

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

Dow AgroSciences
Event DAS-81419-2 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 DAS-81419-2 soybean, the subject of a petition request (APHIS Number 12-272-01p) by Dow AgroSciences LLC (Dow AgroSciences). The DAS-81419-2 soybean is resistant to the herbicide, glufosinate, and also resistant to lepidopteran insects. 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 DAS-81419-2 soybean. The EA assesses alternatives to a determination of nonregulated status of DAS-81419-2 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 DAS-81419-2 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.

Dow AgroSciences has submitted a petition (APHIS Number 12-272-01p) to APHIS seeking a determination that their DAS-81419-2 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.

DAS-81419-2 soybean

DAS-81419-2 soybean has been genetically engineered to express PAT protein to convey resistance to the herbicide glufosinate, and also to express Cry1Ac and CryF for resistance to lepidopterous pests of soybean.

The phosphinothricin acetyltransferase (PAT) protein has been expressed in a variety of crops to provide tolerance to the herbicide glufosinate, which contains the active ingredient phosphinothricin (PPT) (Dow AgroSciences, 2012). The gene for PAT derives from the aerobic soil bacterium, *Streptomyces viridochromogenes*. The L-isomer of PPT is a potent inhibitor of glutamine synthetase (GS) in plants and is used as a non-selective herbicide. Inhibition of GS by PPT causes rapid accumulation of intracellular ammonia which leads to cessation of photorespiration and results in the death of the plant cell (Coetzer and Al-Khatib, 2001; Dow AgroSciences, 2012). The *pat* gene which encodes phosphinothricin acetyltransferase (PAT) acetylates the free NH₂ group of PPT (in the presence of acetyl coenzyme A) and thereby prevents autotoxicity in the producing organism (Wehrmann et al., 1996; Dow AgroSciences, 2012).

Glufosinate is a broad-spectrum systemic herbicide used to kill weeds. It is registered with the Environmental Protection Agency (EPA) for non-selective weed control for both non-food use and food use plants. Dow AgroSciences indicates that there will be no change in the use pattern

for glufosinate on this glufosinate-resistant variety and there was no need to petition EPA for a change in the label for the herbicide. APHIS used current glufosinate herbicide labels as the basis for its evaluation of the potential impacts associated with the use of and exposure to glufosinate.

As described in Human Health subsection of the EA, under FIFRA, all pesticides (including herbicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2011a). 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 should have a reregistration review every 15 years (US-EPA, 2011a). The latest reregistration review for glufosinate was started in March 2008 (US-EPA, 2012). Before a pesticide can be used on a food or feed crop, the EPA must establish the tolerance value, which is the maximum amount of pesticide residue that can remain on the crop or in foods or feed processed from that crop (US-EPA, 2011c). Glufosinate currently has established tolerances for residues, including residue concentrations for glufosinate in soybean, corn (field, grain), cotton (undelinted seed) and several other crops (US-EPA, 2012b).

The EPA regulates plant-incorporated protectants (PIPs), and the two Bt proteins, Cry1Ac and CryF expressed in this soybean are both PIPs under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 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.

DAS-81419-2 soybean provides growers with an additional glufosinate-resistant soybean product on the market today, but also a variety with insect resistance. Herbicide and insect-resistant DAS-81419-2 soybean will provide similar benefits to currently available herbicide-resistant soybean varieties by allowing post emergent applications of glufosinate to control weeds, but with traits for resistance to lepidopterous pests, will allow growers to use less pesticides for the targeted pest species.

Coordinated Framework Review

Food and Drug Administration

DAS-81419-2 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. Dow AgroSciences initiated the consultation process with FDA for the commercial distribution of DAS-81419-2 soybean and submitted a safety and nutritional assessment of food and feed derived from DAS-81419-2 soybean to the FDA on October 15, 2012 (Dow AgroSciences, 2012). On February 7, 2014, the FDA stated that it had no further questions for Dow AgroSciences regarding use of DAS-81419-2 soybean for food or feed.

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 FFDCFA (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. DAS-81419-2 soybean is similar to currently available glufosinate-resistant soybean varieties. Glufosinate is currently labeled for use on resistant soybean varieties and no further EPA herbicide evaluation was needed for use of glufosinate on DAS-81419-2 (L. Han, Dow AgroSciences, personal communication, 2013). APHIS used the current glufosinate labels as the basis for its evaluation of the potential impacts associated with the use of and exposure to glufosinate. EPA has previously assessed Cry proteins Cry1Ac (corn, cotton and soybean) and CryF (corn and cotton) and will need to develop a tolerance only for CryF in soybean.

Scope of the Environmental Analysis

Dow AgroSciences has developed DAS 81419-2 primarily for South American production sites, but would produce seed in the U.S. for export to these markets. Although an APHIS determination of nonregulated status of DAS-81419-2 soybean would allow for new plantings of DAS-81419-2 soybean anywhere in the U.S., APHIS primarily focused the environmental analysis to those states that both support soybean production and have or may have an economically important issue with lepidopteran pests of soybean. These are the areas that are most likely to adopt DAS-81419-2 soybean should it be offered in the future as a commercial product for commodity soybean production under an EPA permit in the U.S. A determination of nonregulated status of DAS-81419-2 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. While an increase in seed production acres may be observed, this production would be on existing soybean acres, and would be small in relation to all the present acreage of commodity soybean. 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. (USDA-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). States with largest use of insecticides for soybean insect control were determined from USDA data (USDA-NASS, 2013).

Public Involvement

On February 27, 2013, APHIS published a notice in the Federal Register (78 FR pages 13307-13308) announcing the availability of the Dow AgroSciences 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 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 submissions were received during the comment period¹. Submissions also contained a total of 561 identical comments. The issues that were raised in the public comments which were related to the DAS-81419-2 soybean petition included:

- Encouraged a thorough USDA-APHIS review of all herbicide resistant crops, in the context of the potential for development of weed resistance to herbicides and other environmental impacts. APHIS recently reviewed herbicide resistance issues in the Draft

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

EIS for 09-349-01 soybean (as well as corn varieties). In addition, recent reviews in EAs for other corn and cotton crop petitions have provided USDA's perspective on the development and averting of further weed resistance to herbicides and also of mitigation practices. Growers are the key participants, and by following the advice and research offered by USDA-ARS and state extension agencies can deal with weed resistance. As noted in the EA, one mechanism for averting or delaying weed resistance is the deployment of new herbicide modes of action to respond to weed resistance to glyphosate, as does this glufosinate resistant soybean variety.

- Concerns about the development of insects resistant to the Cry proteins expressed by the variety. EPA by mandating insect resistance management programs for all GE plant incorporated protectants has actively deterred resistance, and when resistance is detected, has promptly responded, and encouraged technology providers to deal with the issue in affected locations.
- Concerns about admixture of GE soybean with organic soybean. APHIS notes in the EA the mechanisms by which organic growers in partnership with neighbors using nonorganic methods routinely use reliable production practices to prevent such mixing.
- Concerns for admixture of new GE lines with exported commodity soybean when the line has not yet been approved in the importing country. Technology companies are continually working to gain acceptance by foreign market importers for new varieties of GE; domestic commodity buyers do not purchase and receive grain varieties that are not yet accepted by key buyers of US soybean when such purchase would plausibly end up in the export commodity stream.

The following issues were also raised but are outside the scope of this EA:

- A general dislike of the use of GE organisms,
- Health concerns for food or feed consumption of any GE plants
- Concerns for use of additional herbicides in agriculture
- Reference to other open dockets and potential effects from the use of the subjects of those petitions.

APHIS evaluated the issues raised and the submitted documents. 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 DAS-81419-2 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 and feed safety of GE plants, were addressed to analyze the potential environmental impacts of DAS-81419-2 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 DAS-81419-2 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that DAS-81419-2 soybean is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2013), APHIS has concluded that DAS-81419-2 soybean is unlikely to pose a plant pest risk. Therefore, APHIS must determine that DAS-81419-2 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 DAS-81419-2 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. DAS-81419-2 soybean and progeny derived from DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 soybean.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that DAS-81419-2 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 DAS-81419-2 soybean is No Longer a Regulated Article

Under this alternative, DAS-81419-2 soybean and progeny derived from DAS-81419-2 soybean would no longer be regulated articles under the regulations at 7 CFR part 340. DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 soybean, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that DAS-81419-2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2013).

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, 2013), and the scientific data evaluated therein, APHIS concluded that DAS-81419-2 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of DAS-81419-2 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 DAS-81419-2 soybean is unlikely to pose a plant pest risk, (USDA-APHIS, 2013), 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 DAS-81419-2 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 DAS-81419-2 soybean from conventional or specialty soybean production. However, because APHIS has concluded that DAS-81419-2 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 PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of DAS-81419-2 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 DAS-81419-2 soybean, there are no geographic differences associated with any identifiable plant pest risks for DAS-81419-2 soybean (USDA-APHIS, 2013). This alternative was rejected and not analyzed in detail because APHIS has concluded that DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 soybean is available from the Association of Official Seed Certifying Agencies (AOSCA, 2011).

4. Requirement of Testing for DAS-81419-2 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 DAS-81419-2 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 PPA, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for DAS-81419-2 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.

Summary of issues of potential impacts and consequences of Alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Preferred Alternative; Determine Nonregulated Status
Meets Purpose and Need Objectives	No	Yes
Unlikely to Pose a Plant Pest Risk	Satisfied through use of regulated field trials	Satisfied by USDA-APHIS Plant Pest Risk Assessment
Management Practices		
Acreage and Areas of Soybean Production	Continuing under APHIS notification and EPA permits only, no change in current soybean acreage	Under EPA seed increase permits only, no large overall change in total soybean acreage is expected; existing soybean acres will be used for new seed production. If DAS chooses commodity production for DAS-81419-2, this will replace existing varieties

Attribute/Measure	Alternative A: No Action	Alternative B: Preferred Alternative; Determine Nonregulated Status
Agronomic Practices	Standard practices will be maintained	Standard practices will be maintained for small scale seed production. If the crop is commercialized for the US market, less insecticide will be used in treating lepidopteran infestations. Some increase in glufosinate use may occur if the developer decides to pursue US commercialization of the trait
Soybean Seed Production	Unchanged	Practices for seed production will remain similar to current seed production, including the unlikely use of glufosinate for weed control.
Organic Soybean Production	No expected changes in production of organic soybean varieties. 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.	No expected change in organic soybean practices or increase in present total acreage of GE soybean
Environment		
Water Resources	No expected changes to water resources	No expected changes to soybean seed production or to water resources; if used in areas with lepidopteran pests, use could decrease insecticides in water

Attribute/Measure	Alternative A: No Action	Alternative B: Preferred Alternative; Determine Nonregulated Status
Soil Quality	Unchanged	If released commercially for commodity soybean production, some regions with economically important lepidopteran pests may have decreased insecticides in soil
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Animal Communities	Unchanged. Under notifications, test protocols are required that confine the seed and plant variety and prevent environmental impacts	DAS-81419-2 is not expected to have any effect on vertebrate animals or most invertebrate animals. DAS-81419-2 exhibits insecticidal activity against certain lepidopteran insects. Those pests that feed directly on DAS-81419-2 soybeans would be expected to die or have delayed growth. If DAS-81419-2 soybean is commercialized in the U.S., there are potential benefits due to reduced insect pressure and reduced need for insecticide applications
Plant Communities	The most agronomically important members of the surrounding plant community are often those that behave as weeds. Soybean growers use production practices to manage weeds in and around fields. Resistant weeds will continue to increase because of the use of herbicides, especially glyphosate.	No increased impacts because only seed production will be increased and glufosinate will likely not be used; if commercialized, may be a trend in some parts of the country for increased glufosinate use against glyphosate resistant weeds. No large increase in acres planted to DAS-81419-2 expected, so considerable change in glufosinate use is not likely

Attribute/Measure	Alternative A: No Action	Alternative B: Preferred Alternative; Determine Nonregulated Status
Gene Flow and Weediness	Cultivated soybean varieties can cross pollinate. Growers use various production practices to limit undesired cross pollination.	Unchanged from No Action Alternative
Soil Microorganisms	Unchanged	Unchanged
Biological Diversity	Unchanged	Unchanged
Human and Animal Health		
Risk to Human Health	Unchanged. EPA regulates the safe use, handling and exemptions for tolerances of all pesticides.	Unchanged. EPA regulates the safe use, handling and exemptions for tolerances of all pesticides.
Risk to Animal Feed	Unchanged. Processed soybeans are the largest source of protein in animal feed.	Unchanged. A compositional analysis concluded that forage and grain from DAS-81419-2 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	No new impacts. The widespread adoption of herbicide-resistant soybean has been attributed to the cost savings for production, and also other non-monetary benefits.	If commercialized, then somewhat less use of insecticides in some parts of the country.

Attribute/Measure	Alternative A: No Action	Alternative B: Preferred Alternative; Determine Nonregulated Status
Trade Economic Environment	Likely no change of exported soybean seed for planting. Developer will not increase foreign sales of seed produced unless DAS 81419-2 is determined as nonregulated.	May increase exports of soybean seed for planting to some markets, especially South American markets. Dow AgroSciences intends to submit dossiers to request import approval of DAS-81419-2 soybean to the proper regulatory authorities of several countries that already have regulatory processes in place for GE soybean. These include, but are not limited to: Canada, Mexico, Japan, the EU, South Korea, and China.
Other Regulatory Approvals		
U.S.	FDA food consultation complete, EPA Cry1F tolerance exemptions and conditional pesticide registrations complete	FDA food consultation complete, EPA Cry1F tolerance exemptions and conditional pesticide registrations complete
Other Countries	Currently seeking foreign approvals for feed and food	Will seek approvals from South American countries for planting. Currently seeking foreign approvals for food and feed.

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 DAS-81419-2 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 DAS-81419-2 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 or seed 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 DAS-81419-2 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 DAS-81419-2 soybean is expected to neither directly cause an increase in overall soybean production acreage, nor GE soybean acreage. The availability of DAS-81419-2 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 DAS-81419-2 soybean, if Dow AgroSciences elects to do so, could add another GE soybean variety to the conventional soybean market, but one with resistance to certain key insect pests. To complete this process, it would be necessary to request a commercial permit for commercial production of the crop in the US, beyond the permit requested for seed increase. It 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 Dow AgroSciences for DAS-81419-2 soybean (Dow AgroSciences, 2012), APHIS has concluded that the availability of DAS-81419-2 soybean would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE soybean seed or commodity production (USDA-APHIS, 2013). A determination of nonregulated status of DAS-81419-2 soybean will not require a change to seed production practices, nor current production practices. The introduction of DAS-81419-2 soybean provides a soybean variety with both herbicide resistance and lepidopteran insect resistance.

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

A determination of nonregulated status of DAS-81419-2 soybean would have no significant impacts on human or animal health. Compositional tests conducted by the petitioner indicate that DAS-81419-2 soybean is compositionally similar to other commercially available soybean (DAS, 2012). Dow AgroSciences initiated the consultation process with FDA for the commercial distribution of DAS-81419-2 soybean and submitted a safety and nutritional assessment of food and feed derived for DAS-81419-2 soybean to the FDA on October 15, 2012. Based on the information Dow AgroSciences submitted, laboratory data and scientific literature provided by Dow

AgroSciences (Dow AgroSciences, 2012) and safety data available on other herbicide-resistant products, and the completed FDA consultation APHIS has concluded that DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 soybean are not highly controversial. Although APHIS received public comments opposed to a determination of nonregulated status of DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 soybean could add another GE soybean variety to the conventional soybean market (if Dow AgroSciences decides to offer DAS-81419-2 for commodity soybean production) especially for those growers needing protection of the crop from lepidopterous insects. DAS-81419-2 is not expected to change the market demands for GE soybean or soybean produced using organic methods. A determination of nonregulated status of DAS-81419-2 soybean will not change current practices of planting, tillage, fertilizer application or use, cultivation, pesticide application or use, or control of volunteer soybean. Management practices and seed standards for production

of certified soybean seed would not change. The effect of DAS-81419-2 soybean on wildlife or biodiversity is not different from 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 DAS-81419-2 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 DAS-81419-2 soybean will not result in changes in the current practices of planting, tillage, fertilizer application and use, pesticide application and use or volunteer control. Management practices and seed standards for production of certified soybean seed would not change. The effect of DAS-81419-2 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 3 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), DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 soybean, APHIS would no longer have regulatory authority over this soybean. In the event of a determination of nonregulated status of DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 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 DAS-81419-2 soybean, APHIS has concluded that a determination of nonregulated status of DAS-81419-2 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 DAS-81419-2 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of DAS-81419-2 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. Dow AgroSciences initiated the consultation process with FDA for the commercial distribution of DAS-81419-2 soybean and submitted a safety and nutritional assessment of food and feed derived from DAS-81419-2 soybean on October 15, 2012 (DAS, 2012).

Based on the information Dow AgroSciences submitted, and that FDA had no further questions for Dow AgroSciences regarding DAS-81419-2 soybean as food or feed (FDA, BNF 000140, February 7, 2014) APHIS has concluded that a determination of nonregulated status of DAS-81419-2 soybean would have no effect on the environment. DAS-81419-2 soybean is compositionally similar to currently available glufosinate-resistant soybean varieties on the market, with the exception of an opportunity to reduce the use of insecticides for control of lepidopteran pests of soybean. A tolerance for Cry1F proteins in soybean has been issued by the EPA (Federal Register 79, 8293, February 12, 2014) although current tolerances already exist for this same protein when expressed in corn and cotton. EPA registration for DAS-81419-2 was completed January 30, 2014. There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

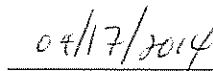
NEPA Decision and Rationale

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 DAS-81419-2 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 DAS-81419-2 soybean, the continued regulated status of DAS-81419-2 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 DAS-81419-2 soybean will not have any significant environmental effects.



Michael J. Firko,
Deputy Administrator,
Biotechnology Regulatory Services



Date

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Response to Comments (Petition 12-272-01p)

There were a total of five comments received on the draft EA during the public comment period. Four of the comments were generally against granting nonregulated status to DAS-81419-2 soybean and GE plants in general but did not provide support for their position. The fifth comment, from Food and Water Watch, was also opposed to the petition and provided discussion on several issues pertaining to GE plants in general, and several issues specific to DAS-81419-2 soybean. Responses to those questions pertinent to DAS-81419-2 soybean are as follows:

1. Comment: Insect resistance to Bt is exacerbated by continued widespread planting of this trait. The commenter cited a letter to EPA from entomologists concerned that more cases of insect resistance are sure to come with Bt hybrids. The commenter also referred to a study published in 2013 by the National Academy of Sciences (NAS) reporting that resistance was strengthened by multiple insect resistance traits like pyramided Bt varieties.

Response: APHIS does not agree that the cited study is applicable to DAS-81419-2 soybean. The published study involved cotton pyramided with Cry1Ac and Cry2Ab and the subsequent resistance to *Helicoverpa zea* (Brevault et al, 2013). DAS-81419-2 soybean has been engineered to express Cry1Ac and Cry1F. As discussed in the EA, these two Bt toxins have been shown to bind to different receptors in the midgut of the target soybean insect pest tobacco budworm (*H. virescens*) (Jurat-Fuentes and Adang, 2001). Cry1Ac binds to at least three sets of receptors while Cry1F binds to at least two, only one of which also binds Cry1Ac. The major receptor in the insect gut for Cry1Ac does not bind Cry1F (Jurat-Fuentes and Adang, 2006). *Bt* gene pyramiding in DAS-81419-2 soybean offers potentially greater durability than Bt crops carrying a single Bt trait and provides deterrence to the development of insect resistance. The cited study which involved different toxins, targeting different insects, on a different crop, is not comparable with effects likely to occur with the planting of DAS-81419-2 soybean. Further, the study does not indicate that pyramiding fails to prevent or delay resistance in pest populations, but that there are factors that could reduce redundant killing and decrease the effectiveness of the pyramid strategy for pests such as *Helicoverpa zea* that have a low susceptibility to BT toxins, and that these factors should be considered in Bt management plans.

2. Comment: Consumption of Cry proteins is unsafe. The commenter questioned the safety of DAS-81419-2 soybean pointing to effects of the Cry proteins on mice in that “a 2013 study found “hematotoxicity of *Bt* spore-crystals engineered to express different Cry proteins including Cry1Ac.”

Response: The paper cited by the commenter does not investigate Bt delta endotoxin producing GE food or the Bt delta endotoxin, but instead studies the toxicity of the bacteria that produces the Bt delta endotoxins. It has no relevance to the consideration of potential toxicity of any GE crops, including DAS-81419-2 soybean. This paper was withdrawn from *Food and Chemical*

Technology. It was later published online in a new journal *Journal of Hematology & Thromboembolic Diseases* (Mezzomo et al, 2013). The paper's methodology and conclusions have been widely criticized especially for not following established protocols for studies with mice and not being applicable to GE crops.

On September 26, 2012, DAS initiated the consultation process with FDA for DAS-81419-2 soybean and submitted a Biotechnology Notification File (BNF 00140) for safety and nutritional assessment of food and feed derived from DAS-81419-2. On February 7, 2014, FDA concluded the consultation stating that they had no further questions concerning food and feed derived from DAS-81419-2 soybean.

The food and feed safety of Cry proteins has been assessed by regulatory agencies worldwide, and *Bt* crops have been adopted in numerous countries (Betz et al., 2000). For example, WideStrike[®] cotton (DAS-21023-5; DAS-24236-5, expressing the same Cry1Ac and Cry1F proteins as DAS-81419-2 soybean) has received regulatory approval in Canada (import), Australia (food, feed), Brazil (cultivation, food, feed), Japan (import, food, feed), Mexico (food, feed); EU (food, feed) and Korea (food, feed) (Biotechnology Industry Organization, 2012).

3. Comment: Ubiquitous Roundup application has resulted in numerous glyphosate resistant weeds. As a result, farmers are forced to resort to mechanical weed control methods at great cost. In addition, increased weed resistance will result from planting crops with resistance to multiple herbicides.

Response: APHIS acknowledges that weed resistance to glyphosate has increased because of the increase of glyphosate use, largely from the widespread adoption of glyphosate tolerant crops. Growers use a variety of methods to help combat this, including use of mechanical weed control. These methods are similar to those used prior to the adoption of herbicide tolerant GE plants.

DAS-81419-2 soybean is only resistant to the single herbicide glufosinate. However, APHIS acknowledges that DAS-81419-2 soybean is expected to be crossed with glyphosate tolerant varieties already deregulated, to result in cultivars that have multiple herbicide resistance. Glyphosate and glufosinate have different modes of action. As stated in the EA, combining resistance to herbicides with different modes of action within the same plant allows for flexibility in the use of multiple herbicides to target weeds that may be resistant to one of the herbicides. This use is expected to actually delay herbicide resistance because weeds killed do not pass on their resistance to progeny.

4. Comment: The use of glufosinate will increase if DAS-81419-2 soybean is granted nonregulated status.

Response: As discussed in the EA, growers will chose to use DAS-81419-2 soybean if glyphosate resistant weeds were present in the soybean fields. Thus, a glufosinate resistance trait would augment the control potential for glyphosate, but only when growers needed the variety's insect resistance trait for locally important lepidopteran pests. However, commercial plans for

DAS-81419 -2 soybean in the US are at present confined to seed production on less than 250,000 acres (Dow-Agrosciences, 2012) and that seed will be mostly exported. No commercial use can be made of the variety unless EPA has issued a permit for unrestricted commercial sale of the variety and for various stacks or combinations of traits including DAS-81419-2 soybean that are licensed for that stack. Seed production could reach 0.3% of total acreage of all planted soybean acres. Use of glufosinate is not anticipated on these seed production acres, but overall use of glufosinate may increase should the variety be offered for commercial commodity soybean production. Glufosinate will likely be used when incorporated into widely sold glyphosate resistant soybean varieties if growers have no economical alternatives for control of glyphosate resistant weeds, and primarily if the trait for glyphosate resistance becomes in some measure ineffective. Glyphosate remains highly effective on a broad range of weeds, has flexibility in application windows, and is more economical than many herbicides. Glyphosate will continue to be a high use herbicide. Glufosinate will be used where glyphosate resistant weeds are prevalent, but will not likely attain the usage rate of glyphosate for the reasons noted.

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