000 acres)		1000 Metric Tons
North Dakota	1,410	1,400	1,130.35
Oklahoma	140	115	59.47
Montana	82	78	41.04
Washington	37	34	16.96
Idaho	28	27	17.15
Minnesota	23	22	18.33
Oregon	4.3	1.8	1.47
Other States	53	37	19.31
U.S. Total	1,777.00	1,714.50	1,304.08

Source: (USDA-NASS 2016c)

From 1991/92 to 2015/16, harvested canola acreage increased from 147,000 acres to 1.71 million acres, respectively (Figure 3-4). Yields have also steadily increased, from 1,300 lbs/acre in 1991/92 to 1,677 lbs/acre in 2015/2016 (USDA-ERS 2016c; USDA-NASS 2016b).

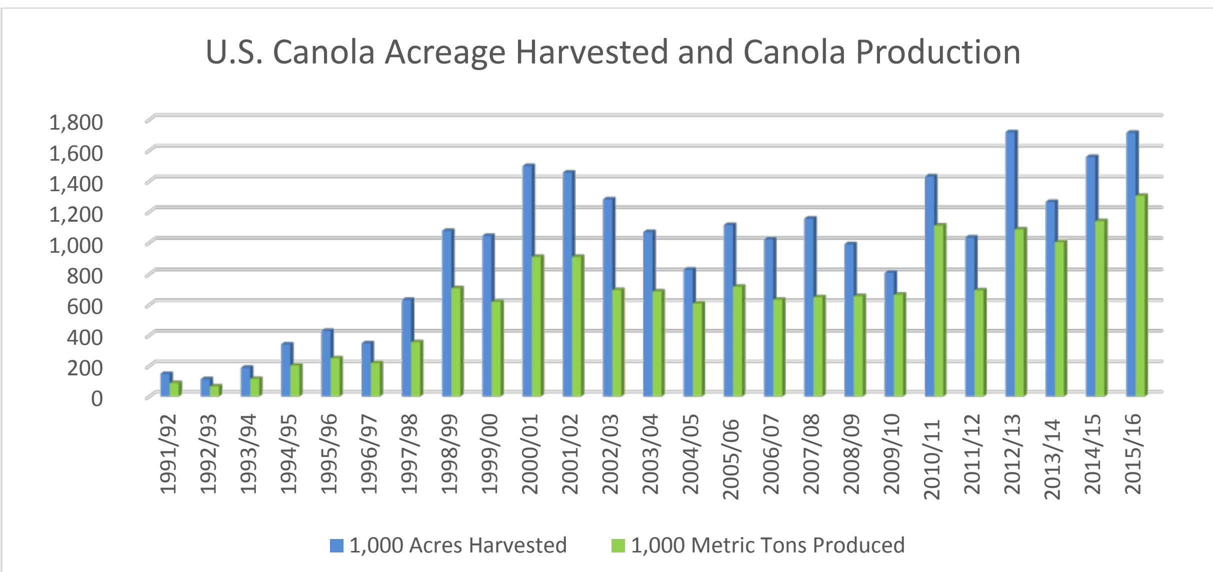

Figure 3-4. Harvested Canola Acreage and Production in the United States, 1991 – 2016
Source: (USDA-NASS 2016c)

Canola is a cool season crop with both spring and winter varieties. In the United States, three different types of canola are grown:

- Spring canola
- Winter canola that requires vernalization (winter chilling to promote spring flowering)
- Winter canola that does not require vernalization

Most U.S. canola is grown in North Dakota, and is mostly spring canola (NDSU 2011). Spring canola is typically planted in March and harvested in September or October (Brown et al. 2008). Winter canola is planted in the fall, overwinters, and is harvested in summer (Brown et al. 2008). Some winter cultivars require vernalization to produce flowers and seed (Brown et al. 2008; NDSU 2011). These are generally produced in the Pacific Northwest, Great Plains, and Midwest regions of the United States. Winter cultivars that do not require vernalization are grown in the Southeast United States where they may be part of a double-crop production system and grown in the cooler portion of the year (Monsanto 2016).

3.2.2.1 Conventional Canola

Approximately, 90% of the United States and Canadian canola crops are GE HR varieties (Fernandez-Cornejo et al. 2016) There are several conventional cultivars available in the United States. These are bred for use in specific areas such as the Pacific Northwest, Great Plains, and Southeast (Brown et al. 2008).

3.2.2.2 GE Canola in the United States

APHIS has issued determinations of non-regulated status for 9 varieties of GE canola, three of which were extensions (Table 3-4). Of these, all are either resistant to glyphosate or glufosinate, save for laurate canola (petition 94-090-01p).

Table 3-4. APHIS Determinations of Non-regulated Status for GE Canola

Petition	Petitioner	Petition Subject	GE Trait	Date of Determination
94-090-01p	Calgene	pCGN3828-212/86-18 and pCGN3828-212/86-23	Laurate production	10/31/1994
97-205-01p	AgrEvo (Bayer CropScience)	T45	Phosphinothricin (glufosinate) tolerant *	1/29/1998
01-206-02p Extension of 97-205-01p	Aventis	Topas 19/2	Phosphinothricin (glufosinate) tolerant & pollination control	1/23/2002
98-278-01p	AgrEvo (Bayer CropScience)	MS8 and RF3	Phosphinothricin (glufosinate) tolerant and pollination control	1/22/1999
01-206-01p Extension of 98-278-01p	Aventis	MS1, RF1, RF2	Phosphinothricin (glufosinate) tolerant	1/23/2002
98-216-01p	Monsanto	RT73	Glyphosate tolerant	1/27/1999
01-324-01p Extension of 98-216-01p	Monsanto	GT2000	Glyphosate tolerant	1/2/2003
11-188-01p	Monsanto	MON 88302	Glyphosate tolerant	9/25/2013
11-063-01p	Pioneer	73496	Glyphosate tolerant	7/18/2013

Source: APHIS Petitions for Determination of Non-regulated Status:
https://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml
*Herbicides that contain glufosinate (also referred to as Phosphinothricin) or glyphosate may be sold under several product names.

There are currently three primary herbicide resistant (HR) canola varieties available to producers in the United States. Two were developed through genetic engineering, and one through mutagenic breeding.

- Bayer CropScience LibertyLink® and InVigor® GE canola – glufosinate resistant
- Monsanto's Roundup Ready® GE canola – glyphosate resistant
- Pioneer Hybrid's Clearfield® canola – imidazolinone resistant (Clearfield canola was developed through mutagenesis and selection).

There is also a non-GE canola variety that is tolerant to herbicides that contain sulfonylurea-type active ingredients (SU) that is available in the United States; it is marketed by Cibus and sold as SU Canola™.[12]

3.2.2.3 Organic Canola

As of 2015, there were only 2 certified or exempt organic canola farms in the United States, one in North Dakota, the other in Pennsylvania. Acreage and economic data for this production is not available in the USDA's 2015 Census of Agriculture; it was withheld by producers to avoid disclosing data for individual farms (USDA-NASS 2014, 2016d). In brief, organic canola production in the United States is currently limited geographically, and comprises a small proportion of the total canola production. Organic canola production is further discussed in Section 3.8 – Socioeconomics.

3.3 Agronomic Practices and Inputs

Canola production involves the use of a range of agronomic practices and inputs. These practices and inputs may include crop rotation (in some cases double-cropping), tillage, planting, irrigation, fertilizers, pesticides, and harvesting. The practices and inputs that are used by growers depends on several factors such as local conditions, soils, and the weeds and crops pests that may be present. Pesticide use and other practices are often necessary to protect crops from weeds and crop pests. However, they are potentially harmful to humans and the environment when not used properly. It is unlawful to use a pesticide in a way that is not in strict accordance with its EPA approved label instructions. This section considers the agronomic practices and inputs used in the production of canola.

3.3.1 Tillage

Tillage is primarily used to control weeds and soil-borne pests and disease. Also, certain tillage practices may help to dry and warm the soil prior to planting. The tillage systems employed in the United States are conventional tillage, reduced tillage, and conservation tillage; to include no-till (Harper 2017). These practices are characterized, in part, by the amount of plant residue that is left remaining on the field after harvest and the amount of soil disturbance that they cause (Harper 2017). The development of and refinement of various tillage-seeding systems is an active area of research. What tillage practices are used and to what extent has substantial effects on soil quality, erosion, and the surrounding environment, and tillage operations can be costly and time-consuming for growers to implement (Brown et al. 2008; Wallander 2015; Harper 2017). Therefore, decisions concerning the amount and type of tillage to deploy are key considerations for growers and for policymakers who oversee agricultural and environmental programs. These decisions involve the consideration of a wide range of inter-related factors, such as desired crop yield, fuel and other input prices, weather and climate patterns, current and possible future commodity prices, air and water quality issues, the extent of weed and crop pests, and the erosional potential of a particular production area.

Conventional tillage involves intensive plowing leaving less than 15% crop residue in the field; reduced tillage leaves 15 to 30% crop residue; and conservation tillage involves leaving at least 30% crop residue (USDA-ERS 2000). No-till systems leave the crop residue on the production area, unless those residues are removed for other reasons such as biomass production (USDA-ERS 2000). Over the long-term conventional tillage may lead to soil erosion and run-off. This reduces soil quality and can impact water

[12] Cibus – Products: http://www.cibus.com/products.php

resources (USDA-ERS 2000). Reduced tillage lessens soil disturbance and erosional potential, and can in some cases improve soil quality. Conservation tillage systems, such as direct seeding and no-till, are the least intensive and, as the name implies, are designed to improve or maintain soil quality and conserve topsoil (Fernandez-Cornejo et al. 2012; Roth 2015). Conservation tillage provides a variety of agronomic and economic benefits, such as reduction in fuel use due to fewer tillage passes over the field, preservation of soil organic matter, and reductions in soil erosion and water pollution (Fernandez-Cornejo et al. 2012; Roth 2015).

Canola can be cultivated using conventional tillage, reduced, or conservation tillage. Conservation tillage, to include no-till, is often employed for canola production in North Dakota and Canada (Gusta et al. 2011; Awada et al. 2014). Tillage practices in North Dakota for canola production are estimated to be around 75% no till and 25% conventional till (S&T 2010). A survey of 571 GE canola farmers in Canada found that many producers have moved to minimum or zero-tillage operations (Gusta et al. 2011), with more than half of those surveyed indicating they no longer use tillage in their cropping system, with little difference in adoption rates between the three GE HR technologies (Table 3-5). While GE HR canola production correlates strongly with conservation and no-till practices, a clear causal relationship between the production of GE HR canola and minimum or zero-tillage hasn't been established (Gusta et al. 2011; NAS 2016; USDA-ERS 2016b). This considered, where GE HR canola is produced, farmers largely employ conservation and no-till practices.

Table 3-5. Tillage Practices in GE HR Canola Production

Tillage method	Clearfield (n=40)	Liberty Link (n=135)	Roundup Ready (n=154)	Average
Zero-till	60.0%	53.3%	50.6%	53.5%
Cultivation	22.5%	20.0%	24.0%	21.8%
Harrow	12.5%	11.9%	9.7%	10.6%
Cultivation and harrow	5.0%	14.8%	15.6%	14.1%

Margin of error: Clearfield® 15.5%; Liberty Link™ 8.4%; Roundup Ready™ 7.9%; Total 5.3%

Source: (Gusta et al. 2011)

3.3.2 Crop Rotation

Crop rotation is used to maximize economic returns and sustain the productivity of an agricultural operation over time. The benefits of rotating crops include: (1) maintaining or increasing soil organic matter; (2) reducing the prevalence of insect pests and diseases; (3) controlling weeds; (4) limiting the potential for weeds to develop herbicide resistance; (5) and controlling volunteer plants, and other economic and agronomic benefits (CCoC 2016b).

Because of issues related to disease and insect pests it is recommended that canola and other *Brassica* crops not be planted on a given soil more often than once every four years (CCoC 2016b), and many GE canola farmers follow 3 and 4 year rotation schedules (Gusta et al. 2011). In the Northern Plains, canola is typically rotated with small grains such as wheat, barley, oats, and flax, although rotations vary considerably and include a variety of other crops (USDA-ERS 2016c). Crop rotation is necessary to suppress canola diseases such as sclerotinia and phoma blackleg. Likewise, when canola is incorporated in small grain crop rotation systems, disease incidence on cereal crops decreases and product quality increases (Brown et al. 2008). In the United States, wheat following canola has significantly less take-all root rot disease[13] than wheat planted after plowed or burned cereal stubble (Brown et al. 2008). Compared to continuous cereal production, 17% to 20% yield increases have been found when canola crops are

[13] See http://www.apsnet.org/edcenter/intropp/lessons/fungi/ascomycetes/Pages/Takeall.aspx

included in rotation with wheat (Brown et al. 2008). Why certain canola rotations may result in yield increases is not fully understood. The glucosinolates found in the non-seed plant parts break down in soil into compounds that have insecticidal, nematicidal, and fungicidal properties (Brown et al. 2008); hence, a possible pest and disease suppressant effect may be occurring. In addition, these practices may improve soil structure and increases soil fertility. Canola has a long taproot that can improve soil pore structure and canola can produce as much crop residue, as certain cereal crops (Brown et al. 2008). A canola crop yielding 2,000 kilograms per hectare of seed produces approximately 3,000 to 4,000 kilograms per hectare of plant residue, which contributes organic matter to the soil (Brown et al. 2008).

Many site-specific factors can affect the crop rotation practices chosen, including the soil type and conditions present in a given field, the expected commodity price, and the costs of labor, fuel, seed, and agricultural inputs (Duffy 2015; Wallander 2015). Market factors, particularly commodity and input prices, can greatly affect crop rotation decisions.

3.3.3 Agronomic Inputs

3.3.3.1 Fertilizers

Canola producers apply nitrogen (N), phosphorus (P), sulfur (S), and potassium (K) before or at planting. Canola N, P, and K requirements are similar to those of small grains, although canola's S requirements are higher than most crops (Franzen and Lukach 2016). Fertilizer application rates vary depending on the region and inherent soil characteristics, and depend on the potential yield per acre of a given canola cultivar; the higher the yield potential, the greater the need for sufficient nutrients. For instance, the yield potential of winter canola is higher than spring canola, so soil fertility requirements are higher (KSU 2012).

Recommended fertilizer requirements for canola are similar to those for winter wheat, with two exceptions. Canola needs slightly more N and S than comparable yields of wheat (KSU 2012). For the Southern Great Plains total plant N needs for maximum yield are around 120 to 300 lbs/acre, depending on the yield potential of the cultivar and area. N is applied at rates of around 5 lbs/acre with seed, and supplemented to maintain required soil N level. Any amount exceeding plant N needs decreases yield (KSU 2012).

Canola and mustard are good scavengers of P, and a starter fertilizer rate of 10 to 50 lbs P_2O_5/acre is recommended for most soils; K applications rates are about the same, around 20-50 lbs/acre of K_2O (KSU 2012). Canola has special requirements for sulfur. For example, a 2,000 lb/acre canola crop contains about 12 lbs of sulfur/acre in the straw and 15 lbs of sulfur /acre in the seed. A comparable wheat crop, on the other hand, contains only 7 lbs/acre in the straw and 5 lbs/acre of sulfur in the seed (KSU 2012). The consequences of low soil S levels are quite serious in canola production, as low S can result in crop failure (KSU 2012). In the Southern Plains region, recommended sulfur application rates are in the 10 to 30 lb/acre range. For the High Plains, soil fertility requirements are similar to that of the Southern Plains, however, recommended application rates for winter canola in the High Plains are somewhat higher (KSU 2012).

3.3.3.2 Insecticides and Fungicides

Insecticides and fungicides are commonly applied to U.S. canola crops to control a range of plant pests and diseases. Canola is subject to damage by insects throughout its developmental stages, with several species (i.e., beetles, moth larvae, midges) potentially feeding on the seeds, roots, stalk, leaf, or seed pod. Insects considered pests to canola are managed by insecticide treatment of seeds or soil, foliar application of insecticides, and use of crop rotation practices. In many regions where canola is grown it is economically beneficial to use seeds treated with insecticides to prevent flea beetle damage, and fungicides to help control seed-borne blackleg disease, sclerotinia (fungal pathogen) stem rot, and damping-off (wirestem) (Brown et al. 2008).

Fungicidal crop protection products containing strobilurin, cyazofamid, and triazole are commonly used to control plant disease in canola. Triazole products such as ipconazole and metconazole are registered by the EPA as soil and foliar fungicides (US-EPA 2004, 2014b, 2015f). Strobilurin fungicides are also used to control pathogenic fungi such as mildews, molds, and rusts (US-EPA 2016f).

Neonicotinoid insecticides (NNI) are nicotine-based compounds that are formulated into insecticides that can be applied to seeds or soils, typically during the early stages of growth (Douglas and Tooker 2015; Sekulic and Rempel 2016). Examples of NNI include, products that contain imidacloprid, clothianidin, and thiamethoxam. Due to their efficacy in the protection against insect pests, such as flea beetles, NNI seed treatments have been commonly used in canola production in Western Canada (Sekulic and Rempel 2016), and have increased in use in the United States since 2003 (Douglas and Tooker 2015). Due to their systemic activity, NNI can be applied to seeds or soils at low rates and provide extended protection to crops during the early growth stages (Sekulic and Rempel 2016). This reduces the number of foliar insecticide applications required. In general, foliar applications are at much greater per-acre application rates and may pose more hazards to non-target organisms than soil or seed treatments (Sekulic and Rempel 2016). There is some evidence that NNIs can adversely affect certain sensitive bird species. At concentrations relevant to field exposure scenarios from seed treatments, imidacloprid and clothianidin can impact certain granivorous bird species under test conditions (Gibbons et al. 2015), particularly smaller species such as house sparrows and canaries. The EPA examined the estimated daily intake of clothianidin, assuming that birds only eat a diet of treated seeds (DeCant and Barrett 2010). They reported that clothianidin, when used to treat oilseed rape, could reduce the survival of certain small birds (DeCant and Barrett 2010; Gibbons et al. 2015). A review by Mineau and Palmer suggests that the risks of acute intoxication with imidacloprid applied on oilseeds or cereals are such that birds need only ingest a small amount of treated seeds (Mineau and Palmer 2013). Whether or not birds avoid eating treated seeds, or the extent to which NNI ingestion may be reduced by birds discarding the outer seed husks is not fully understood. Incidents of bird poisoning by imidacloprid-treated seed have been documented, suggesting that NNI treated seeds can present risks to certain species of birds (Gibbons et al. 2015).

Pollinators are critically important to agricultural production and to plant and animal communities. NNI are also potentially harmful to pollinator species such as honeybees (Douglas and Tooker 2015; Sekulic and Rempel 2016). In June 2014, the White House issued a memorandum establishing a Pollinator Health Task Force, co-chaired by the USDA and the EPA, to create a National Pollinator Health Strategy that promotes the health of honey bees and other pollinators, such as birds, bats, and butterflies, and other insects. In January 2017, the EPA issued preliminary pollinator-only risk assessments for the neonicotinoid insecticides clothianidin, thiamethoxam, and dinotefuran and an update to its preliminary risk assessment for imidacloprid (US-EPA 2017). The EPA is proposing a plan to prohibit the use of neonicotinoids and other pesticides that are toxic to bees when crops are in bloom and bees are under contract for pollination services. The plan also recommends that states and tribes develop pollinator protection plans and best management practices.

3.3.3.3 Herbicides

Compared to other crops in the United States (e.g., corn, soybean, wheat, barley), there are relatively fewer herbicide options available to canola growers (Brown et al. 2008). Herbicides registered by the EPA for use on canola are summarized in Table 3-6.

Table 3-6. EPA Registered Herbicides for Use on Canola			
Herbicide (Trade Name)	**Application**	**Weeds**	**Mode of Action**
Ethalfluralin (Sonalan®)	Preplant incorporated	Annual broadleaf, foxtail, barnyard grass	Microtubule inhibitor
Trifluralin (Treflan™)	Preplant incorporated	Annual broadleaf, foxtail, barnyard grass	Microtubule inhibitor
Clopyralid (Stinger®)	Foliar spray at 2 to 6 leaf stage	Annual and perennial broadleaf	Synthetic auxins (plant growth hormone)
Quizalofop (**Assure® II**)	Foliar spray	Annual grasses	Inhibition of acetyl CoA carboxylase (ACCase)
Sethoxydim (Poast®)	Foliar spray	Annual grasses	Inhibition of acetyl CoA carboxylase (ACCase)
Clethodim (Select®)	Foliar prior to bolting	Annual grasses	Inhibition of acetyl CoA carboxylase (ACCase)
Glufosinate - for LibertyLink® Cultivars	Foliar until early plant bolting	Annual broadleaf and grasses	Glutamine synthase inhibitor
Glyphopsate - for RoundupReady® cultivars	Foliar from seed emergence to plant bolting	Annual broadleaf and grasses	EPSP synthase inhibitor
Imazamox (Beyond®) - for imazamox tolerant cultivars	Apply foliar from seedling emergence to full bloom	Many annual broadleafs and grasses	Inhibition of acetolactate synthase ALS (acetohydroxyacid synthase AHAS)

Source: (Brown et al. 2008)

Herbicide use is a key factor in decisions regarding canola crop rotations. Canola is highly sensitive to carryover and residual amounts of herbicides in the soils that may be present from prior applications to other crops. Growers need to know the herbicide use history of fields before planting canola. Plant damage from herbicide carryover can cause yield loss and in some cases crop failure. Therefore, many herbicides used in cereal crops have plant back restrictions for canola, such as minimum lag periods required before canola can be planted (Brown et al. 2008). These periods vary among herbicides. For example, Buctril (active ingredient bromoxynil) has a 30-day restriction, while Pursuit (active ingredient imazethapyr) requires a 40 month lag period and a field bioassay before canola can be planted. Pursuit, used commonly on legume crops in the Pacific Northwest, has been found to damage canola crops planted up to six years after the last Pursuit application (Brown et al. 2008). Hence, soil type, rainfall, and other environmental conditions can affect canola plant back restrictions.

Canola farmers can bypass some of the plant back restrictions by growing GE herbicide resistant cultivars. For example, the standard plant back restriction for glufosinate is 120 days, but there is no plant back restriction if HR LibertyLink® canola cultivars (glufosinate resistant) are planted (Brown et al. 2008). For this and other reasons the crop variety and the herbicide used must be closely coordinated by growers.

Glufosinate

Phosphinothricin, also known as glufosinate, to which MS11 canola has been genetically engineered to be resistant, is a naturally occurring compound. It was isolated from the soil bacteria in the genus *Streptomyces*. It is formulated into products that are typically used as a non-selective, foliar-applied herbicides. Products may be registered for pre-plant and post-emergence control of grass and broad leaf weeds in crops and in certain non-crop sites (US-EPA 2016d).

Herbicides containing the active ingredient glufosinate were first registered by the EPA in 1993. These products have been used on over thirty crops, and for other approved uses, between 1998 and to the present. Glufosinate-containing herbicides are currently registered for use on several crops, including apples, berries, canola, citrus, com, cotton, currants, grapes, grass grown for seed, potatoes, rice, soybeans, sugar beets, and tree nuts (US-EPA 2016d). Non-crop use sites include weed control on golf course turf, residential lawns, industrial and residential landscape plantings, utility and roadside rights-of-way, and timber site preparation for tree plantings (US-EPA 2016d). Glufosinate-containing herbicides are currently registered for use on rice in the United States, but they are not used domestically for that purpose. This is because Bayer CropScience, the registrant of glufosinate, submitted a request to the EPA to terminate the use on rice on December 3, 2015.

From 2010 –2014, more than 3.8 million pounds of glufosinate were applied to field, nut, fruit, and vegetable crops in the United States (US-EPA 2016d). Over this period, usage increased annually. Pounds applied and acres treated with glufosinate have more than tripled over this period. This is due in part to the increasing number and geographic ranges of weed species that are resistant to other herbicides, and also the introduction and increased production of glufosinate resistant crops (US-EPA 2016d). Currently, over 5 million pounds of glufosinate are used annually on more than 10 million agricultural acres; most of which are in the central United States, Southeast, California's central valley, Oregon, and Washington state (Figure 3-5). Use on soybean, cotton, and corn account for more than 75% of total glufosinate use. Glufosinate-containing herbicides are applied to 9% of cotton acres grown, and to 2% of the soybean and corn acres grown. These glufosinate products are also used on several other crops; more than 40% of pistachios and canola crops are treated with glufosinate; and 20% of almonds, wine grapes, and hazelnuts (US-EPA 2016d).

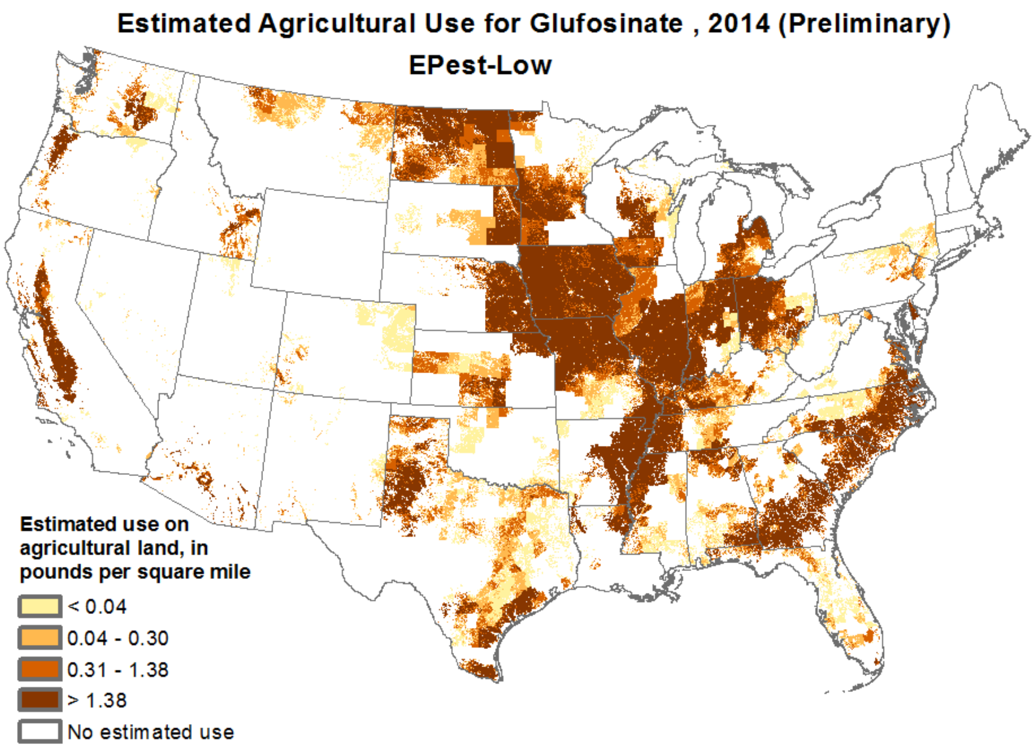

Figure 3-5. Glufosinate Use in the Conterminous United States - 2014
Source: (USGS 2016)

The application of herbicides must be done in strict accordance with the instructions on their labels. Application rates cannot exceed label rates and other restrictions may apply. Within these limits, the application rates and timing of applications for glufosinate in agriculture vary among field and vegetable crops, which are generally treated at lower rates than fruit and nut crops (US-EPA 2016d). For example, 90% of the com and cotton acres are treated with glufosinate at an average rate of 0.6 pounds (lbs) of active ingredient (a.i.) per acre, while 90% of almond acres are treated at a rate of 1.4 lbs a.i./acre. Several other crops, including apples, cherries, grapes (raisin, table, and wine), oranges, peaches, pears, pistachios, and walnuts are treated with glufosinate at rates greater than 1.0 lb a.i./acre (US-EPA 2016d).

Herbicides that contain glufosinate are often applied with a boom-mounted pressurized sprayer that dispenses a medium droplet size spray. However, they can be occasionally applied aerially on canola, com, cotton, potato, and soybean. From 2005 – 2012, less than 1% of the total amount of glufosinate-containing herbicides that were applied were applied from the air, with the largest part on potatoes (22% of potato crops are treated with glufosinate by air) (US-EPA 2016d). Glufosinate-containing herbicides may be applied more than once per year to agricultural crops if this is necessary to achieve effective weed control. However, application frequencies and rates cannot exceed those on the label and other restrictions may apply. The maximum application frequency allowed by the EPA is six applications per year (US-EPA 2016d). Most crop production systems employ two or more applications. The EPA is currently reviewing glufosinate and issued preliminary ecological and human health risk assessments in 2016 (US-EPA 2016d).

3.3.4 Weed Resistance Management

Herbicides are the most widely used crop protection agricultural chemical. Forty nine states report the presence of herbicide resistant weed (HRW) populations. This widespread and growing problem is requiring adjustments in production practices (US-EPA 2016d). This is not a recent concern, however. Herbicide resistant weed populations have been occurring since the advent and wide-spread use of chemical herbicides began in the 1950s. However, it should be noted that weeds can become resistant to other control methods as well as to herbicides. Currently, there are 81 reported HRW species in the United States (Heap 2016). Some of these HRW are also resistant to more than one herbicide mode of action (MOA). There are 156 unique cases of HRW (species by MOA). In the United States, 11 weed species have populations with confirmed resistance to 2 MOAs, 5 species with confirmed resistance to 3 MOAs, and 3 species with confirmed resistance to 4 MOAs (Heap 2016). Weeds have developed resistance to 18 of the 26 MOAs that are currently available, and by that, resistance to the 160 herbicide products that contain those active ingredients with those MOAs (Heap 2016), which reduces the number of weed control options available to growers. There have been no herbicides with completely novel MOAs developed and commercialized in recent decades. Consequently, growers cannot rely on products that contain active ingredients with novel MOA to control HRWs. Currently in the United States, there is one weed species reported to be resistant to herbicides that contain glufosinate, Italian ryegrass (*Lolium perenne* ssp. *multiflorum*), with populations in California and Oregon.

Strategies for managing and avoiding the development of HRW populations are becoming increasingly well-developed for use in U.S. agriculture. Crop producers using herbicides, including canola producers, are using integrated pest management (IPM) practices (this can sometimes be referred to as integrated weed management in the specific case of weeds) to address HRW management concerns. These practices are recommended by the crop protection and crop seed industries, the USDA, university extension services, the EPA, state departments of agriculture, Weed Science Society of America, and others (WSSA 2016b). Developers of GE HR canola varieties provide stewardship and HRW management guidance to canola producers (e.g., (Bayer-CropScience 2016; Pioneer 2016)), which is in accordance with and responsive to EPA requirements (US-EPA 2016c) and WSSA recommendations (WSSA 2016b). In

2016, the EPA issued PR Notice 2016-XX, *Draft Guidance for Herbicide-Resistance Management, Labeling, Education, Training and Stewardship* (US-EPA 2016c). PRN 2016-XX indicates that the EPA is considering providing HRW management guidance for herbicide labeling, education, training, and stewardship for herbicides undergoing registration review for existing labels and for label registration (i.e., new herbicide active ingredients, new uses proposed for herbicide-resistant crops, or other case-specific registration actions).

3.3.5 Pest and Pathogen Resistance Management

Economically important canola diseases include the fungal diseases blackleg (*Leptosphaeria maculans*) and sclerotinia stem rot (*Schlerotina sclerotiorum*), and the protist disease clubfoot (*Plasmodiophora brassicae*) (NDSU 2011). In North America, the crucifer flea beetle (*Phyllotreta cruciferae*) and striped flea beetle (*Phyllotreta striolata*) are the most significant insect pests of canola (NDSU 2011; KSU 2012).

As with most all crops, a key strategy for controlling pests and disease is the use of canola cultivars with resistance to the pest or pathogen, as resistant cultivars are the most efficacious means for reducing crop losses. There are no GE insect or disease resistant canola varieties currently available. However, various canola cultivars have been developed through traditional breeding that are resistant to common pathogens such as sclerotinia and clubroot disease (BrettYoung 2017). Concomitant with the increased acreage of canola over the last 20 years, and often shorter crop rotations, resistant strains of *Leptosphaeria maculans* (blackleg disease) have evolved. Because resistance in *Schlerotina sclerotiorum* and *Plasmodiophora* (clubfoot) may likewise evolve, plant breeders continually strive to develop new canola varieties resistant to emerging populations of pathogen variants (Minogue 2016).

In addition to the use of disease resistant canola cultivars, canola producers may use fungicides to control blackleg disease, sclerotinia, and clubfoot disease (NDSU 2011; KSU 2012). Insecticides are likewise used to control pests such as the flea beetle. Pesticides must be used in strict accordance with their label instructions. Canola producers using fungicides, bactericides, and insecticides must do so in accordance with EPA registration and label requirements.

In 2016, the EPA issued PRN 2016-X, *Draft Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling* (US-EPA 2016e). PRN 2016-X revises and updates PRN 2001-5, and applies to all conventional pesticides (i.e., fungicides, bactericides, insecticides, and acaricides). The guidance is intended to provide:

- additional guidance for resistance management on pesticide labels;
- references to external technical resources for guidance on resistance management; and
- updated instructions on how to submit changes to existing labels in order to enhance resistance-management language.

In the EPA's *Guidance on FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants*, any substantiated incidents of pest resistance for any regulated pesticide product must be reported to the EPA.[14] This reporting requirement is in accordance with FIFRA Adverse Effects Reporting Section 6(a)(2), which requires pesticide product registrants to submit information about adverse-effects of their products to the EPA.

3.3.6 Volunteer Management

Seeds from previous crops left on the soil may subsequently emerge voluntarily. The management of volunteer HR canola, particularly stacked-trait varieties (those varieties that contain more than one trait),

[14] See https://www.epa.gov/pesticide-registration/prn-98-3-guidance-final-fifra-6a2-regulations-pesticide-product-registrants

can be a challenge in some canola cropping systems (DuPont-Pioneer 2015; Fleury 2015). Volunteers, whether GE or non-GE, reduce crop yield and can act as hosts for diseases such as blackleg, clubroot, and sclerotinia (DuPont-Pioneer 2015; CCoC 2016a). Volunteer canola occurs when seeds are lost prior to or during harvest. This can be 10% or more of the seeds produced by canola. These seeds can mature in-crop and add to the seedbank in the soil (Gulden 2007; Fleury 2015).

Volunteer GE canola varieties that have single HR traits may acquire additional traits from outcrossing with plants that contain other traits. The progeny of these outcrossings can become “stacked” with two or more traits. Depending upon the traits, this can confer resistance to multiple herbicides with several MOAs, such as herbicides that contain glyphosate, glufosinate, and/or imidazolinone (DuPont-Pioneer 2015; CCoC 2016a). Where volunteers occur, they are controlled primarily with herbicides. Because there can be multiple flushes of volunteers during the growing season, volunteer canola control may require the use of herbicides with residual activity, and/or multiple applications of an herbicide or herbicides without residual activity to provide season-long control (Gulden 2007; Fleury 2015). For stacked-trait volunteers, the use of herbicides with MOAs that the volunteers are not resistant to is typically required (DuPont-Pioneer 2015; Fleury 2015).

Management of volunteer crop plant control is a standard agronomic practice. However, with the expansion of canola production and acreage in the United States and Canada, particularly HR varieties that comprise around 90% or more of canola acreage in both countries, and the fact that canola requires rotation with other crops for successful production, volunteer management has emerged as a frequently required component of canola crop management (e.g., see (Gulden et al. 2003; DuPont-Pioneer 2015; CCoC 2016a)).

3.4 Physical Environment

3.4.1 Soils

In an agricultural setting, concerns regarding soils are the potential for agronomic practices and inputs to affect soil fertility; erosional capacity; off-site transport of sediments, pesticides, and fertilizers; and disturbance of soil biodiversity. Tillage, cover crops, crop rotation, and pesticide and fertilizer inputs can influence the biological, physical, and chemical properties of soil and have a substantial impact on soil fertility, crop yield potential, and the erosional capacity of soils (Baumhardt et al. 2015). Among these, tillage is the primary practice that can facilitate topsoil loss via wind and water erosion; a process that can take centuries to reverse. Moisture, soil organic matter, and carbon loss can also be exacerbated by tillage (VandenBygaart et al. 2015).

Historically, conventional tillage has served as a tool for incorporating crop residues, controlling weeds, and suppressing soil borne diseases. Such practice however has not always resulted in effective soil management and has contributed to substantial soil erosion in some areas of the United States. Soil erosion not only increases fertilizer requirements and production costs, it leads to impaired air and water quality. Soil erosion occurs in all areas of the United States but is more concentrated in those regions where the percentage of total area in cropland is highest and a larger proportion of the land is highly erodible (Magleby et al. 1995; USDA-NRCS 2010). Excessively eroding cropland soils are concentrated in the Midwest, Southern High Plains of Texas, and Northern Plain States, to include certain areas of North Dakota where canola production is concentrated (Figure 3-6). Where soil erosion occurs by natural processes, the rates of which are determined by soil type, local ecology, and weather, certain tillage and cover crop practices have substantial impacts on the erosion potential of soils. Because susceptibility to erosion is a key concern on more than half of U.S. cropland (USDA-NRCS 2010), soil management and conservation are important components in crop production.

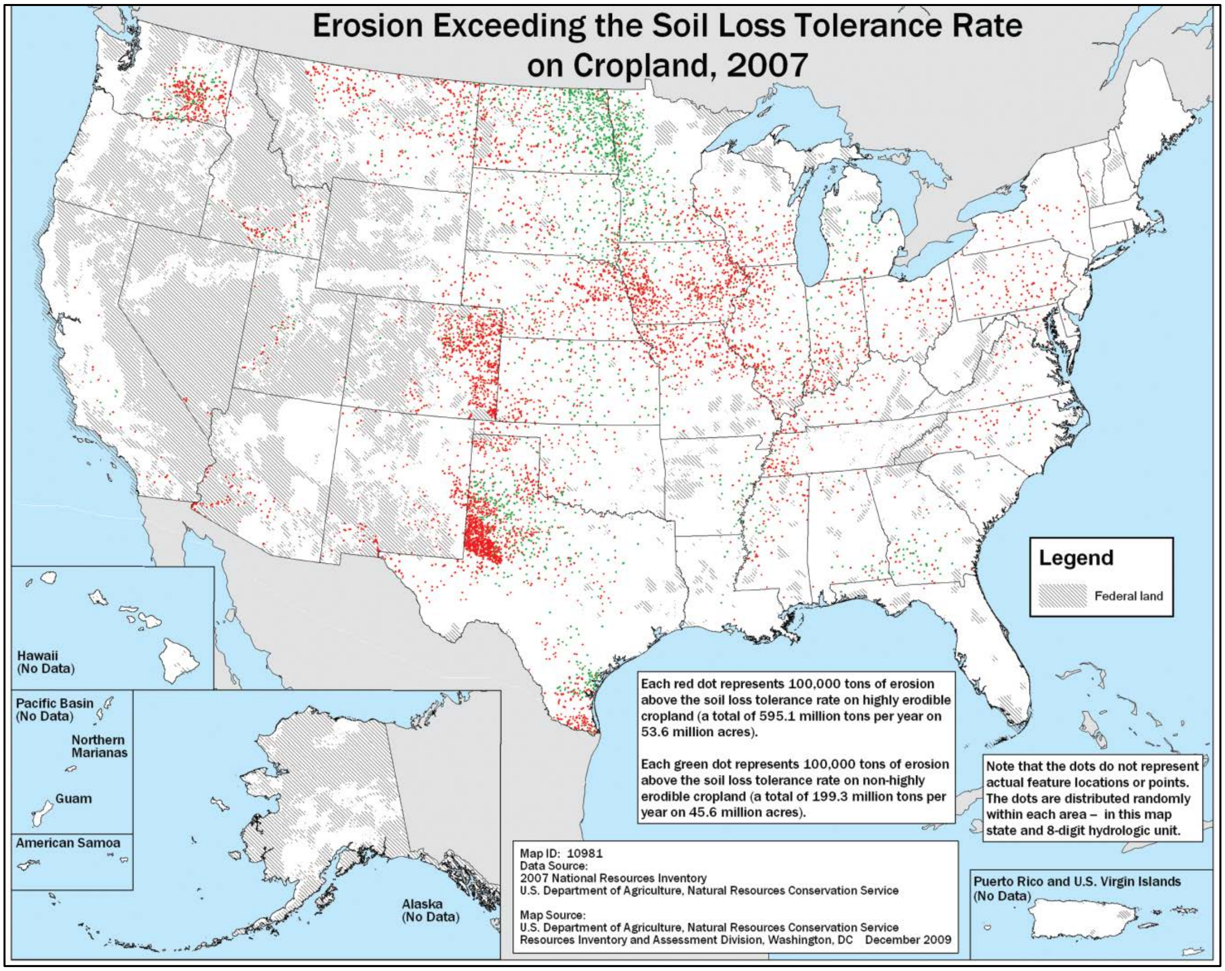

Figure 3-6. Locations and Status of U.S. Croplands Subject to Erosion

Source: (USDA-NRCS 2011)

The current management perspective for sustaining topsoil and soil fertility is to use tillage practices that retain crop residue, employ beneficial crop rotations, and cover crops (Baumhardt et al. 2015). Crop residue management strategies that minimize tillage (i.e., no-till and conservation tillage) can foster the sustaining of soils under intensive cropping systems by maintaining soil organic matter and reducing the erosional capacity of soils (VandenBygaart et al. 2015).

Since 1985, conservation programs have specifically targeted highly erodible lands in the United States. Growers have been implementing more conservation tillage practices and less conventional practices (USDA-NRCS 2006a; CTIC 2015). In addition, they are adopting the use of cover crops to conserve soils and soil quality (Myers 2015). Erosion has significantly declined (USDA-NRCS 2010). Since the mid-1980s, as conservation tillage and no-till practices increased, total soil loss on erodible croplands in the United States decreased from 462 million tons per year to 281 million tons per year, or by 39 % as of 2005 (USDA-NRCS 2006b). In the United States, no-till increased from less than 6% in 1990 to almost 24% in 2008, and conservation tillage increased from about 26% to 42% during the same time period (Baumhardt et al. 2015).

While both GE crops and the percentage of cropland farmed with no-till and reduced-till practices have concurrently increased over the last two decades, a 2016 National Research Council report concluded that a direct causal relationship is difficult to determine (NAS 2016). The adoption of no-till and reduced-till practices began in the 1980s, with the rate of adoption increasing over the years due to a combination of factors: the advent of relatively lower cost and effective herbicides, developments of other technologies that facilitate direct seeding (used in canola production), and, in the United States, soil conservation policy introduced with the Food Security Act of 1985 (NAS 2016). Hence, the initial expansion of no-till and conservation tillage predate the release of the first GE HR crops in the late 1990s (NAS 2016).

While a distinct causal relationship between GE HR crops and the adoption of reduced tillage practices by growers has not been clearly established, the availability of GE HR technologies are recognized as facilitating reduced-till and no-till cropping systems. GE HR systems can employ non-residual, broad-spectrum, foliar applied herbicides as a 'burndown' pre-seeding treatment, followed by a post-emergence treatment once the crop has become established. This has proven to be an effective and commercially attractive weed control system for many crop producers (Beckie H.J et al. 2011; Brookes and Barfoot 2015c): The agronomic and economic advantages provided by certain GE HR crops have, in part, contributed to their widespread adoption, which is, in turn, associated with utilization of reduced-till and no-till cropping systems (Beckie H.J et al. 2011; Gusta et al. 2011; Brookes and Barfoot 2015c).

This is particularly evident with expansion of GE HR canola cropping systems. As described in Section 3.3 – Agronomic Practices, canola farmers largely use minimum or no-till systems, including direct-seeding (Gusta et al. 2011). For example, in Canada, over 50% of farmers use no-till practices in GE HR canola production as means to achieve sufficient levels of weed control (Beckie H.J et al. 2011; Gusta et al. 2011). In North Dakota, tillage practices used in GE HR canola production are estimated to be around 75% no-till and 25% conventional tillage (S&T 2010). The reduction in tillage that is allowed by post-emergence, broad-spectrum herbicide use has had both direct and indirect beneficial environmental impacts by reducing soil losses, and improving soil moisture and carbon retention (Gusta et al. 2011; VandenBygaart et al. 2015).

Fundamentally, land management practices used for canola cultivation can affect soil quality and erosional capacity, either beneficially or adversely, relative to the tillage practices, crop rotation, soil amendment, and cover crop practices employed. Based on extant data, the current reduced and no-till practices that are predominant in U.S. and Canadian canola production are considered beneficial to cropland soils where canola is cultivated, limiting the impacts of canola production on soil erosion and soil quality in these areas. Beneficial in this context meaning relative to conventional tillage.

3.4.2 Water Resources

Crop Irrigation

The seasonal water requirement for canola is in the range of most grain crops. An adequate water supply, particularly during critical periods of development, increases the likelihood of achieving both optimal crop quality and yield. Canola needs about 18 to 22 inches of water to produce good yields, with water use varying from a low of 0.1 inch per day at the rosette stage to a peak of 0.3 inch per day during flowering (Herbek et al. 1992).

Optimal water supplies at critical periods increases the chance of achieving high canola yields. However, few canola farms employ irrigation. In 2012, 133 out of 3,995 canola producers (0.03%) irrigated their crops, which comprised a total of 26,894 out of 1.7 million planted acres (USDA-NASS 2014).

Water Quality

Certain agronomic practices can adversely affect water quality. Tillage and agronomic inputs can potentially lead to the impairment of surface and ground waters through soil erosion and run-off, and leaching of pesticides and fertilizers into groundwater. Agricultural run-off is a primary source of non-point source (NPS) contaminants that can impact surface waters such as rivers and lakes, and the third most noted cause of impairment to estuaries (US-EPA 2008, 2015g). The most common NPS contaminants in agricultural run-off are sediment, nutrients such as nitrogen and phosphorus, and pesticides; all of which can adversely affect aquatic ecosystems (US-EPA 2016b). The EPA lists sediments as the second most frequent cause of impairment of streams and rivers, nutrients third, and pesticides sixteenth (US-EPA 2015e). Hence, sediment and nutrient loading are the principal NPS concerns in crop production, although pesticides will always remain a monitored agronomic input due to their potential to adversely affect both aquatic and terrestrial biota.

Agricultural management practices used in canola production and other factors that determine erosion and NPS pollution include; tillage and irrigation practices; the timing of agronomic practices, pesticide, and fertilizer application (e.g., type, quantity, methods); weather; and regional environmental conditions (i.e., the biotic an abiotic properties governing biological, physical, and chemical processes). Due to the potential impacts of agriculture on water resources, various national and regional efforts are underway to reduce NPS contaminants in agricultural run-off, and run-off itself (US-EPA 2008; USDA-NRCS 2015c, b, a; USDA 2015).

3.4.3 Air Quality

The EPA establishes National Ambient Air Quality Standards (NAAQSs) pursuant to the Clean Air Act (CAA) that are intended to protect public health and the environment. NAAQS are established for six criteria pollutants: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and particulate matter (PM). States enforce the NAAQS s through creation of state implementation plans (SIPs), which are designed to achieve the EPA established NAAQS.

Some crop production practices common to canola, GE and non-GE alike, can generate NAAQS pollutants and contribute to challenges in maintaining regional NAAQS. Agricultural emission sources from canola production include fossil fuels associated with equipment used in tillage, pesticide application, and harvest (CO_2, NOx, SOx); soil particulates from tillage (PM); and pesticide volatilization or drift (Aneja et al. 2009; US-EPA 2013).

Drift, and volatilization of pesticides from soil and plant surfaces, can result in the introduction of constituent chemicals into the air. Volatilization is dependent on soil wetness and temperature. Drift is dependent on wind conditions and applicator practices, to include application equipment features such as nozzle size. Drift and volatilization of pesticides can be a source of concern to both farmers and the general public in regard to potential environmental and human health effects.

The EPA's Office of Pesticide Programs, which regulates the use of pesticides, introduced initiatives to help pesticide applicators minimize off-target drift. The EPA's voluntary Drift Reduction Technology Program was developed to encourage the manufacture, marketing, and use of spray technologies scientifically verified to substantially reduce pesticide drift. The EPA is also working with pesticide manufacturers through the registration and registration review programs on improvements to pesticide label instructions to reduce drift (e.g., see (US-EPA 2015c).

Over the past several years, the EPA has developed USDA-approved measures to manage air emissions from cropping systems and general land management sources to help satisfy SIP requirements. In the 2006 Particulate Matter (PM) National Ambient Air Quality Standards (NAAQS) and 2008 Ozone NAAQS preambles, the EPA recommended that in areas where agricultural activities have been identified as a contributor to a violation of the NAAQS, when properly implemented to control airborne emissions of the desired NAAQS pollutant, USDA-approved conservation systems and activities may be implemented to achieve reasonably available control measure and best available control measure levels of control.

The USDA and the EPA provide guidance for regional, state, and local regulatory agencies on how to manage agricultural air emissions (USDA-EPA 2012). These measures allow stakeholders the flexibility in choosing which measures are best suited for their specific situations/conditions and desired purposes.

3.4.4 Climate Change

Climate change can affect agricultural crop production through changing patterns in precipitation, temperature, and duration of growing season, as well as through influencing weed and pest pressure, or lack thereof (Backlund et al. 2008; IPCC 2014). For instance, the current range of various species of agricultural weeds and pests are expected to shift in response to changes in regional climates, which could present new challenges to crop production in certain areas (Backlund et al. 2008). On the other hand, Field et al. (2007) found that most studies projected likely climate-related yield increases of 5% to 20% for corn, rice, sorghum, soybean, wheat, common forages, cotton, some fruits, and irrigated grains. However, such beneficial impacts would not be evenly distributed across all geographic areas as certain regions of the United States are expected to experience substantial reductions and/or variability in water resources. In general, the wide variability in climate across the United States is expected to result in differing responses of the agricultural sector to climate change, both in terms of yield and the agronomic practices used in crop management (Hatfield et al. 2014).

Agriculture can in turn influence climate change through various aspects of the production process such as combustion of fossil fuels in farm equipment, fertilizer application, tillage and manure management practices, and decomposition of agricultural waste products - all of which can result in emission of greenhouse gases (GHG). GHG emissions from agriculture have increased by approximately 17% since 1990, and agriculture is currently responsible for an estimated 8% of total GHG emissions in the United States (US-EPA 2016a). Methane (CH_4) and nitrous oxide (N_2O) are the primary GHGs emitted by agricultural activities. Methane emissions from enteric fermentation and manure management represent 22.5% and 8.4% of total CH_4 emissions from anthropogenic activities, respectively (US-EPA 2016a). Soil management activities such as fertilizer application and other cropping practices are the largest source of N_2O emissions nationally, accounting for 78.9% of emissions in 2014 (US-EPA 2016a). From 1990 to 2014, on average cropland accounted for approximately 70% of total direct N_2O emissions, while grassland accounted for approximately 30% (US-EPA 2016a). To a much lesser degree, carbon dioxide (CO_2) is also a GHG associated with agricultural land uses and energy consumption. In the United States, estimated emissions from agricultural soils in 2014 were 318.4 million metric tons of CO_2 equivalent.

Factors influencing agricultural GHG emissions are the agronomic practices specific to various crop production systems, the region in which commodities are grown, and the individual choices made by growers. For example, emissions of N_2O, which is produced naturally by soil microbes through nitrification and denitrification[15] processes, can be influenced by fertilizer application practices, cultivation of nitrogen-fixing crops and forage, crop residue management (e.g., conservation tillage), irrigation, and fallowing of land (US-EPA 2013). Similarly, on-site emissions associated with fossil fuel burning farm machinery can be reduced by half for some crops when changing from conventional tillage to no-till systems (Nelson et al. 2009).

As with all agricultural cropping systems, canola cropping systems can both contribute to GHG emissions, as well as result in carbon capture and sequestration. For any cropping system, the combustion of fossil fuels used in farm equipment, the application of pesticides and fertilizers, tillage practices, and the decomposition of agricultural waste products can all result in emission of GHGs to the atmosphere.

[15] Nitrification and denitrification are natural processes involved in what is termed the “nitrogen cycle”, or natural biogeochemical cycling of nitrogen. Nitrification is where soil bacteria convert ammonia to nitrate (nitrification). Denitrification is the opposite, where soil bacteria convert nitrate to gaseous nitrogen which is lost from the soil by release into the atmosphere.

The major types and sources of GHG emissions associated with agricultural production, to include canola crop production, are soil derived N_2O emissions, particulate matter (PM) derived from tillage and agricultural inputs, and CO_2 emissions associated with farm equipment operation.

Conservation tillage, to include no-till practices, commonly practiced in canola production, generally sequester more carbon in the soil due to less soil disturbance, higher soil moisture, and increased biomass inputs from surface residues, as compared to conventional (non-conservation) tillage practices. Similarly, rotation of canola crops, such as with cereals, can reduce the need for nitrogen additions. Brookes and Barfoot found that, in Canada, GE HR canola provided an additional 995 million kg of soil CO_2 sequestration in 2014, relative to non-GE HR cropping systems (Brookes and Barfoot 2016). Aggregate reductions in CO_2 emission from 1996 – 2014 were 1.6 billion kg, arising from reduced tractor fuel use (i.e., less tillage and herbicide application) (Brookes and Barfoot 2016). Smyth et al. (2011) estimated 1 million tons of carbon is either sequestered or no longer released under land management practices facilitated by GE HR canola production, as compared to 1995 production systems. Reductions are largely attributed to minimum and no-till operations, commonly associated with GE HR cropping systems. The value of this carbon off-set is estimated to be around $5 million (Canadian dollars)(Smyth et al. 2011).

MacWilliam et al. (2016) conducted a life cycle assessment of canola production in Western Canada for the years 1990 and 2010. Findings showed the largest contributor to GHG emissions was N_2O (34% to 63%) released as a result of applying synthetic and organic nitrogen to soil and mineralization of crop residues returned to the field. Other contributors to GHG emissions were the combustion of fossil fuels for on-farm processes and tillage, and the manufacturing of synthetic fertilizers used in canola production (MacWilliam et al. 2016). Also reported were that, over the past two decades, the on-farm fuel use and fertilizer applied per ton of canola has decreased, which led to reduced CO_2 and N_2O emissions, respectively. The improvements in the emissions profile for canola production between 1990 and 2010 were attributed to a combination of factors. Notable improvements to management practices included shifts from conventional tillage to conservation tillage and no-till, an increase in direct seeding practices, more efficient use of synthetic fertilizers, and improved weed management strategies that reduced the amount of herbicide used (MacWilliam et al. 2016). In addition, the EPA has determined that canola oil biodiesel meets the lifecycle GHG emission reduction threshold of 50% required by the Energy Independence and Security Act of 2007. Thus, canola oil biodiesel now qualifies as both an advanced biofuel and as biomass based diesel fuel produced from canola oil. To the extent canola is used for biodiesel production, reductions in GHG emissions from biodiesel combustion would be realized.

3.5 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 biological resources.

3.5.1 Soil Biota

Soil biota (i.e., earthworms, nematodes, fungi, bacteria) play a key role in soil formation, soil structure, decomposition of organic matter, biodegradation of pesticides, nutrient cycling, suppression of plant pathogens, promotion of plant growth, and a wide range of biochemical soil processes (Parikh and James 2012). Some microorganisms are plant pathogens and can cause plant diseases. These diseases can result in substantial yield and economic losses. For canola, these include various fungal, bacterial, and viral plant pathogens.[16]

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[16] See Canola Council of Canada Canola Grower's Manual - Chapter 10c – Disease: http://www.canolacouncil.org/crop-production/canola-grower's-manual-contents/chapter-10c-diseases/chapter-10c

The main factors affecting soil biota populations and diversity are soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (that provides specific carbon and energy sources into the soil), and agricultural management practices, such as crop rotation, tillage, herbicide and fertilizer application, and irrigation (Garbeva et al. 2004; Gupta et al. 2007). Climate, particularly the water and heat content of soil, is a principal determinant of soil biological activity. Potential changes to the soil microbial community as a result of cultivating GE crops is an active areas of research (Locke et al. 2008; Hannula et al. 2012; Guan et al. 2016). Potential direct impacts could possibly include changes to the structural and functional community near the roots of GE plants due to altered root exudation or the transfer of trait proteins into soil, or a change in microbial populations due to the changes in agronomic practices used to produce GE crops (e.g., pesticides, fertilizers, and tillage practices).

Herbicides that contain glufosinate can, relative to the dose, duration, and frequency of exposure, impact soil microbial communities. Effects reported in the scientific literature vary (see, e.g., (Bartsch and Tebbe 1989; Gyamfi et al. 2002; Lupwayi et al. 2004; Wibawa et al. 2010). For example, Sessitsch et al. (2005) found that rhizosphere bacteria associated with glufosinate resistant canola were affected by altered root exudates in GE canola; however, the effects were considered minor as compared to the influence of the plant growth stage itself. Other studies suggest that some of the observed microbial population shifts associated with the presence of glufosinate may be caused by an increase in herbicide-degrading soil microbes following glufosinate application; the result of use of glufosinate by microbes as a source of nitrogen. For example, Bartsch and Tebbe (1989) observed that repeated field application of glufosinate can increase populations of certain species of soil microbes. Microorganisms could be differentiated into two groups: those able to utilize glufosinate as a source of nitrogen, and those that did not. Three different glufosinate metabolizing enzymes were identified in these soil microorganisms: a glufosinate oxidase, a glufosinate transaminase, and a glufosinate (phosphinothricin) N-acetyltransferase (Bartsch and Tebbe 1989). Considering the tolerance of the majority of the 300 species studied, which is likely to be conferred by glufosinate degradation enzymes, it was concluded that glufosinate likely presented little risk to these 300 species of soil bacteria. However, only a small proportion of naturally-occurring soil microflora were examined, and extrapolation to other populations is not justified. Studies by Hsiao et al. (2007) likewise suggests that long-term glufosinate exposure promotes bacterial populations having high glufosinate degradation efficiency, and the ability to utilize glufosinate as a nitrogen source.

Other research suggests that glufosinate may inhibit crop pathogens such as those that cause bacterial blight (Pline 1999) and grapevine downy mildew (Kortekamp 2011). Inhibition of the enzyme glutamine synthetase in plants is the MOA for herbicides that contain glufosinate. It has been suggested that glufosinate could inhibit glutamine synthetase activity in pathogenic fungi and fungal like organisms, as it does in plants (Kortekamp 2011). However, glufosinate applied at the EPA label rates is not recognized as having significant or consistent adverse effects on soil microbial diversity (e.g., see (Gyamfi, Pfeifer et al. 2002, Lupwayi, Harker et al. 2004, Wibawa, Mohamad et al. 2010)

Field studies indicate that glufosinate-ammonium rarely migrates deeper than 10-15 cm in soil, presumably because of rapid microbial degradation (HSDB 2016). Microbial degradation is the primary process by which glufosinate is degraded in soil. In all soils, glufosinate-ammonium is biologically transformed to breakdown products that ultimately degrade completely to carbon dioxide (HSDB 2016). The aerobic half-life in soil is typically 3-11 days with an anaerobic half-life of 5-10 days (HSDB 2016). Field dissipation half-lives of 6-20 days (avg.13 days) are commonly reported (HSDB 2016).

Certain crop and soil management practices, such conservation tillage, cover cropping, and crop rotation increase soil organic matter and plant residues, and impart attributes to soil that can enhance pesticide degradation, hinder pesticide movement, and facilitate the natural cycles of soil nutrients.

3.5.2 Animal and Plant Communities

3.5.2.1 Animals

The types and numbers of species found in and around commercial crop fields are less diverse as compared to non-cropland areas. Canola fields can provide some food and habitat for some species of wildlife, including a variety of birds and large and small mammals.

Geese and blackbirds, for example, feed on canola seeds, while horned larks feed on emerging winter canola (Boyles et al. 2012; Schillinger and Werner 2016). Horned larks feed on the cotyledons of emerging canola, but they typically do not eat the stem or seed (Schillinger and Werner 2016). Most animals that use canola fields are ground-foraging omnivores that feed on the remaining plant matter and associated biota following harvest. Small mammals of the Great Plains that may be associated with canola fields are sagebrush voles (*Lemmiscus curtatus*), meadow voles (*Microtus pennsylvanicus*), shrews (*Blarina brevicauda*), and deer mice (*Peromyscus maniculatus*) (Heisler et al. 2013; Heisler et al. 2014). It is likely that predators (e.g., raptors, reptiles) of small mammals use canola fields and surrounding areas as hunting grounds. Within the Great Plains ecoregion, predators such as the western tiger salamander (*Ambystoma mavortium*) use canola fields to ambush a variety of prey such as: insects, worms, and small vertebrates. Large mammals such as white-tailed deer, mule deer, moose, and elk and smaller mammals like coyotes, foxes, rabbits, and prairie dogs are common in North Dakota, and may be found in canola fields (NDGFD 2017).

Many insect and related arthropod species perform valuable functions; they pollinate plants, contribute to the decay and processing of organic matter, reduce weed seed populations through predation, cycle soil nutrients, and attack other insects and mites that are considered to be pests. Although many arthropods in agricultural settings are considered pests, there are many beneficial arthropods which are natural enemies of both weeds and insect pests (Landis et al. 2005). Some of these beneficial species include the convergent lady beetle (*Hippodamia convergens*), carabid beetles, the caterpillar parasitoids (e.g., *Macrocentrus cingulum*), and the predatory mite (*Phytoseiulus persimilis*) (Landis et al. 2005; Shelton 2011). Common pollinators attracted to canola include honey, bumble, and leafcutter bees (Nichols and Altieri 2012; Kamel et al. 2015; Sekulic and Rempel 2016). The yellow coloration, and visible nectar of canola flowers also attracts pollinators such as butterflies (Kamel et al. 2015; Sekulic and Rempel 2016).

The most agronomically significant invertebrates in commercial canola fields are those that feed on canola plants. Insect injury can impact yield, plant maturity, and seed quality. Consequently, insect pests are managed during the seeding and development stages to protect the plants and crop yield. Invertebrates that feed on canola include stinkbugs, cutworms, diamondback moths, flea beetles, root maggots, aphids, armyworms, and grasshoppers (Armstrong et al. 2012; Saroka et al. 2015; Alahakoon et al. 2016; Sekulic and Rempel 2016).

3.5.2.2 Vegetation Associated with Canola Fields

Vegetation associated with canola production comprises both within-field and out-of-field communities. Within-fields, any plants other than canola may be weeds (for the Weed Science Society of America's composite list of weeds see http://wssa.net/wssa/weed/composite-list-of-weeds/). This can also include volunteer plants from other crops, such as those crops that are grown in rotation with canola. Out-of-field communities include crop 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 weed propagules that can reach crop fields. The types of weeds in and around canola production areas varies among regions. The most common weeds of canola in the areas of North Dakota and Minnesota include those listed in Table 3-7.

Table 3-7. Representative Agricultural Weeds in North Dakota		
barnyardgrass	mallow, common	quackgrass
buckwheat, wild	marshelder	ragweed, common
cocklebur, common	mustard, wild	smartweed, annual
foxtail, green	mustard, annual	sunflower
foxtail, yellow	nightshade, black	thistle, Canada
horseweed (marestail)	nightshade, hairy	thistle, Russian
kochia	pigweed, redroot	volunteer cereals (wheat, barley)
lambsquarters	pigweed/waterhemp	wild oat
lanceleaf sage	prickly lettuce	wormwood, biennial

Source: (NDSU 2011)

Barnyardgrass, green foxtail, yellow foxtail, wild oats, and volunteer cereals (barley and wheat) are common annual grass weeds which can occur in canola fields in North Dakota and Minnesota (Nelson et al. 2000). The most serious annual broadleaf weeds which commonly infest canola in the Northern Plains Region are redroot pigweed, Russian thistle, wild buckwheat, and wild mustard. Smartweed is a localized problem in Minnesota. Other common weeds include cocklebur, kochia, lambsquarters, venice mallow, Eastern black nightshade, hairy nightshade, common ragweed, giant ragweed, wild sunflower, and marshelder (Nelson et al. 2000). The perennial weeds that infest canola in Minnesota include Canada thistle, quackgrass and sowthistle (Nelson et al. 2000).

In southeastern states such Georgia, Italian ryegrass (annual) is a weed in most winter canola crops. Wild radish is a common weed in middle and Southern Georgia. Other weeds such as chickweed, henbit, hairy vetch, and wild garlic can compete with seedling canola during establishment (UGA 2017).

3.5.2.3 Herbicide Resistant Weeds

The use of herbicides imparts selection pressures on weeds that results in survival of weeds naturally resistant to the herbicide (Owen 2011; Owen 2012; Vencill et al. 2012). Herbicide resistant plant populations naturally evolve when plants survive and reproduce after repeated exposure to an herbicide, passing the inherent herbicide resistant trait (non-GE) on to future progeny. The development of herbicide resistance in weeds is not unique to a particular crop or herbicide, or to the use of genetically engineered plants. Overreliance on a single herbicide, a single mode of action (MOA), can place significant selection pressure on weed populations. When only one herbicide is consistently used year after year as the primary means of weed control, the weed population selected will be for those varietals naturally resistant to the herbicide. This type of selection pressure can and has resulted in the evolution of herbicide-resistant weed biotypes (Wilson et al. 2009; Shaw et al. 2011; Vencill et al. 2012).

As summarized above in Subsection 3.3.4 – Weed Resistance Management, there are currently 81 species of weeds with confirmed herbicide resistance in the United States (Heap 2016). When considering that some weed species have developed resistance to more than one herbicide MOA, there are 156 unique cases of resistant weeds. In the United States, 11 weed species have populations with confirmed resistance to 2 MOAs, 5 species with confirmed resistance to 3 MOAs, and 3 species with confirmed resistance to 4 MOAs (Heap 2016). Weeds have evolved resistance to 18 of the 26 MOAs available, and to 160 different herbicides (Heap 2016).

Glufosinate is used on a wide variety of crops to control broadleaf and grass weeds, to include those that are herbicide resistant. Currently, there are four glufosinate resistant crops (e.g., LibertyLink®) that have been commercialized in the United States: canola, corn, cotton, and soybean. Between 1998 and 2013 the total number of glufosinate treated acres has risen 4 fold from approximately 1.5 million acres to over 7 million acres (US-EPA 2016d). There is one glufosinate resistant weed in the United States, Italian ryegrass (*Lolium perenne* ssp. *Multiflorum*), with populations in Oregon and California (Heap 2016).

As part of its registration review, the EPA evaluated the benefits of glufosinate as a tool for managing the development of herbicide resistant weeds (US-EPA 2016d). The EPA categorized glufosinate as a high concern with regard to herbicide resistance and so issued updated guidance specifically for glufosinate resistance management in June of 2016 (US-EPA 2016h).

The EPA, which regulates pesticides under FIFRA and the FFDCA, is updating its policies and guidance for management of herbicide resistant weeds. In May of 2016 the EPA issued draft "Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and Stewardship".[17] The EPA is proposing measures for pesticide registrants to provide growers and users with detailed information and recommendations to slow the development and spread of herbicide resistant weeds (US-EPA 2016d). The updated guidance is part of a more holistic, proactive approach recommended by crop consultants, agricultural commodity organizations, professional /scientific societies, researchers, and the registrants themselves.

3.5.3 Gene Flow and Weediness of Canola

3.5.3.1 GE Canola as a Weed & Volunteer Canola

GE HR canola can present as a volunteer in subsequent crops, form feral populations, and hybridize with wild relative species, either through seed dispersal during transport, or pollen flow from GE HR canola fields. While GE HR canola can present as a volunteer and hybridize with wild relative species, *Brassica napus* L., is not a federally or state listed weed in the United States (USDA-NRCS 2016). *Brassica* spp. is listed on the Michigan weed list, but not specifically cultivated canola (*B. napus*).

Volunteer GE HR canola, particularly stacked-trait varieties, can be a management problem (Gulden 2007; Fleury 2015). According to a 2007 survey of Canadian canola producers (latest available data), 8% of those producing GE HR canola reported volunteer canola as problematic, of which 35% reported that additional efforts to control volunteers was needed (Smyth et al. 2011). In general, volunteer canola is considered a weed in commercial crop fields and treated as such (Gulden 2007). Like other weeds found in cultivated crops, volunteer canola competes with a crop for nutrients, water, and sunlight, and can reduce yield. Volunteer canola can also serve as a bridge for diseases and other pests. For example, volunteer canola can act as a host for diseases such as blackleg, clubroot, and sclerotinia so that the pathogen persists in the field to act on subsequent crops (DuPont-Pioneer 2015; CCoC 2016a). For diseases like clubroot, where the incidence is increasing, volunteer canola can serve to perpetuate the problem (Fleury 2015). The HR trait in GE volunteer canola can be considered a weedy characteristic as this can complicate management of volunteer canola in some crops (Gulden 2007). For example, GE HR volunteer canola, which can be resistant to one or more herbicides, can emerge in multiple flushes throughout a growing season, and influence the timing and types of herbicides used in crop management (Gulden 2007).

The primary factors contributing to volunteer canola are seed loss at harvest and insufficient intervals between crop rotations. Relative to other crops, canola seeds are small, some 2 millimeters (0.08 inches) in diameter, and in conjunction with high seed losses at harvest (3% to 10%) can result in large seedbank inputs, around 3,000 seeds/m^2; many times the normal seeding rate for canola (Gulden 2007). In general, around 40% – 45% of canola seed in the soil seedbank will persist for one winter, 1.4 % for two winters, and less than 0.5% for three winters (Gulden et al. 2003; Gulden 2007). While the percentage of seed persistence declines rapidly over time, due to sheer numbers of seeds deposited (3,000/m^2), even low soil

[17] EPA Draft Guidance on Managing Pesticide Resistance: https://www.epa.gov/pesticides/draft-guidance-managing-pesticide-resistance

seedbank persistence can potentially lead to a high number of volunteers in subsequent years (Gulden 2007; Bailleul et al. 2016). Canola seeds can also develop secondary dormancy under sub-optimal germination conditions (i.e., water stress, heat, hypoxia), which can lead to persistence in the soil seedbank for several years (Gulden 2007). Dormancy is removed by a complex of environmental conditions including short exposure to cool temperatures (35-39° F)(Gulden 2007). These factors, collectively, can contribute to high levels of soil seedbank persistence, and economically detrimental volunteer canola populations for several years after the last canola crop was grown (Gulden 2007).

In addition to seed loss at harvest, crop rotations on a 4 to 5 year cycle are now widely recommended for management of volunteer canola, as volunteer canola is more often a problem in tight canola rotations, which can exacerbate seedbank replenishment (Gulden 2007; Fleury 2015; CCoC 2016a). The tighter the canola rotation, the more difficult eradication or minimizing seedbank replenishment will be. Crop rotations on a 4 to 5 year cycle can reduce the incidence and prevalence of volunteers, and disrupt disease cycles (Gulden 2007; Fleury 2015). Avoiding tillage is also recommended. Tillage can bury seed, which can facilitate seedbank persistence for several years (Gulden 2007). Hence, cultural practices such as reducing seed loss at harvest, sufficient intervals in crop rotations, and tillage, are critical to limiting seedbank inputs and minimizing volunteer plants.

Various herbicide regimes are used to manage volunteer canola (Gulden 2007; CCoC 2016a). Volunteer canola control can require herbicides with residual activity, or multiple applications of herbicide without residual activity, as there can often be multiple flushes of volunteers during the growing season (Gulden 2007; Fleury 2015). For control of volunteer canola, both a pre-seed and in-crop treatment can be required. Scouting and early identification of volunteers is critical as herbicides are most effective at the early stages of growth, generally at the 3 leaf stage or less (Gulden 2007).

3.5.3.2 Hybridization and Introgression among Brassica and Related Species

Incorporation of HR canola trait genes into populations of sexually compatible wild species via hybridization, and particularly introgression, can present an ecological concern, as well as an economic concern to producers of canola crops (Knispel and McLachlan 2010). Canola can hybridize with various wild relatives in the United States, and is cross-pollinated via insects and wind (Beckie et al. 2003). Hybridization can occur between two subspecies (intraspecific), two different species (interspecific), and two different genera (intergeneric). While rare, interfamilial hybrids have also been known to occur. For a trait to become incorporated into a species genome (introgression), survival and recurrent backcrossing of hybrids with parental species is necessary (OECD 2006). In the absence of introgression, hybrids may persist for many generations, contributing to gene flow among populations of sexually compatible plants.

Gene flow among GE canola populations and plants among *Brassica* and other genera has been fairly well studied. However, as noted by many investigators, hybridization and introgression among *Brassica* and related genera can be somewhat complex due to the various species and subspecies involved, and environmental factors governing hybridization (e.g., see (FitzJohn et al. 2007; Ellstrand et al. 2013; Harrison and Larson 2014)). Provided here is a synopsis of the sexual compatibility of canola (*B. napus*) and related species, and the propensity for hybridization of *B. napus* with other species. A more thorough discussion on this topic can be found in the literature cited in this section.

Brassica napus plants readily outcross with plants of the same species, and potentially with the related species listed in Table 3-8. It should be noted that currently, in the United States, *B. napus*, *B. rapa*, *B. nigr*a, *B. juncea*, *B. adpressa* and *R. raphanistrum* are listed as weeds by the Weed Science Society of America (WSSA 2016a).

Table 3-8. Outcrossing Potential of *B. napus* with Related Species in the United States			
Pollen Recipient	**Occurs in unmanaged areas**	**States Occurring***	**Field Hybrids Produced?**
B. adpressa, syn. *Herschfeldia incana* (hoary mustard)	Yes	CA, NV, OR	Yes (extremely low)
B. carinata (Ethiopian mustard)	Yes	AL, CA, FL, GA, LA, MS, OR, SC, TX, WA	Yes (0.002% – 0.005%)
B. elongate (elongated mustard)	Yes	CO, NV, OR	NR
B. juncea (Indian/brown mustard)	Yes	All states	Yes (0.1 - 3.3%)
B. napus (rape/rapeseed)	Yes	All but unreported states, which are AZ, FL, MN, ND, NE, PA, SD, UT, WY	Yes
B. nigra (black mustard)	Yes	All but unreported states, which are AK, GA, SC, WY	Yes (extremely low)
B. oleracea (cabbage family)	No	CA, OR, WA, MT, NM, TX, IA, IL, MI, OH, PA, NY, RI, CT, MN, VA, GA, KY, CA, LA, MO	NR
B. rapa (field mustard)	Yes	All states	Yes (0.7 - 1.3%; range: 0–36%)
B. tournefortii (Asian mustard)	Yes	AZ, CA, NM, NV, TX	NR
Erucastrum gallicum (common dog mustard)	Yes	All but unreported, which are NV, NM, AZ, CO, NE, OK, LA, AK, TN, AL, GA	Yes (extremely low)
Raphanus raphanistrum (wild radish)	Yes	All but unreported states, which are NM, UT, WO, SD, NE, OK, AK	Yes (0.2%, only under special circumstances)
Sinapis arvensis syn *B. kaber (*wild mustard)	Yes	All states	Yes (extremely low)
Sinapsis alba syn *B. hirta* (white mustard)	Yes	AL, CO, GA, ID, MN, ND, OR, SD, WA	NR
Diplotaxis muralis (wallrocket)	Yes	All but unreported states, which are ND, WA, NV, ID, WO, OK, AL, MO, TN, KY, NC, GA	NR

Source: ((AgrEvo 1998); (USDA-NRCS 2016))

NR: Not Reported

* The states listed are those where *Brassicaceae* plants have been reported over the years, and canola is produced. Certain species may occur in states not listed. The states listed provide a general scope, the list is not intended to provide a comprehensive overview of the occurrence of species sexually compatible with *B. napus*.

Intraspecific crosses among *B. napus*, and interspecific crosses among *B. napus* and *B. rapa* (field mustard) occur readily (Table 3-9). To a lesser extent, interspecific crosses between *B. napus* and *B. rapa*, and *B. napus* and *B. oleracea* (cabbages), *B. juncea* (brown mustard), *B. carinita* (Ethiopian mustard), and *B. nigra* (black mustard), are possible. Intergeneric crosses between *B. napus and Diplotaxis muralis* (annual wallrocket), *Raphanus raphanistrum* (wild radish), *Sinapis arvensis* (charlock mustard) and *Erucastrum gallicum* (common dogmustard) may occur, but far less frequently.

Gene flow is most likely to occur among *B. napus* and *B. rapa* canola crops, and *B. napus* and *B. rapa* crops with weeds of the *Brassica* genus occurring in or around crop fields (Beckie et al. 2003; Legere 2005; CFIA 2011, 2016). For example, gene flow from GE glyphosate resistant canola (*B. napus*) to wild populations of bird's rape (*B. rapa*) in eastern Canada has been documented (Beckie et al. 2006). Introgression between *B.napus* and *B.rapa* populations under natural conditions has also been observed (Hansen et al. 2001; Legere 2005; Myers 2006).

Table 3-9. Summary: Outcrossing of Brassica and Related Species in the United States	
Intraspecific crosses readily occur among the following	
B. napus	rapeseed, rape, canola (*Brassica napus*)
B. rapa	field mustard (*Brassica rapa*)
Interspecific crosses can occur among the following	
Occur readily	
B. napus	field mustard (*Brassica rapa*)
Occur more rarely	
B. napus or *B. rapa*	field crops of *B. oleracea* (cabbage, kohlrabi, Brussels sprouts, broccoli, cauliflower, collards, and kale) brown mustard (*Brassica juncea*) black mustard (*Brassica nigra*) Ethiopian mustard (*Brassica carinita*)
Intergeneric crosses are possible with varying degrees of probability	
B. napus or *B. rapa*	wild and cultivated radish (*Raphanus raphanistrum* and *R. sativus*) wild/charlock mustard (*Sinapis arvensis* L) common dog mustard (*Erucastrum gallicum*) annual wallrocket *(Diplotaxis muralis)*

Source: (CFIA 2011; Myers 2015; CFIA 2016; USDA-NRCS 2016)

The frequency of hybridization among *B. napus* and relative species has been assessed in greenhouse and field experiments, and under commercial cropping conditions. Interspecific hybridization between *B. napus* and *B. rapa* has been observed to average 7% (range: 0–36%) in field experiments to 13.6% in commercial fields (Warwick et al. 2003). Jorgensen and Andersen reported higher frequencies of *B. napus* x *B. rapa* hybridization, up to 60%, when flowering of *B. rapa* and *B. napus* was synchronized, while the frequency decreased to 13% to 22% when *B. rapa* flowered 1 week earlier than *B. napus* (Jorgensen and Andersen 1994). Katsuta et al. reported that, when cultivated together, the frequency of crossing between GE HR *B. napus* and *B. rapa* was around 0.4% to 17.5% (Katsuta et al. 2015).

Field experiments examining spontaneous hybridization between *B. juncea* x *B. napus* observed the frequency of hybrids to range from 0.14% to 5.91%. *B. juncea* x *B. napus* interspecific crosses produced on average 2.1% hybrids, and the *B. napus* x *B. juncea* cross produced 0.2% hybrids (Heenan et al. 2007). Male fecundity for the *B. juncea* x *B. napus* F1 hybrids from both hand pollination and spontaneous field pollination studies was observed to range from 20.3% and 27.9% viability. Interspecific crossing between GE HR *B. napus* and *B. juncea* has been reported to occur at frequencies of around 0.1–3.3%, when cultivated together (Katsuta et al. 2015). Other studies have reported similar hybridization frequencies (Tsuda et al. 2014).

The probability of gene flow from *B. napus* canola to the wild relatives of *R. raphanistrum*, *S. arvensis*, or *E. gallicum* is considered to be low (Warwick et al. 2003). Hybrids between *B. napus* and *Raphanus raphanistrum* have been observed in the field, although rarely. For example, in field studies conducted during 2000, a single *R. raphanistrum* x *B. napus* first generation (F1) hybrid was detected out of 32,821 seedlings examined (Warwick et al. 2003). Similar hybridization rates between *R. raphanistrum* and *B. napus* have been reported from Australian ($<4 \times 10^{-8}$), French (10^{-7} to 10^{-5}), and Canadian studies (3×10^{-5}) (see review by (Legere 2005)). The hybridization frequency between *B. napus* and *S. arvensis* has been observed to be less than 2×10^{-5}, and that of *B. napus* by *E. gallicum* is less than 5×10^{-5} (Warwick et al. 2003).

Interspecific hand crosses between *B. napus* and *B. nigra* have been difficult to obtain, and in controlled crosses hybridization levels have been observed to be extremely low (hybridization rate of 0 – 0.09). No hybrids have been found in natural crosses when *B. nigra* was the female (OECD 2012). *B. napus* × *D. muralis* hybridization occurs, albeit rarely, with the likelihood of introgression considered very low (OECD 2012).

B. carinata can hybridized under controlled and field conditions with *B. napus*, either with *B. napus* as the male or female parent (Warwick et al. 2009b; Séguin-Swartz et al. 2013). A field study with *B. carinata* and glyphosate-resistant *B. napus* demonstrated these species can cross with each other under field conditions, albeit at a low rate. Overall, field hybridization levels detected with glyphosate resistance *B. napus* and *B. carinata* were 0.005% in an adjacent field (up to 150 m), and 0.002% in a separated field (up to 65 m). Pollen viability of hybrid plants was 14% and 8% for the two sites, and average seed set was 1.5 and 3.8 seeds per plant, respectively (Séguin-Swartz et al., 2013). Other studies have reported an average of 4.1% hybridization in crosses of *B. napus* and *B. carinata* (Roy 1980), and a hybridization frequency of 0.08 seeds per pollination (Getinet et al. 1997). In the latter study, Getinet et al. reported F1 interspecific hybrids to be highly sterile. Based on fitness information under controlled and field conditions, the fertility of hybrid plants is expected to be low (Séguin-Swartz et al. 2013).

Hybrids commonly exhibit inferior fitness relative to parental lines, with the fitness of F1 *B. rapa* x *B. napus* hybrids intermediate to the parent plants (Hauser et al. 1998; Legere 2005; Warwick et al. 2008). *B. rapa* x *B. napus* F1 hybrids are generally observed to have reduced pollen viability, around 55% (Warwick et al. 2003; Legere 2005). While hybrids exhibit less fitness, the lower fitness of second generation (F2) and backcross offspring may deter, but would not necessarily prevent introgression of genes/transgenes from *B. napus* into wild *B. rapa* populations (Hauser et al. 1998; Legere 2005). This assumption is supported by studies conducted by Warwick et al. (2008), who reported putative introgression of a glyphosate resistance transgene from *B. napus* into the gene pool of *B. rapa* under commercial cropping conditions. In this study, populations of GE HR *B. napus* x *B. rapa* hybrids were observed to significantly decline over a 3-year period (2002-2005), from 85 to 5 plants, out of a total of 200. Most hybrids, in both F1 and backcross generations, had reduced male fertility, and intermediate genome structure (Warwick et al. 2008). Although hybrid numbers rapidly declined from 2002 to 2005, the HR transgene persisted in one of the two *B. rapa* populations studied. Persistence of the HR trait occurred over a 6-year period, in the absence of herbicide selection pressure (with the possible exception of exposure to glyphosate in 2002), and in spite of the fitness cost associated with hybridization (Warwick et al. 2008). Similarly, yet under controlled experimental conditions, the glufosinate resistance trait gene was shown to be stably incorporated from *B. napus* into the *B. rapa* genome, and survival and seed production per plant were noted to be similar for GE HR and non-GE HR plants (Snow et al. 1999). Hence, where *B. napus* x *B. rapa* hybrids may have reduced fitness, which may deter introgression of transgenes into wild populations, such reduced fitness would unlikely preclude transgene introgression where conditions were favorable for sustaining hybrid populations over the long-term (Legere 2005).

3.5.3.3 Feral GE Canola Populations

Wild varietals of *B. napus* are considered "primary colonizers;" the first to take advantage of disturbed lands, such as roadsides and construction sites (CFIA 1994). In managed and semi-natural environments, such as croplands and roadsides, there is potential, due their "primary colonizing" nature, for *B. napus* to maintain ever present populations (CFIA 1994). Hence, it is in these types of environments that *Brassica* species are more frequently found in the United States. Outside of disturbed lands, *B. napus* populations are generally displaced by native plants that more readily establish climax communities, or steady state communities, such as perennial grasses, trees, and perennial shrubs (CFIA 1994).

Feral populations of GE HR canola have developed along transport routes as a result of seed spill, and occur in areas adjacent to crops as a result of pollen dispersal via wind and insects. Feral populations of GE HR canola exist in the United States, Canada, and Japan, and have been reported in Switzerland and Australia. Feral populations of GE HR canola in North Dakota are extensive and statewide. Schafer et al. conducted roadside surveys to quantify the presence and abundance of feral GE and non-GE canola populations in North Dakota during June and July of 2010 (Schafer et al. 2011). *Brassica napus* was present at 45% (n=634) of the surveyed sites (3,479 total miles, 39 miles of sampling sites), of which 80% expressed at least one transgene; 41% positive for only glyphosate resistance (CP4 EPSPS); 39% for only glufosinate resistance (PAT); and 0.7% comprised of both transgenes – a hybrid phenotype not produced by seed companies at that time (Schafer et al. 2011). Densities of *B. napus* plants at collection sites ranged from 0 to 30 plants/m^2 and averaged around 0.3 plants/m^2. Populations of feral GE canola were denser along major transportation routes, at construction sites, and near areas of canola cultivation (Schafer et al. 2011). Seed spill during transport is the presumed mechanism of dispersal along transportation routes, and wind and insect dispersal for those areas in proximity to commercial canola fields.

Similar findings have been reported in Japan. Katsuta et al. (2015) examined the distributions of *B. napus*, *B. juncea*, and *B. rapa* populations in the areas of 12 ports during the years 2006–2011. The investigators reported finding GE HR (glyphosate and glufosinate resistant) *B. napus* in 414 of 1,029 populations examined (40%). While no GE canola has been cultivated in Japan to date, dispersion and persistence of GE canola around Japanese ports and roadsides has been documented since around 2005. Dispersal is attributed to seed spillage, as a result of import of GE canola seed for canola oil production.

Instances of wild populations of GE HR canola have also been reported in Switzerland. While cultivation and seed import have been banned in Switzerland, feral GE canola was found growing along railway lines and in port areas at four sites in 2011 and 2012 (Schulze et al. 2014). Over 2,400 plants across 79 railway sites were sampled for the presence of feral GE oilseed rape. At four locations, a total of 50 plants expressing the CP4 EPSPS protein were detected. The authors postulated the feral GE canola populations were probably introduced through seed spills from freight trains, or during the transfer of goods from cargo ships to trains (Schoenenberger and D'Andrea 2012).

In western Canada, feral GE HR canola is found along roadsides and field edge habitats, with a large proportion of the plants glyphosate and glufosinate resistant (93% - 100%) (Knispel and McLachlan 2010). Average GE HR canola counts within 110 m^2 sampling areas ranged from 0.7 to 60.6 plants in roadside habitats to 1.0 to 49.5 plants in field edge habitats (Knispel and McLachlan 2010). As a result of the scale of cultivation, and seed and pollen dispersal, escaped GE HR canola plants have become a permanent feature of agricultural landscapes in western Canada (Knispel and McLachlan 2010). While small local populations may be prone to extinction, consistent dispersal of seed during transport, and pollen dispersal via insects and wind, enables the ongoing establishment of new populations (Knispel and McLachlan 2010).

As in other areas where GE HR canola is cultivated, GE glyphosate-resistant (GR) canola have been found outside agricultural fields in Australia (Busi and Powles 2016). This was the result of wind-transported movement of windrowed GR canola plants into adjacent bushland areas (2009), and seed spilled during transport (2012). Surveys detected the presence of feral GR canola plants and emerging seedlings at seed delivery sites, suggesting that local seed recruitment in addition to continued spillage contributes to feral GE HR canola persistence (Busi and Powles 2016).

As a consequence of ongoing cultivation and transport of GE HR canola seed, feral populations of GE canola are persistent along roadways, in the areas of ports, and other transportation routes, as well as in areas proximate to GE canola crop fields, wherever GE canola is cultivated. Roadside populations of GE canola in the United States and Canada, as well as feral populations in semi-natural and natural habitats proximate to crop fields are persistent from year to year, and contribute to the spread of transgenes outside areas of cultivation (Schafer et al. 2011).

While feral populations of GE *B. napus* have been well documented outside area of cultivation, worldwide (e.g., see (Warwick et al. 2009a; Devos et al. 2012; Luijten et al. 2015)), clear evidence of adverse environmental impacts has not yet been reported in the scientific literature. This may be in part due to the fact that *B. napus* is most commonly associated with managed or disturbed environments (CFIA 1994). Unless habitats are disturbed on a regular basis, populations of *B. napus* can become displaced by plants that form more stable climax communities, such as perennial grasses, tree species, and perennial shrubs (CFIA 2016). The current literature also indicates that without constant replenishment of the soil seedbank, which is supported by pollen flow and/or seed dispersal, feral GE HR canola populations are unlikely to successfully establish and persist outside of crop fields (e.g., see (Knispel et al. 2008; Warwick et al. 2008; Beckie and Warwick 2010; Devos et al. 2012; Bailleul et al. 2016)).

Considering the information reviewed above: As a result of commercial production, feral populations of GE HR canola are expected to persist in areas outside of cultivation, although largely limited to areas in close proximity to GE HR canola fields (i.e., within the range of successful pollen flow), and areas that border canola seed transportation routes; namely roads and railway lines. It is expected that outcrossing to sexually compatible wild plants on the order of 1% to 10% will occur within about a 30ft range (10 meters), and from 0.1% to 0.01% to plants within around 300ft (100 meters) (Myers 2006; EFSA 2013). This considered, pollen flow via wind has been reported at distances of up to 3 km (1.9 miles) (Warwick et al. 2008), albeit rarely.

Introgression of transgenes from GE HR canola into wild populations appears to be limited, with few instances of introgression being documented to date (Warwick et al. 2008; Luijten et al. 2015; Bailleul et al. 2016; Belter 2016; Busi and Powles 2016). Whether this is due to lack of detection, occurrence, or combination of both, has not been well elucidated.

3.5.3.4 Trait-Stacking in Feral GE Canola

Gene flow from cultivated GE HR canola to wild relative species has resulted in trait stacking in feral canola plants in North Dakota. This includes feral canola comprised of glyphosate and glufosinate resistant traits (Schafer et al. 2011). The diversity of feral populations, which emerges from hybridization among feral GE HR canola plants, and feral GE HR canola and wild plants, can increase over time as a result of continued loss of seed during transport, dispersal of pollen by insects and wind, and survival of seed in the soil seed bank (Legere 2005; Allainguillaume et al. 2006; Warwick et al. 2008; Knispel and McLachlan 2010; Schafer et al. 2011; Bailleul et al. 2016).

3.5.3.5 Trait-Stacking in Volunteer Canola

As with trait-stacking in feral GE canola, stacking in canola volunteers in western Canada is common, derived from pollen flow among varieties of GE HR and non-GE HR canola in commercial production, and an increasing management problem in cultivated fields in Canada (Beckie et al. 2003; Beckie and Warwick 2010; Knispel and McLachlan 2010). For example, hybrid canola plants with dual-HR traits (glyphosate–glufosinate, glufosinate–imazethapyr) and triple-HR traits (glyphosate–imazethapyr–glufosinate) have been identified in Canada since the early 2000s (Simard et al. 2005). The persistence of dual-HR and triple-HR hybrid canola volunteers renders volunteer canola a weed problem for canola producers in certain areas of Canada.

Persistence of GE HR canola volunteers have been observed for up to 7 years in Canada (Beckie and Warwick 2010), and 15 years in Germany. A recent study by Belter (2016) found that at two former field trial sites in Germany, in-field GE HR oilseed rape volunteers were observed up to fifteen years after harvest. From 1996 to 2002, a total of 15 field trials with GE winter oilseed rape were conducted at eight sites in central Germany. Released were four varieties of GE canola resistant to glyphosate or glufosinate. In the fall of 2001, MS8 × RF3 hybrid canola was planted at one site in Eickendorf, Germany. Both hybrid plants (MS8 × RF3) and single events (MS8 and RF3) were detected in 2015, the latter due to crossing with conventional canola plants in neighboring non-GE plots and dormant seed from the release in 2001. Similarly, Belter (2016) reported continued finding of MS1 x RF1 hybrid canola 15 years after its cultivation in Etzdorf, Germany. While volunteer plants were persistent, observations over the entire monitoring period of 15 years showed that, based on the former field trial sites and cropland, there was no dispersal of GE canola to surrounding areas (Belter 2016).

In the absence of introduction via seed dispersal by animals and humans, persistence of volunteer populations largely depends upon volunteers completing their life cycle, returning viable seed to the soil seed bank, and seed dormancy. In general, the persistence of volunteers may be characterized by an exponential decline but with a relatively long "tail;" the length of that tail largely dependent on seed bank replenishment, which, in turn, is influenced by landscape, environmental conditions (e.g., wind, precipitation), management practices, and potential for canola seed to develop secondary dormancy (Beckie and Warwick 2010; Haile and Shirtliffe 2014). The potential for secondary dormancy, an important factor, is controlled by canola genetics, environmental conditions, seed size, and harvest practices (Haile and Shirtliffe 2014).

While stacked-trait HR volunteer canola can be controlled with existing herbicides, the persistence of GE HR volunteers, particularly stacked-trait hybrids, will influence the agronomic practices employed in subsequent crops, such as the choice of herbicides or mechanical means used for volunteer control, and may impose restrictions on the choice of crops used in canola rotations (Legere 2005). Alternative herbicides, those other than glyphosate and glufosinate, such as such as metribuzin, 2,4-D, or MCPA, are required to control current varieties of volunteer GE HR canola (Beckie and Warwick 2010; Knispel and McLachlan 2010). Ultimately, contamination of a canola crop with volunteers comprised of multiple HR traits can compromise the marketability of harvested seed. With crops of the *Brassica* family, because of the small seed size and large number of seeds produced by the crop, poor management practices can result in severe volunteer problems in succeeding crops.

Both feral and volunteer populations of canola exhibit stacked-traits derived from commercial GE HR canola crops; the result of hybridization among HR canola crops (glyphosate, glufosinate, imazethapyr), and HR canola and wild relative species (Knispel and McLachlan 2010). Transportation of GE canola seed and GE HR canola cultivation, in tandem with seed and pollen dispersal processes enable the persistence of feral and volunteer plants (Knispel and McLachlan 2010). Seed losses at canola harvest can potentially contribute round 3,000 seeds m^2 to the soil seed bank (Gulden et al. 2003), and viable seeds can persist in the soil for several years, although the majority of seeds germinate in the first year after harvest. Dispersal via seed and cross-pollination precludes prevention of development of in-field and out-of-field GE HR canola hybrid populations (Knispel and McLachlan 2010). At the regional level, these factors contribute to the ongoing establishment of feral and volunteer GE HR canola, which necessitate the integration of cultural and chemical strategies into crop management, and systems controls during transport, for their control.

3.5.3.6 Summary

Canola seed yields range from around 1,200 to 3,000 per plant. Seeds are spherical and about 1 – 2 millimeter in diameter. Even with best management practices employed, seed size and plant fecundity will inevitably lead to seed loss during harvest. Likewise, due to size, seed loss during transport is probable. Herbicide tolerant canola, both GE and non-GE, establishes outside of agricultural environments via pollen flow and seed spillage. Feral GE HR canola is reported from most areas where the crop is grown or seed transported, including Canada, the United States, Europe, Australia, and Japan. It is highly likely that if GE HR canola varieties are grown feral populations will establish, via pollen flow, in areas proximate to the crop. Likewise, establishment of feral populations along seed transport routes appears difficult to prevent. Feral canola will hybridize with wild relative species and while hybridization rates are low, it is probable that HR traits will be transferred to other *Brassica* species (Warwick et al. 2008; Knispel and McLachlan 2010; Smyth et al. 2011; Bailleul et al. 2016).

Feral GE HR canola generally thrives in disturbed sites (OECD 2012), and most studies indicate that, without continued introduction of new pollen or seed, feral GE HR populations are transient, and subsumed in wild populations over the course of several generations (i.e., (Warwick et al. 2008; Luijten et al. 2015; Bailleul et al. 2016; Belter 2016; Busi and Powles 2016)). Outcrossing among feral canola populations has led to the stacking of HR traits in wild *Brassica* populations (Warwick et al. 2008; Beckie and Warwick 2010; Knispel and McLachlan 2010).

Based on hybridization frequencies and fitness data summarized above, where feral GE HR canola persist in a given habitat on an annual basis, and the following species are present; the potential for hybridization with wild *B. rapa* and *B. juncea* is high (OECD 2012). Hybridization with *B. oleracea*, *B. nigra*, and *B. carinata* is possible, although current literature suggests the potential for successful crosses is low. Intergeneric crosses of *B. napus* with *R. raphanistrum*, *S. arvensis*, *E. gallicum*, and *D. muralis* would occur very rarely (OECD 2012). Introgression of transgenes from GE HR canola into wild populations appears to be limited, with few instances of introgression being documented to date (Warwick et al. 2008; Luijten et al. 2015; Bailleul et al. 2016; Belter 2016; Busi and Powles 2016). Whether this is due to lack of detection, occurrence, or combination of both, has not been well elucidated.

GE HR canola varieties have made control of volunteer canola more challenging in some crops. In areas of Canada where GE HR canola has been grown for over 20 years, 2007 surveys found the majority of growers do not consider volunteer canola a particular nuisance (Smyth et al. 2010; Gusta et al. 2011). Around 74% of those surveyed reported they were able to control volunteer canola more easily or about the same as compared to 10 years prior, with 26% reporting volunteer canola control was more difficult. Nine percent of producers reported loss in yields due to volunteer canola (Smyth et al. 2010). Crop rotations of 4 years or more, scouting and early detection, and appropriate herbicide regimes are required to manage GE HR volunteer populations in most crops. However, controlling volunteer populations in some rotational crops may be more challenging due to crop injury from residual herbicides, or where the GE HR canola crop has the same HR mode of action as the volunteer canola population (Gulden 2007).

While canola hybridizes with wild relative species, *B. napus* does not have invasive or weedy characteristics, and is not a federally or state listed weed in the United States. [18] *Brassica* spp. is listed on the Michigan weed list, but not specifically cultivated canola, *B. napus*.

3.5.4 Biodiversity

Biodiversity concerns the variety and abundance of biota in and around canola cropping systems and their roles in ecosystem dynamics. Providing enough food, feed, fiber, and biofuels to meet the needs of a growing, global population is a challenge that faces agricultural systems worldwide. To meet societal needs, cropping systems have intensified to produce more commodities per unit area for the purpose of production efficiency. Although agricultural intensification can produce more food, feed, fiber, and biofuel commodities per unit area, this impacts biodiversity in and around commercial cropping systems (Crowder and Jabbour 2014). Hence, as a highly managed landscape utilized for intensive production of food, feed, fiber, and biofuels, biodiversity in an agricultural setting will be limited.

The removal of woody vegetation, planting of monoculture crops, pesticide use, fertilizer use, and regular planting and harvesting limit the diversity of plants and animals in and around crop fields. Where some crop production practices such as planting of monoculture crops, pesticide and fertilizer use, and regular planting, tilling, and harvesting limit habitat and thereby decrease the diversity of biota, other practices can be used to foster habitat preservation and biodiversity (Scherr and McNeely 2008). Conservation tillage practices can have a positive impact on wildlife through decreased soil erosion, improved water quality, retention of ground cover, availability of waste grain on the soil surface for feed, and increased populations of predaceous invertebrates as well as invertebrates as a food source (Altieri 1999; Landis et al. 2005; Sharpe 2010; Towery and Werblow 2010). Crop rotations can reduce the likelihood of crop disease, and insect and weed pests, thereby reducing the need for pesticides, which can be beneficial by limiting the potential exposure of biota to pesticides. Crop rotations can also result in preservation of wildlife habitat; crop rotations with legumes and small grains have been shown to provide nesting cover, food, and brood-rearing habitat (Sharpe 2010). Allowing field edges to harbor non-crop vegetation can provide nesting and brood habitat for birds, support beneficial arthropods that suppress herbivore insect pests, and provide food and habitat for natural predators of crop pests (Sharpe 2010).

While diversity of biota in an intensively managed agricultural landscape is inherently limited, sustaining as much diversity as possible is important to support species that are vital components of crop production. Such species include pollinators (e.g., bees, butterflies), those species beneficially or adversely affecting pollinators, and species that control plant pests and diseases. Biodiversity also serves functions that affect biogeochemical cycling, soil structure, and local hydrological processes. A loss of biodiversity in agricultural settings can result in the need for costly external inputs in order to provide these types of functions to crop production (Altieri 1999).

3.6 Human Health

Human health considerations associated with GE crops are those related to (1) the safety and nutritional value of GE crops and their products to consumers, and (2) the potential health effects of pesticides that may be used in association with GE crops. As for food safety, consumer health concerns are in regard to the potential toxicity or allergenicity of the introduced genes/proteins, the potential for altered levels of existing allergens in plants, or the expression of new antigenic proteins. Consumers may also be concerned about the potential consumption of pesticides on foods derived from GE crops.

In the United States, GE plants are regulated and evaluated for public health and environmental safety under the Coordinated Framework described in Section 1.3. The safety assessment of GE crop plants, summarized following, includes characterization of the physicochemical and functional properties of the

[18] USDA Plants Database: http://plants.usda.gov/core/profile?symbol=BRRA

introduced gene(s) and gene products, determination of the safety of the gene products (e.g., proteins, enzymes), and potential environmental impacts of the GE crop plant.

3.6.1 Consumer Health

3.6.1.1 Food Safety

Under the Federal Food Drug and Cosmetics Act (FFDCA) and Food Safety Modernization Act (FSMA) food and feed manufacturers are required to ensure that the products they introduce into commerce are safe for human consumption. Food and feed derived from GE crops must comply with the requirements of the FFDCA, FSMA, and all other applicable laws and regulations. GE plants that will be used for food or feed purposes generally undergo a voluntary consultation process with the FDA prior to release of the food or feed into commerce. The FDA established this voluntary consultation process to provide for review of the safety of foods and feeds derived from GE crops.

In such a consultation, a developer who intends to commercialize food or feed derived from a GE plant meets with the FDA to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the food/feed. The developer typically submits to the FDA a summary of its scientific and regulatory assessment of the food/feed.[19] The FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Although a voluntary process, it is believed that all developers who have wanted to commercialize a GE product that would be included in the food or feed supply have completed a consultation with the FDA.

In addition to FDA consultation, foods/feeds derived from GE plants undergo a safety evaluation among international agencies before entering foreign markets, such as reviews by the European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency. The Codex Alimentarius, established by the World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO), is a set of international standards, principles, and guidelines for the safety assessment of foods derived from modern biotechnology. These standards help countries coordinate and harmonize review and regulation of foods derived from GE plants to ensure public safety and facilitate international trade (WHO-FAO 2009). Currently, the Codex Alimentarius Commission is comprised of 187 member countries, to include the United States.[20] Most governments incorporate Codex principles and guidelines in their review of foods derived from GE crop plants. MS8 × RF3 hybrid canola has been reviewed and approved by 11 countries (i.e., Canada, Australia, EU, Japan).[21]

3.6.1.2 Safety of Canola Oil

There has been concern expressed among some consumers, largely that expressed on the internet via blogs and non-peer reviewed literature, that canola oil may not be safe for human consumption. Worldwide, canola oil is considered one of the healthiest food oils; being low in cholesterol, trans-fat, and containing the lowest amount of saturated fat of all vegetable oils. A literature review of 270 research articles examining the effects of canola oil (00-rapeseed oil) consumption on coronary heart disease, insulin sensitivity, lipid peroxidation, inflammation, energy metabolism, and cancer cell growth concluded that available evidence shows a number of potential health benefits may derive form canola oil consumption (Lin et al. 2013). Benefits include substantial reductions in total cholesterol and low-density lipoprotein (LDL) cholesterol, as well as beneficial tocopherol levels, as compared with consumption of

[19] FDA - Consultation Procedures under FDA's 1992 Statement of Policy - Foods Derived from New Plant Varieties: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm096126.htm
[20] Codex Members and Observers: http://www.fao.org/fao-who-codexalimentarius/members-observers/en/
[21] ISAAA GM Approval Database - Event Name: MS8 x RF3: http://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=4

other dietary fat sources (Lin et al. 2013) The American Heart Association recommends use of cooking oils lowest in saturated fats, trans-fats, and cholesterol – such as canola oil, corn oil, and olive oil.[22]

In 2006, the FDA authorized a qualified health claim for canola characterizing the relationship between the consumption of unsaturated fatty acids in canola oil and a reduction in risk of coronary heart disease. The FDA concluded, on review of scientific peer reviewed literature, that "limited and not conclusive scientific evidence suggests that eating about 1 ½ tablespoons (19 grams) of canola oil daily may reduce the risk of coronary heart disease due to the unsaturated fat content in canola oil."[23] The provision for health claims applies to canola-oil and canola oil containing foods.

3.6.1.3 Pesticides used in Canola production

Some consumers may be concerned about potential consumption of pesticide residues on food crops. Before a pesticide can be used on a food crop, the EPA, pursuant to the FFDCA and Food Quality Protection Act of 1996 (FQPA), establishes tolerance limits, which is the amount of pesticide residue allowed to remain in or on each treated food commodity (21 U.S. Code § 346a - Tolerances and exemptions for pesticide chemical residues). Pesticide tolerance limits established by the EPA are to ensure the safety of foods and feed for human and animal consumption (US-EPA 2015a). If pesticide residues are found above the tolerance limit, the commodity will be subject to seizure by the government.

Both the FDA and USDA monitor foods for pesticide residues to enforce these tolerance limits and ensure protection of human health (e.g., see (USDA-AMS 2015a)). By example, the USDA Pesticide Data Program (PDP) collects data on pesticides residues on agricultural commodities in the U.S. food supply, with an emphasis on those commodities highly consumed by infants and children (USDA-AMS 2015a). The EPA uses PDP data to prepare pesticide dietary exposure assessments pursuant to the FQPA. Pesticide tolerance levels for glufosinate have been established by the EPA for a wide variety of commodities, including canola seed (0.4 parts per million) and meal (1.1 parts per million), as described in 40 CFR §180.473. The EPA concluded on glufosinate registration review that the current tolerances are accurate and protective of human health (US-EPA 2016d).

To ensure the continued safety of pesticides and public health the EPA conducts pesticide registration reviews so that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. As part of this program, the EPA recently conducted a human health risk assessment for glufosinate registration review; specifically, quantitative assessments for the dietary, residential, occupational, and aggregate risks associated with the use of glufosinate. The EPA concluded that with uniform implementation of label statements clarifying restrictions on residential lawns application, there are no dietary, residential, or aggregate risks of concern for glufosinate from exposure to residues in food and drinking water, or from residential handler and post-application exposure (US-EPA 2016d).

3.6.2 Worker Safety

Agriculture is considered one of the most hazardous industries in the United States. Worker hazards include those associated with the operation of farm machinery, vehicles, and pesticide application. Agricultural operations are covered by several Occupational Safety and Health Administration (OSHA) standards including Agriculture (29 CFR part 1928), General Industry (29 CFR part 1910), and the

[22] AHA - Healthy Cooking Oils: http://www.heart.org/HEARTORG/HealthyLiving/HealthyEating/SimpleCookingwithHeart/Healthy-Cooking-Oils_UCM_445179_Article.jsp#.V_Jpc3Lr2Uk

[23] FDA - Qualified Health Claims: Letter of Enforcement Discretion - Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease (Docket No. 2006Q-0091): http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072958.htm

General Duty Clause. Further protections are provided through the National Institute of Occupational Safety and Health (NIOSH), which in 1990 began development of an extensive agricultural safety and health program to address the high risks of injuries and illnesses experienced by workers and families in agriculture.

In consideration of the risk of pesticide exposure to field workers, the EPA's Worker Protection Standard (WPS) (40 CFR part 170) was issued in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. The OSHA also requires employers to protect their employees from hazards associated with pesticides and herbicides.

In November 2015, the EPA issued revisions to the WPS regulations intended to enhance the protections provided to agricultural workers, pesticide handlers, and other persons by strengthening elements of the existing WPS such as training, pesticide safety and hazard communication information, use of personal protective equipment, and the providing of supplies for routine washing and emergency decontamination (80 FR 211, November 2, 2015, p. 67495). The EPA expects the final rule to prevent unreasonable adverse effects from exposure to pesticides among agricultural workers and pesticide handlers, vulnerable groups (such as minority and low-income populations, child farmworkers, and farmworker families) and other persons who may be on or near agricultural establishments, and to mitigate exposures that do occur. In order to reduce compliance burdens for family-owned farms, in the final rule the EPA has expanded the existing definition of "immediate family" and continued the existing exemption from many provisions of the WPS for owners and members of their immediate families.

In September, 2016 the EPA in conjunction with the Pesticide Educational Resources Collaborative made available a guide to help users of agricultural pesticides comply with the requirements of the 2015 revised federal Worker Protection Standard. Agricultural workers and handlers, owners/managers of agricultural establishments, commercial (for-hire) pesticide handling establishments, and crop production consultants are advised to employ this guidance. The updated 2016 WPS How to Comply Manual supersedes the 2005 version.[24]

In addition to revisions to the WPS, the EPA is proposing changes to glufosinate product labeling (US-EPA 2016d).The EPA pesticide registration review for glufosinate includes the development of use restrictions that, when followed, have been determined to be protective of worker health (US-EPA 2016d). Farmworkers are required to use pesticides consistent with the instructions provided on the EPA-approved pesticide labels, which may include instruction on personal protective equipment, specific handling requirements, pesticide equipment application specifications, and field reentry procedures.

3.7 Animal Feed

Animal feed derived from canola is in the form of canola meal, which is an oilseed meal similar to linseed, soybean, and other oilseed meals. Canola seeds are first crushed to remove the oil, yielding a cake as the by-product. The cake is further processed for use in animal feeds. Canola meal is one of the most widely used protein sources for livestock, poultry, and fish; the second-most widely traded protein ingredient after soybean meal (CCC 2015).

Most of canola meal in the United States is fed to cattle and pigs as part of a feed rotation. It can also be used as feed for poultry, aquaculture, and specialty animals (Jacob 2013; CCC 2015; USDA-ERS 2016a). Similar to the regulatory oversight for human consumption of canola food products under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they introduce into commerce are safe for animal consumption. Feed derived from GE canola must comply with all applicable legal and

[24] https://www.epa.gov/pesticide-worker-safety/pesticide-worker-protection-standard-how-comply-manual

regulatory requirements, and, as described under consumer health consideration, may undergo a voluntary consultation process with FDA before being released to the market. Bayer has the option to initiate the FDA consultation process by submitting a safety and nutritional assessment for MS11 canola to the FDA. If submitted, the FDA will consult with Bayer on the information submitted to the Agency and provide a decision on MS11 canola prior to commercial cultivation of this variety for food and feed.

Before a pesticide can be used on a feed crop the EPA establishes tolerance limits under Section 408 of the FFDCA and Section 405 of FQPA, which is the maximum amount of pesticide residue that can remain on the crop or in foods or feed processed from that crop (US-EPA 2015a). Glufosinate has established tolerance limits for canola meal at 40 CFR §180.473, which is 1.1 parts per million.

3.8 Socioeconomics

3.8.1 Domestic Economic Environment

Canola oil, meal (feed), and biodiesel are the primary commodities derived from canola. Meal is also used, to a small extent, as a fertilizer and for weed control. After crushing, canola seeds yield about 40% oil and 60% meal.[25] Canola oil is used as cooking/salad oil, as a food and cosmetics ingredient, and for conversion into biodiesel. The meal that remains after oil extraction is utilized by the livestock industry as feed.

U.S. canola production has increased substantially since the early 1990s responding to domestic and international demand for all these commodities. From 1991/92 to 2014/15, total U.S. acres of canola seed harvested increased from around 147,000 to 1.6 million acres, and market value of annual harvest increased from $18.6 to $423 million.[26] Over this time frame, annual canola oil production increased 43 fold, from around 36 million to 1.5 billion pounds, and price per pound from 23.65 to 37.81 cents per pound. Annual canola meal production increased from around 29,000 tons to 1 million tons, and price from $130.64 to $301.20 per ton. Due to demand for vegetable oil, biodiesel, and feedstock, demand for canola is expected to remain high or increase.

As of 2012, there were a total 34 states with commercial canola production (USDA-NASS 2014). Most U.S. canola production is located in the northern tier states contiguous with Canada, primarily North Dakota (USDA-NASS 2014). Of the 1.6 million acres harvested during the 2014/15 growing season, 1.4 million acres was in North Dakota (USDA-NASS 2016a). The 2014/15 market of value of the North Dakota canola harvest was $386.2 million.

3.8.1.1 Canola Oil

Consumer preference for healthy cooking oils and foods low in saturated fat and cholesterol has made canola oil a popular commodity in the United States and abroad, a trend that is expected to continue. Canola oil is the third most consumed vegetable oil in the world after soybean and palm oil, and number two by volume in the United States (USDA-ERS 2016c). U.S. imports of canola oil from Canada are projected to continue to grow strongly through 2025/26, augmenting the U.S. canola oil supplies for domestic consumption.[27]

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[25] Crushing is an industrial process that segregates oilseed into crude oil and meal, both of which are further refined for food, feed, or biofuel use purposes.

[26] http://www.ers.usda.gov/data-products/oil-crops-yearbook.aspx

[27] http://www.ers.usda.gov/amber-waves/2016-may/major-factors-affecting-global-soybean-and-products-trade-projections.aspx#.V_aDhnJTGUk

3.8.1.2 Canola Meal

In the United States, canola meal is the second largest feed meal after soybean meal. The majority of canola meal in the United States is fed to dairy cows because the high fat content of the meal enhances milk production. Poultry, aquaculture, and specialty animals (including racehorses) can also be fed canola meal as a protein source. As population increases both in the United States and globally over the coming decades, the demand for animal products, and soybean and canola based protein meals supporting livestock production will increase.

3.8.1.3 Biodiesel

From 2002 to 2013, biomass based energy consumption in the United States grew more than 60% due to increased consumption of biofuels; mainly ethanol but also a smaller amount of biodiesel (Figure 3-7). Currently, biomass accounts for about half of all renewable energy consumed and 5% of total U.S. energy consumed.[28] Among biomass energy commodities the market for biodiesel[29] is relatively small, but has been growing over the past five years, and currently accounts for approximately 2% of the 50 billion gallon annual diesel market (Schwab et al. 2016).

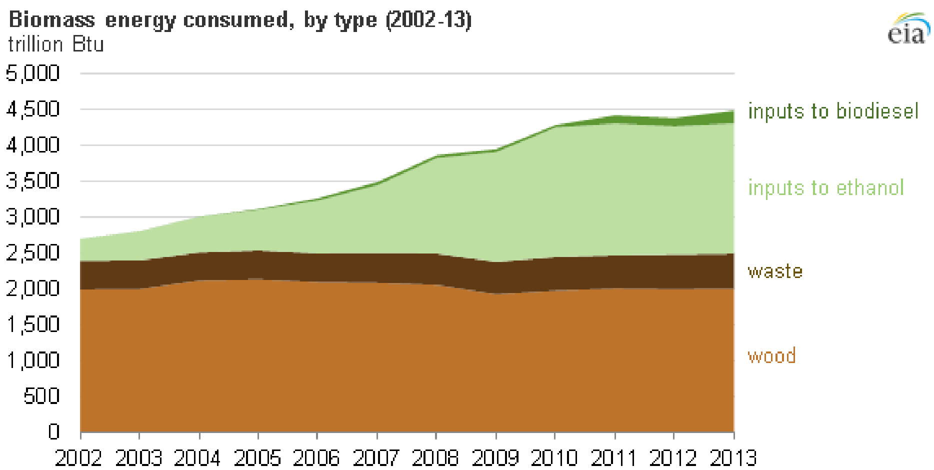

Figure 3-7. Biomass Energy Consumption in the United States, 2002-2013
Source: U.S. Energy Information Administration (EIA), http://www.eia.gov/todayinenergy/detail.php?id=15451

Over 80% of biodiesel is made from vegetable oil with the primary source oils being soybean, corn, and canola, and to a lesser extent of sunflower seed, cottonseed, and camelina. Canola oil inputs to biodiesel production markedly increased from 246 million pounds in 2011 to approximately 1 billion pounds in 2014, declining to 745 million pounds in 2015 (Table 3-10). It was the second largest biodiesel resource during 2011 and 2012, and the third and fourth largest biodiesel source in 2014 and 2015, respectively (EIA 2016).

Table 3-10. U.S. Inputs to biodiesel production			
Feedstock inputs (million lbs)			
Vegetable oils	Animal fats	Recycled feeds	Other Inputs

[28] http://www.eia.gov/

[29] Biodiesel is blended with petroleum based diesel up to 5% or 20% by volume (referred to as B5 and B20, respectively). Biodiesel diesel meets specifications for use in existing infrastructure and diesel engines, so it is not subject to any blending limitations.

Year	Canola	Corn	Cotton	Palm	Soybean	Other	Poultry	Tallow	White grease	Other	Yellow grease	Other	Algae	Other	Alcohol	Catalysts
2014	1,046	977	W	W	4,869	W	176	380	470	31	1,089	197	1	149	943	144
2015	745	1,057	W	W	4,908	W	197	429	589	56	1,254	122	0	91	982	170

Source: (EIA 2016)
W – Withheld to avoid disclosure of individual company data

Biodiesel demand in the United States is driven primarily by the renewable fuel standards (RFS) under two subcategories in the advanced biofuels requirements; biomass-based diesel and other advanced biofuels (Schwab et al. 2016). Congress created the RFS program in an effort to reduce greenhouse gas (GHG) emissions, expand the U.S. renewable fuels resources, reduce reliance on imported oil, and reduce air pollution. The RFS program was created under the Energy Policy Act of 2005, which amended the Clean Air Act (CAA). The Energy Independence and Security Act of 2007 further amended the CAA by expanding the RFS program to increase biofuel production to 36 billion gallons by 2022. Of the latter goal, 21 billion gallons must come from cellulosic biofuel or advanced biofuels derived from feedstocks other than cornstarch.

The EPA implements the RFS program in consultation with the USDA and U.S. Department of Energy. The RFS program requires a certain volume of renewable fuel to replace or reduce petroleum-based fuel, heating oil, or jet fuel. As part of this requirement the RFS requires petroleum refiners and importers to blend a certain percentage of biofuels into their fuels.[30] The four renewable fuel categories under the RFS are:

- Biomass-based diesel (canola)
- Cellulosic biofuel
- Advanced biofuel (canola)
- Total renewable fuel

The first RFS issued in 2007 applied mainly to gasoline and ethanol, and the second RFS (RFS2) took effect for biodiesel in July of 2010. RFS2 mandates the inclusion of other biofuels such as biodiesel into the country's petroleum based fuel supply. The EPA analyses determined that canola oil biodiesel meets the lifecycle greenhouse gas emission reduction threshold of 50% required by the Energy Independence and Security Act of 2007. Canola oil biodiesel also qualifies as both an advanced biofuel and as biomass based diesel. Hence, producers of canola oil biodiesel may generate either advanced or biomass-based diesel Renewable Identification Numbers (RINs).

While a prime source for biodiesel, canola oil is less often utilized for biodiesel production compared with other oils due to the increasing preference for canola oil in food uses, and the increasing availability of less expensive biodiesel feedstocks (i.e., greases and inedible corn oil) (Schwab et al. 2016).

3.8.1.4 Benefits of GE Canola Production

Glufosinate and glyphosate resistant canola varieties have been cultivated in the United States for over 10 years. Currently, around 90% of U.S. canola acreage is comprised of GE HR varieties (Figure 3-8). Adoption and sustained production of GE HR canola varieties has resulted from several factors. Farmers cultivate GE canola due to the net benefits they derive from that particular GE HR crop, such as optimal net returns and crop production efficiencies (Gusta et al. 2011; Brookes and Barfoot 2015a). Net benefits

[30] Biodiesel is most often blended with petroleum diesel in ratios of 2% (B2), 5% (B5), or 20% (B20). Biodiesel can also be used as pure biodiesel (B100).

are a function of pest and disease pressures, market price of inputs and canola commodities, and existing production infrastructure (e.g., machinery, computerization). While GE HR canola seeds are more expensive than conventional seeds, most U.S. canola farmers prefer the use of GE HR based production systems due to factors that include cost savings, time savings from easier weed control, and/or revenue gains that outweigh the additional seed costs (Fernandez-Cornejo et al. 2016).

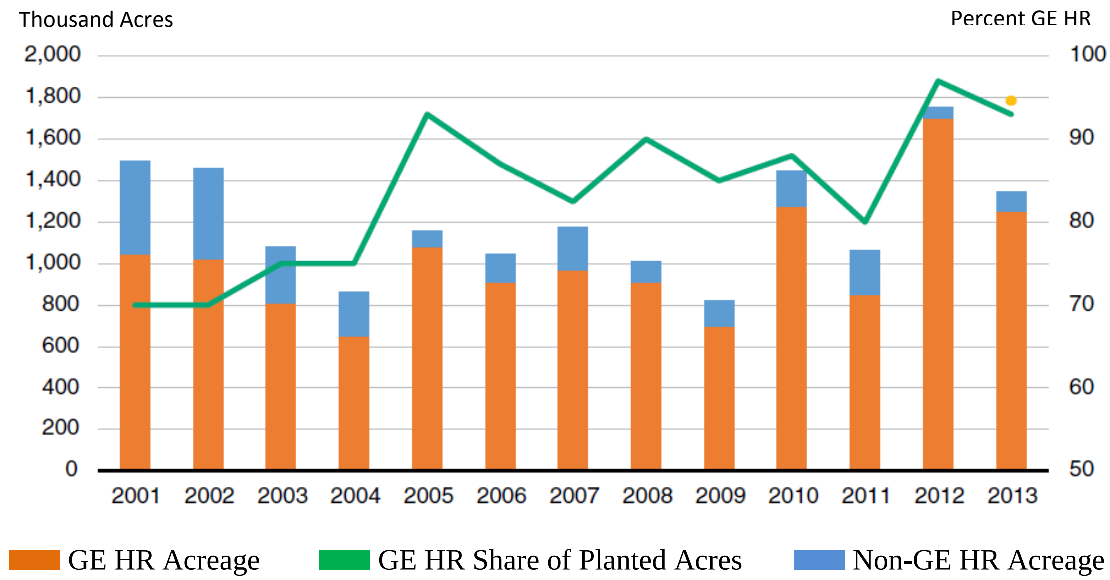

Figure 3-8. Adoption of GE HR Canola in the United States: 2001 – 2013
Source: (Fernandez-Cornejo et al. 2016)

The primary benefit of GE HR canola in the United States has been increased gross margins. From 1996-2013, canola producers realized increases in farm income between +$54/acre and +$222/acre ($185/acre in 2013) for glufosinate tolerant canola, and between +$64/acre and +$151/acre for glyphosate tolerant canola ($74/acre in 2013) (Brookes and Barfoot 2015b). At the national level, total farm income benefit in 2013 was $20.9 million, and the cumulative benefits from 1999 to 2013 was around $289.2 million (Brookes and Barfoot 2015b). The main farm income benefit from 1996 – 2013 has derived largely from yield gains, with gains of 3.1% reported for glyphosate resistant canola, and 10.2% for glufosinate resistant canola (Brookes and Barfoot 2015b).

In Canada, where the majority of canola is produced in North America, the primary benefit in the early years of GE HR canola production was, as in the United States, increased yields of around 11%. From 1996 – 2013, annual cost savings between about $35/acre and $79/acre, and an increase in annual net returns (inclusive of yield improvements and higher quality) between $54/acre and $182/acre have been reported (Brookes and Barfoot 2015b). The national farm income benefit, on an annual basis, from GE HR canola production rose from $6 million in 1996 to $546 million in 2013. The cumulative farm income benefit over the 1996-2013 period (in nominal terms) was $3.91 billion (Brookes and Barfoot 2015b). Similar benefits have been reported for Canadian canola producers by Gusta et al. (2011), who reported that GE HR canola generated between $1.063 billion and $1.192 billion (Canadian dollars) net direct and indirect benefits for producers from 2005-2007; this was partly attributed to lower input costs and partly attributed to better weed control (Gusta et al. 2011).

In the United States and Canada, net economic benefits from GE HR canola have largely been attributed to reductions in the cost of production, mainly through reduced expenditure on herbicides, modest increases in yields/acre, and some savings in fuel and labor costs associated with herbicide application and tillage (Beckie H.J et al. 2011; Gusta et al. 2011; Brookes and Barfoot 2015b).

3.8.1.5 Costs to Non-GE Producers

While there are economic benefits associated with cultivation of GE HR canola, costs may be incurred in controlling volunteer GE HR canola (Beckie and Warwick 2010; Schafer et al. 2011; Munier et al. 2012). Potential external costs may also be associated with control of feral GE HR canola. However, this has not been systematically studied and no data are available. U.S. data for the costs of volunteer control is lacking, and most reports derive from Canada. In a 2007 survey of 571 Canadian GE canola producers, Gusta et al. (2011) found that more than 94% of respondents reported that weed control was the same or had improved, with 62% reporting no difference in practices required for controlling volunteer GE canola, although 8% indicated that they viewed volunteer GE canola to be one of the top five weeds in need of control. Based on 2007 data, the estimated cost of controlling for volunteer canola in Canada was determined to be from $2.00/acre (Gusta et al. 2011) to $4.23/acre (Smyth et al. 2010). Based on a 2005 – 2007 survey of Canadian producers, Smyth et al. (2010) concluded that the monetary benefits derived from GE HR canola, inclusive of weed and volunteer control, were in the range of $10.6 to $11.14/acre, with total annual benefits (in Canada) around $343 to $422 million.

While volunteer GE HR canola can be a management problem (Schafer et al. 2011; Munier et al. 2012), overall, most studies have found the benefits of growing GE HR canola varieties to be greater than that of conventional varieties, outweighing the control costs for volunteers (Smyth et al. 2010; Gusta et al. 2011; Brookes and Barfoot 2015a). This would be consistent with the empirical observation that canola producers in the United States and Canada continue to produce GE HR canola, in lieu of a substantial number of options among conventionally bred cultivars. Management of volunteer GE HR canola is now standard practice for most canola producers (Gulden 2007; Smyth et al. 2010; Fleury 2015; CCoC 2016a), and substantive guidance for implementation of volunteer management programs exist, for example, from the Canola Council of Canada[31], DuPont Pioneer Agronomy Sciences[32], and Extension Services[33].

Contamination of non-GE canola crops, to include certified seed crops, via pollen or volunteers can compromise the marketability of the harvested crop product (Knispel and McLachlan 2010). Contamination of non-GE certified canola seed by GE HR canola was reported in Canada in 2002, although no monetary value of potential losses due to contamination was assessed (Friesen L.F. et al. 2003). In the United States, there are no reports of substantive losses associated with the unintended presence of GE HR canola in non-GE canola crops. However, given the large proportion of GE HR canola varieties in cultivation, the risk of contamination of non-GE canola crops and seed lot contamination exists. Such concerns can be seen in Oregon legislation. In 2013, Oregon signed into law a bill banning the commercial production of canola (rapeseed) until 2019 inside a two million acre Willamette Valley Protected District, one of the world's largest vegetable seed producing regions. Producers desiring to grow canola are required to apply for a contract with the Oregon Department of Agriculture (ODA) that contains requirements for managing the canola crop. 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 (Oregon Revised Statute 570.405).

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[31] http://cdnseed.org/archive/pdfs/Fact%20Sheets/VolunteerCanolaFactSheet.pdf

[32] https://ca.pioneer.com/west/media/1882/management-of-volunteer-canola.pdf

[33] https://www.ag.ndsu.edu/extensionentomology/recent-publications-main/publications/A-1280-canola-production-field-guide

3.8.1.6 Organic Canola Production

In the United States, organic canola must be produced and certified using methods specified by the USDA's Agricultural Marketing Service National Organic Program (NOP) (USDA-AMS 2015b). Congress described general organic principles in the Organic Foods Production Act, and the USDA defines organic standards. These standards cover the product from farm to table, including soil and water quality, pest control, livestock practices, and rules for food additives. Organic certification means that a farm or handling facility complies with the USDA organic regulations. This certification allows a producer to sell, label, and present their products as USDA certified organic. Organic certification is a process-based certification, it is not a certification of the crop commodity; the certification process specifies and audits the methods and procedures by which the product is produced, it does not specify nor require testing for the presence of GE plant material in organically produced commodities.

As of 2015, there were only 2 certified or exempt organic canola farms in the United States, one in North Dakota, the other in Pennsylvania. Acreage and economic value data is not available in the USDA's 2015 Census of Agriculture; it was withheld by producers to avoid disclosing data for individual farms (USDA-NASS 2014). In general, the market for organic canola products is, currently, relatively small. A significant proportion of canola use is in the non-food sector (biofuels, industrial lubricants, animal feed) where there is a limited market for organic canola oil. Further, the large variety of vegetable oils available to consumers (e.g., canola, safflower, soybean, corn, flax, olive) means that the lowest cost organic oils will dominate market use, and contributes to limiting the price premium obtainable for organic canola oil (Brookes and Barfoot 2004). In brief, currently, organic canola production in the United States is limited, which is likely reflective of market demand.

Similar to canola commodities that may be organically produced, there is a market for "non-GMO" commodities. For example, canola oil derived from conventionally bred crop plants, or even if it is produced organically, can be marketed as "non-GMO" through verification programs. For companies that want to have their commodity verified as being free of material derived from GE crop plants, there is a Non-GMO Project Verified seal administered the Non-GMO Project. [34]

3.8.2 International Trade

The EU, China, Canada, and India are the largest producers of canola. The EU does not produce commercial GE canola, but it does import GE canola. Canada accounts for more than half of world trade in canola seed, meal, and oil. In 2014/15, the EU represented approximately 33% of global production, followed by Canada (22%), China (20%), India (10%), Australia (5%), Ukraine (3%), and United States and Russia at 2% (Jervais 2015). In terms of canola oil, the EU is the major producer comprising approximately 38% of global production followed by China (23%), Canada (12%), India (9%), Japan (4%), United States (3%), Russia (2%), and Australia (1%) (Jervais 2015).

Canada is by far the largest exporter of canola seed (2014/15) at 65% of global share, with Australia at 17%, Ukraine at 14%, EU at 4%, and United States and Russia at 1% (Jervais 2015). Exports of canola oil follow a similar trend, with Canada, the EU, Russia, UAE, United States, Australia, and Belarus, being the largest exporters (Jervais 2015).

Identity protection is important in international trade. The low level presence (LLP) and adventitious presence (AP) of GE trait material in internationally traded conventional or organic commodities are important considerations in the trade of canola. Asynchronous Approvals and zero tolerance policies can result in the diversion of trade by some exporters, and rejection or market withdrawals by importers of canola. Consequently, incidents of LLP or AP can lead to income loss for exporters and consequently for

[34] The Non-GMO Project: http://www.nongmoproject.org/

producers, and consumers in importing countries can potentially face higher domestic prices when an import is deterred or directed to another trading partner (Atici 2014).

The challenges associated with maintaining variety identity in international trade can increase costs, as well as the premiums paid, for some GE crops. GE canola is excluded by some countries sensitive to the importation of food or feed derived from GE plants, and other countries may lag approval of new GE canola varieties. In general, LLP or compromise of canola identity can cause disruptions in international trade when GE trait material is inadvertently incorporated into food or feed shipments. As such, GE crop producing countries are required to take those measures necessary in the production, harvesting, transportation, storage, and post-harvest processing of GE crops to avoid the potential for LLP in conventional or organic commodities.

3.8.2.1 Canola Oil and Meal

Demand for canola oil is expected to remain strong because of growing use of vegetable oils in China and India, and canola oil based biodiesel use in the EU, United States, and Canada. The United States is the primary importer of Canadian canola oil and meal due its proximity and the ease of cross-border trade (USDA-ERS 2016b). As Canada's nearest neighbor and fellow North American Free Trade Agreement member, the United States will likely continue to purchase the majority of Canadian exports of canola oil and meal (USDA-ERS 2016b). U.S. imports of canola oil from Canada are projected to grow strongly through 2024, augmenting the U.S. edible oil supplies for domestic consumption (USDA-OCE 2015).

As the global demand for meat increases, so does the demand for animal feed. Protein meal consumption is expected to continue to grow at 1.6% per year through 2024, the majority of this is anticipated to be soybean based (USDA-OCE 2015). Projected increases in meat production, and slowing production of canola meal for feed are expected to lead to projected gains in domestic demand for soybean meal in the coming decade (USDA-OCE 2015). In general, trade in canola meal is limited due to the abundance of higher quality soybean meal and the high cost of transportation relative to the value of canola meal (USDA-ERS 2016b).

3.8.2.2 Biodiesel

In the past few years, fuel standards policy and mandates in the EU and United States have increased demand for canola oil as a source of biodiesel, and seed crushing capacity has expanded considerably. Globally, the EU is the largest producer and consumer of biodiesel, with mandated targets of a minimum of 10% in all member states by 2020 (Lonza et al. 2011). It is projected that the use of vegetable oil as feedstock for biodiesel, globally, will increase by 2.1% per year over the next ten years, with the share of vegetable oil used to produce biodiesel expected to be around 13% of world vegetable oil demand in 2024 (OECD/FAO 2015). In the United States, EU, Argentina, and Brazil, soybean oil is the most dominant biodiesel feedstock. As a result of increasing and inelastic canola oil demand for food use, it is unlikely that significant amounts of canola/rapeseed oil will be traded for biodiesel purposes. Instead, soybean oil and tallow will be preferred for their lower prices and wider availability (USDA-ERS 2016c).

4 ENVIRONMENTAL CONSEQUENCES

This chapter provides APHIS' evaluation of the environmental consequences of the alternatives considered in this EA, namely; denying the petition, or extending a determination of non-regulated status to MS11 canola. Pursuant to CEQ regulations APHIS must consider the direct, indirect, and cumulative impacts of both actions. Potential direct and indirect environmental impacts are discussed in this chapter. A cumulative impacts analysis is presented in Chapter 5.

4.1 Scope of Analysis

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MS11 canola are described in detail throughout this section. An impact would be any change, positive or negative, from the existing (baseline) conditions of the affected environment (described for each resource area in Section 3). 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 due to increased tillage, and worker safety impacts resulting from an increase in herbicide use. Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Certain aspects of this product and its cultivation may be no different between the alternatives. Cumulative impacts are discussed in Section 5.

Although the preferred alternative would allow for new plantings of MS11 canola to occur anywhere in the United States, APHIS will limit the environmental analysis to those areas that currently support canola production. To determine areas of canola production, APHIS used data from various official USDA sources.

4.2 Acreage and Areas of Canola Production

No Action Alternative: Acreage and Area of Corn Production

Under the No Action Alternative, MS11 canola could only be grown under APHIS permit. GE HR canola will continue to be commercially cultivated, with most of the production largely occurring in North Dakota. Demand for canola products is expected to increase through 2024, with canola remaining as, or more profitable (Westcott and Hansen 2015). There may be increased canola production, to some extent, in areas outside of North Dakota, as there are regional reports of farmers planting winter canola on land in the Southeastern United States that would otherwise be left fallow. The number of farmers growing winter canola in Alabama, Tennessee, and Kentucky is expanding (Cebert and Ward 2014). The Carolinas are also seeing an increased interest in the production of winter canola. North Carolina currently produces about 5,000 acres of canola per year. Georgia, the largest canola producer in the Southeast, usually grows around 25,000-30,000 acres per year (Roberson 2011). The demand for canola oil for biodiesel production could increase, albeit modestly, and there may likewise be an increase in demand for canola meal as livestock and poultry feed.

The No Action Alternative would have no effect on the acreage required for U.S. canola production. Acreage utilized for canola production is determined by domestic and international oilseed and cereal markets, and independent of APHIS' regulatory status decisions. In terms of canola cultivars, there are ample GE and conventionally bred options available to farmers, to include multiple cultivars of conventionally bred canola. GE canola varieties include LibertyLink® and InVigor® GE canola (glufosinate resistant), and Genuity® GE canola (glyphosate resistant). Non-GE HR Clearfield® canola (imidazolinone resistant) is also available.

Preferred Alternative: Acreage and Area of Corn Production

An extension of non-regulated status for MS11 canola is unlikely to have any influence on the number of U.S acres planted to canola. As with the No Action Alternative, acreage will be determined by market demand for canola oil, meal, and to some extent biodiesel. It is anticipated that MS11 canola will replace current MS8 canola, and that growers would adopt and continue use of MS11 canola hybrid seed to the extent it provided optimal crop yields and product quality, and net returns commensurate or superior to conventional canola production systems. Hence, MS11 canola, if adopted by growers, would be expected to supplant MS8 canola hybrid varieties in the areas these varieties are currently cultivated.

4.3 Agronomic Practices and Inputs

No Acton Alternative: Agronomic Practices

Practices used for the commercial production of GE and non-GE canola varieties such as tillage, crop rotations, volunteer management, agronomic inputs, weed resistance management, and pest and pathogen resistance management would be unaffected by continued regulation of MS11 canola. A decision to deny the extension request would have no effect on grower access to conventional and GE HR canola varieties, or grower choice in the commercial production of available canola cultivars in the United States. There are numerous conventional (Brown et al. 2008) and GE HR canola varieties available to U.S. canola producers (NDSU 2015). Any potential beneficial and adverse environmental impacts associated with tillage practices, crop rotation decisions, volunteer management, and pesticide and fertilizer use in the production of canola would be unaffected by denial of the petition.

Preferred Alternative: Agronomic Practices

Under the Preferred Alternative, an extension of non-regulated status for MS11 canola is unlikely to affect agronomic practices for U.S. canola production. The agronomic performance of MS11 canola was observed in ten field trials conducted in the canola growing regions of Western Canada and Northwestern United States. MS11 canola demonstrated no biologically relevant differences compared to non-GE conventional counterparts and exhibited equivalent agronomic performance to *B. napus* reference varieties in the field (Weeks et al. 2016). Disease and insect stressors were also evaluated. No statistically significant differences between the non-GE conventional counterpart and the MS11 canola were identified (Weeks et al. 2016).

Bayer asserts in their petition that the MS11 hybrid canola platform allows for production of a higher yielding canola, a more uniform supply of seed that facilitates harvesting and marketing, and can reduce herbicide use, as compared to non-GE open-pollinated canola varieties. This assertion is supported by studies that have found that growers of GE HR canola have realized higher yields, lower dockage,[35] and lower herbicide costs (Beckie et al. 2006; O'Donovan et al. 2006; Gusta et al. 2011; Brookes and Barfoot 2016).

Because MS11 canola is phenotypically and agronomically equivalent to MS8 canola, and MS11 canola is intended to replace MS8 for generation of commercial crop seed, MS11 is not expected to significantly affect the agronomic practices and inputs used in cultivation of current MS8 based cropping systems. Increases in the annual use of glufosinate may occur relative to increased market demand for canola oil, canola meal, and canola based biofuels – and grower election to produce MS11 hybrid seed to meet market demand, relative to other canola varieties (Brown et al. 2008; NDSU 2016b). Any increase, if such occurred, would be expected to be limited.

[35] Dockage in canola consists mainly of wild oats, other weed seeds, volunteer cereal grain, broken seeds, broken pods, and soil particles.

For example: For canola, corn, rice, and sugar beets: 29.0 to 36.0 fl oz/acre of glufosinate can be used for burndown (EPA label). For In-Season applications on LibertyLink varieties – meaning GE glufosinate-resistant, no glufosinate use is allowed. The Season Max for glufosinate use on canola is 36.0 fl oz/acre. Hence, if there were an increase in MS11 canola use that entailed 1,000 new acres, there would be a total maximum increase of 36,000 ounces, or 280 gallons of glufosinate, on an annual basis; this use spread across 1,000 acres of new canola field. The use of glufosinate on MS11 hybrid canola would be subject to the EPA registration and use requirements.

4.4 Physical Environment

4.4.1 Soils

No Action Alternative: Soil Quality

Because the agronomic practices and inputs associated with canola production would not be expected to substantially change under the No Action Alternative, potential impacts on cropland soils, both beneficial and adverse, would likely continue under current trends, unaffected by denial of the extension request. This applies to commercial cropland soils, and to the soils of fields where MS11 canola may be field tested under APHIS authority.

Preferred Alternative: Soil Quality

Because MS11 canola is agronomically and phenotypically similar to MS8 canola (Weeks et al. 2016), a determination of non-regulated status for MS11 canola would have no effect soil quality. Agronomic practices such as tillage and the application of agricultural chemicals that could impact soil quality or its community structure and function would not change from those currently used for production of MS8 hybrid canola. Consequently, potential direct or indirect impacts on soil quality are the same for both the Preferred Alternative and No Action Alternative.

4.4.2 Water Resources

No Action Alternative: Water Resources

Under the No Action Alternative, current acreage and agronomic practices, including irrigation, tillage, and nutrient management associated with canola production would not be expected to substantially change. U.S. growers would continue to cultivate GE HR and non-GE canola varieties currently available (Brown et al. 2008; NDSU 2015), and use the agronomic practices and inputs associated with these varieties. For GE HR varieties these include the more commonly used herbicides glyphosate, glufosinate, and imidazolinones, fertilizers (e.g., N, P, K, S), as well as insecticides and fungicides. All of these inputs can potentially impair surface and groundwater quality. The conservation tillage and no-till practices commonly used in GE HR canola production help to reduce agricultural runoff, and are largely beneficial to water quality, relative to historic uses of conventional tillage. Tillage practices in North Dakota for canola production are estimated to be around 75% no-till and 25% conventional till (S&T 2010). Based on Canadian data nearly two-thirds of GE HR canola producers utilize either zero-tillage or minimum tillage as their preferred form of soil management (Smyth et al. 2011). Hence, tillage practices commonly associated with current GE HR canola production are considered favorable to water resources, relative to conventional tillage.

Overall, herbicide applications in GE HR canola cropping systems have typically been less than that found in conventional cropping systems (Brookes and Barfoot 2015c; Brookes and Barfoot 2015a). From 1996-2013, it is estimated that the use of GE HR canola resulted in a 2.2 million kg reduction in the amount of herbicide active ingredient used in the United States (Brookes and Barfoot 2015c). In Canada, it is estimated the use of GE HR resulted in a 15.8 million kg reduction over the same period (Brookes and Barfoot 2015a). Hence, to the extent GE HR canola varieties are cultivated, the associated reductions in herbicide use and reductions in potential risks to water resources would be expected to continue.

However, any increases in problematic volunteer HR canola and HR weed populations could require increased tillage and herbicide use for management of these. Where this potential exists, significant increases in tillage to control volunteer canola are unlikely. Use of tillage for management of volunteer canola is discouraged in most cases, because it facilitates incorporation of seed into the soil seedbank (Fleury 2015; CCoC 2016a).

U.S. Geological Survey (USGS) studies found glufosinate was seldom detected in the environment. During the years 2001-2006 (latest date available) state cooperative studies found that out of 271 ground and 281 surface water samples none exceeded 0.1 µg/L of glufosinate (Scribner et al. 2007). Over the same period, National Water-Quality Assessment Program studies detected two instances of glufosinate in surface water at 0.11 and 0.56 µg/L. These were in the Mississippi river and White River. During 2002, 171 samples were collected from 51 streams in nine Midwestern states during three periods of runoff. Glufosinate was detected in two samples at concentrations of 0.26 and 0.14 µg/L (Scribner et al. 2007).

The EPA determines the use requirements for glufosinate, which are intended to be protective of water quality and aquatic biota.[36,37] The EPA considers the potential impacts to water resources from the agricultural application of glufosinate-ammonium, and provides label use restrictions and guidance for product handling intended to prevent impacts to water (US-EPA 2015b). Label restrictions specific to water resources include, for example, prohibiting applications directly to water or to areas where surface water is present, managing proper disposal of equipment wash water, and adopting cultivation methods (e.g., no till) to limit runoff to surface water.

Preferred Alternative: Water Resources

Under the Preferred Alternative, no substantial impact to water resources is anticipated from an extension of non-regulated status of MS11 canola. As discussed above in Sections 4.3 – Agronomic Practices and Inputs, MS11 canola would not change the cultivation practices currently employed for MS8 canola, nor would it be expected to affect the total acres and range of U.S. canola production. Because MS11 canola has been shown to be agronomically and phenotypically equivalent to MS8 canola (Weeks et al. 2016), no changes to irrigation and other agronomic practices such as fertilizer and pesticide applications, that have the potential to affect water quality or quantity, are expected to occur as a result of this alternative. Based on these considerations, APHIS has concluded that the potential impacts to water resources are expected to be the same or similar under both the Preferred Alternative and No Action Alternative.

4.4.3 Air Quality

No Action: Air Quality

The emission sources associated with canola cultivation would be unaffected by a decision to deny the extension request. Air quality would continue to be affected along current trends by emission sources such as tillage, pesticide application, and use of farm equipment that combusts fossil fuels. The EPA and USDA efforts to reduce emissions, along with state and local efforts, would likewise continue. Conservation and no-till practices commonly used in canola production (Smyth et al. 2011) limit soil and fuel based emissions (e.g., NAAQS criteria pollutants) – relative to conventional tillage and are expected to continue as currently practiced.

As described for water quality above, overall, herbicide applications in GE HR canola cropping systems have typically been less than that found in conventional cropping systems. Conservation and no-till

[36] For example, EPA - Aquatic Life Benchmarks for Pesticide Registration: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/aquatic-life-benchmarks-pesticide-registration
[37] For example, EPA - Drinking Water and Pesticides: https://www.epa.gov/safepestcontrol/drinking-water-and-pesticides

practices are also employed on the majority of GE HR canola acres. To the extent GE HR canola varieties are cultivated, conservation and no-till practices would be expected to continue, minimizing air emissions.

The benefits of conservation tillage/no-till practices to air quality could decline in some areas if growers increase tillage and herbicide applications to control volunteer GE HR canola, and/or herbicide resistant weeds (HRW). Increased tillage and herbicide application means the use of more fossil fuels. Consequently, the benefits of limited tillage and herbicide use, relative to NAAQS emissions, may be reduced in areas where growers must increase tillage or/and herbicide use to control volunteers and HRW. Where this potential exists, significant increases in tillage to control volunteer canola are unlikely, as described for water resources above.

Preferred Alternative: Air Quality

Because the agronomic practices used in production of MS11 hybrid canola are the same as those used in cultivation of MS8 hybrid canola, no substantial changes to emission sources (i.e., tillage, equipment use, the application of fertilizers and pesticides) are expected. An extension of non-regulated status to MS11 canola would have no effect on the total acreage of U.S. canola production (discussed under Section 3.2); hence, associated increases in fuel and pesticide use are unlikely.

The EPA is currently reviewing glufosinate (registration review) and is proposing new labeling to reduce spray drift from applications to non-residential use sites. Current glufosinate labels are now considered inconsistent with respect to spray drift management language and droplet size (a major factor influencing spray drift) (US-EPA 2016d). The EPA intends to establish spray drift criteria that is consistent across all glufosinate products. Reducing spray drift will reduce potential aerosolization of glufosinate.

Considering the above factors, the potential impacts of the Preferred Alternative on air quality, beneficial and adverse, would be the same as or similar to that described for the No Action Alternative. To the extent that production of MS11 canola hybrids continue to facilitate conservation tillage and no-till practices (Gusta et al. 2011; Smyth et al. 2011), reductions in herbicide use (Beckie et al. 2006; O'Donovan et al. 2006; Gusta et al. 2011; Brookes and Barfoot 2016), and reductions in the use of fossil fuel burning equipment, commensurate benefits to regional air quality would be expected to continue – in terms of emissions of NAAQS pollutants (CO, NOx, O_3, PM, SOx).

4.4.4 Climate Change

No Action: Climate Change

As discussed in Subsection 3.4.4 – Climate Change, canola crops can both contribute to GHG emissions, as well as result in carbon capture and sequestration. The major sources of GHG emissions associated with canola production are soil-derived N_2O emissions, PM derived from tillage and agricultural inputs, and CO_2 emissions associated with farm equipment combusting fossil fuels. The net effect of emissions and sequestration on climate change can, however, be difficult to quantify, and depends on the cropping system, production practices, soil types, and individual grower decisions used in crop production. For instance, conservation tillage, in particular, has been observed to contribute to soil carbon sequestration on croplands through the conservation of biomass (Franzluebbers 2005). Similarly, rotation of crops, such as with grains and legumes, and reduced nitrogen inputs, has been noted to result in carbon footprint reduction of certain crops (Ma et al. 2012). No-till practices generally sequester more carbon in the soil due to less soil disturbance, higher soil moisture, and increased biomass inputs from surface residues. For example, a recent review of the literature suggests that no-till practices can provide small but important reductions in GHG emissions (Powlson et al. 2014).

Conservation tillage, to include no-till practices, commonly practiced in canola production, generally result in greater soil carbon sequestration, as compared to conventional (non-conservation) tillage practices. Similarly, the rotation of canola crops, which is standard practice, can reduce the need for nitrogen additions. For example, canola is typically rotated on 3 to 5 year cycles. In Canada, where the vast majority of canola is produced in North America, GE HR canola was found provided an additional 995 million kg of soil CO_2 sequestration in 2014, relative to non-GE HR cropping systems (Brookes and Barfoot 2016). Aggregate reductions in CO_2 emission from 1996 – 2014 were reported to be around 1.6 billion kg, arising from reduced tractor fuel use (i.e., less tillage and herbicide application) (Brookes and Barfoot 2016). Similarly, Smyth et al. (2011) estimated 1 million tons of carbon is either sequestered or no longer released under land management practices facilitated by GE HR canola production, relative to 1995 production systems. Over the past two decades, the on-farm fuel use and fertilizer applied per ton of canola has been reported to decrease, leading to reduced CO_2 and N_2O emissions, respectively. The improvements in the emissions profile for canola production between 1990 and 2010 were attributed to a combination of factors. Notable improvements to management practices included shifts from conventional tillage to conservation tillage and no-till, an increase in direct seeding practices, more efficient use of synthetic fertilizers, and improved weed management strategies that reduced the amount of herbicide used (MacWilliam et al. 2016).

Based on the data summarized above, the commercial production of GE HR canola contributes to global N_2O and CO_2 emissions, both directly and indirectly. GE HR canola has also, in part, contributed to reductions in GHG emissions from canola cropping systems over the last two decades. For example, GHG emissions of 1 ton of canola produced in Western Canada were found to decline from 350 kg CO_2eq/t canola in 1990, to 330 kg CO_2eq/t canola in 2010; reduction attributed to GE HR canola cropping systems (MacWilliam et al. 2016). Under the No Action Alternative, the contributions to GHG emissions, and emissions reductions, relative to canola production in the 1990s and prior decades, would be expected to continue.

Preferred Alternative: Climate Change

The purpose of MS11 canola is to eventually replace the current MS8 canola line that is used as breeding stock in the production of GE HR canola crop seed. Because MS11 canola is phenotypically and agronomically similar to MS8 canola, MS8 canola has been commercially produced for over 10 years, and MS11 is intended to replace MS8 canola, MS11 canola is not expected to affect the current practices used in cultivation of commercial GE canola. Hence, in terms of agronomic practices and inputs, there is no difference between the No Action Alternative and Preferred Alternative. As with the No Action Alternative, an extension of non-regulated status for MS11 canola is not likely to have any influence on the number of U.S. acres planted to canola. The potential contribution of the commercial production MS11 canola to GHG emissions, as well as the potential for carbon capture and sequestration, would be no different than that of MS8 canola. Likewise, the potential impacts of climate change on the commercial production of MS11 canola, would be no different than those on MS8 canola.

4.5 Biological Resources

Potential risk to biological resources considered in this EA are the effects of the GE trait genes and their gene products through gene flow to wild relative species, and consumption of MS11 canola plant material by wildlife. The potential for GE canola to act as a weedy or invasive species, and for glufosinate to adversely impact biological resources, are also considered.

4.5.1 Overview of Potential Effects on Non-Target Terrestrial and Aquatic Organisms

Bar Gene and the Enzyme Phosphinothricin Acetyltransferase

Phosphinothricin N-acetyltransferase (PAT) is an enzyme (a type of protein) that confers glufosinate resistance to GE plants. It can be encoded by the bar gene derived from the naturally occurring soil bacterium *Streptomyces hygroscopicus*, and by the pat gene derived from *S. viridochromogenes*. In MS11 canola, it is the bar gene that was used to encode for PAT. Environmental release approvals have been issued for at least 8 species of crop plants that have been genetically engineered to contain either the pat or bar genes. Regulatory reviews by United States and international agencies encompass 11 countries, and at least 38 separate transformation events. These reviews indicate that PAT expressed in GE plants has negligible impact on the phenotype (characteristics) of those plants, beyond conferring resistance to the herbicide glufosinate (CERA 2011) .

The EPA has conducted an environmental risk assessment of the pat and bar genes, and PAT. Due to the negligible human health and environmental risks presented by the bar and pat genes, and PAT, they are exempt from the requirement of a tolerance in all raw plant agricultural commodities (US-EPA 2005, 2007). Previous evaluations of the pat and bar genes have shown they do not share amino acid sequence similarities to known toxins and are unlikely to be human allergens (ILSI-CERA 2011). Bioinformatic analyses showed no evidence of similarity between the PAT and any known toxic or allergenic proteins (Herouet et al. 2005). The PAT in MS11 canola has a long history of safe use in a variety of commercially available GE corn, soybean, and cotton cultivars that have been previously reviewed by the FDA and USDA, and approved for commercial use. The naturally occurring soil bacterium *S. hygroscopicus*, from which the bar gene is derived, is widespread in the environment. It stands to reason that vertebrates, invertebrates, and microorganisms are exposed to the bar gene and PAT enzyme on a daily basis.

Barnase and Barstar

The genes encoding barnase and barstar in MS11 were derived from *Bacillus amyloliquefaciens*, a gram positive non-pathogenic bacterium commonly found in air, water, soil, and on plants (EC 2015; US-EPA). Bacterial, streptomycete, and fungal homologues of barnase have been identified in various *Bacillus* and *Aspergillus* species, as well as *Saccharopolyspora erythrea* (Kleter et al. 2005), which are likewise prevalent in the environment. Bioinformatics studies indicated that no similarities exist between the barnase and barstar proteins and known toxic proteins or allergens (EFSA 2012).

Considering the environmental ubiquity of *B. amyloliquefaciens*; incidental exposure of vertebrates (e.g., via diet and inhalation), invertebrates, and microorganisms to background levels of naturally occurring *B. amyloliquefaciens* and constituent genes and gene products are likely to occur on a daily basis, worldwide. Enzymes produced by *B. amyloliquefaciens* are considered generally recognized as safe (GRAS) by the FDA, which has estimated that dietary exposure of *B. subtilis* and *B. amyloliquefaciens* by the U.S. population is 200 mg/day (64 FR 78, April 23, 1999, p. 19887).

Several strains of *B. amyloliquefaciens* are exempt from the requirement of a tolerance for the maximum amount of a pesticide allowed to remain in or on a food commodity. For example, the EPA has exempted *B. amyloliquefaciens* MBI600 (40 CFR §180.1128), *B. subtilis* var. *amyloliquefaciens* strain FZB24 (§180.1243), *B. amyloliquefaciens* strain D747 (§180.1308), and *B. amyloliquefaciens* strain PTA-4838 (§180.1336).

Exposure of vertebrates, invertebrates, and microorganisms to barnase and barstar proteins is expected to be limited. Barnase and barstar proteins are expressed in cells of the flower bud, specifically the cells of the tapetum; they are not detected in seeds, pollen, and unprocessed meal (EFSA 2012). Studies on the previously deregulated MS8 and RF3 canola lines suggest neither protein would be expected to occur in food or feed derived from MS8, RF3, and MS8 × RF3 seed or pollen (EFSA 2012). Bayer performed gene expression analyses of the barnase and barstar genes and proteins in MS11 canola. Mean expression levels of barstar and barnase in three generations of MS11 canola whole plant samples were below the lower limit of quantitation (LLOQ) for the ELISA method (Weeks et al. 2016). The lowest level of detection for barnase was 0.500 ng/ml, 1.000 ng/ml, 0.750 ng/ml, 1.000 ng/ml, and 2.500 ng/ml in leaf, forage, raceme, grain, and root, respectively (Weeks et al. 2016). Barnase protein is expected to be specifically expressed in flower buds during anther development. Since cells expressing barnase protein are quickly disrupted, the levels of barnase protein in MS11 canola tissues would be expected to be low.

This was substantiated in studies where expression levels of barnase protein determined in different tissues of MS11 canola, including flower buds, were below the LLOQ for the ELISA method in all tissues analyzed (Weeks et al. 2016). Barstar protein was only consistently expressed in the roots from field grown plants treated with glufosinate-ammonium (Weeks et al. 2016). The protein expression levels of barstar were consistently below LLOQ in all grain samples and most whole plant samples (Weeks et al. 2016). In Western blot analysis of crude root extracts, there was faint detection of barstar protein (Weeks et al. 2016).

Glufosinate

The natural phytotoxin L-phosphinothricin is a degradation byproduct of bialaphos, a natural compound produced by *S. viridochromogenes* and *S. hygroscopicus*. L-phosphinothricin, also called glufosinate, is employed as a non-selective herbicide used for broad spectrum weed control. Glufosinate, a synthetic mixture of the D- and L-form of phosphinothricin, is the only commercial herbicide that targets the plant enzyme glutamine synthetase (GS), an enzyme directly related to nitrogen metabolism in plants (Carbonari et al. 2016). L-phosphinothricin, (the D-isomer has no biological activity), competes for the glutamate-binding site in GS, inhibiting the enzyme and leading to glutamine deficiency and toxic ammonia accumulation in plants (Dayan et al. 2015; Carbonari et al. 2016), as well as glutamate accumulation. PAT inhibits the activity of glufosinate ammonium by acetylation of the phosphinothricin, thereby conferring resistance to herbicides that contain glufosinate (Carbonari et al. 2016). The EPA is currently reviewing glufosinate (US-EPA 2016d) and issued a preliminary ecological risk assessment in 2014 (US-EPA 2014).

4.5.2 Soil Biota

No Action Alternative: Soil Biota

Under the No Action Alternative, MS11 canola may continue confined field trials under APHIS authority. Limited production of MS11 canola in field trials as a regulated article is not expected to have any substantive adverse effect on soil biota. As discussed in the introduction to this section, MS11 canola contains the bar, barstar, and barnase genes. Because the genes barnase, barstar, and bar and the proteins they produce occur naturally in soil organisms and soil, it is not expected that they would alter soil biota communities (Wu et al. 2015). The agronomic practices associated with current canola production such as tillage and applications of pesticides and fertilizers are not expected to significantly change, with minor variance in practices relative to weed, pest, and disease pressures. Consequently, potential impacts to soil biota, beneficial and adverse, would continue along current trends.

Preferred Alternative: Soil Biota

Because MS11 canola is agronomically and phenotypically equivalent to MS8 canola (Weeks et al. 2016), potential impacts on soil biota would the same as that for the No Action Alternative. Use of glufosinate on MS11 canola and hybrid progeny is not expected to be any different than that currently occurring with MS8 canola and crops derived from MS8 progeny. Use of glufosinate on canola crops utilizing both MS8 and MS11 canola would be subject to EPA use requirements. Soil biota are already exposed to the agronomic practices and inputs that would be used in the commercial cultivation of MS11 canola and its progeny, as well as the barnase, barstar, and bar traits. Hence, there are no differences in potential impacts on soil biota between the No Action Alternative and the Preferred Alternative.

4.5.3 Animal Communities

No Action Alternative: Animal Communities

Under the No Action Alternative, conventional and GE canola production will continue as currently practiced while MS11 canola remains a regulated article. Cultivation of other GE and non-GE canola varieties will continue following the trends summarized in Section 3.2. Potential impacts of GE and non-

GE canola production on non-target terrestrial (insect, bird, and mammal) and aquatic (fish, benthic invertebrate, and herptile) species would be unchanged.

Most wildlife that feed on canola, such as small mammals and birds, do not nest or permanently reside in canola fields during the growing season due to frequent disturbance from use of agricultural equipment, application of pesticides, scouting, and other practices. Pesticide spray drift may inadvertently impact non-target species transiting canola fields, and plants and animals adjacent to canola fields. Similarly, run-off from canola fields carrying pesticides, excess soil nutrients, and sediments, may adversely impact aquatic ecosystems. The EPA considers non-target exposures in the registration and review of pesticides under FIFRA, and has reevaluated environmental exposures to glufosinate to determine safe use of the herbicide (US-EPA 2016d). When used according to EPA label requirements, glufosinate is considered to pose minimal risks to terrestrial and aquatic animals. Risks to terrestrial and aquatic organisms could be reduced per the EPA's registration review (US-EPA 2016d), 2014 ecological risk assessment (US-EPA 2014), and revisions to glufosinate use requirements. Considering cultivation of GE HR canola: From 1996 – 2012, GE HR canola farmers reduced herbicide use by 15 million kg (a 16.7% reduction) and the associated environmental impact of herbicide use on this crop area fell by 26.6% (due to a switch to more environmentally benign herbicides)(Brookes and Barfoot 2014). Under the No Action Alternative, any potential impacts, beneficial or adverse, on animal communities associated with canola production systems are not expected to change.

Preferred Alternative: Animal Communities

Under the Preferred Alternative, potential impacts to animal communities are not anticipated to be substantially different as compared to the No Action Alternative. Potential impacts to animal communities would arise from changes in agronomic inputs associated with the crop modification and direct exposure to the GE crop and its products. MS11 canola is equivalent to and would replace MS8 canola, and potential exposures to barnase, barstar, PAT, and glufosinate would be no different if MS11 is adopted for commercial use. Because MS11 canola is agronomically and phenotypically equivalent to MS8 canola (Weeks et al. 2016) and would be cultivated utilizing the same agronomic practices and inputs any potential impacts on animal communities would be similar to those described under the No Action Alternative. Hence, an extension of non-regulated status to MS11 canola and its progeny would not be expected to affect animal communities adjacent to or within MS11 canola production systems differently from that of currently cultivated MS8 hybrid canola.

The PAT, barnase, and barstar proteins expressed by MS11 canola are currently expressed in commercial MS8 canola hybrids, and PAT expressed in a variety of commercial GE corn, cotton, and soybean crops grown throughout the United States (an elsewhere in the world). As naturally occurring compounds in soils worldwide, and in turn surface waters, the PAT, barnase, and barstar proteins expressed in MS11 canola would not be considered a risk to terrestrial or aquatic animals, particularly at the levels expressed in MS11 canola tissues (Weeks et al. 2016).

4.5.4 Plant Communities

No Action Alternative: Plant Communities

Under the No Action Alternative, MS11 canola would remain a regulated article. The current availability and usage of commercially cultivated canola, to include both GE and non-GE HR varieties, would be unaffected by denial of the petition. Most canola grown in North America is GE HR. The primary potential impacts on plant communities that derive from the cultivation of GE HR canola are from development of herbicide resistant weed communities, and the introgression of transgenes into sexually compatible wild populations as a result of pollen flow from GE HR canola.

Plants that grow in canola cropping systems are considered weeds by growers and specifically targeted with weed management strategies that include the use of herbicides. Some plant communities in close proximity to canola fields can serve as sources of in-field weeds, and may also be managed with herbicides or other non-chemical methods. Herbicide resistant weeds, and the development of such resistant biotypes, are a problem in many agricultural systems, to include commercial canola cropping systems. Development of herbicide resistant weeds is not unique to GE HR canola, selection pressure exists wherever herbicides are used, on GE and non-GE crops alike. This type of potential impact on plant communities is discussed further in the subsection 4.5.4.1 – Herbicide Resistant Weeds.

Pollen flow from GE HR crops to sexually compatible wild relative species is possible, and its occurrence documented, as summarize in Section 3.5.3 – Gene Flow and Weediness of Canola. This is more of a concern with feral populations of GE HR canola. Feral GE HR canola, to include stacked-trait feral hybrids, have been identified in areas where canola is commercially grown and along transport routes. Where feral GE HR canola populations establish, the potential for hybridization with sexually compatible wild relative species exists. This type of potential impact on plant communities is discussed further in Subsection 4.5.5 – Gene Flow and Weediness of Canola. For all canola crops (*B. napus*), it is expected that outcrossing to sexually compatible wild plants on the order of 1% to 10% will occur within about a 30ft range (10 meters), and from 0.1% to 0.01% to plants within around 300ft (100 meters) (Myers 2006; EFSA 2013). However, pollen flow via wind has been reported at distances of up to 3 km (1.9 miles) (Warwick et al. 2008), albeit rarely. Introgression of transgenes from GE HR canola into wild populations appears to be limited, with few instances of introgression being documented to date (Warwick et al. 2008; Luijten et al. 2015; Bailleul et al. 2016; Belter 2016; Busi and Powles 2016). Whether this is due to lack of detection, occurrence, or combination of both, has not been well elucidated.

Under the No Action Alternative, conventional canola production would continue while MS11 canola remains a regulated article. Potential impacts to plant communities associated with canola production are not expected to change in the No Action Alternative.

Preferred Alternative: Plant Communities

MS11 canola would have no impacts to plant communities adjacent to or within agroecosystems that would be different from that of currently available canola cultivars. MS11 canola has been shown to be phenotypically and agronomically similar to MS8 canola (Weeks et al. 2016). Growers are already managing canola to control for competing plant life and surrounding areas that could provide pest and disease reservoirs using treatments and controls. There would be no change in herbicide use or patterns. Potential impacts related to gene flow and weediness are discussed below in Section 4.5.5.

Land use and agricultural production of canola under the Preferred Alternative is likely to continue as currently practiced with MS11 canola replacing MS8 canola. Consequently, any potential impact to other vegetation in canola and the landscapes surrounding canola fields from approving a determination of nonregulated status to MS11 canola is not expected to differ from the No Action Alternative.

4.5.4.1 Herbicide Resistant Weeds

No Action Alternative: Weed Resistance

Under the No Action Alternative, MS11 canola would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) canola are expected to remain the same under the No Action Alternative. As described in Subsection 3.3.4 – Weed Resistance Management, the use of herbicides imparts selection pressures on weeds that results in survival of weeds naturally resistant to the herbicide (Owen 2011; Owen 2012; Vencill et al. 2012). The development of herbicide resistance in weeds is not unique to genetically engineered crop plants. Herbicide resistant weed populations have been occurring since the advent and wide-spread use of chemical herbicides in the

1950s. Overreliance on a single herbicide, a single mode of action (MOA), can place significant selection pressure on weed populations. Herbicide resistant weeds are becoming increasingly common and the evolution of herbicide-resistant weed biotypes is a primary concern for crop producers.

In order to effectively reduce the potential for development of resistant populations, growers must implement integrated weed management (IWM) practices that utilize all available weed resistance control tactics. Anyone using an herbicide is required, by law, to use that herbicide pursuant to the EPA label requirements and other EPA guidance issued for use. The EPA label contains information on weed resistance management consistent with the Weed Science Society of America's (WSSA) recommendations for weed resistance management (WSSA 2012). The EPA issued updated guidance for glufosinate resistance management in 2016 (US-EPA 2016e). It is expected that glufosinate and other herbicides will be used per EPA requirements, as well as WSSA recommendations.

Preferred Alternative: Weed Resistance

An extension of non-regulated status to MS11 canola would not be expected to increase the potential for development of herbicide resistant weeds. MS11 canola hybrids are expected to supplant currently cultivated MS8 canola hybrids. Because MS11 canola is phenotypically and agronomically similar to MS8 canola, the use of herbicides containing glufosinate-ammonium, and the selection pressure for the development of glufosinate resistant weeds would not be expected to differ under the Preferred Alternative and No Action Alternative.

In managing extant herbicide resistant weeds, which are prevalent in major canola growing areas of the Northern Great Plains and Western Canada (Table 4-1), glufosinate, a glutamine synthetase inhibitor, is recognized as an herbicide that may be used to control herbicide resistant weeds, though other herbicides are also available for use. APHIS is not aware of any glufosinate resistant weeds present in North Dakota; the only known glufosinate resistant weed is Italian ryegrass (*Lolium perenne* subsp. *multiflorum*), with resistant populations in Oregon and California. While Table 4-1 summarizes resistant weeds in the primary canola production area of North Dakota, as of 2012, there were a total 34 states with commercial canola farms (USDA-NASS 2014). Each of these other states will likewise have populations of herbicide resistant weeds unique to the area of canola production.

Table 4-1. Herbicide Resistant Weeds in North Dakota

	ACCase inhibitors	ALS inhibitors	Mitotic inhibitors	Growth regulators	Photosystem II inhibitors	EPSPS inhibitor (glyphosate)
HR Weed	**Mode of Action**					
Wild Oat *	X	X				
Green Foxtail	X		X			
Kochia *		X		X	X	X
Waterhemp *		X				X
Common ragweed *		X				X
Marshelder		X				
Wild mustard		X				
Black nightshade		X				
Redroot pigweed						
Horeseweed						X

Lambsquarters						X

Source: (NDSU 2016a)

* Denotes multiple resistance – weeds resistant to two or more herbicide modes of action.

To the extent that growers may cultivate MS11 canola hybrids in lieu of other currently-available canola varietals, the total volume of glufosinate used is not expected to substantially change, other than increases in use of glufosinate that may follow increased canola production to meet increased market demand. As with the No Action Alternative, any use of glufosinate on MS11 canola and its progeny would be subject to EPA registration and labeled use requirements, to include EPA guidance for glufosinate resistance management.

Considering the factors described above, an extension of non-regulated status to MS11 canola, and any subsequent commercial production of MS11 canola and its progeny, is not anticipated to substantially alter the potential for development of glufosinate resistant weeds, relative to the No Action Alternative.

4.5.5 Gene Flow and Weediness of Canola

No Action Alternative: Gene Flow and Weediness

Under the No Action Alternative MS11 canola would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) canola are expected to remain the same under the No Action Alternative.

Considering the current science reviewed in Subsection 3.5.3 – Gene Flow and Weediness of Canola, gene flow from commercially grown GE HR canola to sexually compatible wild relative species will continue to occur (Legere 2005; Schafer et al. 2011). Seed dispersal along transport routes, cross-pollination of feral GE HR canola with wild relatives, and development of hybrid populations in areas of seed dispersal is likely. Feral populations of GE HR x wild type hybrids will likely persist in disturbed habitats. Pollen flow from GE HR canola to sexually compatible wild relative *Brassica* spp. will occur, although largely limited to areas within around 300 feet of crop field edges. The majority of canola pollen disperses within a radius of around 10 meters, and hybrid seeds rarely are detected more than 50 meters (165 feet) from the pollen-supplying parent (Myers 2006); however, rare outcrosses can be detected up to 4 kilometers (2.4 miles) away under special circumstances (Myers 2006). Based on current data, it is assumed that interspecific and intraspecific hybridization will occur, although probably at a low levels (Warwick et al. 2003; Legere 2005; Myers 2006; Warwick et al. 2008). Gene flow is most likely to occur among *B. napus* crops, and *B. napus* crops and wild relative *B. napus* subspecies and *B. rapa* species occurring in or around crop fields, or where canola seed is spilled during transport (Beckie et al. 2003; Legere 2005; CFIA 2011, 2016).

In summary, gene/transgene flow between commercial GE and non-GE canola varieties, and between GE HR canola and wild relative *B. napus* and *B. rapa*, is inevitable (Legere 2005; Beckie and Warwick 2010; Knispel and McLachlan 2010; Bailleul et al. 2016). To date, while feral GE HR canola populations exist worldwide, disruption of wild plant communities, and ecosystems, have not been described in the peer review literature. *B. napus* is not an invasive plant and in this respect not considered of high risk to native plant communities (e.g., see (Katsuta et al. 2015; Belter 2016)). However, the environmental consequences of extant and future GE HR canola and wild type *Brassica* hybrids remain largely unknown, as such consequences have not, to date, been well studied. Currently, the primary impacts are those associated with GE HR volunteers, namely those with multiple HR traits, which can create management problems in current and subsequent crops, and can compromise the marketability of certified seed and contaminated crops.

The persistence of GE HR volunteers and gene flow among GE HR canola and volunteers will likely have agronomic consequences in some areas; requiring adaptation of cultural and chemical management practices. The persistence of feral GE HR canola and hybridization and stable incorporation of GE HR traits in wild *Brassica* populations is likely to exacerbate issues with transgene flow to wild populations. For example, GE HR *B. napus* may cross with *B. rapa* in the wild. Hybrid *B. rapa* (wild mustard) may be considered weedy in cultivated fields and disturbed areas, and may displace desirable vegetation if not properly manage (USDA-NRCS 2012).

Preferred Alternative: Gene Flow and Weediness

The agronomic and phenotypic characteristics of MS11 canola have been evaluated in field trials and determined to be similar to comparator canola cultivars, which includes GE and non-GE canola (Weeks et al. 2016). MS11 canola, and MS11 hybrids would be cultivated as are current canola varieties and present the same potential risk for gene flow, specifically the propensity and frequency of gene flow, as current canola varieties. Hence, an extension of non-regulated status for MS11 canola and its progeny would not be expected to present more or less risk for gene flow to wild relative species as do current canola varieties. This considered, MS11 canola can potentially transfer the bar, barnase, and barstar genes to sexually compatible species via intraspecific or interspecific hybridization. The PAT trait extant in MS11 canola does not result in characteristics commonly observed in weeds (i.e., hardy, prolific, highly competitive, difficult to control), other than its contribution to exacerbation of control of feral and volunteer GE canola plants. The barnase and barstar traits controlling fertility in MS11 canola are not expected to increase the weediness potential of this canola variety, or MS11 canola hybrids. The male sterility trait (barnase) in MS11 canola, which also contains the bar gene, would provide a competitive disadvantage if transferred via hybridization to wild relative species.

Based on the similarity of MS11 canola to the antecedent MS8 canola, the fact that the additional barstar gene is expressed at low levels that do not alter the male sterile and glufosinate resistant phenotype, the determination that the antecedent organism was unlikely to become a weed, and the agronomic data obtained in field trials of MS11 canola, APHIS concluded that it is unlikely that MS11 canola will become a weed. APHIS concluded that it is similarly unlikely that gene introgression from MS11 canola to other organism with which it can interbreed will increase their weediness (USDA-APHIS 2016). Similarly, the potential for occurrence and persistence of MS11 hybrid volunteers would not be expected to be any different than that of MS8 hybrid volunteers. Data from field trials show seed germination characteristics of MS11 canola exhibited no statistical differences as compared to non-GE cultivars (Weeks et al. 2016).

4.5.6 Biodiversity

No Action Alternative: Biodiversity

Biological diversity, or the variety of all life forms in a given area, is highly managed in agricultural systems. Farmers typically plant crops that are genetically adapted to grow well in a specific geographic area, and which have been bred for a specific market. For cropping systems such as canola, growers seek to achieve the highest yield possible from their crop, and will intensively manage plant and animal communities through chemical and cultural controls to facilitate optimal yield, and protect the crop from damage. Consequently, the biological diversity in agricultural cropping systems (the agro-ecosystem) is typically lower than in surrounding habitats.

Under the No Action Alternative, MS11 canola would continue to be regulated by APHIS under 7 CFR part 340. Given the limited acreage and transient nature of field trials (from one to several years), impacts on biodiversity in the areas where MS11 canola may be field tested are unlikely. Growers and other parties who are involved in production, handling, processing, or consumption of canola would continue to have access to conventional canola varieties, 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. Agronomic practices associated with conventional canola production (both GE and non-GE) such as cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment would continue unchanged. Life forms typically associated with canola fields will continue to be affected by currently utilized management plans and systems, which include the use of mechanical, cultural, and chemical control methods. The consequences of current agronomic practices associated with canola production, both traditional and GE varieties, on biodiversity is unlikely to be altered. Impacts to biodiversity associated with agronomic practices in cultivating canola are not expected to change under the No Action Alternative.

Preferred Alternative: Biodiversity

As discussed under Subsection 3.5.2– Animal and Plant Communities, an extension of non-regulated status to MS11 canola and its progeny would not be expected to affect the diversity of life forms adjacent to or within MS11 canola production systems that would differ from that of currently cultivated conventional and GE canola varieties. MS11 canola has no novel phenotypic characteristics that would extend their range beyond the current areas of canola production.

An extension of non-regulated status would not change the acreage, or the agronomic practices required for commercial canola production. MS11 canola is agronomically and phenotypically equivalent to currently cultivated MS8 canola and MS8 hybrid canola (Weeks et al. 2016). Glufosinate, when used per the EPA requirements is not expected to substantially affect biodiversity in or around canola fields. The bar, barstar, and barnase genes and their gene products, which occur naturally in soils and soil organisms, are unlikely to present any risk to biodiversity. Based on these factors, APHIS has determined that approval of Bayer's extension request for MS11 canola will have the same impact on biodiversity as the No Action Alternative.

4.6 Human Health

Public health considerations are those related to (1) the safety and nutritional value of MS11 canola and its progeny, and (2) the potential health effects of pesticides that may be used in production of MS11 canola and progeny. As for food safety, consumer health concerns are in regard to the potential toxicity or allergenicity of the introduced genes/proteins, possibly altered levels of existing allergens in canola, or the expression of new antigenic proteins. Consumers may also be concerned about potential consumption of glufosinate residues on or in food products derived from MS11 canola.

4.6.1 Safety of GE MS11 Canola: Bar, Barnase, and Barstar Transgenes

In a submission dated May 29, 1998, AgrEvo (acquired by Bayer CropScience in 2001) provided the FDA information to support their safety assessment of MS8 canola and RF3 canola. The data was supported by documents submitted to the FDA in 1995 regarding three transgenic canola lines: a male sterile oilseed rape line designated MS1, and two restorer lines designated RF1 and RF2. In a response letter dated September 16, 1998, the FDA, based on the information AgrEvo (Bayer CropScience) presented to the FDA, stated they had no further questions concerning the hybrid canola containing transformation events MS8 and RF3, and that it was AgrEvo's (Bayer CropScience) continued responsibility to ensure that foods the firm markets were safe, wholesome, and in compliance with all applicable legal and regulatory requirements.[38]

The bar, barnase, and barstar proteins in MS11 canola, which is intended to replace MS8, have well-understood biological activities. The bar enzyme occurs naturally in the bacteria *Streptomyces*

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[38] See FDA Biotechnology Consultation Agency Response Letter BNF No. 000057: http://www.fda.gov/Food/IngredientsPackagingLabeling//GEPlants/Submissions/ucm161090.htm

hygroscopicus, found in soils worldwide. It stands to reason that humans and animals, globally, have been and are potentially exposed, incidentally, to the bar gene and PAT enzyme through environmental sources on a daily basis (e.g., ingestion, inhalation). The PAT enzyme is non-pathogenic to humans and does not possess characteristics associated with food allergens (Herouet et al. 2005). The PAT enzyme has been reviewed and approved for human and animal consumption in various countries including the United States, Canada, Australia, Argentina, Japan, South Africa, and the European Union. Glufosinate-ammonium resistant crop plants containing the PAT protein has been widely grown for over a decade, and canola oil and canola meal derived from these plants widely distributed in the global food and feed markets. There are no known reports of adverse effects on human or animal health.

Due to the negligible risk the PAT protein poses to human health, PAT and the genetic material encoding for PAT in all plants are exempt from the requirement of a tolerance when used as plant-pesticide inert ingredients in all plant raw agricultural commodities (62 FR 70, Apr. 11, 1997, p. 17719). Based on the scientific literature, the pat/bar genes and their expression product (PAT) presents negligible risk to human health (Herouet et al. 2005; CERA 2011).

Barnase has been evaluated by the FDA in the above described consult for MS8 and RF3 canola lines, as well as GE corn and radicchio varieties, and the FDA had no concerns as to the food safety of these canola, corn, or radicchio lines.[39] Barstar has also been evaluated by the FDA in several GE canola lines.[40] Bioinformatics studies indicated that no similarities exist between barnase and barstar proteins and known toxic proteins or allergens (EFSA 2012). The European Food Safety Authority (EFSA) GMO Panel is of the opinion that “MS8, RF3, and MS8 × RF3 oilseed rape is as safe as conventional oilseed rape for humans and animals and, in the context of the proposed uses, for the environment” (EFSA 2005).

Barnase and barstar proteins are expressed in the tapetum cells of the flower buds, they are not detected in seeds, pollen, and unprocessed canola meal (EFSA 2012). Studies on the antecedent MS8 and RF3 lines suggested neither protein would be expected to occur in food or feed derived from MS8, RF3, and MS8 × RF3 seed or pollen (EFSA 2012). Because no or little protein is present in the oil extracted from the canola seed, and human consumption of canola products is limited to the refined oil, the potential for human exposure to barnase and barstar proteins is from exceptionally low to non-existent.

Bayer performed expression analyses of the barnase and barstar genes and proteins in MS11 canola. Mean expression levels of barstar and barnase proteins in three generations of MS11 canola whole plant samples were below the lower limit of quantitation (LLOQ) for the ELISA method (Weeks et al. 2016). The lowest level of detection for barnase was 0.500 ng/ml, 1.000 ng/ml, 0.750 ng/ml, 1.000 ng/ml, and 2.500 ng/ml in leaf, forage, raceme, grain, and root, respectively. Barnase was also not detected by western blot analysis in crude extracts or upon immune-affinity purification attempts (Weeks et al. 2016). Barnase protein is expected to be specifically expressed in flower buds during anther development. Since cells expressing barnase protein are quickly disrupted, the levels of barnase protein in MS11 canola tissues would be expected to be low. This was substantiated in the protein expression studies (Weeks et al. 2016). Barstar protein was only consistently expressed in roots from field grown samples treated with glufosinate-ammonium. The protein expression levels of barstar were consistently below LLOQ in all grain samples and most whole plant samples (Weeks et al. 2016).

Lastly, *Bacillus amyloliquefaciens*, from which the barstar and barnasae genes are derived, is ubiquitous in the environment, especially in soils and agricultural environments. Hence, it stands to reason that human exposures to *B. amyloliquefaciens* and barnase and barstar proteins likely has been and does occur

[39] FDA- Biotechnology Consultations on Food from GE Plant Varieties: http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon&sort=FDA_Letter_Dt&order=DESC&startrow=1&type=basic&search=barnase

[40] FDA- Biotechnology Consultations on Food from GE Plant Varieties: http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon&sort=FDA_Letter_Dt&order=DESC&startrow=1&type=basic&search=barstar

on a daily basis via incidental ingestion and inhalation. *B. amyloliquefaciens* has a long history of safe use for the production of enzymes with both food and industrial uses (e.g., amylomaltase enzyme, alpha-amylase). The FDA determined that carbohydrase and protease enzyme preparations derived from *B. amyloliquefaciens* are generally recognized as safe (GRAS) for use as direct food ingredients (64 FR 78, April 23, 1999, p. 19887). The EFSA has listed *B. amyloliquefaciens* as a bacteria with a "qualified presumption of safety" (QPS) because of a long history of apparent safe use in food and feed production (Barlow et al. 2007).

Based on the above factors, and the information reviewed in Section 4.5 – Biological Resources, it is unlikely that the barnase and barstar genes and their gene products expressed in MS11 canola present any risk to human health.

No Action Alternative: Human Health and Worker Safety

Under the No Action Alternative, MS11 canola would continue to be regulated by APHIS. It is highly unlikely consumers would be exposed to food products derived from MS11 canola. Current commercially cultivated (both GE and non-GE) canola varieties, including hybrids containing the same bar, barstar, and barnase traits expressed in MS11 canola, would continue to be cultivated for food (canola oil) and feed. Management practices, and the associated human health effects, are not likely to change under the No Action Alternative. The EPA would continue to regulate residues of glufosinate-ammonium in food and feed. As described in Section 3.6 – Human Health, the EPA provided recent revisions to WPS and glufosinate use requirements that are expected to further protections for worker safety. Risk to glufosinate applicators and handlers is low when glufosinate is used consistent with the EPA label requirements (US-EPA 2016d). No changes to current worker safety are anticipated under the No Action Alternative.

Preferred Alternative: Human Health and Worker Safety

An extension of non-regulated status for MS11 canola would not be expected to result in any potential impacts on human health that differ from those of the No Action Alternative. MS11 canola is equivalent to currently cultivated MS8 canola, which has been on the United States and international markets for more than a decade (Weeks et al. 2016).

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. APHIS considers the voluntary FDA consultation process in evaluating the potential impacts of a determination on non-regulated status for new agricultural products. The FDA has conducted prior reviews for food products derived from GE canola expressing PAT, barnase, and barstar and had no concerns (reviewed above in Subsection 4.6.1). Bayer has the option of consulting with the FDA regarding commercialization of MS11 canola.

Under the Preferred Alternative, cultivation practices and corresponding worker exposures to agronomic inputs are unlikely to change. Bayer demonstrated in its petition that MS11 canola is phenotypically and agronomically the same as currently cultivated MS8 canola (Weeks et al. 2016). Accordingly, the health and safety protocols currently employed by farm workers in canola production do not require changes to accommodate the cultivation of MS11 canola. An extension of non-regulated status to MS11 canola would not be expected to have any effect on glufosinate use, the EPA regulation of glufosinate, or worker protection standards; potential risks and protections would be no different than that of the No Action Alternative.

Based on these factors and the equivalency of MS11 canola with MS8 canola, a determination on non-regulated status for MS11 canola would present negligible risk to human health, to include worker safety.

4.7 Animal Feed

As reviewed above for human health, the PAT protein presents no cause for concern to animal health and welfare (CERA 2011). Barnase and barstar have gone through previous FDA food and feed safety consultations for GE canola. The FDA had no concerns regarding feed derived from these canola cultivars. Barnase and barstar have been also previously reviewed by APHIS, for example corn (Petitions 95-228-01p and 98-349-01p), and canola (Petitions 98-278-01r and 01-206-01p). Based on these reviews, and that information reviewed in Section 4.5 – Biological Resources, and above for human health, it is unlikely that the barnase and barstar proteins expressed in MS11 canola or its progeny pose any risk to animal health and welfare.

No Action Alternative: Animal Feed

Animal feed derived from canola is in the form of canola meal and is one of the most widely used protein sources for livestock, poultry, and fish; the second-most widely traded protein ingredient after soybean meal (CCC 2015). Canola can also be grazed by livestock, and made into hay or silage (NDSU 2008), although this is not a common practice. Under the No Action Alternative, MS11 canola will remain a regulated article and will not be available as an animal feed. Current availability of GE and non-GE canola based animal feed will remain unchanged.

Preferred Alternative: Animal Feed

An extension of non-regulated status to MS11 canola will have no effect on animal health and welfare. The PAT, barstar, and barnase proteins, reviewed above, present negligible risk to animals. Deregulation of MS11 canola would not result in any novel exposure of livestock to these proteins, given they are currently present in commercial GE HR canola used for production of canola meal, as well as in soils and soil microorganisms. The Preferred Alternative and No Action Alternative will have the same potential impacts on animal health and welfare.

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 MS11 canola must be in compliance with all applicable legal and regulatory requirements. GE organisms developed for feed purposes may undergo a voluntary consultation with the FDA prior to release onto the market. As previously noted, because MS11 canola is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering, Bayer may consult with the FDA on the safety of MS11 canola as animal feed.

4.8 Socioeconomics

4.8.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Environment

Under the No Action Alternative, MS11 canola would continue to be regulated by APHIS and would not be produced for commercial purposes. Current canola varieties, including GE and non-GE, would continue to be cultivated, relative to grower preference, to meet market demand for canola oil, canola meal, and perhaps biodiesel stock. Denial of the petition would have no effect on the U.S. domestic canola oil, meal, or biodiesel markets.

Preferred Alternative: Domestic Economic Environment

A determination of non-regulated status for MS11 canola is not expected to adversely impact domestic conventional, organic, and GE canola markets. The availability of MS11 canola is unlikely to influence the area or acreage of canola planted, it is expected that MS11 canola would replace existing

MS8 canola. In this respect, the potential domestic economic impacts associated with the introduction of MS11 canola into commerce, inclusive of conventional, organic, and GE canola markets, would be no different than those currently observed for MS8 hybrid canola.

4.8.2 International Trade

No Action Alternative: Trade Economic Environment

Under the No Action Alternative MS11 canola would remain a regulated article under 7 CFR part 340. There is unlikely to be any change to the current export markets for canola seed, oil, and meal. Current availability and usage of commercially cultivated (both GE and non-GE) canola are expected to remain the same under the No Action Alternative. Consequently, impacts on trade under the No Action Alternative are unlikely.

Preferred Alternative: Trade Economic Environment

Under the Preferred Alternative, MS11 canola would be determined non-regulated and available to U.S. growers. A determination of non-regulated status of MS11 canola is not expected to adversely impact international canola markets. The United States and other countries already have access to GE canola varieties, including GE HR varieties, and a substantial number of non-GE canola cultivars. Because MS11 canola is agronomically similar to other non-regulated canola varieties (Weeks et al. 2016), MS11 canola would serve the same global uses in provision of canola oil, canola meal, and perhaps biodiesel as current GE and non-GE canola commodities. MS11 canola would not be expected to affect food, feed, or biofuels trade any differently than other non-regulated GE HR and non-GE canola varieties. MS11 canola would be subject to the same international regulatory requirements as currently traded canola varieties. MS8 hybrid canola has been reviewed and approved for commercial uses in 11 countries, to include Australia, Canada, the EU, and China.[41] Hybrids based on MS11 canola will be commercialized in the canola growing regions of Canada, United States, and Australia. Because MS11 is equivalent to and intended to replace MS8 canola, the potential for adverse impacts on trade are considered to be negligible.

[41] ISAAA Summary of Regulatory Approvals: http://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=4

5 CUMULATIVE IMPACTS

CEQ regulations implementing NEPA define a cumulative impact as an “impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency [federal or non-federal] or person undertakes such other actions” (40 CFR 1508.7). Hence, cumulative impacts can derive from individually minor actions that when added together, over time, collectively result in adverse environmental impacts. Emissions of air pollutants from a multitude of individual sources is an example of a cumulative impact. For this EA, potential cumulative impacts would be those associated with an extension of non-regulated status to MS11 canola, in combination with past and future determinations of non-regulated status for GE canola with which MS11 canola may be crossbred to produce stacked-trait varieties. These could include herbicide resistance and pest and disease resistance.

5.1 Assumptions Used for Cumulative Impacts Analysis

Cumulative impacts are evaluated for those aspects of the human environment discussed in Chapter 3. If there are no direct or indirect impacts associated with those aspects of the human environment evaluated (discussed in Chapter 4), then APHIS assumes there can be no reasonably foreseeable cumulative impacts. Further assumptions used for evaluation of potential cumulative impacts are summarized as follows.

5.1.1 Similarity

As discussed in Chapter 4, Bayer’s analyses and field studies of MS11 canola found that MS11 demonstrated no agronomically relevant differences compared to non-GE conventional counterparts and exhibited equivalent performance in the field compared to canola reference varieties. Biotic stressors (disease and insect) were evaluated and no statistically significant differences were observed in comparisons to the non-GE conventional counterpart (Weeks et al. 2016). The only difference between MS11 and MS8 as it pertains to the genetic modification is that MS11 includes the barstar gene for low level expression of the barstar protein. This protein is expressed by the restorer line RF3 as well. The low level expression of the barstar protein was included in MS11 to increase transformation efficiency. It has no effect on the male sterile or herbicide resistant phenotypes of MS11. MS11 canola demonstrates the same phenotype as MS8: male sterility conferred by the expression of barnase proteins in the tapetum and glufosinate-ammonium resistance conferred by the expression of PAT in all green tissue. Fundamentally, there are no changes in the purpose and rationales of MS8 and MS11 canola.

Considering the similarity of MS11 and MS8 canola (Weeks et al. 2016; USDA-APHIS 2016), that MS11 canola is to replace MS8 as breed stock, and MS11 hybrid canola seed is to replace MS8 hybrid seed for the commercial market, there is no substantive change in Bayer’s GE HR seed used for commercial canola production. The only difference is that MS11 is comprised of low level expression of the barstar protein, which, as reviewed in Chapter 4, is not a significant change in regard to agronomic properties or environmental interactions. APHIS considers MS11 canola to be agronomically and phenotypically equivalent to MS8 canola.

5.1.2 Future Uses of MS11 Canola and Combined Effects

If APHIS approves the extension request for non-regulated status, APHIS assumes that MS11 canola will be used for commercial canola production. MS11 canola and any progeny derived from it, could potentially be combined with other non-regulated GE and non-GE canola varieties through traditional breeding techniques. Such breeding may be used to produce canola varieties that, for example, may be resistant to two or more herbicides and/or contain other insect and disease resistance traits. These types of progeny, regardless of their plant-trait combinations, would not be subject to the regulatory requirements of 7 CFR part 340. For example, MS11 canola could be crossbred with other non-regulated disease resistant canola varieties that protect against yield loss from sclerotinia stem rot (fungal pathogen) and damping-off (wirestem).

APHIS assumes that next-generation stacked-trait canola varieties would likely be those conferring disease resistance, and to some extent, resistance to herbicides. These may be produced through breeding MS11 canola with previously deregulated GE canola varieties (see Table 3-4), GE varieties that may be deregulated in the future, or non-GE canola cultivars that are bred for resistance to insect pests and pathogens. APHIS assumes that these types of stacked-trait varieties would be produced only as a result of their potential utility; to expand grower choice and production efficiencies in the management of plant pests, pathogens, and agricultural weeds.

Whether MS11 canola, or MS11 canola progeny, will be stacked with traits from any particular non-regulated GE canola variety, or non-GE cultivar, is unknown, nor can this be reasonably predicted. Global demand for oilseed (canola and soybean), canola and soybean meal, and biodiesel; the economics of canola production; canola and soybean pest, disease, and weed pressures; and seed company plans play a substantial role in the development of new canola hybrids. The adoption level of crossbred progeny of MS11 canola would depend on the extent to which producers valued the traits offered by such stacked-trait varieties of MS11 canola over other available varieties of stacked-trait canola, and the pricing and production efficacies of such stacked-trait MS11 canola varieties relative to other canola varieties (of which there are a substantial number).

APHIS assumes that all pesticides applied to canola, inclusive of glufosinate, will conform to EPA registered uses and the EPA approved label use requirements. APHIS assumes that drift from glufosinate and other pesticide applications will be mitigated to an acceptable level by the requirements established by the EPA. APHIS also assumes that weed and insect resistant management practices will be employed in pesticide use, as required by the EPA.

5.2 Cumulative Impacts: Acreage and Areas of Canola Production

Because MS11 canola would likely replace currently cultivated MS8 canola, this would not entail in any cumulative increase in acreage, or affect the areas where canola is produced. Canola acreage may expand over time, but that expansion would be in response to market demand for canola oil, canola meal, and perhaps biofuels. Growers would opt to produce the conventional canola cultivar or GE variety that best suited their needs in supplying market demand, of which there are ample conventionally bred and GE canola options. These currently include GE HR, non-GE HR, and GE HR stacked with resistance to blackleg and clubroot disease, and conventional cultivars bred for cultivation in specific regions of the United States (Brown et al. 2008; NDSU 2016b). APHIS expects that additional conventional and GE canola options will continuously become available to producers in the coming years, this includes any progeny that may be derived from MS11 canola.

5.3 Cumulative Impacts: Agronomic Practices

As discussed in Section 3.3 – Agronomic Practices and Inputs, there is no difference in the agronomic practices used for cultivation of MS11 canola and currently cultivated MS8 canola. Pest, disease, and weed management strategies; crop fertilization; crop rotation; tillage; seeding; and harvesting practices used in current and future canola production would generally follow current practices for GE HR canola. These practices would adapt as need to sustain canola crop yields, efficiencies in crop production, and grower net returns.

Growers would continue using glufosinate and all other available herbicides that are EPA registered for weed control in canola, either alone or in combination, with MS11 canola and its progeny, as well as with all other conventional and GE canola cropping systems. Because the requirements for application and use rates for herbicides that would be applied to MS11 progeny would be established by the EPA, as well as uses for all other non-regulated canola cultivars, the potential cumulative impacts from the use of herbicides under the Preferred Alternative would be the same as those of the No Action Alternative. The total amount of herbicides that could be applied to MS11 canola would be limited by the EPA registered use requirements, and the annual application limits indicated on the labeled instructions for use.[42] As it is a violation of federal law to use an herbicide in a manner inconsistent with its FIFRA labeling, and considering the need and the EPA requirements for controlling the development of resistant weeds, it is expected that growers in coming years will use herbicides judiciously, per the EPA label use requirements, as part of integrated weed management (IWM) programs.

As with herbicides, any insecticides, fungicides, any other regulated synthetic chemical or biopesticides, to include PIPS, which would be used with MS11 and any progeny, would be subject to EPA registration and use requirements. As with herbicides, the EPA applies similar stewardship practices to registered uses for insecticides, to include PIPS, such as insect resistance management.[43]

Considering these factors, there are no reasonably foreseeable adverse cumulative impacts on agronomic practices that would derive from MS11 canola, or any hybrid progeny derived from it (e.g., insect and disease resistant canola).

5.4 Cumulative Impacts: Physical Environment

As discussed in Section 4.4 – Physical Environment, approving the petition for non-regulated status of MS11 canola under the Preferred Alternative would have the same potential impacts to water, soil, and air quality, as that of MS8 canola and MS8 canola hybrids. The agronomic practices used in the cultivation of MS11 canola, and environmental interactions, are no different than that of MS8 canola. If APHIS extend non-regulated status to MS11 canola, and MS11 canola is used for commercial crop production, the agronomic practices used for U.S. canola production would not change, nor the potential environmental impacts of these agronomic practices.

If the extension request for non-regulated status for MS11 canola is approved, it or progeny derived from it may be stacked with other HR, insect, or disease resistant traits via traditional breeding. Stacking MS11 canola or its progeny with other HR traits would enable the use of a combination of herbicides with different modes of action to be applied in an IWM program. Depending on the extent of adoption of stacked-trait HR progeny, these may foster and help sustain conservation tillage and no-till practices in U.S. canola production, and contribute, regionally, to limiting soil erosion and agricultural run-off (Gusta et al. 2011; Brookes and Barfoot 2015c; NAS 2016). APHIS assumes pesticides would be used in an integrated pest management (IPM) program, and that insect resistant management practices will be employed as appropriate and required by the EPA. Utilization of any MS11 canola progeny stacked with insect or disease resistant traits could facilitate reductions in insecticide and fungicide use (NAS 2016). Hence, cultivation of such stacked-trait progeny could potentially help mitigate the potential adverse impacts of chemical pesticides on water, soil, and air quality.

Considering the array of GE and non-GE canola varieties available to commercial producers, any such MS11 progeny would be cultivated in lieu of other canola cultivars to the extent that the progeny improved efficiencies in the production of canola (e.g., pest, disease, weed management), and provided commensurate or better quality in canola products.

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[42] For example - Glufosinate 280 Herbicide: https://www3.epa.gov/pesticides/chem_search/ppls/033270-00035-20150429.pdf

[43] EPA - Introduction to Biotechnology Regulation for Pesticides: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/introduction-biotechnology-regulation-pesticides#resistance

The potential benefits of GE canola considered; issues unique to GE HR canola are feral hybrid populations comprised of HR traits, and volunteer GE HR canola, both of which will likely persist concomitant with commercial GE HR canola cropping systems. Denial or approval of the extension request would not be expected to contribute in a cumulative manner to the prevalence or incidence of volunteer or feral canola populations, nor the herbicides and or mechanical methods used to control volunteer and feral canola. Because MS11 canola would be cultivated in lieu of MS8 canola, additive impacts on the incidence or prevalence of feral GE HR canola, or GE HR volunteers, would not be expected. However, a stacked-trait GE HR variety of volunteer canola derived from MS11 canola could prove more difficult to control, or rather, require the use of herbicides with specific modes of action – herbicides other than glyphosate, glufosinate, or imidazolinone. Hence, it is possible that herbicide use could increase in areas where the incidence or/and prevalence of novel stacked-trait GE HR canola volunteers or HR feral populations increased.

Considering these factors, a determination of non-regulated status for MS11 canola is not anticipated to result in any significant cumulative impacts on water quality or use, or soil or air quality, relative to the No Action Alternative. The potential environmental impacts of commercial cropping systems on soil, air, and water quality are well recognized, as summarized in Chapters 3 and 4. APHIS has not identified any changes in the agronomic practices used for cultivation of MS11 canola, or its progeny, that would present any novel risks to the physical environment. The conservation and no-till practices commonly used in GE HR canola production are largely considered beneficial to the physical environment by conserving soils, reducing agricultural run-off to surface waters, and limiting NAAQS emissions. Herbicide use in canola production has declined over the last two decades (Brookes and Barfoot 2015c), over which time GE canola emerged to comprise around 90% or more canola acres in the United States. These reductions occurred while GE HR volunteer canola increased. If MS11 canola is extended non-regulated status, no cumulative impacts to the physical environment would be expected.

5.5 Cumulative Impacts: Biological Resources

Due to the similarity and purposes of MS11 and MS8 canola the impacts of the Preferred Alternative on animal and plant communities, microorganisms, and biodiversity as discussed in Section 4.5 – Biological Resources would be no different than that experienced under the No Action Alternative.

Agricultural practices can impact wildlife in and around canola fields; albeit such impacts are generally insignificant and transient. Cultivation of MS11 canola would not directly, indirectly, or cumulatively impact wildlife any differently than cultivation of current MS8 canola. Plants in proximity to canola crops, those populations along field borders, will likely be impacted by incidental exposure to herbicides. There may be some degree of cumulative impact on wild plant communities in disturbed habitats via the presence of feral GE canola. These potential impacts are discussed below in Section 5.6 – Gene Flow and Weediness.

5.5.1 Pesticide Use

Neither MS11 canola nor its progeny, to include stacked-trait varieties, would necessitate an increase in the use of glufosinate or other pesticides in commercial crop production. A hybrid based on MS11 canola comprised of traits conferring resistance to other herbicides, insects, or pathogens would provide growers with another canola varietal for the management of pests, disease, and weeds. Such a varietal would not be adopted and consistently used did it not provide efficacies above and beyond extant and future canola cultivars in the management of plant pests, pathogens, and agricultural weeds.

With regard to potential cumulative impacts on terrestrial and aquatic animals and plants from pesticide exposure; the EPA conducts ecological risk assessments as part of its registration, registration review, or registration modification processes. Before a pesticide can be sold in the United States, the EPA evaluates its safety to terrestrial and aquatic animals and plants based on a wide range of laboratory and field studies.[44] These environmental studies include toxicity profiles, environmental transport and fate, environmental exposure characterization, and ecological effects characterization. In determining whether a pesticide will harm the environment and wildlife, the EPA conducts an ecological risk assessment for each pesticide active ingredient and major degradation products. Pesticides are regulated primarily on the basis of active ingredients. Before allowing a pesticide product to be sold on the market, the EPA ensures that the pesticide will not pose any unreasonable risks to plants, wildlife, and the environment, when used according to EPA requirements. There are four general steps in the risk assessment process: hazard identification, exposure assessment, dose/response assessment, and risk analysis. The EPA uses risk assessments for pesticide registration decisions and label use requirements. Any pesticide used on MS11 canola stacked-trait progeny would require registration and review by the EPA, and used pursuant to EPA label requirements. The registration label includes strict limits on the quantities and methods allowed for the use of a pesticide to ensure that the FIFRA standard of "no unreasonable adverse effects on the environment" is met.

5.5.2 Pest and Weed Resistance

The collective and nationwide use of glufosinate and other herbicides will contribute to increased selection pressure for weed resistance. Stacked-trait MS11 canola progeny hybrids may also be comprised of insect and disease resistance traits. These would be developed to provide growers with expanded pest, disease, and weed management options. These types of hybrid progeny would also contribute, in a cumulative manner, to increased selection pressure for pest and pathogen resistance. This fact is not unique to MS11 canola; any pesticide or other agent consistently used to control pests, weeds, and pathogens can potentially serve to select for resistant populations.

Under the No Action and Preferred Alternative, herbicide resistant weeds are likely to be, over time, an increasing issue in most regions of the United States. It is expected that growers will need to depend on additional chemical and non-chemical methods to control HR weeds. Changes in management practices may include diversifying the mode of action of herbicides applied to canola and making adjustments to crop rotation and tillage or cultivation practices. Herbicide use may increase to meet the need for additional integrated weed management tactics to mitigate HR weeds in different cropping systems (Owen, 2008). At present, glufosinate resistance is only present one species in the United States, Italian ryegrass, with resistant populations in California and Oregon. As with HR weeds, under the No Action and Preferred Alternative, populations of pests and pathogens resistant to PIPs and synthetic chemicals used for their control will likely, over time, evolve.

The EPA released PRN 2016-XX (US-EPA 2016c), which applies to herbicides, and communicates the Agency's current thinking and approach to address herbicide-resistant weeds by providing guidance on labeling, education, training, and stewardship for herbicides undergoing registration review or registration (i.e., new herbicide actives, new uses proposed for use on herbicide-resistant crops, or other case-specific registration actions). The updated guidance is part of a more holistic, proactive approach recommended by crop consultants, agricultural commodity organizations, professional /scientific societies, researchers, and the registrants themselves.

The EPA is also updating its policies and guidance for management of pest and weed resistance. The EPA is concerned about resistance issues and believes that managing the development of pesticide resistance, in conjunction with alternative pest management strategies and Integrated Pest Management (IPM) programs, is an important part of sustainable pest management. To address the growing issue of resistance and preserve the useful life of pesticides, the EPA issued PR Notice 2016-X, *Guidance for Pesticide*

[44] EPA - Ecological Risk Assessment for Pesticides: Technical Overview: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical

Registrants on Pesticide Resistance Management Labeling, which applies to all conventional, agricultural pesticides (i.e., herbicides, fungicides, bactericides, insecticides and acaricides). The guidance is focused on pesticide labels and aimed at improving information about how pesticide users can minimize and manage pest resistance. PR Notice 2016-X updates PRN 2001-5 with the following three categories of changes: (a) provides additional guidance to registrants and a recommended format for resistance-management statements or information to place on labels; (b) includes references to external technical resources for guidance on resistance management; and (c) updates the instructions on how to submit changes to existing labels in order to enhance resistance-management language.

IWM and IPM guidelines promote an economically viable, environmentally sustainable, and socially acceptable weed and pest control programs regardless of the pesticide used. As part of IWM and IPM, weed and insect resistance management is recommended by academia, weed and pest specialists, and required by EPA (e.g., (US-EPA 2015b)) to mitigate the development of future resistant populations. APHIS assumes that growers will likely employ these management practices to help deter the development of herbicide resistant weeds, and development of insect resistance, as there are both economic and practical incentives for doing so (Fernandez-Cornejo et al. 2014; Fernandez-Cornejo and Osteen 2015; Livingston et al. 2015). APHIS further assumes that growers would adopt MS11 canola, and any potential stacked-trait progeny, based on the efficiencies provided by this variety in maximizing crop yields, and managing insect pests, pathogens, and weeds, to include weed resistance.

The development of pest, pathogen, and weed resistance to synthetic chemicals and PIPs is, by its very nature, a consequence of the repeated, cumulative use of pesticides (to include PIPs). Hence, past, present, and future uses would contribute to the selection of resistant pest, pathogen, or weed populations. Selection pressures, to varying degrees, for development of resistant pests, pathogens, and weeds will be ever present where pesticides are used. However, the utilization of resistance management practices described, which is assumed will be employed in the production of MS11 canola and its progeny, can reduce selection pressure for resistant pest, pathogen, and weed development. By necessity, growers of commercial canola will have to continuously adapt their pest and weed management strategies and employ the best available science in management of pests, pathogens, and weeds, to include development of resistant biotypes. It is unlikely that a determination of non-regulated status for MS11 canola, or denial of the petition, would adversely impact grower options or choices in the adaptive management of pests, diseases, and weeds over the coming years.

5.5.3 MS11 Canola Trait Genes

As discussed in Section 4.5 - Biological Environment, the bar, barstar, and barnase proteins present negligible risk to individual species of biota. There are no significant direct or indirect impacts on biota associated with the commercial production of MS8 canola hybrids, nor are any expected for MS11 canola. However, there may be some degree of cumulative impact on wild plant communities in disturbed habitats via the presence of feral GE canola.

5.6 Cumulative Impacts: Gene Flow and Weediness

Populations of wild *Brassica* species commonly occur throughout the United States and may hybridize with GE canola to produce novel genotypes (Knispel et al. 2008; Schafer et al. 2011). As discussed in Subsection 3.5.3 - Gene Flow and Weediness of Canola, feral GE canola has been reported in North Dakota and California (Devos et al. 2012). Feral GE canola is persistent in North Dakota as populations are founded by seed spills along transport routes, from the continuous recruitment of seed from feral soil seedbanks, and pollen flow. Feral GE HR canola commonly hybridizes with wild *Brassica* species, some of which have exhibited novel stacked-traits (Warwick et al. 2008; Devos et al. 2012).

APHIS has considered gene flow and weediness in its Plant Pest Risk Similarity Assessment (USDA-APHIS 2016) and in Subsection 3.5.3– Gene Flow and Weediness, and concludes that introgression from GE canola to certain species of wild *Brassica* spp. is possible; this would apply to any progeny derived from MS11 canola. Pollen and seed from MS11 canola and its progeny would likely be distributed to areas outside of commercial crop fields and contribute to the development of feral populations of GE canola, and GE canola x wild type *Brassica* hybrids. To date, the only GE canola varieties produced commercially are those that are herbicide resistant. Currently, there is no scientific data that suggests the presence of a GE HR trait in a wild or weedy relative species presents an ecological risk (e.g., see (Warwick et al. 2008; Devos et al. 2012; Bailleul et al. 2016; Belter 2016)). With HR traits, a selective advantage would only be realized where the herbicide to which the plant is resistant, is used (Warwick et al. 2008).

Currently, feral GE HR populations have not proven to be a particular control problem; canola, to include GE HR canola, is not an invasive plant, and feral populations are largely limited to disturbed sites (e.g., disturbed lands adjacent to commercial canola fields and transport routes) (Katsuta et al. 2015; Belter 2016). Canola is generally regarded as an opportunistic species, not as an invasive species of ecological significance. In undisturbed natural habitats, canola lacks the characteristics that provide for establishment of stable populations, and once established, feral GE HR populations, in the absence of seed dispersal, trend toward extinction over a period of years (Warwick et al. 2008; Devos et al. 2012; Belter 2016). The persistence or recurrence of a feral GE HR canola population and associated hybrids in a given location is attributed to frequency of seed spills, recruitment from seed from the soil seedbank, and pollen flow (Warwick et al. 2008; Devos et al. 2012). For example, seed dispersal via transportation has largely contributed to the current distribution of feral GE canola populations in North Dakota, although re-seeding by fertile hybrid plants further contributes to population persistence (Schafer et al. 2011).

For GE HR feral canola and wild type hybrids, where feral and/or hybrid populations need control or removal, activities involving the use of synthetic chemicals and mechanical means to control or remove feral or hybrid populations could adversely affect biota in these areas. GE HR canola in combination with canola’s seed dormancy can make it a challenging weed to control (Munier et al. 2012). Aggressive control with herbicides and hand pulling of escapees along roadsides has resulted in effective control, if not eradication, of feral populations (Munier et al. 2012). Hence, while control or removal of feral hybrid populations may be warranted in some instances, and could adversely impact biota in these areas, such impacts are expected to be transient in nature, with little influence on the long-term integrity of plant and animal communities.

There are no differences in the potential for gene flow and weediness between the No Action and Preferred Action Alternatives. The risk of gene flow and weediness with MS11 canola is no more or less than that of other non-regulated GE canola varieties.

5.7 Cumulative Impacts: Human and Animal Health

5.7.1 Consumer Health

As described in Section 4.6 –Human Health, there are no potential direct or indirect adverse impacts on human health associated with the consumption of canola oil produced from MS11 canola, or any other GE or non-GE canola. The bar, barstar, and barnase trait genes and their products found in MS11 canola are ubiquitous in the environment and unlikely to pose any risk to human health as constituent genes in GE canola varieties. Under present and expected use conditions, and when used in accordance with EPA label requirements, glufosinate does not pose risks that would compromise human health. The EPA considers the direct and indirect impacts of pesticides on human health and non-target organisms as part of their registration review process and in establishment of label use requirements. The EPA also establishes residue tolerance limits for pesticides on food and feed crops, to include canola. APHIS assumes that applications of glufosinate, and any other pesticide that may be used in conjunction with MS11 canola and MS11 canola progeny, will be done so consistent with EPA labeled use requirements and pesticide residue tolerance limits requirements. Food and feed derived from MS11 canola must be in compliance with all applicable legal and regulatory requirements and Bayer may undergo a voluntary consultation process with the FDA prior to release of MS11 canola to the commercial market to identify and discuss relevant safety, nutritional, or other regulatory issues regarding MS11 derived food products. Considering these factors, it is highly unlikely an extension of non-regulated status for MS11 canola would contribute to any adverse cumulative impacts on human health.

5.7.2 Worker Safety

An extension of non-regulated status for MS11 canola would have no effect on the EPA's Worker Protection Standard (WPS) (40 CFR part 170), which is expected to remain in effect and applicable to the production of MS11 canola. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. The OSHA requires employers to protect their employees from hazards associated with pesticides. Pesticides used on MS11 canola progeny would likewise be subject to EPA registration and label use requirements. There are no reasonably foreseeable cumulative impacts on worker safety that would result from an extension of non-regulated status of MS11 canola, nor any stacked-trait progeny that would derive from MS11 canola.

5.7.3 Animal Feed

Feed derived from MS11 canola must be in compliance with all applicable statutory and regulatory requirements. As with food safety, Bayer may undertake a voluntary consultation process with the FDA prior to the commercial use of MS11 canola to identify and discuss relevant safety, nutritional, or other regulatory issues regarding MS11 derived feed products. Based on these factors, no potential cumulative impacts on animal health and welfare have been identified relative to an extension of non-regulated status for MS11 canola.

5.8 Cumulative Impacts: Socioeconomics

5.8.1 Cumulative Impacts: Domestic Economic Environment

Numerous varieties of GE and non-GE canola are commercially available to growers. These include several varieties of canola resistant to glufosinate, over 20 non-GE cultivars bred for cultivation in specific regions of the United States (e.g., Pacific Northwest cultivars, Great Plains cultivars, Midwest cultivars), and a number of varieties resistant to glyphosate, sulfonylurea, and imidazolinones (Brown et al. 2008; NDSU 2016b). In 2016, 16 new varieties of canola entered the market, with various attributes, to include clubroot resistance, blackleg resistance, glyphosate resistance, fusarium wilt resistance, and better heat and drought tolerance.[45] APHIS expects that the GE and non-GE varieties of canola providing weed, insect pest, and disease resistance, many of these stacked-trait varieties, will increase in the coming years. Once deregulated MS11 canola may be combined, through traditional breeding methods, with any current and future non-regulated canola to produce stacked-trait varieties. Similar varieties possessing glufosinate and disease resistance are already on the market in the United States.[46] Any future stacked-trait progeny

[45] For example, see Grainnews - New canola varieties for 2016: http://www.grainews.ca/2015/10/21/new-canola-varieties-for-2016-5/

[46] For example, InVigor Canola Hybrids: https://www.cropscience.bayer.us/products/seeds/invigor-canola/invigor-canola-hybrids

derived from MS11 canola would compete with these and future canola varieties introduced to the market.

MS11 canola would be but one of many options available to canola producers. Growers would choose to cultivate MS11 canola to the extent it provided optimal yield, oil and meal quality, weed control, facilitated pest and disease control, and provided desired net returns. Likewise, APHIS assumes that growers will adopt stacked-trait progeny derived from MS11 canola to the extent that these canola varieties provide benefits to the grower, namely in the way of yields, reductions in pest, disease, and weed management costs, and net returns.

Considering these factors; it is unlikely that MS11 canola and any progeny derived from it would contribute to any adverse cumulative impacts on canola oil, canola meal, or biodiesel supply and demand; the market price of these commodities; or potential net returns to canola producers.

5.8.1.1 Organic and Non-GMO Canola Production

As of 2015, there were 2 reported certified or exempt[47] organic canola farms in the United States, one in North Dakota, the other in Pennsylvania (USDA-NASS 2016d). Acreage and economic value data is not available in the USDA's 2015 Certified Organic Survey; it was withheld by producers to avoid disclosing data for individual farms. Currently, information on organic canola production in the United States is limited.

Growers have the option to cultivate conventionally bred canola cultivars and GE canola varieties (derived from conventional canola) using synthetic pesticides and fertilizers, or cultivate conventionally bred canola cultivars using an organic cropping system (USDA-AMS 2015b). Similar to the organic canola market, there is a non-GMO canola market. These are products verified to contain GE trait material below an established threshold (e.g, food < 0.9% GE material by weight, feed < 5%),[48] but are not necessarily USDA certified organic products. The non-GMO verified market has expanded rapidly since its inception of the verification program in 2007. According to the Non-GMO Project, Non-GMO Project Verified is the fastest growing label in the natural products industry, with more than 2,800 verified brands representing around 40,000 products, and annual sales of around $19.2 billion.[49] Hence, these factors, collectively, contribute to what is currently a rather limited market for USDA certified organic canola oil and meal.

Organic growers use common practices to maintain the organic status of their canola including employing adequate isolation distances between the organic fields and the fields of neighbors, planting border rows, and planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, to minimize the chance that pollen will be carried between the fields (OSGTA 2014; USDA-AMS 2015b). Because MS11 canola is comprised of the same traits as currently produced MS8 canola, and it is likely to replace current acreage used for MS8 canola, it would present the same potential risks for cross-pollination and commingling with organic canola crops as current MS8 canola crops. MS11 canola would not increase the areas or acreage of GE canola production, nor limit the potential for organic/non-GMO canola production. The availability of another GE canola variety, such as MS11 canola under the Preferred Alternative, is not expected to impact the organic production of canola any differently than other GE varieties grown in the past or

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[47] Certain operations are "exempt" from certification, such as small organic farms with gross agricultural income from organic sales less than $5,000 per year; brokers, distributors, and traders; retail food establishments; and exempt handling operations. Although certification is not required for these "exempt" or "excluded" operations, they may pursue voluntary organic certification. Exempt and excluded operations still need to comply with specific sections of the USDA organic regulations.

[48] The Non-GMO Project: http://www.nongmoproject.org/product-verification/

[49] https://www.nongmoproject.org/product-verification/

presently under the No Action Alternative. Hence, the availability of MS11 canola, or its progeny, to commercial producers is not likely to have any influence, in a cumulative manner, on the number of organic/non-GMO canola producers, or the number of acres planted to organic/non-GMO canola. The value of organic and non-GMO canola is independent of the value of commodities derived from GE canola seed. Commercial growers would opt to produce canola using USDA organic standards, or seek non-GMO verification, where there is market demand for organic/non-GMO canola oil or meal. Current and future organic/non-GMO canola producers can use a variety of measures to preserve the integrity of their production systems, to include those required by USDA organic standards; measures that would be unaffected by the No Action or Preferred Alternative.

5.8.2 Cumulative Impacts: Trade Economic Environment

MS8 canola, which MS11 canola is intended to replace, is authorized for food and feed purposes in 11 countries including trading partners such as Canada, Australia, China, the EU, Japan, and Mexico. The United States, Canada, and Australia are the only countries currently producing MS8 canola, and those countries in which MS11 canola will be marketed (Weeks et al. 2016). Because MS8 and MS11 canola are phenotypically similar, and utilize the same agronomic management practices, approving the petition for non-regulated status is not expected to present any novel plant-trait combination that requires in depth regulatory review among countries in which MS8 canola is already approved.

If MS11 canola is extended non-regulated status in the United States, and not approved for import by another country, this could theoretically present the opportunity for low level presence (LLP). However, adverse impacts on U.S. exports via LLP under this scenario would be unlikely. Bayer states that MS11 will be commercialized in Canada, the United States, and Australia – those countries currently producing MS8 canola (Weeks et al. 2016). APHIS assumes that all other countries that have authorized MS8 canola for food and feed use will also authorize MS11 canola; either for production, or import. Similarly, given any future progeny would derive from cross breeding MS11 canola with non-regulated GE canola (or non-GE canola), such progeny may be authorized for food and feed purposes by other countries. APHIS believes that all developers who have intended to market their commodities internationally have undergone voluntary consultation with the FDA as to the safety of the food and/or feed derived from the GE crop plant. APHIS assumes that developers of future GE canola varieties would consult with the FDA if they intended to market food and feed on international markets.

Because the United States and other countries already have access to MS8 canola and other varieties of GE HR canola, both single and stacked-trait varieties, and MS11 canola and progeny derived from it would present yet another option among stacked-trait canola varieties, its availability to U.S. producers and international markets would not be expected to affect U.S. trade. Growers will cultivate MS11 canola and its progeny, in lieu of other GE canola options, as well as conventional cultivars, to the extent it can meet global demand, and provides growers benefits in the way of yields, production efficacies, and net-returns. Considering these factors, there are no reasonably foreseeable cumulative impacts on the trade of canola that could arise from an extension of non-regulated status for MS11 canola.

5.9 Cumulative Impacts: Climate Change

CEQ's climate change guidance directs agencies to examine the GHG emissions associated with a proposed action as well as the implications of climate change on the proposed action and its environmental impact (CEQ 2016). It recommends that agencies quantify the action's direct and indirect GHG emissions or sequestration using reasonable approaches and best available science, including an assessment of the potential future state of the affected environment. CEQ also advises that, where a quantitative analysis is not possible or applicable, agencies should provide a qualitative discussion focusing on reasonably foreseeable effects of the proposed action and alternatives on GHG emissions. Whether such analyses are quantitative, qualitative, or both, the extent of the analyses should be commensurate with the quantity of projected GHG emissions, and grounded on the principles of proportionality and the rule of reason. Lastly, CEQ directs agencies to consider the effects of climate change on the proposed action, including those aspects of the human environment that are impacted by both the proposed action and climate change, such as when climate change makes some component of the affected environment more vulnerable to impact from the proposed action.

As discussed in 4.4.4 – Climate Change, the commercial production of GE HR canola contributes to global N_2O and CO_2 emissions, both directly and indirectly. Consequently, these emissions contribute in a cumulative manner to atmospheric concentrations of N_2O and CO_2. GE HR canola has also contributed to reductions in GHG emissions from canola cropping systems over the last two decades. For example, in Western Canada, the GHG emissions resulting from production of 1 ton of canola were found to decline from 350 kg CO_2eq/t canola in 1990, to 330 kg CO_2eq/t canola in 2010 (MacWilliam et al. 2016). Reductions in GHG emissions are attributed to shifts from conventional tillage to conservation tillage and no-till, an increase in direct seeding practices, more efficient use of synthetic fertilizers, and improved weed management strategies that reduced the amount of herbicide used (MacWilliam et al. 2016).

Because MS11 canola is phenotypically and agronomically similar to MS8 canola, MS8 canola has been commercially produced for over 10 years, and MS11 is intended to replace MS8 canola, any changes in GHG emissions between the No Action Alternative and Preferred Alternative would be immeasurably minute. Any changes in GHG emissions (direct or indirect, short or long term, cumulative) would result from market forces that drive canola producers to plant more or fewer acres of canola, which would apply to MS8 and MS11 canola equally. Hence, potential cumulative GHG emissions, and associated effects on climate change, from both MS8 and MS11 canola cropping systems would be the same. Similarly, climate change is not expected to impact MS11 canola cultivation any differently than it would impact MS8 canola cultivation.

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 endangered and threatened species – and the ecosystems on which they depend – 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, one of the Services (NMFS or USFWS) must first add it to the Federal list of threatened and endangered wildlife and plants. Threatened and endangered (T&E) species are plants and animals at risk of becoming extinct throughout all or part of their geographic range (endangered species) or species likely to become endangered in the foreseeable future throughout all or a significant portion of their ranges (threatened species).

The Services add a species to the list when they determine it is endangered or threatened because of any of the following factors or a combination thereof:

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

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

6.1 Requirements for Federal Agencies

Section 7(a)(2) of the Endangered Species Act requires that each federal agency, in consultation with the USFWS and/or NMFS, ensure that any action authorized, funded, or carried 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 non-regulated 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 regulatory authority over GE organisms is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR §340.1). In this case, Bayer requests that the USDA APHIS consider that MS11canola is not a plant pest as defined by Plant Protection Act (PPA). After completing a Plant Pest Risk Similarity Assessment (PPRSA), if APHIS determines that MS11 canola seeds, plants, or parts thereof do not pose a plant pest risk, then this article 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 this article is no longer regulated. As part of its EA, APHIS analyzed the potential effects of MS11 canola on the environment including any potential effects to T&E species and critical habitat. As part of this process, APHIS thoroughly reviews GE product information and data related to the GE organism to inform the ESA effects analysis and, if necessary, the biological assessment. For each transgene/transgenic plant the following information, data, and questions are considered by APHIS:

- 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);
- Analysis to determine if the transgenic plant is sexually compatible with any T&E species of plants or a host of any T&E species; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

APHIS met with USFWS officials on June 15, 2011, to discuss and clarify whether APHIS has any obligations under the ESA regarding analyzing the effects on T&E species that may occur from use of pesticides associated with GE crops. 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 pesticide use associated with GE crops because EPA has both regulatory authority over the labeling of pesticides under FIFRA, and the necessary technical expertise to assess pesticide effects on the environment. APHIS has no statutory authority to authorize or regulate the use of pesticides by growers. Under APHIS' current part 340 regulations, APHIS only has the authority to regulate MS11 canola or any other 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 pesticides on those organisms.

In following this review process, APHIS, as described below, has evaluated the potential effects that a determination of non-regulated status of MS11 canola may have, if any, on Federally-listed T&E species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

6.2 Potential Effects of MS11 Canola on T&E Species

As discussed in Chapter 1, Bayer has requested that APHIS consider their extension request based on the similarities of MS11 canola to MS8 canola, one of the two lines for which APHIS reached a determination of non-regulated status in 1999. This extension would apply to any progeny derived from crosses of MS11 canola with traditional or transgenic *Brassica* spp. that have also received a determination of non-regulated status.

As discussed in further detail elsewhere in this EA and in the petition (Weeks et al. 2016), the MS8 and MS11 lines contain the barnase gene that confers male sterility and the bar gene that encodes for the enzyme phosphinothricin N-acetyltransferase (PAT), which confers resistance to glufosinate-ammonium. Plants expressing PAT are resistant to herbicides that contain glufosinate-ammonium. Like MS8 canola, MS11 canola is intended to be crossed with RF3 canola to provide hybrid seed that will produce plants that are glufosinate resistant. Similar to MS8 canola, MS11 canola is intended for commercial canola production in Canada, the United States, and Australia. MS11 canola will not be commercialized as a standalone product; its sole purpose is for use as breeding stock in the production of MS11 canola hybrid seed. The only difference between MS11 and MS8 canola, as it pertains to the genetic modification, is that MS11 includes the barstar gene for low level expression of the barstar protein. This protein is expressed by the non-regulated RF3 canola line as well. The low level expression of the barstar protein was included in MS11 to improve transformation efficiency, it has no effect on the male sterile or herbicide resistant phenotype of MS11. Hence, MS11 canola demonstrates the same phenotype as MS8: male sterility conferred by the expression of the barnase enzyme and glufosinate-ammonium resistance conferred by expression of the PAT enzyme. Fundamentally, there are no changes in the purpose and rationales among petitions 98-278-01p and 16-235-01p. Canola seed derived from MS11 hybrids will be used for the commercial production of canola oil and canola meal (animal feed), as is MS8 canola hybrid seed. It could also be used for other purposes, such as production of canola oil for biodiesel.

Based on the information submitted by the applicant and reviewed by APHIS, MS11 canola is agronomically and phenotypically similar to MS8 canola. Bayer has presented results of ten field trials for MS11 canola (Weeks et al. 2016). The common agricultural practices that would be carried out in the cultivation of MS11 canola are not expected to deviate from current practices, including the use of EPA-registered pesticides. MS11 canola is not expected to directly cause a measurable change in agricultural acreage or area devoted to canola production in the United States (see Subsection 4.2, Environmental Consequences, Preferred Alternative: Acreage and Area of Canola Production). Because MS11 canola is similar to MS8 canola, it is expected that MS11 canola will replace MS8 canola without expanding the acreage or area of canola production.

Canola production is largely concentrated in the Northern Plains where a cooler climate is more amenable to production. As of 2012, there were 3,995 canola farms across 34 states, totaling around 1.7 million acres (USDA-NASS 2014). While canola is produced in many states, around 90% of U.S. production occurs in North Dakota, with significantly less production occurring in Oklahoma, Montana, and other states (see Subsection 3.2.2 – U.S. Production: Conventional, GE, and Organic Canola). Considering that seed derived from MS11 canola is not expected to expand production to areas beyond where canola is currently grown, the effects analysis should be limited to geographic areas within the 34 states where canola is currently grown. APHIS considered limiting the area for analysis geographically based upon the current growing areas. This was not done because of the difficulty of compiling a species list solely for specific canola growing areas; the likelihood that the analysis may not identify any stressors that could affect species or habitat; the issue that canola may naturalize in the environment; and the potential for *Brassica napus* to cross with wild relatives. Instead it was decided to consider effects on all listed and proposed species and all designated and proposed critical habitat in all 50 states. APHIS obtained and reviewed the USFWS list of T&E species (listed and proposed) for all 50 states from the USFWS Environmental Conservation Online System (USFWS 2017) .

For its analysis on T&E plants and critical habitat, APHIS focused on the agronomic differences between the regulated article and canola varieties currently grown; the potential for increased weediness; and the potential for gene movement to native plants, listed species, and species proposed for listing.

For its analysis of effects on T&E animals, APHIS focused on the implications of exposure to the PAT, barnase, and barstar proteins expressed in MS11 canola as a result of the transformation (Weeks et al. 2016), and the ability of the plants to serve as a host for a T&E species.

6.2.1 Threatened and Endangered Plant Species and Critical Habitat

The agronomic data provided by Bayer were used in the APHIS analysis of the weediness potential for MS11 canola, and further evaluated for the potential to impact T&E species and critical habitat.Agronomic studies conducted by Bayer tested the hypothesis that the weediness potential of MS11 canola is unchanged with respect to conventional canola used in hybrid seed production. No differences were detected between MS11 canola and conventional canola in growth, reproduction, or interactions with pests and diseases, other than the intended effect of male sterility and glufosinate resistance (Weeks et al. 2016). Based on the high similarity of the MS11 canola event to the antecedent canola event MS8 expressing similar proteins, the fact that the additional barstar gene is expressed at low levels that do not alter the male sterile phenotype, the finding that the antecedent organism was unlikely to become a weed, and the agronomic data obtained in field trials of the MS11 event, APHIS concludes that the determination of non-regulated status of MS11canola does not present an increased risk of weediness when compared to other currently cultivated conventional canola varieties (USDA-APHIS 2016).

Gene flow among GE and non-GE canola populations, and plants among the *Brassicaceae* family, has been fairly well studied and documented. Subsection 3.5.3.2 - Hybridization and Introgression among Brassica and Related Species provided a synopsis of the sexual compatibility of canola (*B. napus*) and related species, and the propensity for hybridization of *B. napus* with other species. *Brassica napus* plants readily outcross with plants of the same species, and potentially with the related species listed in Table 3-8. It should be noted that currently in the United States., *B. napus*, *B. rapa*, *B. nigra*, *B. juncea*, *B. adpressa* and *R. raphanistrum* are listed as weeds by the Weed Science Society of America (WSSA 2016a).

Based on hybridization frequencies and fitness data summarized in Subsection 3.5.3.2, where feral GE HR canola persist in a given habitat, the likelihood of gene introgression from canola (*B. napus*) to wild *B. rapa* is highly likely. Gene introgression in crosses with *B. oleracea*, *B. nigra*, *B. juncea*, and *B. carinata* is possible, although would require environmental conditions favorable to consistent backcrossing of hybrids with parental GE HR *B. napus*. Intergeneric crosses and introgression from *B. napus* to *R. raphanistrum*, *S. arvensis*, *E. gallicum*, and *D. muralis* would occur very rarely.

As discussed in Chapter 4, MS11 canola is similar to and intended to replace MS8 canola. MS8 canola hybrids have been in commercial production for over 10 years. MS11 canola hybrids would be cultivated as are current MS8 hybrids, in lieu of MS8 hybrids, and present the same potential risk for gene flow as MS8 canola and other non-GE cultivars. In its PPRSA, APHIS evaluated MS11 canola with particular emphasis on its weediness potential (USDA-APHIS 2016), and determined what effect, if any, that could have on designated critical habitat or habitat proposed for designation. Based on the high similarity of the MS11 canola event to the antecedent canola event MS8 expressing similar proteins, the fact that the additional barstar gene is expressed at low levels that do not alter the male sterile phenotype, the finding that the antecedent organism was unlikely to become a weed, and the agronomic data obtained in field trials of the MS11 event, APHIS concludes that it is unlikely that MS11 event will become a weed (USDA-APHIS 2016). APHIS concludes that it is similarly unlikely that gene introgression from MS11 canola to other organisms with which it can interbreed will increase their weediness (USDA-APHIS 2016). Hence, an extension of non-regulated status for MS11 canola and its progeny would not be expected to present more or less risk for gene flow to wild relative species as do the current MS8 canola hybrids. Likewise, the risk for occurrence and persistence of MS11 volunteers would not be expected to be any different.

Taxonomic proximity increases the likelihood of plants' ability to cross with one another. In order to determine if any federally protected species could potentially be at risk from nearby MS11 canola one would need to identify protected species that are closely related to *Brassica napus*. Using the USFWS Environmental Conservation Online System, all species from the plant family *Brassicaceae* that are federally listed as Endangered or Threatened, as well as all those species that have been proposed for listing and candidate species for listing were isolated (Table 6-1). None of the federally protected, proposed, or candidate species fall under the genus *Brassica* (USFWS 2017). All species currently fall within other genera and are therefore relatively unlikely to hybridize with *Brassica*. Plant taxonomists group plant genera into Tribes within a plant family. Among the plant tribes within the family *Brassicaceae*, some are more closely related to the *Brassiceae*, the tribe that *Brassica* falls within, and some are less related. While hybridization is common among closely related species of *Brassicaceae*, there is no evidence that divergent groups hybridize (Bailey et al. 2006; Franzke et al. 2011).

Table 6-1. Federally Listed Threatened and Endangered Species (plus Proposed and Candidate Species) of the Family Brassicaceae in the Lower 48 U.S. States, Hawaii, and Alaska

Scientific Name	Common Name	Tribe	Federal Listing Status	States Occurring
Arabis georgiana	Georgia rockcress	Arabideae	Threatened	AL, GA
Arabis hoffmannii	Hoffmann's rock-cress	Arabideae	Endangered	CA
Arabis macdonaldiana	McDonald's rock-cress	Arabideae	Endangered	CA, OR
Arabis perstellata	Braun's rock-cress	Arabideae	Endangered	KY, TN
Arabis serotina	Shale barren rock cress	Arabideae	Endangered	VA, WV
Boechera pusilla	Rockcress, Fremont County	Boechereae	Candidate	WY
Cardamine micranthera	Small-anthered bittercress	Cardamineae	Endangered	NC, VA
Caulanthus californicus	California jewel flower	Schizopetaleae	Endangered	CA
Erysimum capitatum var. *angustatum*	Contra Costa wallflower	Camelieae	Endangered	CA
Erysimum menziesii	Menzies' wallflower	Camelieae	Endangered	CA
Erysimum teretifolium	Ben Lomond wallflower	Camelieae	Endangered	CA
Eutrema penlandii	Penland alpine fen mustard	Eutremeae	Threatened	CO
Leavenworthia crassa	Fleshy-fruit gladecress	Cardamineae	Endangered	AL
Leavenworthia exigua laciniata	Kentucky glade cress	Cardamineae	Threatened	KY
Leavenworthia texana	Texas golden Gladecress	Cardamineae	Endangered	TX
Lepidium arbuscula	`Anaunau	Lepideaea	Endangered	HI
Lepidium barnebyanum	Barneby ridge-cress	Lepideaea	Endangered	UT
Lepidium orbiculare	Round pepperweed	Lepideaea	Proposed Endangered	HI
Lepidium ostleri	Peppergrass, Ostler's	Lepidieae	Candidate	UT
Lepidium papilliferum	Slickspot peppergrass	Lepideaea	Threatened	ID
Lesquerella congesta	Dudley Bluffs bladderpod	Physarieae	Threatened	CO
Lesquerella kingii ssp. *bernardina*	San Bernardino Mountains bladderpod	Physarieae	Endangered	CA
Lesquerella lyrata	Lyrate bladderpod	Physarieae	Threatened	AL

Lesquerella pallida	White bladderpod	Physarieae	Endangered	TX
Lesquerella perforata	Spring Creek bladderpod	Physarieae	Endangered	TN
Lesquerella thamnophila	Zapata bladderpod	Physarieae	Endangered	TX
Lesquerella tumulosa	Kodachrome bladderpod	Physarieae	Endangered	UT
Physaria douglasii ssp. *tuplashensis*	White Bluffs bladderpod	Physarieae	Threatened	WA
Physaria filiformis	Missouri bladderpod	Physarieae	Threatened	AR, MO
Physaria globosa	Short's bladderpod	Physarieae	Endangered	IN, KY, TN
Physaria obcordata	Dudley Bluffs twinpod	Physarieae	Threatened	CO
Rorippa gambellii	Gambel's watercress	Cardamineae	Endangered	CA
Schoenocrambe argillacea	Clay reed-mustard	Schizopetaleae	Threatened	UT
Schoenocrambe barnebyi	Barneby reed-mustard	Schizopetaleae	Endangered	UT
Schoenocrambe suffrutescens	Shrubby reed-mustard	Schizopetaleae	Endangered	UT
Sibara filifolia	Santa Cruz Island rockcress	Schizopetaleae	Endangered	CA
Streptanthus albidus ssp. *albidus*	Metcalf Canyon jewelflower	Schizopetaleae	Endangered	CA
Streptanthus bracteatus	Twistflower, bracted	Schizopetaleae	Candidate	TX
Streptanthus niger	Tiburon jewelflower	Schizopetaleae	Endangered	CA
Thelypodium howellii spectabilis	Howell's spectacular thelypody	Schizopetaleae	Threatened	OR
Thelypodium stenopetalum	Slender-petaled mustard	Schizopetaleae	Endangered	CA
Thlaspi californicum	Kneeland Prairie penny-cress	Noccaeeae (alt. Lepideaea or Thlaspidae)	Endangered	CA
Thysanocarpus conchuliferus	Santa Cruz Island fringepod	Schizopetaleae	Endangered	CA
Warea amplexifolia	Wide-leaf warea	Schizopetaleae	Endangered	FL
Warea carteri	Carter's mustard	Schizopetaleae	Endangered	FL

Source: (Bailey et al. 2006; FitzJohn et al. 2007; Armstrong et al. 2012; Al-Shehbaz 2014; Kaneko 2014)

A review of the listed and proposed T&E 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 T&E plants that are sexually compatible with *Brassica* spp., so transgenic canola will not cross-pollinate with any T&E plant species. Therefore, there is no evidence indicating that Bayer MS11 canola would directly affect any T&E plant species.

In conclusion, MS11 canola and lines derived from it will require the same inputs and the same agronomic practices as used for canola varieties currently grown; the potential for increased weediness is no different than for other canola varieties; and there is no difference in the potential for gene movement to native plants, listed species, and species proposed for listing. In addition, there is no more likelihood for MS11 canola or lines derived from it to naturalize in the environment, including designated critical habitat. Based on the analysis in the PPRSA and this EA, APHIS has concluded that approval of a petition for non-regulated status for MS11 canola, and its corresponding use in seed breeding, will have no effect on listed T&E plant species or species proposed for listing, and will not affect designated habitat or habitat proposed for designation.

6.2.2 Threatened and Endangered Animal Species

As discussed in Subsection 3.5.2.1 – Animals, the types and numbers of species found in and around commercial crop fields are less diverse as compared to unmanaged areas. Canola fields, however, can provide both food and habitat for some species of wildlife, including a variety of birds as well as large and small mammals.

Geese and blackbirds, for example, feed on canola seeds, while horned larks feed on emerging winter canola (Boyles et al. 2012; Schillinger and Werner 2016). Horned larks feed on the cotyledons of emerging canola, and typically do not eat the stem or seed (Schillinger and Werner 2016). Most animals that use canola fields are ground-foraging omnivores that feed on the remaining plant matter and associated biota following harvest. Small mammals of the Great Plains that may be associated with canola fields are sagebrush voles (*Lemmiscus curtatus*), meadow voles (*Microtus pennsylvanicus*), shrews (Soricidae family), and deer mice (*Peromyscus maniculatus*) (Heisler et al. 2013; Heisler et al. 2014). Of the listed and proposed animal species in the main growing regions of North Dakota, Montana, and Oklahoma, it is conceivable that whooping cranes (*Grus americana*) may be exposed to progeny of MS11 canola. In North Dakota, whooping cranes have short stops statewide during migration in the spring (late April to mid-June) and fall (late September to mid-October). During these migratory periods, whooping cranes reside in North Dakota for only a few weeks (USFWS 2017).

Bayer has provided data in its petition indicating that MS11 canola is agronomically and phenotypically similar to MS8 canola. There are no toxins or allergens associated with either canola varieties, as reviewed in Section 4.6 – Human Health. The bar gene in MS11 canola encodes for expression of phosphinothricin acetyltransferase (PAT), which confers resistance to the herbicide glufosinate-ammonium. The bar gene was isolated from the soil bacterium *Streptomyces hygroscopicus*, which occurs in soils worldwide. Hence, the bar gene and its product, PAT, are naturally present in the environment, and humans and wildlife are potentially exposed to the bar gene and PAT on a daily basis. GE corn, soybean, and cotton plants expressing PAT have been widely grown in the United States, and globally, for over a decade, with no evidence of adverse environmental effects (Herouet et al. 2005). The barnase and barstar genes were isolated from *Bacillus amyloliquefaciens*, a common soil bacterium. The barnase and barstar enzymes, like PAT, naturally occur in soils worldwide. *B. amyloliquefaciens* is a root-colonizing bacterium, and is used as a biocontrol for plant root pathogens in agriculture, aquaculture, and hydroponics (Wu et al. 2015).

The barnase and barstar proteins have a long history of safe use in canola since 1999 (see Section 4.6– Human Health). The barnase protein produced in MS11 canola has an identical phenotype of male sterility to the barnase protein produced in MS8 as determined by the weight of evidence using molecular characterization including PCR and southern blot analysis, and phenotype observations of the inserted DNA (AgrEvo 1998; Weeks et al. 2016). The MS8 event (ACS-BNØØ3-6) was the subject of an FDA consultation in 1998, as summarized in Biotechnology Consultation BNF No. 000057, dated September

16, 1998. The male sterility restorer event (event RF3; ACS-BNØØ5-8) was also included in the FDA Consultation BNF No. 000057.[50]

The safety of the PAT proteins has been previously established (Herouet et al. 2005; ILSI 2011). The safety of PAT in existing commercial transgenic crop products is supported by a permanent exemption from food and feed tolerances in all crops in the United States (US-EPA 2007). The PAT protein expressed in MS11 canola is the same PAT protein expressed in the previously non-regulated GE canola MS8 (AgrEvo 1998).

APHIS considered the possibility that MS11 canola could serve as a host plant for a threatened or endangered species (i.e., a listed insect or other organism that may use the canola plant to complete its lifecycle). A review of the species list reveals that there are no members of the genus *Brassica* that serve as a host plant for any threatened or endangered species (USFWS 2017).

Considering the similarity between MS11 canola and other varieties currently grown and the lack of toxicity and allergenicity of the barnase, barstar and PAT proteins, APHIS has concluded that exposure and consumption of MS11 canola would have no effect on threatened or endangered animal species, including whooping cranes that may come in contact with MS11 canola.

6.3 Summary

After reviewing the possible effects of determining non-regulated status of MS11 canola, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed T&E species or species proposed for listing any differently than canola varieties currently grown. Therefore, a detailed species by species analysis of effects is not necessary. APHIS also considered the potential effect of a determination of non-regulated status of MS11 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 T&E species or species proposed for listing.

MS11 canola and lines derived from it will require the same inputs and the same agronomic practices as used for canola varieties currently grown; the potential for weediness is no different than for other canola varieties; and there is no difference in the potential for gene movement to native plants, listed species, and species proposed for listing. In addition, compared to canola varieties currently grown, there is no more likelihood for MS11 canola or lines derived from it to naturalize in the environment, including designated critical habitat. Consumption of MS11 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 a determination of non-regulated status for MS11 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.

[50] Biotechnology Consultation Agency Response Letter BNF No. 000057: http://www.fda.gov/Food/IngredientsPackagingLabeling//GEPlants/Submissions/ucm161090.htm

7 CONSIDERATION OF FEDERAL AND STATE LAWS AND REGULATIONS, EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

7.1 Federal Laws and Regulations

Those statutes most relevant to APHIS determinations of regulatory status are the National Environmental Policy Act of 1969 (NEPA), the Clean Water Act of 1972 (CWA), the Safe Drinking Water Act of 1974 (SDWA), the Clean Air Act of 1970 (CAA), the Endangered Species Act of 1973 (ESA), and the National Historic Preservation Act of 1966 (NHPA). Compliance with the requirements of the ESA has been addressed in Chapter 6, and requirements of NEPA, CWA, SDWA, CAA, and NHPA specifically summarized in the following subsections.

7.1.1 National Environmental Policy Act

NEPA is designed to ensure transparency and communication on the possible environmental effects of federal actions prior to implementation. The Act and implementing regulations require federal agencies to document, in advance and in detail, the potential effects of their actions on the human environment, so as to ensure that there is a full understanding of the possible environmental outcomes of federal actions by both the decision-makers and the public. This environmental assessment has been prepared to document the potential environmental outcomes of the alternatives considered, and comply with the requirements of NEPA (42 United States Code (U.S.C) 4321, *et seq*.), and Council on Environmental Quality implementing regulations at 40 CFR parts 1500-1508.

7.1.2 The Clean Air Act, Clean Water Act, and Safe Drinking Water Act

The CAA, CWA, and SDWA are environmental statutes that authorize the EPA to regulate air and water quality in the United States. This EA evaluated the potential changes in canola production associated with an extension of non-regulated status for MS11 canola and determined that cultivation of MS11 canola would not lead to an increase in, or expand the area of, canola production. MS11 canola is phenotypically and agronomically equivalent to MS8 canola, and would replace currently utilized MS8 canola for production of commercial canola seed. Hence, the potential for adverse impacts on water resources and air quality are the same under the both No Action and Preferred Alternative. The genetic modifications to MS11 canola are not expected to result in any changes in water usage for cultivation compared to current canola production. As discussed in Subsections 4.4.2 – Water Resources, and 4.4.3 – Air Quality, there are no expected adverse impacts on water resources and air quality from the use of glufosinate with MS11 canola production. APHIS assumes use of glufosinate will be compliant with EPA registration and label requirements. Based on these factors, APHIS concludes that an extension of non-regulated status to MS11 canola and its progeny would comply with the requirements of the CWA, CAA, and SDWA. APHIS will continue to consider and evaluate possible effects of regulatory decisions under 7 CFR part 340, and consult and coordinate with the EPA, when necessary, to ensure compliance with all federal statutes governing air quality, and ground and surface waters.

7.1.3 National Historic Preservation Act

The National Historic Preservation Act (NHPA) of 1966 and its implementing regulations (36 CFR part 800) requires federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 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.

An extension of non-regulated status of MS11 canola is not a decision that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. The Preferred Alternative would have no impact on 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 scientific, cultural, or historical resources. In general, the agricultural activities that would be conducted under this action do not have the potential to introduce visual or atmospheric obstructions, or introduce noise that would affect the continued use and enjoyment of historic properties. Where MS11 canola is cultivated, there may be the potential for increased noise during the operation of combines and other equipment close to historical sites. However, planting and harvesting activities would only have temporary effects in the way of noise, with no consistent long-term effects on the enjoyment of a historical site.

7.2 Executive Orders Related to Domestic Issues

The following executive orders (EO) require consideration of the potential impacts of federal actions on populations deemed particularly sensitive or vulnerable to environmental and human health effects.

- **EO 12898 – Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations**

  The EO 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**

  Children may suffer disproportionately from environmental health and safety risks due to their developmental stage, higher metabolic rates, and behavior patterns, as compared to adults. This EO requires each federal agency to identify, assess, and address the potential environmental health and safety risks that may disproportionately affect children.

- **EO 13175 – Consultation and Coordination with Indian Tribal Governments**

  Executive departments and agencies are charged with engaging in consultation and collaboration with tribal governments; strengthening the government-to-government relationship between the United States and Indian tribes; and reducing the imposition of unfunded mandates upon Indian tribes. The EO emphasizes and pledges that federal agencies will communicate and collaborate with tribal officials when proposed federal actions have potential tribal implications.

The No Action and Preferred Alternatives have been evaluated with respect to EO 12898, EO 13045, and EO 13175. Neither alternative is expected to have a disproportionate adverse impacts on minorities, low-income populations, or children, or adversely affect tribal entities. As reviewed in Chapter 4, the barnase, barstar, and PAT proteins expressed in MS11 canola have a history of safe use and present negligible risks to human health and welfare, inclusive of all persons who might be exposed to these proteins through agricultural production, processing, or consumption of canola oil.

Glufosinate is registered by EPA under FIFRA. The EPA recently updated human health and ecological risk assessments for glufosinate (US-EPA 2016d). Based on these risk assessments, the EPA prescribes use precautions and restrictions on the glufosinate label that are intended to be protective of human health. APHIS assumes that pesticide applicators will adhere to the EPA’s use requirements for glufosinate.

An extension of non-regulated status for MS11 canola is not expected to adversely impact cultural resources on tribal properties. Because tribal entities are recognized as independent governments, agricultural activities on tribal lands would only be conducted if approved by the tribe. Tribes would have control over any potential conflict with cultural resources on tribal properties. The No Action and Preferred Alternatives are not expected to have any effect on Indian tribal self-government and sovereignty, tribal treaties, or other rights.

The following executive order addresses federal responsibilities regarding the introduction, spread, and effects of invasive species.

- **EO 13112 – Safeguarding the Nation from the Impacts of Invasive Species**
  Invasive species are a significant issue in the United States, causing both adverse economic and environmental impacts. This EO directs actions to continue coordinated federal prevention and control efforts related to invasive species. This order maintains the National Invasive Species Council (Council) and the Invasive Species Advisory Committee; expands the membership of the Council; clarifies the operations of the Council; incorporates considerations of human and environmental health, climate change, technological innovation, and other emerging priorities into federal efforts to address invasive species; and strengthens coordinated, cost-efficient federal action.

Brassica napus is not listed in the United States as a noxious weed species by the federal government (USDA-NRCS 2016). Nor is it listed as an invasive species by USDA's invasive species database (USDA-NAL 2017). *Brassica* spp. is listed on the Michigan weed list, but not specifically cultivated canola, *B. napus* (USDA-NRCS 2016). APHIS has evaluated the potential for enhanced weediness in MS11 canola and concluded that it is unlikely that MS11 canola will become a weed (USDA-APHIS 2016).

GE canola is known to present as a volunteer weed in in subsequent crops; hybridize with other GE HR canola; disperse from cultivated fields via pollen and seed and form feral populations; and hybridize with wild relative species. As discussed in Chapters 3, 4, and 5, the majority of studies to date indicate that GE HR canola populations occurring outside of cultivated fields decline over time, and persist as a result of consistent pollen flow and distributed seed. While volunteer GE canola can be considered a weed in agricultural situations, and feral populations of GE canola persist, volunteer and feral GE canola are not considered invasive species, as their persistence depends on seed spillage during crop harvest and seed transport.

Based on data submitted by the applicant and reviewed by APHIS, MS11 canola is sufficiently similar in fitness characteristics to other canola varieties currently grown and is not expected to become more weedy or invasive than non-GE canola (USDA-APHIS 2016; Weeks et al. 2016).

The following executive order outlines federal requirements for the protection of migratory bird populations.

- **EO 13186 – Responsibilities of Federal Agencies to Protect Migratory Birds**
  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.

Agricultural crops can provide habitat for migratory birds in the northern Great Plains of North America during and before migration periods (Hagy et al. 2010), and migratory birds may transit canola fields and forage on canola seed. Oilseeds are an excellent energy and protein source, and can be attractive to many species of birds. As reviewed in Section 4.5 – Biological Resources, Section 4.6 – Human Health, and Section 4.7 – Animal Feed, it is highly unlikely the PAT, barstar, and barnase proteins, which naturally occur in soils worldwide, present any risk to migratory birds. MS11 canola is agronomically and phenotypically similar to MS8 canola, which has been in commercial production for over a decade. Migratory birds that forage on MS11 canola are unlikely to be adversely affected by ingesting the seed or other plant parts. To the contrary, canola seeds provide a valuable source of nutrition to migratory and other birds (Schillinger and Werner 2016). Based on APHIS' assessment of MS11 canola, it is unlikely that an extension of non-regulated status for MS11 canola would have a negative impact on migratory bird populations.

7.3 Executive Orders on International Issues

- **EO 12114 - Environmental Effects Abroad of Major Federal Actions**

  This Order requires federal officials to take into consideration any potential environmental effects that may occur outside the United States, its territories, and possessions, that may result from actions being taken.

The United States is a member of the World Trade Organization (WTO), which deals with the global rules of trade between nations. The Agreement on the Application of Sanitary and Phytosanitary Measures (1995), also known as the "SPS Agreement," is a subsidiary agreement under the WTO. The SPS agreement recognizes three international organizations/frameworks that have established standards and guidelines related to SPS measures including the Codex Alimentarius Commission (food safety), World Organization for Animal Health (OIE) (animal health and diseases), and the International Plant Protection Convention (IPPC) (plant health).

Any international trade of MS11 canola following an extension of non-regulated status would be subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under IPPC. The United States and 181 other contracting parties currently adhere to the 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 2015) .

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the United States, and 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 2014).

In the event of an extension of non-regulated status for MS11 canola, APHIS does not expect adverse environmental impacts outside the United States. Hybrids based on MS11 will be commercialized in the canola growing regions of Canada, the United States, and Australia. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to the introductions of GE crop varieties internationally, apply equally to those covered by an APHIS extension of non-regulated status under 7 CFR part 340.

7.4 State and Local Requirements

The PPA, which 7 CFR part 340 implements, contains a preemption clause (7 U.S.C. § 7756) that prohibits state regulation of any, "plant, biological control organism, plant pest, noxious weed, or plant product" to protect against plant pests or noxious weeds if the Secretary (APHIS) has issued regulations to prevent the dissemination of biological control organisms, plant pests, or noxious weeds within the United States. This creates an opportunity for APHIS to interact with state regulators because states may impose prohibitions or restrictions that are consistent with and do not exceed APHIS regulations. The PPA preemption clause also allows states to impose additional prohibitions or restrictions based on special needs supported by sound scientific data or a thorough risk assessment. Consequently, while the PPA limits states' issuance of laws and regulations governing GE organisms and bars conflicting state regulation, it does allow state oversight when there is a special need for additional prohibitions or restrictions. States commonly institute departments of agriculture, environment and/or natural resources, and health to administer state laws and agency rules in these areas.

States use a variety of requirements to regulate the movement or release of GE organisms within their jurisdiction. For example, South Dakota simply authorizes holders of a federal permit issued under 7 CFR part 340 to use it within the state (SD Stat § 38-12A-31 (2015)). In contrast, Florida issues a "special permit," charges a fee, and requires a bond to protect public health and safety (FL Stat § 581.083 (2015)). Oklahoma issues permits to maintain as well as release GE organisms (OK Stat § 2-11-40 (2015)). Minnesota issues state permits for release of genetically engineered agriculturally related organisms only after federal applications or permits are on file (MN Stat § 18F.07 (2015)). Idaho uses cooperative agreements with APHIS to provide oversight and regulation of GE organisms that may be plant pests, in addition to reviewing notifications and permits, and inspecting facilities and field release sites (ID Code § 22-2016 (2015)). Washington makes rules concerning the movement of GE organisms within the state, and can create in-state quarantines to protect state interests (Wash. Rev. Code §§ 17.24.011 and 17.24.041). Both Illinois and Wisconsin may base permit-reviewing comments to APHIS on technical reviews, public comments, and informational meetings (430 ILCS 95/5 (2015); WI Stat § 146.60 (2015)). Nebraska may rely on APHIS or other experts before they issue their permit (NE Code § 2-10,113 (2015)). Hawaii's Advisory committee on plants and animals (HI Rev Stat § 150A-10 (2015)) assists the Hawaii Department of Agriculture on issues related to the release of plants, animals, and microorganisms based their expertise in island biogeography. These illustrative examples show the range of state approaches to regulating the movement and release of GE organisms within state boundaries.

States with an organic program generally adopt 7 CFR part 205 by reference and may codify provisions. For example, Iowa (Iowa Code 190C.1-190C.26), Puerto Rico (5 L.P.R.A. §§ 131 to 141 (2013)), Oklahoma (Okla. Admin. Code §§ 35:37-15-1 to 35:37-15-11), Texas (Texas Agric. Code Ann. § 18 (2015)), and Utah (Utah Admin. Code r. R68-20 (2016)). When a state adopts the NOP prohibitions on excluded methods, then organic producers cannot not use GE seed unless an exception in 7 CFR § 205.204 applies.

Neither of the alternatives considered would affect APHIS partnerships with states in the oversight of GE organisms, specifically in regulation of interstate movement and environmental releases. Under both alternatives, APHIS would continue working with states. The range of state legislation addressing agricultural biotechnology, namely in the way of permitting, crop protection, seed regulation, and economic development, would be unaffected by denial or approval of the petition.

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