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Environmental Report in Support of Pioneer Hi-Bred International, Inc. Petition for Non-Regulated Status for Herbicide-Tolerant 73496 Canola

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Acronyms and Abbreviations

ALS	acetolactate synthase
AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
BNF	Biotechnology Notification File
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations (United States)
DNA	deoxyribonucleic acid
EPA	Environmental Protection Agency
ERS	Economic Research Service
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FSE	Farm Scale Evaluation
GAT	glyphosate *N*-acetyltransferase
GE	genetically engineered
GHG	greenhouse gasses
GRAS	Generally Recognized As Safe
HEAR	high erucic acid rapeseed
IP	identity preservation (or identity preserved)
IPPC	Integrated Plant Protection Center
IWM	Integrated Weed Management
MAFRI	Manitoba Agriculture, Food and Rural Initiatives
MSGA	Montana Seed Growers Association
NAA	*N*-acetylaspartate
NAG	*N*-acetylglutamate
NAGly	*N*-acetylglycine
NAS	*N*-acetylserine
NASS	National Agricultural Statistics Service
NAT	*N*-acetylthreonine
NCAT	National Center for Appropriate Technology
NDSU	North Dakota State University
NIFA	National Institute of Food and Agriculture
NOP	National Organic Program
NOS	National Organic Standards
NPC	New Protein Consultation
OECD	Organisation for Economic Cooperation and Development
RBD	Refined, Bleached and Deodorized
RED	Re-registration Eligibility Decision
USDA	United States Department of Agriculture
USGC	United States Grains Council

1. PURPOSE AND NEED STATEMENT

1.1 Purpose and Need of Herbicide-Tolerant Canola

Pioneer Hi-Bred International (Pioneer) is submitting an environmental report to assess the potential impact of releasing herbicide-tolerant (HT) 73496 canola into the environment. HT canola varieties were introduced in North America in 1996, and have provided growers with a very valuable tool to manage weeds in their canola crops, to the extent that, today, almost all canola growers choose to grow HT canola. The yield potential of canola can be optimized by the application of herbicides that remove weeds that compete for soil nutrients and moisture. Additional advantages for cultivating HT canola include: increased adoption of low- and no-till practices which are important to minimize soil erosion; reduction in the volume of herbicides applied to canola crops to control weeds; and reduced tillage to improve energy conservation (Ammann, 2005; Dewar, 2009; Duke and Powles, 2009; Smyth *et al*., 2010). There are currently three commonly planted types of HT canola in North America: genetically engineered (GE) glyphosate-tolerant, GE glufosinate-tolerant, and conventionally derived imidazolinone-tolerant (Brown *et al*., 2008). Glyphosate has become especially popular for post-emergence weed control in glyphosate-tolerant canola. As a broad-spectrum herbicide, glyphosate is effective in controlling both grasses and annual broadleaf weeds, while possessing an excellent environmental profile and low mammalian toxicity. Currently, just over half of all canola acres are planted with glyphosate-tolerant canola.

73496 canola, developed by Pioneer, contains glyphosate tolerance to provide growers with an alternative to existing glyphosate-tolerant canola products on the market today. Herbicide-tolerant 73496 canola will provide similar benefits to currently available glyphosate-tolerant canola varieties, in that growers will be able to proactively manage weed populations and delay the development of adverse populations of troublesome weeds. The commercialization of 73496 canola is not expected to have any impact on herbicide-tolerant canola acreage and geography, or existing canola cultivation and weed control practices, but could substitute for a proportion of the glyphosate-tolerant canola products already in the marketplace. The availability of 73496 canola will allow growers to have additional choices of technology providers of HT canola varieties.

1.2. Action

Pioneer is petitioning USDA-APHIS and seeking a determination that the Company's HT 73496 canola, and all progeny derived there from, are unlikely to pose a plant pest risk and, therefore, should no longer be regulated under regulations at 7 CFR Part 340. The 73496 event is currently regulated under 7 CFR part 340. All interstate movements, importations, and field trials have been conducted under permits issued or notifications acknowledged by APHIS.

A New Protein Consultation for the GAT4621 protein was submitted to U.S. Food and Drug Administration (FDA) on January 31, 2007 and completed on October 7, 2009. A safety and nutritional assessment for feed and food derived from 73496 canola was submitted to FDA in March 2011. Submission of a tolerance petition and supporting residue data to the U.S. Environmental Protection Agency (EPA) to amend the glyphosate tolerance to include *N*-acetylglyphosate for canola was submitted on February 18, 2011. Pioneer encourages interagency communication and will supply USDA with reviewer contact information at FDA or EPA if needed.

1.3. Action Area

As described in the next section, the term "canola" encompasses several *Brassica* species, including *Brassica napus* (*B. napus*). Pioneer's glyphosate-tolerant 73496 canola is *B. napus*. *B. napus* canola can be bred into "spring" or "winter" varieties, which are planted in the spring or fall, respectively. Spring and winter canola are generally grown in different regions of the U.S. based on climate zones most suitable for the varieties. At this time, Pioneer does not have a winter canola breeding program or sell winter canola commercial products. Glyphosate-tolerant 73496 canola is a spring canola variety and will be marketed by Pioneer in the northwestern U.S. in states such as North Dakota (where more than 80% of canola in the U.S. is planted). However, in preparing this Environmental Report, we have taken into consideration that at some future time, Pioneer could license the 73496 canola event to another company with a winter canola program or initiate a winter canola program itself. Therefore, this Environmental Report is national in geographic scope.

1.3A. Derivation of Canola

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

The first commercial seed of this modified rapeseed called "Oro" was released in 1966, but endogenous levels of glucosinolates, which have low animal palatability, resulted in limited use of the meal as feed. Subsequently, a *B. rapa* cultivar of rapeseed that had low levels of glucosinolates was identified. The first low erucic acid, low glucosinolate cultivar, "Tower," was released for commercialization in 1974. In 1978, the Canola Council of Canada established a performance standard for these "double low" varieties and chose the vernacular name "canola" to describe them. By definition, canola oil contains less than 2% erucic acid and the meal contains less than 3 mg/g of glucosinolates (Brown *et al.*, 2008). In January 1985, the U.S. Food and Drug Administration (FDA) granted canola oil Generally Recognized as Safe (GRAS) status for use in human foods. This has led to greatly increased sales and demand in the U.S. The FDA has also allowed a qualified health claim for canola oil and it is widely marketed as "healthy oil." Canola varieties have been available since 1989 (Canola Council of Canada, 2003), and currently canola is grown worldwide.

To date, three *Brassica* species have been bred (using traditional plant breeding methods) to meet the low eruic acid, low glucosinolate canola definition:

- *Brassica rapa* or Polish canola;
- *Brassica napus* or Argentine canola (73496 canola is *B. napus*); and

- *Brassica juncea* - canola quality brown mustard.

1.3B. Geographic Distribution

In 2010, 16.1 million acres of canola were grown in Canada (Canola Council of Canada, 2010b) and 1.45 million acres of canola were grown in the U.S. (Table 1). Therefore, the U.S. canola acreage represents approximately 8% of the total canola acreage in North America. In the U.S., canola is grown primarily in nine northern and western states. In 2010 and 2011, North Dakota producers planted over 80% of the U.S. canola crop (Table 1). In all, a total of 32 states representing all regions of the U.S. harvested canola between 2002 and 2007 (USDA-NASS, 2009).

Table 1. Total U.S. Canola Acreage by State, 2010-2011

State	Acres Planted (1,000 acres)	
	2010	2011
Idaho	19.5	12.0
Minnesota	46.0	21.0
Montana	17.5	38.0
North Dakota	1,280.0	940.0
Oklahoma	60.0	100.0
Oregon	6.0	6.5
Colorado, Kansas, and Washington	19.8	25.3
Total	**1,448.8**	**1,142.8**

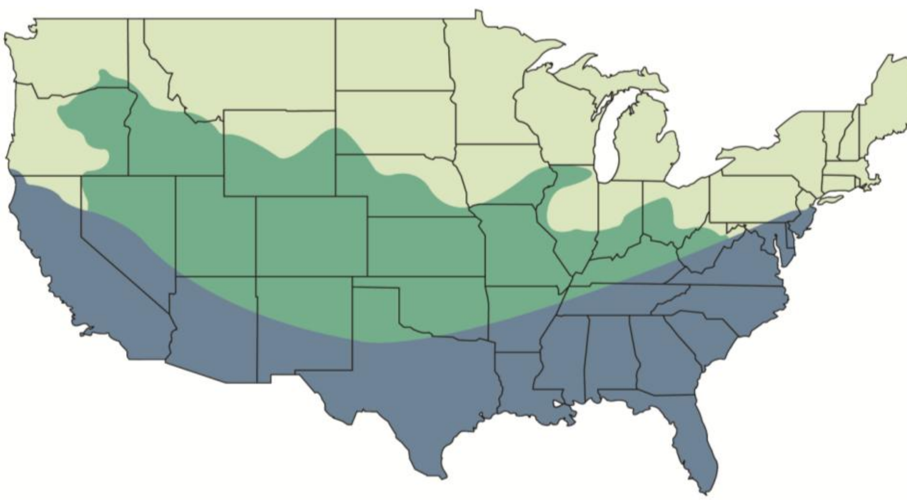
Source: USDA-NASS, 2011

As mentioned above, spring canola is planted in the spring and harvest in the fall; winter canola is planted in fall and harvested the following summer. The general agronomic practices for spring and winter canola are discussed further in Section 2.1B (General Agronomic Practices). Spring and winter canola are generally planted in different but overlapping areas of the U.S. based on climate zones (Figure 1).

It is difficult to find specific information about the number of acres of winter canola. A Pioneer agronomist estimates that less than 5% of the total canola acres in the U.S. are winter canola. Winter canola is relatively new in the U.S. and considered by some to still be an experimental crop. Winter canola varieties have shown a potential for improved yield over spring-planted varieties because winter canola has more time to develop in the field, and it flowers under more ideal weather conditions. The most significant problem with winter canola is its inability to survive winter conditions.

USDA-ARS and university extension agronomists are evaluating protocols for growing winter canola in various regions of the U.S.; commercial winter varieties available from Croplan Genetics, Kansas State University, DL Seeds Inc., and Monsanto.

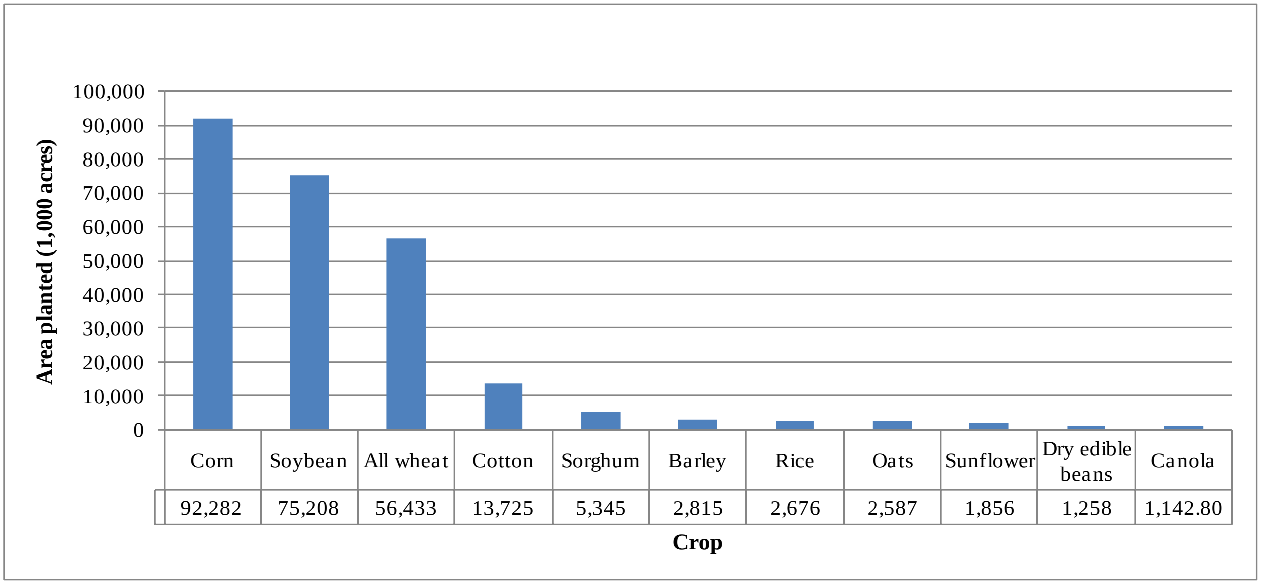
Overall, the canola acreage in the U.S. is low compared to major crops such as corn, soybeans, and wheat (Figure 2).



Climate zone	
	Spring canola
	Winter or spring canola
	Winter canola

Source: adapted from Mills, 1996

Figure 1. Climate Zones Suitable for Production of Spring and Winter Canola



Source: compiled from USDA-NASS, 2011

Figure 2. U.S. Crop Area Planted in 2010

Between 1991 and 1996, canola acreage remained low and fluctuated between 140,000 and 446,000 acres (Table 2). Planted acreage dramatically increased to 671,000 acres in 1997 and since that time has fluctuated between 827,000 acres (2009) and 1.5 million acres (highs in 2000 and 2010). Since 1991, yields have fluctuated between 1,197 and 1,811 pounds per acre with some modest increases in recent years.

Table 2. Total U.S. Canola Acreage, 1991-2011

Year	Planted Acres (1,000 Acres)	Yield per Acre (lbs.)	Production (1,000 lbs.)
1991	155	1,300	191,100
1992	140	1,286	144,037
1993	199	1,350	252,450
1994	354	1,316	447,440
1995	446	1,278	548,447
1996	367	1,385	480,521
1997	671	1,237	780,710
1998	1,115	1,448	1,557,800
1999	1,076	1,306	1,363,680
2000	1,555	1,334	1,998,310
2001	1,494	1,374	1,998,515
2002	1,460	1,197	1,533,420
2003	1,082	1,416	1,512,250
2004	865	1,618	1,339,530
2005	1,159	1,419	1,580,985
2006	1,044	1,366	1,394,312
2007	1,176	1,238	1,430,734
2008	1,011	1,461	1,445,064
2009	827	1,811	1,474,130
2010	1,449	1,713	2,450,947
2011	1,143	NA	NA

Source: USDA-NASS, 2010; USDA-NASS, 2011

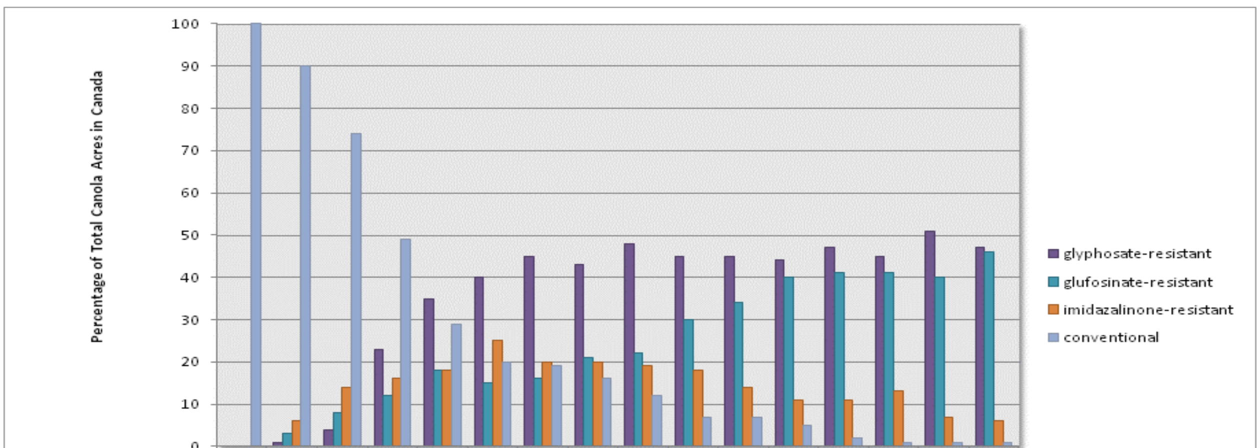
There is still a small market in North America for industrial oil produced from *Brassica* species. Industrial rapeseed (*i.e.,* high erucic acid rapeseed or HEAR) has a higher erucic acid profile than canola, making it inedible (Boland, 2011). High glucosinolate rapeseed is also grown in North America for the condiment mustard market. In 2010, varieties of *Brassica* such as high erucic acid rapeseed and mustard seed were planted on 2,300 and 50,500 acres, respectively (USDA-NASS, 2011). As stated above, canola is cultivated primarily in North Dakota, Oklahoma, Minnesota, Idaho, Minnesota, Oregon, Colorado, Kansas, and Washington (Table 1). Mustard seed is cultivated in California, Colorado, Idaho, Minnesota, Montana, North Dakota, Oregon, South Dakota, Texas, Washington, and Wyoming (USDA-NASS, 2009).

2. AFFECTED ENVIRONMENT

2.1. Agricultural Production

2.1A. Land use

Glyphosate-tolerant 73496 canola is not a new GE crop; significant acreage of genetically modified HT canola has been planted commercially in the U.S. since 1999. Furthermore, of that HT acreage, glyphosate tolerance is predominant. In 2008, GE HT canola was estimated to be 95% of the U.S. canola crop (Brookes and Barfoot, 2010). For North Dakota (where the majority of canola in the U.S. is cultivated) in 2006, there was a 99% adoption of HT canola varieties, with glyphosate-tolerant varieties grown on 57% of acres, glufosinate-tolerant varieties on 37% of acres, and imidazolinone-tolerant varieties (conventional) accounting for 5% of acres (Johnson *et al.*, 2007). For Minnesota (the state with the second highest canola cultivation) in the same survey, there was a 78% adoption of HT canola varieties, with glyphosate-tolerant varieties grown on 50% of acres, glufosinate-tolerant varieties on 25% of acres, and imidazolinone-tolerant varieties (conventional) accounting for 3% of acres (Johnson *et al.*, 2007). Planting of HT canola varieties in North Dakota has been steadily increasing from 25% in 1999 to 99% in 2006, though the planting of glyphosate-tolerant varieties has fluctuated between 48% and 67% since 2000 (Johnson *et al.*, 2007). [For more information on the U.S. canola crop acreage in the U.S., see the Action Area Section 1.3 above]. Similar trends can be seen in the adoption of HT canola in Canada (Figure 3).



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

Source: Canola Council of Canada, 2010a

Figure 3. Growth of Herbicide-Tolerant Canola in Canada from 1995-2010

2.1B. General Agronomic Practices

*Cropping Practices***.** Canola is a cool season crop that requires rich soil and a moist environment. Spring canola requires an average of 100-125 days from seeding to harvesting. Canola grows best when temperatures are between 54 °F and 86 °F (12 ºC and 30 ºC), with the optimal temperature for maximum growth and development being 68 °F (20 ºC) (Brown *et al*., 2008).

Spring canola is planted in early spring and is harvested in late summer. Typically, spring canola is planted in March and harvested in September or October. In the U.S., it is primarily grown in North Dakota (88% of production acreage), Minnesota, and the Pacific Northwest (*i.e.*, Idaho, Washington, and Montana) due to canola's poor performance in warm temperatures.

Winter canola is planted in the Pacific Northwest, Midwest, and Great Plains, but requires vernalization (prolonged exposure to low temperatures) to flower and needs to overwinter. Winter canola that is planted in the southeast region of the U.S. also overwinters, but does not require vernalization (Brown *et al.*, 2008). Winter canola is typically planted in September and harvested in June or July. It is grown on fewer acres than spring canola, but can be grown in a broader range of environments if winters are mild (Figure 1).

Spring and winter canola are impacted by the same insect pests although some insect pests infect one type more than the other (Brown *et al.,* 2008).

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

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

Survey information on tillage practices for Canada is described below. Similar survey information for the U.S. is not readily available. The practices in western Canada, where nearly all of canola is produced (Smyth *et al.,* 2010) are likely indicative of U.S. cultivation trends in states such as North Dakota and Minnesota where the majority of U.S. canola acres are planted (Table 1). Based on the western Canada survey, in HT canola production, conventional tillage has become less expensive over the years from 1999 to 2006 and was estimated to be cheaper than herbicide weed control options (Smyth *et al.*, 2010). When growers were asked about their weed control measures, 77% reported they use herbicide only, 28% said they use herbicides and tillage, and 7% said they used tillage only.

Use of tillage has dropped considerably since 2000, when 89% of the growers reported tillage as a form of weed control. The decline in tillage is attributed to improved weed control with HT canola. A roughly five-fold increase in the use of no-till practices among western Canadian growers of HT canola was observed between 1999 and 2006 (Smyth *et al.*, 2010). The increase in the use of no-till or minimum-till is likely correlated to the increased adoption of HT canola (Duke and Powles, 2009; Smyth *et al.*, 2010). However, despite this ability to broadly apply herbicides to control weeds, cultivation tillage continues to be used on some farms cultivating HT canola. This is most likely due to tillage being less expensive than herbicide control (Smyth *et al.*, 2010). Recently, in some areas of the U.S., individual growers with glyphosate-resistant weeds in fields may turn to tillage to help control glyphosate-resistant populations. (Duke and Powles, 2009). In general, genetically engineered crops have reduced tillage from 89% to 35%, but in individual cases tillage is useful in managing herbicide-tolerant weeds.

Rotational Practices. Crop rotation aids in the management of diseases, insects, and weeds and increases organic matter and soil fertility. In the literature, it has been reported that spring canola best follows cereal grains or fallow land in rotation (Berglund *et al.*, 2007), while winter canola is generally planted once every 2-3 years in a crop rotation with winter wheat (Schoonover, 2010). Canola-on-canola is not recommended due to problems with soil borne fungal diseases such as *Alternaria*, blackleg, clubroot, and *Sclerotinia* (Brown *et al.*, 2008; NDSU, 2005). Canola is also not recommended following pea, lentil, chickpea, soybean, sunflowers, field, or dry bean due to a buildup of soil-borne diseases such as *Sclerotinia*, *Rhizoctonia*, and *Fusarium* root rots (Brown *et al.*, 2008).

In the northern U.S. where Pioneer canola products are sold, approximately half of growers typically use a three-year rotation including canola, a small grain (generally wheat) and soybean. The remaining growers generally use a tighter, two-year rotation of canola and wheat. At the present time, canola is rarely rotated with corn. Although four-year rotations are discussed in the literature, they are not commonly used by larger canola growers in the U.S. (Pioneer Agronomist, personal communication).

Rotation is essential in canola production because it helps in the control of soil-borne diseases. *Sclerotinia* stem rot (*Sclerotinia sclerotiorum)* is a very serious disease in canola and can be found worldwide (Boyles *et al.*, 2007). *Sclerotinia* stem rot caused an average state-wide yield loss of 13% in North Dakota and Minnesota from 1998-2007 with some fields suffering a 50% loss (Markell *et al*., 2009). Once the disease is established, the most important control is rotation with non-susceptible crops. Blackleg disease (*Leptosphaeria maculans/biglobosa)* is found worldwide and throughout the U.S. In North Dakota, yield losses have been known to surpass 50% (Markell *et al.*, 2008). Important control methods are rotation and purchasing disease-free seed with a fungicide seed treatment (Boyles *et al.*, 2007). *Alternaria* black spot is also found in all canola growing areas in the U.S. and is worse in wet years. Yield loss can be up to 20% or more if there is pod shatter (Brown *et al*., 2008). Control methods for *Alternaria* include rotation, sowing clean, disease-free seed, and controlling weeds. Clubroot is found in some areas with varying severity in the U.S. (MAFRI, 2010). In Quebec, areas heavily infested with clubroot had a loss of 90% yield (Mendoza, 2009). There are no chemical controls for management of clubroot, and the fields must be rotated to non-*Brassica* crops (MAFRI, 2010). Information about canola rotation with other crops that share diseases for the Great Plains Region can be found in Table 3.

Table 3. Guide to Timing of Canola Rotation Crops

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

Source: Boyles *et al.*, 2007

Rotations are also used to help control weed populations that impact crop yields and spread the major fungal diseases described above (MacRae *et al*., 2000; NDSU, 2005). Many broad-leaf weeds, including wild mustard, pigweed, lambsquarters, marshelder, Canada thistle, and burdock are hosts of *Sclerotinia*, so it is critical to control these weed populations between rotations (NDSU, 2005). Preceding or following a canola rotation with another crop over which a different herbicide can be used (*e.g*., a cereal rotation prior to planting canola to control broadleaf or perennial weeds) helps keep problematic weed populations low for the canola rotation (NDSU, 2005). Rotation of crops often allows for different herbicide control options depending on the herbicide-tolerance traits available in that crop.

Canola can be damaged by herbicide residues in the soil (*e.g*., herbicide residues from previous crops or burndown in preparation for planting) and in some cases may not be planted for as long as 40 months (Brown *et al.*, 2008; NDSU, 2005). In this way, different crop rotations may be obligatory until herbicide residues have dropped to a level that allows canola planting; glyphosate has no plant back restrictions (see Table 8).

Canola can provide benefits to rotation crops. Canola produces glucosinolates in non-seed parts of the plant; these compounds break down in the soil and have some insecticidal, nematocidal, and fungicidal activity (Brown *et al.*, 2008). Canola plants also produce a significant amount of biomass that is left as plant residue and releases nitrogen stores obtained from deeper in the soil, due to the plant's taproot structure, thus increasing the organic content of the soil for subsequent crops (Brown *et al.*, 2008). Furthermore, canola is well adapted to regions where small grains are grown and thus provides growers additional options for other crops that allow for diversity of farm production and the reduction of market risks (Brown *et al.*, 2008). GE canola has the same benefits as non-GE canola with respect to crop rotation.

Insecticide, Fungicide, and Fertilizer Use. The insecticides bifenthrin, deltamethrin, gammacyhalothrin, lambda cyhalothrin, and methyl parathion are currently registered for canola in the U.S. (Brown *et al.*, 2008). In addition, insecticide seed treatments (with or without fungicides) are registered for canola (Table 4). Spring and winter canola are impacted by the same insect pests, albeit some pests negatively impact one type more than the other (Brown *et al.*, 2008), so similar insecticide regimes would likely be used for both canola types.

Table 4. Insecticide Seed Treatments Registered for Use on Canola

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

Source: Brown *et al.*, 2008

Cost-effective control of fungal diseases is usually achieved by using seed treatments that combine an insecticide and fungicide (Brown *et al.*, 2008). Foliar fungicides are costly and used only in situations of extreme disease pressure or wet weather. Foliar fungicides include Endura and Ronilan EG for control of *Sclerotinia* and Quadris for blackleg (Brown *et al.*, 2008). Planting disease-free certified seed and crop rotation are generally the most effective and economic means of controlling fungal diseases in canola (Boyles *et al.*, 2007).

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

*General Weed management***.** Growers control weeds because they compete with crops for water, nutrients, and sunlight and reduce yield and crop quality. Weeds and volunteers of wheat and barley in canola fields are known to reduce yields substantially (Canola Council of Canada, 2003; Harker *et al*., 2008). Weeds of the *Brassicaceae* family can contaminate the crop and reduce oil and meal quality (Canola Council of Canada, 2003). Closely related weeds are difficult to control in non-HT canola. They produce large numbers of seeds; some weed seeds have prolonged dormancy, which allows a build-up of weed populations (Canola Council of Canada, 2003; CFIA, 1994; OECD 1997). Such closely related weeds of the *Brassicaceae* family include wild mustard (*Sinapis arvensis*), field pennycress (*Thlaspi arvense*), shepherd's purse (*Capsella bursa-pastoris*), ball mustard (*Neslia paniculata*), flixweed (*Descurainia sophia*), wormseed mustard (*Erysimum cheiranthoides*), hare's ear mustard (*Coringia orientalis*), and common peppergrass (*Lepidium densiflorum*) (Council of Canada, 2003; CFIA, 1994; OECD 1997). Other difficult and expensive to control weeds include cleavers, stork's bill, and quackgrass (*Elytrigia repens)* (Canola Council of Canada, 2003).

Predominant weed species found in North Dakota canola fields during a survey in 2000 by Zollinger *et al.*, (2003) are listed in Table 5.

Table 5. Weed Species in North Dakota Canola

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

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

A 1997 survey conducted in Montana indicated that kochia, wild buckwheat, Canada thistle, annual mustards, wild oats, and volunteer grain were the most prevalent weeds in canola (Petroff and Miller, 1999).

Both the winter and summer complex of weeds can cause problems in canola in Kentucky. Wild garlic bulblet contamination reduces the market value of canola seed. Common chickweed, henbit, yellow rocket, and volunteer wheat can overcome canola during the fall or late winter. Johnsongrass may cause harvesting problems in the spring, particularly when canola stands are thin. Volunteer corn, annual ryegrass and thistles have also been identified as causing problems in Kentucky canola fields according to a 2010 survey (Johnson *et al.*, 2010).

Weed management is a key component of winter canola production in Oklahoma where the crop is commonly grown in rotation with wheat, sorghum, and corn. In a 2007 survey of Oklahoma producers, downy brome and Italian ryegrass were identified as the major weed problems (Luper *et al.*, 2007).

Early weed control is critical as canola does not compete well with many weeds in early developmental stages (Harker *et al*., 2008; NDSU, 2005). Studies of various HT varieties have shown that early application, before the 3- to 6-leaf stage, preserves crop yields (Harker *et al.*, 2008; Martin *et al.*, 2001). Once established, canola is a good competitor with most weeds. As discussed earlier, appropriate selection of rotation crops can suppress troublesome weeds; for example, a wheat rotation prior to canola planting may reduce Canada thistle populations because selective broadleaf herbicides that effectively control the perennial weed can be applied to wheat (NDSU, 2005).

Decisions about weed management may be the most complex ones that growers make because each weed control option has trade-offs and affects the feasibility of using other options. Generally, growers must manage a wide array of broadleaf and grass weeds simultaneously. In selecting a weed management strategy, growers choose the most economical means to control weeds that do not decrease the quality or quantity of the crop. Growers will often use a combination of weed management techniques including application of different herbicides to effectively control weeds in their fields. Ultimately, the weed management practice utilized by a grower will depend on the types of weeds in their field, the level of infestation, the cropping system, the type of soil, cost, weather, time, and labor.

Use of Herbicide-Tolerant Canola. There are three different types of HT canola varieties currently available in the U.S. (Brown *et al.*, 2008):

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

Most biotech commercialized crops are insect resistant and /or herbicide tolerant. Genetically engineered (GE) crops have been heavily adopted by farmers since their introduction in 1996 (USDA-ERS, 2011a). GE crops were quickly adopted by farmers because of the high short-term profitability compared to the initial investment (Scandizzo and Savastano, 2010). Additionally, GE crops are more simplistic and flexible, allowing farmers to save management time that can allow for extra income performing off-farm work (Fernandez-Cornejo and Caswell, 2006). Environmental benefits were also taken into account by farmers such as reduction in pesticide and herbicide use, along with better conservation practices. Presently, overuse of glyphosate has resulted in resistant weeds in some field crops in the U.S. Growers with glyphosate-resistant weeds in their fields may need to turn to alternative practices to help control glyphosate-resistant populations (Duke and Powles, 2009). U.S. consumers have not been fully accepting of biotech crops, but these concerns have yet to be seen in the marketplace (Fernandez-Cornejo and Caswell, 2006). In 2010, Barfoot and Brookes discussed how farmers were adopting transgenic crop varieties globally. Factors influencing adoption of HT and insect-resistant crops included:

- Ease of use associated with broad-spectrum, post-emergent herbicides and the increased/longer time window for spraying;
- Reduction in damage to crop arising from the application of post-emergent herbicide;
- Ability to use alternative production technologies such as no/reduced tillage practices;
- Time and fuel savings from the adoption of no/reduced till compared to equivalent conventional crop husbandry practices;
- Ease of weed control leading to cleaner crops hence reduced harvesting costs, and time spent for harvesting. Resultant effect is improved harvest quality and premium price for quality;
- Avoidance of potential damage from soil-incorporated residual herbicides in follow-on crops;
- Improved quality of family life arising from social benefits derived from time savings made from crop husbandry practices.

Since the introduction of glyphosate-tolerant canola on the market place in 1999, canola production has been fairly level, fluctuating between 0.8 million and 1.5 million acres planted (Table 2). The high of 1.5 million acres occurred in 2000, and again recently in 2010. As discussed earlier, the planting of HT varieties has increased significantly from 1999 to 2006, as benchmarked in a primary state of production, North Dakota (25% to 99% from 1999 to 2006; Johnson *et al.*, 2007); however, despite this trend of increasing HT varieties, overall canola cultivation has not seen a similar increase. There is no indication that the introduction of glyphosate-tolerant varieties in 1999, significantly changed cultivation acreage of canola in the U.S. Furthermore, the planting of HT varieties has reached a high percentage in the primary states of production (99% in North Dakota in 2006; 78% in Minnesota in 2006; Johnson *et al.*, 2007) with similar trends seen in Canada as a comparison (99% of Canada acreage is herbicide tolerant (Figure 3)). Therefore, the introduction of additional HT varieties, such as 73496 canola, would not be expected to increase acreage and would likely be a replacement for other HT varieties already being planted. The introduction of another glyphosate-tolerant variety to the marketplace would provide a market alternative and would not likely lead to significant changes to current canola acreage in the U.S.

As mentioned above, adoption of HT varieties is also high in Canada (Figure 3). Commercial adoption of HT canola varieties in Canada has increased steadily since 1996, so that by 2010, 99% of Canada's 16.1 million acres of canola were planted to HT varieties, both GE and non-GE (Figure 3). Approximately 47% of Canada's HT canola acres were planted with glyphosate-tolerant Roundup Ready® varieties, 46% were planted with glufosinate-tolerant InVigor varieties, and 6% were planted with imidazolinone-tolerant Clearfield® varieties. Smyth *et al*. (2011) used this information to conclude that "adoption rates like this demonstrate that producers are recognizing a substantial economic and environmental benefit from HT canola" over non-HT varieties.

Pioneer has analyzed the long-term market for HT canola and expects glyphosate and glufosinate-tolerant canola to remain popular with producers (Figure 4). Pioneer does not expect producers to plant significant acreages of canola varieties with stacked tolerance to glyphosate and glufosinate due to limitations for volunteer canola control. Inadequate weed control with imidazolinone-tolerant canola is expected to limit demand for those varieties.

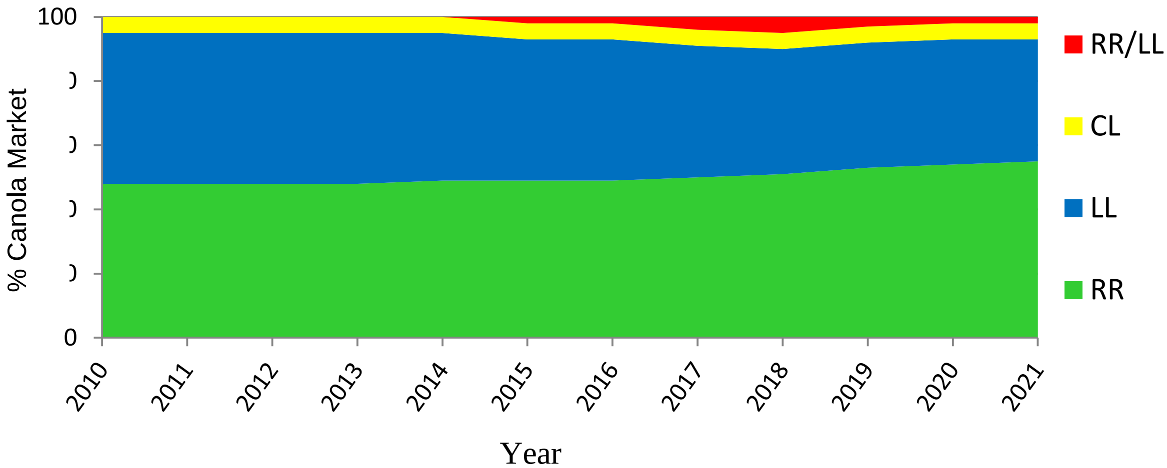


Figure 4. Ten-year Projection of Herbicide-tolerant Canola Market Growth in the U.S. and Canada

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

Source: Pioneer Hi-Bred Marketing

Herbicide use and Weed Resistance. Compared to major crops such as corn, soybeans, and wheat there are relatively few herbicides available to canola growers. Currently registered herbicides for traditional canola and HT canola are listed in Tables 6 and 7.

Table 6. Registered Herbicides Commonly Used on Canola in the U.S.

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

Souce: Pioneer agronomist, personal information

Table 7. Registered Herbicides for Herbicide-Tolerant Canola

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

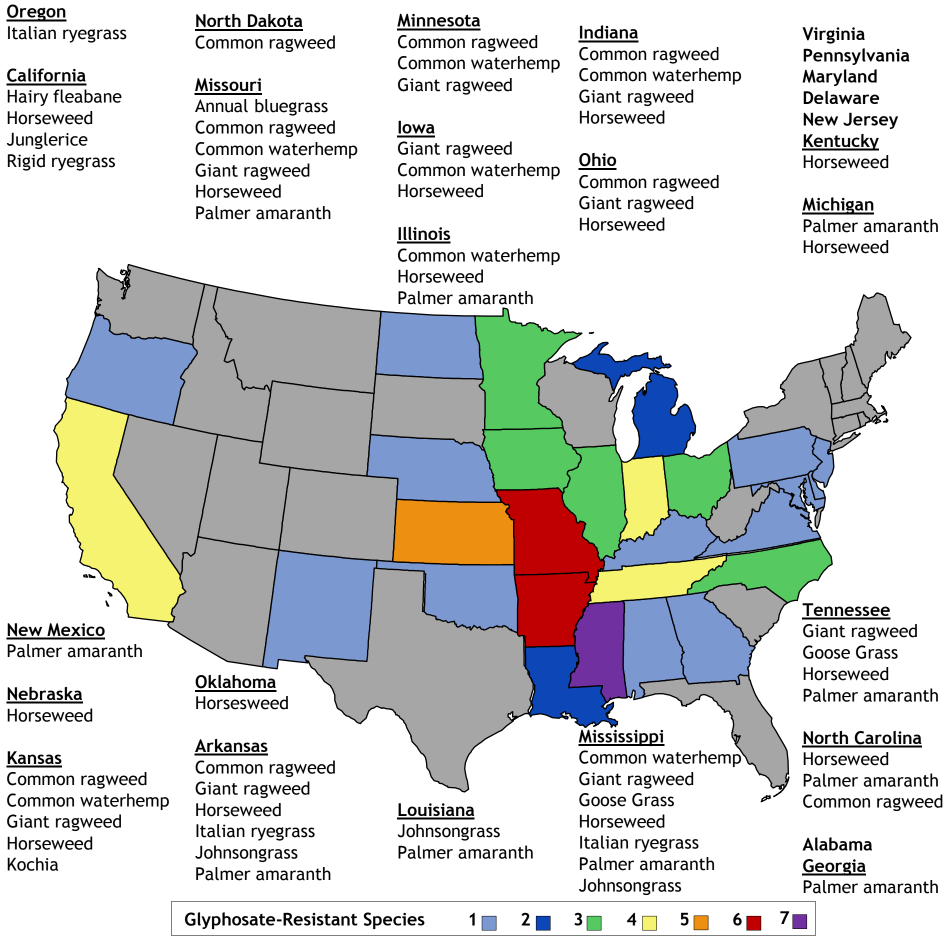
Crop pests respond to the repeated use of any mechanism that attempts to control them by evolving biological tactics to escape control. The first documented case of a weed developing resistance in response to repeated use of an herbicide occurred in the mid 1960s (Ryan, 1970). During the 1970s, growers in North America and Europe began to realize that one class of herbicides (triazines) that had successfully controlled many different weeds was no longer effective against certain populations of as many as 30 different weed species (Bandeen *et al.*, 1982; LeBaron and McFarland, 1990). By 1990, weed scientists had evidence that at least 99 weed species contained individuals (biotypes) that had evolved resistance to one or more herbicides (Holt and LeBaron, 1990). Currently, more than 365 biotypes of herbicide resistant weeds occur around the world (Heap, 2010b). For additional information about the evolution of herbicide-resistant weeds and stewardship of HT canola see Petition Appendix 9.

To date, 13 glyphosate-resistant weed species have been reported in the U.S. (Figure 5). Of these, only two (common ragweed and kochia) are found in canola weed surveys in North Dakota (Table 5). In 2007, glyphosate-resistant common ragweed was confirmed in North Dakota soybean fields by the International Survey of Herbicide Resistant Weeds (Heap, 2010a). All glyphosate-resistant weed species, except for *Poa annua* (annual bluegrass), are found in states reporting some canola crop acreage in 2007 (Heap, 2010a).

Weeds with multiple herbicide resistance (glyphosate resistance plus resistance to at least one other herbicide family) have been reported in several states:

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

Herbicides currently registered for use on canola that are most commonly used to control glyphosate-resistant weeds in canola can be found in Table 6.



Source: WSSA, 2011 (Accessed September 7, 2011)

Figure 5. Distribution of Glyphosate-Resistant Weeds in the U.S.

Whether herbicide use overall has increased as a result of the adoption of HT crops is a matter of current debate. One study has claimed that the volume of herbicide use is greater due to glyphosate-tolerant crops (Benbrook, 2004), while other studies demonstrate a decrease in overall herbicide usage related to the increased use of HT crops (Fernandez-Cornejo, 2006; Gianessi and Reigner, 2006; Heimlich *et al.*, 2000; Johnson *et al.*,2007; Sankula, 2006). Benbrook (2004) evaluated USDA-NASS data from 1996 to 2004 on genetically modified crop acreage along with data on pesticide volumes used and determined that genetically modified corn, soybeans, and cotton led to a 138 million pound or 5% increase in herbicide use since 1996. Glyphosate-tolerant corn also showed a trend for increasing use of non-glyphosate herbicides from 42% of planted acreage in 2002 to 55% of planted acreage in 2006. Benbrook (2004) attributed this increase to increasing weed resistance to glyphosate and reduction in glyphosate prices after the patent expired.

Others have indicated there has not been a significant increase in the amount of herbicide usage since the advent of glyphosate-tolerant crops. They noted that using glyphosate has resulted in the replacement of herbicides that are at least three times as toxic and persist almost twice as long as glyphosate (Heimlich *et al.,* 2000). An analysis also revealed that 3.27 million kg of other herbicides have been replaced with 2.45 million kg of glyphosate in soybean fields in the U.S. (Heimlich *et al*., 2000). Carpenter and Gianessi (2003) concluded that the introduction of glyphosate-tolerant soybeans resulted in a decrease in the total volume of herbicides used. Gianessi and Reigner (2006) noted that an increase in glyphosate usage coincided with a decrease in total amount of herbicide usage by 61 million pounds (of active ingredient) between 1997 and 2002. Much of this reduction occurred in cotton and soybeans, where several herbicides were replaced by glyphosate. Johnson *et al.,* (2007) evaluated the USDA-NASS database and concluded that herbicide use in 2006 was reduced by 100.5 million pounds of active ingredient, based on estimates of biotechnology-derived crop replacement of conventional crops. Other studies showed a decrease in the overall amount of herbicide applied to HT crops. For example, Sankula (2006) evaluated the impact of biotechnology-derived crops planted in the U.S. in 2005 and determined the following:

- HT canola used less herbicide active ingredient per acre than conventional canola, which represented a reduction of 690,000 pounds of herbicide use in 2005.
- HT corn reduced herbicide use in corn by 21.8 million pounds in 2005, which corresponds to a grower cost savings of $269 million.
- Compared to 2004, grower returns were 94 percent higher and pesticide use was 18 percent lower due to a 67 percent increase in the adoption of HT corn (due to EU approvals).
- HT cotton reduced pesticide use by 18 million pounds and reduced production costs by $39 million.
- On average, glyphosate-tolerant soybean programs used 1.03 pounds active ingredient per acre (lb. a.i./A) whereas conventional herbicide programs used an additional 0.32 lb. a.i./A. This translates to a reduction of 39.4 million pounds of herbicide and a cost savings of $134 million.

A recent Canadian study assessed the environmental impact of HT canola (Smyth, *et al.,* 2011). This study surveyed nearly 600 canola farmers and asked them about their crop production experience in 2005-2006 and expected crop planting in 2007. They concluded that herbicide use was reduced by nearly 1.3 million kg annually, tillage was reduced and under land management of HT canola 1 million tons of carbon was either sequestered or no longer released, as compared to 1995 (Smyth *et al.*, 2011). In the northern U.S., it is likely that similar results could be expected from the production of HT canola.

Canola can be damaged or killed by residues of certain herbicides in the soil; therefore, there are plant back restrictions for many of the herbicides that are applied to control vegetation prior to canola planting or are applied to previous rotational crops such as cereals (Table 8). For example, canola cannot be planted for 40 months following application of imazethapyr unless the canola is an imidazolinone-tolerant variety. In North Dakota, where most U.S. canola is grown, glyphosate or a tank mix of glyphosate and carfentrazone is commonly used to control grasses and small broadleaf weeds prior to planting since neither herbicide has plant-back restrictions (Pioneer Agronomist, personal communication, 2011).

Table 8. Herbicide Plant-back Restrictions for Canola

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

Table 8. Herbicide Plant-back Restrictions for Canola (continued)

Herbicide Common Name	Plant Back Restriction on Herbicide Label
Flucarbazone	9 months
Tribenuron	60 days
Triallate	12 months
Chlorsulfuron	14-18 months
Chlorsulfuron	None
Paraquat	None
Thifensulfuron	45 days
Thifensulfuron	60 days
Diclofop	None
Pyrasulfotole + Bromoxynil	9 months
Diuron	12 months
Glufosinate	120 days
Linuron	12 months
Sulfosulfuron	22 months
MCPA	3 months
Propoxycarbazone	22 months
Propoxycarbazone + Mesosulfuron	12 months
Florasulam + MCPA	9 months
Mesosulfuron	10 months
Dimethenamid	None
Quinclurac	10 months
Prosulfuron	10 months
Sethoxydim	None
Pyroxulam	9 months
Pendimethalin	Next season
Fenoxyprop	None
Imazethapyr	40 months plus bioassay
Glyphosate	None
Clethodim	None
Metribuxin	12 months
Ethalfluralin	None
Sulfentrazone	24 months
Fluroxypyr	120 days
Clopyralid	None

Table 8. Herbicide Plant-back Restrictions for Canola (continued)

Herbicide Common Name	Plant Back Restriction on Herbicide Label
MCPB	None
Picloram	36 months or field bioassay
Trifluralin	None
2, 4-D	3 months

Based on Brown *et al.*, 2008

2.1C. Specialty Canola Production

While the majority of U.S. canola is planted as a commodity crop where co-mingling of the harvested grains and bulk transport and processing is standard practice, a small proportion of the crop has unique "value-added" characteristics that command a premium in the marketplace and hence warrant identity preservation (IP) throughout production, harvest, and processing. Canola is mainly self-pollinating but can outcross to other *Brassica* crops through insect pollinators at rates of up to 30%. Nevertheless, IP markets exist for different value added canola types (*e.g.*, high-oleic canola and high-erucic acid rapeseed oil) as well other oilseeds (rapseed, crambe), condiment mustard, and sexually compatible vegetables. Since both commodity and specialty IP crops are likely to be grown in similar environments and geographies, neighboring growers need to find ways to "coexist," so that each may successfully grow a crop without cross-contamination.

Various practices are available to avoid cross-contamination of sexually compatible canola or other *Brassica* crops (Graef, 2007). Coexistence is not a new issue, nor is it unique to the cultivation of GE crop varieties. Agricultural producers who successfully grow and market different products using different processes in proximity to one another are all models of coexistence.

Agriculture has an impressive track record of successfully addressing the economic and market-based issues associated with coexistence, whether neighbor-to-neighbor or through state seed certifying agencies or other local, state, or regional initiatives. For example, grains that are known as IP crops are produced for a specific purpose and are referred to as specialty, high value, premium, or niche market grains (Massey, 2002). These higher-value IP crops have been able to survive alongside commodities because growers and the value chain developed ways for these two diverse approaches to agriculture to coexist.

High-oleic canola. High-oleic acid canola is a variety of canola that is high in monosaturated fat, low in saturated fat, and has no trans-fats or cholesterol. It is one of the healthiest oils sold in the marketplace. Varieties are cultivated in the U.S. under contract and under IP systems. While acreage and state information is not available, these varieties are being tested in U.S. variety trials and being marketed by Cargill and SK Food International indicating that a certain percentage of growers are producing these specialty varieties.

Although statistics do not exist for the U.S. acreage, the combination of high-oleic and High-Erucic Acid Rapeseed (HEAR) varieties represented approximately 4% of the Canadian crop in 2003 (Brookes and Barfoot, 2004). In Canada in 2002, high-oleic canola varieties were grown on two to three times the acreage of HEAR varieties (Phillips and Smyth, 2003). Similarly low levels of production are likely in the U.S.

High Erucic Acid Rapeseed. High erucic acid rapeseed (HEAR) is a specialty rapeseed selected for its high erucic content. It has over 50% erucic acid and is grown as a key ingredient for plastics, personal care products and pharmaceuticals (www.techcrops.com), as well as industrial and consumer products such as lubricants, fuel, and paints (USDA-ERS, 2010a). HEAR oil cannot be marketed as canola oil due the presence of more than 2% erucic acid in the processed oil (Boyles *et al.*, 2007). The seed, the crop, and the oil are visually identical to canola; therefore, every step of the supply chain demands robust and effective identity preservation processes (www.techcrops.com). HEAR was planted on approximately 2,300 acres total in 2010, a fraction of the domestic canola acreage (USDA-NASS, 2011). HEAR varieties are currently non-GE.

To promote co-existence, HEAR varieties are grown under contract and under IP systems. Such practices prevent cross-pollination and segregate non-edible HEAR seed from other canola handling systems (Phillips and Smyth, 2003; USDA-ERS, 2010a). Technology Crops International, a company that manages and supplies technology crops including HEAR, encourages growers to use a 500 ft. isolation distance from canola to minimize cross-pollination and mechanical mixing. Growers of HEAR usually discuss cropping plans with their neighbors and have mutual agreements to prevent any co-existence issues (Brookes and Barfoot, 2004).

Specialty Brassica Crops. *Brassica* species include not only canola and rapeseed but also vegetables known as crucifers in which cross-hybridization is known to occur. Reproductive compatibility among *Brassica* crops is complex. Because experimental hybridization studies are designed to optimize the likelihood of successful hybridization, they may create bias toward positive reports of hybridization between species that may be unlikely to cross in natural conditions (FitzJohn *et al.*, 2007). The ease with which a crop and its wild relatives can hybridize through manual cross-pollination reveals little about the potential influence of pre-pollination and other ecological barriers (FitzJohn *et al.*, 2007). Additionally, manual cross-pollination forces a cross between related species; however, the possibility of the cross actually occurring in nature can be extremely rare. Studies that observe cross-hybirdization in a natural setting are more informative (FitzJohn *et al.*, 2007).

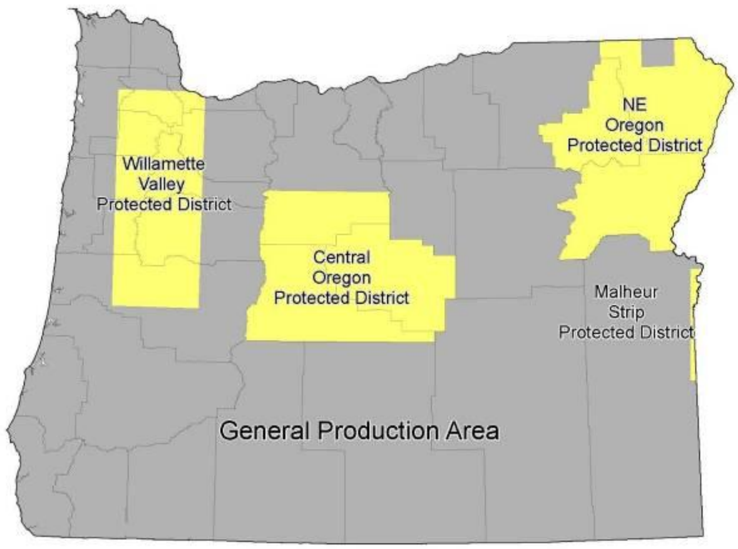
Many studies have been conducted to gather experimental data to infer the likelihood of hybridization using a variety of techniques: experimental crosses (manual hand pollination), spontaneous crosses (non-assisted crosses under field conditions), and *in vitro* methods (*e.g.*, embryo rescue). Cross-compatibility varies with the particular genotype used and with the polarity of the cross (*i.e.*, dependent upon which species was the maternal parent; Andersson and de Vicente, 2010). Most combinations are unsuccessful and where crosses are successful, rates of hybrid production are typically very low (FitzJohn *et al.*, 2007). For further information about out-crossing with relevant *Brassica* crops see Petition, Section IX.

Oregon provides an example of successful application of co-existence practices. The most highly productive land in the state is located in the Willamette Valley with over 170 different crops produced (ODA, 2009). Growers of *Brassica* vegetables and rapeseed growers have cooperated through coexistence plans over the last 20 years. In the early 1990s, Administrative Rules (Chapter 603, Division 52) were enacted in Oregon to prevent cross-pollination between *Brassica* crops (ODA, 2010). These rules successfully established rapeseed production areas and isolation distances for rapeseed producers. A system of "pinning" maps in Marion and Linn counties also delineated areas for seed growers and producers to mark out areas of production on a first-come, first-served basis. Additionally, a 3-mile isolation distance was established to prevent cross-pollination from *Brassica* crops (Ehrensing, 2008).

In the last several years, canola has become an increasingly popular crop in Oregon due to its adaptability to the region and the escalating interest in biodiesel (Ehrensing, 2008). The rise in canola production has concerned the Willamette Valley vegetable seed growers. In 2005, the Administrative Rules were revised and four restricted areas were established where only specialty seed and *Brassica* vegetables are grown (Figure 6). The four areas where canola oilseed cropping is restricted are:

- Willamette Valley;
- Central Oregon (Crook, Deschutes, and Jefferson counties);
- Northeast Oregon (Baker, Union and Wallowa counties (except near Flora); and
- Malheur County within 3 miles of the Idaho border (this strip of land is adjacent to a protected district in Payette County, Idaho).

Canola can be grown in these protected areas as forage or cover crops but must not be allowed to flower. However, *Brassica* oil seed crops can be grown in these protected areas with an exemption request (ODA, 2009). In 2006, an exemption was given to researchers to grow non-genetically modified canola at the Central Oregon Experiment Station. The following year another exemption was given to Oregon State University for the Willamette Valley to conduct limited canola trials for assess its commercial potential (Ehrensing, 2008). Minor revisions were made to the Administrative rules in 2009, and the next revision of the rules will be in 2012 (ODA, 2009).



Source: ODA, 2010

Figure 6. Map of Oregon's Four Restricted Areas Where Only Specialty Seed and *Brassica* Vegetables are Grown

Other specialty crops in the U.S. related to canola and rapeseed include mustard and crambe (MSGA, 2010). In the U.S., mustard grows best is the Pacific Northwest (Herdrich, 2001). Crambe is successfully grown in several areas in the U.S. but most of its production is in North Dakota (Hansen and Huntrods, 2010).

Unlike organic certification, which is a process-based certification, IP products have certifications earned based on the purity and quality of the product. Therefore, there are seed certification standards that prevent cross-hybridization of canola, crambe, mustard, and rapeseed. Montana is one of the largest producers of mustard crops and follows seed certification standards adopted by the Montana Seed Growers Association (MSGA, 2010)
It is recommended that not more than one variety or crop of canola, crambe, mustard, or rapeseed be produced by a certified producer in any given year. A crop of canola, crambe, mustard, or rapeseed must not have been grown or planted on the land for five, four, and three years prior to stand establishment for producing the Foundation, Registered, and Certified classes, respectively. Manure or other contaminating material should not be applied to the land in preparation for planting of all certified classes or during the productive life of the stand. Reseeding of a field, due to failure or partial failure of the first seeding, may be done with the permission of the certifying agency. All roadways, ditchbanks and other areas adjacent to a certified field must be free of volunteer canola, crambe, mustard, and rapeseed (wild or tame).

Other important standards include isolation distances from cross-pollinated, self-pollinated, and certified fields of the same varieties (Table 9). There are general and specific field criteria, field inspections from the growers, and preparing of the seed for final certification that are all important to ensure seed identity preservation of the canola, crambe, mustard, and rapeseed crop.

Table 9. Canola Seed Identity Preservation Distances from Neighboring Fields

Class	Fields of Cross-Pollinated Varieties	Fields of Self-Pollinated Varieties	Certified Fields of Same Varieties
Foundation	1,320 feet	660 feet	15 feet
Registered	1,320 feet	660 feet	15 feet
Certified	660 feet	330 feet	15 feet

Source: MSGA, 2010

Growers of canola and condiment mustard must coexist since contamination through shared equipment, volunteers, or gene flow from one product to the other can result in the devaluation of either crop. Mustard and canola crops are similar in appearance and are generally grown in similar areas (*i.e.*, North Dakota, Montana and Washington); however, there is not complete overlap in geography since mustard generally is grown in drier areas than canola (*i.e.*, less than 15” of rain per year).

Unlike canola, which is a commodity crop grown for its oil, mustard is grown under contract and used for flour (in meat products) and condiment mustard. Growers must have a contract to deliver their product to a specific end user in order to obtain crop insurance.

Mustard seed contains high levels of glucosinolates. However, glucosinoate levels of >30 µM will cause canola seed to not meet the canola definition and potentially be rejected at a crushing plant. Therefore, contamination of canola seed with mustard seed can result in reduced value of the canola crop. Because virtually all of the canola grown today is HT, canola growers can use herbicides to rid their fields of volunteer mustard plants and use appropriate isolation, if needed, to ensure product quality.

Canola contamination of mustard can be more problematic. Mustard seeds are most often brown or yellow, and *B. napus* canola seeds are generally black. Too much black seed in yellow mustard seed can cause flour discolor. In addition, condiment mustard is a non-GM crop. Any black seeds found in mustard seed are assumed to be canola and assumed to be GE. Therefore, there are limits on the number of black seeds that can be in mustard seed. There are no broadleaf herbicides registered for use in mustard that can control canola volunteers. Therefore, in order to meet quality standards, mustard growers are advised to use land that has not had canola grown on it for the past 4-5 years. For growers that grow both canola and mustard, thorough cleanout of equipment is necessary. Physical isolation of mustard fields from canola fields is also recommended, although no specific isolation distances are specified. Information for this section was obtained from two mustard processers: Minn-Dak Growers, Ltd., which has a mustard flour processing facility in Grand Forks, ND; http://www.minndak.com/; and Olds Products Company, which has a condiment mustard processing facility in Pleasant Prairie, WI. For context, Olds Products Company obtains more than half of their needed mustard seed from contract growers in southern Alberta and Saskatchewan; the remainder of their needs is met using contract growers in North Dakota and Montana.

2.1D. Organic Canola Production Practices

Organic farming, as defined in this document, includes any production system that falls under the USDA National Organic Program (NOP) definition of organic farming and is a certified organic production system. The National Organic Program is administered by USDA's Agricultural Marketing Service (AMS). Organic farming operations, as described by the NOP, require organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards (NOS), including the prohibition on the use of excluded methods. Excluded methods include a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes. In organic systems, the use of synthetic pesticides, fertilizers, and genetically engineered crops is strictly limited.

An accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards. Practices growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields. Although the NOS prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the NOS (USDA-AMS, 2005). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan. Organic certification of a production or handling operation is a process claim, not a product claim.

There is a small specialty market for organic canola. The USDA Economic Research Service collects acreage statistics for organic canola but they are combined in an "unclassified" or "other oilseeds" category that includes safflower and excludes flax, sunflower, peanuts and soybean acreage (USDA-ERS, 2010b). According to the USDA-ERS, organic "other oilseeds" cultivation occurs mostly in California with 23,891 acres and at a distant second Utah cultivates 2,453 acres (USDA-ERS, 2010b). Other states that have less than 2,000 acres of "other oilseed" include Colorado, Idaho, Michigan, Montana, Nebraska, North Dakota, Oregon, Vermont, Washington, and Wisconsin. The tracking of other oilseeds such as rapeseed and mustard in total yearly agriculture statistics are also tracked in the organic acreage; however, they are combined in a category with multiple crops denoted as "unclassified" or "other oilseed" (USDA-ERS 2010c).

Unclassified/other oilseeds acreage was 5,380 acres in 2007, and 29,159 acres in 2008, representing an overall high since 1997 (USDA-ERS, 2010b). In general, the planted acreage reported for "other oilseeds" has not followed any specific trend since 1997. Excluding the acreage high in 2008, the planted acreage of "other oilseeds" has fluctuated between 12,487 acres in 1997 and 5,310 acres in 2002 (USDA-ERS, 2010b).

To estimate the acreage of organic canola oilseed production from these combined statistics, one can use past total yearly acreage for the crops. In general, 2007 and 2008, canola acreage was approximately 1.2 and 1 million acres, respectively (USDA-NASS, 2010). This represented approximately 80% of overall oilseed cultivation that included safflower, rapeseed, and mustard seed (USDA-NASS, 2010). Using this 80% estimate, organic canola cultivation in 2007 can be calculated to be approximately 4,300 acres and 23,000 acres in 2008. Even if one assumed that all reported "unclassified" organic oilseed acreage was 100% canola, organic canola represented approximately 3% of the total canola crop area in 2008 (1,011,000 acres) as compared to 0.45% of the total crop area in 2007 (1,183,000 acres) (USDA-NASS, 2010). This may indicate that organic canola cultivation is increasing but remains a minor contributor to overall U.S. canola production. Organic canola acreage has been historically low (below 0.1% of total) because it is difficult to produce organically and organic canola has a limited market compared to other oilseeds (Brookes, 2004; Brookes and Barfoot, 2004).

2.2. Physical Environment

2.2A. Soil Quality

Canola can be grown on most soil types, but cannot tolerate standing water or waterlogged soils. Disturbance and exposure of the top soil surface layer by certain agronomic practices (*e.g.*, tillage) associated with the cultivation of canola causes impacts and may leave crop soils prone to degradation (Hoeft *et al*., 2000). Two environmental impacts of soil degradation are the decline in water quality and the contribution to the greenhouse effect (Lal and Bruce 1999). A decline in soil quality and soil resilience enhances the greenhouse effect through emissions of radiatively active gases (carbon dioxide [CO_2] and nitrous oxide [N_2O]) and depletion of the soil carbon pool (Lal 2003; US-EPA 2011). In turn, a decrease in carbon aggregation and sequestration in the soil leads to increased runoff and soil erosion.

The use of conventional tillage has dropped considerably in recent years while conservation tillage practices have increased. The increase in the use of no-till or minimum-till practices may be correlated with the increased adoption of HT canola (see Section 2.1 Affected Environment, Agricultural Production of Canola – Tillage).

2.2B. Water Resources

Canola is less tolerant to drought than other small grain crops, but canola is not an intensively irrigated crop in the U.S. Canola has a taproot that allows it to gain access to deep water and nutrients (Johnson *et al*., 2009). Approximately 1% of the 1.176 million acres of canola planted in 2007 were irrigated. The states reporting significant irrigated acres (>1000 acres in 2002 and 2007) are Colorado, Idaho, Montana, Oregon, and Washington (USDA-NASS, 2009).

Research is currently being conducted in the U.S. on irrigation management for canola and also to develop varieties for more arid climates. Currently, canola grown in semi-arid regions requires irrigation if adequate subsoil moisture is not available to sustain the crop during the flowering and seed filling period (Johnson *et al*., 2009). The cost of irrigation may limit the crop's expansion into semi-arid regions. There are new drought-tolerant GE and non-GE corn hybrids under development by various technology providers; it is not clear whether these technologies will be deployed in canola.

2.2C. Air Quality

Many agricultural activities affect air quality including smoke from agricultural burning, tillage, traffic and harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (Aneja *et al*., 2009; Hoeft *et al*., 2000). These agricultural activities individually have potentially adverse environmental impacts on air quality. Tillage contributes to the release of greenhouse gases (GHG) because of the loss of CO_2 to the atmosphere, and the exposure and oxidation of soil organic matter (Baker *et al*., 2005). Emissions released from agricultural equipment (*e.g.*, irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA, 2011). Nitrous oxide may also be released following the use of nitrogen fertilizer (US-EPA, 2011). Aerial application of pesticides may cause impacts from drift and diffusion. Pesticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel *et al*., 2008). Agriculture, including land-use changes for farming, is responsible for an estimated 6 % of all human-induced GHG emissions in the U.S., and nitrous oxide emissions from agricultural soil management are a large part of this, 68 % of all U.S. nitrous oxide emissions (US-EPA, 2011).

2.2D. Climate Change

Climate change is possibly interrelated with agriculture in several relevant ways. Production of agricultural commodities is one of the many human activities that could contribute greenhouse gases to the air (Aneja *et al*., 2009; Hoeft *et al*., 2000; Isermann, 1994). First, this may occur through the combustion of fossil fuels to run farm equipment, the use of fertilizers, or the decomposition of agricultural waste products including crop residues and animal wastes. Second, the classes of crops planted are relevant to climate change, whether trees, grasses or field crops (Cole *et al*., 1997; Freibauer *et al*., 2004). The location and the soil types in which they are planted also affect production of greenhouse gases (Flessa *et al*., 1998; Kamp *et al*., 2001). Third, climate change itself may force changes to agricultural practices by extending the ranges of weeds and pests of agriculture (IPCC, 2007). Many of the indirect effects of these organisms will be determined by the traits engineered into organisms and the management strategies used in the production of these organisms.

The influences that genetically engineered agricultural organisms may have on global climate change are unclear, though it is likely dependent upon cropping systems, production practices, geographic distribution facilities, and individual grower decisions**.** In response to climate change, the current range of weeds and pests of agriculture is expected to change and current agricultural practices may be required to change as well (IPCC, 2007). Climate-changing greenhouse gas production will not be significant unless large amounts of crop plantings produce changes in measureable concentrations. A recent forecast (IPCC, 2007) for aggregate North American impacts on agriculture from climate change actually projects yield increases of 5-20% for this century. The IPCC report notes, however, that certain regions of the U.S. will be more heavily impacted because water resources may be substantially reduced. While agricultural impacts on existing crops may be significant, North American production is expected to adapt with improved cultivars and responsive farm management (IPCC, 2007).

2.3. Biological Resources

2.3A. Animal Communities

The landscape surrounding a canola field varies depending on the region. In certain areas, canola fields may be bordered by other crops and may also be surrounded by woodland and/or pasture/grassland areas. Therefore, the types of animals in and around a canola field depend on the immediate area in which the canola is planted. The animal species present will also vary depending on the geographic region where the canola is planted. As previously stated, North Dakota is where the more than 80% of the canola is planted in the U.S. According to the U.S. Fish and Wildlife Service, there are seven animals listed as threatened or endangered species in North Dakota: whooping crane (*Grus americana*), black footed ferret (*Mustela nigripes*), pipping plover (*Charadrius melodus*), pallid sturgeon (*Scaphirhynchus albus*), tern (*Sterna antillarum*), American burying beetle (*Nicrophorus americanus*), and the gray wolf (Canis lupus) (US-FWS, 2011). None of these animals listed above are known to live or forage in agricultural fields.

Several species of birds and mammals are known to visit canola fields for forage and grit. Recently in 2008, a consumption study was done using several species of captive birds that were fed canola seed, including four dove/pigeon species, one finch species and two duck species, seed generally was well macerated after passage through the digestive system. Whole seed was found only in fecal pellets obtained from wood ducks. However, the amount of seed detected was <0.01% of that consumed and the germination rate of the seed was less than 50 % (5 out of 11 seeds) (Twigg *et al.*, 2008). Omnivorous/herbivorous species such as ducks are less efficient at digesting seeds compared to most obligate seed eaters. Therefore, it is likely that dissemination of GE canola seed by wild birds consuming seed directly from the crop would be very low.

As for mammals, the deer mouse feeds on a wide variety of plant and animal matter depending on availability, but primarily feeds on seeds and insects. The deer mouse has been considered beneficial in agroecosystems because it consumes both weed and pest insect species. The meadow vole (*Microtus pennsylvanicus*) feeds primarily on fresh grass, sedges, and herbs, but also on seeds and grains (Smith, 2005). The meadow vole may also be considered beneficial for its role in the consumption of weeds, but can be a significant agricultural pest where abundant as they rely on cover absent from tilled agriculture. Studies suggest that canola seed is likely to be non-viable after passage through the animal digestive system. Sheep fed canola seed were foundto excrete seed up to five days after consumption. However, only 1-1.5 % of the seed was excreted whole and, of this, only 10-40 % of seed was capable of germination. Therefore, overall less than 0.5 % of seed consumed was capable of germinating after excretion (Stanton *et al*., 2003). In a German study, Wiedemann *et al*. (2009) found no intact rape (*B. napus*) seed in the feces of wild boars fed a diet of maize and rape seed.

2.3B. Plant Communities

The landscape surrounding a canola field varies depending on the region. In certain areas, canola fields may be bordered by other crops and may also be surrounded by woodland and/or pasture/grassland areas. Therefore, the types of plants in and around a canola field depend on the immediate area in which the canola is planted. Weed species present will also vary depending on the geographic region where the canola is planted. Weeds compete with crops for water, nutrients, light, and other growth factors. For a discussion of weeds impacting canola production see Section 2.1 Affected Environment, Agricultural Production of Canola – Weed management.

Volunteers are crops that grow without being intentionally planted. Characteristics that contribute to the production of volunteer canola plants include dry conditions causing pod shatter before and after harvest, large seedbank inputs and stress-induced seed dormancy. These characteristics can produce volunteers that are detrimental to rotational crops for subsequent years (Gulden, 2007). The survival in seedbanks of canola is low compared to its relatives. However, seed dormancy allows dispersal in time and maintains seeds of many generations that can become a reservoir for transgenes (Gulden, 2007; Mallory-Smith and Zapiola, 2008). Other opportunities for seed dispersal are by human interactions, animals, water, and wind (Andersson and de Vicente, 2010). Research on GE canola determined that its seed was still viable after digestion by chickens (Andersson and de Vicente, 2010). The small size of canola seeds, their abundance, and the tendency of canola seed pods to shatter mean that canola is likely to appear as a volunteer in following crops and must be removed to preserve yield and crop quality.

Problems associated with controlling canola volunteers are not common (Boyles *et al.*, 2007). They can be controlled by tillage or by herbicides in no-till systems. Tillage is generally a good way to control volunteers, but if seed is buried to a depth of 10 cm it may persist for several years and become an annual weed (Gulden, 2007). To control weeds and canola volunteers in rotational crops, most producers rely on herbicides. There are many different types of pre- and post-emergence herbicides for control of canola volunteers. In general, 2,4-D, saflufenacil, thifenensulfuron, tribenuron can be used to control canola volunteers in wheat, fomsafem and cloransulam-methyl can be used to control canola volunteers in soybean, and mesotrione and tembotrione can be used to control canola volunteers in corn (Pioneer agronomist, personal communication). Each of these herbicides can also be used to control glyphosate-tolerant canola volunteers. Canola volunteers in rotational crops are difficult to control with herbicides if not sprayed before the 6-leaf stage when plants begin to bolt (Boyles *et al.*, 2007). In general genetically engineered crops have reduced tillage from 89% to 35%, but in individual cases tillage is useful in managing herbicide tolerant weeds.

Feral canola plants are crop-derived plants occurring outside of cultivated areas, most commonly in ruderal (*i.e.*, non-cropped, disturbed) habitats such as field margins, along transportation corridors (*e.g.*, roadsides, paths, railway lines), near seed/grain handling facilities (*e.g.*, ports, storage facilities), and wastelands where they can survive and reproduce without human intervention (Bagavathiannan and Van Acker, 2008). There are a number of ways by which feral canola populations can originate including from spillage of seed during its transport to and from the field, redistribution of seed by field equipment, seed dispersal by birds and mammals, or as a result of bulk seed handling operations.

Canola can be present in disturbed habitats, in that it has the ability to take advantage of disturbed sites due to its early germination potential and capacity to capture resources quickly. However, canola is a poor competitor and lacks the ability to establish stable populations in undisturbed natural habitats (Crawley *et al.*, 1993; Crawley *et al.*, 2001; Warwick *et al.*, 2008). Unless the habitat is regularly disturbed, or seed replenished from outside, canola will be displaced over time by other plants.

As reviewed by Devos *et al.* (2011), while many feral canola populations have been found to be transient at a local scale, persisting from one to four years (*e.g.*, Crawley and Brown, 1995; Crawley and Brown, 2004), this is likely counterbalanced at a landscape scale by repeated seed addition and redistribution. The contribution of seed derived from resident feral plants to the persistence of feral canola populations is still a matter of some discussion. A survey conducted in central France indicated that local seed input from resident feral plants accounted for less than 10 percent of subsequent feral populations (Pivard *et al.*, 2008), while a four-year field survey and assessment of genetic variation in feral canola populations in northwest Germany indicated that the percentage of feral plants setting seeds ranged between 30‒48% (Elling *et al.*, 2009). Thus, feral canola may be considered long-lived at a landscape scale, where the high rate of local population extinctions is compensated by the establishment of new populations founded by repeated fresh seed spills from agricultural fields and transport, with some proportion of populations resulting from seed emerging from the feral soil seedbank.

Due to concerns that transgenic HT canola might be more weedy or invasive than it conventional counterpart, or that the introduced genes could be transferred by pollen to wild relatives, whose hybrid offspring might be more weedy or invasive, there have been numerous monitoring surveys conducted to assess the presence of transgenes in feral canola populations (Table 10). Not surprisingly, in regions where there has been widespread adoption of transgenic HT canola over a number of years, such as western Canada and some states in the U.S., the prevalence of transgenes in feral canola populations is similar to the proportion of cultivated canola that is GE (Knispel *et al.*, 2008; Yoshimura *et al.*, 2006). For example, in a survey of feral canola plants conducted in North Dakota, approximately 86% of the feral plants collected tested positive for either the glyphosate- or the glufosinate-tolerance trait, and there were two instances where these two traits were found combined within single plants (Schafer *et al.*, 2010).

Likewise in countries that import significant quantities of canola, but where transgenic HT canola is not commercially cultivated, surveys of feral canola populations occurring around transportation routes and port areas have confirmed the presence of glyphosate- and glufosinate-tolerance traits (Aono *et al.*, 2006; Kawata *et al.*, 2009; Nishizawa *et al.*, 2009; Saji *et al.*, 2005). In Japan, which imports more than 2 million tonnes of canola annually for crushing, the frequency of herbicide-tolerance traits in feral canola populations has been found to vary significantly over time and across sampling sites, ranging from 0.2 to 100% (Kawata *et al.*, 2009; Nishizawa *et al.*, 2009). The occurrence of herbicide-tolerance traits in feral canola populations in Japan is attributed to accidental loss and spillage of imported viable canola seed, of which approximately 90% is sourced from Canada, where up to 95% of the canola crop is comprised of transgenic HT varieties. Plants containing multiple HT (a.k.a. stacked) traits (*i.e.*, glyphosate-plus glufosinate-tolerant) have never been commercialized, but have been reported in feral canola populations (Aono *et al.*, 2006; Kawata, 2010) as has the occurrence of herbicide-tolerance traits in interspecific (*e.g.*, *B. oleracea*) and intergeneric (*e.g.*, *Sisymbrium altissimum*; a Brassicaceae weed) hybrids with *B. napus* collected from roadsides in Japan (Kawata *et al*., 2009; Saji *et al*., 2005). However, it was noted that most hybrids with *Sisymbrium sp*. were sterile and did not produce seed (Kawata, 2010). Other surveys conducted in Japan have failed to detect the presence of herbicide-tolerance traits in seed collected from wild relatives of *B. napus* (*e.g.*, *B. rapa* and *B. juncea*) sampled from ruderal habitats (Aono *et al.*, 2006; Saji *et al.*, 2005). At least in these two studies, the theoretical possibility of spilled feral transgenic HT canola germinating, surviving, hybridizing with sexually compatible wild relatives and the hybrids surviving, reproducing and containing the transgene was below the level of detection.

Canola itself is not considered a noxious or invasive weed in the U.S., although it does demonstrate some of the common characteristics of weeds as described by Baker (1974): high seed output under favorable conditions, continuous germination combined with long-lived seeds and self-compatibility (but not obligatorily self-pollinated or apomictic). However, canola has undergone many years of selective breeding and domestication and is a poor competitor with other species. Canola populations, even if containing herbicide-tolerant transgenes, do not persist outside of agricultural production.

Table 10. Surveys to Monitor Transgene Presence in Feral Canola Populations

Country	Surveyed area	Period	Transgene detection	Sampled material
Belgium	Roadsides nearby and field margins of cropped fields in Wallonia	2007–2008	DNA analysis	Leaf
	Port areas (Antwerpen, Gent, Izegem and Kluisbergen)	Not specified	DNA analysis	Leaf
Canada*	Roadsides nearby and field margins of cropped fields in southern Manitoba (central Canada)	2004–2006	Herbicide screening, biochemical (protein) analysis	Seed, Leaf
	Roadsides and railway lines in Saskatchewan and at the port of Vancouver	2005	Biochemical (protein) analysis	Leaf
Japan	Port areas (Kashima, Chiba and Yokohama), roadsides and riverbanks in the Kanto district	2004	Herbicide screening, biochemical (protein) analysis, DNA analysis	Seed
	Port areas, roadsides and riverbanks in western Japan (Shimizu, Yokkaichi, Sakai-Senboku, Uno, Mizushima, Kita-Kyusyu and Hakata)	2005	Herbicide screening, biochemical (protein) analysis, DNA analysis	Seed
	Port areas and roadsides in the area of Yokkaichi	2004–2007	Biochemical (protein) analysis	Leaf
	Roadside (Route 51) in eastern Japan	2005–2007	Biochemical (protein) analysis, DNA analysis	Leaf
USA*	Roadsides (interstate, state and country roads) in North Dakota	2010	Biochemical (protein) analysis	Leaf

* Country where GE HT canola is grown commercially
Source: adapted from Devos *et al.*, 2011.

2.3C. Microorganisms

The soil is a complex environment rich in microorganisms and arthropods. Canola has a symbiotic or beneficial relationship with soil microbes (OECD, 1997). The highest microbial population usually is bacteria, followed by fungi. These microbial groups play an important and particular role in the ecology of the soil, including nutrimental cycling and the availability of nutrients for plant growth. In addition, certain microbial organisms may contribute to the protection of the root system against soil pathogens (OECD, 2003).

2.3D. Biodiversity

Species diversity and abundance in canola agro-ecosystems may differ between the three canola production methods: conventional with GE varieties, conventional with non-GE varieties, and organic. Many studies over the last ten years have investigated the differences in biological diversity and abundance between GE and non-GE fields, particularly those GE crops that are resistant to insects (*e.g.*, *Bt* crops) or herbicides (*e.g.*, glyphosate-tolerant or glufosinate-tolerant crops). Different studies have indicated potential decreases in biological diversity or abundance due to GE crops, or the presence of a pesticidal *Bt* protein in some GE crops (*e.g.*, Hansen Jesse and Obrycki, 2000; Pilcher *et al.*, 2005; Ponsard *et al*., 2002). Some studies investigating decreases in weed populations following the use of herbicides and HT crops have observed decreases in animal populations using the weeds as a food or refuge source. Herbicide inputs in some cases may reduce overall biological diversity in farmed fields (Marshall *et al*. 2003). Other studies of GE crops, such as Bt corn, when compared to non-GE crops sprayed with insecticides demonstrate that GE crops do not cause any changes in arthropod abundance or diversity (*e.g.*, Bitzer *et al*., 2005; Chen *et al*., 2008; Marvier *et al*., 2007; Romeis *et al*., 2006; Torres and Ruberson, 2005; Wolfenbarger *et al*., 2008). Some reports show that GE crops may even increase biological diversity (*e.g.*, Marvier *et al*., 2007; Romeis *et al*., 2006) in agro-ecosystems. HT crops, when compared to non-GE crop production, may not result in changes in arthropod abundance and may even increase species diversity during different times of the year (*e.g.*, Brooks *et al*., 2003; Haughton *et al*., 2003; Hawes *et al*., 2003; Wolfenbarger *et al*., 2008). Since biological diversity can be defined and measured in many ways, determining the level of biological diversity in any crop is complex and hard to achieve concurrence. Another difficulty with biodiversity studies is separating expected impacts from indirect impacts. For example, reductions of biological control organisms are seen in some *Bt*-expressing GE crops but are caused by reduction of the pest host population following transgenic pesticide expression in the transformed crop plant.

Concerns have been raised about the potential for the transfer of transgenes from the cultivated oilseed *Brassica* species to their weedy relatives in Europe and North America where *Brassica* crop species are widely grown. Some *Brassica* crops and their wild relatives will hybridize only under artificial conditions in laboratories or highly contrived field conditions; others will hybridize at very low rates under natural conditions. However, major barriers to introgression exist, including spatial and temporal isolation, sexual incompatibility, or lack of fertile progeny, thereby reducing the likelihood of gene flow. See Barton and Dracup, 2000; Raybould, 1999; and the 73496 canola Petition, Section IX-D (Gene Flow Assessment) for a discussion of species with reports of hand pollinated or spontaneous hybridization with *B. napus*.

2.4. Human Health

2.4A. Consumer Health

Public health concerns surrounding GE canola, like 73496 canola, focus primarily on human consumption**.** Canola oil is the third most consumed oil in the world (second by volume in the United States) and is widely perceived to be a "healthy oil" because of its low level of saturated fat. Canola oil is the typically consumed food commodity from canola; however recent developments in the processing of canola meal have produced protein isolates that may have possible human use applications in beverages, nutritional products, dairy products, grain products, powdered egg or egg substitutes, emulsifiers in dressings, meat substitutes, bars, or baked foods (Archer Daniels Midland Co., 2010).

Food products derived from 73496 canola must be in compliance with all applicable legal and regulatory requirements. Non-GE canola varieties, both those developed for conventional use and for use in organic production systems, do not require routine evaluation by any regulatory agency in the U.S. for food or feed safety prior to release in the market. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Any GE organisms for food may undergo a voluntary consultation process with the FDA prior to release onto the market.

2.4B. Worker Health

Field workers routinely exposed to canola through dermal contact or inhalation are not subject to any hazards not encountered by workers exposed to other crops in similar situations. Glyphosate used on glyphosate-tolerant canola is the same as glyphosate used for other glyphosate-resistant crops.

Glyphosate herbicide will be applied to only glyphosate-tolerant canola, and workers should follow all precautions described on herbicide product labels to prevent necessary exposure. In any case, based on EPA's toxicological, ecotoxicology and fate databases, glyphosate is considered to be a toxicologically and ecologically low-risk herbicide (Cerdeira and Duke, 2006). According to the Re-registration Eligibility Decision (RED) document for glyphosate (US-EPA, 1993), glyphosate is of relatively low oral and dermal acute toxicity to humans. For this reason, glyphosate has been assigned to Toxicity Categories III and IV for these effects (*i.e*., Toxicity Category I indicates the highest degree of acute toxicity, and Category IV the lowest). An acute inhalation study was waived by EPA because glyphosate is a non-volatile solid and the studies conducted on the end-use product formulation are considered sufficient. With regard to subchronic and chronic toxicity, one of the more consistent effects of exposure to glyphosate is loss of body weight. Other general and non-specific signs of toxicity from subchronic and chronic exposure to glyphosate include changes in liver weight, blood chemistry (may suggest mild liver toxicity), liver pathology, and weight of the pituitary gland (USDA-FS, 2003). Glyphosate is not considered a carcinogen and has been classified by EPA as a Group E carcinogen (evidence of non-carcinogenicity for humans) (US-EPA, 1993).

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

A very small group of workers who are intensively exposed to canola, such as plant breeders, may be at risk of developing allergy to *B. napus* pollen (Fell *et al*., 1992) although allergy to *Brassica* pollen in the population is rare (Soutar *et al*., 1994).

2.5. Animal Feed

Canola meal is extensively used as a supplement in animal feed (Canola Council of Canada, 2011). Canola meal is traditionally flaked, cooked for 20 minutes at 80-90^{o}C, pressed and solvent extracted to remove the oil. The remaining de-solventized meal is toasted at 95-115^{o}C for 30 minutes. The meal is high in protein, for example, the minimum crude protein guarantee for Canadian canola meal is 36.0% (8.5% moisture basis), although the actual protein content usually is 36-39% (Canola Council of Canada, 2009b).

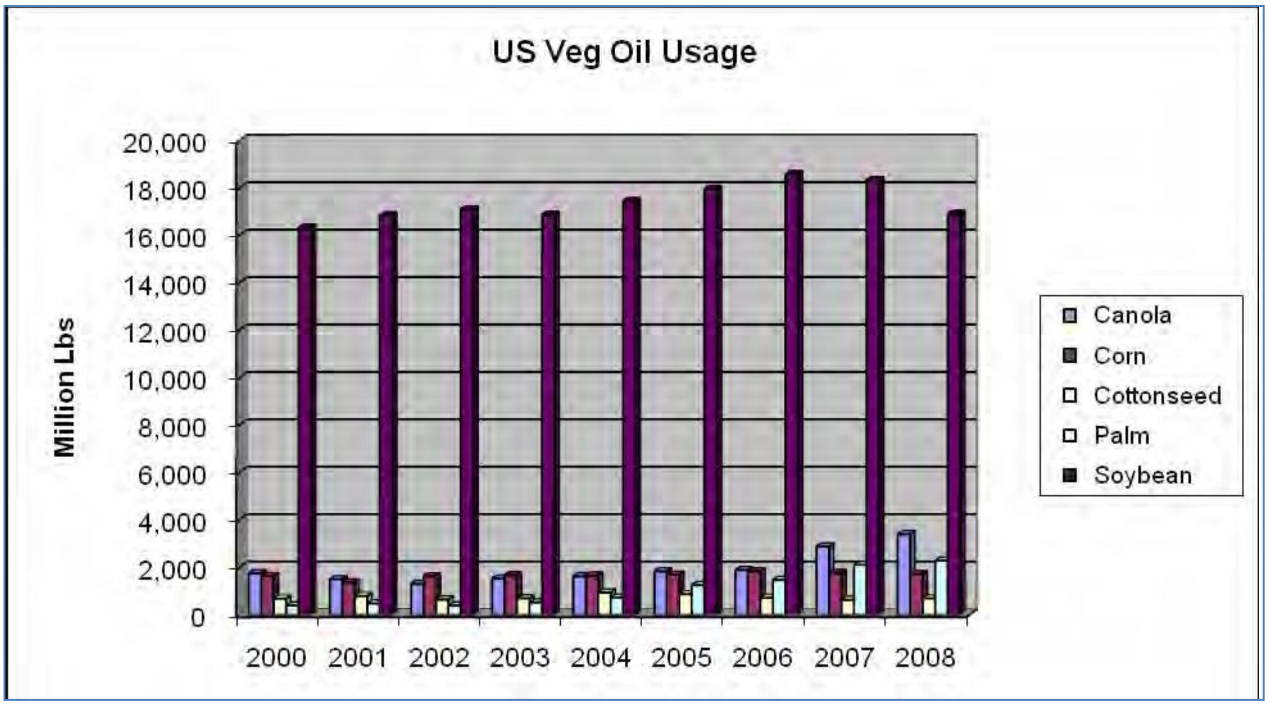
Feed, including meal, derived from 73496 must be in compliance with all applicable legal and regulatory requirements. Non-GE canola varieties do not require routine evaluation by any regulatory agency in the U.S. for feed safety prior to release in the market. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Any GE organisms for feed may undergo a voluntary consultation process with the FDA prior to release onto the market.

2.6. Socioeconomic

2.6A. Domestic Economic Environment

The U.S. imported an average of $184 million per year in canola seed in 2005-07 from Canada. Canada’s exports account for more than half of the canola meal, oil, and seed traded globally (USDA-ERS, 2010a). Of this, over 90% was destined for North Dakota, Minnesota and Montana. And of this, less than 10% was used for seeding purposes and the rest went to crush plants, primarily in North Dakota (Canola Council of Canada, 2009a). U.S. imports of Canadian canola oil are projected to increase in 2010-2011, making the U.S. Canada’s biggest consumer and importer of canola oil (Agricultural Commodity Prices, 2010). Imports of canola oil from Canada usually need further processing which creates jobs and economic growth for the U.S. The states that accrued the most economic benefit from processing canola crude oil in 2005-07 were Iowa, Louisiana, and Tennessee. Other states where canola crude oil is important are North Carolina, Minnesota, Illinois, and Washington (Canola Council of Canada, 2009a). Dairy farms in Washington, Idaho, Oregon, and California use 50% of the canola meal in the U.S. with two-thirds of it coming from Canadian imports (Canola Council of Canada, 2009a).

In 2009, domestic canola oil consumption was second to soybean oil consumption representing roughly 8% of all edible oils consumed and equal with corn oil consumption (SoyStats, 2010). Use of canola oil in the food market in the U.S. has been increasing. Canola oil is steadily increasing and may replace soybean oil usage in the food market, which is decreasing due to the trans fat issues associated with soybean oil (Figure 7). In regards to industrial uses, increasing prices for canola oil and a significant food use demand has resulted in little industrial or biodiesel demand for canola oil in the U.S. Biodiesel producers in the U.S. prefer soybean oil and tallow over canola oil due to lower cost and greater availability (USDA-ERS, 2010a). Approximately two-thirds of canola oil consumed in the U.S. is imported with approximately 2.3 billion pounds imported in 2009 and 2010. Canola oil imports have doubled over the past decade (USDA-ERS, 2011b).



Source: U.S. Canola Association, 2010

Figure 7. U.S. Vegetable Oil Use from 2000-2008

Canola meal imports are significant and account for approximately 70% of the canola meal consumed domestically. Approximately 1.8 million short tons of meal were imported annually in 2008 and 2009, with a high of nearly 2 million short tons imported in 2007 (USDA-ERS, 2011c). Canola meal is second to soybean meal as an animal feed source but its use is generally limited by location of oil processing facilities and by low feeding rates in livestock operations (USDA-ERS, 2010a).

Canola seed, like canola oil and meal, is also imported. Approximately 1.3 billion pounds were imported in 2010, with a high of 1.9 billion pounds in 2007. Imports of canola seed have increased substantially from approximately 0.5 billion pounds in 2000 (USDA-ERS, 2011d). Canadian canola seed exports are mostly used by the U.S. for crushing into raw crude oil, further refining raw crude oil, integrating into food products such as baked goods or margarine, and enhancing performance of livestock meal (Canola Council of Canada, 2009a). Importation of Canadian canola seed to U.S. seed crushing, processing, and refining facilities (Table 11) is especially beneficial to the U.S. economy, resulting in millions of dollars worth of revenue (Canola Council of Canada, 2009a).

Table 11. U.S. Canola Crushing and Processing Plants

Company Name and Location		Facility Type	
Name	**Location**	**Crusher/ Processor**	**Refiner**
Riceland Foods, Inc.	Stuttgart, AR	X	X
Adams Vegetable Oil Inc.	Arbuckle, CA	X	X
Liberty Vegetable Oil Co.	Santa Fe Springs, CA	X	X
Pokonobe Industries, Inc.	Santa Monica, CA	X	X
ADM	Decatur, IL	X	X
Nexcel Natural Ingredients	Springfield, IL	X	X
CHB Proteins, LLC	Presque Isle, ME	X	
ADM Northern Sun	Redwing, MN	X	
SunOpta Grains and Foods Group	Hope, MN	X	X
Montana Specialty Mills LLC	Great Falls, MT	X	X
Penta Manufacturing Company, Inc.	Livingston, NJ	X	X
ADM Processing	Velva, ND	X	X
ADM Northern Sun	Enderlin, ND	X	X
Producers Cooperative Oil Mill	Oklahoma City, OK	X	X
Omega Nutrition U.S.A. Inc.	Bellingham, WA	X	

Source: Soyatech, 2010

Biodiesel is another alternative use for canola oil. Over the last five years, consumer concern over the cost and environmental effects of fossil fuels has led to increased interest in biodiesel as a fossil fuel alternative (Brown *et al.*, 2008). The leading source of biodiesel is soybean oil, although canola and rapeseed oil are also currently used (Brown *et al.*, 2008; OSU, 2011). Rapeseed and canola oil are well suited to biodiesel production due to the lower saturated fat content of the oils (compared to soy oil) that prevents the oil from gelling at high temperatures (Anderson, 2008; Brown *et al.*, 2008). Additionally, rapeseed and canola oils have low saturated fat levels that improve cold weather performance. Pure canola biodiesel also contains 10 percent oxygen by weight. It is this oxygen that leads to a reduction in of “greenhouse” gases. Finally, canola seed has a high oil content (44% oil compared to 18% oil from soybean) which makes it an efficient biofuel source (Anderson, 2008).

In 2009, total biodiesel production in the U.S. was 545 million gallons with a producer capacity of 2.69 billion gallons. U.S. production of canola biodiesel in 2009 was 200 million gallons and capacity is expected to expand if the vegetable oil market and global economics are favorable (Brown *et al*., 2008).

2.6B. Trade Economic Environment

The U.S. imports canola oil, meal and seed from Canada, due to consumer demand for the products; the U.S. exports canola seed to Canada, mainly for processing at their large canola crushing facilities (Agricultural Commodity Prices, 2010; USDA-ERS, 2010a). Canada has a well-established regulatory system and has approved 11 GE Plants with Novel Traits HT canola varieties for commercial release as of August 2011 (CFIA, 2011). In 2010, 93% of the canola acres in Canada were planted to GE HT canola (Figure 3). In the U.S. seven petitions for genetically modified canola have been approved:

- Calgene’s laurate canola (altered fatty acid profile) in 1994 – unclear if commercial
- AgrEvo’s glufosinate-tolerant canola (event T45) in 1997 – not commercial
- Monsanto’s glyphosate-tolerant canola (event RT73) in 1998 – widely commercial
- AgrEvo’s glufosinate-tolerant and male sterile canola (events MS8 and RF3) in 1998 – widely commercial
- Aventis’s glufosinate-tolerant canola (event Topas 19/2) in 2001 – not commercial
- Aventis’s glufosinate-tolerant and male sterile canola (events MS1 & RF1/RF2) in 2001 – not commercial
- Monsanto’s glyphosate-tolerant canola (event RT200) in 2001 – not commercial

3. ALTERNATIVES

Table 12 briefly summarizes the results for each of the issues raised in the Environmental Consequences (Section 4) for the following alternatives:

- **Alternative A: No Action**—Continuation as a Regulated Article.
- **Alternative B: Preferred Alternative**—Determination that 73496 canola is no longer a Regulated Article.

Table 12. Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	**Alternative A: No Action** (Commercialization of Existing GE Canola)	**Alternative B: Determination of Nonregulated Status** (Commercialization of 73496 Canola and Existing GE Canola)
Meets Purpose and Need	**No**	**Yes**
Unlikely to Pose a Plant pest Risk	Satisfied through use of regulated field trials	Awaiting USDA-APHIS plant pest risk assessment
Agricultural Production		
Land use	Unchanged	Unchanged
General Production Practices	Unchanged	Unchanged
Pesticide use	Unchanged	Unchanged
Specialty Crop Production	Unchanged	Unchanged
Organic Production	Unchanged	Unchanged
Environment		
Soil Quality	Unchanged	Unchanged
Water resources	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Biological resources		
Animal Communities	Unchanged	Unchanged
Plant Communities	Unchanged	Unchanged
Biodiversity	Unchanged	Unchanged
Human Health		
Consumer health	Unchanged	Unchanged
Worker health	Unchanged	Unchanged
Animal Feed	Unchanged	Unchanged
Socioeconomic		
Domestic Economic	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Cumulative Effects	Unchanged	Unchanged
Other Regulatory Approvals	Unchanged for existing deregulated GE organisms	Completion of FDA consultation pending

4. ENVIRONMENTAL CONSEQUENCES

4.1. Agricultural Production

4.1A. Land use

The annual acreage planted to canola in the U.S. is highly variable, but appears to be increasing moderately (Table 2). However, canola still comprises a very small proportion of the overall U.S. crop acreage (Figure 2) and is predominantly grown in North Dakota which, in 2011, planted over 88% of the total U.S. canola crop (Table 1)

Land Use – No Action Alternative

Current trends in canola production will likely continue unchanged. The total production of canola in the U.S. continues to be mainly in North Dakota; unless demand for or profitability of canola products increases, no change in land use is predicted. Under the No Action alternative, land use, including areas where canola is grown, would not change because 73496 canola would still be a regulated article and would not be grown commercially.

Land Use – Petition Approved Alternative

Herbicide-tolerant canola has been planted in the U.S. since 1999, and by 2008, 95% of the crop was HT (Brookes and Barfoot, 2010). That percentage is likely nearer 99% today, based on Canadian planting patterns (Figure 3). More than half the acreage of HT canola in North Dakota was planted with glyphosate-tolerant varieties in 2006.

Herbicide-tolerant 73496 canola does not alter the growth habits of canola or confer any selective advantage to insect pests or diseases compared to currently available varieties. Although growers will have more choice among varieties of glyphosate-tolerant canola available in the marketplace, the percentage of the GE canola crop planted to glyphosate-tolerant varieties will likely remain the same. A determination of nonregulated status for 73496 canola would not significantly increase or decrease the annual acreage planted to canola or the geographic distribution of canola cultivation in the U.S.

4.1B. General Agronomic Practices

Cropping Practices. The economics of canola production drive grower choice in determining how the crop will be selected and produced. Growers make choices to plant certain varieties and use certain cropping practices, based on factors such as yield, weed and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury and ease and flexibility of the production system (Brown *et al*., 2008; Gianessi, 2005). Therefore, when taking these factors into account, growers will base their choice of cropping practices and inputs based on individual requirements. No changes in cultivation or management practices such as planting times, row spacing, irrigation, crop residue management, tillage or pesticide use are anticipated with the introduction of glyphosate-tolerant 73496 canola, which is comparable to other currently available canola types in phenotypic, agronomic, ecological, and compositional characteristics (see Petition Section VII). Pioneer's 73496 canola is an alternative product for currently available glyphosate-tolerant canola varieties, and because 73496 canola has similar agronomic characteristics to conventional canola and currently available GE HT varieties, no change in general production practices are anticipated.

Tillage. Conventional tillage and removal of plant residue from the soil are considered cropping practices that accentuate loss of soil organic carbon (Lal and Bruce, 1999). HT canola varieties allow growers to use direct-seed or no-till methods which conserve soil health and moisture and reduce soil erosion (Brown *et al*., 2008). In conservation tillage, glyphosate-tolerant canola allows the grower to plant without using a pre-plant incorporated herbicide, as a result reducing overall tillage. In recent years, the proportion of growers using no-till practices in Canada has been increasing significantly (Smyth *et al*., 2010) and a similar trend is likely among U.S. growers. The increase in the use of no-till or minimum-till may be correlated to the increased adoption of HT canola (Duke and Powles, 2009; Smyth *et al*., 2010). However, in some areas of the U.S., HT crops have seen an increase of conventional tillage due to the presence of glyphosate-resistant weeds (Dukes and Powles, 2009). In general glyphosate-resistant crops have reduced tillage from 80-35%, but in individual fields, tillage is useful in managing herbicide-tolerant weeds.

Crop Rotation. Canola is commonly grown in rotation with other crops. Crop rotation practices help with management of diseases, insects, weeds and soil moisture conservation and increase organic matter and soil fertility. Glyphosate-tolerant canola is typically rotated with wheat in a two-year rotation or wheat and soybeans in a three-year rotation. Glyphosate has no residual activity and therefore no re-cropping restrictions, so if producers choose to spray only glyphosate (and not other herbicides labeled for canola) on glyphosate-tolerant canola there will be no re-cropping restrictions.

Insecticide, Fungicide, and Fertilizer Use. Choice of control agents for control of insect and fungal pests and fertilizers necessary to improve soil nutrient status depends on individual grower circumstances, anticipated pest and disease pressure, and knowledge of the soils in a grower's fields. There are no special recommendations for insecticide, fungicide, or fertilizer use specifically with HT products that are currently in the marketplace.

Since canola is prone to shattering, volunteers are likely in the following crop. HT GE wheat is not commercially available, so other herbicides commonly used for weed control in wheat can be used to control glyphosate-tolerant canola volunteers in a two-year canola-wheat rotation. If glyphosate-tolerant canola is planted in a rotation with glyphosate-tolerant soybean as part of a three-year canola-wheat-soybean, growers must be careful to select appropriate crop/herbicide combinations so that canola volunteers can be effectively controlled.

General Weed Management. In selecting a weed management strategy, growers choose the most economical means to control weeds that do not decrease the quality or quantity of the crop. Young canola plants are very sensitive to early weed competition and effective weed control programs often include a combination of cultural, mechanical and chemical methods (Berglund *et al*., 2007). Ultimately, the weed management practice utilized by a grower will depend on the types of weeds in their field, the level of infestation, the cropping system, the type of soil, cost, weather, time, and labor. Glyphosate herbicide has many beneficial aspects for growers such as economic benefits, production efficiency and flexibility, enhanced weed control, and the facilitation of conservation tillage (Dill *et al*., 2008).

Glyphosate has proved effective against all of the economically important weeds in canola in the U.S. Glyphosate inhibits aromatic amino acid synthesis by inhibiting the EPSPS enzyme which is present in plants, fungi, and bacteria but absent in mammals. Glyphosate is particularly effective because most plants metabolically degrade it very slowly or not at all, and it translocates well to metabolically active tissues such as meristems (Cerdeira and Duke, 2006).

The excellent weed control afforded by glyphosate has driven grower adoption of glyphosate-tolerant canola. Canola growers that have used HT crops, together with other GE crops in their farming operations have seen a large increase in revenue – an additional $1.83 billion dollars from 1996 to 2008 (Brookes and Barfoot, 2010). Improved weed control in glyphosate-tolerant canola results in higher yields and crop quality. In some areas, this has led to quality price bonuses (*e.g*. HT soybeans and canola in Romania and Canada). Additionally, improved weed control results in lower residual soil herbicide residue as a result of less spraying in follow-up crops (Brookes and Barfoot, 2010).

Other benefits to producers who plant HT crops include increased management flexibility and convenience from use of broad spectrum, post emergence herbicides like glyphosate that can be applied within a longer application window than other herbicides. This is convenient for the producer, especially if bad weather interferes with timely spraying. By burning down weeds prior to planting, glyphosate facilitates reduced- and no-tillage systems that reduce soil erosion, conserves soil moisture, and cuts fuel and labor costs.

Furthermore, human safety concerns are lower due to less herbicide spraying and less environmental impact. Glyphosate has a positive environmental and safety profile (see Section 2.4 Human Health – Worker Health). Pioneer's 73496 canola would be available to growers wishing to decrease the use of more toxic chemicals, such as atrazine, and replace them with glyphosate, a more "environmentally friendly" herbicide, without compromising yield.

Glyphosate-Resistant Weeds. Over-reliance on a single chemical weed control product can lead to weed populations that are no longer susceptible. Glyphosate has been used in agriculture for the last 35 years with only a limited evolution of glyphosate-resistant weeds (Dukes and Powles, 2009). However, with the advent of glyphosate-tolerant soybean in 1966 and subsequently glyphosate-tolerant corn, glyphosate use has increased significantly and the chemical has been sprayed on some of fields on a yearly basis (sometimes twice per year). This has led to strong selection pressures for glyphosate-resistant weeds allowing for glyphosate-resistant weeds to out-compete other weeds (Duke and Powles, 2009). Thirteen North American weed species have now been confirmed as glyphosate-resistant (Figure 5).

No glyphosate-resistant weeds have been reported in canola fields in the U.S. (WSSA, 2011). This is probably because canola is generally grown in rotation with other crops (*e.g.,* oats, barley, wheat and flax). Glyphosate-tolerant varieties of these crops are not yet available. Therefore, the glyphosate selection intensity on weed species in cropping systems where canola is rotated with these small grain crops is much less than exists in glyphosate-tolerant soybean and glyphosate-tolerant corn cropping systems (Powles, 2008). It is unlikely that the planting of glyphosate-tolerant canola will result in the development of weed resistance if this diversity in cropping rotations is maintained. Crop rotations should continue to prevent diseases, insects, and weeds, and increases organic matter and soil fertility.

In order to minimize the development of herbicide resistant weeds, growers can adopt Integrated Weed Management (IWM) programs. IWM uses all available strategies to manage weed populations in an economically and environmentally sound manner; such strategies include cultural, mechanical, chemical and biological methods.

Specific recommendations include:

- Using alternative weed management practices, such as mechanical cultivation, delayed planting, and weed-free crop seeds.
- Cleaning equipment before leaving fields suspected to have resistant weeds to minimize the spread of weed seed.
- Scouting fields prior to the application of any herbicide to determine the species and the need for an herbicide application.
- Scouting fields after application to detect weed escapes or shifts and applying alternative control methods to avoid seed deposition in the field.
- When using herbicides, use full label rates and tank mix partners.
- Using mixtures or sequential treatments of the herbicides having a different mode of action.
- Limiting the number of applications of a single herbicide(s) with the same mode of action in a single growing season and in successive years.
- Rotating crops with an accompanying rotation of herbicides to avoid using herbicides with the same mode of action of the same field.
- Where practical, use cover crops and other methods to reduce weed seeds in the soil.

Technology developers are active in promoting awareness of herbicide resistant weeds and promoting resistance prevention and management (Jeschke, 2011). If growers use a diversity of weed control practices, evolution of weed resistance will likely slow down (Duke and Powles, 2009). There is evidence that in the absence of selective pressure, weeds may lose their resistance. In 2004, a study was conducted on the ecological impact of glyphosate on weed resistance; the research assessed the fitness costs and benefits of herbicide tolerance of glyphosate-resistant *Ipomoea purpurea* (tall morning glory) (Baucom and Mauricio, 2004). In an agricultural field in Georgia, 32 random *I. purpurea* plants which had been sprayed with Roundup for approximately 8 years were chosen for this evaluation. All seeds collected from each plant shared the maternal genetic contributions which were then used as the unit for the genetic analysis. Seeds from each of the 32 lines were self-pollinated for one generation; the seeds from the F2 generation were grouped according to each maternal line and planted in five spatial blocks to account for habitat heterogeneity. All plants were sprayed with amounts of Roundup previously shown to reduce biomass production by 90%. Results demonstrated that the tolerant line produced 35% fewer seeds in the absence of Roundup than the most susceptible lines. These results suggest that in the absence of herbicide selection (*e.g.,* spraying with Roundup, herbicide tolerance would be lost in subsequent generations due to higher metabolic costs to resistant weeds). Therefore, it is possible that weeds may lose their resistance trait if herbicide use is discontinued (Baucom and Mauricio, 2004).

Herbicide Use and Weed Resistance. Growers using genetically engineered crops have various options for weed control methods, including herbicides. The majority of canola fields are planted with glyphosate-tolerant canola and sprayed with glyphosate. Since the adoption of glyphosate-tolerant crops, several studies have shown that even though more glyphosate is being sprayed, overall there has been a reduction in total herbicides over time (Johnson *et al.,* 2007). Glyphosate is also less toxic and harmful to the environment than many other herbicides currently available. If growers decide that glyphosate-tolerant canola is not suitable for their fields, there are currently two other HT canola types available that use chemistries other than glyphosate (Table 7). In addition, there are other herbicides that could be used on genetically-engineered canola fields (Table 6). Overall, the use of glyphosate has reduced total herbicide use, but resistant weeds could occur require alternative weed management practices.

Multiple Herbicide-Tolerant Canola. Although corn varieties that contain two genetically modified herbicide-tolerance traits, brought together by traditional breeding, are currently found in the marketplace and in agricultural production (NCGA, 2011), multiple HT canola varieties have not been commercialized, at this time. The literature has suggested that multiple HT canola varieties might prove useful for some canola growers, providing flexibility in herbicide choice and an alternative volunteer and weed control regime through the application of sequential or mixed applications of herbicides with different modes of action (Green *et al*., 2008). The potential already exists to construct multiple HT canola stacks (*i.e*., combinations of approved HT varieties with glyphosate, glufosinate, and imidazolinone tolerance traits). Glufosinate tolerance may be a particularly useful trait for use in stacks since the herbicide controls a broad spectrum of weeds and there are no reports of glufosinate-resistant weeds (Green *et al*., 2008).

At present, there are no stacked herbicide canola products in the marketplace. Pioneer marketing research does not predict a market demand for these products (Figure 4) due to limitations for volunteer canola control. Pioneer has sold two different types of HT canola (GE glyphosate-tolerant canola and conventional imidazolinone-tolerant canola) in the U.S. since the late 1990's and has not combined these traits into a stacked-trait product.

In April 2011, Pioneer licensed the glufosinate-tolerance canola trait from Bayer CropScience, giving Pioneer the ability to offer growers glufosinate-tolerant (*i.e.,* InVigor) canola varieties. This will be especially beneficial in areas where growers desire to rotate glufosinate-tolerant canola with glyphosate-tolerant soybeans. In addition to the 73496 canola petition, there is currently one additional glyphosate-tolerant canola petition pending on the USDA-APHIS-BRS listing: http://www.aphis.usda.gov/biotechnology/not_reg.html.

General Agronomic Practices - No Action Alternative

Cropping Practice. The production of canola under the No Action Alternative will not change from the current cropping practices. Growers will continue to make choices on which canola variety and cropping practices are best for their needs.

Tillage. The trend toward increased use of conservation practices in soil tillage for canola cultivation will not be positively or negatively impacted under the No Action alternative, since growers have existing choices of HT varieties compatible with reduced tillage practices.

Crop Rotation. Under the No Action alternative, the type of crop rotation and the specific herbicide needs of the rotational crop will not be impacted as growers will continue to choose rotational crops based on product availability, market needs, and cultural practices. Alternative HT varieties with tolerance to glyphosate will still be available if 73496 canola is not deregulated and these varieties can be incorporated into current rotational practices.

Insecticide, Fungicide, and Fertilizer Use. Pioneer's 73496 canola is agronomically equivalent to conventional and other GE canola varieties currently on the market. The amount, type, and method of insecticide, fungicide, and fertilizer use will not be impacted by a No Action decision on 73496 canola.

General Weed Management. Effective weed management products and practices are available to U.S. canola growers (See Section 2.1 Agricultural Production of Canola – Weed management, Herbicide-Tolerant Canola and Pesticide Use). Glyphosate in combination with glyphosate-tolerant canola has proved an extremely effective and safe way to control weeds that threaten canola yields. Under the No Action alternative, 73496 canola would not be available to growers; however, they could continue to select glyphosate-tolerant varieties from those already on the market for effective and safe weed control. Weed management practices would be unaffected.

Glyphosate-Resistant Weeds. Glyphosate-resistant weeds are a concern for growers; however, if growers use diversity in weed control practices, evolution of weed resistance will likely slow down (Duke and Powles, 2009). As discussed above, diversity is incorporated into typical agricultural practices with canola which reduces the likelihood of developing weed resistance to glyphosate herbicide. Weed scientists, companies, and university scientists are also constantly working to design management strategies/practices to help control weeds and to develop alternative HT crops for growers (Purdue Weed Science, 2008; Service, 2007). Since glyphosate-tolerant varieties with similar agronomic properties to Pioneer's 73496 canola are already on the market, a decision not to act on the petition for nonregulated status of 73496 canola will have no impact on the use of glyphosate herbicide or change the rotational practices that may reduce the potential for herbicide-resistant weeds to develop.

Herbicide Use and Weed Resistance. Under the No Action alternative, 73496 canola would not be commercially available, and growers would continue to plant existing varieties of glyphosate-tolerant canola. Canola acreage and adoption of glyphosate-tolerant canola varieties have remained relatively stable over the last decade (Table 2 and Figure 3, respectively), and Pioneer marketing does not predict a significant increase in grower demand for glyphosate-tolerant canola in future years (Figure 4). Therefore, glyphosate use is not predicted to increase significantly if 73496 canola is not deregulated. With the potential increase in glyphosate-resistant weeds, there could be a modest increase in herbicides other than glyphosate if canola growers use alternative herbicides to control resistant weed populations.

Multiple Herbicide-Tolerant Canola. Under the No Action alternative, 73496 canola will not be available for use in commercial breeding programs and so there will be no potential for Pioneer to develop stacked canola products using 73496 canola. Because deregulated GE glyphosate-tolerant canola, deregulated GE glufosinate-tolerant canola and conventional imidazolinone -tolerant canola are all currently available as separate products in the U.S., the potential for companies to develop multiple HT canola products exists even if 73496 canola is not deregulated. However, as discussed previously, Pioneer does not predict a significant market for multiple HT canola.

General Canola Agronomic Practices - Petition Approved Alternative

Cropping Practice. Approval of 73496 canola will not change cropping practices as they are presently performed. Growers will have more market choices for glyphosate-tolerant varieties and can make the appropriate choices for their production needs.

Tillage. The trend toward conservation practices in soil tillage will not be impacted by a determination of nonregulated status for 73496 canola. The deregulation of this product will add to the existing choices of HT varieties compatible with reduced tillage practices.

Crop Rotation. Recommendations for specific glyphosate-tolerant products for a grower planting 73496 canola will take into account existing crop rotation practices with cereal crops, just as they do currently for conventional and other HT canola varieties, including those tolerant to glyphosate herbicide. The availability of 73496 canola will not significantly alter grower decisions regarding rotational practices.

Insecticide, Fungicide, and Fertilizer Use. Pioneer's 73496 is agronomically equivalent to conventional and other GE canola varieties currently on the market. The amount, type, and method of insecticide, fungicide and fertilizer use will not be impacted by a determination of nonregulated status for 73496 canola.

General Weed Management. Pioneer believes that there will be a small increase in demand for glyphosate-tolerant canola varieties at the expense of glufosinate-canola over the next 10 years (Figure 4) which will be accompanied by a proportional increase in glyphosate use. This projection is independent of a decision that 73496 canola is no longer a regulated article, but based on the assumption that growers will be able to purchase GE glyphosate-tolerant products similar to those already in the market. The introduction of 73496 canola may result in substitution of one glyphosate-tolerant variety for another, but there will be no overall increase solely due to the availability of this variety.

Glyphosate-Resistant Weeds. As discussed above, glyphosate-resistant weeds have been reported in fields with crops other than canola. Typical crop management practices reduce the potential for development of herbicide-resistant weeds in canola crops, including currently available glyphosate-tolerant varieties. Furthermore, over the past decade, the volume of all herbicides applied to glyphosate-tolerant canola has been shown to be less than that applied to conventional canola (Brookes and Barfoot, 2010). Cumulatively since 1999, the amount of herbicidal active ingredient use has fallen by 39% and the Environmental Impact Quotient load has been reduced by 48% by the adoption of herbicide-tolerant canola (Brookes and Barfoot, 2010). Moreover, glyphosate use is restricted to no more than two applications from emergence to bolting on HT canola (Berglund *et al.*, 2007) and no changes to the glyphosate label are expected. Since 73496 canola is a market alternative to existing glyphosate-tolerant canola varieties, and the introduction of Pioneer's 73496 canola would not change cropping practices or rates or frequency of glyphosate applications, the potential for the development of glyphosate-resistant weeds will not be significantly increased by a determination of nonregulated status for 73496 canola.

Herbicide Use and Weed Resistance. Because 73496 canola is a market alternative to existing glyphosate-tolerant canola varieties, and because the seasonal use rate of glyphosate on 73496 canola will be identical to existing glyphosate-tolerant canola varieties on the market, commercialization of 73496 canola is not expected to change the amount of glyphosate herbicide used on canola. With the potential increase in glyphosate-resistant weeds, there could be a modest increase in herbicides other than glyphosate if canola growers use alternative herbicides to control resistant weed populations. However, this potential increase in the use of alternative herbicides would happen whether or not 73496 canola is deregulated. Overall, no significant change in the amount of type of herbicides used on canola is anticipated as a result of a determination of Non-regulated status for 73496 canola.

Multiple Herbicide-Tolerant Canola. Under the Petition Approved alternative, Pioneer would have the option to use 73496 canola as part of a stacked trait, multiple HT canola variety. However, since glyphosate-tolerant and glufosinate-tolerant events are already deregulated and commercially available in the U.S. (in addition to conventional, imidazolinone-tolerant canola), multiple HT canola could be developed whether 73496 canola is deregulated or not. Importantly, market research shows that there is little commercial potential for a multiple HT canola product (Figure 5). The outcome of a Petition Approved alternative is not significantly different from a No Action alternative with respect to development of multiple HT canola.

4.1C. Specialty Canola Production

Specialty crop acreage of products such as High-Oleic, HEAR rapeseed, crambe, and mustard in the U.S. are very small compared to commodity canola acreage. These markets rely on established identity preservation practices to maintain the purity of the crop and processed fractions as demanded by end-users, such as food processors (see 2.1 Agricultural Production of Canola - Specialty Canola Production).

Specialty Canola Production – No Action Alternative

Methods available to growers of specialty canola crops to maintain identity preservation and thus derive a premium price for their crop would not be impacted by the availability of 73496 canola.

Specialty Canola Production – Approve Petition Alternative

Practices in place today should not change due to the introduction of 73496 canola as it poses no more of a co-existence issue than the glyphosate-tolerant canola that is currently on the market.

4.1D. Organic Canola Production

Organic grains are considered a specialty crop and receive a higher price premium. Typically, growers use more than one method under organic practices to prevent unwanted material from entering their fields including isolation of the farm, physical barriers or buffer zones between organic production and non-organic production, and formal communications between neighboring farms (NCAT, 2003). U.S. organic standards are process based and no threshold values have been established for the presence of genetically modified materials in certified organic food products However, certain foreign markets impose thresholds, making it difficult for U.S. organic producers to sell their products at premium prices (NASDA, 2006).

The plan used as the basis for organic certification should include a description of practices used to prevent or reduce the likelihood of unwanted substances, like genetically modified pollen or seed, at each step in the farming operation such as planting, harvesting, storing and transporting the crop (Krueger, 2007; Kuepper *et al.*, 2007; Riddle, 2004). Organic plans should also include how the risk of pollen or comingling of seed from genetically modified crops will be monitored (Kuepper *et al.*, 2007). Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the organic farmer reduce contamination events (Krueger, 2007; NCAT, 2003). Organic canola farmers who protect their crop in this manner will greatly reduce the likelihood of accidental gene flow between genetically modified canola and non-GE canola fields, and will maximize their profits and price premiums from canola under organic production.

In the end, trace amounts of foreign substances (including adventitious presence of genetically modified seeds) do not detract from the organic nature of a product, although it may prevent marketability of the product. This is the position of regulatory authorities in Canada and the U.S. with respect to organic products because there is no decertification threshold for genetically modified content in any organic crop (Wager, 2010).

Adoption of organic farming is low with approximately 0.7% of all U.S. cropland under organic production practices (USDA-ERS, 2010c). Farmers take a substantial monetary risk when implementing organic production practices. Other factors that contribute to low conversions to organic farmland include: (1) high managerial costs and risks of shifting to a new way of farming, (2) lack of knowledge of organic farming systems, (3) deficient marketing and infrastructure, and (4) failure to capture marketing economies. However, U.S. producers are still adopting organic farming in order to reduce input costs, conserve nonrenewable resources, capture high-value markets and improve farm income (USDA-ERS, 2010c).

The organic agriculture sector has continued to grow and prosper along with the biotech sector. Organic production has more than doubled since the 1990s and is now well established in the marketplace. Growth of organic products remains around 20% since the 1990s; however, the expectation is that it will moderate over the next decade (Johnson, 2008). In 2010, organic sales reached $26.7 billion, a 7.7% increase over 2009 sales (OTA, 2011). The total product share for organic sales remains small, however, with food share at only 4% (NBJ, 2011).

The value of U.S. canola production in 2008-2009 was $270 million (USDA-ERS, 2010a). Of that, organic canola production (including "other oilseed" crops) accounted for approximately 3% or $8 million in 2008. There could be several reasons why organic canola production is low and has not kept up with the increase in organic food sales. Organic canola has a limited market compared to other oilseeds. Organic canola is difficult to produce due to limited weed, insect, and disease control methods while the crop's high nitrogen demand limits yield if fertility levels are not optimal (Brookes, 2004; Brookes and Barfoot, 2004). Finally, due to the cost of transporting harvested seed, producers may only grow organic canola if organic crushing facilities are nearby.

Organic Canola Production – No Action Alternative

Under the No-Action alternative, commercial production of conventional and organic canola will not change.

Organic Canola Production – Approve the Petition Alternative

Under the Approve Petition alternative, commercial production of conventional and organic canola will not change as a result of the market introduction of 73496 canola. A large proportion of the canola planted in the U.S. is GE and growers of organic non-GE continue to produce crops that meet NOP standards. Since 73496 canola will replace existing glyphosate-tolerant varieties, its introduction will not have positive or negative effects on organic canola production.

4.2. Physical Environment

4.2A. Soil Quality

The soil environment in and around crop fields is complex and rich in microorganisms and arthropods. Plants can have direct or indirect chemical, physical and biological effects on the soil. Bacteria typically represent the most abundant microbes in the soil followed by fungi. Microbes play an important and particular role in the nutrient cycling capacity of the soil (Hoorman and Islam, 2010). Specific crop management practices used for canola, such as pesticide applications, tillage, and application of inorganic and organic fertilizers can alter soils and the microbial and arthropod populations associated with it.

Soil Quality – No Action Alternative

Cultivation practices for canola would not be affected by a No Action decision for 73496 canola.

Soil Quality – Approve Petition Alternative

Pioneer's 73496 canola is intended as a market alternative to glyphosate-tolerant canola currently available. The agronomic performance of 73496 canola is not different from conventional canola, and crop management practices are not likely to be different from current canola crop management practices.

After harvest, residue of 73496 canola will remain at the site of cultivation. These crop residues will likely contain very small amounts the novel protein GAT4621, although protein expression in whole plants has not been measured at senescence. Small amounts of 73496 canola seed may also remain at the site of cultivation and the presence of GAT4621 protein has been confirmed in seed at a level of 6.2 ± 0.94 ng/mg dry weight (Weber, 2011). The GAT protein was developed by a DNA shuffling process using three native *gat* genes from *Bacillus licheniformis* as parental templates (Castle *et al*., 2004). *Bacillus licheniformis* is a common saprophytic bacterium that is widespread in nature, especially in soils. It has been used in the fermentation industry for production of proteases, amylases, antibiotics, and specialty chemicals for over a decade with no known reports of adverse effects to human health or the environment (US-EPA, 1997). Hence, enzymes closely related to the GAT4621 protein are already present in soils. Moreover, the GAT4621 protein will be susceptible to degradation and adsorption to humus or minerals as are other proteins in agricultural soils. Soils contain numerous organisms and enzymatic activity from decomposed organisms that degrade a wide array of molecules including proteins (Bastida *et al*., 2009). These processes would metabolize or sequester the GAT4621 protein with no likely effect on the soil. Therefore there should be no unique impacts on soil resulting from a determination of nonregulated status for 73496 canola.

4.2B. Water Resources

Canola water use is in the range of most grain crops, consuming up to 20" of water during a growing season and using as much as 0.3" per day during peak periods (Bauder, 2005). As discussed previously, canola is not typically irrigated. Water quality concerns from canola cultivation would most likely be from agricultural non-point source pollution (*e.g*., fertilizers, herbicides, insecticides, and salt from irrigation practices), the primary source of discharge pollutants to above- and below-ground bodies of water (US-EPA, 2010). Crop type, tillage practices and application of fertilizers and pesticides influence the frequency and amount of non-point source pollution. Discharge pollutants can occur in the form of direct chemical contaminants or physical particulates. These can indirectly contribute to higher water turbidity, increased algal blooms and decreased oxygen content in a body of water (US-EPA, 2005).

Water Resources – No Action Alternative

Irrigation of canola is not typically practiced; in 2007, just 1% of U.S. canola was irrigated (USDA-NASS, 2009). Due to the limited practice of irrigation on canola crops, the No Action alternative for 73496 canola should not have any impact on agricultural irrigation practices in the U.S.

Water Resources – Approve Petition Alternative

Cropping practices associated with canola production, including tillage, fertilizer and pesticide application, are not likely to be different between 73496 canola and conventional canola or existing glyphosate-tolerant canola. The agronomic performance of 73496 canola is not different from conventional canola or existing glyphosate-tolerant canola and is therefore not likely to impact water resources differently from cultivation practices employed with canola varieties on the market today.

4.2C. Air Quality

Air quality may be affected by a variety of agricultural-related activities, including smoke from agricultural burning, tillage, traffic and harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizers (Aneja *et al.*, 2009; Hoeft *et al.*, 2000). These agricultural activities individually have potentially adverse environmental impacts on air quality. Tillage contributes to the release of GHGs because of the loss of CO2 to the atmosphere and the exposure and oxidation of soil organic matter (Baker *et al.*, 2005). Emissions released from agricultural equipment (*e.g.*, irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA, 2011). Nitrous oxide may also be released following the use of nitrogen fertilizer. Aerial application of pesticides may cause impacts from drift and diffusion. Pesticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel *et al.*, 2008).

Air Quality – No Action Alternative

Cultivation practices for commercial canola production would not change under the No Action alternative for 73496 canola. Air quality would still be affected by agricultural practices associated with production of commercial canola crops such as tillage, pesticide application, and the use of agricultural equipment.

Air Quality – Approve Petition Alternative

Cropping practices associated with canola production including tillage, fertilizer, and pesticide application are not likely to be different between 73496 canola and conventional canola. The agronomic performance of 73496 canola is not different from conventional canola and is therefore not likely to impact air quality differently from cultivation practices employed with canola varieties on the market today.

4.2D. Climate Change

Production of agricultural commodities is one of the many human activities that could possibly increase GHGs that affect climate (see discussion in Affected Area, Physical Environment). Carbon dioxide (CO_2), nitrogen dioxide (NO_2), and methane (CH_4) may be produced through the combustion of fossil fuels to run farm equipment, the use of fertilizers, or the decomposition of agricultural waste products including crop residues and animal wastes. Classes of crops planted are relevant to climate change, as are the locations and the soil types in which they are planted. Climate change itself may force changes to agricultural practices by extending the ranges of weeds and pests of agriculture (IPCC, 2007). Indirect effects of new crops will be determined by the traits engineered into organisms and the management strategies used in the production of these organisms.

Climate Change – No Action Alternative

Under the No Action Alternative, environmental releases of 74396 canola would remain under APHIS regulation. There would be no measurable effect from these confined environmental releases. Cultivation practices associated with commercial canola production, such as tillage, pesticide application and use of agricultural equipment, would not be affected.

Climate Change – Approve Petition Alternative

Production of 73496 canola does not change cultivation practices for canola. A determination of nonregulated status of 73496 canola will not change the use of tillage, use of agriculture equipment, irrigation, pesticide applications and fertilizer applications in commercial canola production and no impact on climate change is anticipated

4.3. Biological Resources

4.3A. Animal Communities

Canola production systems in agriculture are host to many animal species. Mammals and birds may seasonally use grain, and invertebrates can feed on the plant during the entire growing season.

One of the safety considerations for genetically engineered crops is their potential effect on these organisms, including beneficial organisms such as honey bees that are the primary pollinators of canola (Hayter and Cresswell, 2003), as well as threatened or endangered species. Effects can be due to toxicity or allergenicity of novel proteins or altered expression of plant produced toxicants and anti-nutrients or the formation of novel toxins as a desired or unintended consequence of the genetic modification. Additionally, the effects of changes in agricultural practices, such as increased application of chemicals registered for use with the new crop, should be considered.

The toxic potential of genetically engineered crops is typically evaluated by examining the amino acid sequence homology of novel proteins to known toxins and, where appropriate, feeding of whole grains, oilseeds, or other appropriate plant fractions to animals.

Indirect effects on plant and animal biodiversity are related to, but not directly associated with, the expression of the HT trait (*i.e.*, shifts in weed communities and decreased weed abundance and diversity as a result of glyphosate application). The potential indirect effects associated with HT crops on non-target organism biodiversity have been assessed previously in the large-scale Farm Scale Evaluations (FSE) (Brooks *et al.*, 2003; Champion *et al*., 2003; Haughton *et al.*, 2003; Hawes *et al.*, 2003; Heard *et al*., 2003a; Heard *et al*., 2003b). The goal of the FSEs were to compare the non-target organism community structure between glufosinate-ammonium tolerant and conventional canola as well as maize and beet crops in an effort to determine if weed management strategies in HT crops would indirectly affect arthropod assemblages (Firbank *et al.*, 2003). Glyphosate and glufosinate-ammonium are both broad-spectrum herbicides that are used similarly for weed control, and the weed management strategy employed for glyphosate and glufosinate-ammonium tolerant canola would be similar. Numerous endpoints, including soil invertebrate (Brooks *et al.*, 2003), aerial and epigeal arthropod (Haughton *et al.*, 2003), and invertebrate abundance and diversity were assessed in the FSE fields (Hawes *et al.*, 2003). Despite the fact that the results generated from the FSE project compared glufosinate ammonium-tolerant canola to conventional canola, the results of this study provide good insight about the potential indirect effects that cultivation of canola modified to be tolerant to a broad-spectrum herbicide could have on non-target organisms biodiversity.

Results from the FSE showed that glufosinate ammonium-tolerant canola received significantly less herbicide application and significantly less number of active ingredients than conventional canola (*i.e.*, conventional canola received propaquizafop and fluazifop-P-butyl, metazachlor, quinmerac, benazolin, and clopyralid, whereas the glufosinate ammonium-tolerant canola received Liberty (also known as Ignite), predominantly; Champion *et al*., 2003). This study also concluded that weed biomass was decreased in glufosinate ammonium-tolerant canola compared to conventional canola (Hawes *et al*., 2003; Heard *et al*., 2003a; Heard *et al*., 2003a). The decrease in weed biomass was observed to have some effects on non-target organism abundance; however, many of the effects appeared transient and dependent on the crop, sampling time, and species. For instance, there were no differences in the seasonal abundance of total pollinators and the total abundance of butterflies were significantly decreased in the glufosinate ammonium-tolerant canola, relative to conventional canola, which the authors attributed to a decrease in flowering weed abundance (Haughton *et al.*, 2003).

The long-term impacts of glyphosate-tolerant canola on non-target organism communities are likely to be indirect and highly dependent on weed abundance. It has been shown that weed community abundance is decreased in glyphosate-tolerant canola, which may subsequently lead to adverse effects on herbivores, pollinators and higher trophic groups (ACRE, 2004). However, the magnitude of these effects must be taken into context in terms of environmental significance and relevance:

1. Modern agricultural practices, including tillage (Cerdeira and Duke, 2006), chemical herbicide application and crop rotation (Ball and Miller, 1993) are all known to affect weed communities (Albajes *et al.*, 2009) and impact the environment. Tillage, for example, can lead to a reduction in topsoil, can consume large inputs of fossil fuel energy (Ammann, 2005; Dewar, 2009), can have drastic effects on weed community dynamics (Owen, 2008), and can negatively impact soil dwelling invertebrates and predatory carabid populations (Bigler and Albajes, 2011). Cultivation of HT crops may result in reduced tillage (Ammann, 2005; Dill *et al.*, 2008), which is correlated with many environmental benefits, for example, reduced soil loss due to water and wind erosion, improved soil carbon sequestration, increased moisture conservation, reduced soil compaction, reduced fuel consumption, and enhanced biological activity in the topsoil (Bennett *et al*. 2004; Holland, 2004; Lal *et al*., 2007; Montgomery, 2007).

2. All weed management strategies, including those used in concert with HT crops, are applied to decrease weed biomass and increase crop yield.
3. The shifts in weed communities and subsequent shifts in invertebrate assemblages that may occur due to indirect effects associated with glyphosate-tolerant canola are small relative to the effects that are observed when a new crop is planted in place of canola (Smith *et al*., 2008).
4. Glyphosate application for weed control in glyphosate-tolerant canola does not correlate with increased risk to the agroecosystem, above that of the other broad-spectrum herbicide treatments or weed management strategies that are currently used by canola growers (Bennett *et al*., 2004; Brimner *et al*., 2005; Holland 2004; Kleter *et al*., 2007; Montgomery, 2007).
5. Glyphosate-tolerant canola has been shown to have significantly decreased herbicide application, relative to conventional canola (Brimner *et al*., 2005).
6. Finally, glyphosate-tolerant canola will be grown in a similar manner to conventional canola and therefore, the basic management techniques associated with weed control in glyphosate-tolerant canola remains unchanged (*i.e.*, application of a broad-spectrum herbicide). The use of glyphosate should not be considered as a novel agronomic or management technique specific to glyphosate-tolerant canola, but merely a flexible herbicide option for weed control.

Overall, the benefits of glyphosate-tolerant canola include reduced tillage and reduced application of herbicides with a less favorable environmental profile. A few individual growers may be using more herbicides if they are managing fields with glyphosate-resistant weeds, but there is no expectation herbicide use will return to previous levels. As with all modern weed management practices, glyphosate application in glyphosate-tolerant canola is intended to reduce weed biomass, which in turn may be correlated with indirect effects on arthropod communities. Nevertheless, these indirect effects are common to all weed management strategies that effectively reduce weeds, and the biological relevance of potential impacts on non-target organism populations due to weed control in agroecosystems needs to be taken in this context. Furthermore, large-scale population level impacts from glyphosate-tolerant canola are unlikely to be increased compared to other modern agricultural practices.

Animal Communities – No Action Alternative

Threatened or endangered species are generally found outside of agricultural fields. As previously stated, North Dakota is where the more than 80% of the canola is planted in the U.S. and according to the U.S. Fish and Wildlife Service there are seven animals listed as threatened or endangered: whooping crane (*Grus americana*), black footed ferret (*Mustela nigripes*), pipping plover (*Charadrius melodus*), pallid sturgeon (*Scaphirhynchus albus*), tern (*Sterna antillarum*), American burying beetle (*Nicrophorus americanus*), and the gray wolf (*Canis lupus*) (US-FWS, 2011). None of these animals listed above are known to live or forage in agricultural fields. Habitat disruption within fields will be unaffected by a No Action decision. Any environmental releases of 73496 canola will be as small confined field trials under APHIS regulation and would have no significant effect on animal communities.

Animal Communities – Approve Petition Alternative

The native GAT protein produced by *Bacillus licheniformis* is already present in the environment. The novel GAT4621 protein is not a potential food allergen (see Section 4.4 Human Health). Based on lack of homology to known toxins, tests conducted in rodents (mouse acute study) (see Petition, Appendix 11) and poultry (42-day broiler study submitted to USDA in support of the petition for nonregulated status for maize event DP-Ø9184Ø-6), GAT4621 is not toxic to either mammals or birds. A New Protein Consultation for the GAT4621 protein was submitted to FDA on January 31, 2007 and completed on October 7, 2009.

The composition of 73496 canola seed is nutritionally comparable to commercially available canola. Concentrations of two acetylated amino acids, N-acetyl aspartate and N-acetyl glutamate, were slightly elevated. These two analytes are natural compounds commonly found in meats, eggs, and seeds such as corn and soybeans (see Petition, Appendix 8) and would not be expected to impact any organism that might feed on 73496 canola.

There is no direct information on the toxicity of 74396 canola pollen for honeybees. However, since honeybees are the main pollinators of canola (Hayter and Cresswell, 2003), and seed yields were similar between 73496 canola and equivalent non-genetically modified plants, it can be inferred that 73496 canola has no significant impact on honeybees or honeybee pollination success. The potential for allergenicity of 73496 canola was evaluated by examining the allergenic potential of canola as a crop and by assessing the allergenic potential of the GAT4621 protein (see Section 4.4 Human Health).

Observations of the responses of 73496 canola to naturally occurring insect and disease stressors during U.S. and Canadian field trials showed no unexpected differences from control (see Petition ,Section VII-C). These results support the conclusion that 73496 canola will have no significant positive or negative impacts on insects and disease responses relative to conventional canola.

Pioneer concludes that 73496 canola is safe for animal consumption and will not adversely affect organisms that might consume seeds or other parts of the plant. If deregulated, 73496 canola is expected to replace some of the acres currently planted to glyphosate-tolerant varieties, but is not expected to cause new canola acres to be planted in areas that are not already in agricultural use. The presence of 73496 canola in the marketplace will not result in altered or increased application of pesticides or glyphosate (because 73496 canola will have the same glyphosate seasonal use rate as current glyphosate-tolerant canola); therefore, no significant impacts on animal communities are anticipated.

4.3B. Plant Communities

Canola production acreage is host to many plant species, including a number that are regarded as weeds. The landscape surrounding a canola field varies depending on the region. In certain areas, canola fields may be bordered by other canola or any other crop. Fields may also be surrounded by wooded or pasture/grassland areas. Therefore, the types of vegetation, including weeds, around a canola field depend on the area where the canola is planted. A variety of weeds dwell in and around canola fields; those species will also vary depending on the geographic region where canola is planted. Weeds common in the major canola growing area of the U.S. are listed in Table 4.

HT canola is no more likely to form feral populations than unmodified canola, nor is it more likely to be more invasive or competitive or persistent in habitats where the target herbicide is not applied (Andersson and de Vicente, 2010; Warwick *et al*., 2009). Field studies in which both conventional and transgenic glufosinate-tolerant canola varieties were repeatedly introduced into 12 different habitats in the U.K. between 1990 and 1992, followed by monitoring over a period of up to ten years, failed to find any evidence that canola is invasive of natural habitats or that transgenic HT canola is more invasive of, or more persistent in, disturbed habitats than unmodified canola (Crawley *et al*., 2001). As reported by Hall *et al*., (2005), grower survey data from western Canada, where transgenic HT canola has been grown extensively over many years, did not indicate any evidence of altered weediness or invasiveness potential.

Control of volunteer canola plants can be accomplished with appropriate herbicides, taking into account the tolerance of the current crop and any tolerance of the previously planted canola variety. Failure to adequately control volunteers can lead to stacking of multiple herbicide-tolerance traits through cross pollinations, as has been observed in canola volunteers (Beckie *et al*., 2004; Hall *et al*., 2000). However, multiple HT does not significantly alter plant fitness in the absence of herbicide pressure (Simard *et al*., 2005).

Based on the lack of any alterations in survival and reproductive biology characteristics of currently commercialized transgenic HT canola, Devos *et al.*, (2011) concluded that the likelihood of unintended environmental effects due to the establishment and spread of such plants will be no different than from conventional unmodified canola. The ability of transgenic HT canola to successfully establish feral populations in disturbed habitats is limited by the availability of competition-free seed germination sites, just as for unmodified non-HT canola.

Plant Communities – No Action Alternative

Under the No Action alternative, any environmental releases of 73496 canola will be as small confined field trials under APHIS regulation and would have no significant effect on plant communities.

Plant Communities – Approve Petition Alternative

Under the Approve Petition alternative, 73496 canola is expected to replace some of the acres currently planted to glyphosate-tolerant varieties, but is not expected to cause new canola acres to be planted in areas that are not already in agricultural use. Neither will the presence of 73496 canola in the marketplace result in altered or increased application of glyphosate or other pesticides, therefore, no significant impacts on plant communities are anticipated.

The comparison of phenotypic characteristics between 73496 and non-transgenic canola demonstrated an absence of any biologically meaningful differences with respect to early population, vegetative growth, reproductive parameters, yield and ecological interactions. The

73496 canola does not have an increased weediness potential and unconfined cultivation should not lead to increased weediness.

In unmanaged environments, HT crops have no advantage over non-HT crops since no herbicide is applied. Based on this characterization, 73496 canola is no more likely to establish feral populations than either existing transgenic HT canola varieties or unmodified non-HT canola, and these populations would not be more likely to be persistent or invasive. If it were to establish in a feral population and needed to be removed, alternative weed control practices could be used.

Volunteers of 73496 canola have the same potential to become multiple HT (stacked) through crosses with previously deregulated HT canola events and to establish feral populations. Multiple HT volunteers can still be controlled by application of herbicides with different modes of action (See Tables 6 and 7), or through rotation and/or tillage practices.

4.3C. Microorganisms

Microorganisms produce aromatic amino acids through the Shikimate pathway, similar to plants (USDA-FS, 2003). Because glyphosate inhibits this pathway, it could be expected that glyphosate would be toxic to microorganisms. However, field studies show that glyphosate has little effect on soil microorganisms, and, in some cases, field studies have shown an increase in microbial activity due to the presence of glyphosate (USDA-FS, 2003).

Glyphosate use has been identified as potentially causing increases in certain disease-causing microbes (Fernandez *et al*., 2009). Reported increases in infections from pathogenic soil fungi have been determined to be more closely related to reduced tillage and continuous cropping using HT crops, rather than application of glyphosate (Fernandez *et al*., 2009).

Microorganisms – No Action Alternative

Under the No Action Alternative there would be no change to current agricultural production. The majority of canola grown is glyphoate tolerant. Therefore, microorganisms located in glyphosate-tolerant canola fields would continue to be exposed to glyphosate.

Microorganisms – Approve Petition Alternative

Bioinformatic analyses demonstrated that the GAT4621 protein retains the characteristics found in other N-acetyltransferases that are ubiquitous in plants and microorganisms (Neuwald and Landsman, 1997). GAT4621 contains the conserved domains of the GNAT acetyltransferase family. This superfamily of proteins is present in all organisms, including plants, mammals, fungi, algae, and bacteria (Dyda *et al*., 2000). Because members of the GAT protein family are already widespread in the environment, the GAT4621 protein in 73496 canola is unlikely to have any potential additional or adverse effects on microorganisms found in canola fields.

4.3D. Biodiversity

The diversity, or the variation in species or life forms, is highly managed in agricultural systems. In conventional agriculture, farmers want to encourage high yields from their canola crop, and will intensively manage the ‘plant communities,’ or weeds, found in the crop through chemical, cultural, or mechanical means. Animal pests, particularly insect and other pest species, will also be managed through chemical and cultural controls to protect the crop from damage. Therefore, the biological diversity in agricultural systems (the agro-ecosystem) is highly managed and may be lower than in the surrounding habitats. It must not be forgotten that the purpose of an intensively managed agriculture field is to sustainably deliver food or feed while maintaining the appropriate abiotic and biotic conditions (*i.e.*, soil and water quality, pollinators and natural enemy populations). The primary aim of an agricultural field is not so much to promote biodiversity, which is better delivered via a natural ecosystem, but neither is it to negatively impact upon it.

Canola is sexually compatible with any other *Brassica* species found in the U.S. Gene flow potential from cultivated *B. napus* to other Brassica crops and to wild *Brassica* species is thoroughly discussed in the Petition (see Section IX).

If glyphosate-tolerant individuals arise through interspecific or intergeneric hybridization, the tolerance will not confer any competitive advantage to these plants unless selected by glyphosate herbicide. This would only occur in managed ecosystems where glyphosate-containing herbicides are applied for broad-spectrum weed control, or in plant varieties developed to exhibit glyphosate tolerance and in which glyphosate is used to control weeds. As with glyphosate-tolerant canola volunteers, these individuals, should they arise, would be controlled using other available chemical or mechanical means. Furthermore, there are cropping methods can help reduce the likelihood of cross-pollination in non-GE fields. These methods generally aim at reducing gene flow by increasing the time span between successive canola plantings, isolating fields of IP canola, and introducing isolation distances, modified tillage, and sowing and harvesting at a modified time schedule using other varieties (Graef, 2007).

Intraspecific gene flow resulting in stacking of HT traits of in canola volunteers can occur and volunteer crops are not confined to agricultural fields (Knispel *et al.*, 2008). The extent to which feral canola populations have stacked HT traits is not known; however, research in Canada and the U.S. has found the presence of stacked HT traits in feral population in areas around agricultural fields and around roadsides (Table 10). To date, there is no knowledge of stacked traits causing advantageous qualities for increased gene flow or persistence in the wild.

There are also no compelling data to suggest that the presence of a herbicide-tolerance trait in a wild or weedy relative, as a consequence of pollen-mediated gene flow from transgenic HT *B. napus*, is inherently risky (Warwick *et al.*, 2008).

Biodiversity – No Action Alternative

Under the No Action alternative, any environmental releases of 73496 canola will be as small confined field trials under APHIS regulation and would have no significant effect on biodiversity. Animal and plant species that typically inhabit commercial canola production systems will continue to be affected by the crop management practices, including the use of mechanical, cultural, and chemical control methods, whether they plant existing GE HT or conventional canola products.

Biodiversity – Approve Petition Alternative

The 73496 canola requires the same agronomic practices as HT canola already in the marketplace. Animal and plant species that typically inhabit canola production environments will be managed in the same way as other GE HT canola and conventional canola.

The novel GAT4621 protein expressed in 73496 canola is closely related to GAT proteins occurring naturally in the common soil bacterium *B. licheniformis*. The GAT4621 protein does not exhibit pest resistance qualities and is not a toxin or an allergen. Observations of the responses of 73496 canola to naturally occurring insect and disease stressors during U.S. and Canadian field trials showed no unexpected differences from control (see Petition ,Section VII-C). These results support the conclusion that 73496 canola will have no significant positive or negative impacts on insect and disease responses relative to conventional canola.

The assessment of the ecological data detected no biologically significant differences between 73496 canola and control canola lines indicative of a selective advantage that would result in increased weed potential or capacity to invade natural ecosystems and impact biodiversity.

Unconfined cultivation should not lead to increased weediness of other sexually compatible relatives, as HT varieties generally do not have a selective advantage. Canola is unlikely to persist in unmanaged habitats and would not be expected to persist in the natural environment. Canola fields are typically highly managed agricultural areas that can be expected to be dedicated to crop production for many years. Cultivation of Pioneer 73496 canola is not expected to differ from typical canola cultivation. Pioneer expects 73496 canola to replace some of the presently available canola varieties but does not expect that Pioneer 73496 canola will cause new canola acres to be planted in areas that are not already in agricultural production.

The evaluation of agronomic and phenotypic properties of 73496 canola, including those characteristics associated with reproductive biology, indicated no biological meaningful differences that are likely to affect the potential for gene flow from 73496 canola to sexually compatible species. Although gene flow from 73496 canola to relatives is possible, it will not result in increased weediness or invasiveness of these relatives based on the agronomic and ecological assessments (see Petition, Section VII and Appendix 5). The consequences of gene flow and introgression of the glyphosate-tolerance trait from 73496 canola to the same or sexually compatible species is anticipated to be the same as for existing commercial glyphosate-tolerant canola varieties. If glyphosate-tolerant individuals arise through interspecific or intergeneric hybridization, the tolerance will not confer any competitive advantage to these plants unless selected by glyphosate herbicide. This would only occur in managed ecosystems where glyphosate-containing herbicides are applied for broad-spectrum weed control, or in plant varieties developed to exhibit glyphosate tolerance and in which glyphosate is used to control weeds. As with glyphosate-tolerant canola volunteers, these individuals, should they arise, would be controlled using other available chemical or mechanical means.

Large-scale cultivation of HT canola has occurred for nearly 15 years in Canada and the United States. To date, there are no reports of problems with interspecific crosses and introgression of HT genes into cultivated or wild relatives of canola (Andersson and de Vicente, 2010). Commercial scale planting of 73496 canola is unlikely to have effects on non-target organisms common to the agricultural ecosystem or threatened or endangered species. There will be no significant positive or negative effects on biodiversity as a result of a determination of nonregulated status for 73496 canola.

4.4. Human Health

4.4A. Consumer Safety

Under the FFDCA, it is the responsibility of food manufacturers to ensure that the products they market are safe and properly labeled. Food derived from 73496 canola must be in compliance with all applicable legal and regulatory requirements. GE organisms for food may undergo a voluntary consultation process with the FDA prior to release onto the market.

The GAT4621 protein, as expressed in 73496 canola, is equivalent to the GAT4621 protein expressed in Pioneer's 98140 glyphosate-tolerant maize that was deregulated by USDA in 2009. In 2007, Pioneer submitted to FDA a New Protein Consultation (NPC) on the GAT4621 protein (see also Petition: Appendix 10) and a safety and nutritional assessment of event 98140 to FDA. The Agency subsequently issued an Agency Response Letter (NPC 000005) in which the agency had no further questions on Pioneer's conclusion that GAT4621 would not raise any food or feed safety concerns (US-FDA, 2009). Additionally, a Biotechnology Consultation Agency Response Letter (BNF No. 000111) stating that the Agency had completed the Consultation and had no further questions concerning the food safety of the variety (US-FDA, 2008).

Consumer exposure to canola is largely through the consumption of canola oil. Methods used in the processing of vegetable oils typically remove virtually all the protein (Gylling, 2006; Hefle and Taylor, 1999).

Consumer Safety – No Action Alternative

The FDA is currently conducting a Consultation on the food safety of Pioneer's 73496 canola expressing the GAT4621 protein. The Agency has already completed a New Protein Consultation for the GAT4621 protein and completed a Consultation on 98140 maize, which expresses the identical GAT4621 protein. Under the No Action Alternative, there would be no changes to the completed GAT 4621 NPC or the pending 73496 canola Consultation at FDA.

Consumer Safety – Approve Petition Alternative

Consumer exposure to 73496 canola will be largely through consumption of the extracted oil which contains essentially no protein, thus consumers should not be exposed to the GAT4621 protein through canola oil in the diet. Furthermore, compositional analysis of fatty acids present in 73496 canola seed compared to with non-transgenic canola (see Petition, Section VII) demonstrates that the oils will be comparable. Recent developments in the processing of canola meal have produced protein isolates that may have possible human use applications in beverages, nutritional products, dairy products, grain products, powdered egg or egg substitutes, emulsifiers in dressings, meat substitutes, bars, or baked foods (Archer Daniels Midland Co., 2010). A finding of nonregulated status for 73496 canola will not affect consumer health.

As discussed previously, the GAT4621 protein was developed from naturally occurring GAT enzymes from the common soil bacterium *B. lichiniformis*. There are no toxins associated with this bacterium which is widely used in the food industry (US-EPA, 1997). A comparison of the amino acid sequence of GAT4621 with known toxins failed to show any significant homologies. There was no evidence of acute toxicity in mice for GAT4621 at a dose of 1640 mg protein per kg of body weight (see Petition, Appendix 10). Pioneer concludes that the GAT4621 protein is extremely unlikely to be a human or animal toxin.

Canola is not a common allergenic food and the modification in 73496 canola did not cause significant compositional changes relative to conventional canola and is not expected to alter the allergenic potential of canola. The allergenic potential of the GAT4621 protein was assessed using a weight-of-evidence approach using guidance from the Codex Alimentarius Commission (Codex Alimentarius Commission, 2009). Bioinformatic analyses revealed no biologically significant identities to known or putative protein allergens or toxins for the GAT4621 protein sequences (see Petition, Appendix 10). The GAT4621 protein is not glycosylated and is rapidly digested (within 30 seconds) in simulated gastric fluid. In simulated intestinal fluid, the GAT4621 protein hydrolyzed within 5 minutes. These data support the conclusion that the GAT4621 protein is unlikely to cause an allergic reaction in humans or be a toxin in humans or animals and therefore support the food and feed safety of GAT4621.

Although the primary substrate of the GAT4621 protein is glyphosate, GAT4621 is also known to *N*-acetylate certain free amino acids (L-aspartate, L-glutamate, glycine, L-serine, and L-threonine) resulting in production of *N*-acetylaspartate (NAA), *N*-acetylglutamate (NAG), *N*-acetylglycine (NAGly), *N*-acetylserine (NAS), and *N*-acetylthreonine (NAT). The efficiency of acetylation of free amino acids by GAT proteins is considerably lower than the activity displayed toward glyphosate. Therefore, the concentrations of these five acetylated amino acids were measured in seed, whole plant, and processed product samples derived from 73496 canola.

Concentrations of NAA and NAG, and in some instances NAGly, NAS, and NAT, are elevated in 73496 canola, when compared with the corresponding concentrations of these substances in unmodified canola. Low but quantifiable amounts of each *N*-acetylated amino acid were found in each sample type from 73496 canola except refined, bleached, deodorized (RBD) oil, the only fraction consumed by humans, where levels were either not detectable or below the limit of quantification (see Petition, Section VIII).

These five acetylated amino acids are not novel food substances. They are present in conventional canola as well as in other food plants (see Petition, Section VIII and Appendix 10. No significantly increased consumer exposure to these acetylated amino acids is anticipated as a result of the unconfined use of 73496 canola.

Pioneer's 73496 canola will also be reviewed by the FDA for use in food.

4.4B. Worker Health

Workers can be exposed to safety hazards while working with canola. Herbicide usage could potential cause health concerns; however, the use of glyphosate has been noted to result in the replacement of herbicides that are at least three times as toxic and persist almost twice as long as glyphosate (Heimlich *et al.*, 2000). Furthermore, human safety concerns are lower due to less herbicide spraying and less environmental impact. Glyphosate has a positive environmental and safety profile (see Section 2.4 Human Health – Worker Health). Pioneer's 73496 canola would be available to growers wishing to decrease the use of more toxic chemicals, such as atrazine, and replace them with glyphosate, a more "environmentally friendly" herbicide, without compromising yield. An additional concern for worker's health would be the development of allergies to canola pollen. As noted previously, a very small group of workers who are intensively exposed to canola, such as plant breeders, may be at risk of developing allergy to *B. napus* pollen (Fell *et al*., 1992) although allergy to *Brassica* pollen in the population is rare (Soutar *et al*., 1994).

Furthermore, capacity of oilseed rape pollen proteins to induce allergic responses has been a matter of debate because a number of investigators consider oilseed rape mainly as a species that cross-reacts with birch and various grass pollen allergens, which are much more prevalent in the atmosphere compared to rapeseed pollen allergens (Fell *et al*., 1992; Murphy, 1999). Because individuals experiencing allergic symptoms with rapeseed are generally atopic, it is likely that most of the rapeseed allergic pool is a subset of the more extensive pool of individuals with grass and birch pollen allergies, who also recognize cross-reacting epitopes in oilseed rape pollen (Focke *et al*., 1998; Smith *et al*., 1997).

It can be concluded that oilseed rape pollen may on rare occasions mono-sensitize specific individuals, particularly in those subject to extensive occupational exposure to the plant, but this crop does not appear to be an extremely potent allergen (Hemmer *et al*., 1997). A few case reports of occupational allergies to oilseed rape seed meal have been reported predominantly in settings such as animal feed factories, grain mills, and farms (Alvarez, *et al*., 2001; Monsalve *et al*., 1997). Many of the observed symptoms have also been attributed to the inhalation of irritant volatile substances released by the plant during the flowering season (Alvarez *et al*., 2001; Butcher *et al*., 1995; McSharry, 1997).

Worker Health – No Action Alternative

Under the No Action alternative, canola production and processing practices would be unaltered. Cropping practices, including pesticide application would not change. Worker exposure to safety hazards associated with the cultivation, harvesting and processing of canola would remain the same.

Worker Health – Approve Petition Alternative

Worker exposure to safety hazards associated with canola production and processing would remain the same if 74396 canola were granted nonregulated status. The amount of herbicide applied to the crop would not change since 73496 canola would replace existing glyphosate-tolerant products and would not result in an overall increase in acreage planted to HT canola or any change in labeled rates of glyphosate applied to the crop. The GAT4621 protein has been evaluated and found not to pose a toxic or allergenic risk to workers who may come into contact with 73496 canola or processed products thereof.

Oilseed rape pollen may on rare occasions mono-sensitize specific individuals, particularly in those subject to extensive occupational exposure to the plant, but there is no indication that

73496 canola would be any more likely to sensitize individuals than other GE or conventional varieties that are currently planted in the U.S.

4.5. Animal Feed

Canola seed is typically not fed to animals, but is crushed at processing facilities into oil and meal. Crushing removes most of the oil and nearly all of the remaining material is a suitable meal for livestock feed. Canola meal is the second largest protein meal produced in the world. In marketing year 2008/09, global canola meal production was 30.8 million metric tons, versus 151.6 million for soybean meal. Canola meal has lower protein content than soybean meal (34-38% versus 44-49%) and fewer key amino acids. Therefore, canola meal is an economical protein source for animals that do not have high energy or lysine requirements (USDA-ERS 2010a).

Canola meal is primarily fed to cattle and pigs as part of a feed ration. The majority of canola meal in the U.S. is fed to dairy cows because the high fat content of the meal enhances milk production. Poultry, aquaculture, and specialty animals (*e.g.*, racehorses) can also be fed canola meal as a protein source, although limited crushing locations, high fiber content, and low palatability limit feeding rates.

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 73496 canola must be in compliance with all applicable legal and regulatory requirements.

The GAT4621 protein, as expressed in 73496 canola, is equivalent to the GAT4621 protein expressed in Pioneer's 98140 glyphosate-tolerant maize that was deregulated by USDA in 2009. In 2007, Pioneer submitted to FDA New Protein Consultation (NPC) on the GAT4621 protein (see Petition, Appendix 11) and a safety and nutritional assessment of 98140 maize to FDA. The Agency subsequently issued an Agency Response Letter (NPC 000005) stating no further questions regarding the Company's conclusion that the inadvertent presence of low levels of GAT4621 protein in feed would not raise safety concerns (US-FDA 2009) and a Biotechnology Consultation Agency Response Letter (BNF No. 000111) stating that the Agency had completed the Consultation and had no further questions concerning the feed safety of the variety (US-FDA, 2008).

Animal Feed - No Action Alternative

The FDA is currently conducting a Consultation on the feed safety of Pioneer's 73496 canola expressing the GAT4621 protein. The Agency has already completed a New Protein Consultation for the GAT4621 protein and a Consultation for 98140 maize, which expresses the identical GAT4621 protein. Under the No Action Alternative, there would be no changes to the completed GAT 4621 NPC or the pending 73496 canola Consultation at FDA.

Animal Feed – Approve Petition Alternative

The FDA considers Pioneer's Consultation on the GAT4621 protein to be complete (US-FDA, 2009). The GAT4621 shows no toxic or allergenic potential. Based on measurements of GAT4621 protein present in 73496 seed, exposure levels in meal based animal diets would be exponentially lower than that (1640 mg/kg) found to have no indications of toxicity in a mouse acute oral study (see Petition, Appendix 10).

Data submitted on agronomic performance, disease and insect susceptibility, and compositional analyses showed that 73496 canola and non-transgenic control canola were comparable and therefore would not be expected to cause either a direct or indirect adverse effects on any raw or processed plant commodity used as animal feed.

Glucosinolates are generally considered to be innocuous; however the hydrolysis products negatively affect palatability. The total glucosinolate concentration for 73496 canola was 5.66 μmoles/g dry weight, which is within the acceptable definition for canola (maximum 30 μmoles/g dry weight; OECD, 2001).

Seed of 73496 canola did contain higher levels of certain acetylated amino acids (NAA, NAG, NAS, NAT, and NAGly) and elevated levels of those substances also occurred in the meal following oil extraction (see Petition, Section VII). Acetylated amino acids, including NAA, NAG, NAS, NAT, and NAGly are normal components of canola meal and other feedstuffs. In addition, there was no evidence of toxicity in short or long terms feeding studies with purified acetylated amino acids, as reported by Pioneer (see Petition, Section VII).

Meal produced from 73496 canola is expected to be as safe as and as nutritious as canola meal produced from existing commercial canola varieties used as standard rations in feed.

4.6. Socioeconomic

4.6A. Domestic Economic Environment

The U.S. share of world canola production remains small, but is of growing importance to regional economies in the Northern Plains. In 2010/11, the projected farmgate value of U.S. canola production is projected to be $473 million, double the 2009/10 value of $239 million, reflecting much higher acreage planted in 2010 (1,449,000 acres versus 827,000 acres) and higher commodity prices ($16.20/cwt versus $18.50-20.10/cwt) (USDA-ERS 2011d). The 2009/10 planted acreage is more typical of recent years. Trends in the much larger Canadian canola industry have a significant impact on production and processing of canola in the U.S.

Canola yields have increased approximately 35% in the last 10 years (USDA-ERS 2011d). Research in canola breeding and cultivation is expected to continue at both universities and seed companies. In April 2011, the National Institute of Food and Agriculture announced an $800,000 grant program (USDA-NIFA-OP-003439) for canola research with a goal "to significantly increase canola crop production and/or acreage by developing and testing of superior germplasm, methods of planting, cultivation, harvesting, and then transferring new knowledge to producers (via Extension) as soon as practicable."

Since the introduction of glyphosate-tolerant canola in 1999, U.S. canola production has fluctuating between 0.8 million and 1.5 million acres planted. The high of approximately 1.5 million acres occurred in 2000 and again in 2010 (USDA-NASS, 2011). As discussed earlier, the planting of HT varieties has increased significantly from 1999 to 2006, as benchmarked in North Dakota, the primary production state (25% to 99% from 1999 to 2006; Johnson *et al.*, 2007). Despite this trend overall canola cultivation has not seen a similar increase. There is no indication that the introduction of glyphosate-tolerant varieties in 1999 significantly changed cultivation acreage of canola in the U.S.

Domestic Economic Environment – No Action Alternative

Under the No Action alternative, 73496 canola would remain a regulated article and would require an APHIS permit for release into the environment. There would be no impact on the domestic economic environment.

Domestic Economic Environment – Approve Petition Alternative

HT canola varieties dominate the market. In the primary U.S. production state, North Dakota, the planting of HT varieties has reached 99% (Johnson *et al.,* 2007) mirroring similar trends seen in Canada where 99% of Canada acreage is also HT (Canola Council of Canada, 2010a). Therefore, the introduction of HT 73496 canola following a determination of nonregulated status, is not expected to increase U.S. acreage. Varieties derived from 73496 canola would provide market alternatives that would substitute for other glyphosate-tolerant varieties already being planted. Pioneer's 73496 canola does not have a yield advantage over conventional canola and so is not likely to increase overall canola yields or the prices obtained by growers for their crop.

4.6B. Trade Economic Environment

There is a small export trade in U.S. canola oil, meal, and seed, but much larger amounts of canola seed, meal and oil are imported from Canada. For example, in 2009/10, the U.S. exported 454 million pounds of seed, 553 million pounds of oil, and 0.3 million short tons of meal, but imported 1,252 million pounds of seed, 1,278 million short tons of meal, and nearly 2,351 million pounds of oil (USDA-ERS, 2011b; USDA-ERS, 2011c; USDA-ERS, 2011d). Major export markets for canola are China, E.U. Japan, Mexico, Pakistan, United Arab Emirates (Canola Council of Canada, 2011). Most of these countries have regulations governing the approval of imported GE crops and new GE traits must undergo extensive regulatory assessment before they are approved for import. Production in the U.S. of new GE canola varieties without appropriate approvals in key importing countries may result in trade disruption.

Trade Economic Environment – No Action Alternative

Under the No Action alternative, 73496 canola would remain a regulated article and would require an APHIS permit for release into the environment. There would be no impact on the trade economic environment.

Trade Economic Environment – Approve Petition Alternative

A decision to grant nonregulated status to 73496 canola will likely result in commercial varieties of 73496 canola being planted in the U.S. In the absence of any practical method of separating commodity canola, 73496 canola seed, meal and oil will be co-mingled with other varieties, including GE varieties that have all necessary approvals in major export markets. Absent such approvals for 73496 canola, there could be disruptions in trade. Under the Approve Petition alternative, Pioneer will perform a market assessment, in consultation with the value-chain, for 73496 canola and will obtain appropriate regulatory approvals for 73496 canola in major U.S. export markets with functioning regulatory systems prior to release for commercial production, as requested by the grains industry (USGC, 2007).

5. CUMULATIVE IMPACTS

5.1 Agricultural Production

5.1A. Land Use - Cumulative Effects

The 73496 canola will be grown in the same regions and on the same land types as the non-GE crop and other GE HT varieties and will not result in any significant change in the area planted to canola in the U.S. or to the current geographic limits of production for spring or winter canola. The introduction of 73496 canola may result in substitution of one HT variety for another, but should not increase or decrease the proportion of the crop planted to glyphosate-tolerant varieties.

No significant cumulative land use effects are anticipated as a result of approving the Petition for nonregulated status of 73496 canola.

5.1B. General Agronomic Practices - Cumulative Effects

Cropping Practices. Canola production practices will not change with the deregulation of 73496 canola. 73496 canola would not use different cropping practices than what is currently being used on genetically engineered products.

Tillage. Glyphosate-tolerant canola allows growers to use methods that conserve soil health and moisture and reduce soil erosion (Brown *et al*., 2008). Because there are already glyphosate-tolerant varieties in the marketplace and 73496 canola will provide a market alternative to these existing varieties, a determination of nonregulated status for 73496 glyphosate-tolerant canola will have no cumulative effect on tillage practices.

Crop Rotation. Because rotational practices are similar for both winter and spring canola, and the agronomic properties of 73496 canola are similar to currently available commercial canola lines, including glyphosate-tolerant canola, a determination of nonregulated status for 73496 canola will have no cumulative effect on rotational practices.

Insecticide, Fungicide, and Fertilizer Use. The use of insecticides, fungicides, and fertilizer will be unchanged in the event that 73496 canola is deregulated. There will be no significant cumulative effects.

*General Weed Management***.** Weed management practices for canola are well established and glyphosate-tolerant canola varieties already comprise approximately 50% of the market. The availability of 73496 canola will provide growers additional seed product choices, but will not impact the choice of weed control products already available in the marketplace. Canola is commonly rotated with cereal grain crops, especially wheat. The potential development by technology providers of glyphosate-tolerant wheat could significantly reduce options to manage canola volunteers in wheat and wheat volunteers in canola (Gurian-Sherman, 2003). However, no new weed and volunteer management issues would impact growers rotating canola with glyphosate-tolerant wheat than would exist with currently available glyphosate-tolerant canola varieties. A determination of nonregulated status for 73496 glyphosate-tolerant canola will not have any significant cumulative effect on weed management practices or the overall acreage of HT canola that is planted.

Glyphosate-Resistant Weeds. Deregulation of 73496 canola will not change cropping practices (*e.g.*, crop rotations) or rates or frequency of glyphosate applications currently employed to control weeds in canola, so there will be no cumulative effects on the potential for the development of glyphosate-resistant weeds.

Herbicide Use and Weed Resistance. According to Pioneer's marketing outlook, glyphosate-tolerant canola will continue to maintain the majority of the market share and will increase slightly in the foreseeable future (Figure 4). If growers decide that glyphosate-tolerant canola is not suitable for their fields, there are currently two other HT canola varieties available that use alternate chemistries (Table 7). There are also other herbicides that could be used on genetically-engineered canola fields (Table 6). Overall, the extensive use of glyphosate has reduced herbicide use, but resistant weeds could occur, requiring alternative weed management practices.

The deregulation of 73496 canola should have no significant cumulative effect on herbicide use or weed resistance. 73496 canola is similar to glyphosate-tolerant canola that has been deregulated and is widely grown in the U.S. The amount of glyphosate used on 73496 canola will be identical to existing glyphosate-tolerant varieties (because the season use rate is identical), so 73496 canola will not positively or negatively affect weed resistance.

Multiple Herbicide-Tolerant Canola. In the event that 73496 canola were deregulated, Pioneer would have the option to develop a stacked glyphosate/glufosinate canola product. The market for such a product is small (<5%) and in the event that such a stack were developed, it would have a minimal, if any, cumulative impact on glyphosate or glufosinate herbicide use, but could provide growers with an improved management option to delay the onset of weed resistance or a mange already resistant weed populations.

In the future, additional HT traits may be engineered into canola. By determining that 73496 canola is nonregulated, Pioneer could, in principle, be able to develop varieties with additional tolerances to herbicides with diverse modes of action that would offer growers a wider choice of weed management options. However, these same combinations of HT traits could be developed using glyphosate-tolerant varieties already available in the marketplace.

In summary, no significant cumulative effects on canola production are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.1C. Specialty Canola Production – Cumulative Impacts

The availability of methods used to separate specialty canola products from canola used for commodity oil and meal production would be the same as currently used in identity preserved canola production systems and no changes are foreseeable as a result of the introduction of HT 73496 canola.

No significant cumulative effects on specialty canola production are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.1D. Organic Canola Production – Cumulative Impacts

There are already a number of GE canola varieties in the marketplace. The NOS prohibit the use of GE varieties in organic production. Organic canola growers have developed practices to maintain the organic status of their crops in the presence and these GE varieties and these practices would be unchanged as a result of the introduction of 73496 canola.

No significant cumulative effects on organic canola production are anticipated as a result of approving the petition for nonregulated status of 73496 canola. In the foreseeable future, the majority of the canola market is expected to be glyphosate-tolerant (Figure 4). There are currently IP practices that facilitate the prevention of cross-pollination between genetically engineered and organic canola production.

5.2 Physical Environment

5.2A. Soil Quality – Cumulative Impacts

Varieties of 73496 canola will grown as substitutes for current HT canola varieties and tiny amounts of the novel GAT4621 protein may remain in the soil following cultivation, but any adverse impacts on soil are highly unlikely, since similar microbial proteins already exist in the soil and no cumulative impacts are likely.

No significant cumulative effects on soil quality are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.2B. Water Resources – Cumulative Impacts

Research is currently being conducted in the U.S. to develop varieties for more arid climates. Currently, canola grown in semi-arid regions requires irrigation if adequate subsoil moisture is not available to sustain the crop during the flowering and seed filling period (Johnson *et al*., 2009). Should new varieties of canola for semi-arid regions be developed, regions where canola could be cultivated in the U.S. might change leading to changes in irrigation practices and water resources as well. However, these changes would be independent of the availability of 73496 canola.

No significant cumulative effects on water resources are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.2C. Air Quality – Cumulative Impacts

The agronomic performance of 73496 canola is not different from conventional canola and is therefore, not likely to impact air quality differently from cultivation practices employed with canola varieties on the market today.

No significant cumulative effects on air quality are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.2D. Climate Change – Cumulative Impacts

The use of 73496 canola is not expected to have cumulative effects on climate change that are not already apparent through the cultivation of canola and the widespread use of HT varieties.

No significant cumulative effects on climate change are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.3 Biological Resources

5.3A. Animal Communities - Cumulative Impacts

Pioneer considered the potential impact on animal communities, including federally listed threatened or endangered species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. In this analysis, the biology of 73496 canola as well as typical agricultural practices associated with cultivation of canola was considered. Based on the safety of the GAT4621 protein expressed in 73496 canola, the compositional similarity of 73496 canola to equivalent non-GE canola and the absence of any changes in agricultural practices (*e.g.*, pesticide application), Pioneer does not expect any cumulative effects on animal communities, including beneficial organisms such as honeybees and threatened or endangered species.

No significant cumulative effects on animal communities are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.3B. Plant Communities - Cumulative Impacts

Pioneer’s 73496 canola shows no altered capacity to be weedy or to become invasive of natural habitats or to establish feral populations. The potential for 73496 volunteers to become tolerant to multiple herbicides is no greater or smaller that the potential of other de-regulated glyphosate-tolerant varieties. Such volunteers can still be controlled by application of herbicides with different modes of action, or through rotation and/or tillage practices (See Section General Agronomic Practices 2.1B). Herbicide-tolerance does not confer any competitive advantage in unmanaged environments where herbicides are not applied.

No significant cumulative effects on animal communities are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.3C. Microorganisms – Cumulative Impacts

Canola has a symbiotic or beneficial relationship with soil microbes (OECD, 1997). These microbial groups play an important and particular role in the ecology of the soil, including nutrimental cycling and the availability of nutrients for plant growth. In addition, certain microbial organisms may contribute to the protection of the root system against soil pathogens (OECD, 2003).

73496 canola is a replacement product; therefore it will be no difference in the cumulative impact on microorganisms as the current glyphosate-tolerant canola.

5.3D. Biodiversity - Cumulative Impacts

Genetically engineered HT canola lines have been available on the market since 1999, without any apparent negative impacts on biodiversity. A comprehensive literature search revealed inconclusive results on the impact from the cultivation of HT canola and oilseed rape on biodiversity. M.J. Whittingham (2009) discussed the outcome of a biodiversity study on birds in herbicide-tolerant oilseed rape, maize, and sugarbeet in Europe. The study noted indirect effects on bird populations due to the reduced amount of weeds in the herbicide-tolerant fields compared to the conventional fields. A lower density of weeds will decrease habitat, food abundance and efficiency, along with increased predation risk. However, Whittingham concluded that it is still unclear how these differences may affect bird population, and that potential large-scale changes to GE crops remain poorly understood. Additionally, another review of biodiversity in herbicide-tolerant canola fields discussed the positives and negatives of planting herbicide-tolerant oilseed rape or canola and suggested growers monitor for adverse effects (Graef, 2007). Overall it is difficult to say how agricultural biodiversity will be impacted by production of herbicide-tolerant canola.

73496 canola does not exhibit traits that would differentiate it from glyphosate-tolerant canola that is currently in production. Biodiversity should not have any significant cumulative impacts since this is a replacement product.

No significant cumulative effects on biodiversity are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.4 Human Health

5.4A. Consumer Health – Cumulative Effects

The composition of 73496 canola is equivalent to conventional canola, with the exception of slightly elevated levels of certain acetylated amino acids, which are present in other food crops, but were absent from 73496 canola RBD oil, which is the major 73496 fraction likely to be consumed by humans.

Protein isolates derived from canola (Puratein®, Supertein™) are under development as ingredients in powdered egg and egg substitutes, dairy products, processed meats, grain products, vegetable/fruit juices and beverages, salad dressings, protein supplement powders and meal replacement/nutritional bars (Archer Daniels Midland Co., 2010). The GAT 4621 protein may co-purify with these protein isolates, but since it has no toxic or allergenic potential and has been previously reviewed by FDA, there will be no cumulative impact.

No significant cumulative effects on human health are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.4B. Worker Health – Cumulative Effects

Worker safety issues associated with the cultivation and processing of canola would be unchanged as a result of a determination of nonregulated status for 73496 canola. Workers would be exposed to pollen and dust containing the GAT4621 protein, but the protein has been thoroughly evaluated and shows no allergenic potential and has no homology to grass and pollen allergens that share cross reactivity with existing canola allergens. Taken together, these findings indicate that there would be no significant change in cumulative effects for workers subject to occupational exposure by de-deploying another line of glyphosate-tolerant canola.

No significant cumulative effects on human health are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.5 Animal Feed

Animal Feed – Cumulative Effects

Canola meal is the major processed fraction fed to animals. Meal produced from 73496 canola is expected to be as safe as and as nutritious as canola meal produced from existing GE and conventional commercial canola varieties.

No significant cumulative effects on human health are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.6 Socioeconomic Impacts

5.6A. Domestic Economic Environment – Cumulative Effects

Pioneer currently does not sell winter canola in the U.S., but it is possible that event 73496 could be deployed in winter canola in the future. Pioneer considers that any potential changes in domestic economic environmental impacts of 73496 canola across the U.S., whether deployed in spring or winter canola are likely to be market driven and not related, specifically, to the availability of 73496 canola. For example, through tax incentives and a federal mandate to increase the use of renewable fuels, government policy may in the future stimulate the growth of canola production for use in the production of biodiesel. If these policies are realized, there would be an added incentive to produce canola for biodiesel and canola planted acres in the U.S. could increase, however, the availability of 73496 canola would not in itself influence this acreage increase.

No significant cumulative effects on the domestic economic environment are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

5.6B. Trade Economic Environment – Cumulative Impacts

While Pioneer currently does not sell winter canola in the U.S., it is possible that event 73496 could be deployed in winter canola in the future. Pioneer considers the potential trade economic environmental impact of 73496 canola within the U.S., whether deployed as spring or winter canola, are likely to be market driven and not related, specifically, to the availability of 73496 canola. Planting of 73496 canola varieties would have no cumulative impact on canola production or prices for canola and canola processed products in international markets.

Pioneer is aware of the trade implications of planting nonregulated GE crops without approvals in major export markets and will seek such approvals prior to commercialization of 73496 canola. To help prevent unapproved events in the marketplace, commercial techniques will be in place to identify adventitious presence of unapproved seed.

No significant cumulative effects on the trade economic environment are anticipated as a result of approving the petition for nonregulated status of 73496 canola.

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