NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

Syngenta Seeds, Inc. and Bayer CropScience AG.
Event SYHT0H2

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

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

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 12-215-01p) by Syngenta Seeds, Inc. and Bayer CropScience AG (Syngenta-Bayer) for their genetically engineered soybean Event SYHT0H2 (SYHT0H2 soybean) which has been genetically engineered to tolerate herbicides that inhibit p-hydroxyphenylpyruvate dioxygenase (HPPD) and glufosinate-ammonium herbicide. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from approving the petition seeking nonregulated status for SYHT0H2 soybean. The EA assesses alternatives to a determination of nonregulated status of SYHT0H2 soybean and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

Regulatory Authority

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

Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and

products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of "unreasonable" risk.

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

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

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

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

Regulated Organisms

The APHIS Biotechnology Regulatory 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 Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated

article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest risk provisions of the Plant Protection Act 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 Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS' Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as SYHT0H2 soybean. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment (PPRA), that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

Syngenta-Bayer has submitted a petition (APHIS Number 12-215-01p) to APHIS seeking a determination that their genetically engineered soybean SYHT0H2 is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR part 340.

SYHT0H2 Soybean

SYHT0H2 soybean is engineered to tolerate herbicides that inhibit p-hydroxyphenylpyruvate dioxygenase (HPPD) and glufosinate-ammonium herbicide. Most soybeans currently grown in the United States are glyphosate-tolerant transgenic varieties. SYHT0H2 soybean is a new cultivar that is resistant to three herbicides: mesotrione, isoxaflutole, and glufosinate-ammonium. Cultivation of SYHT0H2 soybean will provide growers with an opportunity to use glufosinate and two HPPD-inhibitor herbicides (mesotrione and isoxaflutole) for control of problematic weeds in soybean production systems. SYHT0H2 soybean will offer growers much-needed flexibility to use herbicides with two alternative modes of action in their weed management programs and will help minimize or delay the evolution of herbicide resistance in weed populations.

Coordinated Framework Review

Food and Drug Administration

SYHT0H2 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. Syngenta-Bayer initiated the consultation process with FDA for the commercial distribution of SYHT0H2 soybean and submitted a safety and nutritional assessment of food and feed derived from SYHT0H2 soybean to the FDA on August 28, 2012. FDA is presently evaluating the submission.

Environmental Protection Agency

The EPA has authority over the use of pesticidal 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, which are determined during the pesticide registration process, and are listed on the label for each product containing a particular pesticide active ingredient. SYHT0H2 soybean is similar to currently available glufosinate-resistant soybean varieties, with the exception of an opportunity to use mesotrione and isoxaflutole in addition to glufosinate. Syngenta-Bayer submitted labeling to the U.S. EPA that proposes to allow the use of mesotrione and isoxaflutole on SYHT0H2 soybean (Syngenta-Bayer, 2012). APHIS used the current glufosinate labels and the proposed mesotrione and isoxaflutole labels as the basis for its evaluation of the potential impacts associated with the use of and exposure to glufosinate, mesotrione, and isoxaflutole.

Scope of the Environmental Analysis

Although a determination of nonregulated status of SYHT0H2 soybean would allow for new plantings of SYHT0H2 soybean anywhere in the U.S., APHIS primarily focused the environmental analysis on those geographic areas that currently support soybean production. A determination of nonregulated status of SYHT0H2 soybean is not expected to increase soybean production, either by its availability alone or accompanied by other factors, or 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 soybeans are produced in the U.S. (UDA-NASS, 2014). In 2013, the United States cultivated soybeans in 31 states on approximately 76.5 million acres (USDA NASS, 2014b).

Public Involvement

On February 27, 2013, APHIS published a notice in the Federal Register (78 FR pages 13305-13307, Docket no. APHIS-2012-0090) announcing the availability of the Syngenta-Bayer petition for a 60-day public review and comment period. Comments were required to be received on or before April 29, 2013. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 584 comments were received from individuals during the comment period. Comment documents may be viewed at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2012-0090.

The majority of the comments received expressed a general dislike of the use of GE organisms or were form letters from individuals expressing concerns about weed resistance, the direction of modern farming, and unknown health risks. It also referenced other open dockets and potential effects from the use of the subjects of those petitions. These issues are outside the scope of the EA. The issues related to the Syngenta-Bayer SYHT0H2 soybean petition which were raised in these comments are addressed in the EA; the issues raised 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 SYHT0H2 soybean and its associated herbicide use on conservation tillage
- 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
- The effects of SYHT0H2soybean and associated herbicide use on human health
- Concerns that SYHT0H2 soybean is not approved in all export markets and that this could cause trade disruptions and economic losses to occur.

APHIS has included a discussion of issues relative to this petition in the EA. No new issues, alternatives, or new information were identified in any of the comments received by APHIS. Responses to comments are included as an attachment to this Finding of No Significant Impact.

Major Issues Addressed in the EA

Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for the petition for nonregulated status of SYHT0H2 soybean as well as for other environmental assessments of genetically engineered organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of soybean using various production methods, and the environmental food/feed safety of genetically engineered plants, were addressed to analyze the potential environmental impacts of SYHT0H2 soybean.

The EA describes the alternatives considered and evaluated using the identified issues. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25):

Soybean Production

- Acreage and areas of soybean production
- Agronomic practices
- Commercial soybean production and uses
    - Seed production
    - Raw and processed soybean commodities
    - Organic soybean production
    - Specialty soybean systems

Physical Environment

- Soil
- Water quality and use
- Air quality
- Climate

Natural Biological Communities (Non-target organisms)

- Animals
- Plants
- Soil microorganisms
- Biodiversity
- Gene movement in the natural environment

Public Health

- Human health
- Animal (livestock) health
- Worker safety

Socioeconomic Factors

- Domestic trade environment
- Foreign trade environment
- Social and economic environment

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of SYHT0H2 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that SYHT0H2 soybean is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2013), APHIS has concluded that SYHT0H2 soybean is unlikely to pose a plant pest risk. Therefore, APHIS must determine that SYHT0H2 soybean is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of SYHT0H2 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. SYHT0H2 soybean and progeny derived from SYHT0H2 soybean would continue to be regulated articles under the regulations at 7 CFR part 340. Permits or notifications acknowledged by APHIS would still be required for introductions of SYHT0H2 soybean and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of SYHT0H2 soybean.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that SYHT0H2 soybean is unlikely to pose a plant pest risk (USDA-

APHIS, 2013). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

Preferred Alternative: Determination that SYHT0H2 soybean is No Longer a Regulated Article

Under this alternative, SYHT0H2 soybean and progeny derived from SYHT0H2 soybean would no longer be regulated articles under the regulations at 7 CFR part 340. SYHT0H2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2013). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of SYHT0H2 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 Plant Protection Act. Because the agency has concluded that SYHT0H2 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of SYHT0H2 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 SYHT0H2 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 SYHT0H2 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 SYHT0H2 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 SYHT0H2 soybean, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that SYHT0H2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2013).

In enacting the Plant Protection Act, Congress found that

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

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

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

Based on the PPRA (USDA-APHIS, 2013), and the scientific data evaluated therein, APHIS concluded that SYHT0H2 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of SYHT0H2 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 SYHT0H2 soybean is unlikely to pose a plant pest risk, (USDA-APHIS, 2013), there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3. Isolation Distance between SYHT0H2 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 SYHT0H2 soybean from conventional or specialty soybean production. However, because APHIS has concluded that SYHT0H2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2013), an alternative based on requiring isolation distances would be inconsistent with statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of SYHT0H2 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 SYHT0H2 soybean, there are no geographic differences associated with any identifiable plant pest risks for SYHT0H2 soybean (USDA-APHIS, 2013). This alternative was rejected and not analyzed in detail because APHIS has concluded that SYHT0H2 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 Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE production systems from SYHT0H2 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

SYHT0H2 soybean is available from the Association of Official Seed Certifying Agencies (AOSCA, 2014).

4. Requirement of Testing for SYHT0H2 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 SYHT0H2 soybean does not pose a plant pest risk (USDA-APHIS, 2013), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for SYHT0H2 soybean would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

Environmental Consequences of APHIS' Selected Action

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

Attribute/Measure	**Alternative A: No Action**	**Alternative B: Determination of Nonregulated Status**
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials.	Satisfied through plant pest risk assessment (USDA-APHIS, 2013).
Soybean Production		
Acreage and areas of soybean production	The size and distribution of soybean production will not change much over the next 10 years.	SYHT0H2 is not expected to change extent of soybean production.
Cropping practices	Continuing use of same rotation crops in various growing regions depending upon economics, markets and convenience.	SYHT0H2 will not generally alter current practices, although plant-back times may increase for some crops and lead to changes in rotations.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Pesticide use	Patterns of herbicide use may see increased use of alternatives to glyphosate to respond to resistant weeds.	Growers with glyphosate resistant weeds may begin to use SYHT0H2 and increase use of mesotrione, glufosinate and isoxaflutole and decrease glyphosate use with little overall change in weed management practices.
Organic soybean production	Organic soybean will continue increase in production but be a small part of total US soybean production.	SYHT0H2 will not impact organic soybean any differently than does conventional soybean.
Specialty soybean production	Identity preserved soybean will continue to respond to specialized market requirements.	SYHT0H2 will have no impacts on specialty soybean different from those of current varieties.
Physical Environment		
Water Quality	Current use of conservation tillage reduces runoff of nutrients and pesticides.	SYHT0H2 will not deleteriously affect water quality as current tillage and irrigation practices are continued for production and weed control.
Soil	Use of conservation tillage will continue except in some circumstances in which tillage is the only control for herbicide resistant weeds.	Soil practices will remain unchanged, especially since growers will have an additional MOA for resistant weeds to allow continued use of conservation tillage.
Air Quality	Conservation tillage which reduces air particulates will continue unchanged.	No changes expected with production of SYHT0H2 soybean.
Climate	Greenhouse gas production from tillage and vehicle emissions will likely remain unchanged.	Production of GHGs will not be altered by use of SYHT0H2 soybean, although in some cases where resistant weeds exist, additional spraying may be needed which increases GHGs.
Biological Environment		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Animal Communities	Agricultural impacts to crop associated animals in general will remain unchanged.	SYHT0H2 will not change impacts on animal populations.
Plant Communities	Weeds will continue to develop resistance and growers will respond with other herbicides and cultural or mechanical techniques.	Management techniques may change mostly by use of additional herbicide MOAs for growers of SYHT0H2 soybean. Cumulative use of mesotrione, isoxaflutole and glyphosate on corn could increase exposure of weeds to these herbicides and increase possibilities of resistance. However, increased use of multiple herbicides can potentially deter such resistance development.
Soil Microorganisms	Soil microorganisms will continue to be impacted by conventional agricultural practices with little consequence to soybean production.	SYHT0H2 will not alter populations of soil microorganisms differently than do conventional soybean varieties.
Biological Diversity	A variety of EIQs from the use of different herbicides may impact biodiversity.	The EIQs of the three new herbicides that would be used for soybean in SYHT0H2 are slightly lower than for glyphosate, but would likely not change biodiversity.
Gene Movement	No gene flow expected.	SYHT02 would not change gene flow between other varieties of soybean.
Public Health		
Human Health	Existing varieties have no impacts on health.	The proteins avHHPD-03 and PAT are unlikely to be allergens and are not toxic.
Animal (livestock) Health	Current varieties and herbicides used on them have no health impacts on animals that feed on soybean.	The SYHT0H2 soybean and herbicides applied to it when used under EPA restrictions are safe for animals exposed to the variety.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Worker Safety	Worker exposure to herbicides is regulated by EPA for safety.	Use of EPA registered herbicides will convey no health risks to workers when used according to label requirements.
Social and Economic Factors		
Domestic trade environment	Growers will continue to choose varieties based on maximizing profits and environmental benefits.	Additional choices of herbicides to improve weed control could provide economic benefit to growers, increasing price competition for seed and herbicides.
Foreign trade environment	Additional soybean varieties will continue to be developed and available to foreign trade.	No change in trade is expected, although potential exists for increasing efficiency in production and possible profit increases for growers.
Social and economic environment	No social or economic effects are anticipated.	Consumer choice or regulatory decision making on GE soybean would not change.
Threatened and Endangered Species	Mesotrione, isoxaflutole and glufosinate are all registered for use on other crops including corn, and were approved for use following restrictions that should mitigate possible impacts on T&E species.	No new herbicides would be used on SYHT0H2 other than those approved by EPA at similar rates for other crops. EPA label requirements that take T&E species into account will not change possible impacts of existing herbicides.
Other Regulatory Approvals		
U.S.	Unchanged for existing non-regulated varieties.	FDA consultation is pending.
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 2003-2013, the average soybean production in the U.S. has been about 74.6 million acres (USDA-NASS, 2014). In 2013 approximately 76.5million acres of soybean were cultivated in 31 states (USDA-NASS, 2014b). In 2013, GE herbicide-resistant soybean was estimated to be 93% of the U.S. soybean crop (USDA-ERS, 2013). A determination of nonregulated status of SYHT0H2 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 SYHT0H2 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 SYHT0H2 soybean will have no significant environmental impact in relation to the availability of GE, conventional and organic soybean varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of SYHT0H2 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. Based on the data provided by Syngenta-Bayer for SYHT0H2 soybean (Syngenta-Bayer, 2012), APHIS has concluded that the availability of SYHT0H2 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 SYHT0H2 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 soybeans 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, 2012). This represented about 0.13 percent of total U.S. soybean production in 2011 (USDA-NASS, 2012). Based on the data provided by Syngenta-Bayer for SYHT0H2 soybean (Syngenta-Bayer, 2012), APHIS has concluded that the availability of SYHT0H2 soybean would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE-soybean-seed production (USDA-APHIS, 2013). A determination of nonregulated status of SYHT0H2 soybean will not require a change in seed production practices, nor current production practices. The introduction SYHT0H2 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 SYHT0H2 soybean would have no significant impacts on human or animal health. Compositional tests conducted by the petitioner indicate that SYHT0H2 soybean is compositionally similar to other commercially available soybean (Syngenta-Bayer, 2012). Syngenta-Bayer initiated the consultation process with FDA for the commercial distribution of SYHT0H2 soybean and submitted a safety and nutritional assessment of food and feed derived from SYHT0H2 soybean to the FDA on August 28, 2012. FDA is presently evaluating the submission. Based on the assessment of laboratory data provided by Syngenta-Bayer (Syngenta-Bayer, 2012) in the submitted petition and an analysis of the scientific literature (USDA-APHIS, 2013), APHIS has concluded that a determination of nonregulated status of SYHT0H2 soybean would have no adverse 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 SYHT0H2 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 SYHT0H2 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 SYHT0H2 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 SYHT0H2 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 SYHT0H2 soybean are not highly controversial. Although there is some opposition to a determination of nonregulated status of SYHT0H2 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. The availability of SYHT0H2 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 SYHT0H2 soybean would 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 SYHT0H2 soybean will not result in changes in the current agronomic practices of planting, tillage, fertilizer application/use, cultivation, pesticide application use, and volunteer control. Management practices and seed standards for production of certified soybean seed would not change. The effect of SYHT0H2 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. During the public comment period, APHIS received comments opposing a determination of nonregulated status of SYHT0H2 soybean. Many of these public comments expressed a general opposition to genetically modified organisms (GMOs) or GE crops and the domestic regulatory process surrounding GE plants; perceived negative effects on public and animal health, biodiversity, and the environment; and a lack of consideration regarding organic production systems and the public right to choose non-GE containing food products. No new issues, alternatives or new information were identified in any of the comments received by APHIS. APHIS has addressed comments in the response to public comments document attached to this FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*
   Based on the analysis documented in the EA, the possible effects on the human environment are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of SYHT0H2 soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production, or those acres devoted to GE-soybean cultivation. A determination of nonregulated status of SYHT0H2 soybean will not result in changes in the current agronomic practices of planting, tillage, fertilizer application/use, and volunteer control. Management practices and seed standards for production of certified soybean seed would not change. The effect of SYHT0H2 soybean on wildlife or biodiversity is no different than that from other herbicide resistant soybean varieties currently used in conventional agriculture in the U.S. As described in Chapter 2 of the EA, well established management practices, production controls, and production practices for GE, conventional, and organic soybean production are currently being used in soybean production systems (i.e., commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce GE, conventional non-GE, or organic soybean crops, will continue to use these 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 2013) (USDA-ERS, 2013). 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 SYHT0H2 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 SYHT0H2 soybean would not establish a precedent for future actions with significant effects or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and undergoes this independent review to determine if the regulated article poses a plant pest risk. Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as SYHT0H2 soybean. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment, that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code(U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have enough information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act 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 Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

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

No significant cumulative effects were identified through this assessment. The EA discussed cumulative effects on soybean management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative effects analysis is provided in Chapter 5 of the EA. APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of SYHT0H2 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 SYHT0H2 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 SYHT0H2 soybean would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historic resources. This action is limited to a determination of nonregulated status of SYHT0H2 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. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of SYHT0H2 soybean is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the soybean production regions. The cultivation of SYHT0H2 soybean does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

9. *The degree to which the action may adversely affect 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 SYHT0H2 soybean on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the

Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of SYHT0H2 soybean, APHIS has concluded that a determination of nonregulated status of SYHT0H2 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 SYHT0H2 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of SYHT0H2 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. Syngenta-Bayer initiated the consultation process with FDA for the commercial distribution of SYHT0H2 soybean and submitted a safety and nutritional assessment of food and feed derived from SYHT0H2 soybean to the FDA to on August 28, 2012. FDA is presently evaluating the submission.

    SYHT0H2 soybean is compositionally similar to currently available glufosinate resistant soybeans on the market, with the exception of an opportunity to use mesotrione and isoxaflutole in addition to glufosinate on soybean. Syngenta-Bayer submitted labeling to the U.S. EPA that proposes to allow the use of mesotrione and isoxaflutole on SYHT0H2 soybean (Syngenta-Bayer, 2012). 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 SYHT0H2 soybean is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the Plant Protection Act.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of GE organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with SYHT0H2 soybean, the continued regulated status of SYHT0H2 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 SYHT0H2 soybean will not have any significant environmental effects.

/s/ Sidney W. Abel

for Michael J. Firko

Deputy Administrator

Biotechnology Regulatory Services

7/17/2014

Date

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Response to Public Comments on the Petition for SYHT0H2 Soybean

Summary of comments received

On February 27, 2013, APHIS published a notice in the Federal Register (78 FR pages 13305-13307, Docket no. APHIS-2012-0090) announcing the availability of the Syngenta-Bayer petition for a 60-day public review and comment period. Comments were required to be received on or before April 29, 2013. The docket folder containing the comments can be located at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2012-0090. All comments were carefully analyzed. A total of 584 comments were received during the comment period. APHIS evaluated all issues raised by the comments and the submitted documentation. 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-2012-0090.

Issue 1

One commenter expressed the view 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 SYHT0H2 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 SYHT0H2 soybean, and has determined that SYHT0H2 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 SYHT0H2 soybean. APHIS carefully considered the possible environmental impacts of the proposed product, and is satisfied that the EA developed for SYHT0H2 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 SYHT0H2 soybean. These sources include, but are not limited to the Syngenta-Bayer petition, technical reports, and peer-reviewed literature.

Issue 2

A number of comments expressed concern about increased use of herbicide-resistant crops and the association with "increase in herbicide-resistant weeds". Commenters 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. Commenters asserted that increases in herbicide-resistant weeds, especially those resistant to multiple herbicides will "be harder and harder to manage, threatening the environment as well as the agricultural industry."

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 2.4.2 and 4.4.2). 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, SYHT0H2 soybean will enable growers to control weeds using mesotrione, isoxaflutole, and glufosinate where, for example, glyphosate resistant weeds are present.

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.

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). For example, rotating crops, rotating types of herbicides, using multiple herbicides for the same principal weeds, using cover crops, scouting for weeds and using mechanical tillage to prevent weeds from flowering, are just some of the practices that can be followed to reduce or delay the selection of herbicide resistant weeds. Weed management is an important part of any agricultural system. The commercialization of soybean varieties with glufosinate-resistance such as SYHT0H2 soybeans and the anticipated stacking of SYHT0H2 soybean with other GE soybean, would permit existing and widely-adopted management strategies to continue. Societies such as the Weed Science Society of America (WSSA), university extension agents, and industry, have made a concerted effort to increase grower awareness of best management practices for herbicide resistant weeds. The extent to which growers will adopt best management practices is unknown and therefore it is difficult to accurately predict the extent to which mesotrione resistant weeds will become a problem.

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 reasonably 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. More diversified weed management practices will result in less selective pressure for resistance to any given herbicide or management technique.

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 SYHT0H2 soybean would increase the incidence of resistant weeds, as the factors resulting in resistance in weeds would remain unchanged.

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Issue 3

Several commenters expressed concerns that conventional, organic, or GE-sensitive markets are at risk of contamination from SYHT0H2 soybean. A number of comments focused on the potential economic impact on organic farming from contamination by SYHT0H2 soybean stating that “any contamination or damage to organic crops could result in huge economic losses for farmers.” APHIS also 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.

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 SYHT0H2 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 2013 were GE.

Ultimately, organic producers are obligated to manage their operations to avoid unintentional contact or admixture with excluded seeds, or chemicals and the use of excluded methods. A number of techniques have been developed in order to maintain coexistence of organic and conventional GE crops 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 SYHT0H2 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.

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 employed appropriate measures (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 SYHT0H2 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 SYHT0H2 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 SYHT0H2 soybean.

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Issue 4

Several commenters expressed concerns with herbicide application and potential increased use. One commenter noted that “APHIS must consider the use and any changes in use patterns of HPPD inhibitor herbicides on SYHT0H2 soybean.” Other commenters were concerned about the increased use of herbicides due to the development of herbicide resistant weeds, noting studies conducted by Penn State University weed scientist Dave Mortenson which “suggests that efforts to control newly resistant weeds could increase pesticide use 70 percent by 2015.” One commenter also noted that “If weeds develop resistance, growers will begin to apply herbicides at greater than label rates when weed pressure is high.”

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 mesotrione, isoxaflutole, glufosinate, or any other herbicide used by soybean growers. APHIS relies on EPA’s analyses and evaluations 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 mesotrione and isoxaflutole application rates in section 4.2.2., Agronomic Practices. The glufosinate-resistant trait in SYHT0H2 soybean is already present in currently available soybean varieties. Because this identical glufosinate-resistant trait is already established in the U.S. soybean market, and SYHT0H2 soybean itself does not require any changes in glufosinate application, a determination of nonregulated status of SYHT0H2 soybean will not promote changes in current practices of glufosinate application. APHIS expects that glufosinate use will increase, but as replacement for glyphosate, since both are foliar active, and

not soil active, both have a broad spectrum of herbicidal activities and may be used as burndowns before planting.

Nonregulated status of SYHT0H2 soybean and approval of use of mesotrione on soybeans crops will cause growers to change management practices; namely mesotrione use is expected to increase. Furthermore, mesotrione, isoxaflutole and glufosinate applications are expected to be employed over a wider part of the growing season. If SYHT0H2 soybean is granted nonregulated status, mesotrione and isoxaflutole use is expected to increase if EPA approves use of these herbicides on SYHT0H2 soybean. However, increases in other herbicide sites of action could potentally be lessened because the three herbicides are expected to be preferentially deployed if approved for use on the SYHT0H2 soybean by EPA. It should be noted, however, that current recommendations by weed specialists for integrated weed management in consideration of development of herbicide resistance tends to support overlapping herbicide activity for potentially resistant or problem weeds with different sites of action (e.g., B. Young, 2014, Annual Meeting of the American Soybean Association). Recommendations of this type could have the potential for generally increasing herbicide use. The availability of cost efficient and effective herbicides used with SYHT0H2 soybean may delay the adoption of non-chemical management strategies. Fewer growers would be expected to adopt aggressive tillage when herbicides remain effective for weed control. However, growers currently employing conservation tillage practices will choose to continue to these practices, given the benefits to erosion control and reducing pesticide runoff into water resources.

APHIS acknowledges differing interpretations of data related to GE soybean adoption and herbicide use. 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.

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. 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 pattern of heating degree units increases the abundance of weeds throughout the growing season necessitating more frequent herbicide application.

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.

Issue 5

APHIS received a number of comments on the issues related to the potential human health effects associated with herbicide use. One commenter noting that “exposure to herbicides has long been linked to health problems such as cancer and reproductive issues.”

APHIS Response

The EA has reported on the safety of the use of mesotrione, isoxaflutole, and glufosinate 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 SYHT0H2 soybean.

The general use of herbicides is outside of the scope of this EA. 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). It addresses, among other things, level and pattern of use (e.g., allowable application methods, minimum and maximum rates; timing of treatments).

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 mesotrione, isoxaflutole, and glufosinate, or any other herbicide used by soybean growers. 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 mesotrione or isoxaflutole, which is being made by EPA. 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.

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 mesotrione, isoxaflutole, and glufosinate have been established for a wide variety of commodities, including soybean (EPA, 2012b). For glufosinate, the tolerance for soybean seed is 2 parts per million (ppm) (EPA, 2012a), the established tolerance of isoxaflutole is 0.05 ppm (EPA, 2012a), and the mesotrione tolerance for soybean seed is 0.01ppm (40 CFR part 180.571). Crop metabolism and residue studies have been conducted to support establishment of a tolerance for mesotrione residues in or

on soybean as required under the FIFRA. A tolerance petition and label amendment application for post-emergence use of mesotrione on soybean has been submitted to EPA.

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).

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).

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Issue 6

Several commenters asserted that Syngenta-Bayer has not thus far been successful in obtaining sufficient authorizations to import SYHT0H2 soybean. The commenters state 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. Several commenters recommended the voluntary restriction of SYHT0H2 soybean commercialization pursuant to a corporate stewardship plan. Commenters noted that "the biotechnology provider should be required to develop, implement and enforce binding stewardship programs and supply chain management" and "the biotechnology provider should be required to determine a level, if any, at which it is inappropriate for such traits to be present in the general commodity stream." Commenters also noted that the stewardship plan should include "responsibility for economic damages to downstream stakeholders caused by the developer's failure to effectively manage this product."

APHIS Response

To support commercial introduction of SYHT0H2 soybean in the U.S. and avoid adversely affecting international trade, Syngenta-Bayer intends to submit dossiers to request import approval of SYHT0H2 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, Columbia, Japan, Republic of Korea, Republic of China, People's Republic of China, Philippines, Indonesia, Thailand, Singapore, Australia/New Zealand, Republic of South Africa, the Russian Federation, and the EU (Syngenta-Bayer, 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).

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 stewardship plan required of growers by their signature on a Technology Use Agreement. In this case, Syngenta-Bayer has developed a stewardship plan for SYHT0H2 soybean as indicated in their petition (Syngenta-Bayer, 2012). 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 (Syngenta-Bayer, 2012).

References

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Response to Public Comments Received on the EA for SYHT0H2 Soybean Petition (12-215-01p)

The Syngenta Environmental Assessment was published for public comment on May 30, 2014, with comments accepted until June 30, 2014. There were a total of five comments received on the EA during the public comment period. Four of the comments were generally against granting nonregulated status to SYHT0H2 soybean and GE plants in general but did not provide support for their position. The fifth comment, from an organization that incorrectly identified the petition 12-215-01 as being one for a GE crop whose HPPD resistant trait had never been previously assessed by APHIS, did not articulate specific concerns on the EA for possible environmental or agronomic impacts of the soybean. APHIS found no comments on the EA that were new or substantive ones, that is, offered any new evidence for potential agronomic or environmental impacts. The issues raised were those that were either outside the scope of the EA, or had been discussed in the EA or FONSI.