NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

Bayer CropScience LP

Event FG72 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 genetically engineered (GE) event FG72 soybean, the subject of a petition request (APHIS Number 09-328-01p) by Bayer CropScience LP (Bayer). The FG72 soybean is resistant to the herbicides, glyphosate and isoxaflutole. The EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from approving the petition seeking nonregulated status for FG72 soybean. The EA assesses alternatives to a determination of nonregulated status of FG72 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 GE varieties) can increase farm income, and provide benefits to the environment and consumers.

Since 1986, the United States government has regulated GE organisms pursuant to 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 APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

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

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are GE. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those GE, 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 foods.

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA, 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. 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 Cosmetics Act (FFDCA) and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA).

Regulated Organisms

The APHIS Biotechnology Regulatory Services' (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 PPA, as amended (7 United States Code (U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism is 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 does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency for a determination that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest risk provisions of the PPA or the regulations at 7 CFR part 340. The petitioner is required to provide information under §§340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest risk provisions of the PPA 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 PPA 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 FG72 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 GE organism is unlikely to pose a plant pest risk, it is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340.

Bayer has submitted a petition (APHIS Number 09-328-01p) to APHIS seeking a determination that their GE FG72 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.

FG72 soybean

FG72 soybean has been genetically engineered to express the 2mEPSPS and HPPD W336 proteins to convey resistance to the herbicides glyphosate and isoxaflutole respectively. FG72 soybean provides growers with an alternative to existing glyphosate-resistant soybean products on the market today. Herbicide-resistant FG72 soybean will provide similar benefits to currently available herbicide-resistant soybean varieties by allowing post emergent applications of glyphosate and isoxaflutole to control weeds. FG72 soybean was developed to enable the use of isoxaflutole to manage soybean weed populations, including those weed populations that are resistant to glyphosate, without injury to soybean plants.

Coordinated Framework Review

Food and Drug Administration

FG72 soybean is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced by genetic engineering. Bayer initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 3, 2009 (Bayer, 2011). Based on the information Bayer submitted, and as of August 7, 2012, the FDA has no further questions regarding FG72 soybean (FDA, 2012).

Environmental Protection Agency

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

EPA has authority under FIFRA to establish pesticide use restrictions; these use restrictions are presented on pesticide labels which are prepared during the pesticide registration process. FG72 soybean is similar to currently available glyphosate-resistant soybean varieties, with the exception of an opportunity to use isoxaflutole in addition to glyphosate. Bayer submitted labeling to the U.S. EPA in July 2010 for EPA Registration Number 264-600, that propose to allow the use of isoxaflutole on isoxaflutole resistant soybean varieties (Bayer, 2010). APHIS used the current glyphosate labels and the proposed isoxaflutole label as the basis for its evaluation of the potential impacts associated with the use of and exposure to glyphosate and isoxaflutole.

Scope of the Environmental Analysis

Although a determination of nonregulated status of FG72 soybean would allow for new plantings of FG72 soybean anywhere in the U.S., APHIS primarily focused the environmental analysis to those states that both support soybean production and permit the registered use of isoxaflutole on soybean, as these are the areas that are most likely to adopt FG72 soybean. A determination of nonregulated status of FG72 soybean is not expected to increase soybean production by its availability alone or accompanied by other factors, nor should it cause an increase in overall GE soybean acreage. To determine areas of soybean production, APHIS used data from the National Agricultural Statistics Service (NASS) to determine where soybean is produced in the U.S. (UDA-NASS, 2012). In the U.S., soybeans are cultivated in 31 states, with approximately 77.2 million acres of soybean cultivated in 2012 (USDA-NASS, 2012).

Public Involvement

On July 13, 2012, APHIS published a notice in the Federal Register (77 FR pages 41358, Docket no. APHIS-2012-0029) announcing the availability of the Bayer petition, draft EA, and draft PPRA for a 60-day public review and comment period. Comments were required to be received on or before September 11, 2012. All comments were carefully analyzed to identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in the evaluation of the petition. A total of 5,096 comments were received during the comment period[1]. The issues that were raised in the public comments which were related to the Bayer FG72 soybean petition included:

- Development of herbicide resistant weeds and weeds with multiple resistance
- Use of herbicides on herbicide resistant crops including increased herbicide use and change in use patterns
- The effects of FG72 soybean and its associated herbicide use on conservation tillage
- The potential for increased weediness of FG72 soybean volunteers
- The fate of glyphosate and isoxaflutole in air, water, and soil

[1] Comment documents may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0029

• The effects of glyphosate and isoxaflutole use on biological organisms including Threatened and Endangered Species
• The effects of FG72 soybean and its associated herbicide use on climate change
• The effect of glyphosate drift on outcrossing to weedy or wild relatives
• The effect of glyphosate and isoxaflutole drift on nontarget plants including nontarget crops
• Increase in plant pathogens or susceptibility to plant pathogens from the use of herbicides
• The effects of FG72 soybean and associated glyphosate and isoxaflutole use on human health
• Concern that cross-pollination between GE and organic or crops for GE-sensitive markets will affect sales for growers of these crops.
• The economic costs of herbicide resistant weeds
• Concerns that Bayer FG72 soybean is not approved in all export markets.

APHIS evaluated these raised issues and the submitted documentation. APHIS has included a discussion of these issues in the EA or in the response to comments attached to this document.

Major Issues Addressed in the EA

Issues discussed in the EA were identified by considering public concerns and issues described in public comments for the petition for nonregulated status of FG72 soybean and other environmental assessments of GE organisms. Issues identified in lawsuits, and those submitted by various stakeholders were also discussed. These issues, including those regarding the agricultural production of soybean using various production methods, and the environmental food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of FG72 soybean.

The EA describes the alternatives considered and evaluated using the issues identified. These include the following that 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

Environmental Considerations:

- Soil Quality
- Water Resources
- 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
- Organic Soybean Production
- Trade Economic Environment

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of FG72 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that FG72 soybean is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2011), APHIS has concluded that FG72 soybean is unlikely to pose a plant pest risk. Therefore, APHIS must determine that FG72 soybean is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of FG72 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. FG72 soybean and progeny derived from FG72 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 FG72 soybean and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS would choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of FG72 soybean.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011). 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 FG72 soybean is No Longer a Regulated Article

Under this alternative, FG72 soybean and progeny derived from FG72 soybean would no longer be regulated articles under the regulations at 7 CFR part 340. FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of FG72 soybean and progeny derived from this event. The preferred alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. Because the agency has concluded that FG72 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of FG72 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.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for FG72 soybean. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the PPA, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for FG72 soybean. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

1. Prohibit any FG72 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 FG72 soybean, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011).

In enacting the PPA, Congress listed findings in Section 402(4), including the following one:

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

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

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

Based on the PPRA (USDA-APHIS, 2011), and the scientific data evaluated therein, APHIS concluded that FG72 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of FG72 soybean.

2. Approve the petition in part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that FG72 soybean is unlikely to pose a plant pest risk, (USDA-APHIS, 2011), and it is the only line described in the petition, there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

3. Isolation Distance between FG72 soybean and Non-GE Soybean Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating FG72 soybean from conventional or specialty soybean production. However, because APHIS has concluded that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011), an alternative based on requiring

isolation distances would be inconsistent with statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of FG72 soybean based on the location of production of non-GE soybean in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' PPRA for FG72 soybean, there are no geographic differences associated with any identifiable plant pest risks for FG72 soybean (USDA-APHIS, 2011). This alternative was rejected and not analyzed in detail because APHIS has concluded that FG72 soybean does not present a plant pest risk, and will not exhibit a greater plant risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the PPA 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 PPA. However, individuals might choose on their own to geographically isolate their non-GE production systems from FG72 soybean or to use isolation distances and other management practices to minimize gene movement between soybean fields. Information to assist growers in making informed management decisions for FG72 soybean is available from the Association of Official Seed Certifying Agencies (AOSCA, 2011).

4. Requirement of Testing for FG72 soybean

During the comment periods for other petitions for nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. APHIS notes that there are no nationally established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because FG72 soybean does not pose a plant pest risk (USDA-APHIS, 2011), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for FG72 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**

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2012d)
Management Practices		
Acreage and range of soybean production	93% of all soybean produced in US are GE herbicide-resistant varieties. Soybean total acreage is likely to remain steady.	Unchanged from No Action Alternative
Agronomic practices	Crop rotation can reduce selection pressure for weed resistance to herbicides. Reduced or conservation tillage has largely replaced conventional tillage.	Unchanged from No Action Alternative
Pesticide use	EPA-approved uses of glyphosate on soybean have been reviewed since the introduction of glyphosate resistant varieties, and have remained unchanged. Isoxaflutole underwent an ecological risk assessment in April 2010 for use on soybeans.	Isoxaflutole use on soybean is predicted to increase, but remain below an adoption rate of 5 percent of U.S. soybean acres.
Organic soybean production	Specialty crop growers employ practices and standards for seed production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops. Certified organic soybean acreage is a small but increasing percentage of overall soybean production.	Unchanged from No Action Alternative
Environment		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Soil quality	Agronomic practices such as crop type, tillage, and pest management can affect soil quality. Growers will adopt management practices to address their specific needs in producing soybean	Unchanged from No Action Alternative
Water resources	The primary cause of agricultural NPS pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as conservation tillage, crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff	Unchanged from No Action Alternative
Air quality	Agricultural activities such as burning, tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Aerial application of herbicides may impact air quality from drift, diffusion, and volatilization of the chemicals, as well as motor vehicle emissions from airplanes or helicopters.	Unchanged from No Action Alternative
Climate change	Agriculture-related activities are recognized as both direct sources of greenhouse gases (GHGs) (e.g., exhaust from motorized equipment) and indirect sources (e.g., agriculture-related soil disturbance, fertilizer production)	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Animal communities	Invertebrates that feed on soybean are typically considered pests and may be controlled by the use of insecticides or other production practices. The toxicity of glyphosate to animal species from registered uses poses minimal risks to animals. EPA concluded that the level of concern for acute and chronic risks for birds, mammals, and fish was not exceeded as a result of isoxaflutole application	Unchanged from No Action Alternative
Plant communities	Soybean fields can be bordered by other agricultural fields (including other soybean varieties), woodlands, or pasture and grasslands. The most agronomically important members of a surrounding plant community are those that behave as weeds. Soybean growers use production practices to manage weeds in and around fields.	Unchanged from No Action Alternative
Gene flow/weediness	Cultivated soybean varieties can cross pollinate. Growers use various production practices to limit undesired cross pollination.	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Soil microorganisms	APHIS has previously examined potential impacts of glyphosate on microorganisms in soils of field under cultivation with HR crops, and has not found evidence linking applications of glyphosate to changes in soil microbial communities that have adverse effects on plants grown in those soils. Isoxaflutole is readily degraded in soil by soil microorganisms. No long term effects on soil microorganisms were identified with isoxaflutole use.	Unchanged from No Action Alternative
Biodiversity	HR crops, such as soybean, have been correlated with an increase in conservation tillage in U.S. crop production, which promotes biodiversity by allowing the establishment of other plants, and the accumulation of more plant residue that increases soil organic matter, food, and cover for wildlife. Effects of GE crops have been associated with positive impacts on biodiversity because of increased yields, fewer applications of less toxic pesticides, and facilitation of conservation tillage.	Unchanged from No Action Alternative
Human and Animal Health		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Human/worker health	2mEPSPS and HPPD W336 proteins pose no potential for toxicity or allergenicity for humans. Agricultural workers that routinely handle glyphosate may be exposed during spray operations. Because of low acute toxicity of glyphosate, absence of evidence of carcinogenicity and other toxicological concerns, occupational exposure data is not required for reregistration. However, EPA has classified some glyphosate formulations as eye and skin irritants. Isoxaflutole also exhibits low acute toxicity but is classified as "likely to be a human carcinogen however, EPA has determined no harm to human health will result from aggregate exposure to isoxaflutole or its residues. The EPA's Worker Protection Standard (WPS) (EPA, 1992); 40 CFR Part 170.1, *Scope and Purpose*) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.	A comprehensive assessment of the safety of 2mEPSPS and HPPD W336 demonstrated that the proteins are nontoxic to mammals and unlikely to be a food allergen. EPA-registered pesticides that are currently used for soybean production would continue to be used by growers under the Preferred Alternative. Agricultural production with FG72 soybean does not require any change to the agronomic practices or chemicals currently used (i.e., pesticides) for conventional soybean. Therefore, worker safety issues associated with the agricultural production of FG72 soybean would remain the same as those under the No Action Alternative.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Livestock health/animal feed	Processed soybeans are the largest source of protein in animal feed. EPSPS proteins are not expected to be allergenic, toxic, or pathogenic in mammals or poultry. The maximum tolerance level for glyphosate in soybean is 20 ppm for grain and is 100 ppm for forage. The maximum tolerance level for Isoxaflutole in soybean is 0.05 ppm for grain and is 0.3 ppm for seed and grain, aspirated fractions.	A compositional analysis concluded that forage and grain from FG72 soybean hybrids are considered similar in composition to forage and grain from both the non-transgenic comparator and conventional soybean hybrids. Therefore this is unchanged from the No Action Alternative
Socioeconomic		
Domestic economic environment	The widespread adoption of herbicide-resistant soybean has been attributed to the cost savings for production, among other non-monetary benefits.	Under the preferred alternative, growers would have an additional tool to use against glyphosate resistant weeds (isoxaflutole) which may reduce economic loss.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Trade economic environment	The primary US soybean export destinations are also the largest world importers of soybean and do not have major barriers for importing food or feed commodities produced from transgenic crops, including those with herbicide resistance traits. Nevertheless, import of each specific trait requires separate application and approval by the importing country	The trade economic impacts associated with a determination of nonregulated status of FG72 soybean are anticipated to be similar to the No Action alternative because Bayer does not intend to globally launch FG72 soybean until the proper regulatory approvals have been obtained. To support commercial introduction of FG72 soybean in the U.S., Bayer intends to submit dossiers to request import approval of FG72 soybean to the proper regulatory authorities of several countries that already have regulatory processes for GE soybean in place. These include, but are not limited to: Canada, Mexico, Japan, the EU, South Korea, and China.
Other Regulatory Approvals		
U.S.	Completed FDA consultation	Completed FDA consultation
Compliance with Other Laws		
CWA, CAA, Eos	Fully compliant	Fully compliant

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.

From 2002-2012, the average soybean production in the U.S. has been about 74.3 million acres (USDA-NASS, 2012). In 2012 approximately 77.2 million acres of soybean were cultivated in 31 states (USDA-NASS, 2012). In 2012, GE herbicide-resistant soybean was estimated to be 93% of the U.S. soybean crop (USDA-ERS, 2012). A determination of nonregulated status of FG72 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 FG72 soybean will not 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.

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 FG72 soybean will have no significant environmental impact on the availability of GE, conventional, or organic soybean varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of FG72 soybean is expected to neither directly cause an increase in overall soybean production acreage, nor GE soybean acreage. The availability of FG72 soybean will not change the cultivation areas for soybean production in the U.S., and there are no anticipated changes in the availability of GE and non-GE soybean varieties on the market. A determination of nonregulated status of FG72 soybean could add another GE soybean variety to the conventional soybean market, but is not expected to change the market demands for GE soybean or soybean produced using organic methods. In 2011, there were approximately 96,000 acres of organic soybean produced across 1,203 farms in the United States (USDA-NASS, 2012b). This represented about 0.13 percent of total U.S. soybean production in 2011 (USDA-NASS, 2012b). Based on the data provided by Bayer for FG72 soybean (Bayer, 2011), APHIS has concluded that the availability of FG72 soybean would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE soybean seed production (USDA-APHIS, 2011). A determination of nonregulated status of FG72 soybean will not require a change to seed production practices, nor current production practices. The introduction FG72 soybean provides an alternative soybean variety with herbicide resistance.

2. *The degree to which the proposed action affects public health or safety.*
   A determination of nonregulated status of FG72 soybean would have no significant impacts on human or animal health. Compositional tests conducted by the petitioner indicate that FG72 soybean is compositionally similar to other commercially available soybean (Bayer, 2011). Bayer initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 3,

2009. Based on the information Bayer submitted, and as of August 7, 2012, FDA has no further questions regarding FG72 soybean (FDA, 2012). Based on the FDA's consultation, laboratory data and scientific literature provided by Bayer (Bayer, 2011), and safety data available on other herbicide-resistant products, APHIS has concluded that FG72 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 FG72 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, 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 FG72 soybean. The product will be deployed on agricultural land currently suitable for production of soybean, will replace existing varieties, and is not expected to increase the acreage of soybean production. This action would not convert land to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to FG72 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 FG72 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 FG72 soybean are not highly controversial. Although APHIS received public comments opposed to a determination of nonregulated status of FG72 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 is not expected to directly cause an increase in agricultural acreage devoted to soybean production, or those acres devoted to GE soybean cultivation. The availability of FG72 soybean will not 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 FG72 soybean could add another GE soybean variety to the conventional soybean market and is not expected to change the market demands for GE soybean or soybean produced using organic methods. A determination of nonregulated status of FG72 soybean will not change current practices of planting, tillage, fertilizer application/use, cultivation, pesticide application/use, or volunteer control. Management practices and seed standards

for production of certified soybean seed would not change. The effect of FG72 soybean on wildlife or biodiversity is not different than that of other herbicide resistant soybean currently used in agriculture, or other GE or non-GE soybean produced in conventional agriculture in the U.S.

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 FG72 soybean is expected to neither directly cause an increase in agricultural acreage devoted to soybean production, nor increase those acres devoted to GE soybean cultivation. A determination of nonregulated status of FG72 soybean will not result in changes in the current practices of planting, tillage, fertilizer application/use, pesticide application/use or volunteer control. Management practices and seed standards for production of certified soybean seed would not change. The effect of FG72 soybean on wildlife or biodiversity is neither different than that from other herbicide-resistant crops currently used in agriculture, nor that of other GE or non-GE soybean produced in conventional agriculture in the U.S. As described in Chapter 2 of the EA, well established management practices, production controls, and production practices (GE, conventional, 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), FG72 soybean, or produce soybean using organic methods, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural soybean production. GE soybean is also planted currently on the majority of soybean acres (93% of acreage in 2012) (USDA-ERS, 2012). Based upon historic trends, conventional production practices that use GE varieties will likely continue to prevail in terms of acreage with or without a determination of nonregulated status of FG72 soybean. Given the extensive experience that APHIS, stakeholders, and growers have with the use of GE soybean products, the possible effects to the human environment from the release of 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 for FG72 soybean would not establish a precedent for future actions with significant effects, nor would it represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and 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 PPA 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 FG72 soybean. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism is unlikely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment, that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code(U.S.C.) 7701-7772), regulate the introduction (i.e., importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA nor the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have enough information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency for a decision that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the PPA or the regulations at 7 CFR part 340. The petitioner is required to provide information under §340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

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 provided in Chapter 5 of the EA. In the event APHIS reaches a determination of nonregulated status of FG72 soybean, APHIS would no longer have regulatory authority over this soybean. In the event of a determination of nonregulated status of FG72 soybean, APHIS has not identified any significant impact on the environment that may result from the incremental impact of a determination of nonregulated status of FG72 soybean when added to past, present, and reasonably foreseeable future actions.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.*
   A determination of nonregulated status of FG72 soybean will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe's request; thus, the tribes have

control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of FG72 soybean would not impact districts, sites, highways, structures, or objects listed in, or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historic resources. This action is limited to a determination of nonregulated status of FG72 soybean. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of FG72 soybean is a decision that will not 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. These cultivation practices are also being conducted currently throughout the soybean production regions. The cultivation of FG72 soybean does not inherently change any of these agronomic practices in ways that would cause any impact under the NHPA.

9. *The degree to which the action may adversely affect the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*
   As described in Chapter 6 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of FG72 soybean on federally listed threatened and endangered species (TES), species proposed for listing, and 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 FG72 soybean, APHIS has concluded that a determination of nonregulated status of FG72 soybean would have no effect on federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*
    The proposed action would be in compliance with all Federal, state, and local laws. Because the agency has concluded that FG72 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of FG72 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. Bayer initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72

soybean to the FDA to on December 3, 2009 (Bayer, 2011). Based on the information Bayer submitted, and as of August 7, 2012, FDA has no further questions regarding FG72 soybean (US-FDA, 2012). FG72 soybean is compositionally similar to currently available glyphosate-resistant soybean varieties on the market, with the exception of an opportunity to use isoxaflutole in addition to glyphosate on soybeans. Bayer submitted amended labeling to the U.S. EPA in July 2010 for EPA Registration Number 264-600, which proposes to allow the use of isoxaflutole on isoxaflutole resistant soybean varieties (Bayer, 2010). 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 FG72 soybean is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the safe development and use of GE organisms consistent with the plant pest provisions of the PPA.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of GE organisms; (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with FG72 soybean, the continued regulated status of FG72 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 FG72 soybean will not have any significant environmental effects.

M. J. Fuito for

Michael C. Gregoire

Deputy Administrator

Biotechnology Regulatory Services

13 August 2013

Date

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Response to Public Comments on Bayer FG72 Soy

Summary of comments received

On July 13, 2012, APHIS published a notice in the Federal Register (77 FR pages 41358, Docket no. APHIS-2012-0029) announcing the availability of the Bayer petition, draft EA, and draft PPRA for a 60-day public review and comment period. Comments were required to be received on or before September 11, 2012. The docket folder containing the comments can be located at http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0029 .All comments were carefully analyzed. A total of 66 organizations and individuals submitted comments during the comment period. One organization submitted 4,601 form letters. APHIS evaluated all issues raised by the comments and the submitted documentation. Many of the comments referenced other dockets that were open at the same time as this docket. Many of these comments were generically opposed to GE organisms, the use of herbicide resistant crops, discussed concerns about other open dockets, or were concerned that APHIS had published a group of dockets on the same day. These issues are outside of the scope of this EA. APHIS has responded below to the issues that were raised which relate to docket APHIS-2012-0029.

Issue 1

Several comments were concerned that the scope of APHIS authority under the PPA is too narrow**.** The comments were critical of APHIS interpretation of its regulations at 7 C.F.R. Part 340. These commenters believe that APHIS should expand the scope of its authority to include the designation of GE organisms, resistant to herbicides as noxious weeds. Some commenters were critical of the scope of what APHIS considers "plant pest risks". These commenters stated that APHIS conclusion that FG72 soybean is unlikely to pose a plant pest risk was legally incorrect.

APHIS Response

APHIS regulations were promulgated prior to the consolidation of the Noxious Weed Act and the Federal Plant Pest Act in the Plant Quarantine Act. However, the PPA maintained the separate regulatory framework for plant pests and noxious weeds that were originally promulgated under the Federal Plant Pest Act and the Federal Noxious Weed Act, and as stated in Center for Food Safety v. Vilsack No 12-15052, D.C. No. 3:11-cv-01310-SC, opinion of the United States Court of Appeals for the 9th Circuit, "neither the PPA nor APHIS's regulations, … require APHIS to conduct a separate noxious weed analysis in response to a party's petition to deregulate a plant pest under 7 CFR section 340.6". If a person wishes to have APHIS consider whether a particular plant is a noxious weed, that person may petition the agency pursuant to the process contained at 7 C.F.R. part 360.

While the noxious weed definition in the Plant Protection Act includes many kinds of physical harms beyond harm to other plants (e.g. harm to public health and the environment), the commenter misinterprets the level of impacts that would warrant APHIS to determine a plant to be a "noxious weed" precipitating Federal action. The commenter uses the term "noxious weed" inconsistently with the definition of weeds, encompassing plants with traits which in all likelihood, would not be considered "noxious" under APHIS regulatory programs for noxious

weeds deriving from the Plant Protection Act and prior authorities. APHIS has explained the distinction between "weeds" and "noxious weeds" as ‘’Weeds,’ in the broadest sense of the word, could include any plant growing where and/or when it is unwanted; even plants that are desirable in some settings may be considered weeds in others. In a narrower sense, weeds are invasive, often non-native, plants which impact natural and managed ecosystems, often with significant negative consequences due to lost yields, changes in management practices, altered herbicide use, etc. Only a fraction of these problematic weeds are considered to be so invasive, so harmful, and so difficult to control that Federal regulatory intervention to prevent their introduction or dissemination is justified, and these are the focus of the regulatory controls placed on them by APHIS" [73 Fed. Reg. 60008, 60013 (Oct. 9, 2008)]. The comment also raises the concern that herbicide use associated with FG72 Soybean will create a pathway to the development of noxious weeds, as support for the regulation of FG72 Soybean as a noxious weed under existing authority. This once again misinterprets what would be considered a noxious weed. According to the commenter's theory, the soybean would be considered a noxious weed because a plant that might germinate beside it might become more difficult to kill or develop a resistance to an herbicide. Nonetheless, the issue of the risk of herbicide-resistant weeds is addressed in the EA. Although plant species have and will continue to develop resistance to certain herbicides when used in agriculture, APHIS has never made a determination to regulate a plant species as a noxious weed, solely on the basis that the plant has acquired resistance to an herbicide. As with any weed species that evolves resistance to an herbicide, APHIS will consider that herbicide resistance along with other factors such as invasiveness, significance of damage, and difficulty of control in determining whether to use Federal authority to prevent its dissemination.

Issue 2

A commenter asserted that APHIS's NEPA analyses are pre-determined or limited by APHIS's plant pest risk assessment (PPRA). The comment question the adequacy of APHIS's analysis of alternatives, expressing the view that APHIS had "rejected" several reasonable alternatives from consideration including: (1) an alternative that would prohibit the release of FG72 soy entirely; (2) an alternative that would approve the petition in part, only allowing some strains applied-for to be released; (3) an alternative that would partially deregulate FG72 soy by imposing isolation distances and/or geographical restrictions to keep the crops away from conventional crops and mitigate contamination; and (4) an alternative that would require mandatory testing for transgenic contamination". The commenter went on to say that,

"APHIS also failed to even mention several other reasonable alternatives, including:

- A partial deregulation alternative with requirements to reduce the development of weed resistance (including resistance to isoxaflutole, mesotrione, glufosinate, or glyphosate, or a combination of these pesticides)
- A partial deregulation alternative with mandatory restrictions to prevent or mitigate substantial harms to agriculture through crop injury from herbicide drift and runoff to irrigation and drinking water that is a reasonably foreseeable consequence of unrestricted deregulation of FG72 soy.

- A partial deregulation containing comprehensive measures to prevent contamination of organic and non-GE seed or feed and food products, including but not limited to provisions on seed cleaning, mixing, transportation, and other protections. “

A number of commenters indicated that the USDA should complete an EIS on this decision.

APHIS Response

The EA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from a determination of nonregulated status of FG72 Soybean. APHIS assembled a list of alternatives that might be considered for FG72 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 FG72 Soybean. As described in the EA, APHIS evaluated two alternatives; (1) no action and (2) determination of nonregulated status of FG72 Soybean. In addition, APHIS rejected several other alternatives. These alternatives are discussed briefly in EA along with the specific reasons for rejecting each.

As described in Chapter 3 of the EA, several “in part” alternatives were considered but rejected, each for the same reason. APHIS has determined that FG72 Soybean is not likely to pose a plant pest risk, thus, the only reasonable alternative to nonregulated status would be the no action alternative; additional consideration of any other alternative would have been arbitrary. For example, geographic restrictions were rejected as an Alternative and not analyzed in detail because, based upon the scientific evidence presented, APHIS had no basis to conclude that FG72 Soybean would exhibit plant pest characteristics in certain geographic areas and not others. Consequently, a Geographic Restriction 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; furthermore, the imposition of geographic restrictions would not meet APHIS’ purpose and need to respond appropriately to a petition for nonregulated status.

A regulated GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 when it has been demonstrated, and the Administrator has determined, that it does not present a plant pest risk. The petitioner requesting deregulation of a product is required to provide certain information which the agency uses to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism from which it was derived. If, based on the information, the agency determines that the regulated article is unlikely to pose a plant pest risk, then the agency no longer has reason to regulate the article as a plant pest and the article must be granted a determination of nonregulated status. In this case, APHIS has determined that FG72 Soybean is not a plant pest and therefore, APHIS will approve the petition for a determination of nonregulated status.

As stated in Center for Food Safety v. Vilsack No 12-15052, D.C. No. 3:11-cv-01310-SC, opinion of the United States Court of Appeals for the 9th Circuit,

"NEPA requires that an agency take a "hard look" at the environmental effects of a proposed action that could significantly affect the environment by evaluating all reasonable alternatives to the proposed action. .... Here, there were no reasonable alternatives to deregulation because the agency lacks jurisdiction to regulate RRA. APHIS was not required to look at alternatives to the unconditional deregulation of RRA absent any jurisdiction to adopt them."

APHIS has prepared the EA to consider the potential environmental effects of the proposed action and the reasonable alternative to that action, the no action alternative, consistent with NEPA requirements (40 CFR parts 1500-1508, 7 CFR 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from the deregulation of FG72 Soybean. In addition, APHIS has no reason to believe, based on the EA that the deregulation of FG72 Soybean would cause significant impacts on the environment and therefore, APHIS does not need to prepare an EIS before deregulating this product. APHIS has been reviewing petitions for deregulation since 1992 and has considered a wide variety of species including tomato, corn, cotton, soybean, canola, squash, papaya, and plum. Although APHIS regulations (7 CFR part 340.6(d) (3) (i)) allow for an "in part" determination, such a determination is made relative to plant pest risk. APHIS has found that FG72 Soybean does not present a plant pest risk, thus, APHIS has no basis to continue to regulate the soybean "in part."

Issue 3

An organization expressed the view that APHIS's decision "lacked a basis in sound science", by "excluding significant harms such as contamination, superweeds and herbicide impacts", and being based on the petitioners non peer reviewed studies. APHIS according to the commenter "largely ignored data on how FG72 soy may increase the weediness of volunteer soy, IFT resistant weeds, pest-like harm to non-target crops, and the issue of stacking". Several comments suggested that APHIS had relied on the applicants' analysis and data; frequent citation of dubious, industry-sponsored white papers with little or no scientific merit or review; and egregious factual errors biasing decisions in favor of applicants among other unscientific practices" and had ignored high-quality data and information.

APHIS Response

APHIS disagrees with the suggestion that it failed to base its analysis on sound science. APHIS ' analysis and decision within the PPRA regarding the plant pest risk posed by FG72 soybean is based on the best available scientific and technical information. APHIS used sound science to inform its regulatory decision regarding the plant pest risk of FG72 soybean, and has determined that FG72 soybean is not a plant pest risk. APHIS carefully reviewed the information provided by the petitioner and others and considered all other relevant information sufficient to make the determination on whether to deregulate the FG72 soybean. APHIS carefully considered the possible environmental impacts of the proposed product, and is satisfied that the EA developed for FG72 soybean is adequate and sufficient.

In the EA, APHIS has considered opposing views, has reviewed data submitted by those who supported or opposed deregulation, and has not relied on biased information. APHIS has included an analysis of each of the alternatives and evaluated and used the best available

information from various sources, including peer-reviewed scientific literature that was reviewed and incorporated into APHIS' analysis. APHIS has relied on a variety of sources to support its analysis of the potential impacts of the decision to approve the petition for nonregulated status for FG72 soybean including those pertaining to herbicide weed resistance. These sources include, but are not limited to the Bayer petition, technical reports, and peer-reviewed literature.

Issue 4

A number of commenters expressed in similar worded form letters the concern that APHIS had "failed to consult" on the potential effects on threatened and endangered species and their critical habitats, as is required under Section 7 of the Endangered Species Act (ESA), and that "APHIS must prove" its deregulation of the FG72 soy will neither jeopardize any species nor harm any critical habitat anywhere the crop system may be grown. A common assertion was that APHIS that "APHIS has broad authority under the PPA to restrict crop systems' harms to protect endangered species and their habitats through partial deregulation or other means. Another common assertion was that APHIS had a duty to consider the effects of pesticide application that deregulation of FG72 soy would facilitate. One commenter noted that APHIS's assessment under Section 7(a)(2) must also include the effects of all activities "interrelated or interdependent" with the deregulation, including , as the commenter explained the "indirect effects or 'those that are caused by the proposed action and are later in time, but still reasonably certain to occur." According to the commenter, indirect effects, would "clearly include effects of the herbicides that will be used with the deregulated crop, since use of, and tolerance for, those herbicides is the crop's very (and sole) purpose. Another comment was critical of APHIS's analysis, asserting that "APHIS cannot substitute the EPA's herbicide registration review process under FIFRA for its own independent duty to consider indirect effects

One comment expressed the concern, in light of endangered species, that "APHIS had failed to adequately assess" the changes in amounts and patterns of use of isoxaflutole and other potential herbicides to which FG72 is resistant. The commenter explained that "Isoxaflutole is a broad--spectrum herbicide, 'toxic at very low levels to non-target plants via drift and runoff". The commenter expressed the concern that in dry years, dust from isoxaflutole-treated fields "may pose a hazard to non-target plants. The comment noting that "APHIS did not take into account the potential toxicity of FG72 soybean to listed species that might eat leaves, roots, stems, or flower parts". Migrating birds, for example as the commenter explained, "eat parts of the soybean plant", while "Bees consume the pollen and nectar, and presumably other insects do as well".

APHIS Response

As required under Section 7, APHIS considered the potential for effects from the proposed determination of nonregulated status for Bayer FG72 Soy on federally listed threatened and endangered species and species proposed for listing as well as designated critical habitat and habitat proposed for designation. APHIS obtained a list of species from USFWS/NMFS. After analyzing the potential for any effect, APHIS reached a determination that the determination of nonregulated status for the Bayer FG72 plant will have no effect on federally listed threatened or

endangered species or species proposed for listing, and no effect on designated critical habitat or habitat proposed for designation.

APHIS met with USFWS officials on June 15, 2011, to discuss whether USDA-APHIS has any obligations under the ESA regarding analyzing the impacts of herbicide use associated with all GE crops on TES. As a result of these joint discussions, USFWS and USDA-APHIS have agreed that it is not necessary for USDA-APHIS to perform an ESA effects analysis on herbicide use associated with GE crops because US-EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under the FIFRA. Consequently, consultation with the United States Fish and Wildlife Service was not required.

As stated in Center for Food Safety v. Vilsack No 12-15052, D.C. No. 3:11-cv-01310-SC, opinion of the United States Court of Appeals for the 9th Circuit,

"The ESA's consultation duty is triggered, however, only when the agency has authority to take action and discretion to decide what action to take. There is no point in consulting if the agency has no choices. …

Here, once APHIS concluded that RRA [Roundup Ready Alfalfa] was not a plant pest because it did not cause plant pest injury to plants, the agency had no jurisdiction to continue regulating the crop. The agency's deregulation of RRA was thus a nondiscretionary act that did not trigger the agency's duty to consult under the ESA."

Like with RRA, APHIS' is not the responsible federal agency for consulting with the Services concerning the effects of registration and use of herbicides. The EPA has authority over the use of pesticide substances and plant-incorporated protectants (PIPs) under the FIFRA as amended (7 USC §136, *et seq.*) and the FFDCA (21 USC §301, *et seq.*). Under FIFRA the EPA has authority to establish pesticide use restrictions; these use restrictions are presented on pesticide labels which are prepared during the pesticide registration process. FG72 soybean is similar to currently available glyphosate-resistant soybean varieties, with the exception of an opportunity to use isoxaflutole in addition to glyphosate. Bayer submitted labeling to the U.S. EPA in June 2010 for EPA Registration Number 264-600, that propose to allow the use of isoxaflutole on isoxaflutole resistant soybean varieties (Bayer, 2010). APHIS used the current glyphosate labels and the proposed isoxaflutole label as the basis for its evaluation of the potential impacts associated with the use of and exposure to glyphosate and isoxaflutole. APHIS fully anticipates EPA will consult with the Services if in its final review EPA determines that registration and subsequent use of any herbicide will affect listed species or critical habitat.

Issue 5

One commenter expressed the concern that "APHIS used erroneous analysis in assessing application rates and in making comparisons between chemicals and crops. The commenter explaining that the DEA compares the application rate of IFT with that of atrazine and metochlor based only on weight/area, "ignoring" that IFT is a much more potent weed killer, compared to other corn herbicides, such as atrazine (0.9 – 1.8 kg/ha) and metochlor (0.7 – 1.4 kg/ha), with

IFT is typically applied at the rate of 0.05 – 0.11 kg/ha"). As the comment explained that although "atrazine is likely an appropriate comparator to show how widely IFT will be adopted by soy farmers", but that the measurement of "pounds/acre of pesticides with different potencies is not a meaningful measure for comparing impacts".

Some comments were concerned with herbicide application and potential increased use and critical of the agency "in failing to quantify the increased use of IFT and glyphosate", in context of what the commenter characterized as, "APHIS's own admission in the DEA's that the average use of IFT on corn between 2000 and 2010 was steadily near the maximum allowable dose.

Some comments expressed the concern that APHIS had not estimated of the magnitude of the expected increase in use of isoxaflutole and the application window of isoxaflutole". One commenter suggested that the approval of FG72 soybean "will result in a different pattern of isoxaflutole use throughout the season (later in the summer), over the years (in successive years on the same acreage), and across the landscape (in both corn and soybean fields in a region) than occurs now" and that these changes will result in a very large increase in isoxaflutole use. One comment was concerned in regard to crop rotation. The commenter explaining that rotating soy that is resistant to glyphosate and IFT with corn that is resistant to glyphosate with a natural resistance to IFT will "predictably create superweeds.

Some comments expressed concern for potential stacking of traits and more herbicide use, leading to "the evolution of glyphosate-tolerant weeds. Some concern was raised in regard to the DEA's analysis in extrapolating predicted isoxaflutole use from corn data to FG72 soybean. One comment suggested that APHIS "extrapolation from the use of isoxaflutole in corn to FG72 soybean" was not appropriate. The commenter explained that that corn is naturally tolerant of isoxaflutole at certain levels, but FG72 is genetically engineered to be resistant to isoxaflutole and that "biological constraints removed, growers will be more comfortable using the herbicide on the engineered FG72 soybean than on conventional corn.

One commenter complained that "APHIS had failed to account for increase in isoxaflutole use in its DEA analysis", for as the commenter estimated, if FG72 soybean is approved, there may be a 4-fold increase in isoxaflutole use in American agriculture as it is likely that more acres of corn will be treated with isoxaflutole if FG72 soybean is approved. Another comment noted that "Corn and FG72 soybean in rotation on the same acreage with isoxaflutole applied in succession also may have cumulative impacts. Another comment expressed the view that FG72 soybean will increase isoxaflutole use is by increasing the total number of acres that are treated with these herbicides.

Some issues arose in regard to herbicide half-life in relation to rotation intervals. One commenter raised a technical issue in regard to herbicide half-life calculations in relation to crop rotational intervals, the commenter noting that APHIS had "misunderstood the meaning of herbicide half-life in relation to rotation intervals required before crops other than corn can be planted after isoxaflutole applications". The commenter suggesting that the "half-life of DKN is not a fixed property, like molecular weight" and suggested that the matter of how quickly DKN is broken down depends on many other factors, from types of microbes to soil structure and weather (Sims et al. 2009; Swarcewicz et al. 2002). Also, the commenter noted that the term half-life means that "half of the parent molecule has degraded or been metabolized, but half is still there", and "that

the half that is present may still be enough to kill or injure plants". The commenter noted that although the recommended rotation intervals are designed to mitigate injury, they "do not remove all risk of injury "and besides the "direct toxicity of the increased herbicides used on FG72 soybean to plant population diversity within soybean fields and ramifications for animals from changes in plant diversity", that "there will also be an increase in herbicide exposure from residues and their degradates or metabolites in FG72 soybean tissues". The commenter expressed concern noting that "a wide variety of animals feed on soybean leaves, flower parts, and seeds, including many beneficial organisms such as honeybees and wild pollinators.

APHIS Response

The EPA regulates all pesticides under FIFRA and has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment. APHIS has no statutory authority to authorize or regulate the use of isoxaflutole, or any other herbicide used by soybean growers. APHIS relies on EPA's analyses and evaluations of in evaluating the potential cumulative effects resulting from its regulatory decisions. In the cumulative impacts section of DEA, APHIS has included an analysis of past herbicide use and has made some qualitative predictions on future use based on past uses and current trends in crop adoption and weed management. APHIS has no way to accurately predict herbicide use. Accordingly, the potential environmental effects resulting from the considered alternatives for APHIS' regulatory decision on the petition for nonregulated status is the focus of the EA.

APHIS has reviewed isoxaflutole application rates in section 4.2.2, Agronomic Practices, and has revised the section to more accurately compare herbicides used on soybeans by comparing percentage of treated acres. With regards to the adoption rates of FG72 soybeans, APHIS revised section 4.2.2, Agronomic Practices, with estimates obtained from Bayer for anticipated FG72 adoption rates and isoxaflutole use. The glyphosate-resistant trait in FG72 soybean is already present in currently available soybean varieties. Because this identical glyphosate-resistant trait is already established in the U.S. soybean market, and FG72 soybean itself does not require any changes in glyphosate application, there is no reason to believe that a determination of nonregulated status of FG72 soybean will promote changes in current glyphosate use practices.

APHIS acknowledges differing interpretations of data related to GE soybean adoption and herbicide use in section 4.2.2 of the EA (e.g.,(Benbrook, 2012) and (Brookes et al., 2012). APHIS recognizes that different reports base their analysis on differing interpretations of available data. The action on this petition will not change the overall trends associated with herbicide use in agriculture or the contribution of GE crops generally to that herbicide use. Global trends in GE soybean adoption and management practices are outside the scope of this EA. The potential environmental impacts on the human environment are discussed in the EA. The analysis in the EA indicates that the area planted to soybean and the management practices associated with soybean / corn rotation will not change when compared to the no action alternative. APHIS disagrees that it needs to expand the scope of this EA to include issues related to general adoption herbicide-resistant soybean varieties and herbicide use, as herbicide use is regulated by the EPA, not the USDA.

APHIS revised section 4.2.2, Agronomic Practices, with estimates obtained from Bayer for anticipated FG72 adoption rates and isoxaflutole use. As stated throughout the EA, the glyphosate-resistant trait in FG72 soybean is already present in currently available soybean varieties. Because this identical glyphosate-resistant trait is already established in the U.S. soybean market, and FG72 soybean itself does not require any changes in glyphosate application, there is no reason to believe that a determination of nonregulated status of FG72 soybean will promote changes in current glyphosate use practices.

The rate of herbicide application and the frequency of application are regulated by the EPA and it is unlawful to exceed the rate and frequency of application. It is recommended that glyphosate be used at the maximum rate to reduce the evolution of glyphosate resistant weeds. Glyphosate is such an effective herbicide that it sometimes is applied at suboptimal rates to save costs and rarely needs to be used at the maximum frequency. With weed shifts to species that inherently have a higher resistance to glyphosate, it is expected that glyphosate will be more routinely applied at the maximum rate in an attempt to control these species. In areas where weeds have evolved glyphosate resistance, farmers are likely to use tank mixes of glyphosate and additional herbicide modes of action, and tillage if necessary to control the resistant weed. There are numerous factors that determine how much herbicide needs to be used in a given year. In some years, the amount of rainfall or temperature increases the abundance of weeds throughout the growing season necessitating more frequent herbicide application.

APHIS disagrees that it misused the term half-life in the EA with respect to DKN. Second, APHIS disagrees that it is within the scope of this EA to evaluate isoxaflutole with respect to the toxicity of isoxaflutole or DKN on plants or animals. As detailed in the EA, the Environmental Protection Agency (EPA) is responsible for herbicide registration and safe use. Additionally, as detailed in the EA, EPA has completed three ecological risk assessments for isoxaflutole and DKN. From these ecological risk assessments and the existing registration of isoxaflutole, EPA has concluded that there is no unreasonable environmental risk if the end user adheres to the label use restrictions when applying isoxaflutole herbicide formulations (EPA, 2011a; EPA, 2011b). However, isoxaflutole is currently undergoing a registration review by EPA. If EPA determines that additional restrictions beyond current restrictions (Appendix A) on isoxaflutole use are required to mitigate environmental risk to non-target plant communities, then it is expected that EPA would amend isoxaflutole use labels accordingly.

Benbrook, CM (2012) "Impacts of genetically engineered crops on pesticide use in the U.S. -- the first sixteen years." *Environmental Sciences Europe.* 24 (24). http://www.enveurope.com/content/24/1/24 >.

Brookes, G; Carpenter, JE; and McHughen, A (2012) "A review and assessment of "impact of genetically engineered crops on pesticide use in the US - the first sixteen years: Benbrook C (2012)"." *Environmental Sciences Europe.* 24 (24): p 14.

EPA (2011a) "Isoxaflutole Summary Document Registration Review: Initial Docket June 2011." Environmental Protection Agency.

EPA (2011b) "Preliminary Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Isoxaflutole." Environmental Protection Agency.

Issue 6

One comment expressed concern about "a volunteer problem" and the difficulty in controlling volunteers through conventional methods. The commenter was similarly concerned about "the likely stacking of FG72 soy", and expressed the concern that farming and environmental costs will be higher in FG72 soy fields where volunteer corn is present.

APHIS Response

Controlling volunteers from previous crops in the current crop is a common agricultural issue. According to the petition:

"Double-herbicide-tolerant soybean transformation event FG72 is tolerant to two herbicides with different modes of action; class G (glyphosate) and class F (isoxaflutole), and remains sensitive to herbicides registered for pre-plant and pre-emergence use for weed control in soybean and other crops which are common in rotation with soybean. Volunteer soybeans can be treated with a pre-emergence or post-emergence herbicides such as 2,4-D, atrazine, glufosinate, mesotrione, acetochlor, dicamba, and others. These products are also widely used for weed control in the rotational crops of soybean."

Issue 7

A concern was raised in the comments in regard to the potential for cross resistance as it related to FG72 Soy. One commenter expressed the opinion "that it is logical to expect that there might be some cross-resistance to other HPPD inhibitor herbicides based on expression of the transgene for isoxaflutole resistance in FG72 soybean". The commenter expressing the view that "although if FG72 soybean is in fact resistant to mesotrione because of a transgene", it should be dealt with as a primary rather than a cumulative impact in the DEA. The commenter explained, "cross-resistance of FG72 soybean to other HPPD-inhibitor herbicides would indeed have impacts in the context of both the DEA and DPPRA". The commenter complained that "if FG72 soybean can withstand applications of other herbicides and Bayer Crops Science did not disclose this in its Petition", that such failure to disclose would be a serious omission of information.

APHIS Response

According to the petitioner, FG72 Soybean is not cross-resistant to mesotrione at the levels of commercial application of the herbicide and will not be marketed as a mesotrione resistant product (Weeks, 2013). The EA has been updated to remove references to cross-resistance.

Weeks, M to: Stankiewicz Gabel, Rebecca. (2013). Mesotrione Cross Resistance.

Issue 8

A number of comments expressed concern about increased use and the association with "increase in herbicide-resistant weeds". One commenter asserted that introducing GE crops with tolerance to herbicides with new modes of action will "not replace the long-term need to diversify weed management tactics and current crop management systems are already in jeopardy given the pace at which weed populations are evolving glyphosate resistance".

One comment expressed the concern that as mixtures of different herbicides are used on crops, that some weeds are developing multiple resistances to chemicals with different modes of action. Another comment expressed concern that crops designed to be tolerant to these chemicals "have a growth advantage and can transfer that genetic trait to their weedy relatives". A number of commenters were unsatisfied with APHIS overall assessment of FG72 soybean and the development of resistance to isoxaflutole. The commenter suggested that APHIS had "underestimated" the extent of current GR resistance by citing "outdated figures" for glyphosate-resistant infested acreage. Other comment expressed concern in regard to the he cumulative impacts of approving FG72 soybean and "the likelihood that isoxaflutole will be used in sequential years on the same ground as corn and FG72 soybean are rotated", facilitating the "selection of isoxaflutole-resistant weeds".

Some comments were concerned about "continuous cropping" and advocating for the application of integrated pest management in commercial agricultural row crop soy production. Specifically, a number of commenters expressed concern about the threat posed widespread use and reliance on glyphosate and that "current crop management systems were in jeopardy" given the "evolving glyphosate resistance". The commenter advocated for a "sustainable, integrated approach to long-term weed management that did not rely on toxic chemicals.

APHIS Response

APHIS acknowledges the occurrence of herbicide resistant weeds in the U.S. and discusses management strategies to deal with the issue in the EA (Sections 2.3.2 and 4.3.3). The use of multiple herbicides with different modes-of-action on crops (whether tank-mixed or applied sequentially) is already a common agricultural practice in order to manage weeds. In this case, FG72 soybean will enable growers to control weeds using isoxaflutole where, for example, glyphosate resistant weeds are present.. APHIS revised section 4.2.2, Agronomic Practices, with estimates obtained from Bayer for anticipated FG72 adoption rates and isoxaflutole use.

A variety of genetic, biological/ecological, and operational factors contribute to the evolution of herbicide resistance in weeds. Genetic factors include the frequency of genes in a particular weed species (that promotes resistance to a particular herbicide), the mechanism of resistance and the capacity of genes to facilitate this resistance, how resistance is inherited, and the fitness of the weed in the presence and absence of the herbicide (Georghiou and Taylor, 1986; Neve, 2008). Biological/ecological factors include the method of weed reproduction, seed production capacity, seed bank turnover, and the amount and frequency of gene flow between weed populations (Maxwell and Mortimer, 1994; Jaseniuk et al., 1996). Collectively, these issues illustrate that different plant species may present different risks of resistance. With respect to the factual errors related to mesotrione resistance in the EA, APHIS recognizes these errors and has revised Cumulative Impacts Sections 5.1, 5.3, 5.4, 5.5, 5.8, 5.9, 5.11, 5.13, and 5.14, of the EA. As noted in the Bayer petition FG72 soybeans do not confer resistance to mesotrione as mesotrione can be used to control volunteer FG72 soybeans (Bayer, 2011).

However, what can be generally observed in regard to resistance is the influence a management strategy exerts in the evolution of herbicide resistance in weeds. Operational factors influencing development of weed resistance include farm-level management practices such as the chemistry of the applied herbicide and its respective mechanism, olfaction, and the application

rates/frequency of herbicide application (Georghiou and Taylor, 1986; Jaseniuk et al., 1996). Weed management is an important part of any agricultural system. The commercialization of soybean varieties with glyphosate-resistance such as FG72 soybeans and the anticipated stacking of FG72 with GE soy, would permit existing and widely-adopted management strategies to continue. Relying on glyphosate alone as the only weed-removal strategy may influence the number of weed species that may become glyphosate-resistant.

The issue of crop rotation was discussed in sections 2.1.2 and 4.2.2, Agronomic Practices, section 4.4.2, Plant Communities, and section 5.9 Cumulative Impacts: Plant Communities. In the EA, APHIS concurs that adding a crop with a different herbicide resistance in the rotation with FG72 soybean will provide diversity of the herbicide mode of action which will reduce the selection pressure for glyphosate and isoxaflutole resistance. Continuous cropping is done in some areas, but is not the overwhelming strategy adopted by growers for corn and soybean production, rather rotation between these and other crops, depending upon geographic area and optimal crops, is the most common strategy taken by growers.

Although management plays an important role in stemming the pace of resistance, APHIS is not relying on such management strategies, to stem the evolution and adverse environmental impacts of resistant weeds. Weed management is important to any agricultural system, and growers have adopted integrated weed management techniques to prolong the usefulness and benefits of herbicide technology. The commercialization of soybean varieties stacked with herbicide resistant traits would allow existing and widely-adopted management strategies to continue. Management recommendations to mitigate the development of resistant weeds are guidance, and although a reasonable informed grower would be fully expected to read, know and follow such guidance to maintain safety and effectively achieve desired production results, as guidance they are not enforceable in the absence of a specific contractual obligation.

In regard to soybean varieties stacked with resistant traits, it is unlikely that this GE-hybrid soybean variety would alter any baseline influence of established management strategies that are currently practiced in GE-soybean cultivation systems. It is also unlikely that any GE-hybrid soybean variety stacked with FG72 soybean would increase the incidence of resistant weeds, as the factors resulting in resistance in weeds would remain unchanged.

Bayer (2011) "Petition for the Determination of Nonregulated Status for Event FG72." Submitted by Registration Manager. Bayer Crop Science. < http://www.aphis.usda.gov/biotechnology/not_reg.html >.

Georghiou, GP and Taylor, CE (1986) "Factors Influencing the Evolution of Resistance." *Pesticide Resistance: Strategies and Tactics for Management*. Washington, D.C.: National Academy of Sciences.

Jaseniuk, M; Brule-Babel, AL; and Morrison, IN (1996) "The Evolution and Genetics of Herbicide Resistance in Weeds

" *Weed Science.* 44 p 176-93.

Maxwell, BD and Mortimer, AM (1994) "Selection for Herbicide Resistance." *Herbicide Resistance in Plants: Biology and Biochemistry*. Boca Raton, Florida: Lewis Publishers. p 1-25.

Neve, P (2008) "Simulation Modeling to Understand the Evolution and Management of Glyphosate Resistance in Weeds." *Pest Management Science*. 64 p 392-401.

Issue 9

A number of comments concerned FG72 soybean and conservation tillage. Commenters questioned the contribution of herbicide resistant crops to adoption of no-till and the environmental benefits of the practice**. C**omments further questioned the relationship between conservation tillage and reductions in soil erosion. One comment noted that if HR soybeans, corn and cotton did in fact promote greater use of conservation tillage that "one would clearly expect to see sharply falling soil erosion rates over the period of their widespread adoption. Concern was also raised that herbicide facilitated no-till methods do not always increase soil quality or reduce water pollution", and that "under some conditions actually increase agrichemical runoff, degrading water quality".

APHIS Response

APHIS acknowledges that there is no strong direct relationship between GE herbicide-resistant soy adoption and use of conservation tillage in soy production (e.g., section 2.2.2.1 and 4.2.2 of the DEA). However, APHIS disagrees with one commenter assertion that FG 72 Soy hybrids, will not support continued use of conservation tillage systems in soy. As stated in the DEA at section 4.2.2.2, "Under the Preferred Alternative, current trends and practices related to tillage are unlikely to be substantially different than that which is occurring under the No Action Alternative in Subsection 4.2.2.1 – Agronomic Practices."

Glyphosate-resistant trait in FG 72 Soy is already present in currently-available soy hybrid varieties. Because this identical glyphosate-resistant trait is already established in the U.S. soybean market, and the fact that FG72 Soy itself does not require any changes in glyphosate application, there is no indication that any change would occur in glyphosate use or conservation tillage practices following a determination of nonregulated status of FG72 Soy.

Conservation tillage practices by U.S. soybean growers increased following the commercialization of glyphosate-resistant soybean in 1996 The adoption of conservation tillage practices by U.S. soybean growers increased from 51 percent of planted acres in 1996 to 63 percent in 2008, or an addition of 12 million acres (CTIC, 2008; NRC, 2010). Brookes and Barfoot (2012), in their analysis of GE crop impact, stated: "[the use of no-till and reduced-till] have increased significantly with the adoption of GM HT crops because the GM HT technology has improved growers' ability to control competing weeds, reducing the need to rely on soil cultivation and seed-bed preparation as means to getting good levels of weed control." In a review of organic farming and the benefits of no-till agriculture in the United Kingdom, the author stated: "GM herbicide-tolerant crops in the USA are responsible for the considerable USA take-up of no-till agriculture"(Trewavas, 2004). As stated in sections 2.1.2 and 4.2.2, Agronomic Practices of the EA, growers will utilize the most effective and economical means of weed control at their disposal. While mechanical tillage is one recommended practice for controlling

herbicide tolerant weeds and an important part of an Integrated Weed Management (IWM) program, the availability of dual herbicide tolerant crops such as FG72 soybean, give growers the option to use different herbicides to control weeds in addition to or instead of tilling.

Brookes, G and Barfoot, P (2012) "Global impact of biotech crops: Environmental effects, 1996–2010." *GM Crops.* 3 (2): p 9. http://www.landesbioscience.com/journals/gmcrops/article/20061/2012GMC0002R.pdf >.

CTIC (2008) "2008 Amendment to the National Crop Residue Management Survey Summary." Conservation Technology Information Center. http://www.ctic.purdue.edu/media/pdf/National%20Summary%202008%20(Amendment).pdf >.

NRC (2010) "The Impact of Genetically Engineered Crops on Farm Sustainability in the United States." National Academies Press.

Trewavas, A (2004) "A critical assessment of organic farming-and-food assertions with particular respect to the UK and the potential environmental benefits of no-till agriculture." *Crop Protection.* 23 (9): p 757-81. http://www.sciencedirect.com/science/article/pii/S0261219404000274 >.

Issue 10

A number of concerns focused on glyphosate and isoxaflutole use and the potential for its detection in surface water and groundwater. A concern raised, was the potential for Glyphosate to contaminate surface water as it does not readily break down in water or sunlight and that isoxaflutole can rapidly degrade to a stable and its phytotoxic degradate, diketonitrile (DKN) that is “mobile and toxic”, even at low levels. Other comments expressed concerns related to the risk of runoff to water supplies, runoff as a “possible route” to the exposure of non-target plant communities, and a concern as characterized that the “landscape-level increase” in isoxaflutole use, will “likely impacts water quality”. With one comment predicting that “within a watershed draining corn and soybean fields there will be twice the load of isoxaflutole entering the system”.

Specific concern was raised in the comments included: the risk associated with isoxaflutole herbicidal active degradate DKN (a diketonitrile derivative), to injure plants via uptake in water through both their roots and shoots” (Bayer CropScience 2005); that rains may reactivate isoxaflutole and carry DKN into surface and ground water”,(as “DKN is more mobile in water and has a much longer half- life, so is detected at higher levels in the environment”); that plants will “take up a lot of DKN resulting in concentrations in their tissues” (and increase the risk of injury to plants in the affected watersheds); that no-till methods may “increase agrichemical runoff and degrade water quality” (as fertilizers broadcast on the soil surface are washed off field by rain, polluting waterways); and in regard to the cumulative impacts of “more non-point sources of isoxaflutole and DKN pollution”. The commenter noting that as “most of U.S.’ corn and soybeans are grown in roughly equal amounts, in rotation with each other, and thus on the same plots of ground” and thus, as the commenter suggested that “the number of agricultural non-point sources for isoxaflutole pollution will increase.

APHIS Response

EPA has the primary responsibility for the protection of the nation's waters pursuant to the Federal Water Pollution Control Act of 1972, generally known as the Clean Water Act (CWA). The EPA establishes water quality standards, permitting requirements, and monitors water quality. The EPA also sets the standards for water pollution abatement for all waters of the United States under the CWA, working cooperatively with qualified State authorities that will issue and enforce permits. APHIS authority is confined to assessment of the plant pest risk potential of GE crops. The specific requirements for a pesticide is based on procedures outlined in the Label Review Manual (EPA, 2013). It addresses, among other things, level and pattern of use (e.g., allowable application methods, minimum and maximum rates; timing of treatments). As is true for all pesticides, specification for the safe use of glyphosate and IFT are codified on the product label.

Agricultural non-point source (NPS) pollution, is known to be the primary source of discharge pollutants to groundwater, flowing water (permanent or intermittent streams), or semi-static water (Ramanarayanan et al., 2005). NPS pollutants in the context of modern agriculture can include agricultural inputs, such as fertilizers or pesticides. Although meteorological influences such as precipitation and temperature and land use, soil type can affect water quality, human activity influencing product use, agricultural management and tillage practices are the most relevant and variables that are under direct grower control on a soybean farm. Most notably soil erosion can cause the released of sediments, fertilizers, and pesticides into surface waters (EPA, 2005).

Glyphosate is applied to most U.S. soybean acreage (Dill, 2005). The current use pattern for glyphosate is unlikely to change following a determination of nonregulated status for FG72 soybean. As some commenters noted, IFT degradation occurs rapidly in both soil and aqueous environments (Beltrán et al., 2002; Taylor-Lovell et al., 2002; Rice et al., 2004), so is detectable only briefly after field application (Scribner et al., 2006). Therefore, it is not expected to persist in groundwater (aquifers) or surface water (EPA, 2001; DATCP, 2002). Some commenters suggested that because DKN (diketonitrile), the bioactive metabolite of IFT, is more stable and mobile in the aqueous phase than IFT (EPA, 2011b), it poses a long term risk of surface water degradation. In the DEA, APHIS reviewed results of laboratory and tile-drain studies that demonstrated the greater stability of DKN, as compared to IFT, in aqueous environments (DATCP, 2002; EPA, 2011b) and considered it potential to persist in surface water. Detection of DKN in surface water resources surrounding corn fields in the Midwest further demonstrate the persistence and mobility of DKN (EPA, 2001; EPA, 2002; Rector et al., 2003; Scribner et al., 2006). However, the presence of a metabolite in a water resource does not, in itself, equate to a negative impact. More relevant is the plausibility of an impact, and if one exists, its magnitude and the availability of ways to mitigate it. This consideration has been recognized by EPA, which concluded that phytotoxicity risks to non-target, terrestrial plants caused by DKN residue in field runoff and surrounding surface water could be reduced to an acceptable level by classifying IFT as a restricted use pesticide (EPA, 2011a). Risk to aquatic plants, birds, mammals, invertebrates, and fish from IFT and DKN were determined to be below the EPA level of concern, suggesting that the toxicity of IFT and DKN is low (EPA, 2011a). Compared to other herbicides applied to U.S. soybean fields, IFT and its degradation products fall within the range of the environmental impact quotient (EIQ) for several parameters related to water resources, such as leaching potential, and effects on fish, birds, beneficial organisms, and ecology (see the

DEA, Table 6). These data indicate that IFT has an average leaching potential when compared to other herbicides applied to soybean.

As a consequence of a restricted use registration for IFT, EPA has effectively ensured that there is no unreasonable environmental risk, if the end user adheres to the label use restrictions when applying IFT herbicide formulations. Label directions include application restrictions that make it possible for certified applicators to minimize effects on the environment. IFT is currently undergoing a registration review by EPA (EPA, 2011a). If EPA determines that additional restrictions should be imposed to mitigate environmental risk to non-target plant communities, then it has the regulatory authority to amend the IFT registration by modifying the labeled uses.

The EPA has authority under FIFRA to establish pesticide use restrictions and label requirements through the pesticide registration process. FG72 soybean is similar to currently available glyphosate-resistant soybean varieties, with the exception of an opportunity to use isoxaflutole in addition to glyphosate. Bayer submitted labeling to the U.S. EPA in June 2010 for EPA Registration Number 264-600, that propose to allow the use of isoxaflutole on resistant soybean varieties (Bayer, 2010). APHIS used the current glyphosate labels and the proposed isoxaflutole label as the basis for its evaluation of the potential impacts associated with the use of and exposure to glyphosate and isoxaflutole. APHIS in the DEA evaluated the potential impacts of glyphosate on microorganisms in soils of field under cultivation with HR crops, and has not found evidence linking applications of glyphosate to changes in soil microbial communities that have adverse effects on plants grown in those soils. In addition APHIS identified that Isoxaflutole was known to be readily degraded in soil by soil microorganisms and no long term effects on soil microorganisms were identified with isoxaflutole use.

Bayer. "Isoxaflutole Draft Label." 2010. 9.

Beltrán, E; Fenet, H; Cooper, J-F; and Coste, C-M (2002) "Fate of Isoxaflutole in Soil under Controlled Conditions." *Journal of Agricultural and Food Chemistry.* 51 (1): p 146-51. Last Accessed: 2011/11/14 < http://dx.doi.org/10.1021/jf0207878 >.

DATCP (2002) "Final Environmental Impact Statement for the Use of Pesticides Containing Isoxaflutole in Wisconsin." Wisconsin Department of Agriculture, Trade and Consumer Protection Water Quality Section. http://www.midwestadvocates.org/archive/DATCPisoxaflutole/EIS_Final_17.pdf >.

Dill, GM (2005) "Glyphosate-resistant crops: history, status and future." *Pest Management Science.* 61 (3): p 219-24. http://dx.doi.org/10.1002/ps.1008 >.

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EPA (2002) "Isoxaflutole Monitoring Data from Missouri: Update on Reservoirs." Environmental Protection Agency.

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EPA (2011b) "Preliminary Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Isoxaflutole." Environmental Protection Agency.

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Issue 11

Concerns were raised in the comments regard to the cumulative impacts of “the new generation of IFT crop systems on global warming and GHG emissions”. APHIS was criticized for its association of conservation tillage with: increased carbon sequestration in soils, decreased fuel consumption, and the reduction of nitrogen soil amendments. The comments asserting that the “benefits for climate change of a purported preservation of no-till soybean acreage are generally unsubstantiated”, citing Blanco-Canqui and Lal (2008) and Baker et al. (2007), as casting doubt that conservation tillage results in more carbon sequestration than conventional tillage.

APHIS Response

APHIS recognizes and understands that agricultural activities including, but not limited to tillage and other management strategies, contribute to the release of GHG emissions that may affect global climate change. The EA addresses the issue of climate change and agriculture as it relates to FG72 Soy in Chapter 2.2.4. APHIS finds that management practices between FG72 soybean and currently available soybean varieties are likely to be similar. This finding takes into

consideration the likelihood of stacking FG72 soybean with other soybean events that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the Plant Protection Act, and the almost universal adoption of genetically engineered soybean production systems in the U.S.. Importantly, the relationship between conservation tillage strategies and GHG emissions is known to be dependent on a number of factors, including geographic location, soil structure, moisture availability, and agronomic management practices. Given the variability of these parameters, tillage impacts may be beneficial, neutral, or detrimental.

Issue 12

Concerns were raised in the comments in regard to effects of FG72 Soy upon non-target animals. Specifically the affects upon biological resources, the risk of glyphosate use upon insects, earthworms, and fish, birds and small mammals". A number of other non-target concerns were raised about Isoxaflutole these include: that it is "an endocrine disruptor as it has been observed to induce thyroid tumors in male rats and has been classified as a Group B2 carcinogen"; that "there is evidence of developmental and reproductive toxicity"; and that amphibians were "at particular risk" from exposure noting studies "indicating chronic exposure to environmentally-relevant caused disruption of hormone signaling". The commenter noted that "glyphosate, its salts and metabolite, AMPA, are likely to adversely impact the California red-legged frog based on prey and habitat reduction" and that "increased use of glyphosate in agricultural systems will further put these organisms at risk".

Several commenters took exception to APHIS use of the fact that food and feed safety data on FG72 soybean has cleared the FDA assessment process to support the idea that ingestion of FG72 soybean will have no impacts on wild animals: According to the commenter, "food safety assessment for humans are not appropriate for wildlife" as the "increased ingestion of isoxaflutole residues and degradates puts animals at risk, including pollinators, and threatened and endangered species.

One comment was critical of the DEA comparison of the environmental profile and leaching potential of isoxaflutole to other soybean herbicides. The commenter cited APHIS as concluding that "Given that the leaching potential of IFT is not substantially higher than many currently-registered soybean herbicides, it is unlikely that IFT poses any more of a risk to non-target plants than the herbicides that would otherwise be utilized under the No Action Alternative". The commenter noted that "comparing Environmental Impact Quotients and leaching potentials from this secondary source is not a rigorous scientific assessment of the likelihood that non-target plants will be at more risk from isoxaflutole in runoff from FG72 soybean". In addition the commenter expressed concern about how APHIS had calculated leaching potential and whether it is a good predictor of the levels of herbicides in runoff and shallow groundwater".

Another comment was that potential herbicide drift of Isoxaflutole was an emissions concern and that the possibility that drift could harm the environment and exposure non-target plants to "direct exposure in the agricultural field and through runoff". Another commenter was similarly concerned about the implications of drift in light of FS72 soy and noted that "the DEA failed to adequately analyze reasonably foreseeable harm from drift of IFT to non-target crops in nearby

fields". Similar concerns were raised in regard to Dicamba, specifically, that it was carcinogenic, causes reproductive abnormalities, and is toxic to non-target plants.

APHIS Response

The EA has reported on the safety of the use of glyphosate and isoxaflutole in the environmental consequences and cumulative impacts sections under various headings, including those on animals, plants, biodiversity, microbes and human health. Based upon information and analysis presented in the petition, plant pest risk assessment, and EA, APHIS has not identified any potential for chemical harm to the environment deriving from FG72 soybean.

Under the Coordinated framework, EPA regulates pesticides, including crops with plant-incorporated protectants (pesticides intended to be produced and used in a living plant) to ensure public safety from their use, including pesticide residue on food and animal feed. FDA has primary responsibility for ensuring the safety of food and animal feed. The EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under the FIFRA. A determination of specific requirements for a pesticide is based on procedures outlined in the Label Review Manual (EPA, 2013a). APHIS relies on the EPA's risk assessments and expertise because these are the best available information. APHIS uses this and other information from the scientific literature in its assessment. APHIS has no statutory authority to authorize or regulate the use of glyphosate and isoxaflutole, or any other herbicide used by soybean growers. APHIS has carefully considered the possible environmental impacts of the proposed action, and is satisfied that the EA prepared by APHIS is adequate and sufficient.

Glyphosate and isoxaflutole, when used according to the label, have been shown not to have unreasonable adverse effects on species and the environment. To make such determinations, EPA reviews a large number of scientific studies and tests from applicants (EPA, 2013b). Prior to allowing a pesticide product to be released on the market, EPA ensures that the pesticide will not pose any unreasonable risks to wildlife and the environment. EPA evaluates the data submitted in regards to the potential hazard to non-target fish and wildlife species . In considering whether to register a pesticide, EPA conducts ecological risk assessments to determine what risks are posed by a pesticide and whether changes to the use or proposed use are necessary to protect the environment. A pesticide cannot be legally used if it has not been registered with EPA's Office of Pesticide Programs. EPA has already concluded that glyphosate and isoxaflutole pose no unreasonable risks to wildlife and the environment (EPA, 1993; EPA, 2011).

Glyphosate is slightly toxic to amphibians; however, some formulations of glyphosate with the surfactant polyethoxylated tallowamine (POEA) can be toxic to amphibians. POEA is a non-ionic surfactant used in many herbicide formulations to increase the ability of active ingredients to penetrate leaf cuticles. POEA has been found to be more toxic to amphibians and other aquatic animals than the herbicide itself (Lajmanovich et al., 2003). EPA has already determined that, when used according to the label, glyphosate does not pose any unreasonable risks to wildlife and the environment. Estimated and measured concentrations of glyphosate use in wetlands and different bodies of water has shown that the risk to aquatic organisms is negligible or small at application rates less than 4 kg/ha (kilogram/hectare) and only slightly greater at application

rates of 8 kg/ha (rates at, or significantly above, the recommended application rates of 0.21 to 4.2 kg/ha for glyphosate)(Solomon and Thompson, 2003; Cerdeira and Duke, 2006).

Cerdeira, AL and Duke, SO (2006) "The current status and environmental impacts of glyphosate-resistant crops: A review." *Journal of Environmental Quality.* 35 (5): p 1633-58. http://www.scopus.com/inward/record.url?eid=2-s2.0-33749370114&partnerID=40&md5=395e23186cdf39e71389b84b04315df2 >.

EPA (1993) "R.E.D. Facts - Glyphosate." Environmental Protection Agency. http://www.epa.gov/oppsrrd1/REDs/factsheets/0178fact.pdf >.

EPA (2011) "Isoxaflutole Summary Document Registration Review: Initial Docket June 2011." Environmental Protection Agency.

EPA (2013a) "Label Review Manual." United States Environmental Protection Agency. http://www.epa.gov/oppfead1/labeling/lrm/label-review-manual.pdf >.

EPA (2013b) "Pesticide Registration." Environmental Protection Agency< http://www.epa.gov/pesticides/factsheets/registration.htm >.

Lajmanovich, RC; Sandoval, MT; and Peltzer, PM (2003) "Induction of mortality and malformation in Scinax nasicus tadpoles exposed to glyphosate formulations." *Bulletin of Environmental Contamination and Toxicology.* 70 (3): p 612-18. http://www.scopus.com/inward/record.url?eid=2-s2.0-0242417510&partnerID=40&md5=4e98e9c7261c309a9c25c97a7d401df0 >.

Solomon, K and Thompson, D (2003) "Ecological Risk Assessment for Aquatic Organisms from Over-Water Uses of Glyphosate." *Journal of Toxicology and Environmental Health, Part B.* 6 (3): p 289-324. Last Accessed: 2013/08/08 < http://dx.doi.org/10.1080/10937400306468 >.

Issue 13

The comments raised concerns in regard to pollen drift and the perceived risk to biodiversity, industry, growers and individuals. Gene flow in the environment was characterized as a problem that “has been left unchecked” and “resulting in an increasing population of resistant weeds”. One comment identified that in the Union of Concerned Scientist (UCS) report, Gone to Seed, UCS, had “found that about 50% or more of the certified non-GE corn, canola, and soybean seed has been contaminated with transgenes”. The commenter referenced another report, A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops, UCS that was said to demonstrate “how difficult it is to prevent contamination, even for pharmaceutical crops that would be grown on small acreage and under stringent confinement”.

APHIS Response

As noted in sections 2.3.3 and 4.4.3, of the EA, Gene Flow and Weediness, soybeans are a self-pollinating crop (OECD, 2010), which is not native to the United States and there are no feral or weedy relatives. Consequently, soybean in the United States can cross only with other

commercial soybean varieties. Data submitted in the petition gave no indication of altered weediness potential, flower morphology, yield, dormancy or germination in FG72 soybean (Bayer, 2011). The administrative record supports the fact that FG72 soybean is not different from conventional soybean or other GE soybean in terms of pollen viability, and that it is not expected to have an increased ability to cross- pollinate with other soybean varieties when compared to other soybean varieties that are currently available for commercial planting. The natural movement of genes through normal cross-pollination is not considered a plant pest harm within the meaning of the PPA.

Bayer (2011) "Petition for the Determination of Nonregulated Status for Event FG72." Submitted by Registration Manager. Bayer Crop Science. < http://www.aphis.usda.gov/biotechnology/not_reg.html >.

OECD (2010) "Consensus Document on the Biology of Glycine Max (L.) Merr. (Soybean)." Organisation for Economic Co-operation and Development. http://www.oecd.org/dataoecd/16/56/46815668.pdf >.

Issue 14

Two commenters expressed similar concerns about allergenicity based on Bayer's molecular analysis of the insert. They noted that in its US petition, Bayer claims: "The junctions between the inserted sequences and the original genome, as well as the junction created at the translocation point, have been analyzed by means of bioinformatics tools (open reading frames, promoter and gene predictions)". According to the commenter, Bayer's finding of "no evidence of any potential unintended genes or any disruption of pre-existing genes was found", was "erroneous" as "Bayer must have submitted different information to European regulators, because the Norwegian assessment states, "the Applicant reports the creation of forty-six new ORFs within the transgenic locus and 19 interrupted ORFS in the non-transgenic sequences". Further the commenter indicates that "18 promoters were identified in the nontransgenic sequences, where three were interrupted by the insertion event". The commenter took exception to the applicant's analysis noting that "however, the applicant's analysis suggests that since these findings did not occur in known functional genes, or did not lead to the creation of known allergens or toxins, and the changes were inconsequential". According to the commenter "the Norwegian assessment was that the changes were, in fact, consequential", making the recommendation that "the Applicant's analysis should include the effect of the transformation not only on functional genes, but also on non-coding or regulatory disruptions."

The commenter went on to state, "It is terribly disturbing that US regulators do not know about and are not reviewing the unintentional deletions and insertions of genes that Bayer found. For consumers, this means that we're going to be exposed to unexamined potential allergens and toxins."

APHIS Response

APHIS disagrees that the transformation event in FG72 soybean will expose consumers to potential allergens or toxins due to the FG72 transformation event. In the APHIS Plant Pest Risk Assessment (PPRA), it was concluded that the transformation event in FG72 soybean did not

lead to any potential toxins or allergens (APHIS, 2012). While the reports cited by the commenter details only an *in silico* analysis of FG72 soybean, an analysis of growth, development, and composition of FG72 soybean undertaken in the APHIS PPRA demonstrates that FG72 soybean is similar to other soybean varieties, with the exception of glyphosate and isoxaflutole tolerance (USDA-APHIS, 2012). To further support the safety of FG72 soybean, the FDA has "…concluded that food and feed derived from FG72 soybean is not materially different in composition, safety, and other relevant parameters from soybean-derived food and feed currently on the market and that the genetically engineered soybean event FG72 does not raise issues that would require premarket review or approval by the FDA" (FDA, 2012).

FDA (2012) "Completed Consultations on Bioengineered Foods BNF No. 122." FDA. http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=bioListing&id=89 >.

USDA-APHIS (2012) "Plant Pest Risk Assessment of FG72 Soybean." < http://www.aphis.usda.gov/biotechnology/not_reg.html >.

Issue 15

APHIS received a number of comments on the issues related to the potential human health effects associated with herbicide use. Other commenters were concerned about the perceived health effects of eating GE soybeans. Some comments were critical of APHIS's analysis and "reliance" upon EPA's registration of IFT and glyphosate herbicides. Some comments expressed concern that "more frequent, pre- and post-emergence applications of IFT would increase soy farm workers' exposure to herbicides. Another comment asserted that "Roundup/glyphosate has been shown to inhibit steroidogenesis, and that both "Roundup and glyphosate have been found to inhibit the aromatase enzyme involved in estrogen production. Another noted that isoxaflutole has been classified as "likely to be a human carcinogen" by EPA. EPA was said to have listed isoxaflutole as a "probable (B2) human carcinogen", because of the "potential for isoxaflutole to leach to groundwater" and its "potential for this action to cause unsafe drinking water". The commenter noting that in carcinogenicity studies, isoxaflutole "induced liver and thyroid tumors in rats and liver tumors in mice". Some commenters were critical of APHIS's cumulative impacts analysis. A common concern was that "EPA's FIFRA analysis never accounted for the potential adoption of FG72 soy and the increased use of IFT on soybeans". Some comments suggested that APHIS delay its regulatory decision until EPA had finished its review of isoxiflutole.

APHIS Response

The general use of herbicides is outside of the scope of this EA. APHIS considered the potential for increased glyphosate and isoxaflutole if FG72 soybeans are approved. As discussed in the EA glyphosate use is not likely to increase over the current use patterns. Based on estimates of adoption rates of FG72 soy, isoxaflutole use would likely increase, compared to its current use levels, although it is not likely to be wildly used on soybeans. It is estimated that it may be adopted on about 5% of the soybean acres. All pesticides are regulated by the U.S. Environmental Protection Agency (EPA). A determination of specific requirements for a

pesticide is based on procedures outlined in the Label Review Manual (EPA, 2013b). It addresses, among other things, level and pattern of use (e.g., allowable application methods, minimum and maximum rates; timing of treatments). EPA, not USDA, regulates the use of pesticides under FIFRA. Before isoxaflutole can be used on FG72 soybeans, EPA would need to approve its use on FG72soybeans. EPA considers the effects of herbicide use on natural resources and living organisms.

Herbicide use on soybeans is widespread and common (USDA-NASS, 2007) and may result in residues in or on soybean and soybean products. To ensure safety of the soybean food supply, the EPA establishes limits or tolerances. In addition, the FDA and the USDA monitor foods for pesticide residues and work with the EPA to enforce these tolerances (see(USDA-AMS, 2013). In setting pesticide tolerances, the EPA will consider (EPA, 2013c) the toxicity of the pesticide and its break-down products. Pesticide tolerance levels for glyphosate and isoxaflutole have been established for a wide variety of commodities, including soybean (EPA, 2012b). For glyphosate, the tolerance for soybean seed is 20 parts per million (ppm) (EPA, 2012a), while the established tolerance of isoxaflutole is 0.05 ppm (EPA, 2012a).

APHIS acknowledges that the EPA is currently reviewing its registration of isoxaflutole. The EPA docket for isoxaflutole for the most recent information may be found (EPA-HQ- OPP-2010-0979) at http://www.regulations.gov.

APHIS relies on the EPA's risk assessments and expertise because these are the best available information. APHIS uses this and other information from the scientific literature in its assessment. APHIS' decision on the petition is based on the plant pest risk of the subject organism and as such it is a decision independent of the decision to reregister isoxaflutole, which is being made by EPA. APHIS disagrees with the commenter that the agency should delay its regulatory decision while EPA's regulatory decision is pending because EPA's decision will not affect the plant pest status of FG72 soybean.

In regard to the human health concerns raised by commenters ie. the consumption of GE soybean products, contact with associated herbicides, potential toxicity or allergenicity of the introduced proteins, pesticide residues and in regard to the composition of the GE soybean itself. With regard to the general safety of the soybean itself, under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from GE soybean must be in compliance with all applicable legal and regulatory requirements. GE soybean for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. The FDA evaluates the submission and responds to the developer by letter (FDA, 2012b).

Compositional tests conducted by the petitioner indicate that FG72 soybean is compositionally similar to other commercially available soybean (Bayer, 2011). Bayer initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and

nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 3, 2009. Based on the information Bayer submitted, and as of August 7, 2012, FDA had no further questions regarding FG72 soybean (FDA, 2012a)(FDA, 2012). Based on the FDA's consultation, laboratory data and scientific literature provided by Bayer (Bayer, 2011), and safety data available on other herbicide-resistant products, APHIS has concluded that FG72 soybean would have no significant impacts on human or animal health.

Agricultural workers are the segment of the population most likely to encounter risks related to soybean production. Worker hazards in farming are common to all types of agricultural production, and include hazards of equipment and plant materials. Pesticide application represents the primary exposure route to pesticides for farm workers. However, common farm practices, training, and specialized equipment can mitigate exposure to pesticides by farm workers (Baker et al., 2005).

All pesticides sold or distributed in the U.S. must be registered by the EPA (EPA, 2013a). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered prior to November 1, 1984, such as glyphosate, must also be reregistered to ensure that they meet the current, more stringent standards and have a reregistration review every 15 years (EPA, 2013a). Glyphosate was first registered in the U.S. in 1974; the latest reregistration decision for glyphosate was issued in 1993 (EPA, 1993; EPA, 2009a; EPA, 2009b). It is currently under reregistration review, which began in July 2009 and is scheduled for completion in 2015 (EPA, 2009a). Isoxaflutole was first registered in the U.S. in 1998; the most recent isoxaflutole ecological risk assessment was conducted in April 2010 for use on soybeans (EPA, 2011). It is currently under reregistration review, which began in June 2011 and is scheduled for completion in 2017 (EPA, 2011).

Agricultural workers that routinely handle glyphosate may be exposed during spray operations. Because of low acute toxicity of glyphosate, absence of evidence of carcinogenicity and other toxicological concerns, occupational exposure data is not required for reregistration. However, EPA has classified some glyphosate formulations as eye and skin irritants. Isoxaflutole also exhibits low acute toxicity but is classified as "likely to be a human carcinogen however, EPA has determined no harm to human health will result from aggregate exposure to isoxaflutole or its residues. The EPA's Worker Protection Standard (WPS) (40 CFR Part 170.1, *Scope and Purpose*) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.

The EPA's Worker Protection Standard (WPS) (40 CFR part 170) was published in 1992 requiring actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protection 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. Furthermore, the Occupational Safety and Health Administration require all employers to protect their employees from hazards associated with pesticides and herbicides.

On a practical note, growers are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. For example, pesticide labels specify the appropriate worker safety practices that must be followed, including the necessary PPE to be worn by mixers, loaders, other applicators and handlers. These label restrictions carry the weight of law and are enforced by the EPA and the states (FIFRA 7 U.S.C. 136j (a)(2)(G) Unlawful Acts).

Baker, J; Southard, R; and Mitchell, J (2005) "Agricultural Dust Production in Standard and Conservation Tillage Systems in the San Joaquin Valley." *Journal of Enviromental Quality*. 34 (4): p 1260-69. https://www.soils.org/publications/jeq/abstracts/34/4/1260 >.

Bayer (2011) "Petition for the Determination of Nonregulated Status for Event FG72." Submitted by Registration Manager. Bayer Crop Science. < http://www.aphis.usda.gov/biotechnology/not_reg.html >.

EPA (1993) "R.E.D. Facts - Glyphosate." Environmental Protection Agency. http://www.epa.gov/oppsrrd1/REDs/factsheets/0178fact.pdf >.

EPA (2009a) "Glyphosate Final Work Plan." Environmental Protection Agency.

EPA (2009b) "Registration Review- Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Glyphosate and Its Salts (PC Code 417300, 103601, 103604, 103607, 103608, 103613, 103603, 103605, 128501)." Environmental Protection Agency.

EPA (2011) "Isoxaflutole Summary Document Registration Review: Initial Docket June 2011." Environmental Protection Agency.

EPA (2012a) "Index to Pesticide Chemical Names, Part 180 Tolerance Information, and Food and Feed Commodities (by Commodity)." Environmental Protection Agency. http://www.epa.gov/opp00001/regulating/tolerances-commodity.pdf >.

EPA (2012b) "Pesticide Tolerances " Environmental Protection Agency< http://www.epa.gov/pesticides/regulating/tolerances.htm >.

EPA (2013a) "Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)." Environmental Protection Agency< http://www.epa.gov/oecaagct/lfra.html >.

EPA (2013b) "Label Review Manual." United States Environmental Protection Agency. http://www.epa.gov/oppfead1/labeling/lrm/label-review-manual.pdf >.

EPA (2013c) "Setting Tolerances for Pesticide Residues in Food." Environmental Protection Agency< http://www.epa.gov/opp00001/factsheets/stprf.htm >.

FDA (2012a) "Completed Consultations on Bioengineered Foods BNF No. 122." FDA. http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=bioListing&id=89 >.

FDA (2012b) "Plant Biotechnology for Food and Feed." U.S. Food and Drug Administration< http://www.fda.gov/Food/Biotechnology/default.htm >.

USDA-AMS (2013) "Pesticide Data Program Annual Summary, Calendar Year 2011." U.S. Department of Agriculture, Agricultural Marketing Service. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5102692 >.

USDA-NASS (2007) "Agricultural Chemical Usage - 2006 Field Crops Summary." United States Department of Agriculture - National Agricultural Statistics Service.

Issue 16

One commenter asserted that Bayer has not thus far been successful in obtaining sufficient authorizations to import FG72 Soybean. The commenter states that failure to obtain the authorizations in key markets within the world would create a risk of significant economic losses to U.S. grain and oilseed producers and markets.

APHIS Response

To support commercial introduction of FG72 soybean in the U.S., Bayer intends to submit dossiers to request import approval of FG72 soybean to the proper regulatory authorities of several countries that already have regulatory processes for GE soybean in place. These include, but are not limited to: Canada, Mexico, Japan, the EU, South Korea, and China (Bayer, 2011c; Coates, 2012). According, prior to commercialization of FG72 soybean, Bayer will meet all applicable regulatory requirements in key countries that are likely to import FG72 soybean (Coates, 2012). When international acceptance of a specific event has not been attained, US elevators and grain buyers may either refuse to purchase the grain, or may require that it be diverted to elevators that are solely designated as sources for domestic grain sale (Anonymous, 2011).

Anonymous. "Cargill Bars Syngenta Corn Variety at U.S. Wet Mills." *Reuters U.S. Edition* September 1, 2011 2011. Print.

Issue 17

Some commenters suggested that APHIS should require voluntary restrictions pursuant to a stewardship plan, One criticism was that there was “no empirical assessment of farmer use of resistant weed mitigation measures” or of Bayer CropSciences’s stewardship program”.

APHIS Response

A stewardship plan is not required for regulatory review of herbicide-resistant crops. However, major developers provide these for the benefit of their customers and to serve the broader needs of agriculture. APHIS may note in an EA that a developer has published a required stewardship plan in connection with a Technology Use Agreement. In this case, Bayer has developed a stewardship plan for FG72 soybean along with their petition (Bayer, 2011). The stewardship plan succinctly summarizes their weed resistance management plan

in which they recommend using several herbicides with different modes of action, either as tank mixes or sequentially, multiple weed management practices such as rotation, and mechanical cultivation among others (Bayer, 2011). Because herbicide resistance in weeds is not a plant pest risk, APHIS does not have the authority to require any specific management practices.

Bayer (2011) "Petition for the Determination of Nonregulated Status for Event FG72." Submitted by Registration Manager. Bayer Crop Science. < http://www.aphis.usda.gov/biotechnology/not_reg.html >.

Issue 18

A concern was raised in regard to "seed market concentration", the comment suggested that such concentration in the industry have "undermined independent researchers' ability to investigate patented crops' performance". The commenter suggested that "research and development suffer from seed market concentration", as seed companies "want the right to approve all publications", which researchers find unreasonable. This was said to "chill research on GE crops".

APHIS response

APHIS disagrees that approving the petition for of nonregulated status of FG72 Soybean will reduce soybean seed options for farmers, thus reducing the choice of affordable seed options to farmers. This decision is not likely to change the base line dynamics or market forces within the soybean seed industry or the way that soybean seed is tested, researched, developed or marketed in the United States. Soybean varieties are developed at considerable cost, have value as intellectual property and as such patent holders may seek legal means to preserve, protect and limit access to such intellectual property at their discretion. Such rights are subject to the rule of law, the baseline relationship of patent holders to others seeking to use intellectual property, as administrated by the U.S. Patent and Trade Office, and this would not be changed by the deregulation of FG72 Soybean. Therefore issues of the rights of others to do research are within the existing norm of patent law and as such generally outside the scope of the EA. The action on the petition will not effect that existing baseline as to what can or cannot be patented and rights individuals may have in regards to patented seed. It will not change how seed is marketed. Companies will continue make decisions to supply seed varieties based on factors such as available markets and potential returns.

Issue 19

Another comment suggested that conventional, GE-sensitive markets are "also at significant risk" by deregulating FG72 soy. Comments were critical of "APHIS's conclusion that organic farmers wishing to avoid transgenic contamination should isolate their farms, create physical barriers and buffer zones, and delay or stagger planting so that neighbors' GE crops do not contaminate theirs.

A number of comments focused on "the potential impact on organic farming from contamination by FG72 soy". One often repeated assertion was that "the burden of preventing contamination was being placed entirely on organic farmers and producers" and that "consumer expectations" of organic products were not the same the National Organic Standard. One comment raised concerns in regard to the socioeconomic impacts of" transgenic contamination on the entire organic industry", for "organic products require 100% organic feed; there is no de minimus exception". According to the commenter "contamination of organic feed soy with the transgene will render the soy ineligible for organic certification and will eliminate it as a permissible feed for organic livestock". The, commenter also raised concern in regard to the difficulty that "transgenic contamination places on growing and sourcing organic feed".

APHIS received comments dealing with the issue, as characterized, "as the right to choose non GE soy", the commenter describing that "[a] federal action that eliminates a farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food, as an undesirable consequence. One commenter expressed concern in regard to "the potential socio-economic, cultural, and agricultural impacts faced by farmers in Mexico and other parts of the world where transgenic contamination will quickly [a]ffect the agricultural economy".

APHIS Response

The essential dynamics relating to the principals of coexistence of conventional soybean and organic soybean production would not change by the deregulation of FG72 soybean. Although producing a particular crop for a specific market and meeting the specifications for growing a product to be marketed might be characterized by some as a "burden", this burden is intrinsic to plant production in general and 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. 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)).

The U.S. Department of Agriculture's Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) has released a final set of recommendations on enhancing coexistence among different crop production methods (Ihnen, 2012). The AC21 presented its report to Agriculture Secretary, Tom Vilsack, to be used as guidance to enhance working relationships among farmers growing different types of crops, specifically GE- and non-GE crops. The committee also made recommendations to the USDA emphasizing education,

stewardship and good neighbor-to-neighbor communications. The report indicates that technological innovations and market diversity have become key drivers of increased productivity and product quality for all forms of American agriculture. As mentioned in the EA, approximately 93% of all soybean varieties planted in the United States in 2012 were GE.

However, ultimately organic producers are obligated to manage their operations to avoid unintentional contact with excluded methods. A number of techniques have been developed in order to maintain the concept of coexistence and to prevent cross-pollination. Isolation distances between fields help to minimize the effects of pollen flow. In addition to spatial isolation, growers can use reproductive isolation to minimize or eliminate cross-pollination (i.e. plant varieties with different maturity dates) or stagger planting dates (to obtain different flowering stages), with a minimum of three to four weeks difference between the planting of their crop and neighboring crop. Isolation distances, reproductive isolation (e.g., staggering planting dates or growing varieties with differential maturity times), and farmer communication can be successfully used to minimize the effects of pollen-mediated gene flow.

APHIS acknowledges that the public has a right to choose non-GE foods (Anderson, 2008). Recent comments by Secretary Vilsack demonstrate USDA's goal to "ensure that all forms of agriculture thrive so that food can remain abundant, affordable, and safe" and thereby promoting an individual's choice to purchase or grow food produced by either conventional, GE, or organic methods. To fulfill its commitment to NEPA, APHIS has conducted an environmental assessment analyzing the potential impacts of FG72 soybean on all forms of agriculture. Based on the analysis provided in the EA, APHIS concluded that there is no evidence for significant environmental impact on conventional or organic agriculture.

APHIS acknowledges that the public may have varying perceptions of the term "organic" and the term often may take on different meanings in the context of advertising, cultural values, pharmaceuticals, chemistry, food, agriculture and contemporary thought as expressed in literature and media. To accommodate the need for an appropriate food standard, the USDA established the National Organic Program (NOP), under the Organic Foods Protection Act and established the National Organic Program regulations. 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, 2010). The NOP prohibits the use of excluded methods in organic operations.

Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. Under the NOP, certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Act. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2007). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded

methods and has taken reasonable steps (such as isolation zones, use of buffer rows surrounding the organic crops, adjusting planting dates, and appropriate cleaning of planting and harvesting equipment) to avoid contact with the products of excluded methods as detailed in their approved organic system plan.

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 varieties 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 the production burden of supplying products for diverse market requirements."

APHIS expects FG72 soybean will be used to breed soybean varieties suitable to a range of environments and replace some of the herbicide-resistant soybean varieties. The effect on agricultural practices (e.g., cultivation, spray programs, crop rotation practices, planting rates, etc.) from its introduction into the environment should not be significantly different than for the previously deregulated herbicide-resistant soybean lines already in agricultural production, and the baseline of effects would not reasonably be expected to change. 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 (Fernandez and Polansky, 2006; Ronald and Fouche, 2006; Anonymous, 2010).

Major buyers of organic commodities have allowances for a certain percentage of GE traits. While some buyers may require testing for unintentional GE-trait content, this is one of the costs that presumably makes organic products more costly at purchase, and for which the grower is reimbursed. It is not likely that organic farmers or other farmers who choose not to plant transgenic varieties or sell transgenic grain will be significantly impacted by the commercial use of FG72 soybean. Non-transgenic soybean will likely still be sold and will be readily available to those who wish to plant it. Given this baseline, the potential impact on organic farming should not change from the current situation, and organic or other growers who choose not to plant or sell GE soybeans (a) will still be able to purchase and grow non-GE soybeans; (b) will be able to coexist with GE-soybean producers as they do now. APHIS therefore finds no basis of a burden being imposed, of burden shifting, or an increased burden being placed upon other farmers as a result of the deregulation of FG72 soybean.

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Issue 20

One commenter stated, “This petition for deregulation of this genetically modified plant should be refused. It is engineered to be resistant to herbicide application which would make it a plant pest because herbicides damage the soil, increasing crop pathogen populations and increasing diseases like fusarium wilt.”

APHIS Response

APHIS has evaluated the impacts of both Glyphosate and Isoxaflutole on microorganisms in soils of field under cultivation with HR crops, and has not found evidence of long term effects. Soil quality determines the carrying capacity of a site for biomass vigor and production in terms of physical support, air, water, temperature moderation, protection from toxins, and nutrient availability. These soil properties can change over time as temperature, acidity or alkalinity (pH), salinity, organic matter, carbon-nitrogen, and the number of microorganisms and soil fauna will vary seasonally and over time (USDA-NRCS, 1999). Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004) and in suppressing soil-borne plant diseases and in promoting plant growth (Doran et al., 1996). The main factors affecting microbial population size and diversity include soil type, plant type, and agricultural management practices such as crop rotation, tillage, herbicide and fertilizer application, and irrigation (Garbeva et al., 2004). Plant roots, release compounds into the soil creating a unique environment for microorganisms in the rhizosphere where microbial diversity may be extensive. While management practices, such as tillage and the use of agronomic inputs such as fertilizers and the use of pesticides, can improve soil quality, they can also cause damage if not properly used. Cultivation concerns such as erosion, compaction, soil structure, nutrients, salinity, pH, and biological activity (USDA-NRCS, 2001) and agronomic practices such as crop type, rotation,

tillage, herbicide use and pest management can affect soil quality, and growers will generally adopt management practices to address their specific needs in producing soybean.

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