NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
PRELIMINARY FINDING OF NO SIGNIFICANT IMPACT

Monsanto Company
Event MON 88302 Canola

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) has developed this decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) regulations implementing NEPA, and the USDA APHIS NEPA implementing regulations and procedures. This NEPA decision document, Preliminary Finding of No Significant Impact (FONSI), sets forth this APHIS NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a regulatory determination about the status of a petition request (APHIS Number 11-188-01p) by Monsanto Company (Monsanto) for their GE (genetically engineered) Event MON 88302 Canola (hereafter referred to as MON 88302 Canola) which is resistant to the herbicide, glyphosate. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from approving the petition seeking nonregulated status for MON 88302 Canola. The EA assesses alternatives to a determination of nonregulated status of MON 88302 Canola, and the potential environmental and social effects that result from the proposed action and the alternatives.

Regulatory Authority

"Protecting American agriculture" is the basic charge of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of GE varieties) can increase farm income, and provide benefits to the environment and consumers.

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

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

APHIS is responsible for regulating GE organisms and plants under the plant pest provision of the Plant Protection Act of 2000 (PPA), as amended (7 USC §§ 7701 *et seq*.) to ensure that they do not pose a plant pest risk to the environment.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. The FDA policy statement concerning regulation of products derived from new plant cultivars, including GE varieties, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues, and other related regulatory issues (e.g., labeling) are resolved prior to commercial distribution of food and feed derived from products of GE plants.

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This responsibility encompasses regulation of the sale, distribution and use of pesticides, including those that are produced from GE organisms. EPA also has authority granted under the FFDCA to establish maximum contaminant levels referred to as tolerances for pesticides. Tolerances are maximum pesticide residue levels allowed in or on food for human consumption, and in feed for animals used as human food sources. One other statute, the Toxic Substances Control Act, authorizes EPA to regulate certain biological control organisms.

Regulated Organisms

The mission of APHIS Biotechnology Regulatory Services (BRS) is to protect America's agriculture and environment using a dynamic, science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340 promulgated under the authority of the PPA, as amended (7 United States Code (U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to a taxon that includes plant pests and is listed as such in 7 CFR 340.2. A GE organism is also regulated under Part 340 when APHIS does not have sufficient information to determine if the GE organism is unlikely to pose a plant pest risk.

An individual may petition the agency for a determination that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer subject to the plant pest risk provisions of the PPA and corresponding regulations at 7 CFR part 340. The petitioner is required to provide information under §§340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism.

APHIS' Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the PPA, APHIS has issued regulations (7 CFR part 340) for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as MON 88302 Canola. When a petition for nonregulated status for a GE organism is submitted, APHIS must determine whether or not it poses a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment (PPRA), that the GE organism is unlikely to pose a plant pest risk, it is no longer subject to the plant pest provisions of the PPA and regulations of 7 CFR part 340.

Monsanto has submitted a petition (APHIS Number 11-188-01p) to APHIS seeking a determination that GE MON 88302 Canola is unlikely to pose a plant pest risk and therefore, should no longer be a regulated article under 7 CFR part 340.

MON 88302 Canola

MON 88302 Canola has been genetically modified to express the CP4 EPSPS protein, which conveys resistance to the herbicide, glyphosate. MON 88302 Canola provides growers with an alternative to existing glyphosate-resistant- (GR-) canola products on the market today. MON

88302 Canola will provide added benefits of more effective weed control, compared to currently available GR-canola varieties because glyphosate can be applied at a higher rate to later developmental stages of crops planted in MON 88302 Canola..

Coordinated Framework Review

Food and Drug Administration

MON 88302 Canola is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including GE ones. Monsanto initiated the consultation process with FDA for the commercial distribution of MON 88302 Canola and submitted a safety and nutritional assessment of food and feed derived from MON 88302 Canola to the FDA on March 23, 2011 (Monsanto, 2011).

Environmental Protection Agency

The EPA has authority over the use of pesticidal substances and plant-incorporated protectants under the FIFRA as amended (7 USC §136, *et seq.*) and the FFDCA (21 USC §301, *et seq.).* APHIS considers the EPA regulatory assessment when assessing potential impacts that may result from a determination of nonregulated status of a GE organism.

EPA has authority under FIFRA to establish pesticide use restrictions, which are determined during the pesticide registration process, and are listed on the label for each product containing a particular pesticide active ingredient. MON 88302 Canola is similar to currently available GR-canola varieties with the exception of allowing for glyphosate applications to a broader range of developmental statges at a higher application rate. Monsanto submitted a request for amended labeling requirements to the U.S. EPA in February 2011 for EPA Registration Numbers 524-537 and 524-549, that would modify the current use pattern allowed for glyphosate on MON 88302 Canola (Monsanto, 2011). The glyphosate application rate will be similar to the rates for GR maize and soybeans. APHIS considered the proposed changes to the currently approved glyphosate uses on canola in its evaluation of the potential impacts associated with a determination of no regulatory authority for MON 88302 Canola.

Scope of the Environmental Analysis

Although a determination of nonregulated status of MON 88302 Canola would allow for new plantings of MON 88302 Canola anywhere in the U.S., APHIS primarily focused the environmental analysis on those geographic areas that currently support canola production. A determination of nonregulated status of MON 88302 Canola is not expected to increase canola production, either by its availability alone or accompanied by other factors, so no increase in overall GE canola acreage is likely. To determine areas of canola production, APHIS used data from the National Agricultural Statistics Service (NASS) to determine where canola is produced in the U.S. (UDA-NASS, 2012). In North America, the primary canola-growing region is

in areas of the Great Plains characterized by high quality soil, but shorter, drier growing seasons than that preferred by most corn and soybean varieties. Most of this region is in the prairie provinces of Canada, but part of it extends into North Dakota. From 2003-2012, the average canola production in the U.S. has been about 1.1 million acres (USDA-NASS, 2012). According to the 2007 Census of agriculture North Dakota produced about 93% of all the canola grown in the U.S.

Public Involvement

On July 13, 2012, APHIS published a notice in the Federal Register (77 FR pages 41357-41358, Docket no. APHIS-2012-0035) announcing the availability of the Monsanto petition for a 60-day public review and comment period. The deadline for receipt of comments was September 11, 2012. All comments were carefully analyzed to identify potential environmental and interrelated economic issues and impacts that APHIS determined should be considered in the evaluation of the petition. A total of 70 dockets containing 4,670 comments[1] was received during the open review period.

Comments were screened and sorted into categories according to the subject matter addressed and classified as either non-substantive or substantive. Substantive comments were defined as those not previously considered by APHIS that included new information and/or contributed to a broader understanding of the issue, and advanced the goal of an informed decision by the agency to regulate or not regulate MON 88302 Canola. Such substantive comments required a formal technical response by APHIS, and these have been addressed in the appropriate sections of the EA. Substantive comments identified the following issues:

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

In this EA, APHIS evaluated these comments and has included a discussion of them and other related issues with relevant documentation and citations where appropriate.

[1] Comments are available for review on line at: http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2012-0035.

Responses to specific substantive comments are included in an attachment to this Preliminary Finding of No Significant Impact.

Major Issues Addressed in the EA

Issues addressed in the EA were identified by considering public concerns and issues described in public comments for the petition for nonregulated status of MON 88302 Canola and other EAs of GE organisms. Issues identified in previous lawsuits, and those submitted by various stakeholders were also discussed. These issues, including those regarding the agricultural production of canola using various production methods, and the environmental food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of MON 88302 Canola .
The EA describes the alternatives considered and evaluated using the identified issues. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25):

Agricultural Production Considerations:

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

Environmental Considerations:

- Water Resources
- Soil
- Air Quality
- Climate Change
- Animals
- Plants
- Gene Flow
- Microorganisms
- Biological Diversity

Human Health Considerations:

- Public Health
- Worker Safety

Livestock Health Considerations:

- Livestock Health/Animal Feed

Socioeconomic Considerations:

- Domestic Economic Environment
- Trade Economic Environment

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status for MON 88302 Canola. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 88302 Canola is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2013), APHIS has concluded that MON 88302 Canola is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 88302 Canola is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of MON 88302 Canola. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section of the EA.

No Action: Continuation as a Regulated Article

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

This alternative is not the preferred alternative because APHIS has concluded through its PPRA that MON 88302 Canola is unlikely to pose a plant pest risk (USDA-APHIS, 2013). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

Preferred Alternative: Determination that MON 88302 Canola is No Longer a Regulated Article

Under this alternative, MON 88302 Canola and progeny derived from MON 88302 Canola would no longer be regulated articles under the regulations at 7 CFR part 340. MON 88302 Canola is unlikely to pose a plant pest risk (USDA-APHIS, 2013). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 88302 Canola and progeny derived from this event. The preferred alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. Because the agency has concluded that MON 88302 Canola is unlikely to pose a plant pest

risk, a determination of nonregulated status of MON 88302 Canola is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Alternatives Considered but Rejected from Further Consideration

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

1. Prohibit any MON 88302 Canola from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of MON 88302 Canola, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate because APHIS has concluded that MON 88302 Canola is unlikely to pose a plant pest risk (USDA-APHIS, 2013).

In enacting the Plant Protection Act, Congress found (§402(4) that:

> "[D]ecisions affecting imports, exports, and interstate movement of products regulated under this title [the Plant Protection Act] shall be based on sound science;"

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

> "Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandate of each agency;"

Based on the PPRA (USDA-APHIS, 2013), and the scientific data evaluated therein, APHIS concluded that MON 88302 Canola is unlikely to pose a plant pest risk. Consistent with this conclusion, there is no basis in science for prohibiting the release of MON 88302 Canola.

2. Approve the petition in part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that MON 88302 Canola is unlikely to pose a plant pest risk, (USDA-APHIS, 2013), there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

3. Isolation Distance between MON 88302 Canola and Non-GE Canola Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating MON 88302 Canola from conventional or specialty (e.g., organic) canola production. However, because APHIS has concluded that MON 88302 Canola is unlikely to pose a plant pest risk (USDA-APHIS, 2013), an alternative based on requiring isolation distances would be inconsistent with statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of MON 88302 Canola based on the location of production of non-GE canola in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in the APHIS PPRA for MON 88302 Canola, there are no geographic differences associated with MON 88302 Canola relevant to potential plant pest risks (USDA-APHIS, 2013), so this alternative was rejected and not analyzed in detail because APHIS has concluded that MON 88302 Canola does not present a plant pest risk, and will not exhibit a greater plant risk in any geographically restricted area. Therefore, such an alternative would not be consistent with the APHIS statutory authority under the plant pest provisions of the PPA, regulations in Part 340 and those biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet the APHIS purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. However, individuals might choose on their own to geographically isolate their non-GE production systems from MON 88302 Canola or to use isolation distances and other management practices to minimize gene movement between canola fields. Information to assist growers in making informed management decisions for MON 88302 Canola is available from the Association of Official Seed Certifying Agencies (AOSCA, 2011).

4. Requirement of Testing for MON 88302 Canola

During the comment periods for other petitions for nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. APHIS notes that there are no nationally established regulations involving testing, criteria, or

limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Because MON 88302 Canola also does not pose a plant pest risk (USDA-APHIS, 2013), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA, regulations at 7 CFR part 340 and those biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MON 88302 Canola would not meet the APHIS purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

Environmental Consequences of the APHIS Selected Action

The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
Meets Purpose, Need and Objectives	**No**	**Yes**
Unlikely to Pose a Plant Pest Risk	Satisfied by regulated field trials.	Satisfied – plant pest risk assessment (USDA-APHIS, 2013)
Management Practices		
Acreage and Areas of Canola Production	Since the 1999 introduction of herbicide-resistant canola in the U.S., production has fluctuated between 0.8-1.6M acres. Average U.S. canola acreage **is** about 1.1M acres. About 93% of it was located in North Dakota. Nearly all (99%) of the ND crop was herbicide resistant; 57% of that was glyphosate resistant.	No change from Alternative A

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
Agronomic Practices	Conservation tillage, which tends to provide a competitive advantage to canola production by promoting earlier crop emergence, has increased since the introduction of HR- canola varieties. In the northern U.S., use of tillage has declined from 89% to 35%; in some individual instances it remains useful in managing herbicide-resistant weeds. About half of growers rely on a 3-year rotation of canola, a small grain, and soybean. The remaining growers use a two-year rotation of canola/wheat.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa).
Canola Seed Production	Most seed production is in Alberta. In the U.S, seed production occurs in the Columbia Basin in eastern Washington, the Grand Ronde Valley in Union County in northeastern Oregon, and the San Luis Valley in south central Colorado. Most seed companies have off-season seed production locations in the southwestern U.S. About 5,000 acres of commercial seed production supply enough seed to plant the entire U.S. canola crop.	No change from the No-Action Alternative
Pesticide Use	EPA-approves uses of herbicides on canola. Specific treatment	The approved in-crop glyphosate application rate for

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
	rates and crop stage restrictions apply to HR canola.	MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa).
Organic Canola Production	Certified organic production is an extremely small component of canola production conducted primarily in regions remote from major GE-canola-crop sites.	No change from No-action Alternative
Environment		
Soil Quality	Herbicide applications in conjunction with HR canola have promoted conservation tillage, which preserves soil quality by reducing erosion. Growers currently use best management practices to address their specific needs in producing canola.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa), which do not have unacceptable impacts on soil quality.
Water Resources	The most important source of non-point source pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Glyphosate has a high affinity for binding with most types of soils, where it is	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa), which

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
	degraded. This limits its mobility and transport into surface and groundwater.	do not have unacceptable impacts on water resources.
Air Quality	Agricultural activities such as tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Applications may impact air quality from: drift; diffusion; volatilization of chemicals; exhaust emissions from motor vehicles and aircraft.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa), which do not have unacceptable impacts on air quality.
Climate Change	Agriculture-related activities are direct sources of greenhouse gases (e.g., exhaust from motorized equipment) and indirect sources (e.g., soil disturbance from tillage, fertilizer production)	No change from No-action Alternative
Animal Communities	Invertebrates that feed on canola are typically considered pests and may be controlled by the use of insecticides or other production practices. Seed treatments are recommended to prevent flea beetle damage of young plants and foliar insecticide applications are recommended if damage reaches an economic threshold.	No change from No-action Alternative

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
Plant Communities	Plants growing in canola fields are considered weeds. Weeds can complete with growing canola plants for resources such as water, light, and soil nutrients. Young canola seedlings are very sensitive to early weed competition. Growers control weeds in and around fields using cultural, mechanical and chemical methods. Canola can form feral populations. Canola can hybridize with certain sexually compatible mustard plants.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa). The changes in the effects on plant communities associated with the preferred alternative would be minimal, and could have an overall positive effect on reducing weed resistance when compared to the No-action Alternative.
Soil Microorganisms	APHIS has previously examined potential impacts of glyphosate on microorganisms in soils of field under cultivation with HR crops, and has not found evidence linking applications of glyphosate to changes in soil microbial communities that have adverse effects on plants grown in those soils.	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other GR-crops (e.g., soybean, maize, cotton, alfalfa), which do not have unacceptable impacts on microorganisms.

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
Biological Diversity	HR crops, such as canola, have been correlated with an increase in conservation tillage in U.S. crop production, which promotes biodiversity by allowing the establishment of other plants, and the accumulation of more plant residue that increases soil organic matter, food, and cover for wildlife. Effects of GE crops have been associated with positive impacts on biodiversity because of increased yields, fewer applications of less toxic pesticides, and facilitation of conservation tillage.	No change from No-action Alternative
Land Use	Canola is minor crop produced on approximately 0.04% of the harvested cropland in the U.S. Current trends influencing the acreage of canola planted annually are driven by market conditions (e.g., increased demand for US canola products and animal feed)) and Federal policy.	No change from No-action Alternative
Human and Animal Health		
Risk to Human Health	Canola oil has one component (erucic acid) of human health significance because of its toxic properties. Varieties that produce oil with less than 2% of this fatty acid are defined as canola, and are generally	The approved in-crop glyphosate application rate for MON 88302 Canola will increase from the rate currently approved for other GR-canola varieties to the rate currently approved for other

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
	regarded as safe by FDA. Residues, such as that that might arise from the CP4 EPSPS protein are removed during filtration. Workers that routinely handle glyphosate, may be exposed during spray operations. Because of low acute toxicity of glyphosate, absence of evidence of carcinogenicity and other toxicological concerns, occupational exposure data is not required for reregistration. However, EPA has classified some glyphosate formulations as eye and skin irritants. When used consistent with the label, pesticides present minimal risk to human health and safety.	GR-crops (e.g., soybean, maize, cotton, alfalfa). Application at the higher rate does not pose any unacceptable risks to consumer health and worker safety when applied in accordance with the glyphosate registration label requirements approved by USEPA.
Risk to Animal Feed	Most canola cultivated in the U.S. is used to produce vegetable oil and animal feed. Canola-based animal feed is currently produced from GE canola varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. This includes HR GE canola varieties.	No change from No-action Alternative
Socioeconomic		
Domestic Economic Environment	Farm income is positively impacted by currently available HR canola by reducing	No change from No-action Alternative

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
	production costs or increasing revenues. GR canola generally has a positive impact on farm income due to cost savings from reduced fuel and pesticide use.	
Trade Economic Environment	Because the U.S. crushes more canola seed than it produces, the U.S. imports canola seed to meet the demand of the oil market. The U.S. exported 150-300 thousand metric tons of canola each year between 2007 and 2011. The majority of the canola exported went to Canada where it was processed. Foreign sales are mostly to Canadian crushing plants. The U.S. share of world production remains small, but is an increasingly important component of regional economies in the Northern Plains.	No change from No-action Alternative
Other Regulatory Approvals		
U.S.	FDA completed consultations.	No change from No-action Alternative. Satisfied: consultations with other agencies participating in the Coordinated Regulatory Framework completed.
Compliance with Other Laws		

Attribute/Measure	Alternative A: No-Action	Alternative B: Determination of Nonregulated status
CWA, CAA, EOs	Fully compliant	No change from No-action Alternative:

Finding of No Significant Impact

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree with this conclusion and therefore find that an EIS need not be prepared. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27).

Context - The term "context" recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic canola production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; foreign and domestic commodity markets.

From 2003-2012, the average canola production in the U.S. has been about 1.1 million acres (USDA-NASS, 2012). According to the 2007 Census of agriculture North Dakota produced about 93% of all the canola grown in the U.S. In 2008, GE (glyphosate and glufosinate) HR canola was estimated to be 95% of the U.S. canola crop (Brookes and Barfoot, 2010). In 2006, 99% of the production in the principal U.S. canola-growing state of North Dakota was derived from HR-canola varieties, with GR varieties grown on 57% of that acreage (Johnson et al., 2007). A determination of nonregulated status of MON 88302 Canola is not expected to directly cause an increase in agricultural acreage devoted to canola production, or those canola acres devoted to GE canola cultivation. The availability of MON 88302 Canola will not change cultivation areas for canola production in the U.S., and there are no anticipated changes to the availability of GE and non-GE canola varieties on the market.

Intensity – Intensity is a measure of the degree or severity of an impact, and the following ten factors were considered and used as a basis for this decision:

1. *Impacts that may be both beneficial and adverse.*
   A determination of nonregulated status of MON 88302 Canola will have no significant environmental impact in relation to the availability of GE, conventional, and organic canola varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 88302 Canola is not expected to directly cause an increase in agricultural

acreage devoted to canola production, or those canola acres devoted to GE canola cultivation. The availability of MON 88302 Canola will not change the cultivation areas for canola production in the U.S., and there are no anticipated changes in the availability of GE and non-GE canola varieties on the market. A determination of nonregulated status of MON 88302 Canola would add another GE canola variety to the conventional canola market, but is not expected to change the market demands for GE canola or canola produced using organic methods. The 2008 Census of Agriculture indicated that there were approximately 232 acres of organic canola grown in four states, with a value of about 0.03% of the total value of the canola crop in the same year (USDA-NASS, 2008). Based on the data provided by Monsanto for MON 88302 Canola (Monsanto, 2011), APHIS has concluded that the availability of MON 88302 Canola would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE canola seed production (USDA-APHIS, 2013). A determination of nonregulated status of MON 88302 Canola will not require a change in seed production practices, nor current production practices. The introduction MON 88302 Canola provides an alternative canola variety with glyphosate resistance.

2. *The degree to which the proposed action affects public health or safety.*
   A determination of nonregulated status of MON 88302 Canola would have no significant impacts on human or animal health. Compositional tests conducted by the petitioner indicate that MON 88302 Canola is compositionally similar to other commercially available canola (Monsanto, 2011). Monsanto initiated the consultation process with FDA for the commercial distribution of MON 88302 Canola and submitted a safety and nutritional assessment of food and feed derived from MON 88302 Canola to the FDA in March 2011. Based on the information Monsanto submitted, and as of April 23, 2012, FDA has no further questions regarding MON 88302 Canola (US-FDA, 2012). Based on the FDA's consultation, laboratory data and scientific literature provided by Monsanto (Monsanto, 2011), and safety data available on other HR products, APHIS has concluded that MON 88302 Canola would have no significant impacts on human or animal health.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*
   There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of MON 88302 Canola. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property, wildlife habitat, or landscapes; do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of

nonregulated status of MON 88302 Canola. The product will be deployed on agricultural land currently suitable for production of canola, will replace existing varieties, and is not expected to increase the acreage of canola production. This action would not convert land to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 88302 Canola including the use of EPA-registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of MON 88302 Canola, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to canola production sites.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

   The effects on the quality of the human environment from a determination of nonregulated status of MON 88302 Canola are not highly controversial. Although there is some opposition to a determination of nonregulated status of MON 88302 Canola, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to canola production, or those acres devoted to GE-canola cultivation. The availability of MON 88302 Canola will not change cultivation areas for canola production in the U.S., and there are no anticipated changes to the availability of GE- and non-GE-canola varieties on the market. A determination of nonregulated status of MON 88302 Canola would add another GE-canola variety to the conventional canola market; it is not expected to change the market demands for GE canola or canola produced using organic methods. MON 88302 Canola is currently registered by the EPA for breeding and seed increase activities. A determination of nonregulated status of MON 88302 Canola will not result in changes in the current practices of planting, tillage, fertilizer application/use, cultivation, pesticide application/use and volunteer control. Management practices and seed standards for production of certified canola seed would not change. The effect of MON 88302 Canola on wildlife or biodiversity is not different than that of other HR canola currently used in agriculture, or other GE or non-GE canola produced in conventional agriculture in the U.S. During the public comment period, APHIS received comments opposing a determination of nonregulated status of MON 88302 Canola. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. APHIS has addressed substantive comments in the response to public comments document attached to this preliminary FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*
   Based on the analysis documented in the EA, the possible effects on the human environment are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 88302 Canola is not expected to directly cause an increase in agricultural acreage devoted to canola production, or those acres devoted to GE-canola cultivation. A determination of nonregulated status of MON 88302 Canola will not result in changes in the current practices of planting, tillage, fertilizer application/use, and volunteer control. Management practices and seed standards for production of certified canola seed would not change. The effect of MON 88302 Canola on wildlife or biodiversity is no different than that from other HR crops currently used in agriculture, or other GE or non-GE canola produced in conventional agriculture in the U.S. As described in Chapter 2 of the EA, well-established management practices, production controls, and production practices for GE, conventional, and organic canola production are currently being used in canola cropping systems (i.e., commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce GE, conventional non-GE, or organic canola crops will continue to implement these reasonable, commonly accepted best management practices for their chosen systems and varieties in agricultural canola production. An additional consideration is that GE canola is planted on the majority of canola acres (95% of acreage in 2008) (Brookes and Barfoot, 2010). Based upon historic trends, conventional production practices that use GE varieties will likely continue to dominate in terms of acreage with or without a determination of nonregulated status of MON 88302 Canola. Given the extensive experience that APHIS, stakeholders, and growers have in implementing the use of GE-canola products, the possible effects to the human environment from the release of an additional GE-canola product are already well known and understood. Therefore, the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*
   A determination of nonregulated status for MON 88302 Canola would not establish a precedent for future actions with significant effects or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and independently undergoes this review process to determine if the regulated article poses a

plant pest risk. Under the authority of the plant pest provisions of the PPA , APHIS has issued regulations (7 CFR part 340) for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as MON 88302 Canola. When a petition for nonregulated status is submitted, APHIS must make a determination about whether or not the GE organism poses a plant pest risk. If APHIS determines, based on its PPRA, that the GE organism is unlikely to pose a plant pest risk, it is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code(U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have enough information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the PPA or the regulations at 7 CFR part 340. The petitioner is required to provide information under §340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*

   No significant cumulative effects were identified through this assessment. The EA discussed cumulative effects on canola management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative effects analysis is provided in Chapter 5 of the EA. In the event APHIS reaches a determination of nonregulated status of MON 88302 Canola, APHIS would no longer have regulatory authority over it. In the event of a determination of nonregulated status of MON 88302 Canola, APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of MON 88302 Canola when added to past, present, and reasonably foreseeable future actions.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.*
   A determination of nonregulated status of MON 88302 Canola will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe's request. Thus, the tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of MON 88302 Canola would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historic resources. This action is limited to a determination of nonregulated status of MON 88302 Canola. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA-registered pesticides. Adherence to EPA label use restrictions for all pesticides by the applicant will mitigate impacts to the human environment. A determination of nonregulated status of MON 88302 Canola is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act (NHPA). In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. An inherent mitigating factor for this issue is that use of these methods is transitory, so they have temporary effects on the audible nature of a site that can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Furthermore, these cultivation practices are already being conducted throughout the canola production regions. The cultivation of MON 88302 Canola would not inherently change any of these agronomic practices, qualitatively or quantitatively, so as to give rise to an impact relevant to the NHPA.

9. *The degree to which the action may adversely affect the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*
   As described in Chapter 4 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of MON 88302 Canola on federally listed threatened and endangered species (TES) 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. After reviewing possible effects of a determination of

nonregulated status of MON 88302 Canola, APHIS has concluded that a determination of nonregulated status of MON 88302 Canola would have no effect on federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*
The proposed action would be in compliance with all Federal, state, and local laws. Because the agency has concluded that MON 88302 Canola is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 88302 Canola is a response that is consistent with the plant pest provisions of the PPA, regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. Monsanto initiated the consultation process with FDA for the commercial distribution of MON 88302 Canola and submitted a safety and nutritional assessment of food and feed derived from MON 88302 Canola to the FDA on March 23, 2011 (Monsanto, 2011). Based on the information Monsanto submitted, and as of April 23, 2012, FDA has no further questions regarding MON 88302 Canola (US-FDA, 2012).

    MON 88302 Canola is compositionally similar to currently marketed canola, with the exception that it provides a product that can be treated with glyphosate at a higher application rate over a broader range of developmental stages than is currently recommended and authorized. Monsanto submitted requests for amended labeling to the U.S. EPA in February 2011 for EPA Registration Numbers 524-537 and 524-549, that propose to modify the current use pattern of glyphosate for MON 88302 Canola (Monsanto, 2011). There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative 2: Determination that MON 88302 Canola is No Longer a Regulated Article. This alternative meets the APHIS purpose and need to allow the safe development and use of GE organisms consistent with the plant pest provisions of the PPA.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of GE

organisms; (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with MON 88302 Canola, the continued regulated status of MON 88302 Canola would be inconsistent with the plant pest provisions of the PPA, regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of MON 88302 Canola will not have any significant environmental effects.

_____ _____

Michael C. Gregoire Date

Deputy Administrator

Biotechnology Regulatory Services

References

AOSCA. (2011). Programs and Services. Association of Official Seed Certifying Agencies. Retrieved December 19, 2012, from http://www.aosca.org/programs%20services.htm.

Brookes, G., & Barfoot, P. (2010). GM Crops: Global Socio-Economic and Environmental Impacts 1996-2008 (pp. 165). PG Economics Ltd, United Kingdom.

Johnson, S.R., Strom, S., & Grillo, K. (2007) Quantification of the Impacts on US Agriculture of Biotechnology-Derived Crops Planted in 2006. (pp. 88). National Center for Food and Agricultural Policy, Washington, DC.

Monsanto. (2011). Monsanto Company Petition for Determination of Nonregulated Status for Herbicide-Tolerant MON 88302 Canola. Submitted by M. Wideman. (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

USDA-APHIS. (2013) Plant Pest Risk Assessment for Event MON 88302 Canola. Riverdale, MD: United States Department of Agriculture, Biotechnology Regulatory Services. Retrieved from

USDA-NASS. (2008). Organic Field Crops Harvested from Certified and Exempt Organic Farms: 2008.

USDA-NASS. (2009). 2007 Census of Agriculture, United States, Summary and State Data

USDA-NASS. (2012). QuickStats Canola Production. Retrieved from http://quickstats.nass.usda.gov/results/2904E4C8-C882-3F85-B141-1DF20129AFB4

US-FDA. (2012). Biotechnology Consultation Agency Response Letter BNF No. 000127 Retrieved February 26, 2013, from http://www.fda.gov/Food/Biotechnology/Submissions/ucm304085.htm