NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

Monsanto
Improved Fatty Acid Profile MON 87705 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 09-201-01p) by Monsanto for their transgenic soybean, event MON 87705 (hereafter referred to as MON 87705 Soybean), that is genetically enhanced to suppress the endogenous *FATB* and *FAD2* ribonucleic acid (RNA) in the developing soybean seed. This enhancement improves the fatty acid profile to contain lower saturated (palmitic and stearic) fatty acids, lower polyunsaturated (linoleic) fatty acid levels, and higher levels of monounsaturated (oleic) fatty acid (Monsanto, 2010). MON 87705 Soybean also expresses CP4 EPSPS protein throughout the plant conferring tolerance to glyphosate, which is the active ingredient in the Roundup® family of agricultural herbicides. 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 87705 Soybean. The EA assesses alternatives to a determination of nonregulated status of MON 87705 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 genetically engineered (GE) varieties) can provide benefits to the environment, consumers, and farm income.

[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).

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. 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 Federal Food, Drug and Cosmetic Act (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 87705 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 09-201-01p) to APHIS seeking a determination that their transgenic soybean, MON 87705 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.

Improved Fatty Acid Profile Monsanto 87705 Soybean

Monsanto has developed a transgenic soybean, MON 87705 Soybean, that produces soybean seeds with lower levels of saturated (palmitic and stearic) and polyunsaturated (linoleic) fatty acids, and higher levels of monounsaturated (oleic) fatty acid than those found in non-modified soybean seeds. MON 87705 Soybean contains DNA segments designed to suppress endogenous delta-12 desaturase (*FAD2*) and Acyl-ACP thioesterase (*FATB*) genes which encode for two enzymes in the soybean fatty acid biosynthetic pathway. MON 87705 Soybean also contains the 5-enolpyruvylshikimate-3-phosphate synthase (*cp4 epsps)* gene encoding the CP4 EPSPS protein. The *cp4 epsps* gene is used as a selectable marker to identify transgenic plants during

the transformation process. The CP4 EPSPS protein confers tolerance to glyphosate and has been used in many Roundup Ready® crops (e.g., canola, corn, cotton, soybean, and sugar beet).

The MON 87705 Soybean oil fatty acid profile provides new formulation options for food companies interested in the development of lower saturated fat food products to support heart health. Low saturated fats and high (>70%) oleic acid levels are also key attributes for vegetable oils targeted for biodiesel and industrial uses (Monsanto, 2010). These characteristics are vital to improved cold weather performance, improved stability, and reduced nitrous oxide emissions (Graef et al., 2009; Knothe, 2005). In addition to the altered fatty acid profile, the soybeans were engineered with glyphosate tolerance to provide growers of these soybeans with weed control options as well.

Coordinated Framework Review

Food and Drug Administration
MON 87705 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). In compliance with this policy, Monsanto initiated a consultation with the FDA on the food and feed safety and nutritional assessment summary for MON 87705 Soybean. A copy of the completed FDA review is provided in Appendix A of the EA.

Environmental Protection Agency
EPA has authority under FIFRA to establish pesticide use restrictions; these use restrictions are presented on pesticide labels which are prepared during the pesticide registration process. The CP4 EPSPS protein expressed in MON 87705 Soybean is similar and functionally identical to endogenous plant EPSPS enzymes and is identical to the CP4 EPSPSs in other Roundup Ready® crops including Roundup Ready® soybean (40-3-2 and MON 89788). Monsanto indicates that there will be no change in the use pattern for glyphosate on this glyphosate tolerant variety and there will be no need to petition EPA for a change in the label for glyphosate (G.Rogan, personal communication, 2011). APHIS used current glyphosate labels as the basis for its evaluation of the potential impacts associated with the use of and exposure to glyphosate.

Scope of the Environmental Analysis
Although a determination of nonregulated status of MON 87705 Soybean would allow for new plantings of MON 87705 Soybean to occur anywhere in the U.S., APHIS limited the environmental analysis to those geographic areas that currently support soybean production. A determination of nonregulated status of MON 87705 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). Table 2-2 in the EA, presents an overview of the 2009 and 2010 acreage of soybeans planted by state.

Public Involvement
On June 28, 2011, APHIS published a notice in the Federal Register (76 FR 37771-37772, Docket no. APHIS-2011-0046) announcing the availability of the Monsanto petition, and the

APHIS PPRA and draft EA for a 60-day public review and comment period. Comments were required to be received on or before August 29, 2011. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 36 comment responses were received from various groups and individuals during the comment period, with 29 comments providing support of the EA's preferred alternative and 7 comments in opposition. Comment documents may be viewed at http://www.regulations.gov/#!searchResults;dct=PS;rpp=10;po=0;s=aphis-2011-0046. 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 87705 Soybean. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments 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 87705 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):

Soybean Production:

- Acreage and Areas of Soybean Production
- Seed Production
- Organic Farming
- Specialty Soybean Production
- Soybean Cultivation Practices

Environmental Considerations:

- Soil and Land Use
- Water Resources
- Air Quality and Climate Change
- Gene Movement and Weediness
- Animals
- Plants
- Microorganisms
- Biodiversity

Public Health Considerations:

- Worker Safety
- Human Health

Animal Feed
Socioeconomic Issues:

- Domestic Economic Environment at Risk
- Trade Economic Environment at Risk
- Social Environment at Risk

Alternatives that were fully analyzed
The EA analyzes the potential environmental consequences of a determination of nonregulated status of MON 87705 Soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87705 Soybean is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2010) APHIS has concluded that MON 87705 Soybean is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 87705 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 87705 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 87705 Soybean and progeny derived from MON 87705 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 87705 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 87705 Soybean.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment (USDA-APHIS, 2010) that MON 87705 Soybean is unlikely to pose a plant pest risk. 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 87705 Soybean is No Longer a Regulated Article
Under this alternative, MON 87705 Soybean and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR Part 340. MON 87705 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 87705 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 87705 Soybean are unlikely to pose a plant pest risk, a

determination of nonregulated status of MON 87705 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 87705 Soybean and progeny derived from this event if the developer decides to commercialize MON 87705 Soybean.

Alternatives Considered but Rejected from Further Consideration
APHIS assembled a list of alternatives that might be considered for MON 87705 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 87705 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 87705 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 87705 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 87705 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 Plant Pest Risk Assessment (USDA-APHIS, 2010) and the scientific data evaluated therein, APHIS has concluded that MON 87705 Soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87705 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 87705 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 87705 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 87705 Soybean from non-GE soybean production. However, because APHIS has concluded that MON 87705 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 87705 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 87705 Soybean, there are no geographic differences associated with any identifiable plant pest risks for MON 87705 Soybean (USDA-APHIS, 2010). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87705 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 87705 Soybean or to use isolation distances and other management practices to minimize gene movement between soybean fields.

Requirement of Testing For MON 87705 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 87705 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 87705 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 – risk assessment (USDA-APHIS, 2010)
Management Practices		
Acreage and Areas of Soybean Production	Unchanged	Unchanged
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
Biodiversity	Unchanged	Unchanged
Human Health		
Worker Safety	Unchanged	Unchanged
Human Health	Unchanged	Unchanged (potential health benefits)
Animal Feed	Unchanged	Unchanged
Socioeconomic		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Social Environment	Unchanged	Unchanged
Threatened and Endangered Species	Unchanged	Unchanged
Other U.S Regulatory Approvals	FDA completed consultations	FDA completed consultations
Compliance with Other Laws		
CWW, CAA, EOs	Fully compliant	Fully compliant

Notes:

1. Unchanged – the current conditions will not change as a result of the selection of this alternative.
2. Minimal – the current conditions may change slightly as a result of the selection of this alternative, but the changes, if any, are not deemed significant.

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 2009 and 2010, over 75 million acres in the U.S. were planted in soybean, with over 93% of the soybean expressing herbicide tolerance (USDA-ERS, 2010a, 2010b). In the U.S., soybeans are cultivated in 31 states; Table 2-2 in the EA, presents an overview of the 2009 and 2010 acreage of soybeans planted by state. Most of the soybean acreage in the U.S. is planted to GE soybean. Adoption of genetically engineered herbicide-tolerant soybeans increased from 17% of U.S. soybean acreage in 1997 to 68% in 2001 and 93% in 2010 (USDA-ERS, 2010a, 2010b). A determination of nonregulated status of MON 87705 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 87705 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.

Although a determination of nonregulated status of MON 87705 Soybean would allow for new plantings of MON 87705 Soybean to occur anywhere in the U.S., APHIS limited the environmental analysis to those geographic areas that currently support soybean production. A determination of nonregulated status of MON 87705 Soybean is not expected to increase soybean production, or result in an increase in overall GE soybean acreage or cultivation in new regions.

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 87705 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 87705 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 87705 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 87705 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 87705 Soybean is expected to be cultivated as a high-value specialty soybean product, produced under identity protection system management practices so as to preserve the value of the oil (Monsanto, 2010). As a specialty soybean variety, Monsanto anticipates that MON 87705 Soybean would be cultivated following existing specialty crop practices to preserve product identity from seed production through harvesting, handling, and processing (Monsanto, 2010). Specialty soybean varieties are already cultivated on 12% of the U.S. soybean acreage, and the industry anticipates that specialty soybean acreage could expand to over 25% of the crop in certain states within the next decade (MSA, 2009). Based on demonstrated agronomic characteristics and cultivation practices, and because the market share of specialty soybean varieties is unlikely to change by the introduction of MON 87705 Soybean, APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact specialty soybean producers and consumers. Most of the soybean acreage in the U.S. is planted to GE soybean. MON 87705 Soybean would be an additional glyphosate-tolerant variety. Adoption of genetically engineered herbicide-tolerant soybeans increased from 17% of U.S. soybean acreage in 1997 to 68% in 2001 and 93% in 2010 (USDA-ERS, 2010a, 2010b). 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. 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, 2010c). The acreage devoted to organic soybean is expected to remain small regardless of whether new varieties of GE or non-GE soybean varieties, including MON 87705 Soybean, become available for commercial soybean production. For the time period of 2005 to 2008, when the total U.S. acreage dedicated to soybean fluctuated between 72 million and 64 million acres, the acreage devoted to organic soybeans was relatively stable, reported between 122,000 and 126,000 acres (USDA-ERS, 2010c). MON 87705 Soybean should not present any new or different issues and impacts for organic and other specialty soybean producers and consumers. MON 87705 Soybean is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (Monsanto, 2010; USDA-APHIS, 2010). No differences were observed in pollen diameter, weight, and viability (Monsanto, 2010; USDA-APHIS, 2010). Consistent with the lack of difference in agronomic properties, MON 87705 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 87705 Soybean are not expected. A determination of nonregulated status of MON 87705 Soybean is not expected to result in changes in the current soybean cropping practices, including pesticide use. As discussed in Chapter 4 of the EA, studies demonstrate MON 87705 Soybean is essentially indistinguishable from other soybean varieties used in terms of agronomic characteristics and cultivation practices (Monsanto, 2010). Monsanto did not identify any differences between MON 87705 Soybean and conventional in dormancy, germination potential, disease or insect response, seedling vigor, or plant maturity (Monsanto, 2010; USDA-APHIS, 2010). A determination of nonregulated status of

MON 87705 Soybean is not expected to affect the use of glyphosate as a post-emergent weed herbicide. The mechanism for glyphosate tolerance is the same as that expressed by other varieties, so the application rates for glyphosate are not expected to change (Monsanto, 2010). It is anticipated that herbicide use will continue the trends noted by Benbrook associated with the wide adoption of glyphosate-tolerant soybean and the emergence of glyphosate-resistant weeds (Benbrook, 2009).

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

A determination of nonregulated status of MON 87705 Soybean would have no significant impacts on human or animal health. Monsanto's intention in developing MON 87705 Soybean is the development of a fatty acid profile which provides nutritional benefits by presenting a healthier composition of saturated and unsaturated fats, as well as improved oil stability. As discussed in Chapter 4 of the EA, other than corresponding differences in fatty acid composition, no differences in human health impacts are anticipated. The FDA analysis (US-FDA, 2011) and Monsanto's data (Monsanto, 2010) suggest that replacing food oils with the soybean oil extracted from the MON 87705 Soybean may have a positive impact on human health in those cases where the replaced oil is a polyunsaturated product. The reduction in levels of polyunsaturated fatty acids in the MON 87705 Soybean oil is considered heart healthy. The extent to which this positive benefit may be observed is contingent upon the market share of the MON 87705 Soybean and the types of food products adapting the modified oil product. The FDA has completed its consultation on MON 87705 Soybean and has concluded that the product is not materially different in any respect relevant to food safety compared to soybean varieties currently on the market (US-FDA, 2011). The FDA's conclusions are based on an evaluation of the introduced protein, CP4 EPSPS, as well as the changes in the expression of the two endogenous genes resulting in modified fatty acid content. 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 expressed in MON 87705 Soybean is the same as that previously reviewed by the EPA. Accordingly, MON 87705 Soybean is anticipated to be safe for human and animal consumption with regard to the *cp4 epsps* gene. Based on the FDA's consultation (US-FDA, 2011), our analysis 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 87705 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 87705 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 87705 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 87705 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 87705 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 87705 Soybean are not highly controversial. Although there is some opposition to a determination of nonregulated status of MON 87705 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 87705 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 87705 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 87705 Soybean is not expected to result in changes in the current soybean cropping practices, including pesticide use. MON 87705 Soybean would be an additional glyphosate-tolerant variety. MON 87705 Soybean is not expected to affect the use of glyphosate as a post-emergent weed herbicide. The mechanism for glyphosate tolerance is the same as that expressed by other varieties, so the application rates for glyphosate are not expected to change (Monsanto, 2010). It is anticipated that herbicide use will continue the trends noted by Benbrook associated with the wide adoption of glyphosate-tolerant soybean and the emergence of glyphosate-resistant weeds (Benbrook, 2009). The effect of MON 87705 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 87705 Soybean is highly unlikely to have direct 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 87705 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 87705 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. A determination of nonregulated status of MON 87705 Soybean is not expected to result in changes in the current soybean cropping practices, including pesticide use. As discussed in Chapter 4 of the EA, studies demonstrate MON 87705 Soybean is essentially indistinguishable from other soybean varieties used in terms of agronomic characteristics and cultivation practices (Monsanto, 2010). Monsanto did not identify any differences between MON 87705 Soybean and conventional in dormancy, germination potential, disease or insect response, seedling vigor, or plant maturity (Monsanto, 2010; USDA-APHIS, 2010). A determination of nonregulated status of MON 87705 Soybean is not expected to affect the use of glyphosate as a post-emergent weed herbicide. MON 87705 Soybean would be an additional glyphosate-tolerant variety. The mechanism for glyphosate tolerance is the same as that expressed by other varieties, so the application rates for glyphosate are not expected to change (Monsanto, 2010). It is anticipated that herbicide use will continue the trends noted by Benbrook associated with the wide adoption of glyphosate-tolerant soybean and the emergence of glyphosate-resistant weeds (Benbrook, 2009). The effect of MON 87705 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 87705 Soybean is highly unlikely to have direct 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 87705 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 87705 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 87705 Soybean is expected to be cultivated as a high-value specialty soybean product, produced under identity protection system management practices so as to preserve the value of the oil (Monsanto, 2010). As a specialty soybean variety, Monsanto anticipates that MON 87705 Soybean would be cultivated following existing specialty crop practices to preserve product identity from seed production through harvesting, handling, and processing (Monsanto, 2010). Specialty soybean varieties are already cultivated on 12% of the U.S. soybean acreage, and the industry anticipates that specialty soybean acreage could expand to over 25% of the crop in certain states within the next decade (MSA, 2009). Cultivation of MON 87705 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 change by the introduction of MON 87705 Soybean, APHIS has determined

that there are no past, present, or reasonably foreseeable changes that would impact specialty soybean producers and consumers. Additionally, most of the soybean acreage in the U.S. is planted to GE soybean. MON 87705 Soybean would be an additional glyphosate-tolerant variety. Adoption of genetically engineered herbicide-tolerant soybeans increased from 17% of U.S. soybean acreage in 1997 to 68% in 2001 and 93% in 2010 (USDA-ERS, 2010a, 2010b). Based upon historic trends, conventional production practices that use GE varieties will likely continue to dominate in terms of acreage with or without a determination of nonregulated status of MON 87705 Soybean. 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 87705 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 87705 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 management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative effects analysis is included for each environmental issue analyzed in Chapter 4 of the EA. In the event of a determination of nonregulated status, MON 87705 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 other herbicides, but may also have progeny with no transgenes at all. There is no guarantee that MON 87705 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. In the event of a determination of nonregulated status of MON 87705 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 87705 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 87705 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 87705 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 87705 Soybean. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87705 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 87705 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 87705 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 4 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of MON 87705 Soybean on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of MON 87705 Soybean, APHIS has determined that a determination of nonregulated status of MON 87705 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 87705 Soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87705 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 87705 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). In compliance with this policy, Monsanto initiated a consultation with the FDA on the food and feed safety and nutritional assessment summary for MON 87705 Soybean. A copy of the completed FDA review is provided in Appendix A of the EA. EPA has authority under FIFRA to establish pesticide use restrictions; these use restrictions are presented on pesticide labels which are prepared during the pesticide registration process. The CP4 EPSPS protein expressed in MON 87705 Soybean is similar and functionally identical to endogenous plant EPSPS enzymes and is identical to the CP4 EPSPSs in other Roundup Ready® crops including Roundup Ready® soybean (40-3-2 and MON 89788). 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 expressed in MON 87705 Soybean is the same as that previously reviewed 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 87705 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 87705 Soybean, the continued regulated status of MON 87705 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 87705 Soybean will not have any significant environmental effects.

Michael C. Gregoire — 10/7/11

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

Date:

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Monsanto. (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).

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

USDA-APHIS. (2010). Assessment of Plant Pest Risk for MON 87705 Soybean. Riverdale, MD: US Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services.

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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). Adoption of Genetically Engineered Crops in the U.S. Retrieved November 29, 2010, from http://www.ers.usda.gov/data/biotechcrops/

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

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. (2011). Biotechnology Consultation - Note to File No. 000121. College Park, MD: Department of Health and Human Services, Food and Drug Administration.

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Attachment
Finding of No Significant Impact
Response to Comments
Petition 09-201-01p

Comment: While Monsanto in the petition and in the Addendum have presented a detailed risk management plan, and outlined clear responsibilities for the parties and their obligations for maintaining channels for a segregated product, they will neither manage possible impacts nor accept responsibility or liability for the execution of the risk management plan. Thus, Monsanto will not insure compliance or commit to remedy adverse supply chain events. The industry consortium disagrees with Monsanto that a risk mitigation plan is not necessary to support the product.

Response: APHIS understands the difficult situation for industry entities that process, produce and use oils if admixture of MON 87705 and commodity or other specialty oils should occur. However, APHIS has no statutory authority for issues of liability following adverse incidents in food and industrial oil production. 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.

Monsanto does not expect that mitigation may be needed, since it will be averted by combinations of economic incentives, contracts and agreements, stewardship providing strong SOPs and the existing competence of the processors and sellers of oil products. Monsanto proposes to maintain identity preservation of high oleic soybean through a closed loop stewardship plan; this comprehensive management plan is acceptable to the commenter. Product integrity will be preserved by requirements for oil analysis throughout the supply chain, standard operating procedures, contracts or agreements, and segregated storage at each level of purchaser, processor and user. Critical control points are specified within the handling protocols at which certain processes and procedures must be undertaken. All parties to soybean oil production will be asked and must agree to observe conditions of the management plan. The components of the plan together serve to maintain the integrity of the seller and protect the interests of the buyer (see Appendix D, Fig. 2, p. 8 of Addendum to Petition, Monsanto, 2010). The maintenance of product identity is thus enforced by mutually beneficial mechanisms agreed upon by the parties that buy, sell, use or transport the product oils. Finally, processors have sufficient experience in segregating, testing, and blending diverse specialized oils, and one more oil with different fatty acid content would not likely provide any new challenges to product identity (see EA, Appendix D: Monsanto, 2010, section 5. Stewardship: Market and Trade Assessment).

The components of the proposed stewardship plan are intended to prevent admixture of MON 87705 soybean oil with standard commodity oil. The value of the specialty oil is dependent upon maintenance of integrity of the fatty acid profile with no admixture with standard commodity oils. It is reasonable to assume that economic self-interest is a primary concern within the supply chain and among users and that the market will adequately regulate itself to preserve the identity of this and other oils produced for the food industry. Historically, the identity of other types of soybean oils have been maintained using closed loop mechanisms, and with full integrity (e.g., as in the early years of production of various low linolenic acid varieties

and high sucrose soybeans (Elbehri, 2007); various commercial specialty oilseeds supplied to processors, Clarkson, 2004)). APHIS is not aware of any large scale failures of these special IP procedures when active stewardship is maintained by a developer, and as noted by Redick, (2005) "grower and grain associations ... insist[ed] on the use of well tested closed-loop identity preservation" systems even in the context of industrial traits expressed in commodity crops.

According to an USDA-ERS study of grain product identity preservation, risk to the businesses involved in production and marketing arise from complying with contracts (deviating from specific standards, commingling issues, liability for quality problems, contract defaults in the supply chain) or are related to pricing factors (loss of premiums or uncertainty of return on long-term investment) (Elbeheri, 2007). To earn premiums from producing and processing specialty oils, producers necessarily have additional investments in the costs of segregating and preserving product identity, as well as for the cost of mitigating risks (Elbehri, 2007). Risk management in closed loop identity preserved systems is more robust than that of segregation mechanisms, since the risk manager oversees every detail of product use from seed production through acceptance by the end user; necessary risk management procedures entail rigorous quality control and tight chain of custody processes (Redick, 2005; Elbehri, 2007). Typically, risk may be shared under terms of a contract between producer and user; contracts may also be used to minimize production and transaction costs (Elbehri, 2007).

In the EA, APHIS has concluded that the risk of impacts from wide scale production of MON 87705 to industry using soybean oil is not likely to be significant given the comprehensive management plan offered by Monsanto, and given the likelihood that this closed loop identity preserved plan is likely to be successful in preventing admixture, because similar management plans for specialty soybean oils have also been successful.

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. (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).

Redick, T.P. (2005). Liability Prevention and Biotechnology: A Brief History of Successful Industrial Stewardship. NABC Report 17: Agricultural Biotechnology: Beyond Food and Energy to Health and the Environment. http://nabc.cals.cornell.edu/pubs/nabc_17/parts/NABC17_Module4_2.pdf

Comment: Monsanto plans to effectively commercialize MON 87705 soybean before all major markets have completed regulatory approval for legal importation. One soybean purchaser that has not granted approval at this point is South Korea, which may become an even larger customer for US soybean when the current Free Trade Agreement with them is signed. Future soybean trade may be jeopardized if MON 87705 soybean is commingled in current shipments and arrives without such approval. The full potential costs of products of new technology should be shared between Monsanto and production chain partners by agreements made between the parties.

Response: APHIS understands the importance of obtaining the necessary regulatory approvals prior to commercializing MON 87705 Soybean and the associated trade implications. Global sensitivities to GE products, including international restrictions on import of GE products and inability of the petitioner to gain approval for cultivation or importation, will continue to impede trade with those countries. These challenges to international trade in GE products are already in place. Restrictions on international trade in GE products, including MON 87705 Soybean, are unlikely to change with a determination of nonregulated status of MON 87705 Soybean.

To support commercial introduction of MON 87705 Soybean in the U.S., Monsanto has indicated in their petition request of nonregulated status of MON 87705 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. and have established regulatory approval processes in place (Monsanto, 2010). To further limit commingling of MON 87705 Soybean with commodity soybeans, Monsanto proposes to maintain identity preservation of high oleic soybean through a closed loop stewardship plan; this comprehensive management plan is acceptable to the commenter. Product integrity will be preserved by requirements for analysis, standard operating procedures, contracts or agreements, and segregated storage between each level of processor and user (Monsanto, 2010). In the EA, APHIS has determined that the risk of impact on the soybean-using food industry following wide scale production of MON 87705 is not likely to be significant given the management plan offered by Monsanto, and given that similar management plans for specialty soybean oils have been successful in preventing admixture (see previous Response to Comment).

The commenter notes that South Korea has thus far not approved the MON 87705 soybean line. If some soybean could not be shipped to this country until acceptance of MON 87705 Soybean by South Korea's regulatory system had been completed, minimal impacts would be expected on overall U.S. soybean trade, since U.S. whole soybean exports in 2010 to South Korea represented only 1.6% of the U.S. world export market (FAS, 2011a and 2011b). In addition, no new market opportunities are anticipated for U.S. Soybeans. The USDA has predicted that U.S. exports will remain flat during much of the period extending through 2019 (FAPRI, 2009; USDA-ERS, 2009).

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. Because APHIS has concluded that MON 87705 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010a), APHIS does not have the statutory authority to impose further restrictions on MON 87705 Soybean.

FAPRI (2009). U.S. and World Agricultural Outlook Food and Agricultural Policy Research Institute. 395pp. http://www.fapri.iastate.edu/outlook/2009/

Monsanto. (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).

USDA-ERS (2009). Cotton: Background. USDA Economic Research Service. http://www.ers.usda.gov/Briefing/Cotton/background.htm

USDA-FAS (2011a). Table 07: Soybeans: World Supply and Distribution. Foreign Agricultural Service.
http://www.fas.usda.gov/psdonline/psdreport.aspx?hidReportRetrievalName=BVS&hidReportRetrievalID=706&hidReportRetrievalTemplateID=8
USDA-FAS (2011b). Oilseeds. Production Supply Distribution (PSD Online Home / Downloadable Data Sets). Updated 9/12/11.
http://www.fas.usda.gov/psdonline/psdDownload.aspx

Comment: Two organizations representing grain handling businesses and allied end users, and of another representing companies and cooperatives producing and providing services to grain and oilseed exporting industry comment that they have concerns for impacts on international agriculture if MON 87705 moves outside the closed loop system. While they appreciate that the management system proposed by Monsanto will appropriately manage the potential for commercial disruptions, they are concerned that Monsanto has not publically made "its commitment to corporate responsibility... to all stakeholders in the value chain."

Response: Monsanto has indicated in their petition requesting nonregulated status for MON 87705 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. 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 Section 4.6 of the EA, APHIS assesses that impacts resulting from adverse events, such as admixture of the specialty oil following a determination of nonregulated status of MON 87705 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, three quality parameters important to oil users can vary by as much as 14-15% without impacts on oil function, sensory properties, labeling requirements, or on oil marketing and uses. At the farm level, an exceptionally large number of misdirected trucks carrying MON 87705

soybean would be needed to effect significant change in these parameters characteristic of commodity soybean oil, given the large dilution volumes to which these oils are typically subjected (Monsanto, 2010, Addendum to Petition).

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. (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).

Comment: Concerns were expressed that genetically engineered crops might affect honey bee populations, already stressed from Colony Collapse Disorder. Decades of research and monitoring may be needed to study impacts on insects, wildlife and birds.

Response: First observed on the eastern U.S. coast in the second half of 2006, honey bee colony collapse disorder (CCD) accounted for a decline of approximately 36 percent of the honey bee population (Johnson, 2010). In contrast to other previous bee colony losses, CCD can be distinguished by several unusual attributes, including: 1) failure of adult worker bees to return to the hive, despite the presence of a brood and queen remaining in the hive; 2) relatively wide-spread and rapid colony loss throughout the entire year (i.e., not seasonal); and 3) that the mechanisms of the loss still remain unknown. Possible causes of CCD include pathogens, parasites, environmental stresses, and bee management stresses (e.g., poor nutrition); however, recent evidence suggests that CCD may represent a syndrome caused by a suite of factors interacting synergistically to produce rapid and wide-spread colony collapse (USDA, 2009; Ratnieks et al., 2010, Mullin et al., 2010). Potential biotic and abiotic stresses correlated with CCD include, but may not be limited to: the single-celled parasite *Nosema ceranae*; Israeli acute paralysis virus (IAPV) and its potential vector, the *Varroa* mite; or neonicotinoids, synthetic insecticides that bind the insect nicotinic acetylcholine receptor and other insecticides (Vidau et al., 2011). However, correlation is not the same as causation. While several factors have been observed to be strongly correlated with CCD, few hypotheses have been experimentally verified and thus it is not currently known with certainty which factors produce CCD.

As the petitioner noted, APHIS states in the EA that soybeans are mostly self-pollinated; some research indicates that different cultivars are visited more or less frequently by honey bees (Erickson, 1975). Although foraging honey bees and brood could potentially come into contact with MON 87705 pollen, toxins are not synthesized by the genetic material altered in MON 87705 soybean. MON 87705 specifically down-regulates two enzymes producing fatty acids by an RNA interference mechanism. The site of the gene regulation is directed to the seeds, so pollen is not likely affected. Consequently, pollen safety is assured.

APHIS and FDA evaluated the changes in composition of MON 87705 Soybean with the non-transformed host variety, and with a number of other commercial cultivars. Aside from the

expected changes in fatty acid concentration, there were no biologically significant differences between MON 87705 Soybean and these other cultivars (FDA, Biotechnology Consultation Note to File 121). FDA's BNF states that "Monsanto has concluded that, with the exception of the intended change in fatty acid composition, soybean MON 87705 and the foods and feeds derived from it are not materially different in composition, safety, or any other relevant parameter from other soybean varieties now grown, marketed, and consumed in the U.S. At this time, based on Monsanto's data and information, the agency considers Monsanto's consultation on soybean MON 87705 to be complete." FDA analysis concluded that there were no biologically significant differences between this soybean and others in commercial use that would have impacts on animal feed. Impacts on non-target animals and plants in the environment from consuming or using MON 87705 as habitat are unlikely, since there are no significant differences from the conventional cultivars.

APHIS evaluated in the EA Monsanto's presentation of observations made of populations of pest insects (Monsanto, 2010, Table G-8) and of beneficial insects (Monsanto, 2010, Table G-9). APHIS concluded that there are no insect population differences between the MON 87705 Soybean and control plants over multiple field sites. Insect population diversity represents one measure of general impacts, and there were no differences observed at various times during development of the crop. In the absence of any observable acute stresses or impacts, there is no reason to presume that long term impacts would be expected, nor that a need exists to monitor for them.

The MON 87705 Soybean will also have a glyphosate tolerance trait, which has already been widely used in many crops over numerous years. In the petition for MON 87705 Soybean, section, "O.2 Potential Impact of Glyphosate on Human Health," and "O.3 Potential Impact of Glyphosate on the Environment," Monsanto summarizes EPA data on the use of glyphosate and impacts on the environment, and notes that EPA concluded that glyphosate does not provide an unreasonable risk to the environment (Monsanto, 2010).

From analyses of the effects of the genetic material in MON 87705, the lack of toxicity of the soybean, no expected changes in agronomic practices between MON 87705 and conventional soybean, any potential impact of MON 87705 on the honeybee population or on other wildlife is unlikely.

Erickson, E.H. (1975). Effect of Honey Bees on Yield on Three Soybean Cultivars. Crop Science, 15, 84-86.

Johnson, R. (2010). Honey Bee Colony Collapse Disorder. Congressional Research Service. January 7. Retrieved, April 12, 2011, from: http://books.google.com/books?id=SxaJTt3KgoEC&lpg=PP1&dq=Honey%20bee%20colony%2 0collapse%20disorder&pg=PP1#v=onepage&q&f=false.

Monsanto. (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).

Mullin, C.A., Frazier, M., Frazier, J.L., Ashcraft, S., Simonds, R., vanEngelsdorp, D., Pettis, J.S. (2010). High Levels of Miticides and Agrochemicals in North American Apiaries: Implications for Honey Bee Health. PLoS ONE 5:e9754.

Ratnieks, F.L.W., Carreck, N.L. (2010) Clarity on honey bee collapse? Science 327: 152–153.
USDA (2009). Colony Collapse Disorder Progress Report. CCD Steering Committee. June 2009. Retrieved on March 24, from http://www.ars.usda.gov/is/br/ccd/ccdprogressreport.pdf
Vidau, C., Diogon, M., Aufauvre, J., Fontbonne, R., Vigue, B., Brunet, J.L., Texier, C., Biron, D.G., Blot, N., El Alaoui, H., Belzunces, L.P., Delbac, F. (2011). Exposure to Sublethal Doses of Fipronil and Thiacloprid Highly Increases Mortality of Honeybees Previously Infected by Nosema ceranae. PLoS ONE 6(6): e21550. doi:10.1371/journal.pone.0021550.

Comment: One comment states that Monsanto is not sharing safety tests on new products with peer reviewed science panels.

Response: APHIS is responsible for regulating GE organisms and plants under the plant pest authorities 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. 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. There is no regulatory requirement that information submitted by petitioners to APHIS must be peer reviewed by a scientific panel.

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) (see 7 U.S. C. §7701(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"

To assist APHIS in their scientific technical review of a petition request, in accordance with APHIS regulatory requirements set forth in 7 CFR part 340, APHIS makes each complete petition available for a 60 day public comment period. Petitions submitted by developers are announced in a *Federal Register* Notice and made publicly available on the APHIS website*. Petitions submitted by developers are made available to the public and include the methods used for experiments along with the subsequent observations and results. APHIS typically receives and fully considers responses from scientists made on the methodology used and the results summarized in the petition. These inputs allow APHIS to make an informed decision on the petition request, benefitting from external scientific expertise. APHIS may also directly consult

with experts and scientists on specific issues to assure adequate analysis of possible environmental impacts.

* http://www.aphis.usda.gov/biotechnology/not_reg.html

Comment: Another comment asserts that GMOs increase cancer, increase spontaneous abortions, facilitate incorporation of new pathogens, and cite the letter to Agriculture Secretary Vilsack from retired Professor Don Huber as support for this contention.

Response: Professor Huber's letter alleges that either the gene to produce glyphosate tolerant crops or the use of glyphosate (Roundup) is either a promoter or cofactor that facilitates a pathogen capable of infecting a variety of soybean, corn, their products, various livestock and "probably human beings." The letter claims evidence for the pathogen in electron micrographs (which are not published) and alleges animal infertility (anecdotes, none published, with no general corroboration), and a claim for escalating frequency of Goss' wilt in corn, and sudden death syndrome in soybean (no data to support the claims). Where animal abortions were noted, an inference was made that animals consumed a wheat product, on which glyphosate may have been used. While these hypotheses are certainly remarkable, there was insufficient information on methodology and results with which to make an evaluation. APHIS welcomes additional information from Professor Huber and others and will continue to evaluate new information with respect to APHIS decisions. APHIS encourages Professor Huber to publish his methods, results and conclusions, so that APHIS and the greater scientific community can fully evaluate his claims.

Comment: Various commenters allege that use of glyphosate has adverse effects on human and animal health, and that a safety review is needed.

Response: The EA has reported on the safety of the use of glyphosate in the environmental consequences and cumulative impacts sections under various headings, including those on animals, plants, biodiversity, microbes and human health.

The CP4 EPSPS protein used in MON 87705 Soybean confers tolerance to glyphosate. This protein is structurally homologous and similar functionally to endogenous plant EPSPS enzymes and is identical to the CP4 EPSPSs in other 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 (http://www.aphis.usda.gov/biotechnology/not_reg.html). The first generation of Roundup Ready® soybean (40-3-2) was determined by APHIS to be no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act in 1995 (http://www.aphis.usda.gov/biotechnology/not_reg.html). The *cp4 epsps* gene has been assessed extensively in the last 15 years. 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; see also Hammond et al., 1996; Padgette et al., 1996). The FDA has reviewed the safety of human consumption of the CP4 EPSPS protein in MON 87705 Soybean, and concluded that this protein presents negligible risk to human health from consumption (US-FDA, 2011).

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). This exemption is based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The CP4 EPSPS protein expressed in MON 87705 Soybean is the same as that previously reviewed by the EPA. Accordingly, MON 87705 Soybean is anticipated to be safe for human and animal consumption with regard to the *cp4 epsps* gene.

EPA's Worker Protection Standard (WPS) (40 CFR Part 170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. During agricultural production of soybean, agricultural workers and pesticide applicators may be exposed to a variety of EPA registered pesticides (see, e.g., http://www.cdc.gov/niosh/topics/pesticides/). Such chemicals would be expected to include those products currently used for insect pest and plant pest management in both GE and non-GE soybean cultivation, including the use of glyphosate. Worker safety is taken into consideration when a pesticide label is developed during the registration process. When use is consistent with the label, pesticides including the glyphosate to be used with MON 87705 present minimal risk to the worker.

Hammond, B. G., Vicini, J. L., Hartnell, G. F., Naylor, M. W., Knight, C. D., Robinson, E. H., . . . Padgette, S. R. (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, L. A., Bailey, M. R., Naylor, M. W., Ream, J. E., Hammond, B. G., Nida, D. L., . . . Padgette, S. R. (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.

Padgette, S. R., Taylor, N. B., Nida, D. L., Bailey, M. R., MacDonald, J., Holden, L. R., & Fuchs, R. L. (1996). The composition of glyphosate-tolerant soybean seeds is equivalent to that of conventional soybeans. *The Journal of Nutrition, 126*(3), 702-716.

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. (2011). Biotechnology Consultation - Note to File No. 000121. College Park, MD: Department of Health and Human Services, Food and Drug Administration.