NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

Monsanto
Stearidonic Acid MON 87769 Soybean

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, a Finding of No Significant Impact (FONSI), sets forth 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 determination on the regulated status of a petition request (APHIS Number 09-183-01p) by Monsanto for their transgenic soybean, event MON 87769 (hereafter referred to as MON 87769 Soybean), that is genetically engineered to express high levels of the fatty acid stearidonic acid (SDA) in soybean seed. MON 87769 Soybean is a specialty trait soybean characterized by a fatty acid profile containing SDA, an omega-3 fatty acid, which is not found in conventional soybean (Monsanto, 2010b). SDA (an 18-carbon fatty acid with four double bonds or 18:4) is metabolically converted in humans to eicosapentaenoic acid (EPA; 20:5) and docosahexaenoic acid (DHA; 22:6), both of which may be involved in promoting heart health and other physiologically healthful conditions. These fatty acids may commonly be derived from fish oils, but a soybean source containing SDA that provides a precursor to these would be more efficiently produced in human nutrition. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from a determination of nonregulated status of MON 87769 Soybean. The EA assesses alternatives to a determination of nonregulated status of MON 87769 Soybean and analyzes 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

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §508.14).

genetically engineered (GE) varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). 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's 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 provisions in the Plant Protection Act of 2000, 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. All food and feed derived from GE crops currently on the market in the United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, 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 or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food.

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the FFDCA and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

Regulated Organisms

The APHIS Biotechnology Regulatory Service's (BRS) mission is to protect America's agriculture and environment using a dynamic and 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, which were promulgated pursuant to authority granted by the Plant Protection Act, 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 Plant Protection Act 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 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 Plant Protection Act or the regulations at 7 CFR 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. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS' Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR Part 340, APHIS has issued regulations 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 87769 Soybean. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

Monsanto has submitted a petition (APHIS Number 09-183-01p) to APHIS seeking a determination that their transgenic soybean, MON 87769 Soybean, is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

Stearidonic Acid Monsanto 87769 Soybean

Monsanto has developed a transgenic soybean, MON 87769 Soybean, that is engineered to express high levels of the fatty acid stearidonic acid in soybean seed. As detailed in the petition, smaller amounts of three other fatty acids are produced in addition to the SDA, and expression of linoleic acid is reduced (Monsanto, 2010b). MON 87769 Soybean is a specialty trait soybean characterized by a fatty acid profile containing SDA, an omega-3 fatty acid, which is not found

in conventional soybean. SDA (an 18-carbon fatty acid with four double bonds or 18:4) is metabolically converted in humans to eicosapentaenoic acid (EPA; 20:5) and docosahexaenoic acid (DHA; 22:6), both of which may be involved in promoting heart health and other physiologically healthful conditions. These fatty acids may commonly be derived from fish oils, but a soybean source containing SDA that provides a precursor to these would be more efficiently produced in human nutrition. Since SDA has fewer double bonds than the omega-3 fatty acids, eicosapentaenoic acid (20:5) or docosahexaenoic acid (22:6), SDA soybean oil is more stable to oxidation (i.e., less prone to fishy or rancid odors and taste) than fish oils, thereby expanding the potential formulation options for food companies and food products for consumers.

SDA production in MON 87769 Soybean is accomplished by inserting two desaturase genes, Primula juliae Δ6 desaturase (Pj.D6D) and Neurospora crassa Δ15 desaturase (Nc.Fad3), into a conventional soybean variety. The PjΔ6D and NcΔ15D proteins found in MON 87769 Soybean also produce gamma-linolenic acid (GLA), another fatty acid not in conventional soybean. In MON 87769 Soybean, the NcΔ15D protein converts linoleic acid (LA) to alpha-linolenic acid (ALA) and the protein PjΔ6D converts the ALA to SDA and LA to gamma linolenic acid (GLA) (Monsanto, 2010b).

MON 87769 Soybean would not be grown for the commodity soybean market; instead, it is anticipated that a specialty soybean oil from MON 87769 Soybean would be produced. Compared to commodity soybean oil, SDA soybean oil contains two additional fatty acids, SDA and GLA. SDA omega-3 soybean oil produced from MON 87769 Soybean contains approximately 20 to 30% SDA (weight percent of total fatty acids), 5 to 8% GLA, and slightly higher levels of ALA and palmitic acid than in conventional soybean oil (Monsanto, 2010b). It also contains lower levels of oleic acid and linoleic acid (LA) than those present in conventional soybean oil. Since oleic acid, LA, and ALA are directly involved in the pathway to SDA, their concentrations are inter-related with those of other fatty acids and, therefore, were expected to be different in MON 87769 Soybean seed.

Coordinated Framework Review

Food and Drug Administration

MON 87769 Soybean is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering (57 FR 22984-23005). Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87769 soybean and submitted a safety and nutritional assessment of food and feed derived from MON 87769 soybean to the FDA on March 23, 2009 (BNF No. 00117) (Monsanto, 2010b). FDA is currently evaluating the submission.

FDA also administers the Generally Recognized as Safe (GRAS) Notification Program (US-FDA, 2011). A substance that will be added to food is subject to premarket approval by FDA unless qualified experts determine its use is generally recognized as safe (GRAS). Under the GRAS program (62 FR 18938), a notification procedure is established whereby FDA is notified by a person that they have made a determination that a particular use of a substance is GRAS. FDA evaluates the submission to determine whether a sufficient basis for a GRAS determination has been provided or issues exist on whether use of the substance is GRAS. Monsanto submitted a GRAS Notice for SDA soybean oil (No. GRN 000283) to FDA on February 25, 2009 (US-

FDA, 2009b). FDA issued a response letter on September 4, 2009, indicating the agency has no further questions about the characteristics of the oil, and the safety of its use in foods (US-FDA, 2009a).

Environmental Protection Agency
EPA regulates plant-incorporated protectants (PIPs) under FIFRA (7 U.S.C. 136 et seq.) and certain biological control organisms under TSCA (15 U.S.C. 53 et seq.). MON 87769 Soybean does not express a pesticidal property, and, accordingly, is not regulated by the U.S. EPA.

Scope of the Environmental Analysis
Although a determination of nonregulated status of MON 87769 Soybean would allow for new plantings of MON 87769 Soybean to occur anywhere in the U.S., the scope of analysis of the EA focuses on those areas that are expected to support production of MON 87769 Soybean. According to the developer (Monsanto, 2010a), cultivation of MON 87769 Soybean will be limited to the Northern Tier states of North and South Dakota, Minnesota, Wisconsin, and Michigan. A combination of geographically delimited seed sales, released maturity groups and soybean purchases, and contracts will provide a means to define the production area. A determination of nonregulated status of MON 87769 Soybean is not expected to increase soybean production, or result in an increase in overall GE soybean acreage or cultivation in new regions. In the U.S., soybeans are cultivated in 31 states, with over 77 million acres dedicated to soybean cultivation, projected to increase to nearly 80 million acres by 2020 (USDA-NASS, 2011a, 2011b; USDA-OCE, 2011). Monsanto anticipates that MON 87769 Soybean will provide a niche product, which in five years, if all demand for SDA was provided by this variety, would equate to about 100,000 acres of MON 87769 Soybean being grown in the U.S. (Monsanto, 2010b).

Public Involvement
On December 27, 2011, APHIS published a notice in the Federal Register (76 FR 80,871-80,872, Docket No. APHIS–2011–0095) announcing the availability of the Monsanto petition, and the APHIS PPRA and draft EA for a 60-day public review and comment period. Public comments were solicited for a 60-day public comment period ending February 27, 2012. All comments were carefully analyzed to identify new issues, alternatives, or information. APHIS received a total of 226 comments from various individuals and groups on the MON87769 soybean petition, PPRA, and draft EA. Comment documents may be viewed at http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=APHIS%25E2%2580%25932011%25E2%2580%25930095. The majority of the comments opposed the development and use of genetically engineered foods or MON87769 soybean, while 21 comments supported a determination of nonregulated status of MON87769 soybean. Public comments included individual submissions, form letters, and various electronic media encompassing both the peer-reviewed and non-peer-reviewed literature. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. Responses to substantive comments are included as an attachment to this Finding of No Significant Impact.

Major Issues Addressed in the EA
The issues considered in the EA were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, and for this particular EA, the specific petition seeking a

determination of nonregulated status of MON 87769 Soybean. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other EAs of genetically engineered organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of soybean using various production methods, and the environmental and food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of MON 87769 Soybean.

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 Soybean Production
- Agronomic/Cropping Practices
- Soybean Seed Production
- Organic Soybean Production
- Specialty Soybean Production

Environmental Considerations:

- Water Resources
- Soil and Land Use
- 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
  - Implications for Food Use
  - Implications for Industrial Use
- Trade Economic Environment
- Social Environment

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of MON 87769 Soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87769 Soybean is unlikely to pose a plant pest risk. Based

on its PPRA (USDA-APHIS, 2010) APHIS has concluded that MON 87769 Soybean is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 87769 Soybean is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of MON 87769 Soybean. 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 87769 Soybean and progeny derived from MON 87769 Soybean would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of MON 87769 Soybean and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MON 87769 Soybean.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA that MON 87769 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010). 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 87769 Soybean is No Longer a Regulated Article

Under this alternative, MON 87769 Soybean and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87769 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87769 Soybean and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that MON 87769 Soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87769 Soybean is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. Under this alternative, growers may have future access to MON 87769 Soybean and progeny derived from this event if the developer decides to commercialize MON 87769 Soybean.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87769 Soybean. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, 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 87769 Soybean. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

Prohibit any MON 87769 Soybean 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 87769 Soybean, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MON 87769 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010).

In enacting the Plant Protection Act, Congress found that

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science… § 402(4).

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

> "[D]ecisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency"

Based on our PPRA (USDA-APHIS, 2010) and the scientific data evaluated therein, APHIS has concluded that MON 87769 Soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87769 Soybean.

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 87769 Soybean is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

Isolation distance between MON 87769 Soybean and non-GE soybean 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 87769 Soybean from non-GE soybean production. However, because APHIS has concluded that MON 87769 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of MON 87769 Soybean based on the location of production of non-GE soybean in organic production systems in response to

public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' plant pest risk assessment for MON 87769 Soybean, there are no geographic differences associated with any identifiable plant pest risks for MON 87769 Soybean (USDA-APHIS, 2010). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87769 Soybean does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet 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 Plant Protection Act. Nevertheless, APHIS is not expecting significant effects. However, individuals might choose on their own to geographically isolate their non-GE soybean productions systems from MON 87769 Soybean or to use isolation distances and other management practices to minimize gene movement between soybean fields.

Requirement of Testing For MON 87769 Soybean

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing to identify GE products in non-GE production systems. APHIS notes 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. Additionally, because MON 87769 Soybean does not pose a plant pest risk (USDA-APHIS, 2010), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MON 87769 Soybean would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

Environmental Consequences of 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.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – PPRA (USDA-APHIS, 2010)
Management Practices		
Acreage and Areas of Soybean Production	Unchanged	Unchanged

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Seed Production	Unchanged	Unchanged
Organic Farming	Unchanged	Unchanged
Specialty Soybean	Unchanged	Unchanged
Soybean Cultivation Practices	Unchanged	Unchanged
Physical Environment		
Water Resources	Unchanged	Unchanged
Soil and Land Use	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Biological Resources		
Gene Movement and Weediness	Unchanged	Unchanged
Animals	Unchanged	Unchanged
Plants	Unchanged	Unchanged
Microorganisms	Unchanged	Unchanged
Biological Diversity	Unchanged	Unchanged
Human and Animal Health		
Worker Safety	Unchanged	Unchanged
Risk to Human Health	Unchanged	Unchanged (potential health benefits)
Risk to Animal Feed	Unchanged	Unchanged
Socioeconomic		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Other Regulatory Approvals		
Other U.S Regulatory Approvals	Unchanged for existing nonregulated GE organisms	FDA consultation pending, U.S. EPA tolerance exemptions and conditional pesticide registrations not required.
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

Notes:

1. Unchanged – the current conditions will not change as a result of the selection of this 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 soybean production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets. In the U.S., soybeans were harvested on 76.4 million acres in 2009 and 76.6 million in 2010 (USDA-NASS, 2011a). At least 31 states grew soybean as an annual crop in 2010 (USDA-NASS, 2011a). For the 2010 growing season, more than one million acres of soybeans were grown in each of the following 18 states (from highest to lowest acreage): Iowa, Illinois, Minnesota, Indiana, Missouri, Nebraska, Ohio, Kansas, South Dakota, North Dakota, Arkansas, Michigan, Mississippi, Wisconsin, North Carolina, Tennessee, Kentucky, and Louisiana (USDA-NASS, 2011a). Harvested soybean is projected to slightly increase to nearly 80 million acres by 2020 (USDA-NASS, 2011b; USDA-OCE, 2011). GE soybeans currently are planted on the majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2011). All of these GE soybean varieties are herbicide resistant. A determination of nonregulated status of MON 87769 Soybean is not expected to increase soybean production, or result in an increase in overall GE soybean acreage or cultivation in new regions. There are no anticipated changes to the availability of GE and non-GE soybean varieties on the market. Monsanto anticipates that MON 87769 Soybean will provide a niche product, which in five years, if all demand for SDA were provided by this variety, would equate to about 100,000 acres of MON 87769 Soybean being grown in the U.S. (Monsanto, 2010b). Although a determination of nonregulated status of MON 87769 Soybean would allow for new plantings of MON 87769 Soybean to occur anywhere in the U.S., the scope of analysis of the EA focuses on those areas that are expected to support production of MON 87769 Soybean. According to the developer (Monsanto, 2010a), cultivation of MON 87769 Soybean will be limited to the Northern Tier states of North and South Dakota, Minnesota, Wisconsin, and Michigan. A combination of geographically delimited seed sales, released maturity groups and soybean purchases, and contracts will provide a means to define the production area.

Intensity – Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision:

1. *Impacts that may be both beneficial and adverse.*
   A determination of nonregulated status of MON 87769 Soybean will have no significant environmental impact in relation to the availability of GE, conventional, organic or specialty soybean varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 87769 Soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production or those soybean acres devoted to GE soybean cultivation. The availability of MON 87769 Soybean is not expected to change cultivation areas for soybean production in the U.S., and there are no anticipated

changes to the availability of GE and non-GE soybean varieties on the market. A determination of nonregulated status of MON 87769 Soybean will add another GE variety to the existing soybean market and is not expected to change the market demands for GE soybean or soybean produced using organic methods or specialty systems. MON 87769 Soybean is expected to be cultivated as a high-value specialty soybean product, produced and marketed as an identity protected oil. Monsanto plans to exercise product stewardship in a "closed loop" system (Monsanto, 2010b) and would supervise the sale and movement of the soybean from growers to designated buyers, and then after extraction, continue to oversee the product through a system of required SOPs, contracts and agreements to ultimate users. Under a full stewardship plan (*see* Appendix C of the EA; Appendix 1 (Monsanto, 2010b)) buyers and users of the oil would be given full information about maintaining product segregation, about necessary procedures and equipment, and Monsanto would make themselves available for consulting with entities in the supply chain. Specialty soybean varieties are produced on approximately 12% of the U.S. soybean acreage and, according to the Midwest Shippers Association (MSA, 2009) this acreage could grow to over 25% of the crop acreage in certain states within the next decade. Fehr reported that in 2006, about 700,000 acres in the U.S. were planted to low and ultralow linolenic acid varieties (Fehr, 2007). Based on demonstrated agronomic characteristics and cultivation practices, and because the market share of specialty soybean varieties is unlikely to substantially change following the introduction of MON 87769 Soybean, APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact specialty soybean producers and consumers. Based upon recent trend information, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share. MON 87769 Soybean would be an additional GE variety. GE soybean varieties are currently cultivated on 93% of the U.S. soybean acreage (USDA-ERS, 2010a), and organic varieties comprise less than 1% of the total soybean acreage (USDA-ERS, 2010b). In the affected area, only 0.3% of soybean acreage is organic certified. MON 87769 Soybean should not present any new or different issues and impacts for organic and other specialty soybean producers and consumers. According to the petition, agronomic trials conducted in 2006 and 2007 at 21 field locations in the U.S. demonstrated that MON 87769 Soybean in combined site analysis is not significantly different for plant growth, yield, and reproductive capacity from its nontransgenic counterpart (Monsanto, 2010b; USDA-APHIS, 2010). No differences were observed in pollen diameter, and viability (Monsanto, 2010b; USDA-APHIS, 2010). Consistent with the lack of difference in agronomic properties, MON 87769 Soybean is not expected to have an increased ability to cross pollinate other soybean varieties. Changes in the agronomic practices and locations for soybean seed production using MON 87769 Soybean are not expected. A determination of nonregulated status of MON 87769 Soybean is not expected to result in changes in the current soybean cropping practices, including herbicide use. As discussed in Chapter 4 of the EA, studies demonstrate MON 87769 Soybean is essentially indistinguishable from other soybean varieties used in terms of agronomic characteristics and cultivation practices (Monsanto, 2010b; USDA-APHIS, 2010). Monsanto did not identify any differences between MON 87769 Soybean and conventional soybeans in dormancy, germination potential, disease or insect response, seedling vigor, or plant maturity

(Monsanto, 2010b; USDA-APHIS, 2010). A determination of nonregulated status of MON 87769 Soybean is not expected to alter the use of herbicides currently being used for GE or non-GE soybean production. Similar to farming practices currently used for conventional soybean production, a preplant burndown herbicide would be used, followed by a pre-emergence residual herbicide, with timely post plant herbicide applications (Sprague, 2006). The use of glyphosate as a post-emergent weed herbicide would likely continue to be the pattern for the majority of soybean production. GE soybeans currently are planted on the majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2011). All of these GE soybean varieties are herbicide resistant. Monsanto has stated that MON 87769 Soybean would be stacked with either glyphosate or other available nonregulated herbicide resistance traits (Monsanto, 2010a). It is anticipated that herbicide use will continue the trends noted by Beckie and Tardif (2012) associated with the wide use of glyphosate-tolerant soybean along with crops stacked with multiple herbicide resistances as they are available or become so, and that alternative herbicides will more frequently be used sequentially, or in mixtures, or as required in crop rotations, to manage herbicide resistant weed populations. Use of pest control strategies, such as those for insects or pathogens would also be unchanged.

2. *The degree to which the proposed action affects public health or safety.*

A determination of nonregulated status of MON 87769 Soybean would have no significant impacts on human or animal health. Monsanto's intention in developing MON 87769 Soybean is to provide a plant source of omega-3 fatty acid that can efficiently be converted to the long chain polyunsaturated fatty acids, eicosapentaenoic acid and docosahexaenoic acid, which are important in prevention or improvement of human health conditions. As discussed in Chapter 4 of the EA, Monsanto's data (Monsanto, 2010b) suggest that enhancing food oils with the soybean oil extracted from the MON 87769 Soybean may have a positive impact on human health when used in many foods for which it is suitable. The addition of SDA using oil derived from MON 87769 Soybean oil may benefit many health conditions, both as preventative and as remedial. The extent to which positive benefits may be observed is contingent upon the market share of the MON 87769 Soybean and the types of food products to which manufacturers add the modified oil. Monsanto submitted a GRAS Notice for SDA soybean oil (No. GRN 000283) to FDA on February 25, 2009 (US-FDA, 2009b). FDA issued a response letter on September 4, 2009, indicating the agency has no further questions about the characteristics of the oil, and safety of its use in foods (US-FDA, 2009a). Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87769 Soybean and submitted a safety and nutritional assessment of food and feed derived from MON 87769 Soybean to the FDA on March 23, 2009 (BNF No. 00117) (Monsanto, 2010b). FDA is currently evaluating the submission. Monsanto has stated that MON 87769 Soybean would be stacked with either glyphosate or other available nonregulated herbicide resistance traits (Monsanto, 2010a). As discussed in Chapter 5 of the EA, the CP4 EPSPS protein that confers tolerance to glyphosate is structurally homologous and similar functionally to endogenous plant EPSPS enzymes and is identical to the CP4 EPSPS in other commercially available Roundup Ready® crops, including Roundup Ready® soybean (40-3-2 and MON 89788), Roundup Ready® canola, Roundup Ready® sugar beet, Roundup Ready® flax, and Roundup Ready® cotton (USDA-APHIS, 2010). The safety of CP4 EPSPS protein present in

biotechnology derived crops has been evaluated as part of comprehensive reviews of the safety of glyphosate exposure and ingestion (Harrison et al., 1996; Hammond et al., 1996; Padgette et al., 1996). The EPA has also reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities (US-EPA, 1996; 40 CFR §174.523). The CP4 EPSPS protein that could be stacked with MON 87769 Soybean is the same as that previously reviewed by the EPA. Accordingly, if Monsanto stacks MON 87769 Soybean with a soybean variety that confers tolerance to glyphosate, it is anticipated that this stacked variety would be safe for human and animal consumption with regard to the cp4 epsps gene. Based on FDA's response letter (US-FDA, 2009a); APHIS' review of field and laboratory data and scientific literature provided by Monsanto (Monsanto, 2010b); and safety data available on other GE soybean including those that are tolerant to glyphosate, APHIS has concluded that a determination of nonregulated status of MON 87769 soybean 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 87769 Soybean. 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; do not cause any alterations of property, wildlife habitat, or landscapes; and 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 87769 Soybean. The product will be deployed on agricultural land currently suitable for production of soybean and is not expected to increase the acreage of soybean production. This action would not convert land use 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 87769 Soybean, 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 87769 Soybean, 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 soybean 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 87769 Soybean are not highly controversial. Although there is some opposition to a determination of nonregulated status of MON 87769 Soybean, 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 of MON 87769 Soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production or those soybean acres

devoted to GE soybean cultivation. The availability of MON 87769 Soybean is not expected to change cultivation areas for soybean production in the U.S., and there are no anticipated changes to the availability of GE and non-GE soybean varieties on the market. MON 87769 Soybean is not expected to result in changes in the current soybean cropping practices, including pesticide use. It is anticipated that herbicide use will continue the trends noted by Beckie and Tardif (2012) associated with the wide use of glyphosate-tolerant soybean along with crops stacked with multiple herbicide resistances as they are available or become so, and that alternative herbicides will more frequently be used sequentially, or in mixtures, or as required in crop rotations, to manage herbicide resistant weed populations. Use of pest control strategies, such as those for insects or pathogens would also be unchanged. The effect of MON 87769 Soybean on wildlife or biodiversity is no different than that of other GE or non-GE soybean produced in conventional agriculture in the U.S. Cultivation of MON 87769 Soybean is highly unlikely to have toxic effects on non-target organisms and is likely to be neutral to biodiversity compared with conventionally managed GE and non-GE soybean. During the public comment period, APHIS received comments opposing a determination of nonregulated status of MON 87769 Soybean. 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 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 87769 Soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production or those soybean acres devoted to GE soybean cultivation. Monsanto's field trial and laboratory analyses demonstrated that the agronomic performance of MON 87769 soybean was functionally identical to its non-transgenic counterpart (Monsanto, 2010b). No increases in fertilizers and pesticides were required, nor were any changes in cultivation, planting, harvesting, and volunteer control required (Monsanto, 2010b). According to the petition, agronomic trials conducted in 2006 and 2007 at 21 field locations in the U.S. demonstrated that MON 87769 Soybean in combined site analysis is not significantly different for plant growth, yield, and reproductive capacity from its nontransgenic counterpart (Monsanto, 2010b; USDA-APHIS, 2010). No differences were observed in pollen diameter, and viability (Monsanto, 2010b; USDA-APHIS, 2010). Consistent with the lack of difference in agronomic properties, MON 87769 Soybean is not expected to have an increased ability to cross pollinate other soybean varieties. Changes in the agronomic practices and locations for soybean seed production using MON 87769 Soybean are not expected. A determination of nonregulated status of MON 87769 Soybean is not expected to result in changes in the current soybean cropping practices, including pesticide use. It is anticipated that herbicide use will continue the trends noted by Beckie and Tardif (2012) associated with the wide use of glyphosate-tolerant soybean along with crops stacked

with multiple herbicide resistances as they are available or become so, and that alternative herbicides will more frequently be used sequentially, or in mixtures, or as required in crop rotations, to manage herbicide resistant weed populations. Use of pest control strategies, such as those for insects or pathogens would also be unchanged. The effect of MON 87769 Soybean on wildlife or biodiversity is no different than that of other GE or non-GE soybean produced in conventional agriculture in the U.S. Cultivation of MON 87769 Soybean is highly unlikely to have toxic effects on non-target organisms and is likely to be neutral to biodiversity compared with conventionally managed GE and non-GE soybean. As described in Chapter 4 of the EA, well established management practices, production controls, and production practices (GE, conventional, specialty and organic) are currently being used in soybean production systems (commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional soybean (GE and non-GE varieties), MON 87769 Soybean, or produce soybean using organic methods or specialty systems, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural soybean production. MON 87769 Soybean will add another GE variety to the existing soybean market and is not expected to change the market demands for GE soybean or soybean produced using organic methods or specialty systems. MON 87769 Soybean is expected to be cultivated as a high-value specialty soybean product, produced and marketed as an identity protected oil. Monsanto plans to exercise product stewardship in a "closed loop" system (Monsanto, 2010b) and would supervise the sale and movement of the soybean from growers to designated buyers, and then after extraction, continue to oversee the product through a system of required SOPs, contracts and agreements to ultimate users. Under a full stewardship plan (see Appendix C of the EA; Appendix 1 (Monsanto, 2010b)) buyers and users of the oil would be given full information about maintaining product segregation, about necessary procedures and equipment, and Monsanto would make themselves available for consulting with entities in the supply chain. Specialty soybean varieties are produced on approximately 12% of the U.S. soybean acreage and, according to the Midwest Shippers Association (MSA, 2009) this acreage could grow to over 25% of the crop acreage in certain states within the next decade. Fehr reported that in 2006, about 700,000 acres in the U.S. were planted to low and ultralow linolenic acid varieties (Fehr, 2007). Cultivation of MON 87769 Soybean as a new specialty soybean variety should not present any new or different issues and impacts for specialty soybean producers and consumers. Based on demonstrated agronomic characteristics and cultivation practices, and because the market share of specialty soybean varieties is unlikely to substantially change following the introduction of MON 87769 Soybean, APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact specialty soybean producers and consumers. Additionally, GE soybeans currently are planted on the majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2011). All of these GE soybean varieties are herbicide resistant. A determination of nonregulated status of MON 87769 Soybean is not expected to increase soybean production, or result in an increase in overall GE soybean acreage or cultivation in new regions. There are no anticipated changes to the availability of GE and non-GE soybean varieties on the market. Monsanto anticipates that MON 87769 Soybean will provide a niche product, which in five years, if all demand for SDA was provided by this variety,

would equate to about 100,000 acres of MON 87769 Soybean being grown in the U.S. (Monsanto, 2010b). Given the extensive experience that APHIS, stakeholders, and growers have in dealing with the use of GE soybean products and specialty soybean varieties, the possible effects to the human environment from the release of a an additional GE soybean 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 of MON 87769 Soybean 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 upon an independent determination 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 undergoes this independent review to determine if the regulated article poses a plant pest risk. Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR Part 340, APHIS has issued regulations 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 87769 Soybean. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, 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 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 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 Plant Protection Act or the regulations at 7 CFR 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. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

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 soybean production practices, physical environment,

biological resources, human and animal health, and socioeconomic impacts and concluded that such impacts were not significant. A cumulative effects analysis for each environmental issue is included in Chapter 5 of the EA. In the event of a determination of nonregulated status, MON 87769 Soybean may be stacked (combined) with non-GE and GE soybean varieties by traditional breeding techniques, resulting in a plant that, for example, may also be resistant to herbicides. There is no assurance that MON 87769 Soybean will be stacked with any particular non-GE or GE soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, as company plans and market demands play a significant role in those business decisions. Thus, predicting all potential combinations of stacked varieties that could be created using both non-GE and GE soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 is hypothetical and purely speculative. Monsanto has stated that MON 87769 Soybean would be stacked with either glyphosate or other available nonregulated herbicide resistance traits (Monsanto, 2010a). If MON 87769 Soybean is stacked with the glyphosate tolerance trait, growers would continue to use glyphosate predominately for post-emergent weed control. The Roundup Ready® soybean system has become the standard weed control program in the U.S. cultivation of soybean. Approximately 92% of the U.S. soybean acreage is planted in Roundup Ready® soybean varieties. Monsanto anticipates that MON 87769 Soybean will not replace commodity type glyphosate-tolerant soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. Rather, MON 87769 Soybean will remain a minor product with limited acreage. Monsanto anticipates that MON 87769 Soybean will provide a niche product, which in five years, if all demand for SDA was provided by this variety, would equate to about 100,000 acres of MON 87769 Soybean being grown in the U.S. (Monsanto, 2010b). In the event of a determination of nonregulated status of MON 87769 Soybean, 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 87769 Soybean when added to other 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 historical resources.

A determination of nonregulated status of MON 87769 Soybean is not expected to adversely impact cultural resources on tribal properties. Any farming activity 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 87769 Soybean 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 historical resources. This action is limited to a determination of nonregulated status of MON 87769 Soybean. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87769 Soybean, 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. A determination of nonregulated status of MON 87769 Soybean 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. 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. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the soybean production regions. The cultivation of MON 87769 Soybean does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

9. *The degree to which the action may adversely affect an 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 6 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of MON 87769 Soybean on federally listed threatened and 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. After reviewing possible effects of a determination of nonregulated status of MON 87769 Soybean, APHIS has determined that a determination of nonregulated status of MON 87769 Soybean would have no effect on federally listed threatened or endangered species 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 87769 Soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87769 Soybean 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. MON 87769 Soybean falls within the scope of the 1992 FDA's policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA, 1992). Monsanto submitted a GRAS Notice for SDA soybean oil (No. GRN 000283) to FDA on February 25, 2009 (US-FDA, 2009b). FDA issued a response letter on September 4, 2009, indicating the agency has no further questions about the characteristics of the oil, and safety of its use in foods (US-FDA, 2009a). Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87769 Soybean and submitted a safety and nutritional assessment of food and feed derived from MON 87769 Soybean to the FDA on March 23, 2009 (BNF No. 00117) (Monsanto, 2010b). FDA is currently evaluating the submission. The EPA regulates plant-incorporated protectants (PIPs) under FIFRA (7 U.S.C. 136 et seq.) and certain biological control organisms under TSCA (15 U.S.C. 53 et seq.). MON 87769 Soybean does not express a pesticidal property, and, accordingly, is not regulated by the

EPA. 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 87769 Soybean is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the Plant Protection Act.

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 genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with MON 87769 Soybean, the continued regulated status of MON 87769 Soybean would be inconsistent with the plant pest provisions of the PPA, the 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 87769 Soybean will not have any significant environmental effects.

Michael C. Gregoire

5/15/2012

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

Date:

Literature Cited:

Beckie, H.J. and Tardif, F.J. (2012). Herbicide cross resistance in weeds. Crop Protection 35, 15-28.

Fehr, WR. (2007). Breeding for Modified Fatty Acid Composition in Soybean. *Crop Sci., 47*((S3)), S72-S87

Hammond, BG, Vicini, JL, Hartnell, GF, Naylor, MW, Knight, CD, Robinson, EH, Fuchs, RL, and Padgette, SR. (1996). The feeding value of soybeans fed to rats, chickens, catfish and dairy cattle is not altered by genetic incorporation of glyphosate tolerance. *The Journal of Nutrition, 126*(3), 717-727.

Harrison, LA, Bailey, MR, Naylor, MW, Ream, JE, Hammond, BG, Nida, DL, Burnette, BL, Nickson, TE, Mitsky, TA, Taylor, ML, Fuchs, RL, and Padgette, SR. (1996). The expressed protein in glyphosate-tolerant soybean, 5-enolypyruvylshikimate-3-phosphate synthase from *Agrobacterium* sp. strain CP4, is rapidly digested in vitro and is not toxic to acutely gavaged mice. *The Journal of Nutrition, 126*(3), 728-740.

Monsanto (2010a). Phone Record. C.Roseland Conversation with Cherian George, Monsanto Co. Submitted by Registration Manager.

Monsanto (2010b). Petition for the Determination of Non-Regulated Status for MON 87769. Submitted by C George and GJ Rogan, Registration Manager. Monsanto Company, St. Louis MO

MSA (2009). Market Trends for IP Crops Retrieved November 29, 2010, from http://www.mnshippers.com/html/news.cfm?ID=44

Padgette, SR, Re, DB, Barry, GF, Eichholtz, D, Delannay, X, Fuchs, RL, Kishore, G, and Fraley, RT. (1996). New weed control opportunities: Development of soybeans with a Roundup Ready gene. In SO Duke (Ed.), *Herbicide Resistant Crops: Agricultural, Environmental, Economic, Regulatory, and Technical Aspects* (pp. 53–84). New York: Lweis Publishers.

Sprague, C (2006). Growing non-GMO soybeans: What do you need to know? Michigan State Crop and Soils Department. Retrieved 2011 from http://ipmnews.msu.edu/fieldcrop/fieldcrop/tabid/56/articleType/ArticleView/articleId/1884/categoryId/2/Growing-nonGMO-soybeans-What-do-you-need-to-know.aspx

US-EPA (1996). 40 CFR Part 180 Plant Pesticide Inert Ingredient CP4 Enolpyruvylshikimate-3-D and the Genetic Material Necessary for Its Production in All Plants. *Federal Register, 61*(150), 40338-40340.

US-FDA (1992). Statement of Policy - Foods Derived from New Plant Varieties. Retrieved January 18, 2011, from http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096095.htm

US-FDA (2009a).Agency Response Letter GRAS Notice No. GRN 000283. U.S. Food and Drug Administration, Washington, D.C. Last accessed from http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm185688.htm

US-FDA (2009b).GRAS Notice for Stearidonic (SDA) Omega-3 Soybean Oil. Center for Food Safety and Applied Nutrition (CFSAN)

USDA-APHIS (2010). Plant Pest Risk Assessment for MON 87769 Soybean. (Report: Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html

USDA-ERS (2010a). Adoption of Genetically Engineered Crops in the U.S. - Soybeans Varieties Retrieved November 29, 2010 from http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable3.htm

USDA-ERS (2010b). Table 3--Certified Organic and Total U.S. Acreage, Selected Crops and Livestock, 1995-2008 Economic Research Service. Retrieved November 5, 2010 from http://www.ers.usda.gov/Data/Organic/

USDA-ERS (2011). Adoption of Genetically Engineered Crops in the U.S. Genetically Engineered Soybean Varieties. Retrieved from http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable3.htm

USDA-NASS (2011a). Acreage. Washington, DC. Last accessed 9-29-2011, from http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2011.pdf

USDA-NASS (2011b). USDA Long-Term Agricultural Projection Tables. Table 24: U.S. soybeans and soybean products long-term projections Washington, DC. Last accessed 9-30-2011, from http://usda.mannlib.cornell.edu/MannUsda/viewStaticPage.do?url=http://usda.mannlib.cornell.edu/usda/ers/94005/./2011/index.html

USDA-OCE (2011). USDA Agricultural Projections to 2020. USDA, Office of the Chief Economist, World Agricultural Outlook Board, Washington, D.C. Last accessed September 30, 2011, from http://usda.mannlib.cornell.edu/usda/ers/94005/2011/OCE111.pdf

Attachment
Finding of No Significant Impact
Response to Comments
Petition 09-183-01p

On December 27, 2011, APHIS published a notice in the Federal Register (76 FR 80,871-80,872, Docket No. APHIS–2011–0095) announcing the availability of the Monsanto petition, and the APHIS PPRA and draft EA for a 60-day public review and comment period. Public comments were solicited for a 60-day public comment period ending February 27, 2012. APHIS received a total of 226 comments from various individuals and groups on the MON 87769 Soybean petition, PPRA, and draft EA. Comment documents may be viewed at http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=APHIS%25E2%2580%25932011%25E2%2580%25930095. The majority of the comments opposed the development and use of genetically engineered foods or MON 87769 Soybean, while 21 comments supported a determination of nonregulated status of MON 87769 Soybean. Public comments included individual submissions, form letters, and various electronic media encompassing both the peer-reviewed and non-peer-reviewed literature.

APHIS received 21 public comments supporting a determination of nonregulated status of MON 87769 Soybean and these were submitted from farmers expecting a new product to increase soybean sales (7), soybean grower associations (2), food research and development companies (6), nutritionists and medical research professionals (5), and one food products manufacturer. Those individuals and entities cited the potential benefits of MON 87769 Soybean, including: 1) health benefits of providing a sustainable, accessible land-based source of an omega-3 fatty acid that would be more useable in foods; 2) increased economic benefit for growers because this specialty crop may be able to restore the previous market position of soybean oils; and 3) a first GE crop whose benefits were primarily for consumers and not producers of soybean,

There were over 200 single-entry public comments received opposing a determination of nonregulated status of MON 87769 Soybean submitted by individuals and non-governmental organizations (NGO). Two organizations involved in oil processing and another in grain handling and grain exports opposed a determination of nonregulated status of MON 87769 because certain parts of Monsanto's stewardship plans were not addressed to their satisfaction. One environmental advocacy group submitted a portfolio containing 12,873 letters of nearly identical material. Many of the public comments expressed a general opposition to genetically modified organisms (GMOs) or GE crops and the domestic regulatory process surrounding GE plants; perceived negative effects on public and animal health, biodiversity, and the environment; and a lack of consideration regarding organic production systems and the right of the public to choose non-GE containing food products. The majority of these public comments did not explain or identify specific elements in the MON 87769 Soybean PPRA or EA that were perceived to be inadequate or provide any supporting evidence for their claims. Several specific issues related to the MON 87769 EA were, however, identified from the collective pool of public comments and form letter submissions. These were organized into categories and addressed below.

Socioeconomic Impacts

Comment 1: A soybean grower says that improved (that is, supplying SDA) and affordable soybean seed supplying oil for new food applications will allow farmers to regain share in the US vegetable oil supply. Market share had been lost to other oils because functional properties of soybean oils needed improvement. When these properties are altered with hydrogenation, the process incidentally forms undesirable trans-fats. Trans-fat labeling was instituted by FDA, and soybean oils began to be replaced with other vegetable oils, including imported oils.

APHIS Response 1: APHIS agrees that this product will provide a crop that will promote development of new markets. However, these are unlikely to displace other soybean varieties or oilseed crops, because this is not a general purpose soybean product, but one that will be used for special nutritional augmentation of foods. Monsanto does not expect that production of this crop will be widely adopted (Monsanto, personal communication, 2011), nor extensively planted geographically, especially since the intent is to focus production on a limited number of northern soybean producing states.

Comment 2: Do not approve the new stearidonic acid soybean because the more genetically engineered products Monsanto makes, the more control they have over independent farmers, and the more risk they pose to non-genetically engineered crops.

APHIS response 2: Although APHIS recognizes that new technologies developed and owned by a private firm have the potential to lead to increased market concentration when introduced in the market, introduction of new technologies or increased market concentration do not in themselves lead to unfair competition. Fair competition and business practices are enforced through United States anti-trust laws and institutions and are beyond the scope of this EA. Soybean growers will continue to have multiple seed sources for those varieties that are genetically modified with desirable agronomic traits, including those with other fatty acid profiles and herbicide tolerance. APHIS does not expect that this SDA soybean will significantly increase the soybean production in the US, but rather may lead to substitution of a limited number of acres with this specialty soybean, as noted in the EA. Growers with a need for non-GE and non-specialty seed will continue to find the desired varieties available to supply the type of commodity product they wish to sell, since acreage in cultivation with the MON 87769 seed will likely be small.

As presented in the EA, this crop does not create any additional risk issues for non-genetically engineered crops and that organic growers have been successfully cooperating with neighboring growers under conventional agriculture to achieve legal requirements for labeling produce as organic. Organic growers in a survey overwhelmingly indicated (88%) that they do not have concerns for admixture of GE traits into their seed supply (Organic-&-Non-GMO-Report (2010). If inadvertent pollination did occur in a few instances, they are not disqualified from using the organic label on produce provided that they have adhered to all USDA organic standards (USDA AMS, 2012).

Organic-&-Non-GMO-Report (2010) Survey: organic farmers want seed tested for GMOs. Organic & Non GMO Report, 10(4), 7. http://www.non-gmoreport.com/downloadables/org&nongmo_april10.pdf. Evergreen Publishing, Inc.

USDA AMS (2012). National Organic Plan, http://www.ams.usda.gov/AMSv1.0/nop). USDA Agricultural Marketing Service.

Comment 3: One industry organization for oil processors said they cannot support commercialization ahead of major market approvals and considers a "pre-commercial release" no different than a product commercialization since the potential risks and impacts are the same. The organization cannot support, and urges technology developers to fully bear the risks and liabilities associated with, any commercialization of their products ahead of major market approvals. The organization does not believe the oilseed sector should be expected to absorb the financial costs associated with export testing program at origin and /or product rejection at destination.

APHIS Response 3: Monsanto has indicated in their petition requesting nonregulated status of MON 87769 Soybean that the necessary regulatory submissions will be made by the petitioner to countries that import significant quantities of soybean or its processed fractions from the U.S. (Monsanto, 2010). Regulatory packages will only be submitted to those countries which have established regulatory approval processes; notifications will be given those importing countries without formal approval systems (Monsanto, 2010). During the time international authorizations for soybean are being sought for likely importing countries, Monsanto proposes to grow and market this product under a Closed Loop System (Monsanto, 2010). Monsanto would supervise the sale and movement of the soybean from growers to designated buyers, and then after extraction, continue to oversee the product through a system of required SOPs, contracts and agreements to ultimate users Historically, the identity of other types of soybean oils have been maintained using closed loop mechanisms, and with full integrity (e.g., low linolenic acid varieties during early production years, low saturate soybean, etc. (Elbehri, 2007); various commercial specialty oilseeds supplied to processors, Clarkson, 2004)). Deployment of a closed loop system is consistent with the recommendations of soybean industry organizations which have requested "rigorous systems" to prevent unapproved (in the importing country) soybean varieties from entering foreign channels during trait development and seed production (ASA, 2011 download). APHIS is not aware of any large scale failures of these IP procedures when the developer has instituted concerted stewardship efforts. In the EA, APHIS assesses that impacts resulting from adverse events, such as admixture of other specialty oil following a determination of nonregulated status of MON 87769 Soybean would not be different in consequence from those occurring under the No Action Alternative.

While industry would appreciate assurance that adverse incidents would receive compensation from developers, APHIS assessment in the EA does not indicate that such events would cause significant overall impacts to U.S. trade. Given the types of agreements, SOPs and practices that will be actuated in the proposed management system, these events are likely to be infrequent and their consequence in all likelihood not significant. If these types of events were to occur, potential impacts would be expected to be minimal. As Monsanto notes in the Addendum to the petition, one typical oil quality parameter important to oil users, oxidative stability, did not exceed that of typical soybean oil when up to 12.5% MON 87769 oil was mixed with commodity oil. At the farm level, an exceptionally large number of misdirected trucks carrying MON 87769 Soybean would be needed to effect significant change in the parameters characteristic of

commodity soybean oil, given the large dilution volumes to which these oils are typically subjected (see EA Appendix C, Monsanto Co. (2011), Addendum to Petition). The introduction of closed loop systems is one strategy that Monsanto hopes will be an interim measure to deal with market uncertainties before export market approvals are completed.

ASA. (2011 download). ASA Position. Biotechnology [Commercialization of deregulated traits in major foreign markets]. American Soybean Association. http://www.soygrowers.com/issues/biotechnology.htm

Clarkson, L. (2004). Niche oilseeds require identity preservation. Processing Article. Inform 15 (8) 513 http://aocs.files.cms-plus.com/inform/2004/8/niche.pdf

Elbehri, A. (2007). The Changing Face of the U.S. Grain System: Differentiation and Identity Preservation Trends, ERR-35. U.S. Dept. of Agr., Econ. Res. Serv. Feb. 2007.

Monsanto Co. (2010). Petition for the Determination of Nonregulated Status for Improved Fatty Acid Profile MON 87705 Soybean. Submitted by G. Rogan. Monsanto Company, St. Louis, MO (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

Monsanto Co. (2011). Potential Market Impact of MON 87769. Addendum to Petition. Submitted July, 2011.

Comment 4: Monsanto recognized the need to establish a closed-loop supply chain to keep this product segregated and ensure that MON 87769 does not escape into the commodity supply chain above the impact level/threshold. The organization appreciates the level of detail that Monsanto has outlined in terms of its grain channeling plan and obligations that will be required of participants in Monsanto's supply chain program.

APHIS Response 4: APHIS agrees that this plan represents an adequate stewardship plan to maintain confinement and segregation for this new soybean variety.

Comment 5: A grain and feed handling organization and a grain export organization concurred that they would not support non-regulated status until Monsanto provides written assurances to value-chain stakeholders and as part of the public record of this proceeding that it will commit to implementing its closed loop system and accept such commercial responsibility for supply chain disruptions throughout the lifecycle of this biotechnology-enhanced event once the trait is deregulated and commercialized.

APHIS Response 5: While this comment is directed towards domestic liabilities should the closed loop scheme fail to keep general commodity and SDA soybeans separate, the concerns are similar to those addressed in Comment 3 above with respect to the trade implications, and the APHIS Response is the same.

Comment 6: The burden of gene movement by transgenic crop pollen into organic production is on the organic grower. Appropriate buffers may be too small, and delayed planting dates may

cause decreased crop production for the organic grower. The USDA's standards prohibit GE crops. Seed testing may be a costly investment for the non-GE grower.

APHIS Response 6: Growers have, for decades, been successfully growing crops bearing different traits and often on adjoining fields despite the method by which traits were introduced (conventional breeding or recombinant DNA technology). Growers have always had the choice of what crops to grow, and have had to contend with commingling, admixtures, and other unintended material in their crops (Ronald and Fouche, 2006). Studies of coexistence of major GE and non-GE crops in North America and the European Union (EU) have demonstrated that there has been no significant introgression of GE genes, and that GE and non-GE crops are coexisting with minimal economic effects (Brookes and Barfoot, 2004a; Brookes and Barfoot, 2004b; Gealy et al., 2007). Ultimately, under NOP regulations, organic producers are obligated to manage their operations to avoid unintentional contact with excluded methods. Isolation distances, reproductive isolation (e.g., staggering planting dates or growing soybeans with differential maturity times), and farmer communication can be successfully used to minimize the effects of pollen-mediated gene flow.

As noted by Ronald and Fouche (2006), "While 100% purity (zero tolerance for any undesired components) is very difficult to attain for any agricultural commodity, standard procedures involving spatial separation, border rows, planting dates, maturity dates, cleaning of equipment, and post-harvest handling have traditionally been able to provide products that meet diverse market requirements." The NOP specifically discusses buffer zones and defines them as areas located between a certified organic production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact with prohibited substances applied to adjacent land areas and the organic grower can incur costs associated with the establishment of these buffer zones. As presented in Section 4.2 of the EA, it is clear that organic soybean acreage has remained relatively stable in spite of concurrent increases and overwhelming adoption of GE soybean production, suggesting that current methods to limit soybean gene flow are sufficient and that the large presence of GE soybean has not negatively impacted the cultivation of soybean by organic methods.

The possible cost to organic producers resulting from proximity to GE-based agriculture is dependent upon the acceptable level of GE material that may be inadvertently present and on consumers' expectations and perceptions. The NOP identifies four levels of product composition for organic agriculture certification (7 CFR 205.301): 1) 100 percent organic; 2) 95 percent or more organic; 3) 70 to 95 percent organic; and 4) less than 70 percent organic. A third party organic certification system based on thresholds is also in place to reassure organic customers (Non-GMO-Project, 2010). If there is a negative public perception of the adventitious presence of GE material in organically-produced products, profitability of an organic enterprise may be diminished through the loss of price premiums earned by these products. Survey evidence presented in the Brookes and Barfoot (2004a) study showed that the vast majority (92 percent) of U.S. organic farmers had not incurred any direct additional costs or incurred losses due to GE crops having been grown near their crops. According to the report, four percent had experienced lost organic sales or downgrading of produce as a result of GE organism presence and the remaining four percent of farmers had incurred small additional costs only for testing.

However, as observed in Apted and Mazur (2007), the Brookes and Barfoot (Brookes and Barfoot, 2004a) study was not able to quantify the impact of measures undertaken by organic producers to avoid GE material coming into contact with organic crops. Nonetheless, there is data to indicate that farmers using organic production systems are being compensated for the unidentified costs associated with meeting any contractual obligations and NOP standards for corn produced through organic systems. For example, in April 2007-March 2008, conventional corn averaged $3.67/bushel (USDA-NASS, 2011), whereas organic corn averaged $9.69/bushel in the same time period (USDA-ERS, 2011).

NOP approved practices can be sufficient to maintain the integrity of a crop and the purity of seed, especially if there are economic/market motivations to implement these practices, e.g., for organic farmers who receive higher price premiums for their crop (Ronald and Fouche, 2006). In terms of purity, for example, a bag of "pure" seed corn will cost $100 per bag, whereas one that exceeds the 5% tolerance is worth $2 per bag (Fernandez and Polansky, 2006).

In one survey of organic growers, testing by seed producers for the presence of GE was desired by a large percentage (72%), but the overwhelming number (88%) said that presence of GE traits in the current seed stock was not a major concern (Organic & Nonorganic Report, 2010). Major buyers of organic commodities have allowances for a certain percentage of GE traits (such as 0.5% for high risk food items (Non-GMO Project, 2012 download)). While some buyers may require testing for unintentional GE trait content, this is one of the costs that presumably make organic products more costly at purchase, and for which the grower is reimbursed.

In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS 2012). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced. Consequently, USDA-certified organic labeling requires that growers develop and submit an organic production plan in order to outline the steps taken to avoid contact or mixing with the products of excluded methods (e.g., non-approved synthetic pesticides or fertilizers). In accordance with NOP regulations, organic operators are required to manage the potential exposure of organic commodities with other substances not approved for use in organic production systems, whether from the non-organic portion of a split operation or from neighboring farms. The use of GE products is specifically prohibited in organic production and handling; however, the inadvertent presence of GE material in organic products is not sufficient to preclude USDA-certified organic labeling if the organic producer followed his/her submitted organic production plan (USDA-AMS, 2012). Implementation of procedures to maintain seed and commodity integrity within the context of an individual organic system plan required for NOP certification has proven effective in preventing the presence of excluded materials in certified organic products.

Apted S and Mazur K (2007) Potential Impacts from the Introduction of Gm Canola on Organic Farming in Australia, Abare Research Report 07.11. Prepared for the Australian Government Department of Agriculture, Fisheries and Forestry. Retrieved October, 2011 from http://adl.brs.gov.au/data/warehouse/pe_abare99001362/organic_farming.pdf

Brookes, G. and Barfoot, P. (2004a) Co-Existence in North American Agriculture: Can Gm Crops Be Grown with Conventional and Organic Crops? Dorchester, UK: PG Economics Ltd.

Brookes, G. and Barfoot, P. (2004b) Coexistence of Gm and Non-Gm Crops: Case Study of Maize Grown in Spain. Dorchester, Uk: Pg Economics Ltd.

Fernandez, M. and Polansky, A. (2006). Presented at Peaceful Coexistence Among Growers of: Genetically Engineered, Conventional, and Organic Crops. Summary of a Multi-Stakeholder Workshop, Boulder, CO.

Gealy, D., Bradford, K., Hall, L., Hellmich, R., Raybould, A, Wolt, J, and Zilberman, D. (2007). Implications of Gene Flow in the Scale-up and Commercial Use of Biotechnology-Derived Crops: Economic and Policy Considerations. Council for Agricultural Science and Technology (CAST).

Non-GMO-Project (2010) Non-Gmo Project. Retrieved July 31, 2010, from http://www.nongmoproject.org/

Non-GMO Project. (2009). Non-GMO Project Working Standard. http://www.nongmoproject.org/wp-content/uploads/2009/06/NGP-Standard-v8-Final1.pdf

Organic-&-Non-GMO-Report (2010) Survey: organic farmers want seed tested for GMOs. Organic & Non GMO Report, 10(4), 7. http://www.non-gmoreport.com/downloadables/org&nongmo_april10.pdf. Evergreen Publishing, Inc.

Ronald, P. and Fouche, B. (2006). Genetic Engineering and Organic Production Systems. University of California, Agriculture and Natural Resources. Retrieved September 2011, from http://ucanr.org/freepubs/docs/8188.pdf

USDA-ERS (2011). Organic Prices. United States Department of Agriculture, Economic Research Service. Retrieved October, 2011 from http://www.ers.usda.gov/data/OrganicPrices/

USDA-NASS. (2011). Quick Stats 2.0. Survey. Corn Prices/bushel. Washington, DC. Last accessed 4-18-2012, from http://www.nass.usda.gov/Quick_Stats/index.phpUSDA AMS (2012). National Organic Plan. http://www.ams.usda.gov/AMSv1.0/nop.

USDA AMS (2012). National Organic Plan. http://www.ams.usda.gov/AMSv1.0/nop.

Comment 7: Cross pollination in non-GE soybean deriving from this transgenic crop could result in lawsuits from the technology companies.

APHIS Response 7: APHIS acknowledges the comment, but notes that because soybean is mostly self-pollinating, this issue is not significant in non-GE soybean production.

Comment 8: Minimal nutritional benefits of these omega-3 seeds may be easily exceeded by their higher costs, and the added cost to the consumer of the closed loop production system, segregation and the soybean's specialty status was not sufficiently calculated in the Environmental Assessment.

APHIS Response 8: The benefits of the product if any will provide a value for enhanced healthfulness to the consumer. The economics of this product will likely be similar to that of any specialty soybean product, and that is if the product has extra value, consumers will pay for this added value. If consumers are unwilling to pay additional costs for an improved product, soybean-containing products without the properties offered in the more nutritive soybean will continue to be available to consumers.

Comment 9: What will the future be like if we move to a world with a modified gene pool available for crop improvement, controlled by one or two major companies?

APHIS Response 9: The US Seed industry is extensive and from observing the hundreds of members of the American Seed Trade Association, appears to be economically robust (ASTA 2012). More than 90% of the association's members are small businesses and participate in developing, marketing and improving seed and cooperating in seed trade governance through state and regional associations, and international organizations. Among developers of genetically engineered traits for seed, in the US there are four large companies, all of which are multinational and these provide a competitive environment for growers seeking advanced technology seed. Two more multinationals are also building seed businesses on GE crop traits. Needless to say, there are many providers of non-GE seed and organic seed from which growers may select the desired traits and agronomic characteristics. Many seed providers have large amounts of germplasm available for continued improvement of yield and other characteristics, and continue to search for new germplasm sources.

ASTA (2012). About ASTA. American Seed Trade Association. http://www.amseed.org/about.asp

Changes in Nutrition caused by the Product

Comment 10: SDA is another "Band-Aid" solution that will not address our nation's 'nutrition' problem, which is that people eat too much processed food containing soybean and corn, and not eating nutrient rich wholesome foods. This product might make the problem worse.

APHIS Response 10: APHIS acknowledges this comment. This concern is discussed below in Reponses # 11, #12 and #14.

Comment 11: SDA soybean provides an omega-3 fatty acid which is efficiently converted into EPA, a fatty acid which will provide human health benefits, including improved immune function, reducing cardiovascular disease, reduce obesity factors and certain cancer risks. American Heart Association recommends fish oil be consumed to attain minimal levels of DHA and EPA, and NHANES shows that Americans do not get enough in their diet. While fish oil is

a good source of these fatty acids, because of its flavor and shelf life properties, it cannot be incorporated into baked goods, dressing and other products as can a plant source such as SDA soybean.

APHIS Response 11: APHIS acknowledges this comment. Potential human health issues associated with the proposed action are thoroughly discussed in Section 4.5 of the EA and below in Response 43.

Comment 12: In a survey of Consumer Perceptions of Food Technology, 56% of respondents were trying to follow recommended practice of limiting certain classes of fats, and 62% recognized the value of fish oils and 50% of omega-3s in their diets. Edible oil with stearidonic acid would allow consumers to obtain this nutrient from a much broader range of foods.

APHIS Response 12: APHIS acknowledges this comment. Potential socioeconomic issues associated with the proposed action, including potential end uses of this product are thoroughly discussed in Section 4.7 of the EA and below in Response 43.

Comment 13: Why do we allow chemicals in 83% of our foods, and reduce healthy organic foods to 5% of the shelf space in supermarkets?

APHIS Response 13: Stearidonic acid is not an artificial or synthetic chemical; it is a naturally occurring fatty acid that occurs in some foods, and one whose benefits for improving human health and alleviating disease symptoms are generally accepted by food scientists and nutritionists (see for example, American Heart Association recommendation, AHA, 2002; Kennedy et al., 2012). The fatty acid SDA is a natural constituent of seeds of some plants (*see* EA Section 2.5.2 and 4.5.2) and a naturally occurring constituent of fish. SDA is already a common supplement recommended by independent health organizations.

AHA (2002). Fish Consumption, Fish Oil, Omega-3 Fatty Acids, and Cardiovascular Disease. AHA Scientific Statement. Penny M. Kris-Etherton, PhD, RD; William S. Harris, PhD; Lawrence J. Appel, MD, MPH; for the Nutrition Committee Circulation 106: 2747-2757 http://circ.ahajournals.org/content/106/21/2747.full

Kennedy, E.T., Luo, H., Ausman, L.M. (2012). Cost implications of alternative sources of (n-3) fatty acid consumption in the United States. Journal of Nutrition 142 (3), pp. 605S-609S 2

Comment 14: This soybean variety will not solve America's nutrition problems via a one-crop solution, and a wide range of healthy foods should be promoted by USDA support of locally grown organic foods, while removing subsidies on milk and meat.

APHIS Response 14: The USDA maintains a website titled, Know Your Farmer, Know Your Food Compass (USDA, 2012) which has resources to identify your local food producers, and provide support for local and regional food production. USDA understands the value of locally produced food, and encourages consumers to use these sources. However, manufactured food can also provide a healthy choice, and in combination with efforts of the FDA, USDA promotes wise consumption of mass-produced food.

USDA (2012). Know Your Farmer, Know Your Food Compass, US Department of Agriculture. Website. (http://www.usda.gov/wps/portal/usda/usdahome?navid=KYF_COMPASS)

Comment 15: A registered dietician noted that Americans get only 100-150 mg per day of omega-3 fatty acids, which is only a meager 25% of the amount recommended for health by several reputable national organizations. Omega-3 fats are essential polyunsaturated fatty acids, cannot be made by the body and must be obtain from food sources. For a variety of reasons, consumers have found it difficult to obtain enough foods with omega-3s to include in their diet.

APHIS Response 15: APHIS acknowledges this comment. Potential human health issues associated with the proposed action are thoroughly discussed in Section 4.5 of the EA.

Comment 16: A large commercial cereal and convenience foods company wrote that the availability of SDA omega-3 soybean oil would help food companies deliver a broader range of food products containing omega-3s. The availability of more product options can help consumers make healthier choices and can contribute to increasing the level of omega-3s in their daily diet.

APHIS Response 16: APHIS acknowledges this comment. Potential socioeconomic issues associated with the proposed action, including potential end uses of this product are thoroughly discussed in Section 4.7 of the EA.

Comment 17: New seeds and technologies will create value for the US soybean industry while providing greater functionality and better nutrition for consumers; SDA soybean can deliver increased yield and profit potential for farmers.

APHIS Response 17: APHIS acknowledges this comment. Potential socioeconomic issues associated with the proposed action are thoroughly discussed in Section 4.7 of the EA.

Comment 18: Use of omega-3 soybeans in animal feed could be detrimental to the health of fish and livestock populations, which could provide unhealthy supplies for consumers.

APHIS Response 18: As discussed in Section 4.6 of the EA, APHIS has concluded that a determination of nonregulated status of MON 87769 Soybean would have no significant impacts on animal feed or animal health. Monsanto has submitted compositional and nutritional characteristics of MON 87769 Soybean to APHIS (Monsanto 2010). APHIS has reviewed Monsanto's results and has concluded that with the exception of the changes in fatty acid composition, the levels of nutrients, anti-nutrients, and secondary metabolites in MON 87769 Soybean are not statistically different from those likely to be expressed by conventional varieties.

Use of soy products in production systems for carnivorous and many omnivorous fish is limited because of 1) cost of the optimal soy protein form 2) the effectiveness of soy for supporting normal growth of fish, and 3) other issues (Sales, 2009; Naylor, et al., 2009). When soybean is used as a direct protein replacement for feed fish, requirements for fish in the optimal diet of many fish are not alleviated completely (Burr et al., 2012, Naylor, et al., 2009). From numerous experimental papers, it is clear that soy would not be the sole choice of fish farms for optimal

growth of many farmed oceanic carnivorous fish (Naylor et al. 2009). To ensure that cultured fish fed with soybean concentrate have some of the same healthy fatty acids in the muscle as compared to wild caught fish, growers may consider feeding SDA soybean. Wild-caught fish attain significant levels of SDA, DHA and EPA by ingesting other fish, and have ultimately incorporated these from algal and planktonic sources. In results thus far, feeding SDA alone when compared to feeding alpha linolenic acid, a DHA precursor at 0.5-2% levels, SDA fed fish may have a higher muscle concentration of DHA (Bharadwaj et al., 2010; Codabaccus et al., 2011).

Bharadwaj, A.S., Hart, S.D., Brown, B.J., Li, Y., Watkins, B.A. and Brown, P.B. (2010). Dietary Source of Stearidonic Acid Promotes Higher Muscle DHA Concentrations than Linolenic Acid in Hybrid Striped Bass, Lipids 45 (1) , pp. 21-27.

Burr, G.S., Wolters, W.R., Barrows, F.T., Hardy, R.W. (2012). Replacing fishmeal with blends of alternative proteins on growth performance of rainbow trout (Oncorhynchus mykiss), and early or late stage juvenile Atlantic salmon (Salmo salar) Aquaculture, 334–337, (7) 110–116.

Codabaccus, B.M. , Bridle, A.R. , Nichols, P.D. (2011). An extended feeding history with a stearidonic acid enriched diet from parr to smolt increases n-3 long-chain polyunsaturated fatty acids biosynthesis in white muscle and liver of Atlantic salmon (Salmo salar L.). Aquaculture 322-323, pp. 65-73.

Monsanto (2010). Petition for the Determination of Non-Regulated Status for MON 87769. Submitted by C George and GJ Rogan, Registration Manager. Monsanto Company, St. Louis MO.

Naylor, R. L., Hardy, R. W. Bureau, D. P. Chiu, A. Elliott, M. Farrell, A. P. Forster, I. Gatlin, D. M. Goldburg, R. J. Hua, K. Nichols, P. D. (2009). Feeding aquaculture in an era of finite resources. Proc. Nat'l Acad. Sci. 106 (no. 36), 15103–15110.

Sales, J. (2009). The effect of fish meal replacement by soyabean products on fish growth: a meta-analysis. British Journal of Nutrition 102, 1709-1722.

Comment 19: Changes in the food we eat will allow changes in our bodies also, and diseases may not show up right away.

APHIS Response 19: As discussed in Section 4.5 of the EA, based on APHIS' review of field and laboratory data and scientific literature provided by Monsanto (Monsanto 2010), and safety data available on other GE soybean, APHIS has concluded that a determination of nonregulated status of MON 87769 Soybean would have no significant impacts on human health. The soybean that is offered in MON 87769 will be used in the human diet mostly for extracted oils, rather than whole soybean use in food. FDA has granted the extracted oil the status of "generally recognized as safe" and has no concerns for the oil in food products (US-FDA, 2009). The high SDA oil will substitute for oil components of complex foods. No significant changes to the total soy protein, except for inconsequential amounts of new enzymes (PjD6D and Nc.Fad3) involved in the SDA production whose biological safety was demonstrated (EA Section 4.5.2. safety of

new proteins; Protein expression concentrations, Section VI.C.1.Monsanto, 2010; total protein, amino acids, VII.B.5. Compositional Equivalence, Monsanto, 2010).

Monsanto (2010). Petition for the Determination of Non-Regulated Status for MON 87769. Submitted by C George and GJ Rogan, Registration Manager. Monsanto Company, St. Louis MO.

US-FDA (2009). Agency Response Letter GRAS Notice No. GRN 000283. U.S. Food and Drug Administration, Washington, D.C. Last accessed from http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm185688.htm

Comment 20: Analysis showed that 19 of 26 nutrient analyses detected statistically significant differences from a comparator variety. In all cases, the differences were not determined to be "biologically meaningful," but no feeding studies have been done to test this evaluation. A description of differences without data showing that these differences are "safe" is inadequate and unacceptable.

APHIS Response 20: The differences deemed "not biologically meaningful" are changes for example in content of specific amino acids, and are not meaningful because the small variability of these is likely to be similar to variability present in any group of amino acids arising from the multiple protein sources that make up human diets, including those from plants, animals and microorganisms. These small variations in amino acid content of this soybean variety would have no consequence for human health, since human metabolism is capable of incorporating variable levels of amino acids, especially when specific amino acid shortages are not present. The petitioner has identified no specific deficiencies of nutrients typically supplied from soybean consumption (Monsanto 2010).

Monsanto (2010). Petition for the Determination of Non-Regulated Status for MON 87769. Submitted by C George and GJ Rogan, Registration Manager. Monsanto Company, St. Louis MO.

Impacts on Soil or water Resources

Comment 21: A consumer advocacy organization asserts that the product will be stacked with a glyphosate tolerance trait, and this will lead to weed resistance and the necessity of abandoning conservation tillage. Other impacts may be an increase in the use of glyphosate, which can be washed off field sites and enter water bodies.

APHIS Response 21: This product is expected to be a niche product, and will likely be planted as an alternative replacing other existing varieties of soybean, produced for oil extraction. Changes in the agronomic practices and locations for soybean seed production using MON 87769 Soybean are not expected. A determination of nonregulated status of MON 87769 Soybean is not expected to result in changes in the current soybean cropping practices, including herbicide use. As discussed in Chapter 4 of the EA, studies demonstrate MON 87769 Soybean is essentially indistinguishable from other soybean varieties used in terms of agronomic

characteristics and cultivation practices (Monsanto, 2010; USDA-APHIS, 2010). Similar to farming practices currently used for conventional soybean production, a preplant burndown herbicide would be used, followed by a pre-emergence residual herbicide, with timely post plant herbicide applications (Sprague, 2006). The use of glyphosate as a post-emergent weed herbicide would likely continue to be the pattern for the majority of soybean production. GE soybeans currently are planted on the majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2011). All of these GE soybean varieties are herbicide resistant. Monsanto has stated that MON 87769 Soybean would be stacked with either glyphosate or other available nonregulated herbicide resistance traits (Monsanto, 2010). It is anticipated that herbicide use will continue the trends noted by Beckie and Tardif (2012) associated with the wide adoption of glyphosate-tolerant soybean along with the use of crops stacked with multiple herbicide resistances. Alternative herbicides will be used sequentially, in mixtures, or as required in crop rotations, to manage herbicide resistant weed populations.

Beckie, H.J. and Tardif, F.J. (2012). Herbicide cross resistance in weeds. Crop Protection 35, 15-28.

Monsanto (2010). Petition for the Determination of Non-Regulated Status for MON 87769. Submitted by C George and GJ Rogan, Registration Manager. Monsanto Company, St. Louis MO.

Sprague, C (2006). Growing non-GMO soybeans: What do you need to know? Michigan State Crop and Soils Department. Retrieved 2011 from http://ipmnews.msu.edu/fieldcrop/fieldcrop/tabid/56/articleType/ArticleView/articleId/1884/categoryId/2/Growing-nonGMO-soybeans-What-do-you-need-to-know.aspx

USDA-APHIS. (2010) Plant Pest Risk Assessment for MON 87769 Soybean. (Report: Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html

USDA-ERS (2011). Adoption of Genetically Engineered Crops in the U.S. Genetically Engineered Soybean Varieties. Retrieved from http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable3.htm

Changes in Soybean properties

Comment 22: One commenter requested more regulation over products that modify soybeans to produce substances not naturally found in soybean.

APHIS Response 22: Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). 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's APHIS, the Food and Drug Administration, and the Environmental Protection Agency.

Comment 23: GMOs have not proved to be as benign as manufacturers portray them to be, such as by the creation of superweeds.

APHIS Response 23: This MON 87769 Soybean does not express any herbicide tolerant traits and therefore farming practices similar to those that are currently used for conventional soybean production would be used to produce MON 87769 Soybean, including the use of a preplant burndown herbicide, followed by a pre-emergence residual herbicide, with timely post plant herbicide applications (Sprague, 2006). Commercial soybean production may require at least one herbicide application for effective weed control. Most commonly, weeds are controlled by planting glyphosate-tolerant soybean varieties, and applying glyphosate at least once during production. In 2002, it was calculated that 96 percent of all planted soybeans were treated with at least one type of herbicide, ranging from 0.04 to 0.71 pounds (lbs) of product per acre. In 2006, herbicides were used on 98 percent of soybean acres of surveyed states (USDA-NASS, 2007).

The use of glyphosate as a post-emergent weed herbicide would likely continue to be the pattern for the majority of farms in soybean production regardless of a determination of nonregulated status of MON 87769 Soybean. GE soybeans currently are planted on the majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2011). All of these GE soybean varieties are herbicide resistant. Monsanto has stated that MON 87769 Soybean would be stacked with either glyphosate or other available nonregulated herbicide resistance traits (Monsanto, 2010). It is anticipated that herbicide use will continue the trends noted by Beckie and Tardif (2012) associated with the wide use of glyphosate-tolerant soybean along with crops stacked with multiple herbicide resistances as they are available or become so, and that alternative herbicides will more frequently be used sequentially, or in mixtures, or as required in crop rotations, to manage herbicide resistant weed populations. As discussed in Section 5.3 of the EA, currently, thirteen weeds have been identified as glyphosate-resistant in the US (Heap, 2012), with seven of these weeds identified as difficult to control weeds in soybean: common ragweed (*Ambrosia artemisiifolia*), common waterhemp (*Amaranthus rudis*), giant ragweed (*Ambrosia trifida*), horsetail (marestail) (*Conyza canadensis*), Italian ryegrass (*Lolium multiflorum*), Johnsongrass (*Sorghum halapense*), and Palmer amaranth (*Amaranthus palmeri*) (Benbrook, 2009). These resistant weeds can be managed by applying herbicide combinations with different modes of action, as well as crop rotation, varying row spacing, and mechanical removal of weeds (Woodruff et al., 2010).

Beckie, H.J. and Tardif, F.J. (2012). Herbicide cross resistance in weeds. Crop Protection 35, 15-28.

Benbrook, C. (2009). Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years. Critical Issue Report Number 3 (pp. 107): The Organic Center.

Heap I. (2012). International Survey of Herbicide Resistant Weeds. Weed Science. Retrieved April 2012, from http://www.weedscience.org/In.asp.

Monsanto (2010). Petition for the Determination of Non-Regulated Status for MON 87769. Submitted by C George and GJ Rogan, Registration Manager. Monsanto Company, St. Louis MO.

Sprague, C (2006). Growing non-GMO soybeans: What do you need to know? Michigan State Crop and Soils Department. Retrieved 2011 from http://ipmnews.msu.edu/fieldcrop/fieldcrop/tabid/56/articleType/ArticleView/articleId/1884/categoryId/2/Growing-nonGMO-soybeans-What-do-you-need-to-know.aspx

USDA-ERS (2011). Adoption of Genetically Engineered Crops in the U.S. Genetically Engineered Soybean Varieties. Retrieved from http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable3.htm

USDA-NASS (2007). Agricultural Chemical Usage 2006 Field Crops Summary Retrieved from http://usda.mannlib.cornell.edu/usda/nass/AgriChemUsFC//2000s/2007/AgriChemUsFC-05-16-2007_revision.pdf

Woodruff, J, Whitaker, J, Prostko, E, Roberts, P, Kemerait, R, Smith, N, Smith, A, Sumner, P, Harrison, K, and Harris, G. (2010). Soybean Weed Control (Report: University of Georgia College of Agriculture and Environmental Sciences. Retrieved from http://www.caes.uga.edu/commodities/fieldcrops/soybeans/documents/Compiled2010SoybeanProductionGuide.pdf

Comment 24: Stearidonic acid is readily oxidized compared to lesser unsaturated fatty acids, and if the soy product contained only 15% of MON 87769, quality and taste can be affected.

APHIS Response 24: Stearidonic acid can be stabilized by a variety of natural ingredients, such as tocopherols, some of which are already present in soybean, or by additives such as citric acid (Hildebrand et al, 1984; Appendix C of the EA). The developer has indicated that they will be employing product development specialists to maximize the functional properties and organoleptic qualities of products that might use stearidonic acid soybean, and assure that stability is not an issue (Monsanto, (2009) and Cosgrove (2010). As the commenter noted, the Addendum to the Petition (attached as Appendix C to the EA) describes \that products enhanced with stearidonic acid at less than 15% of total frying oils did not alter consumer perception of taste properties of fried food. If a greater percentage of oils were to be used than in current versions of a product, it is reasonable to assume that food developers and food scientists would likely make the necessary formulation changes to ensure that organoleptic properties were

acceptable to the consumer (*see* petition Appendix C to the petition, Monsanto's petition addendum, Potential Market Impact., p. 11-17).

Cosgrove, J. (2010). SDA from GM Soybeans. Monsanto-Solae partnership testing Soymega, an SDA omega 3 ingredient that converts to heart-healthy EPA. Neutraceuticals World. Rodman Publishing. June 2, 2011. http://www.nutraceuticalsworld.com/contents/view_online-exclusives/2011-06-02/sda-from-gm-soybeans/

Hildebrand, D.H., Terao, J. and Kito, M. (1984). Phospholipids plus tocopherols increase soybean oil stability. American Oil Chem. Soc. 61, 552-555.

Monsanto Co. (2009). SDA Omega-3 Soybean Oil Now GRAS. Monsanto Press Release. http://www.foodproductdesign.com/news/2009/10/sda-omega-3-soybean-oil-now-gras.aspx

Product Safety

Comment 25: There is no non-industry science to prove the safety of this and other novel products in the environment, or in human and animal health long term. There are no double blind studies on the safety of this GE product and Monsanto should not subject us to the consumption of this type of soybean.

APHIS Response 25: The Coordinated Framework, published by the Office of Science and Technology Policy (51 FR 23302, 57 FR 22984), 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 U.S. Food and Drug Administration (FDA) regulate 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. All food and feed derived from GE crops currently on the market in the United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the *Federal Register* (FR) 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 or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food. Monsanto has provided the FDA with information on the identity, function, and characterization of the genes, including expression of the gene products. The submittal to the FDA included information on the safety of the altered fatty acid profile in MON 87769 Soybean oil, including a dietary risk assessment. Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87769 and submitted a safety and nutritional assessment of food and feed derived from MON 87769 to the FDA on March 23, 2009 (BNF No. 00117). FDA is currently evaluating the submission (Monsanto, 2010).

As discussed in Section 4.5 of the EA, based on APHIS' review of field and laboratory data and scientific literature provided by Monsanto (Monsanto 2010), and safety data available on other GE soybean, APHIS has concluded that a determination of nonregulated status of MON 87769 Soybean would have no significant impacts on human health. The soybean that is offered in MON 87769 will be used for oil extraction, rather than whole soybean use in food. FDA has granted the extracted oil the status of "generally recognized as safe" and has no concerns for the oil in food products (US-FDA, 2009).

As discussed in Section 4.6 of the EA, APHIS has concluded that a determination of nonregulated status of MON 87769 Soybean would have no significant impacts on animal feed or animal health. Monsanto has submitted compositional and nutritional characteristics of MON 87769 Soybean to APHIS (Monsanto 2010). APHIS has reviewed Monsanto's results and has concluded that with the exception of the changes in fatty acid composition, the levels of nutrients, anti-nutrients, and secondary metabolites in MON 87769 Soybean are not statistically different from those likely to be expressed by conventional varieties.

As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridizing and genetic engineering (NRC, 2004) The NRC also noted that at the time, no adverse health effects attributed to genetic engineering had been documented in the human population. Reviews on the nutritional quality of GE foods have generally concluded that there are no significant nutritional differences in conventional versus GE plants for food or animal feed (Faust, 2002; Flachowsky et al., 2005).

Faust, MA. (2002). New feeds from genetically modified plants: the US approach to safety for animals and the food chain. Livestock Production Science 74(3), 239-254.

Flachowsky, G, Chesson, A, and Aulrich, K. (2005). Animal nutrition with feeds from genetically modified plants. Archives of Animal Nutrition, 59(1), 1 - 40.

Monsanto (2010). Petition for the Determination of Non-Regulated Status for MON 87769. Submitted by C George and GJ Rogan, Registration Manager. Monsanto Company, St. Louis MO.

NRC. (2004). Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects (Report: Washington DC: National Resource Council.

US-FDA. (2009). Agency Response Letter GRAS Notice No. GRN 000283. U.S. Food and Drug Administration, Washington, D.C. Last accessed from http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm185688.htm

Comment 26: Opposition to this trait and to biotechnology in general is based on fear and ignorance or cynical fundraising. Base your decision solely on efficacy, consistency and safety of the end products.

APHIS Response 26: Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). 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.

APHIS has carefully considered the possible plant pest risks and environmental impacts of the proposed action, and is satisfied that the PPRA and EA prepared by APHIS for this petition of nonregulated status received from Monsanto is adequate and sufficient to make an informed decision on this regulatory action. When a petition for nonregulated status is submitted, APHIS must make a determination if the genetically engineered organism is unlikely to pose a plant pest risk. If APHIS determines based on its PPRA that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject the plant pest provisions of the Plant Protection Act and 7 CFR part 340. The EA follows all applicable laws, regulations, and guidelines in analyzing potential impacts of this action, including those established by NEPA.

In making an informed decision of potential plant pest risks and environmental impacts, APHIS used the best available scientific information, data and expert advice. In enacting the Plant Protection Act, Congress found that

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science… § 402(4).

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

> "[D]ecisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency"

Based on our PPRA (USDA-APHIS, 2010) and the scientific data evaluated therein, APHIS has concluded that MON 87769 Soybean is unlikely to pose a plant pest risk.

USDA-APHIS (2010). Plant Pest Risk Assessment for MON 87769 Soybean. (Report: Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html

Comment 27: A commenter expresses opposition to Monsanto's patents on genetically modified seeds because the technology has proven to cause harm: employ the precautionary principle. The commenter proposes a method by which new developments can be rejected because of the theoretical possibility of an event which might appear under unlikely circumstances.

APHIS Response 27: APHIS is responsible for regulating GE organisms and plants under the plant pest provisions in the Plant Protection Act of 2000, as amended (7 USC § 7701 *et seq*.) to ensure that they do not pose a plant pest risk to the environment. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. APHIS is unaware of any plant pest issues caused by genetic engineering in general, and specifically, is unaware of any GE crop variety no longer subject to the requirement of Part 340 and the plant pest provisions of the Plant Protection Act or stacked varieties combining GE varieties that has resulted in unexpected plant pest risks or impacts. If plant pest risks are discovered after a determination of nonregulated status by APHIS, APHIS has the authority to bring the GE organism back in under its regulatory oversight.

Comment 28: SDA soybeans available means the consumers would have more option to get their omega-3s in everyday foods in a cost effective manner.

APHIS Response 28: APHIS acknowledges this comment. Potential socioeconomic issues associated with the proposed action, including potential end uses of this product are thoroughly discussed in Section 4.7 of the EA.

Comment 29: When we eat soybeans, we end up eating Roundup, too.

APHIS Response 29: The EPA sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act (FFDCA). As a condition of registration, EPA determines whether pesticides applied at specific rates are safe for use. As part of EPA's process for establishing pesticide tolerances, the level at which pesticide residues may persist in the environment or on agricultural products are compared with concentrations likely to cause adverse effects on humans or plants. Acceptable application rates for all pesticides are derived by EPA during this process as are total combined annual application rates. In the case of glyphosate, EPA use restrictions state it may be sprayed on soybean only up to two weeks before the harvest so that residues are minimized. This application allowance takes into account whether an unacceptable dose could be present on a commodity for humans in food or for

livestock in feed. EPA has determined that no more than 20 ppm of glyphosate residue should be allowed on soybean seed (45 FR 64911, Oct. 1, 1980; 40 CFR 180.364 - Glyphosate; tolerances for residues). The EPA determined that the No Observed Effect Level for glyphosate was 500mg/kg body weight, or 500 ppm (EPA, 1993). Thus, Roundup is not likely found in soybean for consumption at a dose that EPA had previously determined to be hazardous or unacceptable.

EPA (1993). Reregistration Eligibility Decision. US EPA.
http://www.epa.gov/REDS/old_reds/glyphosate.pdf

Environmental Benefits

Comment 30: One grower wrote that he benefitted from biotech crops by reducing soil erosion, increasing conservation tillage, reducing overall herbicide and insecticide applications, and made his farm more economically and environmentally sustainable, and that this was the first crop that also would allow consumers to directly benefit from biotech products.

APHIS Response 30: APHIS acknowledges this comment and directs the reader to Section 2.2 of the EA for additional information on agricultural practices used in soybean production.

Comment 31: Without doing a more thorough environmental review, USDA cannot claim that this crop is safe for the environment or for consumers. I urge you not to approve Omega-3 soybeans.

APHIS Response 31: APHIS carefully considered the possible environmental impacts of the proposed action, and is satisfied that the EA prepared by APHIS for this petition request from Monsanto is adequate and sufficient. The EA follows all applicable laws, regulations, and guidelines in analyzing potential impacts of this action, including those established by NEPA. In making an informed decision of potential environmental impacts, APHIS used the best available scientific information, data and expert advice. APHIS has determined that the analysis in its EA showed no significant impact on the quality of the human environment from a determination of nonregulated status of MON 87769 Soybean and that APHIS did not have to prepare an environmental impact statement (EIS). The EA took a hard look at the need for action, the issues, alternatives, and environmental consequences. APHIS also reviewed and carefully considered all comments submitted by respondents to the public involvement efforts. As a result of this analysis, APHIS prepared a final EA, from which came the NEPA decision document and a finding of no signification impact (FONSI) that discussed, under each of the ten Council for Environmental Quality (CEQ) points of significance, why each point was not significant, and why an EIS was not required. The agency followed CEQ NEPA regulations and Agency NEPA implementing procedures.

Adverse Environmental Impacts

Comment 32: Monsanto has practices that pollute organic farms with roundup ready seed; we do not want organic foods to be tampered with.

APHIS Response 32: APHIS acknowledges this comment. Potential impacts to organic farms are discussed above in Response 6 and Section 4.2 of the EA.

Comment 33: No more GMOS. Unnatural creations destroy the balance of our ecosystem. There are many proven ways to grow crops in balance with nature and without chemicals. We oppose releasing another GMO that will have adverse environmental impacts and detrimental effects on farmers, especially organic farmers.

APHIS Response 33: APHIS acknowledges this comment. Potential impacts to organic farms are discussed above in Response 6 and Section 4.2 of the EA.

New Impacts

Comment 34: The costs were not assessed in the EA to organic and non-genetically engineered soybean farmers to protect against product admixture and those imposed on them if they are in fact admixed.

APHIS Response 34: APHIS has obtained no evidence that large amounts of seed for planting organic crops have been mixed with GE seed, and from the earlier comment (*see* Comment 6), APHIS notes that surveys of growers indicate that they do not consider this an important issue. Also, admixture of soybean by cross pollination is likely to be inconsequential, because the pollination range of nearly all pollen is quite short, mainly because soybean is a predominately self-pollinating plant.

Comment 35: The cost of a specialty soybean closed loop system on processed food for consumers was not addressed.

APHIS Response 35: APHIS acknowledges this comment. Costs of closed loop production systems on consumers are discussed above in Response 7.

Indirect Impacts

Comment 36: Omega-3 soybeans once stacked with glyphosate resistance will further the evolution of glyphosate-resistant weeds, the abandonment of conservation tillage practices and degradation of natural resources. The impact of glyphosate use on this variety, specifically, was largely ignored.

APHIS Response 36: APHIS acknowledges this comment. This concern is discussed above in Responses 19 and 21.

Comment 37: Health implications of GE crops have been noted by some investigators such as the Paganelli et al. study (2010) that glyphosate herbicides caused deformities and neurological problems in vertebrates.

APHIS Response 37: MON 87769 Soybean does not express any herbicide tolerant traits. The trait being considered for nonregulated status is only stearidonic acid production. However,

Monsanto has stated that MON 87769 Soybean would be stacked with either glyphosate or other available nonregulated herbicide resistance traits (Monsanto, 2010).

APHIS notes that the Paganelli et al. (2010) study cited involved exposure of embryos to unrealistically high doses far in excess of those that would occur in natural habitat (Saltmira, 2011). Herbicide concentrations were attained that would not have been present if EPA labeled rates had been followed. Regulatory agencies have reviewed the literature, and conclude that glyphosate is not a teratogen or mutagen, and the mode of exposure, direct injection in embryos, would not resemble exposure in the environment (Saltmira, 2011). This paper is not an indication of likely consequences of environmental exposure to glyphosate rates that would be used by growers in accordance with EPA label use restrictions.

Monsanto (2010). Petition for the Determination of Non-Regulated Status for MON 87769. Submitted by C George and GJ Rogan, Registration Manager. Monsanto Company, St. Louis MO.

Paganelli, A., Gnazzo, V., Acosta, H., López, S.L., Carrasco, A.E. (2010). Glyphosate-Based Herbicides Produce Teratogenic Effects on Vertebrates by Impairing Retinoic Acid Signaling, Chem. Res. Toxicol., 23 (10), pp 1586–1595.

Saltmiras, D., Bus, J. S., Spanogle, T., Hauswirth, J., Tobia, A., Hill, S. (2011). Letter to the Editor Regarding the Article by Paganelli et al. Chem. Res. Toxicol., 2011, 24 (5), pp 607–608

Comment 38: Vendomois et al., (2009) showed after consuming GE corn, deterioration of liver and kidney functioning was demonstrated by histological analysis.

APHIS Response 38: This paper has been evaluated by several competent scientific authorities, and the conclusion is that because it uses inappropriate statistical methods and faulty scientific reasoning, that the study "provides no new evidence of toxic effects" (European Food Safety Authority, quoted in Monsanto (2010)). For a summary of regulatory reviews and notable errors, see Monsanto (2010).

Monsanto (2010). Monsanto Response: de Vendômois et al. 2009. http://www.monsanto.com/newsviews/Documents/SpirouxdeVendimois.pdf

de Vendômois J.S., Roullier F., Cellier D., Séralini, G.E. (2009). A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health. Int J Biol Sci. 5(7):706-726. Available from http://www.biolsci.org/v05p0706.htm

Comment 39: Monsanto has done no safety testing on livestock for this petition.

APHIS Response 39: A significant portion of FDA's analysis of the MON 87769 Soybean is relegated to assessing likely impacts on livestock. No results from animal studies have been obtained that might indicate that adverse impacts on livestock would be of concern (Monsanto, 2010), since the altered part, soybean oil containing stearidonic acid, has been found to be "General Recognized as Safe" by FDA (US-FDA, 2009). No other studies submitted by

Monsanto suggest that this product shows any significant and consequential difference from standard, unmodified soybeans (Monsanto 2010). Consistent with all tiered risk analysis studies, if first level acute assays provide some indication of adverse effects on the test organism, then second level (tier) analyses are assigned, such as more livestock testing. Since no adverse impacts on small animals have been observed (nor have there been reason to expect them), there have been no scientific basis to continue with advanced testing protocols. Because improving animal proteins with desirable fatty acids is an important health goal, feeding SDA to livestock for this reason has been accomplished with a determination of health benefits in dairy cow milk (Bernal-Santos et. al., 2010). Broilers have also been fed the SDA containing soy oil, and final weights and meat properties (other than omega-3 content) were not different from controls (Rymer et al., 2011).

Bernal-Santos, G., O'Donnell, A. M., Vicini, J. L., Hartnell, G. F., Bauman, D. E. (2010). Hot topic: Enhancing omega-3 fatty acids in milk fat of dairy cows by using stearidonic acid-enriched soybean oil from genetically modified soybeans. Journal of Dairy Science, 93, 32–37.

Rymer, C., Hartnell, G.F., Givens, D.I. (2011). The effect of feeding modified soyabean oil enriched with C18: 4n-3 to broilers on the deposition of n-3 fatty acids in chicken meat. British Journal of Nutrition 105 (6) , pp. 866-878.

Monsanto (2010). Petition for the Determination of Non-Regulated Status for MON 87769. Submitted by C George and GJ Rogan, Registration Manager. Monsanto Company, St. Louis MO.

US-FDA. (2009). Agency Response Letter GRAS Notice No. GRN 000283. U.S. Food and Drug Administration, Washington, D.C. Last accessed from http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm185688.htm

Comment 40: There is inadequate research to know whether levels of soy feed being released into the aquatic environment for fish in fish farms are harmful to the ecology in the area or cause habitat destruction, especially considering that fish fed with soy proteins may produce higher levels of excrement.

APHIS Response 40: It is widely known as part of current fish production protocols that fish producers may provide soybean proteins to fish as part of their dietary supplement and that soybean feed may increase waste excretion (e.g., nitrogen, Tantikitti et al, 2005). The possible inclusion of SDA modified soybean protein in fish diets would not likely be any more frequent than those that include conventional soybean protein. Because of the relatively extensive amount of conventional soybean supplies that would continue to be available for use, feeding fish with SDA-soybean would most likely not significantly increase the total load of soybean-derived excreta already present at fish rearing sites. Thus, SDA-containing soybean should have little impact on aquatic fish production and consequent excretory wastes of fish.

Tantikitti, C., Sangpongb, W. Chiavareesajja, S. (2005). Effects of defatted soybean protein levels on growth performance and nitrogen and phosphorus excretion in Asian seabass (Lates calcarifer), Aquaculture 248, 2005, 41–50.

Comment 41: Few if any industry studies follow the flow of GE genes through the soil and soil microbes, birds, bees, honey, human gut flora and human and farm animal waste streams for example. Without such thorough review, the USDA cannot claim that this crop is safe for the environment or for consumers.

APHIS Response 41: APHIS' Plant Pest Risk Assessment addresses the risk of horizontal gene flow from soybean into other organisms, and notes that the consensus of scientific studies is that such gene movements are unlikely (USDA-APHIS 2010). In general, the persistence of intact genes in the soil or excreta is likely to be low, since the molecules are subject to degradation outside the cell nucleus. The new proteins expressed in MON 87769 Soybean would possibly be more likely to persist than the transgenes, but as noted in Section 4.4.1 of the EA these are not likely to have any adverse effects, since these enzymes that alter the soybean fatty acid ratios can already be found in diverse organisms that humans and animal species already ingest in typical diets.

USDA-APHIS. (2010). Plant Pest Risk Assessment for MON 87769 Soybean. (Report: Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html

Comment 42: Research evidence regarding the effects of DHA and EPA omega-3 fatty acids on human health is still somewhat uncertain and we really don't know how much is too much. Thus, using the "blanket" approach to dosing the entire population with a substance known to have toxic effects at higher concentrations, is taking a pointless risk.

APHIS Response 42: It is likely that there is a deficit of omega-3s in human populations, and no public concerns about the possibility that too much might be consumed (AHA, 2002; Danaei, et al., 2009). From animal models that were treated with high doses of SDA-containing oil, no adverse effects were detected (Monsanto, 2010) and human consumption trials had relatively minor few side effects (AHA (2002). Thus, it is unlikely that consumers may receive an unhealthy level of SDA in foods based on scientific evidence of non-toxicity, and the fact that the FDA has approved consumption of omega-3 fish oils up to 3g/day as GRAS (generally recognized as safe)(*see* AHA (2002)), which is a concentration greater than average consumption of all omega-3 fatty acids such as linolenic acid (AHA, 2002).

AHA (2002). Fish Consumption, Fish Oil, Omega-3 Fatty Acids, and Cardiovascular Disease. AHA Scientific Statement. Penny M. Kris-Etherton, PhD, RD; William S. Harris, PhD; Lawrence J. Appel, MD, MPH; for the Nutrition Committee Circulation 106: 2747-2757 http://circ.ahajournals.org/content/106/21/2747.full

Danaei, G., Ding, E.L., Mozaffarian, D,, Taylor, B., Rehm, J., et al. (2009). The Preventable Causes of Death in the United States: Comparative Risk Assessment of Dietary, Lifestyle, and Metabolic Risk Factors. PLoS Med 6(4): e1000058. doi:10.1371/journal.pmed.1000058

Kris-Etherton, P.M., Harris, W.S., and Appel, L.J. (2002). Fish Consumption, Fish Oil, Omega-3 Fatty Acids, and Cardiovascular Disease. Circulation 106:2747-2757

Monsanto (2010). Petition for the Determination of Nonregulated Status for Improved Fatty Acid Profile MON 87705. Monsanto Co., St. Louis MO.