Finding of No Significant Impact

Animal and Plant Health Inspection Service

Petition for Non-regulated Status for GlyTol™ Cotton, Line GHB614

(APHIS 06-332-01p)

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has prepared an environmental assessment (EA) prior to making its determination of whether or not to approve a petition (APHIS number 06-332-01p) for a determination of nonregulated status received from Bayer CropScience, under APHIS regulations at 7 CFR part 340. The subject of this petition, cotton (*Gossypium hirsutum*) line GHB614, is genetically engineered to express the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from corn (*Zea mays*) that allows the plant to tolerate application of the broad spectrum herbicide glyphosate. On June 18, 2008, APHIS published a notice in the *Federal Register* (73 *FR* 34698-34700, Docket no. 2007-0017) announcing the availability of the draft EA for public review and comment for a 60-day comment period, ending August 18, 2008. APHIS received nine comments regarding the EA. APHIS' responses to the issues raised during the comment period are included as an attachment to this document.

In the draft EA, APHIS considered two alternatives: Alternative A – No Action: Continuation as a Regulated Article; Alternative B – Determination that GlyTol™ cotton is No Longer a Regulated Article. APHIS proposed Alternative B as its preferred alternative because of the lack of plant pest characteristics displayed by GlyTol™ cotton. APHIS has not identified any greater plant pest risk characteristics in this transformed cotton than non-transformed or other nonregulated glyphosate tolerant cotton that would warrant denying the petition. Based upon the analyses described in the final EA, the pest risk assessment, and in APHIS' response to comments attached to this document, APHIS has determined that the preferred alternative, to grant the petition, will not have a significant impact on the quality of the human environment for the following reasons:

1. APHIS' analysis of data on agronomic performance, disease and insect susceptibility, and compositional profiles of GlyTol™ cotton and its non-genetically engineered counterpart indicates no significant differences between the two that would be expected to cause either a direct or indirect plant pest effect on raw or processed plant commodities from the deregulation of GlyTol™ cotton. Based on the analysis, there should be no direct or indirect plant pest effects and no resulting significant environmental effects on raw or processed plant commodities by deregulating this line (Alternative B). There should also be no significant environmental impacts from continuing to regulate the line (Alternative A).

2. There should be no significant environmental impact as a result of gene introgression from this transformed cotton. In assessing the potential risks associated with gene introgression from GlyTol™ cotton into its sexually compatible relatives, APHIS considered two primary issues: a) the potential for gene flow and introgression; and b) the potential impact of introgression. The genus *Gossypium* consists of 39 species; four of which are generally cultivated in the world. The most commonly cultivated species in the

United States is *G. hirsutum* (common name, Upland cotton); comprising 97% of the U.S. cotton crop. Limited amounts of *G. barbadense* are cultivated in Hawaii. Other cultivated species around the world are *G. arboreum*, *G. barbadense*, and *G. herbaceum*. There are two wild species of cotton found in the United States; *G. thurberi* and *G. tomentosum*, of Arizona and Hawaii, respectively. APHIS has concluded based on scientific evaluation of gene ploidy that gene transfer to wild cotton species in the United States is limited because of ploidy differences (Table 3, page 18-19 of the petition). There is a lack of documented natural out-crossing to wild species and a limited success of interspecific hybrids produced through controlled breeding; therefore, the probability of gene flow and introgression of GlyTol™ cotton into wild cotton species is essentially zero and consequently the potential impact of introgression is not foreseeable. Therefore, there should be no significant environmental impacts related to out-crossing by deregulating this line (Alternative B). There should also be no significant environmental impacts from continuing to regulate the line (Alternative A). Alternative A would be chosen if there was insufficient data to conclude that gene introgression would not occur to sexually compatible relatives from the transformed cotton.

3. Transfer and expression of DNA from GlyTol™ cotton to soil bacteria is unlikely to occur. Horizontal gene transfer to soil bacteria has been extensively studied and many genomes (or parts thereof) have been sequenced from bacteria that are closely associated with plants including *Agrobacterium* and *Rhizobium* (Kaneko, Nakamura et al. 2000). There is no evidence for horizontal gene transfer. Even in the unlikely event transfer were to occur, the gene would be poorly expressed at best because transgene promoters and coding sequences are optimized for plant expression and function poorly in prokaryotic cells. Based on this evidence, there should be no significant impact of horizontal gene transfer by deregulating this line (Alternative B). There should also be no significant impact from continuing to regulate the line (Alternative A).

4. Cotton is not considered to be a weed and it does not persist in unmanaged ecosystems. In the United States, cotton is not listed as a weed in the major weed references, it is not present on the lists of noxious weed species distributed by the Federal Government, and cotton has been grown throughout the world without any report that it is a serious weed. It is not generally persistent in undisturbed environments without human intervention. In the year following cultivation, cotton may grow as a volunteer only under specific conditions and can be easily controlled by herbicides or mechanical means. It does not compete effectively with cultivated plants or primary colonizers. No data of which APHIS is aware indicate that the presence of the *2mepsps* gene improves the ability of this transformed cotton to survive without human intervention, nor is there any known reason to conclude that this gene would affect this line's survival in the wild. APHIS has reviewed field performance data submitted by the petitioner, and these data indicate that the engineered cotton plant is not different in any fitness characteristics from its parent that might cause GlyTol™ cotton to become a weed or to become invasive. Therefore, this cotton line (and any similar cotton line) is unlikely to become a weed or invasive through the introduction of the glyphosate resistance trait. For these reasons granting nonregulated status to this genetically engineered line (Alternative B) and its subsequent release should not increase the weediness or invasiveness potential of this line relative to

the release of any conventional cotton line. There should also be no significant impacts from continuing to regulate the line (Alternative A).

5. Analysis of available information indicates that GlyTol™ cotton exhibits no traits that should cause increased weediness, and that its unconfined cultivation should not lead to increased weediness of other sexually compatible relatives. Glyphosate use and crop production practices are not expected to change, regardless of the alternative chosen. Use of glyphosate in glyphosate resistant cotton (GlyTol™ cotton or Roundup Ready® cotton as recommended and according to product labels) is not expected to cause significant impacts on biodiversity outside the agroecosystem based on the chemical and toxicological properties of glyphosate. It is not considered to be a significant soil or water contaminant when used in recommended doses according to label instructions; in general, there is little effect of glyphosate on soil microflora, aquatic organisms, arthropods, and mammals. Based on these conclusions, there should be no significant impact to biodiversity by deregulating this line (Alternative B). There should also be no significant impact to biodiversity from continuing to regulate the line (Alternative A).

6. APHIS does not expect GlyTol™ cotton to have any effect on the development of herbicide resistant weeds, or a cumulative impact in combination with other glyphosate tolerant crops to effect any significant development of herbicide resistant weeds. This is because Roundup Ready® cotton makes up a significant portion of cotton grown in the U.S., - close to 70% of U.S. cotton production is already planted with Roundup Ready® cotton and 87% of planted cotton have both insect and herbicide tolerant traits. GlyTol™ cotton, which has a similar glyphosate resistance trait as Roundup Ready® cotton, is expected to provide an additional consumer choice for glyphosate-tolerant cotton plantings. Furthermore, total cotton acreage is not expected to increase as estimates of the 2007 cotton crop indicate that planting has decreased 28% in acreage compared to 2006 (http://www.nass.usda.gov/Charts_and_Maps/Field_Crops/cotnac.asp). Moreover, since the publication of this draft EA, new data shows the 2008-2009 US cotton crop acreage has been at its lowest since 1983-1984 season and as a result, the harvested US cotton crop is 30 percent lower than in 2007 (Meyer et al., 2008). Because GlyTol™ cotton would provide an additional consumer choice to a product already on the market, and total cotton acreages in the U.S. continue to decrease, APHIS reasonably concludes that GlyTol™ cotton should not have any significant effect on the rate of the development of herbicide resistant weeds whether it is deregulated (Alternative B) or remains a regulated article (Alternative A).

7. If GlyTol™ cotton were to be grown commercially, the effect on agricultural practices from introducing GlyTol™ cotton into the environment should be no different than for the previously deregulated Roundup Ready® cotton line expressing a similar EPSPS protein from *Agrobacterium* sp. strain CP4, with which APHIS has over 10 years of experience. APHIS has evaluated field trial data reports submitted on the GlyTol™ cotton event and progeny, and the previously deregulated Roundup Ready® cotton line has been grown commercially for over 10 years, including on approximately 86% of the 2008 cotton acreage. No significant effects have been noted on non-target organisms, no

increase in fitness or weediness characteristics, and no effect on the health of other plants. Herbicide and other cultivation practices with GlyTol™ cotton are expected to be no different from those of previously deregulated Roundup Ready® cotton based on its level of herbicide resistance and other agronomic characteristics and approved and recommended application rates for glyphosate herbicides. Based on these conclusions, there should be no significant environmental impacts on commercial use by deregulating this line in whole (Alternative B). There should also be no significant environmental impacts from continuing to regulate the line (Alternative A).

8. If GlyTol™ cotton were to be grown commercially, APHIS expects GlyTol™ cotton will be used to breed varieties suitable to a range of environments and maturity zones and replace some to all of the presently available glyphosate tolerant cotton. The potential impact on organic farming should not change from the current situation where approximately 70% of cotton produced is Roundup Ready® and organic farmers or other farmers who choose not to plant or sell Roundup Ready® cotton or other transgenic cotton (a) will still be able to purchase and grow nontransgenic cotton and (b) will be able to coexist with biotech cotton producers as they do now. Cotton is a highly self pollinated plant with large, sticky seeds that are not easily dispersed; thus minimal buffer zones are needed to prevent cross-pollination to other cotton or seed contamination of adjacent agricultural land. Based on these considerations, there should be no apparent potential for any significant environmental impacts on organic farming by deregulating this line (Alternative B). There should also be no significant environmental impacts on organic farming by continuing to regulate the line (Alternative A).

9. APHIS considered the potential impact from the stacking of herbicide resistance traits that could result if GlyTol™ cotton were to be grown commercially. The factors that were considered in evaluating the potential impact of stacking of herbicide resistance traits were: (1) the availability of deregulated herbicide resistance events, (2) the level of commercial production of each of the events, (3) the effect of stacked traits on the plant and on herbicide use, (4) the number of effective alternative herbicides for cotton production, (5) the probability of developing weeds with multiple resistance to various herbicide modes of action, (6) the probability of cross pollination in the field, and (7) the probability of a stacked cotton becoming a weed. Based on these considerations as analyzed in the EA, there should be no significant environmental impacts resulting from the stacking of herbicide resistant traits by deregulating this line (Alternative B). There should also be no significant environmental impacts from continuing to regulate the line (Alternative A).

10. APHIS does not expect GlyTol™ cotton to have any significant impacts on non-target organisms, including beneficial organisms and threatened or endangered species because the 2mEPSPS protein is not known to have any toxic properties and has minimal potential to be a food allergen. This protein has over a 10 year history of safe use in several crops – including soybeans, corn, and canola and cotton. APHIS evaluated the potential for any significant impacts from cultivation of GlyTol™ cotton and its progeny on non-target organisms, including effects on those species federally listed as threatened or endangered species (TES), or species proposed for listing, and their proposed and

designated critical habitat. In addition to evaluating the toxicity and allergenicity of the 2mEPSPS protein, APHIS reviewed the expected use of glyphosate on this glyphosate tolerant cotton line. Glyphosate tolerant cotton has been grown commercially for over ten years and has been treated with glyphosate for over ten years. EPA communicated to APHIS that it has not received any reports of adverse effects on threatened or endangered species or their critical habitats from the use of glyphosate on glyphosate tolerant cotton. Therefore, there should be no significant impact to non-target organisms, including beneficial organisms, and no significant effects are expected on federally listed TES, species proposed for listing, or their designated or proposed critical habitat from exposure to the 2mEPSPS protein expressed in GlyTol™ cotton or from exposure to label rates of glyphosate expected to be used in conjunction with this GlyTol™ cotton as a result of deregulating this line (Alternative B). There should also be no significant environmental impacts or effects from continuing to regulate the line (Alternative A).

11. Neither of the alternatives analyzed are expected to have significant human health or environmental effects, nor are they expected to establish a precedent for future actions with potentially significant effects. None of the potential effects on the human environment are highly controversial, highly uncertain, or involve unique or unknown risks. The potential environmental effects are similar in kind to (and no worse than) those environmental non-significant effects already observed for currently commercially available and widely grown Roundup Ready® cotton varieties and to those observed for the use of glyphosate and several other herbicides in agriculture production systems.

Based on all of the analyses and reasons above, I have determined that there should be no significant environmental impacts to the human environment from the implementation of the chosen alternative (Alternative B) and, therefore, no EIS needs to be prepared to analyze the potential environmental effects resulting from the proposed determination of the nonregulated status of the cotton (*Gossypium hirsutum*) line GHB614.

Michael C. Gregoire

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

Date: 4-30-09

Attachment
Finding of no significant impact
Response to comments
APHIS No. 06-332-01p

On June 18, 2008 APHIS published a notice in the *Federal Register* (73 *FR* 34698-34700, Docket no. 2007-0017) announcing the availability of the draft EA for public review and comment for a 60-day period, ending August 18, 2008. APHIS reviews a petition to determine if the genetically engineered (GE) organism should continue to be considered a regulated article under the APHIS biotechnology regulations found at 7 CFR part 340. In order for a GE organism to be considered a regulated article under these regulations, APHIS has concluded the GE organism poses or may pose a plant pest risk, and the GE organism is modified by recombinant DNA techniques (genetic engineering under the definition of the regulation). Prior to making a decision on the petition requesting a determination of nonregulated status for cotton line GHB614, APHIS prepared a plant pest risk assessment to evaluate the likelihood of the cotton line GHB614 to pose a plant pest risk. After preparing the plant pest risk assessment and reviewing its finding that GHB614 is unlikely to pose a plant pest risk and is therefore eligible for nonregulated status, APHIS prepared an EA to evaluate the significance of potential environmental impacts resulting from a decision to grant nonregulated status to cotton line GHB614. APHIS prepared the EA as part of its obligation to analyze the potential environmental impacts that could result from its proposed actions as required by the National Environmental Policy Act of 1969 (NEPA). As part of this entire determination of nonregulated status process, APHIS considered public comments on the proposed deregulation as well as the environmental analyses in the draft EA that APHIS prepared pursuant to NEPA.

APHIS amended the draft EA and clarified details to reflect information explained below in responses to comments submitted on this petition. APHIS amended Figure 3 with 2008 data from USDA ERS that shows the rapid growth of GE crops in the US. Table 1a was added, listing the glyphosate-resistant weeds in the major cotton producing states as of 2008. APHIS amended Tables 3, 5, and 6 to include NASS 2007 cotton data. Two new tables (7 and 8) were created to show total herbicide and total glyphosate use of active ingredient per acre. Two new figures (4 and 5) that graphically reflect the data in Tables 7 and 8 were created. Figure 6 was created to show the percentage of GE varieties of Upland cotton for years 2000-2007 from new USDA ERS data. The additional information added to the draft EA do not substantially alter our original analysis and do not substantively change any of our original underlying conclusions. Nothing in the additional information caused APHIS substantively to alter any of its original conclusions.

APHIS received nine comments regarding the EA. APHIS' responses to the issues raised during the comment period are included below.

There were six comments that supported deregulation, two from cotton industry groups and four from individuals. There were three comments that opposed deregulation, one comment from a non-governmental organization and two comments from individuals.

The two comments from the cotton industry supporting the deregulation focused on the benefits of the more than 10 year history of the safe use of Roundup Ready® cotton, which have included: improving profit opportunities through improved yields without increasing herbicide use; providing growers with consistent weed control; continuing to have timely advancement of new genetics/traits that enable American farmers to produce cotton economically and safely and to meet the growing demand for food, feed and fuel without a proportional increase in acreage; continuing the widespread adoption of conservation tillage crop production methods that have decreased soil erosion, reduced fuel consumption, helped remove carbon dioxide from the Earth's atmosphere and sequestered the carbon within the soil, and increased the absorption of rainfall with less runoff. The four comments from individuals supporting deregulation were from cotton farmers who also noted benefits similar to those identified by the cotton industry groups.

Of the three comments that opposed deregulation of GlyTol™ cotton, one comment opposed the deregulation based on general opposition to development and use of genetically engineered plants without citing specific issues in the EA or petition.

APHIS has responded below to the two specific comments opposed to the deregulation of GlyTol™ cotton (one an individual, and one from a non-governmental organization, The Center for Food Safety).

Rosenfeld Comment:
"In vitro studies have shown glyphosate affects progesterone production in mammalian cells[38] and can increase the mortality of placental cells.[25] Whether these studies classify glyphosate as an endocrine disruptor is a matter of debate.

Some feel that in vitro studies are insufficient, and are waiting to see if animal studies show a change in endocrine activity, since a change in a single cell line may not occur in an entire organism. Additionally, current in vitro studies expose cell lines to concentrations orders of magnitude greater than would be found in real conditions, and through pathways that would not be experienced in real organism.

Others feel that in vitro studies, particularly ones identifying not only an effect, but a chemical pathway, are sufficient evidence to classify glyphosate as an endocrine disruptor, on the basis that even small changes in endocrine activity can have lasting effects on an entire organism that may be difficult to detect through whole organism studies alone. Further research on the topic has been planned, and should shed more light on the debate."

Agency response: While not citing specific studies (the comment appeared to be related to published scientific literature, and seemed to reference two studies, "[38]" and "[25]";

however no references to published literature were provided in the comment), this commenter is opposed to the deregulation based on the belief that the herbicide glyphosate is an endocrine disruptor because of recently published articles.

APHIS' research noted three articles, not previously reviewed, that suggested that glyphosate is an endocrine disrupter (Benachour et al., 2007; Dallegrave et al., 2007; Hokanson et al., 2007). The paper by Hokanson, et al., 2007, used a retail formulation of glyphosate on an *in vitro* cell line (MCF-7 cells) and analyzed the results via DNA microarray. The concentration of glyphosate used during the experiment was described only as a percentage and dilutions of the percentage. The exact formulation was not provided, nor was the concentration of glyphosate or surfactant in the product described. Therefore it is not possible for APHIS to determine if glyphosate alone, or other chemicals in the retail formulation are the causal factors for the results found in the study. The authors failed to take into consideration that the surfactant and other inert ingredients can adversely affect membrane permeability and cell line behavior in their study. The study done by Benachour, et al., 2007 had a similar flaw in that the surfactant in the formulation used on their *in vitro* cell lines could produce the effects they reported. In addition, both studies were done *in vitro* where measures of dose and quantitative use of the information in a dose-response assessment is not appropriate. The third study (Dallegrave et al., 2007) was an acute toxicity study in Wistar rats that used doses that do not correspond to human dose exposure, as described in the paper and based on the EPA report (EPA, 2006).

APHIS disagrees that glyphosate is an endocrine disruptor based on the safety evaluation of glyphosate in the comprehensive report by the EPA from 2006 (EPA, 2006) and on the review of the herbicide, Roundup® and glyphosate safety and risk assessment by Williams, et al, 2000 (Williams et al., 2000).

Center for Food Safety Comments 1-16
Because the CFS submitted comment did not have page numbers, APHIS has answered their concerns by quoting each point, paragraph by paragraph, in the order presented.

Comment 1:
"CFS strongly opposes the cultivation and commercial use of genetically engineered crops due to unexplored risks to the environment, biodiversity, specific protected species, and potential risks to human health that could result. Genetic engineering is a novel technology that fundamentally alters agriculture, our food supply, and the environment. Neither standard corporate testing practices for, nor U.S. government oversight of, genetically engineered (GE) crops is sufficiently stringent to rule out, with reasonable scientific certainty, unintended adverse impacts to human health or the environment.[1] CFS therefore supports a moratorium on GE crops until the U.S. government establishes a strict, science-based regulatory system."

[1] Freese, W. and D. Schubert (2004). "Safety Testing and Regulation of Genetically Engineered Foods," *Biotechnology and Genetic Engineering Reviews*, Volume 21, November 2004. http://www.foe.org/camps/comm/safefood/gefood/testingregbackgrounder.pdf

Agency response:
Comment 1 makes it clear that CFS is opposed to GE crops because of unintended health affects (cited in footnote 1) as "adverse and unintended effects" that cause the "over-production of allergens, toxins and fusion proteins". The self-cited article by Freese and Schubert (2004) is a chapter section in the annually published Biotechnology and Genetic Engineering Reviews (Volume 21, Chapter 13, 2004) [2] that critiques U.S. regulation of GE organisms as well as the excessive use of Confidential Business Information (CBI) by U.S. companies. The article also criticizes companies that use identical, yet "surrogate" proteins created in bacterial systems to test for equivalence of the protein made in the GE plant. This book section goes on to describe the "adverse and unintended effects" of GE plants by comparing studies on allergenicity with Bt insecticidal sprays and relating them to Bt incorporated proteins in plants and antidotal allergy reports by agricultural workers. Another citation in this book section refers to how any human gene inserted into a human cell line can increase gene expression by 5% using microarray data. This is a gross misunderstanding of how microarray data is used. APHIS does not agree with the commenter's assertion that GE crops over-produce allergens, toxins and allergenic fusion proteins. APHIS also concludes that the citation within the "unintended effects" portion of the article does not relate to the plant pest effects or to the potential environmental impacts of Bayer GlyTol™ cotton (which has no insecticidal component) and therefore does not need to be further discussed.

Comment 2:
"The EA's "Analysis" of the Potential Environmental Impacts Is Wholly Inadequate Because APHIS Failed to Take the "Hard Look" Required By NEPA. These Impacts Require An EIS.

As mandated by Congress, APHIS must comply with NEPA before it attempts to deregulate and allow the commercialization of genetically engineered GHB614 and any progeny derived from it. USDA is the lead federal agency designated to undertake NEPA analysis for the commercialization of genetically engineered plant varieties. USDA's decision whether to deregulate a genetically engineered soy [*sic*] variety is a major federal action that may significantly affect the environment. The commercial planting of genetically engineered GHB614 could impact a vast number of acres and will have significant impacts on the environment, including impacts to human health, as well as cumulative impacts.[3]"

Agency response:
APHIS has adequately addressed in the EA the potential for any impacts to human health, including cumulative impacts resulting from its proposed deregulation of cotton

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[2] SCImago. (2007). SJR — SCImago Journal & Country Rank. Retrieved January 15, 2009, from http://www.scimagojr.com – The H index quantifies both the scientific productivity and the scientific impact of the journal; the H Index for Biotechnology and Genetic Engineering Reviews (Biotechnol Genet Eng Rev), Nature Medicine (Nat Med) and Science (Sci) for year 2005 are 18, 272 and 523, respectively.

[3] 40 Fed. Reg. §§ 1508.27(b)(2), (5), (7)

GHB614. APHIS has concluded that there should not be any significant environmental impacts from its deregulation of cotton line GHB614. APHIS cannot predict or hypothesize on the exact extent of the future commercialization of any additional glyphosate tolerant cotton once cotton line GHB614 is deregulated by APHIS. Nevertheless, APHIS is not aware of any reliable data establishing or confirming that such prospective commercialization will significantly affect the environment. The reliable data cited by APHIS in the final EA confirms that the planting of total cotton acreage is actually continuing to decline and thereby as well as the planting of glyphosate tolerant cotton (see amended Tables 4-8 and Figures 4 and 5). Therefore, based on the current data regarding the current usage trends of GE cotton types, APHIS does not have any reason to foresee that the United States cotton industry will suddenly change course and start to increase its total cotton acreage nor start to substantively increase its usage of glyphosate tolerant cotton due to the commercialization of this product after deregulation of cotton line GHB614.

Comment 3:
"APHIS is required to assess the potential impacts of GHB614 on herbicide use and glyphosate-resistant weed development in the context of an Environmental Impact Statement"

"In this draft EA, APHIS fails to provide a meaningful analysis of the potential impacts of GHB614 on the closely intertwined issues of herbicide use and glyphosate-resistant weed development."

"This [court] decision sets a precedent for future APHIS decision-making with respect to HT crop systems. APHIS must assess the impacts of HT crop systems with respect to HT trait transfer, development of HR weeds from increased selection pressure, as well as cumulative impacts in future decisions regarding HT crop systems."

"APHIS's draft environmental assessment of GHB614 does not meet the standards for environmental assessment of herbicide-tolerant crops established by the court in the case of Roundup Ready alfalfa. Thus, APHIS must conduct an EIS before reaching a decision on whether to deregulate GHB614, particularly in light of the gross deficiencies in the draft EA's consideration of these issues, as detailed below."

Agency response:
As discussed and described in the final EA and in the FONSI, as well as in this response to comments, APHIS has assessed the potential environmental impacts resulting from its deregulation of glyphosate tolerant cotton adequately in this EA and shown that it has found no significant impacts to the human environment can be expected due to the deregulation of this product. Therefore, APHIS has concluded that an EIS is not warranted for analyzing the potential environmental impacts resulting from its proposed deregulation of cotton line GHB614.

Comment 4:
"**<u>USDA Has Officially Recognized the Need for Management of Resistant Weeds Fostered by Herbicide-Tolerant Crop Systems, But Failed to Act</u>**

"Additional support for the position that APHIS must conduct an EIS on GHB614 is provided by its prior recognition that resistant weeds require management. In 2001, USDA and EPA set up an interagency work group to develop management programs to forestall or manage the emergence of herbicide-resistant weeds fostered by herbicide-tolerant (HT) crop systems 67 Fed. Reg. 60934 (Sept. 27, 2002). The formation of this work group represents official USDA recognition of the fact that herbicide-resistant weeds are a serious issue that needs to be addressed in assessments of HT crop systems. Despite the formation of this work group, there is no indication that EPA was ever consulted on these issues in the context of the draft EA on GHB614. As the Court stated in the recent GE alfalfa case: "one would expect that some federal agency is considering whether there is some risk to engineering all of America's crops to include the gene that confers tolerance to glyphosate." *Geertson Seed Farms,* 2007 WL 518624 at 11. However, there is no evidence to suggest that USDA has made any such assessment, or taken any action, to manage potential development of herbicide-tolerant weeds fostered by GHB614, or any other HT crop system."

Agency response:
Excerpt from 67 FR 188 60934 (Sept 27, 2002) being referred to in the comment:

> "In early 2001, EPA and USDA APHIS established an interagency work group for products derived from biotechnology. Through this joint working group, EPA consults on a stewardship plan for each new herbicide-tolerant crop that addresses the management of pest resistance and the potential for weedy volunteer crops in their herbicide-tolerant crops and in crop rotations. This stewardship plan is then incorporated into a full environmental impact assessment by USDA APHIS that addresses the potential for development of resistant weed populations through pollen flow, in addition to effects on non-target organisms and agricultural practices."

The commenter has misunderstood the intent of the interagency work group established in 2001 between EPA and USDA APHIS that was mentioned in EPA's Federal Registry response to public comments for glyphosate pesticide tolerances (67 FR 188 60934). The work group was established to review the voluntarily-submitted stewardship plans created by the applicant with the introduction of each new herbicide-tolerant crop. This stewardship plan addresses the management of pest resistance and potentially weedy volunteer crops in the company's herbicide-tolerant crops and crop rotations. It is also important to note that Bayer's glyphosate tolerant cotton is not a new herbicide-tolerant crop, merely an alternative product created by a different company; Monsanto's glyphosate tolerant cotton has been on the market since 1995. APHIS has concluded that the current stewardship plans are adequate to address the management of pest resistance and potentially weedy volunteer crops in herbicide-tolerant crops and crop rotations.

Because no new stewardship plans were submitted by the company, the EPA-USDA-APHIS workgroup reviewing stewardship plans was not provided with any plan to review.

Also, APHIS recognizes the development of herbicide resistant weeds when **any** herbicide or several herbicides from the same group (same site of action) are used routinely on a cultivated crop. Weeds resistant to herbicides are not exclusive to herbicide-tolerant crops, and develop when **any** herbicide is applied in a routine manner. For example, the first identified herbicide-resistant weed biotype against 2,4-dichlorophenoxyacetic acid (often abbreviated 2,4-D) was the spreading dayflower (*Commelina diffusa*). This resistant biotype was recognized in 1957 in a Hawaii sugarcane field. 2,4-D was first commercialized by the Sherwin-Williams Paint Company in 1946.

Comment 5:
"**Flaws in APHIS's analysis of herbicide use in the draft EA"**

"APHIS made an attempt to deal with the implications of GHB614 cotton on herbicide use and the emergence of glyphosate-resistant weeds in the draft EA. However, the treatment is totally inadequate, undermined by failure to consult the most recent data, fundamental methodological flaws and in general illogical and often contradictory argumentation. As such, APHIS must revisit the issues of herbicide use and the emergence of glyphosate-resistant weeds in the context of an Environmental Impact Statement, assigning personnel to the task who have a better grasp of the relevant data and literature in this field.

APHIS purports to analyze "herbicide usage trends," as indicated by the titles of Tables 3, 5 and 6 in the EA (pp. 9, 14, 15). On the basis of these data, APHIS assessed overall herbicide and glyphosate use since the introduction of genetically engineered crops as follows:

"…total herbicide use on corn, cotton and soybeans in the U.S. have [sic] not shown dramatic increases or decreases; however, glyphosate use has increased during that time (Tables 5 and 6, respectively)" (EA, p. 14-15).

This statement is false. Not only glyphosate use, but overall herbicide use, on cotton (as well as soybeans) have increased dramatically….

First of all, we note that APHIS issued its draft EA (May 16, 2008) five days before its sister agency, the National Agricultural Statistics Service, released its report on 2007 herbicide use on cotton (May 21, 2008). There is no doubt that APHIS was aware of the NASS report, that these data were available before APHIS issued its draft EA, and that APHIS could easily have accessed the data from NASS, and included these data in its analysis. Absent 2007 cotton data, the latest available herbicide usage data for cotton are from crop year 2005, two years ago. Thus,

APHIS's treatment is dramatically weakened by the failure to examine herbicide usage trends in cotton over the past two years."

Agency response:
APHIS BRS was not aware of the exact timeframe for the publication of the NASS 2007 data. Had the data been publically available, APHIS BRS would have certainly included it within the draft EA. Now that the data is publicly available, APHIS has amended tables 3, 5 and 6 in the final EA to show the additional data from 2007. APHIS has also included graphical data from the tables to better demonstrate the trends over time. Analysis of the new data supports and reinforces APHIS' position in the draft EA that herbicide usage trends are continuing as stated in the draft EA.

Comment 6:
"APHIS's treatment also suffers from fundamental methodological flaws. In order to analyze trends over time, one must use data that are comparable from year to year. APHIS failed to do this, undermining its analysis.

First, in Table 5 (EA, p. 14) APHIS incorrectly reports the amounts of overall herbicides applied to acres surveyed without correcting for the substantial differences in acreage surveyed by NASS each year (which for cotton ranges from 82% to 96% of total cotton acreage planted over the period from 1996 to 2007). One must divide the figures in Table 5 by the percent of total acres surveyed to arrive at accurate estimates of total herbicide used on all crop acres. A second error in APHIS's treatment in Tables 5 and 6 is its failure to correct for acreage of cotton planted, which ranged from 10.9 million acres (2007) to 15.5 million acres (2001) over the period from 1996 to 2007. This introduces a substantial error. One must divide the relevant herbicide figures (total, glyphosate) by the number of acres planted to arrive at figures (lbs. per acre per year) that are comparable across years. A third error in APHIS's treatment in Table 6 is its failure to add up all forms of glyphosate. Beginning in 2001, multiple formulations of glyphosate have become common, including the monoammonium, diammonium, iso-propyl ammonium and the trimesium salts. The trimesium salt of glyphosate is listed by APHIS under the name of sulfosate. APHIS merely reports the amount of the most heavily used form of glyphosate in all cases."

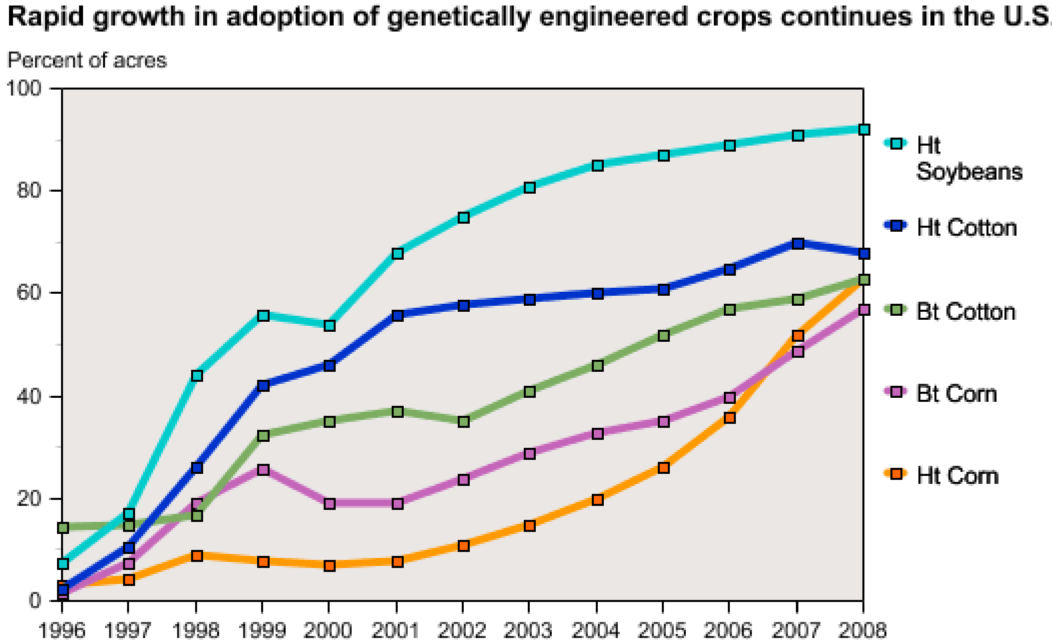
Agency response:
APHIS' original tables in the draft EA expressed the trends in total herbicide usage and also singled out glyphosate usage trends for corn, soybeans and cotton. The commenter noted that the tables showed data that the commenter believed contained a wide margin of error because the surveyed acreage was not taken in consideration. APHIS has recalculated the data from Tables 5 and 6 (including the 2007 data) to show active ingredient per acre (See Tables 7 and 8). Active ingredient per acre accounts for the number of surveyed acres, which differs each year that NASS conducts its surveys. Because the data representations in the tables became somewhat cumbersome, APHIS has created graphs of the data contained in Tables 6 and 7 (see Figures 4 and 5). The usage data show similar trends to the original data presented in the draft EA, and does not

change APHIS' original conclusion that overall herbicide use has not dramatically increased.

The multiple formulations of glyphosate are grouped together within the tables and not separated. NASS separated the diammonium salt from the monoammonium glyphosate salt in 2001 and did not begin reporting all three formulations until 2007. The herbicide registration for sulfosate (the trimesium salt of glyphosate) was cancelled in 2004. Only two states, Arkansas and Louisiana reported sulfosate use in cotton for that year, 235 thousand and 52 thousand pounds respectively. The addition of these numbers to the total yearly poundage does not change the upward trend in glyphosate usage for the year 2003 (total active ingredient for glyphosate 12,635 thousand pounds) in Table 6 (amended and revised with 2007 data) and newly added Table 8. The revisions made to the draft EA (amended Table 6 and the addition of Table 8) do not change the underlying conclusions made by APHIS regarding total herbicide usage and glyphosate use for corn, cotton and soybean.

Amended EA figures and tables including 2008 data

Amended Figure 3



Data for each crop category include varieties with both HT and Bt (stacked) traits. Source USDA ERS.

Amended Table 3. Herbicide Usage Trends in Cotton from 1997 – 2007

Herbicide	1997		2001		2003		2005		2007	
	%Area Treated	Active Ingredient 1000 lb/yr	%Area Treated	Active Ingredient 1000 lb/yr	%Area Treated	Active Ingredient 1000 lbs/yr	%Area Treated	Active Ingredient 1000 lb/yr	%Area Treated	Active Ingredient 1000 lb/yr
Glyphosate	14	1,542	57	8,514	69	12,635	71	14,112	91	17,311[e]
Trifluralin	55	5,461	30	3,066	39	4,156	32	3,522	29	2,763
Diuron	12	883	26	1,545	28	1,738	27	1,707	26	1,325
Pendimethalin	28	2,491	16	1,651	20	1,813	12	1,211	17	1,451
Pyrithiobac-sodium	23	171	10	85	12	124	9	50	10	57
Prometryn	19	1,669	12	1,292	11	1,175	7	669	7	640
Fluometuron	44	4,847	10	977	8	755	5	487	4	277
MSMA/DSMA	33	4,899	11	1,834	7	1,157	6	937	3	380
Metolachlor [a]	5	735	4	419	5	591	6	847	8	277
Clomazone	8	500	NS[c]	NS	<0.5	16	<0.5	12	<0.5	2
Clethodim	2	37	2	28	<0.5	14	1	19	<0.5	4
States surveyed[b]	AL, AZ, AR, CA, GA, LA, MS, MO, NC, SC, TN, TX		AL, AZ, AR, CA, GA, LA, MS, MO, NC, SC, TN, TX		AL, AZ, AR, CA, GA, LA, MS, MO, NC, SC, TN, TX		AL, AR, CA, GA, LA, MS, NC, SC, TN, TX		AL, AR, CA, GA, LA, MO, NC, TN, TX	
Acreage represented in survey[b]	13,075,000 (96%)		12,680,000 (93%)		12,795,000 (90%)		12,425,000 (89%)		10,240,000 (94%)	
Total planted cotton acreage[d]	13,898,000		15,768,500		13,479,600		14,245,200		10,800,000	

[a]Includes both racemic and S-forms of metolachlor.
[b]USDA-NASS, 2007. Agricultural Chemical Usage Database. (http://www.pestmanagement.info/nass/app_usage.cfm)
[c]NS = not surveyed
[d]USDA-NASS, 2007. Cotton, National Statistics Database. (http://www.nass.usda.gov/QuickStats/index2.jsp)
[e] Includes glyphosate, glyphosate amm. salt and glyphosate iso. salt

Amended Table 5. Total Herbicide Usage Trends for Corn, Cotton and Soybean from 1997 – 2007

	Herbicides – Total Active Ingredient x1000 lbs/year										
Crop	**1997**	**1998**	**1999**	**2000**	**2001**[a]	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**[b]
Corn	164051	177012	154059	153464	157239	95777	149136	NA	157575	NA	NA
Cotton	27611	22206	25006	26554	NA	21098	25542	NA	25733	NA	26,214
Soybean	78207	71437	70729	75164	50464	86742	NA	70828	77187	NA	NA

NA = data not available
[a]NASS separated only the mono and diammonium salts out beginning this year. Both chemicals are included in this number
[b]NASS did not separate out glyphosate, glyphosate amm. salt and glyphosate iso. salt out for all surveyed states until this yr., all three chemicals are included in this number.

Amended Table 6. Glyphosate Usage Trends for Corn, Cotton and Soybean from 1997 – 2007

	Glyphosate – Total Active Ingredient (x1000 lbs/year)										
Crop	**1997**	**1998**	**1999**	**2000**	**2001[a]**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007[b]**
Corn	1429	2601	4162	4438	6868	3307	11913	NA	NA	NA	NA
Cotton	1542	3726	5122	9529	8514	NA	12635	NA	14112	NA	17311[a]
Soybean	14915	28123	38447	41847	32806	59962	NA	57701	NA	88903	NA

NA = data not available
[a]NASS separated only the mono and diammonium salts out beginning this year. Both chemicals are included in this number
[b]NASS did not separate out glyphosate, glyphosate amm. salt and glyphosate iso. salt out for all surveyed states until this yr., all three chemicals are included in this number.

Table 7. Total Herbicide Usage Trends (active ingredient per acre) for Corn, Cotton and Soybean from 1997 – 2007

Crop	**1997**	**1998**	**1999**	**2000**	**2001[a]**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007[b]**
Corn Herbicides (a.i.x1000 lb) % of total acres Total ac planted (x1000)	164051 96 79,537	177012 96 80,165	154059 98 77,386	153464 97 79,551	157239 98 75,702	95777 89 78,894	149136 95 78,603	NA NA 80,929	157575 97 81,779	NA NA 78,327	NA NA 93,600
Cotton Herbicides (a.i.x1000 lb) % of total acres Total ac planted (x1000)	27611 97 13,898	22206 99 13,393	25006 97 14,874	26554 95 15,517	21098 90 15,769	NA NA 13,958	25542 98 13,480	NA NA 13,659	25733 95 14,245	NA NA 15,274	26,214 97 10,240
Soybean Herbicides (a.i.x1000 lb) % of total acres Total ac planted (x1000)	78207 97 70,005	71437 95 72,025	70729 96 73,730	75164 97 74,266	50464 96 74,075	86742 99 73,963	NA NA 73,404	70828 97 75,208	77187 98 72,032	NA NA 75,522	NA NA 64,736

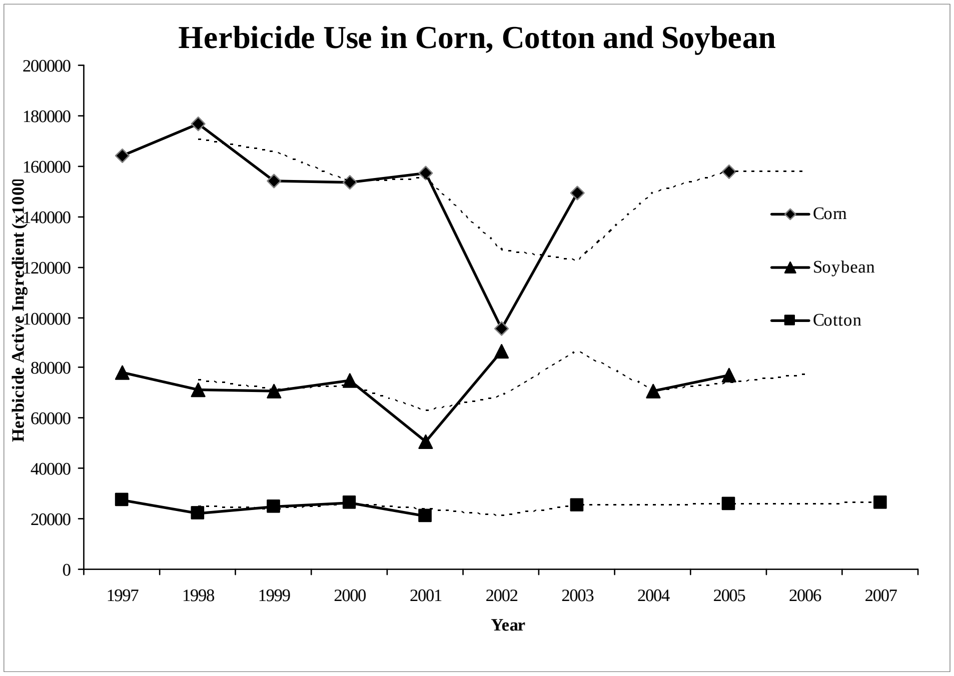
NA = data not available
[a]NASS separated only the mono and diammonium salts out beginning this year. Both chemicals are included in this number
[b]NASS did not separate out glyphosate, glyphosate amm. salt and glyphosate iso. salt out for all surveyed states until this yr., all three chemicals are included in this number.

Table 8. Glyphosate Usage Trends (active ingredient per acre) for Corn, Cotton and Soybean from 1997 – 2007

Crop	**1997**	**1998**	**1999**	**2000**	**2001[a]**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007[b]**
Corn Glyphosate (a.i.x1000 lb) % of total acres Total ac planted (x1000)	1429 4 79,537	2601 5 80,165	4162 9 77,386	4438 9 79,551	6868 13 75,702	3307 9 78,894	11913 19 78,603	NA NA 80,929	NA 33 81,779	NA NA 78,327	NA NA 93,600
Cotton Glyphosate (a.i.x1000 lb) % of total acres Total ac planted (x1000)	1542 14 13,898	3726 30 13,393	5122 36 14,874	9529 56 15,517	8514 57 15,769	NA NA 13,958	12635 70 13,480	NA NA 13,659	14112 74 14,245	NA NA 15,274	NA 91 10,240
Soybean Glyphosate (a.i.x1000 lb) % of total acres Total ac planted (x1000)	14915 28 70,005	2812 46 72,025	38447 62 73,730	41847 62 74,266	32806 73 74,075	59962 78 73,963	NA NA 73,404	57701 89 75,208	NA NA 72,032	88903 96 75,522	NA NA 64,736

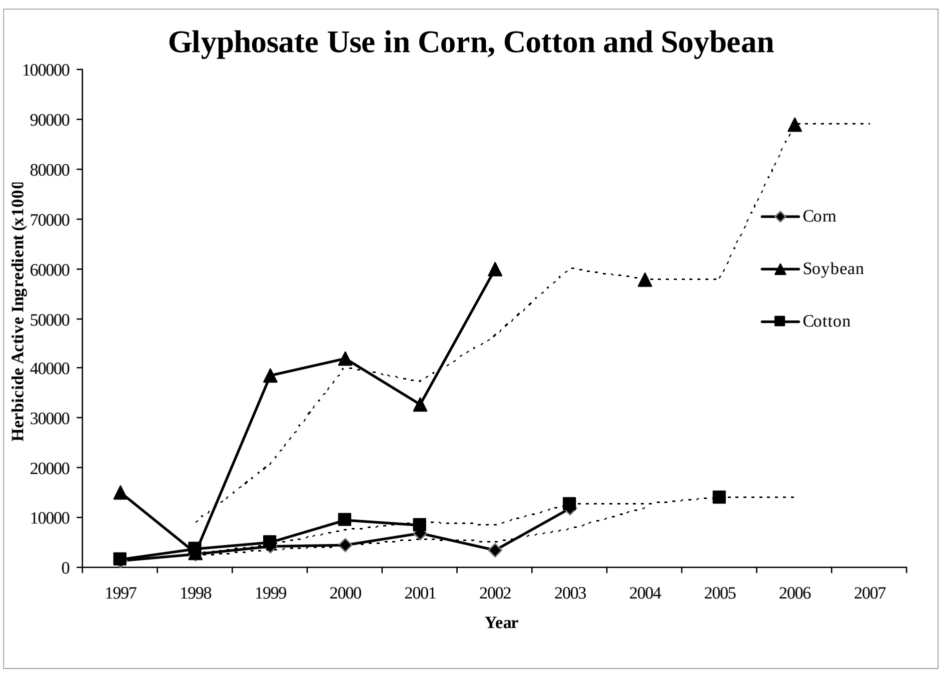
NA = data not available
[a]NASS separated only the mono and diammonium salts out beginning this year. Both chemicals are included in this number
[b]NASS did not separate out glyphosate, glyphosate amm. salt and glyphosate iso. salt out for all surveyed states until this yr., all three chemicals are included in this number.

Figure 4. Data from Table 7



Total herbicide use trends active ingredient per acre are seen as dotted lines and plotted as a moving average in MS Excel. This graph takes into account the year to year variation in acreage in NASS surveys.

Figure 5. Data from Table 8



Total glyphosate use trends active ingredient per acre are seen as dotted lines and plotted as a moving average in MS Excel. This graph takes into account the year to year variation in acreage in NASS surveys.

Comment 7:
"**<u>Correct analysis show dramatic rise in both overall herbicide and glyphosate use on cotton"</u>**

"When one considers the 2007 cotton herbicide usage data that APHIS ignored, and corrects the methodological errors, one sees dramatic increases in herbicide use."

"Figure 1 shows that overall herbicide use on cotton, expressed correctly in a form that is comparable from year to year (i.e. in lbs. per acre per year), jumped a dramatic 35% from 1996 to 2007. Glyphosate use per acre climbed more than 19-fold over the same period. Closer examination of Figure 1 reveals that up through 2001, glyphosate displaced other herbicides; that is, the overall herbicide rate remained roughly constant at about 1.9 lbs. per acre per year, with glyphosate's share rising from 4% to 41%. This reflects rising adoption of Roundup Ready cotton. No cotton herbicide usage figures were available in 2002. <u>Beginning in 2003, glyphosate effectively ceased to displace use of other herbicides, and sharply rising glyphosate use was accompanied by constant use of non-glyphosate herbicides.</u> From 2003 to 2007, glyphosate use on cotton rose dramatically by 66% (from 0.985 to 1.637 lbs. per acre per year), while over the same period, use of other herbicides remained roughly constant at just over 0.9 lbs. per acre per year, with a slight decrease from 2003 to 2005 and a slight increase from 2005 to 2007. Figure 2 shows increasing herbicide use on soybeans, and to a lesser extent on corn. As discussed further below, the reasons for dramatically increasing glyphosate use coupled with constant use of non-glyphosate herbicides is the continuing emergence of glyphosate-resistant weeds, which are particularly severe in cotton."

Agency response:
The amended Tables 3, 5 and 6, along with new Tables 7 and 8 and Figures 4 and 5 in the final EA further supports and confirms APHIS' position that overall herbicide use trends have remained constant for the past 10 years during the same period of time that the use of glyphosate has increased. Thus, this cited data in the final EA shows that in the past 10 years although there has been an increased use of glyphosate there has not been an notable increased in total overall herbicide use. Moreover, APHIS is not aware of any reliable data showing that the total overall use of herbicides will increase in the future.

The data cited by APHIS in the final EA confirms that the planting of total cotton acreage is actually continuing to decline, which also includes a decline in the planting of glyphosate tolerant cotton (see amended Tables 4-8 and Figures 4 and 5). Therefore, based on the current data regarding the current usage trends of traditional cotton and GE cotton types, APHIS does not have any reason to foresee that the United States cotton industry will suddenly change course and start to increase its total cotton acreage nor start to substantively increase its usage of glyphosate tolerant cotton due to the commercialization of this product after deregulation of cotton line GHB614. Therefore, the availability of GHB614 will not significantly alter the use of glyphosate in cotton. Additionally, as stated in the EA, cotton has always included the use of multiple herbicides during agricultural production. This product thus will not significantly alter the herbicide usage in cotton production.

Certainly, APHIS is aware that weeds are problematic for the cotton farmer as they not only will decrease acreage due to competition for nutrients and out-growing of the cotton crop, but they decrease the quality of the final cotton lint product. The emergence of glyphosate-resistant weeds in a specific geographic region can be managed appropriately by coordinating and discussing strategies with the local extension agency. Many proven strategies include crop rotation, herbicide rotation and the precise timing of how and when herbicides are used before, during and after crop planting and harvesting.

Comment 8:
"**GHB614 will likely increase total acres planted to glyphosate-tolerant cotton, with corresponding increase in glyphosate use"**

"Besides these fundamental methodological errors, APHIS is very confused about whether or not glyphosate usage will continue to increase or not.

On p. 9 of the EA, APHIS states: "APHIS believes the trends for glyphosate usage will continue to increase even if GlyTol cotton is not deregulated because its sister product (Roundup Ready cotton) would continue to dominate the market as it has for the past 11 years."

But APHIS also maintains that glyphosate-tolerant cotton has achieved "market saturation" (EA, p. 10) and that "[t]he total amount of glyphosate used on GE cotton is not expected to increase with the deregulation of GlyTol cotton…" (EA, p. 13).

Which is it? Will glyphosate usage continue to increase if GlyTol cotton is NOT deregulated, as APHIS maintains on p. 9, or will glyphosate use remain constant in the event that GlyTol IS deregulated, because glyphosate tolerance in cotton has achieved "market saturation," as APHIS maintains on pp. 10 and 13?

Clearly, there is no logic at work here. This thoughtless, slipshod treatment is typical of the entire EA, and constitutes reason enough to have competent personnel conduct a serious review of this issue in the context of an EIS.

APHIS's "market saturation" argument deserves special attention:

"Since glyphosate-resistant cotton has been on the market so long, it is believed that market saturation has already occurred with this type of product (USDA-NASS 2007)." (EP, p. 10)

"The total amount of glyphosate used on GE cotton is not expected to increase with the deregulation of GlyTol cotton because the product provides consumers with a

choice of GE cotton seed to purchase, and the adoption of glyphosate-tolerant cotton is believed [to] have reached its maximum market potential (USDA-NASS 2007)." (EA, p. 13)

APHIS's reference (USDA-NASS 2007) is unclear. The References section (EA, p. 27) provides only the following: "USDA-NASS (2007), Acreage, National Agricultural Statistics Service (NASS)." Presumably, APHIS is referring to NASS figures, reported by ERS, on adoption of various types of GE cotton (IR, HT, and stacked for both traits). This reference provides no support for the assumptions of "market saturation" or "maximum market potential," for several reasons. First, NASS-ERS figures do not break down the two types of herbicide-tolerant cotton (glyphosate-tolerant or Roundup Ready vs. glufosinate-tolerant or LibertyLink). Second, NASS-ERS merely reports figures for adoption of different trait categories, without any arguments re: market saturation or maximum market potential for any specific trait, including glyphosate-tolerant cotton.

In order to analyze whether introduction of GlyTol cotton will increase the market share of glyphosate-tolerant cotton and glyphosate usage, one must consult more nuanced data, such as those provided by USDA's Agricultural Marketing Service (AMS). Analysis of AMS's "Cotton Varieties Planted" report for 2006 reveals that Roundup Ready (Flex) cotton varieties comprised just over 82% of overall cotton acreage planted in that year.[4] This 82% figure includes both varieties with the Roundup Ready (Flex) trait alone as well as varieties with the Roundup Ready (Flex) trait combined with insect resistance.

Thus, nearly 1 in 5 cotton acres in 2006 did NOT contain a glyphosate-tolerance trait. The maximum market potential for glyphosate-tolerance is thus 18% of overall cotton planted. Based on 2007 cotton acreage of 10.9 million acres, this additional market potential comes to roughly 2 million more acres of cotton that could be planted to glyphosate-tolerant varieties. Given the steady increases in cotton planted to herbicide-tolerant cotton over the past decade, there is no rational basis for APHIS's assumption that glyphosate-tolerant varieties have achieved "market saturation" or realized their "maximum market potential."

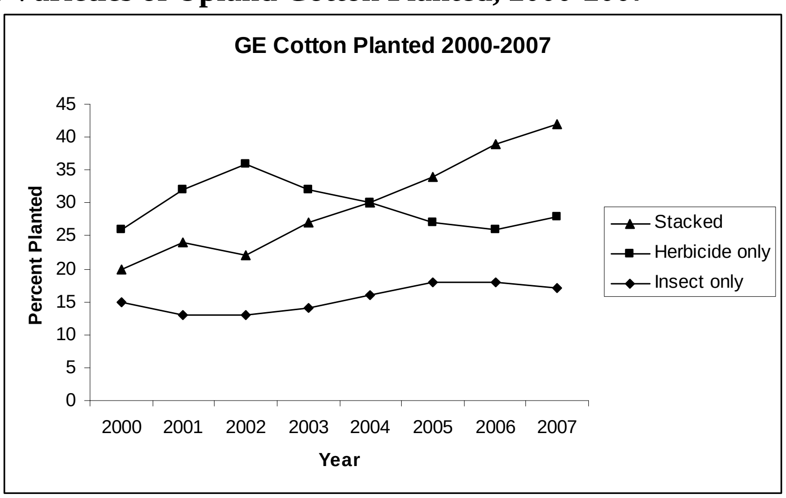
Agency response:
The commenter confuses APHIS' position on how the GlyTol™ cotton will affect herbicide usage. Contrary to the commenter's interpretation of APHIS' position, APHIS has concluded (and is not aware of any reliable data showing otherwise) that the total

[4] USDA AMS (2006). "Cotton Varieties Planted: 2006 Crop," U.S. Dept. of Agriculture, Agricultural Marketing Service, Cotton Program, August 2006. Note that cotton experts consider AMS data more accurate with respect to breakdown of cotton trait categories than NASS-ERS's data. NASS-ERS greatly overestimates the market share of cotton with insect resistance alone and greatly underestimates the market share of stacked (HT/IR cotton). For analysis of AMS data and more, see: Freese, B. (2007). "Cotton Concentration Report: An Assessment of Monsanto's Proposed Acquisition of Delta and Pine Land. International Center for Technology Assessment/Center for Food Safety. http://www.centerforfoodsafety.org/pubs/CFS-CTA%20Monsanto-DPL%20Merger%20Report%20Public%20Release%20-%20Final%20_2_.pdf

overall herbicide trends, including glyphosate use, will continue approximately the same as they have done over the past 10 years, namely, that total overall use of herbicide use will not notably increase in the future, whether or not APHIS deregulates cotton line GHB614, i.e., independent of granting nonregulated status to GlyTol™ cotton. As discussed in response to comment 7 above, the current trend is that total overall use of herbicides will not notably increase in the future and that current trend also includes an increase in glyphosate use. (See also our response to comment 2 above)

The commenter also misconstrues or misunderstands APHIS' use of the term "market saturation." APHIS is using term market saturation to describe a situation in which a product has become diffused (distributed) within a market. APHIS is not and was not using 'market saturation' interchangeably with the distinct term "market potential," which is usually understood to refer to the maximum achievable combined sales volume for all sellers of a specific product, i.e. each market has a potential of 100% sales. APHIS was using market saturation to point out the fact that stacked genes conferring both insect tolerance and herbicide resistance are preferred by GE cotton growers in today's (2008) market; 45% of acreage contained stacked genes for both insect tolerance and herbicide tolerance, and only 23% of acreage was planted to herbicide tolerant only varieties (http://www.ers.usda.gov/Data/biotechcrops/alltables.xls). APHIS has taken the opportunity to create a graph with the USDA AMS data on types of GE cotton planted over the past seven years (see Figure 6).

Figure 6. GE Varieties of Upland Cotton Planted, 2000-2007



Percentage of GE varieties of Upland cotton acreage planted for years 2000-2007. Data source "Cotton Varieties Planted, 2008 Crop", USDA AMS.

We believe the commenter made an error regarding the amount of herbicide tolerant cotton being planted in 2007. Only 28% of all planted cotton acreage was planted with only herbicide-tolerant GE cotton in 2007 (declining to 23% in 2008). The most recent NASS data has adoption of GE cotton for all traits at 94.6% of all planted cotton acreage in the United States in 2008 (USDA-AMS, 2008), while USDA ERS data has a lower percentage of all cotton acreage planted with GE cotton varieties at 86% of all planted cotton acreage. (http://www.ers.usda.gov/Data/biotechcrops/alltables.xls). Using the information from Figure 6, APHIS has concluded that demand for herbicide-tolerant only GE cotton has declined over the years to be replaced by stacked varieties of GE cotton. Using the average of the above cited NASS and AMS percentages, the current amount of all GE cotton planted in the United States can be estimated to have approximately 9 in 10 cotton acres being planted with GE cotton, and approximately 1 in 10 cotton acres being planted with traditional (non-GE) cotton. As explained in the EA, APHIS expects that cotton line GHB614 will be used as a substitute for (and not so much in addition to) its "sister" product, RoundUp Ready® cotton. Accordingly, APHIS does not expect the deregulation of cotton line GHB614 to lead to any substantively additional glyphosate-tolerant cotton acreage beyond the total acreage currently planted with GE cotton (approximately 90%) and therefore no substantively increased glyphosate applications are likewise anticipated. (see also response to comment 2)

Comment 9:

"One must also take into consideration the highly concentrated nature of the cotton seed market. As a condition for approval of Monsanto's 2006-07 acquisition of Delta and Pine Land (DPL), the Dept. of Justice forced Monsanto to divest its Stoneville division, which was acquired by Bayer Crop Science. Based on 2006 cotton seed market shares, Monsanto (with DPL) and Bayer (Fibermax and several other brands, plus Stoneville assets) together control over 90% of the cotton seed market.[5] If Bayer offers its glyphosate-tolerance trait in a substantial portion of its cotton seed offerings, this will substantially increase the number of cotton varieties for sale with glyphosate-tolerance of one form or another, and likely reduce the number of varieties without glyphosate tolerance, making it more likely that overall glyphosate-tolerance market share in cotton will increase, together with glyphosate usage."

Agency response:

APHIS has researched the cotton industry and has found that the predominant companies in the cottonseed industry are Deltapine (Monsanto), Bayer, Stoneville (Bayer), Phytogen, Americot, All-Tex and Dyna-Gro. APHIS understands that while Bayer agreed to purchase Stoneville Pedigreed Seed Co. from Monsanto as part of a consent decree with the Justice Department (May 2007), the acquisition did not include Stoneville's NexGen franchise (regional cotton seed business in Texas or any other assets related to NexGen; http://www.marketwatch.com). Bayer's FiberMax brand and Stoneville's brands are continued to be licensed under Monsanto's cotton trait technologies. Americot, Inc has since acquired Stoneville's NexGen brand. The September 2008 USDA AMS survey (USDA-AMS, 2008) reports:

Company	% US Acreage
Deltapine (Monsanto)	41.5
Bayer's FiberMax	32.1

[5] Freese (2007), op. cit.

Bayer's Stoneville	14.2
Phytogen	4.1
Americot	2.7
All-Tex	1.8
Dyna-Gro	1.5

The USDA AMS report indicates that Monsanto and Bayer together approximately hold 88% of the cotton seed market but not over 90% as the commenter indicted. Contrary to the commenter's assertion that the deregulation of cotton line GHB614 is likely to reduce the number of cotton seed varieties without glyphosate tolerance, APHIS believes that the commenter's presumption is unsubstantiated that more glyphosate-tolerant cotton seed varieties will replace the traditional cotton seed varieties that are currently being used by cotton farmers (and lead to their demise as available seed products to the cotton farmer) due to the major market share held by Monsanto and Bayer. The cotton seed market is dictated by the cotton growers and the various factors that influence and affect their seed product choice. Presently, among other factors, cotton farmers are demanding reliable cotton seed as well as more dependable product tools to combat pest and weed problems in order to obtain higher crop yields while using less energy. As stated in the 2007 updated report on the impacts of biotechnology-derived crops on US agriculture (NCFAP, 2007), "US growers have clearly made the decisions to plant the biotechnology-derived crops because they have realized significant benefits in terms of reduced production costs, limited applications of active ingredients from chemicals and improved yields." Cotton farmers will continue to make cotton seed product choices based on several factors including the type of cotton the farmers wants to grow and that the farmer considers to be the appropriate and effect type of seed in reference to the farmer's respective agricultural and economic situation, among other factors that a cotton farmer considers in deciding which specific cotton seed product they use.

Comment 10:

"A second factor that must be considered is whether or not GlyTol has a greater level of glyphosate tolerance than Roundup Ready (Flex) cotton. If so, displacement of Roundup Ready (Flex) with GlyTol cotton varieties could lead to an increase in glyphosate usage even without an overall increase in total glyphosate-tolerant cotton market share. This is a real possibility. Monsanto's Roundup Ready Flex cotton, for instance, provides resistance to higher levels of glyphosate over an extended application window versus 1st generation Roundup Ready cotton. DuPont-Pioneer's GAT soybeans and possibly corn incorporate a glyphosate-tolerance mechanism that appears to lend GAT varieties of these crops higher levels of glyphosate tolerance. These examples are mentioned merely to support the need for APHIS to assess whether or not GlyTol permits larger applications of glyphosate, something it did not assess in the draft EA. We note that the worsening problem of glyphosate-resistant weeds, coupled with the continuing high percentage of *cotton farmers who use glyphosate as their sole means of weed control* [APHIS emphasis], would make a new glyphosate-tolerant mechanism that allowed for greater rates of application of

glyphosate and/or a broadened window of application an attractive feature, so this factor requires assessment."

Agency response:
Obviously, it is the U.S. Environmental Protection Agency (EPA), not APHIS, that has the statutory authority and duty to regulate pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). Bayer CropScience (BCS), through documents submitted with its petition for deregulation of cotton line GHB614, informed APHIS that it did not request a glyphosate label change with EPA and is using the current label application rate of glyphosate on their GHB614 product. (It is a violation of federal law for any person to apply a registered pesticide in a manner inconsistent with its label. 7 U.S.C. 136 (j)(a)(2)(G)).
Expression of the 2mEPSPS protein can be found on pages 33-40 of the submitted petition from BCS. During BCS' own evaluation of their product, their transgenic plots were sprayed with glyphosate acid equivalent at 0.75 lb ai/ac, while Monsanto's MON88913 glyphosate tolerant cotton product was tested with 0.76 lb ai/ac. APHIS has found that there is no evidence contained in the data provided in the petition that conclusively demonstrated that GlyTol™ cotton has more resistance than its Roundup Ready® "sister" product currently available on the market.

It appears that many if not the majority of CFS' submitted comments on the draft EA for APHIS' proposed deregulation of the GlyTol™ cotton line are were lifted or copied directly by them from their submitted comments on the EA that was prepared for the deregulation of the GAT soybean (petition 06-271-01p - obviously with the word "cotton" replacing "soy or soybean" thorough out). See, for example, the commenter's above italicized (by APHIS) remark about glyphosate being exclusively used on cotton. Soybean and cotton crops, to say the least, are very different types of crops with very different biological and agricultural differences including problems with weeds.

The commenter asserts that APHIS needs to assess whether or not GlyTol permits larger applications of glyphosate. Such an assessment is not necessary and oversimplifies and distorts the reality of dealing with weeds in growing cotton. Because weeds not only compete for natural resources but also degrade the cotton lint quality, weed control is paramount to having a productive cotton crop. There has never been one single herbicide used or applicable in the control of all weeds that create problems in growing cotton in the United States. Whereas, on the other hand, weeds in growing soybeans on the other hand, have been known to be controlled with just glyphosate alone (much to the dismay of weed control scientists).

Table 1 in the GlyTol™ cotton EA describes the common herbicides used in cotton and Table 2 describes different strategies for weed control depending on the type of general weed problem. Note well that one herbicide is never recommended or useful as the sole herbicide for the control of weeds in cotton production. Moreover, glyphosate is known to control broad leaf weeds and has little efficacious effect on most grasses. Other weed types (like grasses) need other types of herbicides with other modes of action than that of glyphosate in order to be effective in controlling weeds in a cotton crop. This fundamental difference in weed control for cotton producing, i.e., different herbicide strategies for weed control depending on the type of general weed problem, is one of the reasons why APHIS has concluded that Bayer's expanded cotton variety offerings in addition to Monsanto's will not encourage cotton farmers in "continuing and increasing their overreliance on glyphosate" when growing cotton.

Comment 11:
"**<u>GHB614 and potential progeny"</u>**
"Bayer is petitioning for deregulation of GHB614 and "any progeny derived from crosses of event GlyTol cotton with traditional cotton varieties, and any progeny derived from crosses of event GlyTol with transgenic cotton varieties that have also received a determination of nonregulated status…." (Petition, p. 3). Thus, granting deregulation on these terms would permit crossing of GlyTol cotton with Roundup Ready cotton varieties for enhanced tolerance to glyphosate. This, too, could lead to increased glyphosate usage even without increasing acreage planted to glyphosate-tolerant cotton as a whole, and hence to an exacerbation of the glyphosate-resistant weed epidemic. APHIS must assess potential restrictions to the deregulation as suggested above in the context of a formal alternative in the context of an EIS. APHIS need not await until completion of its programmatic EIS to propose and assess this alternative, which it could do now under existing authority."

Agency response:
First, APHIS does not agree with the commenter's assertion that there is a "glyphosate-resistant weed epidemic**."** Second, while it is true that the deregulation of GlyTol cotton includes its progeny derived from crosses of traditional or other deregulated transgenic cotton, APHIS has no way to accurately predict or speculate on the possibility or probability of whether or not the two different biotech cotton seed producers will take their respectively owned and controlled GE cotton seed lines and make certain business decisions regarding trying to cross GlyTol™ cotton with Roundup Ready® cotton and, according to the commenter, in order to create a "super" glyphosate tolerant cotton seed product. Third, such possibility of crossing GlyTol™ cotton with Roundup Ready® cotton is not very feasible since the gene positioning, regulatory elements, and gene size would more than likely result in the inactivation of one or both genes conferring glyphosate tolerance. Moreover, any enhanced tolerance to glyphosate would change the amount of glyphosate used on the crop, thereby changing the label rate and thus would require a label change approved by EPA before the product could be used.

The regulations at 7 CFR Part 340.6 (d) (3) (I) state that APHIS may "approve the petition in whole or in part." APHIS might approve a petition in part if this partial approval would mitigate an identified plant pest risk. However, APHIS has determined that cotton line GHB614, like other GE cotton lines already deregulated, does not pose a plant pest risk. APHIS has not identified any greater plant pest risk characteristics in this transformed cotton than non-transformed or other non-regulated glyphosate tolerant cotton that would warrant APHIS not deregulating GHB614 much less just APHIS giving a deregulation "in part" of GlyTol™ cotton**.**

Comment 12:
"**<u>GHB614 will likely accelerate development of glyphosate-resistant weeds"</u>**
"APHIS provides no meaningful analysis of glyphosate-resistant weeds in the draft EA. One measure of this is the failure to even mention the name of a single species of weed that has developed glyphosate-resistant biotypes in the U.S. Another is the repeated generic references to the possibility of using other herbicides to control glyphosate-resistant weeds (EA, p. 4) and the existence of "integrated weed management" strategies, with "easy to follow information on how to use glyphosate-resistant cotton, along with other management tools, to control weeds economically (EA, p. 13).

Merely pointing to websites with "easy-to-follow" information is no substitute for a serious analysis of one of the major problems facing American agriculture. The facts clearly show that *exclusive reliance on glyphosate* [*APHIS emphasis*] in cotton is increasing despite the existence of websites with "easy to follow information," and that glyphosate-resistant weeds are spreading rapidly as a result.

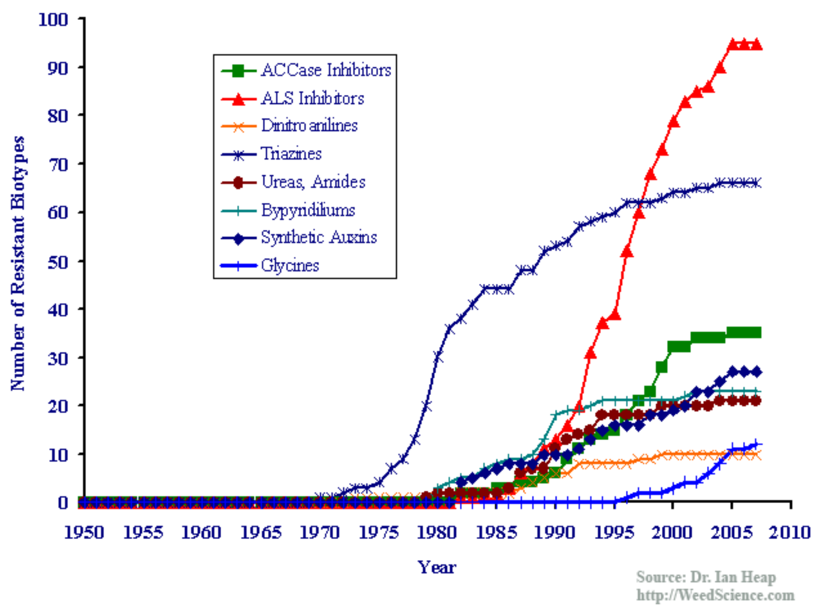
There are reasons to believe that GHB614 cotton will exacerbate glyphosate-resistant weeds. First, the likely increase in overall glyphosate usage argued above. Second, introduction of GHB614 would likely contribute to the trend of increasing reliance on glyphosate to the exclusion of other weed control methods, a key factor that has contributed to glyphosate-resistant weed development. As demonstrated in our analysis above, glyphosate use has increased dramatically since just 2003 (by 66%), with non-glyphosate use remaining constant over the same period. This means a greater proportion of overall herbicide use is attributable to glyphosate (64% in 2007, up from 49% in 2003), and hence greater reliance on glyphosate as the sole means of weed control. Increasing the availability of cotton varieties with glyphosate tolerance (i.e. a greater proportion of Bayer Crop Science's expanded cotton variety offerings in addition to Monsanto's) will encourage farmers in continuing and increasing their overreliance on glyphosate."

Agency response:
Contrary to the commenter's assertion, APHIS did list weeds naturally resistant to glyphosate on page 4 of the draft EA. Glyphosate is known to only affect broad leaf weeds and has little effect on grasses. A list of glycine-resistant weeds can be found on <u>http://www.weedscience.org/</u> (Glycine is a class of herbicides that includes glyphosate). A graphical representation by Dr. Ian Heap indicating the number of resistant biotypes to the eight major herbicide modes of action can also be viewed on that same website. Note that glycines (which include all forms of glyphosate) have one of the lowest instances of resistant weeds.

Moreover, the commenter's arguments and viewpoints are only repetitive of earlier misconstrued comments that are inaccurate and do not reflect the realities of herbicide use for cotton production. As discussed in earlier APHIS responses, glyphosate is not the only herbicide used during cotton production. As stated above and in the final EA, currently approximately 90% of cotton acreage in the U.S. is planted with herbicide-tolerant GE cotton varieties. Tables 1 and 2 of the draft EA clearly indicate that the production of glyphosate-tolerant cotton involves the use by cotton farmers of multiple herbicides, and weed control in cotton production does not rely exclusively on the use of glyphosate (or on any other single herbicide for that matter). Glyphosate is known to control broad leaf weeds and so that is what farmers primarily use it for, to control. Other weed types need herbicides with modes of action different from that of glyphosate in order to be effective in controlling certain weeds in a cotton crop. Because weeds not only compete for natural resources but also degrade the cotton lint quality, weed control is paramount to having a quality and productive cotton crop. There has never been one single herbicide used in the control of all weeds in cotton crops in the United States.

As discussed in earlier APHIS responses, APHIS also believes that GlyTol™ cotton will probably be used by cotton farmers as a replacement product for other glyphosate-resistance cotton varieties currently used by te cotton farmers. Moreover, as likewise stated in previous responses, the label rate for the amount of glyphosate to be used remains unchanged for GlyTol™ cotton. Thus, APHIS has no reason to think that there are any good reasons why there would be a dramatic increase in glyphosate use due to the inclusion of GlyTol™ cotton in cotton production in this country. Moreover, APHIS has no good reasons to think that if cotton line GHB614 is deregulated that its availability will encourage cotton farmers to substantively increase their use of glyphosate.

Figure 7. Number of Herbicide Resistant Biotypes per Herbicide vs Year



Number of herbicide resistant biotype weeds per herbicide type from 1950 until present. Glycines include all forms of glyphosate.

Comment 13:
"**<u>Review of Glyphosate-Resistant Weeds"</u>**

"Glyphosate resistance in weeds has developed with incredible rapidity over just eight years, corresponding with the period of widespread introduction of Roundup Ready soybeans and cotton. In contrast, there was only one confirmed glyphosate-resistant weed in the U.S. in the 22 years from 1976, when Monsanto first introduced the chemical in the U.S., through 1998.[6] Concern began building in 2001, when a farm journal reported:

> **"Resistance to glyphosate (Roundup) is emerging all around the world, potentially jeopardizing the 2.5 billion dollar market for genetically modified herbicide tolerant crops"[7]**

According to a joint statement by ten prominent weed scientists:

> **"It is well known that glyphosate-resistant horseweed (also known as marestail) populations have been selected in Roundup Ready soybean and cotton cropping systems. Resistance was first reported in Delaware in 2000, a mere 5 years after the introduction of Roundup Ready soybean. Since that initial report, glyphosate-resistant horseweed is now reported in 12 states and is estimated to affect 1.5 million acres in Tennessee alone."**

Other weeds being investigated for glyphosate resistance include cocklebur and lambsquarters,[8] morning glories[9] and tropical spiderwort.[10] The spread of tropical spiderwort resistant to glyphosate, particularly in Georgia, is associated with the dramatic increase in Roundup Ready cotton acreage in recent years. Other weeds developing resistance to glyphosate, or at risk of the same, include annual grasses such goosegrass (confirmed glyphosate-resistant biotypes in Malaysia), foxtails, crowfootgrass, signal grasses, panicums, and crabgrasses.[11]

While glyphosate-resistant weeds are worst in the South and East, they are rapidly spreading throughout the Midwest. Missouri is now home to at least three confirmed glyphosate-resistant weeds – common waterhemp, common ragweed and horseweed. Weed experts in the Midwest are predicting further spread of glyphosate-resistant weeds in their states. For instance, Michael Owen, agronomist at Iowa State University, is concerned that with over 90% of soybeans in Iowa planted to Roundup Ready varieties, the rapid adoption of Roundup Ready corn

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[6] The sole resistant weed by 1998 was rigid ryegrass in California. See website of The Weed Science Society of America.
http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go

[7] Farmers Weekly (2001). "Glyphosate resistance is showing a worldwide rise," *Farmers Weekly*, Nov. 23, 2001. http://www.connectotel.com/gmfood/fw231101.txt.

[8] Roberson, R. (2006). "Pigweed not only threat to glyphosate resistance," Southeast Farm Press, Oct. 19, 2006.

[9] UGA (2004). "Morning glories creeping their way around popular herbicide, new UGA research reports," University of Georgia, August 23, 2004.

[10] USDA ARS (2004). "Little-known weed causing big trouble in Southeast," USDA ARS News Service, August 24, 2004.

[11] Robinson, E. (2005). "Will weed shifts hurt glyphosate's effectiveness?" Delta Farm Press, Feb. 16, 2005.

will lead increasingly to "an increasing number of crop acres where glyphosate will follow glyphosate" in the popular corn-soybean rotation.[12]

The list of weeds species with confirmed glyphosate-resistant biotypes in the U.S. now stands at nine: common ragweed, common waterhemp, giant ragweed, hairy fleabane, horseweed, Italian ryegrass, Johnsongrass, Palmer amaranth and rigid ryegrass.[13] **Worldwide, biotypes of 14 different weed species have confirmed glyphosate resistance. We note that glyphosate-resistant biotypes of two new weed species have been discovered in the U.S. in just the past 1-2 years: hairy fleabane (California, 2007) and Johnsongrass (Arkansas and Mississippi, 2007). In addition, glyphosate-resistant weeds have been spreading rapidly over just the past two years, with the first reports of confirmed resistant horseweed in Michigan (2007), resistant giant ragweed in Kansas, Minnesota and Tennessee (2006-07), resistant common ragweed in Kansas (2007), resistant common waterhemp in Illinois, Kansas and Minnesota (2006-07) and resistant Palmer amaranth in Arkansas, Tennessee and Mississippi (2006-08).**

Confirmed glyphosate-resistant weeds are now reported on 3,756 sites covering 2.4 million acres in 20 states in the U.S.[14]**"**

Agency response:
The commenter's statement **"**Glyphosate resistance in weeds has developed with incredible rapidity over just eight years, corresponding with the period of widespread introduction of Roundup Ready soybeans and cotton**"** is misleading and distorted in asserting that weeds have the ability and tendency to "develop" a resistance to glyphosate. Weeds do not "develop" resistance, but are biologically predisposed to such resistance, i.e., they are naturally resistant to glyphosate. Resistant biotypes exist among populations of these broad-leaf weed species and because of glyphosate applications; these naturally occurring biotypes have become prevalent because the mode of action for glyphosate is against broadleaf-type weeds. So, obviously, these **naturally-resistant** weeds have been reported to be a problem in crops that exclusively use one single herbicide year after year (contrary to the continuing advice of weed scientists). As already has been explained, weed control is imperative in cotton production since not only can weeds outgrow cotton and compete for essential nutrients that the cotton needs, but they can also cause staining of the lint product reducing the marketability of the cotton. Likewise, in weed control for cotton production, normally farmers will use more than one herbicide to control weeds in cotton their fields because there are different types of weeds that require the use of different herbicides.

Naturally occurring glyphosate-resistant weeds in the major cotton producing states of

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[12] Owen, M.D.K. (2005). "Update 2005 on Herbicide Resistant Weeds and Weed Population Shifts," 2005 Integrated Crop Management Conference, Iowa State University.
[13] See http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go for this statement and the following discussion in this paragraph.
[14] CFS internal analysis of www.weedscience.com data on glyphosate-resistant weeds.

Texas, Georgia, Arkansas, Mississippi, North Carolina, Tennessee, Louisiana and California are found on the following table (Table 1a). Texas is the largest cotton producing state, responsible for planting 5,015 thousand acres in 2008; nearly 53% of the 9,470 thousand acres planted for all US states. Texas is also one of the largest glyphosate-using state (7,285 lbs for all glyphosate types in 2008; (USDA-NASS, 2008)) and does not have any reported glycine (glyphosate) resistant weeds listed. The commenter's logic incorrectly infers that the higher the glyphosate usage, the greater the weed resistance problem. The data indicating Texas as both the largest cotton producer and largest user of glyphosate does not support this logic. This new table (Table 1a) added in the final EA continues to support and confirm APHIS' conclusion in the draft EA that deregulation of glyphosate-tolerant cotton is not responsible for the existence of naturally-occurring glyphosate-resistant weeds.

APHIS definitely disagrees with the commenter's misinformed assertions that "the facts clearly show that *exclusive reliance on glyphosate* [*APHIS emphasis*] in cotton is increasing … and that glyphosate-resistant weeds are spreading rapidly as a result." Clearly cotton farmers do not exclusively rely on glyphosate for weed control. Likewise, glycine herbicides (which includes all forms of glyphosate) show relatively slower instances of resistant weeds compared to other herbicides. Thus, APHIS definitively disagrees with the commenter's assertion that granting nonregulated status to GlyTol™ cotton will accelerate the development of glyphosate-resistant weeds.

Table 1a. Glyphosate-resistant weeds in major cotton growing states

State	Weed	Year Reported
Texas		
Georgia	*Amaranthus palmeri* (palmer amaranth)	2005
Arkansas	*Sorghum halepense* (johnsongrass) *Conyza Canadensis* (horseweed) *Ambrosia trifida* (giant ragweed) *Ambrosia artemisiifolia* (common ragweed) *Amaranthus palmeri* (palmer amaranth)	2007 2003 2005 2004 2006
Mississippi	*Lolium multiflorum* (Italian ryegrass) *Conyza Canadensis* (horseweed) *Amaranthus palmeri* (palmer amaranth)	2005 2003 2008
North Carolina	*Conyza Canadensis* (horseweed) *Amaranthus palmeri* (palmer amaranth)	2003 2005
Tennessee	*Conyza Canadensis* (horseweed) *Ambrosia trifida* (giant ragweed) *Amaranthus palmeri* (palmer amaranth)	2001 2007 2006
Louisiana		
California	*Lolium rigidum* (rigid ryegrass) *Conyza Canadensis* (horseweed) *Conyza bonariensis* (hairy fleabane)	1998 2005 2007

Comment 14:

"Glyphosate-resistant weeds are already leading to reductions in conservation tillage, increasing soil erosion, increased production costs for growers, and a return to more toxic herbicides to control weeds no longer readily controlled by glyphosate.

Mechanical tillage, once common, has been on the decline for years as farmers switch to "no-till" or conservation (minimal) tillage practices in order to reduce labor costs and fuel expenditures, as well as decrease the soil erosion that often accompanies plowing. The rise of glyphosate-resistant weeds is beginning to reverse this trend.[15] For instance, acreage under conservation tillage in Tennessee dropped by 18% in 2004, as farmers turned back to the plow to control glyphosate-resistant horseweed; Tennessee counties with the largest cotton acreage experienced the largest decline in conservation tillage, from 80% to just 40%. It is estimated that resistant horseweed has reduced the area under conservation tillage in Arkansas by 15%, with similar trends reported in Missouri and Mississippi.[16] The reduction in conservation tillage associated with glyphosate-resistant weeds, and resulting increased soil erosion, is an agronomic and environmental impact that APHIS needs to analyze in the context of an environmental impact statement on GHB614.

An Arkansas weed scientist estimated that the state's growers would have to spend as much as $9 million to combat glyphosate-resistant horseweed in 2004.[17] Larry Steckel, weed scientist at the University of Tennessee, estimates that on average, glyphosate-resistant pigweed will cost cotton growers in the South an extra $40 or more per acre to control.[18] This represents a substantial burden, as cotton farmers' average expenditure on *all* pesticides (insecticides and herbicides) was $61 per acre in 2005.[19] Arkansas extension agent Mike Hamilton estimates that an uncontrolled outbreak of glyphosate-resistant horseweed in his state has the potential to cost Arkansas cotton and soybean producers nearly $500 million in losses, based on projected loss in yield of 50% in 900,000 acres of Arkansas cotton and a 25% yield loss in the over 3 million acres of Arkansas soybeans.[20]

The potential for economic losses to farmers from glyphosate-resistant weeds fostered by the Roundup Ready cotton system, in combination with other Roundup Ready crops systems (soybeans, corn) is a serious issue that APHIS must address in the context of an environmental impact statement on GHB614.

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[15] APHIS, following Monsanto, attributes the rise of conservation tillage to adoption of RR crops in the draft EA (EA, p. 3). It is interesting that APHIS adopts Monsanto's view here, in light of the fact that a USDA expert notes that the steep rise in conservation tillage (at least in soybeans) came from 1990-1996, before the introduction of RR soy, and that the share of soybean acres grown with conservation tillage stagnated after 1996. See Fernandez-Cornejo & McBride (2002), "Adoption of Bioengineered Crops," U.S. Dept. of Agriculture, Economic Research Service, Agricultural Economic Report No. 810, May 2002, p. 29.

[16] Steckel, L., S. Culpepper and K. Smith (2006). "The Impact of Glyphosate-Resistant Horseweed and Pigweed on Cotton Weed Management and Costs," presentation at Cotton Incorporated's "Crop Management Seminar," Memphis, 2006.
http://www.cottoninc.com/CropManagementSeminar2006/SeminarProceedings/images/Steckle%20Larry.pdf

[17] AP (2003). "Weed could cost farmers millions to fight," *Associated Press*, 6/4/03, http://www.biotech-info.net/millions_to_fight.html.

[18] Laws, F. (2006a). "Glyphosate-resistant weeds more burden to growers' pocketbooks," *Delta Farm Press*, November 27, 2006, http://deltafarmpress.com/news/061127-glyphosate-weeds/

[19] USDA ERS (2007b). Cost and return data for cotton production: 1997-2005. USDA Economic Research Service, http://www.ers.usda.gov/data/CostsandReturns/data/recent/Cott/R-USCott.xls.

[20] James, L. (2005). "Resistant weeds could be costly," Delta Farm Press, July 21, 2005.

Over-reliance on Roundup Ready crops and glyphosate has dampened research into new herbicides, meaning none are on the horizon.[21] Meanwhile, growers will increasingly turn to older, more toxic herbicides, such as paraquat and 2,4-D, to control glyphosate-resistant weeds.[22]

The potential for increased use of more toxic herbicides to control glyphosate-resistant weeds requires serious analysis by APHIS in the context of an environmental impact statement on GHB614."

Agency response:
APHIS would like to again point out that the commenter simply recirculated some of its earlier comments on EAs for other GE crops that have been deregulated and reused them in reference to the EA for the deregulation of GlyTol™ cotton. Note, for example, footnote 15 from the commenter that deals with a completely different EA and GE crop event line as well as the company producing the event line:

> "APHIS, following Monsanto, attributes the rise of conservation tillage to adoption of RR crops in the draft EA (EA, p. 3). It is interesting that APHIS adopts Monsanto's view here, in light of the fact that a USDA expert notes that the steep rise in conservation tillage (at least in soybeans) came from 1990-1996, before the introduction of RR soy, and that the share of soybean acres grown with conservation tillage stagnated after 1996…."

Because the commenter is essentially commenting on a completely different crop and production system, with cotton production information mentioned here and there, the arguments fail to properly address cotton production in general but less the GE cotton event GHB614- GlyTol™ cotton. As stated above, glyphosate is one of many herbicides used by cotton farmers to control weeds in their production of cotton. Despite the commenter's misinformed assertions to the contrary, as we have clearly stated in the EA and have repeated above several times, cotton farmers do **not solely rely on** glyphosate to control weeds.

APHIS acknowledges that in areas where naturally glyphosate-resistant weeds predominate (like horsetail and palmer amaranth), conventional tillage is recommended to achieve weed control. APHIS reviewed the citations in footnotes 17, 18, 20 provided by the commenter and cannot substantiate the estimated numbers provided in the MS® PowerPoint presentations and therefore, cannot make a scientifically-based determination or conclusion about the data. APHIS also reviewed the USDA ERS data (footnote 19). The cost data referred to in footnote 19 of the comment includes costs for all pesticides and does not separate out the costs attributed to insecticides, fungicides, or herbicides.

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[21] Mueller, T.C., P.D. Mitchell, B.G. Young and A.S. Culpepper (2005). "Proactive versus reactive management of glyphosate-resistant or –tolerant weeds," *Weed Technology* 19:924-933; Yancy, C.H. (2005). "Weed scientists develop plan to combat glyphosate resistance," *Southeast Farm Press*, June 1, 2005. http://southeastfarmpress.com/mag/farming_weed_scientists_develop/.
[22] Roberson (2006), op. cit.

Thus cost data for all pesticides cannot be used to support conclusions regarding *herbicide costs* alone, as incorrectly suggested by the commenter.

According to Sankula (Sankula et al., 2005), no-till cotton acres increased 371% from 1996 to 2004, while corn and soybeans increased no-till acreage by 20 and 64%, respectively. The availability of glyphosate and glufosinate-tolerant cotton systems serve as valuable tools in managing weed resistance and population shifts due to their diverse mechanisms of action (Sankula et al., 2005). Quantification of the impacts of biotechnology-derived crops planted in 2006 can be found in the NCFAP report (NCFAP, 2007) cited at the end of this document. In brief, production volumes were measured based on yield changes that occurred when the GE crops replaced existing crop production practices with adoption costs associated with the use of the technology taken into account and the changes in pesticide use were also considered. The report concluded that the average cost for weed control was $46.20 per acre. Weed management costs for the glyphosate-tolerant cotton averaged $31.66 per acre. The national impact of glyphosate-tolerant cotton weed management programs **reduced** the total cost of active ingredient used by $14.54 per acre; a **savings** of $228,934,000 for the total cost of weed control for all States. Similar data was complied for glufosinate-tolerant cotton (NCFAP, 2007). This same report also included reduction of tillage costs for all States by $74,551,000 for all States, citing the adoption of no-till or strip-tilling in recent years. Soil conservation saves approximately 1 billion tons of soil per year in the U.S. and 306 million gallons of tractor fuel and its related emissions. According to *Cotton Incorporated* researchers, conservation tillage practices as adopted in the U.S. from 1996-2004 have an effect on carbon dioxide reduction that is equivalent to removing 27,111 cars from the road. The *Environmental Impact Quotien*t (EIQ) developed at Cornell University can be used as a robust measure of environmental impact of technologies, as it incorporates key toxicity and environmental exposure data related to individual products. The EIQ has decreased by 17% in the U.S., largely due to advances in genetically modified cotton as it relates to pesticide use reduction along with air, water, and soil conservation; at the same time, yields have increased 25% from 1994-2004.[23]

APHIS certainly does not agree with the commenter's statement "Over-reliance on Roundup Ready crops and glyphosate has dampened research into new herbicides, meaning none are on the horizon**."** A comprehensive list of common names of herbicides that have been developed and tentatively approved by the International Organization of Standardization can be found in Appleby's paper (Appleby, 2005) since 1976 (the year glyphosate was introduced). On this list approximately 144 herbicides have been developed and tentatively approved from 1976 to 2005.

Finally, APHIS would like to reiterate that glyphosate is currently one of many tools for weed control in cotton production. As stated earlier, cotton production typically requires

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[23] *A Method to Measure the Environmental Impact of Pesticides*. J. Kovach, C. Petzoldt, J. Degni**, and J. Tette, IPM Program, Cornell University, New York State Agricultural Experiment Station Geneva, New York.

multiple herbicides. If glyphosate is somehow removed as a tool for weed control in cotton production, the rest of the tools available remain the same; the same herbicides (except glyphosate) and cultural or mechanical controls would be available. Essentially in this scenario, cotton production would then revert to cotton production methods that existed and were extensively used prior to the release of glyphosate-tolerant cotton.

Comment 15:
"**Mandatory Resistance Management"**
"Despite the serious nature of the glyphosate-resistant weed epidemic, neither Bayer in its petition nor APHIS in its EA offer anything to counter it, beyond the blandest and most generic of advice (consult this website, use herbicides other than glyphosate). Past experience demonstrates that even the most vigorous voluntary efforts by weed experts, extension agents and glyphosate-tolerant crop developers to encourage famers to "manage resistance" through "rotating modes of action" away from exclusive reliance on glyphosate, and rotating Roundup Ready with non-Roundup Ready crops HAS NOT WORKED. Glyphosate-resistant weed development is if anything accelerating, with more weed species developing resistance, and more sites on more acreage in more states being affected. It's time for APHIS to get serious about the growing threat to US agriculture and propose mandatory resistance management programs for herbicide-resistant weeds on the model, perhaps, of EPA's for insect resistance management with Bt crops."

Agency response:
Again, APHIS notes that the majority of the paragraphs from CFS' comments regarding the EA for the deregulation of GlyTol™ cotton are copied directly out of their comments to the EA for the GAT soybean petition 06-271-01p (with the word "cotton" replacing "soy or soybean").

APHIS' Part 340 biotech regulations do not regulate herbicide-resistant weeds and thus those regulations cannot impose "mandatory resistance management for herbicide-resistant weeds" as suggested by the CFS commenter. APHIS does have statutory authority and does regulate "noxious weeds" but just because a specific weed is herbicide-resistant does not in any manner or form make that weed a "noxious" weed pursuant to APHIS' statutory authority under the Plant Protection Act of 2000 as amended**.**

Moreover, the commenter's premise that there needs to be mandatory resistance management is that glyphosate resistant weeds are created by the use of glyphosate on glyphosate-resistant cotton, yet, as APHIS as explained above in other responses, the current scientific data does **not** support this assertion. For example, Texas is the largest cotton producing state, responsible for planting 5,015 thousand acres in 2008; nearly 53% of the 9,470 thousand acres planted for all US states. Texas is also one of the largest glyphosate-using state (7,285 lbs for all glyphosate types in 2008; (USDA-NASS, 2008) and does not have any reported glycine (glyphosate) resistant weeds listed (see Table 9 in Comment 14, agency response).

Comment 16:
"**<u>Conclusion"</u>**
"APHIS is required by federal court precedent to assess Bayer's GHB614 glyphosate-tolerant cotton for its potential to increase glyphosate usage, exacerbate the problem of glyphosate resistant weeds, and for other consequences of its introduction. Our analysis shows that APHIS's treatment of both glyphosate and overall herbicide use on cotton is fundamentally flawed by failure to consider 2007 data available to it from its sister agency, NASS, as well as by fundamental methodological flaws. A correct analysis shows dramatic increases in both glyphosate use (19-fold since 1996) and overall herbicide use (35% since 1996). Still more significant, increasing glyphosate use has stopped displacing use of other herbicides. With glyphosate use on cotton up 66% since 2003, use of non-glyphosate herbicides has remained constant.

We show that GHB614 will likely increase glyphosate-tolerant cotton adoption beyond the 82% market share achieved in 2006, when Monsanto's Roundup Ready trait was the only glyphosate-tolerance mechanism offered in cotton. With increased availability of glyphosate-tolerance provided by the GlyTol trait in Bayer's cotton varieties, adoption of glyphosate-tolerant cotton, glyphosate use, and glyphosate-resistant weed development will all increase. Knock-on effects will likely be increased use of older more toxic herbicides to control resistant weeds that even vastly increased doses of glyphosate no longer kill, increased resort to mechanical tillage to control resistant weeds (already observed in Tennessee and other states) with the increased soil erosion and global warming impacts that entails, and increased production costs for growers.

Therefore, APHIS must assess the twin issues of glyphosate use and glyphosate-resistant weed development and their associated consequences in the context of an EIS."

Agency response:
APHIS has included 2007 NASS data (USDA-NASS, 2008) in amended tables put in the final EA and has also provided a graphical illustration to demonstrate that the additional data inserted in the final EA does not change APHIS' fundamental position on herbicide use trends presented in the draft EA. New ERS data has shown that GE cotton already dominates approximately 91% of the current cotton production plantings. APHIS has explained above its reasons for not expecting this percentage to increase substantially as a result of the deregulation of GlyTol Cotton. The 2007 numbers also show that glyphosate-only cotton planting has remained under the market high of 36% in 2001 (now 28%; see Figure 6). The commenter uses incorrect data to determine glyphosate-tolerant cotton adoption. It is important to note that the ERA data for herbicide-tolerant crop adoption also includes other herbicides, not just glyphosate (although glyphosate-tolerant crops predominate).

APHIS does not agree with the commenter that the deregulation of this product will increase glyphosate-resistant weed development or reduce conservation tillage.

Combining all of the analyses in the final EA, along with all of the responses to comments in this "Response to Comments" section, and especially including APHIS' conclusion that the total overall use of herbicides is not expected to increase in the future (see response to comment 7), and APHIS' determination that its deregulation of cotton line GHB614 should not lead to any substantively additional glyphosate-tolerant cotton acreage beyond the total acreage currently planted with GE cotton (approximately 90%), and therefore its conclusion that no substantively increased glyphosate applications are likewise anticipated (see response to comment 8), and APHIS' conclusion that the planting of total cotton acreage in the United States is actually continuing to decline (see response to comment 2), APHIS has determined that there should not be any significant impacts on the human environment as a result of its decision to deregulate cotton line BGH614. Accordingly, APHIS does not need to evaluate the proposed deregulation of GlyTol™ cotton in the context of an EIS.

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United States
Department of
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Marketing and
Regulatory
Programs

Animal and
Plant Health
Inspection
Service

Determination of Non-regulated Status for Glyphosate-Tolerant (GlyTol™) Cotton, *Gossypium hirsutum*, event GHB614

Petition 06-332-01p

Final
Environmental Assessment
15 April 2009

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Agency Contact:
Cynthia Eck, Document Control Officer
USDA, APHIS, BRS
4700 River Road, Unit 146
Riverdale, MD 20737-1237
Phone: (301) 734-0667
Fax: (301) 734-8669
Email: Cynthia.A.Eck@usda.gov

Table of Contents

I. Purpose & Need

The Animal and Plant Health Inspection Service of the United States Department of Agriculture (USDA-APHIS), Biotechnology Regulatory Service (BRS) protects America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of genetically engineered plants.

APHIS regulations (7 CFR part 340) regulate the introduction (importation, interstate movement or release into the environment) of certain genetically engineered plants or plant pests. An organism is no longer subject to the regulatory requirements of 7 CFR part 340 when it is demonstrated that it does not present a plant pest risk. A genetically engineered 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.

Under these regulations, a petitioner may file an application requesting that APHIS review the regulated article and evaluate submitted data and determine that a particular regulated article does not present a plant pest and, therefore, should no longer be regulated under 7 CFR 340.6 "Petition for Determination of Nonregulated Status." The petitioner is required to provide certain information which the agency uses to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. If, based on the information, the agency determines that the article is unlikely to pose a plant pest risk, the article must be granted deregulated status. Under APHIS regulations 7 CFR part 340, the receipt of a petition application to introduce a genetically engineered organism requires a response from the Administrator:

> *Administrative action on a petition*. The Administrator shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either: (i) Approve the petition in whole or in part in which case the Administrator shall concurrently take appropriate action (publication of a document in the FEDERAL REGISTER amending 340.2 of this part; or (ii) deny the petition in whole or part. 7 CFR part 340.5 (c)(3).

USDA-APHIS, BRS has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 06-332-01p, received on November 20, 2006) submitted by Bayer CropScience (BCS) for a determination of non-regulated status for genetically engineered (GE) GlyTol™ cotton *(Gossypium hirsutum*, event GHB614) developed to express tolerance to the herbicide, glyphosate[1]. GlyTol™ cotton is currently a regulated article under USDA regulations at 7 CFR part 340, and as such, interstate movements, importations, and field tests of the transformed cotton have been conducted under notifications issued by APHIS. BCS has submitted a petition application to APHIS requesting a determination that GlyTol™ cotton does not present a plant pest risk, and therefore, GlyTol™ cotton and its progeny derived from crosses with other non-regulated cotton should no longer be regulated articles under these APHIS regulations.

BCS has developed GlyTol™ cotton (event GHB614) as an alternative glyphosate-tolerant cotton product to Monsanto's Roundup Ready® cotton that has provided an established weed management tool to producers since its deregulation in July 1995. APHIS has reviewed the data

[1] Glyphosate tolerant and glyphosate resistant are used interchangeably in this document.

supplied by the petitioner and current scientific literature, and found GlyTol™ cotton to have a no greater plant pest risk than the unmodified organism. APHIS reviews a GE plant for known and potential differences from the original, unmodified plant. These include disease and pest susceptibilities, expression of the gene product, weediness of the GE plant, impact on the weediness of another other plant with which it can interbreed, agricultural or cultivation practices and transfer of genetic information to organisms with which it cannot interbreed. Information on cotton in general, the weediness of cotton, gene flow and plant pest risks is discussed in this document in Appendix A. If APHIS had found that GlyTol™ cotton demonstrated greater plant pest risks after reviewing the data given by the applicant, APHIS would have chosen to keep GlyTol™ cotton a regulated article (see No Action Alternative, Section III).

In accordance with APHIS procedures for implementing the National Environmental Policy Act of 1969 (NEPA, 7 CFR part 372), this EA has been prepared for GlyTol™ cotton in order to specifically evaluate how the proposed action and alternatives described in the following section, if implemented, may affect the quality of the human environment.

II. Affected Environment

A. Background

1. Cotton

The genus *Gossypium*, a member of the Malvaceae family, consists of 39 species; four of which are generally cultivated in the world (Fryxell 1979). The most commonly cultivated species in the United States is *G. hirsutum* (common name, Upland cotton); comprising 97% of the U.S. cotton crop (www.ers.usda.gov) and is the subject of this EA. Limited amounts of *G. barbadense* are cultivated in Hawaii. Other cultivated species around the world are *G. arboreum*, *G. barbadense*, and *G. herbaceum*. There are two wild species of cotton found in the United States; *G. thurberi* and *G. tomentosum*, of Arizona and Hawaii, respectively.

Cotton is the leading fiber crop in the United States as well as the world. It is the leading textile fiber because the mature dry hairs twist in such a way that fine, strong threads can be spun from them. Other products, such as cottonseed oil, cake, and cotton linters are byproducts of fiber production.

Cotton is a perennial plant cultivated as an annual, and is grown in the United States in just 18 states, from Virginia southward and westward to California; in an area often referred to as the Cotton Belt (McGregor 1976). Cotton is more limited geographically than any other major crop in the United States because it can be grown only in those regions in which there are more than 180 frost-free days per year (those states in the Cotton Belt). Because of its limited geographic production area, this EA will focus its review to the major cotton producing states of Texas, Georgia, Arkansas, Mississippi, North Carolina, Tennessee, Louisiana and California (Meyer, MacDonald et al. 2008).

In the 2008-2009 production years, the United States grew 9.41 million acres of cotton (Meyer, MacDonald et al. 2008). According the Cotton and Wool Situation and Outlook Yearbook 2008, the major cotton-producing states in 2008 were Texas (5,100 thousand bales), Georgia (1,650 thousand bales), Arkansas (1,350 thousand bales), North Carolina (730 thousand bales), Missouri (670 thousand bales), Mississippi (650 thousand bales), Tennessee (535 thousand bales), Alabama (500 thousand bales), California (380 thousand bales) and Louisiana (280 thousand bales). Of the 2008 acreage planted in the United States, it has been estimated that 86% of cotton is genetically-engineered for herbicide-tolerance, insect-tolerance or both (http://www.ers.usda.gov/Data/BiotechCrops/adoption.htm). Cotton Council International (www.cottonusa.org) estimates the use of genetically-engineered (for all traits) cotton in the U.S. to be as much as 95.5%. The remaining percentage of cotton grown is traditional cotton seed with a small (<0.5%) percentage of cotton grown organically. More information on cotton production can be found in the Selected Resource Materials section at the end of this document. The estimates by USDA-FAS and Cotton Council International were based on surveys completed by participating farmers from the areas of interest.

2. Weed Competition and Control in Cotton

Cotton is more susceptible to weeds than soybeans or corn because it is easily out-grown during its early season growth. Weeds also interfere with harvest equipment and can cause lint staining[2], all leading to major crop and economic losses. The key to successful cotton production is a weed management program which includes crop rotation, herbicide application and weed surveillance and monitoring.

Herbicide-tolerant crops, such as BCS' GlyTol™ (glyphosate-tolerant) cotton, are developed to survive application of herbicides (in this case glyphosate) that previously would have destroyed the crop along with the targeted weeds. These herbicide-tolerant crops are providing farmers with a broader variety of options for effective and economically affordable weed control, but data indicates that farmers prefer cotton varieties that have both insect and herbicide tolerance. Based on USDA survey data, plantings of herbicide-tolerant cotton expanded from 14 percent of U.S. acreage in 1997 to 32 percent in 2001, then has decreased to 26 percent in 2006, and fell to 23% in 2008 (http://www.ers.usda.gov/Data/BiotechCrops/adoption.htm).

There are many weeds found in cotton production fields that naturally resist glyphosate or are difficult to control by only applying glyphosate. Bermuda grass, dove weed, Florida pusley, hemp sesbania, morning glory, nutsedge, tropical spiderwort, horseweed and palmer amaranth are examples of naturally resistant weeds (Weed Management in Cotton, http://commodities.caes.uga.edu/fieldcrops/cotton). Because of this natural resistance to glyphosate, cotton growers use a variety of herbicides (not just glyphosate) for successful cotton production. Table 1 contains a list of common herbicides used in cotton production. Table 2 shows typical herbicide strategies for herbicide use on cotton; whether the crop is transgenic for glyphosate-resistance or non-transgenic, and whether there have been glyphosate-resistant weeds surveyed within the cotton acreage (active ingredients and manufacturer can be found in Table 1). The mixing of herbicides is a strategy used by the producer to sustain good weed management. Growers need to consult with their local agricultural extension agent to gain an understanding of what herbicide regime is appropriate in their area. It is the continued and exclusive use of one herbicide that selects for the resistant weeds that creates a problem in any crop production. There are many websites that discuss weed management in herbicide-tolerant crops, e.g. http://www.weedresistancemanagement.com/layout/default.asp as well as the previously mentioned University of Georgia website (http://commodities.caes.uga.edu/fieldcrops). Since the publication of the draft EA, APHIS has created a table that lists all the glyphosate-resistant weeds in the major cotton growing states. Naturally occurring glyphosate-resistant weeds in the major cotton producing states of Texas, Georgia, Arkansas, Mississippi, North Carolina, Tennessee, Louisiana and California are found on Table 1a. Texas is the largest cotton producing state, responsible for planting 5,015 thousand acres in 2008; nearly 53% of the 9,470 thousand acres planted for all US states. Texas is also one of the largest glyphosate-using state (7,285 lbs for all glyphosate types in 2008; (USDA-NASS 2008)) and does not have any reported glycine (glyphosate) resistant weeds listed. The addition of this new data continues to support APHIS' statements found in the Preferred Alternative and subsequent discussion of this alternative in the EA.

[2] Lint staining refers to the coloration of the raw cotton fiber. Color deterioration affects the ability of cotton fibers to absorb and hold dyes and finishes, thus reducing its value.

New Table 1a. Glyphosate-resistant weeds in major cotton growing states

State	Weed	Year Reported
Texas		
Georgia	*Amaranthus palmeri* (palmer amaranth)	2005
Arkansas	*Sorghum halepense* (johnsongrass) *Conyza Canadensis* (horseweed) *Ambrosia trifida* (giant ragweed) *Ambrosia artemisiifolia* (common ragweed) *Amaranthus palmeri* (palmer amaranth)	2007 2003 2005 2004 2006
Mississippi	*Lolium multiflorum* (Italian ryegrass) *Conyza Canadensis* (horseweed) *Amaranthus palmeri* (palmer amaranth)	2005 2003 2008
North Carolina	*Conyza Canadensis* (horseweed) *Amaranthus palmeri* (palmer amaranth)	2003 2005
Tennessee	*Conyza Canadensis* (horseweed) *Ambrosia trifida* (giant ragweed) *Amaranthus palmeri* (palmer amaranth)	2001 2007 2006
Louisiana		
California	*Lolium rigidum* (rigid ryegrass) *Conyza Canadensis* (horseweed) *Conyza bonariensis* (hairy fleabane)	1998 2005 2007

Table 1. Trademark Herbicides and Manufacturers

Registered Trademark	Active Ingredient(s)	Manufacturer[1]
Clarity	Dicamba diglycolamine salt	BASF
2,4 D-Express	2,4-dichlorophenoxy acetic acid + tribenuron methyl + dicamba	DuPont
Harmony Extra	Thifensulfuron methyl + thibenuron methyl	DuPont
Valor	Flumioxazin	Valent
Ignite	Glufosinate-ammonium	Bayer CropScience
Gramoxone	Paraquat	Syngenta
Direx	Diuron	DuPont
Caparol	Prometryn	Syngenta
Prowl	Pendimethalin	BASF
MSMA plus S	Monosodium acid methanearsonate	Dow
Treflan	Trifluralin	Dow
Cotoran	Fluometuron	Makhteshim-agan
Reflex	Fomesafen	Syngenta
Staple	Pyrithiobac sodium	DuPont
Dual Magnum	S-metolachlor	Syngenta
Sequence	Glyphosate and S-metolachlor	Syngenta
Suprend	Trifloxysulfuron sodium + prometryn	Syngenta
Layby Pro	Diuron + Linuron	DuPont

[1] There can be more than one manufacturer for some older products, depending on formulation.

Table 2.[1] Weed Control Programs for Managing Glyphosate- and ALS-Resistant Weeds in Cotton.[2,3]

Cotton Variety	Glyphosate Resistance Suspected	ALS[4] Resistance Suspected	Preplant Incorporated or Preemergence	Postemergence 1- to 4-leaf cotton	Layby Options (Palmer < 3 in.)
Any	Yes or No	Yes or No	**-------------------Burndown Options-------------------** Glyphosate + Clarity, 2,4-D, Express, Harmony Extra, Prowl or Valor; Ignite + 2,4-D or Clarity; Gramoxone + Direx or Caparol		
Roundup Ready® (Monsanto's glyphosate tolerant variety)	No	Yes	Prowl or Treflan PPI or Prowl, Cotoran, or Reflex PRE or Prowl + Cotoran	Glyphosate or Glyphosate + Dual Magnum (or Sequence)	MSMA or Glyphosate + Caparol, Direx, Suprend, or Valor or Layby Pro or Layby Pro + MSMA
***Roundup Ready® (Monsanto's glyphosate tolerant variety)**	Yes	No	Prowl or Treflan PPI followed by Cotoran, Reflex or Staple PRE or Prowl + Reflex or + Staple[5] PRE	No Palmer emerged: Glyphosate + Dual Magnum (or Sequence) as needed	MSMA + Caparol, Direx, Suprend, or Valor or Layby Pro or Layby Pro + MSMA
				Palmer < 2 in: Glyphosate + Staple	Same as Above
Non-Transgenic	Yes or No	Yes	Prowl or Treflan PPI followed by Cotoran or Reflex PRE or Prowl + Cotoran or Reflex PRE	MSMA + Cotoran, or Caparol, only as a directed application	MSMA + Caparol MSMA + Direx MSMA + Layby Pro MSMA + Valor

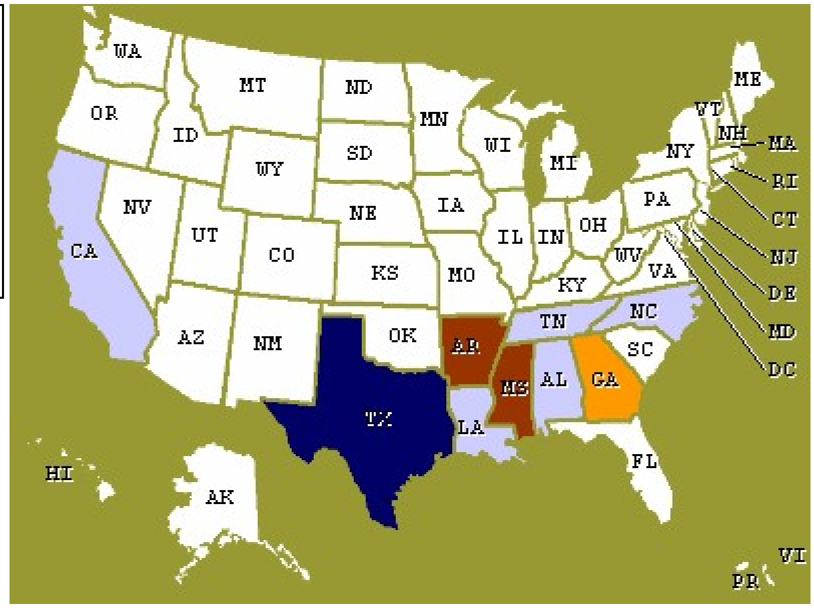
[1]This table from Burgos, et al. (Burgos, Culpepper et al. 2006) was modified to exclude the Liberty Link cotton product. All products are registered trademarks of respective companies.
[2]For glyphosate-resistant Palmer amaranth, hooded sprays with paraquat mixtures, cultivation, and/or hand weeding will often be required.
[3]Herbicide labels vary among regions. Follow labels for soils and regions. Note that in Texas west of I-35, Reflex (Syngenta) cannot be used preemergence, and Suprend (Syngenta) cannot be used postemergence – use as directed.
[4]ALS = Acetolactate Synthase Inhibitors
[5]Limit Staple (DuPont) use to once per season

3. Glyphosate Use on Cotton in the Cotton Belt

The use of the herbicide, glyphosate, is directly proportional to the amount of cotton each state produces (x1000 lbs, Figure 1). As of initial publication of this draft EA, the year 2005 was the latest data available for the major cotton-producing states from the National Agricultural Statistics Service (NASS) Agricultural Chemical Use Database. The 2005 data shows that Texas uses the most glyphosate followed by Arkansas and Mississippi, Georgia, North Carolina, Tennessee, Louisiana and California. This data mirrors the amounts of cotton produced in these states as reported by Cotton Council International (www.cottonusa.org). As of November 2008, U.S. cotton crop declined 30 percent (5.7 million bales) lower than a year earlier at 13.5 million bales (Meyer, MacDonald et al. 2008). The top cotton-producing states were Texas, Georgia, Arkansas, North Carolina, and Missouri (Meyer, MacDonald et al. 2008). The total glyphosate (including all forms) applied to cotton (x1000 lbs) were Texas 7,285, Georgia 1,647, Arkansas 1,730, North Carolina 951, and Missouri 868 (USDA-NASS 2008).

Figure 1. 2005 Glyphosate Use in the Major Cotton-producing States (x1000 lbs)

Color	Equal To/ Greater Than	But Less Than
	No Data	
	278.0	1141.0
	1141.0	2004.0
	2004.0	2867.0
	2867.0	3730.0



4. Glyphosate Tolerant Plants and Effects on Humans, Animals and Plants

The glyphosate herbicide (N-phosphonomethyl-glycine) is registered with the Environmental Protection Agency (EPA) for non-selective weed control on both non-food use and food use plants. Glyphosate tolerance in a plant is made by mutating the *EPSPS* gene. All plants contain the *EPSPS* gene. This gene makes enzyme, 5-enolpyruvyl-3-phosphoshikimate acid synthase (EPSPS). Without this enzyme, the plant cannot process aromatic amino acids (phenylalanine, tryptophan, and tyrosine and some secondary metabolites) and the plant dies. The herbicide glyphosate functions due to its resemblance to the structure of the substrate for EPSPS enzyme and thereby competing with this substrate for the enzyme's active site, thus preventing the synthesis of aromatic amino acids[3] (and killing the plant). Animals (including humans) do not have this EPSPS enzyme and obtain aromatic amino acids from their diet. Consequently, all animals (including humans) are naturally exposed to sources of EPSPS by ingesting plant materials.

GM feed is digested by animals in the same way as conventional feed. Food from animals fed on authorized GM crops is considered to be as safe as food from animals fed on non-GM crops. In a statement published on 19 July 2007, European Food Safety Authority (EFSA) advised that 'Biologically active genes and proteins are common constituents of food and feed in varying amounts. After ingestion, a rapid degradation into short DNA or peptide fragments is observed in the gastrointestinal tract of animals and humans. To date, a large number of experimental studies with livestock have shown that recombinant DNA fragments or proteins derived from GM plants have not been detected in tissues, fluids or edible products of farm animals like broilers, cattle, pigs or quails' (EFSA 2007).

[3] A more comprehensive explanation of the mechanism for glyphosate can be found in Appendix B.

III. Alternatives

This EA analyzes the potential environmental consequences of a proposal to deregulate GlyTol™ cotton. Two alternatives are considered in this EA: (1) no action, and (2) to grant the deregulated status for GlyTol™ cotton. One other alternative was considered and dismissed: the approval of the petition with geographic restrictions (approval of the petition, in part). This alternative is only available when supporting data is not sufficient to determine that GlyTol™ cotton is unlikely to present a greater plant pest risk than the unmodified organism in certain geographical areas. The analysis provided in the risk assessment (Appendix A) shows that there was sufficient data to determine that GlyTol™ cotton does not pose a pest risk. APHIS was not able to envision a scenario upon which mitigation of any plant pest risk posed by this cotton would be necessary. The company has provided sufficient data describing GlyTol™ cotton agronomic traits and there was no evidence to suggest that there is a greater risk of it being a plant pest in a specific geographic location.

A. No Action

Under the no action alternative, APHIS would not deregulate GlyTol™ cotton. As such, GlyTol™ cotton would not be available to the general public in the marketplace as a choice of available glyphosate tolerant cotton. Bayer CropScience would have to continue to request permits and notifications for field tests of GlyTol™ cotton. APHIS' review of the petition together with scientific literature has lead to a finding that there is sufficient evidence to demonstrate the lack of a plant pest risk. Choosing the no action alternative would not meet the purpose and need of this action because it does not allow for the safe development and use of genetically engineered plants.

B. Preferred Alternative

Under the preferred alternative, APHIS would grant the petition for deregulation status for GlyTol™ cotton. Under this alternative, GlyTol™ cotton (event GHB614) would no longer be a regulated article under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of GlyTol™ cotton derived from these events. This product would be used as an alternative market choice that provides an established weed management tool to producers. This alternative would meet the purpose to allow for the safe development and use of genetically engineered plants by deregulating GlyTol™ cotton which has been proven not pose a plant pest risk (see Appendix A).

IV. Environmental Consequences

A. No Action

Under the no action alternative, the product would not be available for the consumer in the marketplace. GlyTol™ cotton would continue to be regulated under permits and notifications by APHIS, BRS.

1. Glyphosate Use on Cotton in the Cotton Belt

If APHIS does not approve the deregulation of GlyTol™ cotton, genetically engineered cotton that is glyphosate-tolerant would continue to be planted in the cotton belt with the continuing trends in herbicide use. The glyphosate tolerant cotton from Monsanto (Roundup Ready® cotton) would continue to be planted. Table 3 shows the herbicide usage trends in cotton since 1997. Data shown is in two year increments NASS surveys are done every two years. APHIS believes the trends for glyphosate usage will continue to increase even if GlyTol™ cotton is not deregulated because its sister product (Roundup Ready® cotton) would continue to dominate the market as it has for the past 11 years. Denying the deregulation of GlyTol™ cotton would not meet APHIS, BRS' mission to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of genetically engineered organisms as APHIS has determined that GlyTol™ cotton does not pose a plant pest risk (see Appendix A).

Amended Table 3. Herbicide Usage Trends in Cotton from 1997 – 2007

Herbicide	1997		2001		2003		2005		2007	
	%Area Treated	Active Ingredient 1000 lb/yr	%Area Treated	Active Ingredient 1000 lb/yr	%Area Treated	Active Ingredient 1000 lbs/yr	%Area Treated	Active Ingredient 1000 lb/yr	%Area Treated	Active Ingredient 1000 lb/yr
Glyphosate	14	1,542	57	8,514	69	12,635	71	14,112	91	17,311[e]
Trifluralin	55	5,461	30	3,066	39	4,156	32	3,522	29	2,763
Diuron	12	883	26	1,545	28	1,738	27	1,707	26	1,325
Pendimethalin	28	2,491	16	1,651	20	1,813	12	1,211	17	1,451
Pyrithiobac-sodium	23	171	10	85	12	124	9	50	10	57
Prometryn	19	1,669	12	1,292	11	1,175	7	669	7	640
Fluometuron	44	4,847	10	977	8	755	5	487	4	277
MSMA/DSMA	33	4,899	11	1,834	7	1,157	6	937	3	380
Metolachlor [a]	5	735	4	419	5	591	6	847	8	277
Clomazone	8	500	NS[c]	NS	<0.5	16	<0.5	12	<0.5	2
Clethodim	2	37	2	28	<0.5	14	1	19	<0.5	4
States surveyed[b]	AL, AZ, AR, CA, GA, LA, MS, MO, NC, SC, TN, TX		AL, AZ, AR, CA, GA, LA, MS, MO, NC, SC, TN, TX		AL, AZ, AR, CA, GA, LA, MS, MO, NC, SC, TN, TX		AL, AR, CA, GA, LA, MS, NC, SC, TN, TX		AL, AR, CA, GA, LA, MO, NC, TN, TX	
Acreage represented in survey[b]	13,075,000 (96%)		12,680,000 (93%)		12,795,000 (90%)		12,425,000 (89%)		10,240,000 (94%)	
Total planted cotton acreage[d]	13,898,000		15,768,500		13,479,600		14,245,200		10,800,000	

[a]Includes both racemic and S-forms of metolachlor.
[b]USDA-NASS, 2007. Agricultural Chemical Usage Database. (http://www.pestmanagement.info/nass/app_usage.cfm)
[c]NS = not surveyed
[d]USDA-NASS, 2007. Cotton, National Statistics Database. (http://www.nass.usda.gov/QuickStats/index2.jsp)
[e] Includes glyphosate, glyphosate amm. salt and glyphosate iso. salt

2. Glyphosate Tolerant Cotton and its Effects on Humans, Animals and Plants

The first glyphosate tolerant cotton to be deregulated by APHIS was Roundup Ready® cotton lines 1445 and 1698, which were submitted as Petition 95-045-01p by Monsanto and deregulated by APHIS in July, 1995. This event was the result of incorporating the gene coding for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (*EPSPS*) gene derived from *Agrobacterium* sp. strain CP4, a common soil bacterium. For the past 11 years, utilization of a glyphosate herbicide plus Roundup Ready® cotton has provided another tool to use in weed control and encouraged the use of conservation-tillage[4] (Brookes and Barfoot 2006). In 1997, Monsanto submitted a petition to deregulate glyphosate-resistant *Zea mays* (corn) with a modified corn EPSPS protein (mEPSPS) (Event GA21; APHIS petition number 97-099-01). This product was deregulated by APHIS in 1998 and approved by Canada for food use in October 1999, demonstrating a 9 year history of safe usage for the corn EPSPS protein[5].

Glyphosate tolerant cotton has been on the market since its deregulation in 1997 after extensive testing by Monsanto and evaluation by APHIS, EPA and FDA. The use of glyphosate tolerant cotton for the past 11 years has continually demonstrated the safety and effectiveness of this weed management tool and has had no known adverse effects on animals (including humans). Choosing the No Action alternative and preventing the deregulation of GlyTol™ cotton would not affect the history of safe use of glyphosate tolerant cotton and Roundup Ready® cotton would continue to dominate the marketplace.

B. Preferred Alternative

Under this alternative, GlyTol™ cotton would be deregulated by APHIS and allowed to compete with its sister product in the marketplace. This alternative would meet APHIS, BRS' mission to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of genetically engineered organisms based on the designation that this article does not pose a plant pest risk (see Appendix A).

1. Glyphosate Use on Cotton in the Cotton Belt

Widespread use of GlyTol™ cotton is not expected to have an impact on typical cotton production since its sister product has been in use for the past 11 years as a successful weed management tool. Since glyphosate-resistant cotton has been on the market so long, it is believed that market saturation has already occurred with this type of product (USDA-NASS 2007). According to the 2005 surveys (USDA-NASS 2007), the market trend is for a product that contains both insect and herbicide resistance in cotton.

The introduction of this product into the market will allow consumers a choice in brand names and is not expected to increase cotton acreage. Other than the glyphosate-resistant gene, the GlyTol™ cotton plant will not produce any other substance that is not normally produced by cotton plants, nor is the composition of the cotton boll produced by these plants different from unmodified cotton. Therefore, APHIS does not expect accumulation of a novel substance in soil,

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[4] Conservation-tillage refers to growing crops with minimal cultivation of soil. New crops are planted into the small strips of tilled soil. Weeds are controlled with cover crops or herbicides rather than plowing or disking plant remains from previous crops into the top soil.

[5] More information on glyphosate and the *EPSPS* gene can be found in Appendix B.

nor does APHIS expect impacts on organisms living in and around cotton production areas because of exposure to GlyTol™ cotton plants.

2. GlyTol™ Cotton and Its Effects on Humans, Animals and Plants

GlyTol™ cotton contains a mutated corn *EPSPS* and its protein differs from the native protein by only two amino acids (Table 8, p.40 of submitted petition). The 2mEPSPS protein has no amino acid sequence similarity to known allergens or toxins. Bayer CropScience has conducted a detailed safety evaluation on the Codex Alimentarius Commission's (Codex 2003) database that included homology searches of allergen databases, *in vitro* digestibility assay and acute toxicity testing in mice.

APHIS authorized the first field testing of the BCS GlyTol™ cotton plants starting in 2002 and they have been field tested in the United States under the APHIS authorization numbers noted in the petition 06-332-01p, Appendix 1 pages 86-105. GlyTol™ cotton plants have been evaluated extensively to confirm that they exhibit the desired agronomic characteristics, that tolerance to glyphosate is stable under field conditions and that they do not present a plant pest risk (petition 06-332-01p, p.126-132). The field tests have been conducted in agricultural settings under physical and reproductive confinement conditions. Plant pest risks are discussed in this EA in Appendix A.

APHIS considered the agronomic data that was submitted by the developer (Section VIII, pg 43-63 of the petition), as well as the cooperating growers' visual field observations to determine if there were changes to non-target species associated with glyphosate-resistant cotton. A comparison of the compositional analysis on the plants containing 2mEPSPS protein with their non-transgenic counterparts indicated no significant changes in the overall gossypol content of the plants or anti-nutrient levels between GlyTol™ cotton event GHB614 and the non-transgenic counterpart (Section VIII.I of the petition). Gossypol is a natural toxin present in cotton and in large amounts is toxic to livestock and humans. For this reason, there are limits to the amount of cotton meal given to livestock and cotton seed oil must be refined before food use. The GlyTol™ cotton plants do not express additional proteins, natural toxicants, pheromones, hormones, etc. that could directly or indirectly result in killing or interfering with the normal growth, development, or behavior of a non-target species. Cooperative growers did not report any visual differences in bird, insect, or other non-target populations between GlyTol™ cotton event GHB614 and its non-transgenic counterpart. Field observations are summarized in termination reports located in Appendix I of the petition.

APHIS further considered the biology of the GlyTol™ cotton with respect to its potential to affect non-target organisms such as beneficial insects (including pollinators such as bees), and biocontrol organisms. No differences between the transgenic and non-transgenic cotton in the flower morphology or time to bloom were found. Additionally the 2mEPSPS protein is expressed at a very low level in cotton pollen (0.16 µg/g fresh weight; p37 in submitted petition). Because no other changes in the bloom pattern or toxicity of the cotton plant were found, it is not anticipated that pollinating species, primarily insects, would be impacted by GlyTol™ cotton. No differences in the development or morphology between the transgenic and non-transgenic cotton lines were found which would indicate any adverse impact on foliar beneficial insects. Because no changes in the overall gossypol content and anti-nutrient levels of the plant were detected, it is not anticipated that the GlyTol™ cotton event GHB614 has a higher degree of risk from the toxin gossypol than non-transformed cotton.

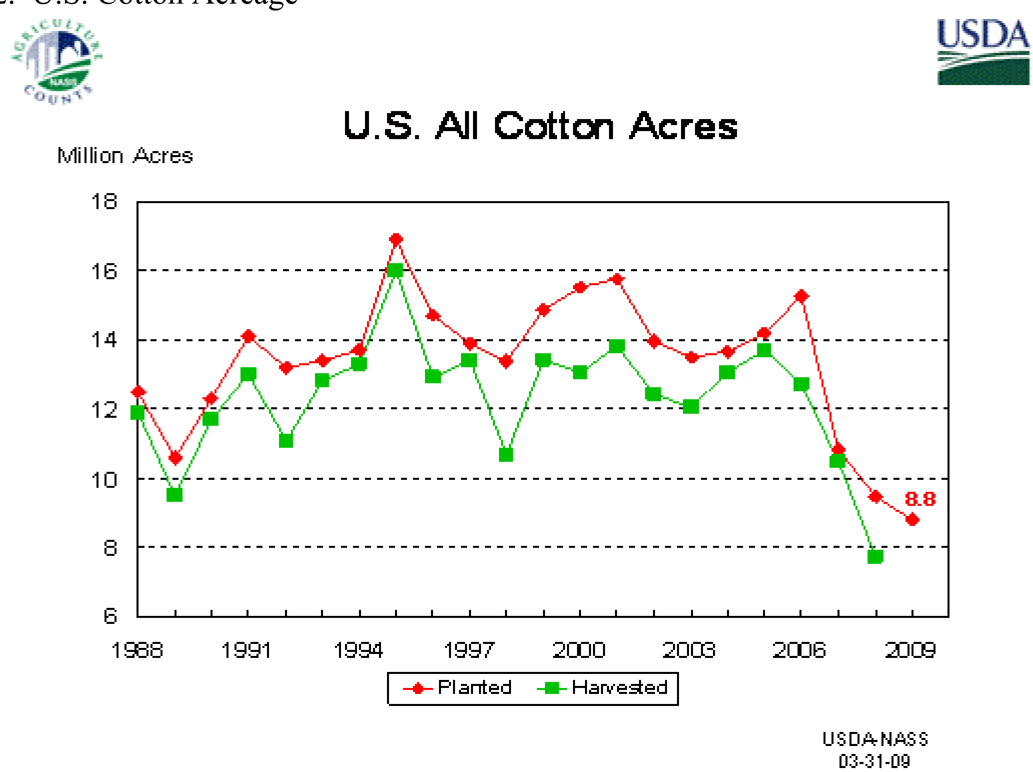
C. Cumulative Effects

APHIS considered whether the proposed action could lead to cumulative impacts, when considered in light of other past, present, and reasonably foreseeable future actions, regardless of what agency or person undertakes such actions.

1. Cotton

Typically, cotton production occurs on land that has been dedicated to agricultural use for greater than three years and has 180 frost-free days. As with most cotton production, it is seasonally rotated with soybeans, corn or cereal crops and would normally include the use of resources to limit the growth of weeds, limit the potential impact caused by insects, animals or disease, and to maximize production (Endrizzi, Turcotte et al. 1984). In 2008, 86% of the cotton acreage was planted to all GE varieties (this includes herbicide tolerant and insect tolerant), about 92% of the soybean acreage was planted to all GE varieties, and about 80% of the corn acreage was planted to all GE varieties (http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable1.htm). Currently, there is no GE wheat or barley available on the market. Deregulation of GlyTol™ cotton is not a product expected to have any additive effects by increasing cotton acreage, but rather will provide farmers and other consumers of cotton seeds with an additional choice of GE cotton product. Due to the planting of higher paying crops destined for biofuels and the lower price of cotton, the total cotton acreage planted in 2008-2009 decreased 56% from 2006 (Figure 2, http://www.nass.usda.gov/Charts_and_Maps/Field_Crops/cotnac.asp).

Figure 2. U.S. Cotton Acreage



2. Weed Competition and Control

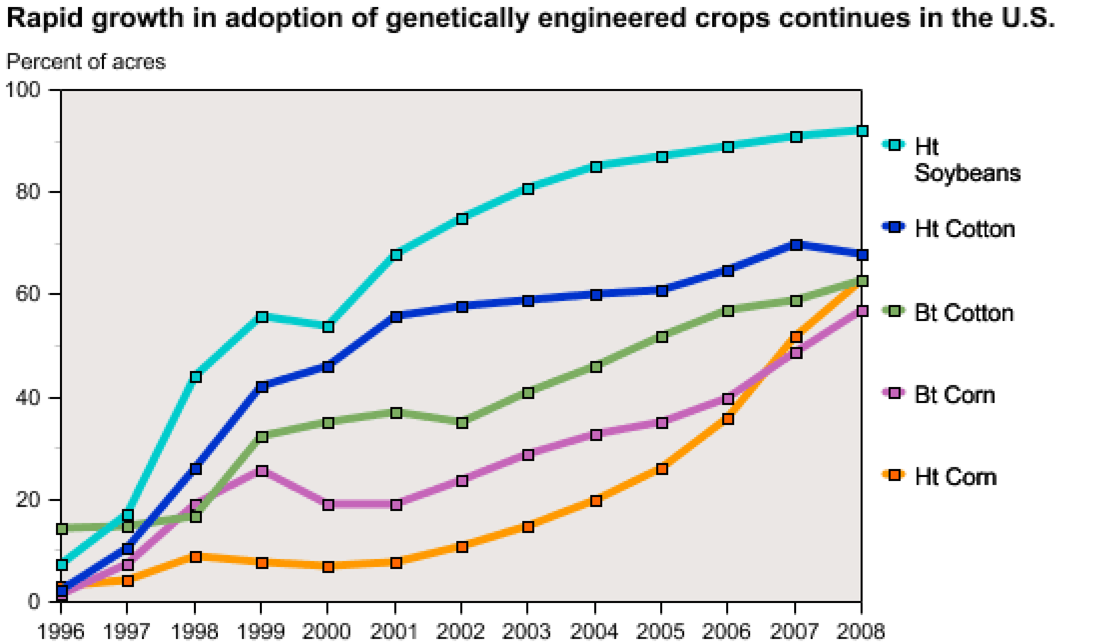
Along with the increasing adoption of these GE crops there is an increasing use of the herbicide glyphosate and the associated decreasing use of other herbicides (see Table 3 for an example how cotton has been affected). Compared to the herbicides it replaces, the glyphosate used on these crops is less toxic to humans and not as likely to persist in the environment as the herbicides it replaces (IPCS 1994; Fernandez-Cornejo and Caswell 2006). The total amount of glyphosate used on GE cotton is not expected to increase with the deregulation of GlyTol™ cotton because the product provides consumers with a choice of GE cotton seed to purchase, and the adoption of glyphosate-tolerant cotton is believed to have reached its maximum market potential (USDA-NASS 2007). APHIS, BRS does not foresee any increased glyphosate use by the addition of GlyTol™ cotton to the market.

As discussed above in the background information, economical weed control in cotton needs an integrated weed management (IWM) strategy to minimize the development of herbicide-resistant weeds. Continuous use of one product to control weeds will select for weed types that are not affected by that one product. Effective management of competitive weeds in cotton requires the use of many tools that include cultural, mechanical, biological and chemical means. There are many websites on IWM (two of which are mentioned above) that provide easy to follow information on how to use glyphosate-resistant cotton, along with other management tools, to control weeds economically.

3. Glyphosate Use on All Major GE Crops in the Cotton Belt

According to data supplied by the USDA Economic Research Service (ERS), U.S. farmers have adopted genetically engineered (GE) crops widely since their introduction in 1996. Soybeans and cotton genetically engineered with herbicide-tolerant (HT) traits have been the most widely and rapidly adopted GE crops in the U.S., followed by insect-resistant cotton and corn (Figure 3, Bt refers to GE protein that is expressed in these insect-resistance crops isolated from *Bacillus thuringiensis*).

Amended Figure 3



Data for each crop category include varieties with both HT and Bt (stacked) traits. Source USDA ERS.

Herbicide-tolerant crops (all herbicide tolerant traits, not just glyphosate tolerance) provide farmers with a broader variety of options for effective weed control. Based on USDA-ERS survey data, HT soybeans went from 17 percent of U.S. soybean acreage in 1997 to 68 percent in 2001 to 95 percent in 2008. Plantings of HT cotton expanded from 10 percent of U.S. acreage in 1997 to 56 percent in 2001 and 70 percent in 2007, but decreasing in 2008. Plantings of Bt cotton expanded more rapidly, from 15 percent in 1997 to 63 percent in 2008. The adoption of HT corn, which had been slower in previous years, has accelerated, reaching 60 percent of U.S. corn acreage in 2008.

Looking at data from 1997 (a year after adoption of GE crops) until 2007 (most recent data available through National Agricultural Statistics Service, http://www.pestmanagement.info/nass/app_usage.cfm), total herbicide use on corn, cotton and soybeans in the U.S. has not shown dramatic increases or decreases; however, glyphosate use has increased during that time (Tables 5 and 6, 7 and 8, respectively).

Since the publication (May 16, 2008) of the draft EA, NASS has released additional data for cotton. Tables 5 and 6 are amended to show the additional data. Public comment requested that the acreage be represented in the trend data for better accuracy. APHIS created Tables 7 and 8 to show the same data as active ingredient (a.i.) per acre for all herbicides and glyphosate, respectively, instead of total poundage per year. The tables appeared to confuse one public commenter, so APHIS has made a graphical representation of Tables 7 and 8 and listed them as Figure 4 and 5 below. The dotted lines indicate the trends for herbicide and glyphosate use.

Amended Table 5. Total Herbicide Usage Trends for Corn, Cotton and Soybean from 1997 – 2007

	Herbicides – Total Active Ingredient x1000 lbs/year										
Crop	**1997**	**1998**	**1999**	**2000**	**2001[a]**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007[b]**
Corn	164051	177012	154059	153464	157239	95777	149136	NA	157575	NA	NA
Cotton	27611	22206	25006	26554	NA	21098	25542	NA	25733	NA	26,214
Soybean	78207	71437	70729	75164	50464	86742	NA	70828	77187	NA	NA

NA = data not available
[a]NASS separated only the mono and diammonium salts out beginning this year. Both chemicals are included in this number
[b]NASS did not separate out glyphosate, glyphosate amm. salt and glyphosate iso. salt out for all surveyed states until this yr., all three chemicals are included in this number.

Amended Table 6. Glyphosate Usage Trends for Corn, Cotton and Soybean from 1997 – 2007

	Glyphosate – Total Active Ingredient (x1000 lbs/year)										
Crop	**1997**	**1998**	**1999**	**2000**	**2001[a]**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007[b]**
Corn	1429	2601	4162	4438	6868	3307	11913	NA	NA	NA	NA
Cotton	1542	3726	5122	9529	8514	NA	12635	NA	14112	NA	17311[a]
Soybean	14915	28123	38447	41847	32806	59962	NA	57701	NA	88903	NA

NA = data not available
[a]NASS separated only the mono and diammonium salts out beginning this year. Both chemicals are included in this number
[b]NASS did not separate out glyphosate, glyphosate amm. salt and glyphosate iso. salt out for all surveyed states until this yr., all three chemicals are included in this number.

New Table 7. Total Herbicide Usage Trends (active ingredient per acre for Corn, Cotton and Soybean from 1997 - 2007

Crop	**1997**	**1998**	**1999**	**2000**	**2001[a]**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007[b]**
Corn											
Herbicides (a.i.x1000 lb)	164051	177012	154059	153464	157239	95777	149136	NA	157575	NA	NA
% of total acres	96	96	98	97	98	89	95	NA	97	NA	NA
Total ac planted (x1000)	79,537	80,165	77,386	79,551	75,702	78,894	78,603	80,929	81,779	78,327	93,600
Cotton											
Herbicides (a.i.x1000 lb)	27611	22206	25006	26554	21098	NA	25542	NA	25733	NA	26,214
% of total acres	97	99	97	95	90	NA	98	NA	95	NA	97
Total ac planted (x1000)	13,898	13,393	14,874	15,517	15,769	13,958	13,480	13,659	14,245	15,274	10,240
Soybean											
Herbicides (a.i.x1000 lb)	78207	71437	70729	75164	50464	86742	NA	70828	77187	NA	NA
% of total acres	97	95	96	97	96	99	NA	97	98	NA	NA
Total ac planted (x1000)	70,005	72,025	73,730	74,266	74,075	73,963	73,404	75,208	72,032	75,522	64,736

NA = data not available
[a]NASS separated only the mono and diammonium salts out beginning this year. Both chemicals are included in this number
[b]NASS did not separate out glyphosate, glyphosate amm. salt and glyphosate iso. salt out for all surveyed states until this yr., all three chemicals are included in this number.

New Table 8. Glyphosate Usage Trends (active ingredient per acre) for Corn, Cotton and Soybean from 1997 – 2007

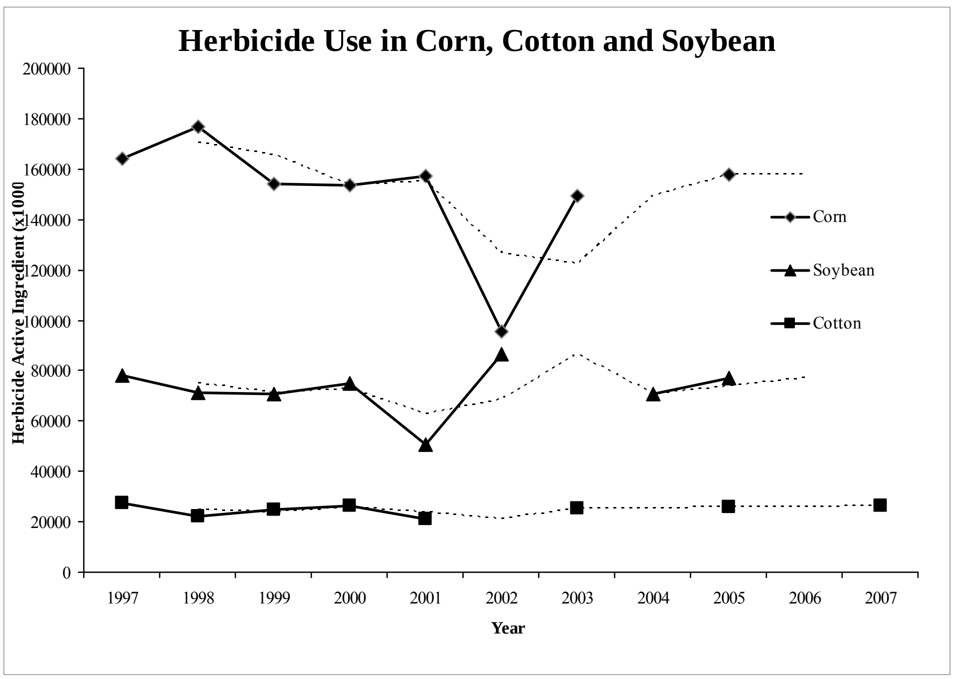
Crop	1997	1998	1999	2000	2001[a]	2002	2003	2004	2005	2006	2007[b]
Corn Glyphosate (a.i.x1000 lb) % of total acres Total ac planted (x1000)	 1429 4 79,537	 2601 5 80,165	 4162 9 77,386	 4438 9 79,551	 6868 13 75,702	 3307 9 78,894	 11913 19 78,603	 NA NA 80,929	 NA 33 81,779	 NA NA 78,327	 NA NA 93,600
Cotton Glyphosate (a.i.x1000 lb) % of total acres Total ac planted (x1000)	 1542 14 13,898	 3726 30 13,393	 5122 36 14,874	 9529 56 15,517	 8514 57 15,769	 NA NA 13,958	 12635 70 13,480	 NA NA 13,659	 14112 74 14,245	 NA NA 15,274	 NA 91 10,240
Soybean Glyphosate (a.i.x1000 lb) % of total acres Total ac planted (x1000)	 14915 28 70,005	 2812 46 72,025	 38447 62 73,730	 41847 62 74,266	 32806 73 74,075	 59962 78 73,963	 NA NA 73,404	 57701 89 75,208	 NA NA 72,032	 88903 96 75,522	 NA NA 64,736

NA = data not available

[a]NASS separated only the mono and diammonium salts out beginning this year. Both chemicals are included in this number

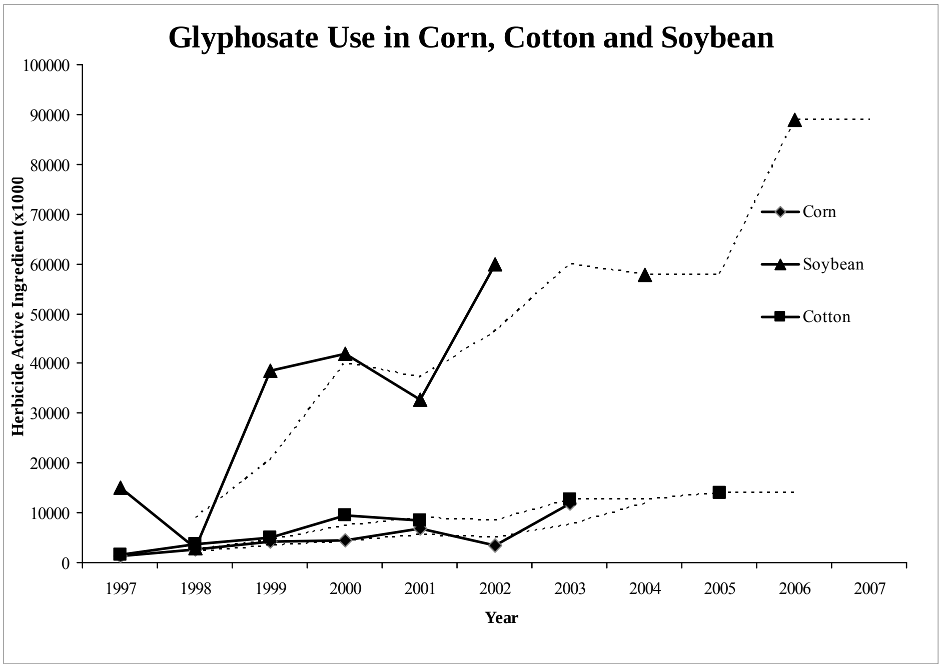
[b]NASS did not separate out glyphosate, glyphosate amm. salt and glyphosate iso. salt out for all surveyed states until this yr., all three chemicals are included in this number.

New Figure 4. Data from Table 7



Total herbicide use trends active ingredient per acre are seen as dotted lines and plotted as a moving average in MS Excel. This graph takes into account the year to year variation in acreage in NASS surveys.

New Figure 5. Data from Table 8

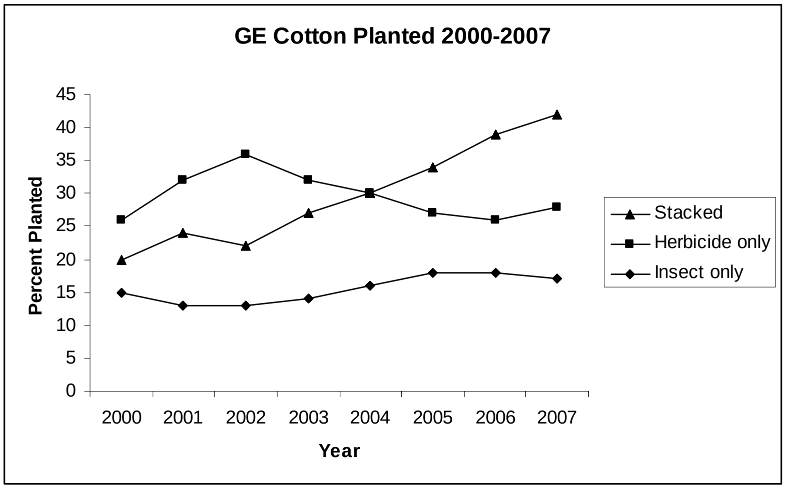


Total glyphosate use trends active ingredient per acre are seen as dotted lines and plotted as a moving average in MS Excel. This graph takes into account the year to year variation in acreage in NASS surveys.

The increased use of glyphosate has been a trend in all major crops due to its low cost and low toxicity to applicators (Sankula, Marmon et al. 2005).

There is an increased trend for the use of the stacked GE cotton traits that contain both insect-tolerant and herbicide-tolerant genes over purely herbicide-tolerant cotton (Fernandez-Cornejo and Caswell 2006) will exist as a consumer choice in a market that has already reached its saturation (USDA-NASS 2007). As seen in Figure 6, use of stacked traits in GE cotton (insect- and herbicide-tolerance) is showing an increase, the adoption rates of a purely herbicide-tolerant or insect-tolerant cotton product use is static or declining (Fernandez-Cornejo and Caswell 2006). It is likely that GlyTol™ cotton could be conventionally bred to an insect-tolerant cotton variety in the future. There is the potential that glyphosate use could increase as much as 13% based on the current adoption rates of stacked gene constructs that contain both insect- and herbicide-tolerant GE cotton. These trends will continue to occur in the future whether GlyTol™ cotton is granted deregulation status or not. GlyTol™ cotton's contribution to these continuing trends will be the addition of a consumer choice. APHIS, BRS does not believe that glyphosate use on any rotated crops within the Cotton Belt will be impacted by the deregulation of GlyTol™ cotton and the herbicide usage trends will continue whether this product is deregulated or not.

New Figure 6. Types of GE Cotton Planted, 2000-2007



Percentage of GE varieties of Upland cotton acreage planted for years 2000-2007. Data source "Cotton Varieties Planted, 2008 Crop", USDA AMS.

4. Glyphosate Tolerant Cotton and Effects on Humans, Animals and Plants

Data supplied by the applicant, including the results of 11 years of glyphosate-resistant cotton already on the market, suggests that GlyTol™ cotton has not had observable or measurable impacts on the ecosystems in which it has been allowed to grow. This data can be found in the Section IX of the petition application. Another source evaluating the minimal environmental impacts of glyphosate can be found in the International Programme on Chemical Safety on Glyphosate (IPCS 1994).

Currently, APHIS, BRS does not have any other herbicide tolerant cotton applications for deregulation. APHIS, BRS does have an insect-tolerant cotton application for deregulation by another company (http://www.aphis.usda.gov/brs/not_reg.html). The deregulation of BCS' GlyTol™ cotton is not dependent upon the deregulation of the insect-tolerant cotton.

Based upon available information, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources (soil, water, ecosystem quality, biodiversity, etc.) associated with the ecosystem in which GlyTol™ cotton is planted. No resources will be impacted due to cumulative impacts resulting from the proposed action.

5. Other Authorities

U.S. Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) Regulatory Authorities

In 1986, the Federal Government's Office of Science and Technology Policy (OSTP) published a policy document known as the Coordinated Framework for the Regulation of Biotechnology. This document specifies three Federal agencies that are responsible for regulating biotechnology in the United States: the U.S. Department of Agriculture's (USDA) Animal and Plant Health

Inspection Service (APHIS), the Environmental Protection Agency (EPA), and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA). Products are regulated according to their intended use, and some products are regulated by more than one agency. Together, these agencies ensure that the products of modern biotechnology are safe to grow, safe to eat, and safe for the environment. USDA, EPA, and FDA apply regulations to biotechnology that are based on the specific nature of each GE organism.

The U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides and GE biopesticide products, be registered prior to distribution or sale, unless exempt by EPA regulation. In order to be registered as a pesticide under FIFRA, it must be demonstrated that when used with common practices, a pesticide will not cause unreasonable adverse effects in the environment. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA, and the U.S. Food and Drug Administration (FDA) enforce the tolerances set by EPA. Bayer submitted the appropriate regulatory package to EPA for registering the use of glyphosate herbicide on GBH614 cotton. Safe use of glyphosate has been established by the EPA through the registration of glyphosate for use on cotton and the setting of tolerances for the herbicide (EPA 2007).

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, and appears at 57 FR 22984-23005. Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food. Cotton seed oil is used in the food industry and cotton seed meal is an excellent source of protein and used in animal feed. In compliance with the FDA policy, BCS has submitted a food and feed safety and nutritional assessment summary for GlyTol™ cotton to the FDA. FDA announced the completion of Bayer's consultation for GlyTol™ cotton, event GHB614 (See BNF No. 109, http://www.cfsan.fda.gov/~lrd/biocon.html) on August 29, 2008 for use in human food and animal feed. The European Food Safety Authority also approved Bayer CropScience GlyTol™ cotton event GHB614 for food and feed uses, import and processing under Regulation (EC) No. 1829/2003 on March 5, 2009 (reference EFSA-GMO-NL-2008-51).

D. Highly Uncertain or Involve Unique or Unknown Risks

The NEPA implementing regulations require consideration of the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risk (40 CFR § 1508.27(b)(5)). None of the effects on the human environment identified above are highly controversial, highly uncertain, or involve unique or unknown risks. The effects are similar in kind to (and no worse than) those already observed for currently commercially available and widely grown glyphosate tolerant cotton varieties and to those observed for the use of glyphosate and several other herbicides in agriculture production systems.

E. Threatened and Endangered Species

In addition to the analysis of potential impact to non-target organisms described above (Section II, A, 4), APHIS also considered potential impact on TES. In this analysis, APHIS considered the biology of the glyphosate-resistant cotton, as well as typical agricultural practices associated with cultivation of cotton. As mentioned previously, GlyTol™ cotton differs from non-transgenic cotton only in the expression of the 2mEPSPS gene that is responsible for glyphosate resistance and which differs only from the native corn *EPSPS* gene by two amino acids. The GlyTol™ cotton plants do not express additional proteins, natural toxicants, pheromones, hormones, etc. that could directly or indirectly result in killing or interfering with the normal growth, development, or behavior of a TES or endangered species or species proposed for listing. The GlyTol™ cotton plant is not sexually compatible with a federally listed TES or a species proposed for listing and therefore, would not be integrated into a threatened and endangered species' genetic material. Finally, cultivation of GlyTol™ cotton is not expected to differ from typical cotton cultivation. Cotton does not typically grow in unmanaged habitat and would not be expected to invade and/or persist in the natural environment. GlyTol™ cotton is being presented as an additional consumer choice to the market that has already been saturated with Roundup Ready® (glyphosate tolerant) cotton for the past 11 years (USDA-NASS 2007). Therefore, no additional acreage of glyphosate tolerant cotton is expected due to the deregulation of this product. GlyTol™ cotton is not expected to be grown in any new type of habitat which would include those inhabited by TES species.

As required by Section 7 of the Endangered Species Act, APHIS has analyzed the best available data (current scientific literature, historical data, data supplied in the petition by BCS and information from the FWS TES website) and has reached a determination that granting a petition to deregulate glyphosate-resistant cotton (application #06-332-01p) will have "no effect" on federally listed threatened and endangered species or designated critical habitat or habitat proposed for designation. The data on mammalian toxicity allows APHIS to reach a "no effect" determination for the 358 mammals on the TES list plus the proposed mammals for the TES list. Based on this analysis, there is no apparent potential for impact on non-target organisms, including beneficial organisms and no effect is expected on listed TES, species proposed for listing, or their proposed or designated critical habitat, if APHIS were to grant the petition for non-regulated status in whole.

In addition to APHIS' analysis of the data supplied by the applicant, the EPA has concluded that when used according to the label, the pesticide glyphosate does not have unreasonable adverse effects to human health or the environment. To make such determinations, EPA requires more than 100 different scientific studies and tests from applicants (http://www.epa.gov/pesticides/regulating/). Many plant and wildlife species can be found near or in cities, agricultural fields, and recreational areas. Before allowing a pesticide product to be sold on the market, EPA ensures that the pesticide will not pose any unreasonable risks to wildlife and the environment. EPA does this by evaluating data submitted in support of registration regarding the potential hazard that a pesticide may pose to non-target fish and wildlife species. In considering whether to register a pesticide, EPA conducts ecological risk assessments to determine what risks are posed by a pesticide and whether changes to the use or proposed use are necessary to protect the environment. A pesticide cannot be legally used if it has not been registered with EPA's Office of Pesticide Programs.

Based on the continued use of glyphosate-tolerant cotton for the past 11 years and the data presented by the developer for GlyTol™ cotton as well as a thorough scientific literature search, APHIS believes there would be no impact on non-target organisms or Federally-listed threatened or endangered species if this product is deregulated.

F. Other Considerations

1. Biodiversity

Analysis of available information indicates that BCS' glyphosate-tolerant GE cotton does not exhibit traits that would cause increased weediness; nor should it lead to increased weediness of other cultivated cotton or other sexually compatible relatives. Furthermore, it is unlikely to harm non-target organisms common to the agricultural ecosystem or threatened or endangered species recognized by the U.S. Fish and Wildlife Service because of the information known about the EPSPS protein and its history of safe use for over a decade. There has been no intentional genetic change in these plants to affect their susceptibility to disease or insect damage. The glyphosate-tolerant gene is not expected to change any plant pest characteristics. There is no reason to believe that weediness or plant pest characteristics are different between the genetically engineered and non-engineered plants.

APHIS has concluded that gene transfer to wild cotton species in the United States is limited because of ploidy differences (Table 3, p.8-19 of petition or Table 4, p. 31), a lack of documented natural out-crossing, and the limited success of interspecific hybrids produced through controlled breeding (Niles and Feaster 1984; Jenkins 1993; Kareiva, Morris et al. 1994). Based on this reasoning, there is no apparent potential for impact to biodiversity if APHIS were to grant the petition for non-regulated status. The biodiversity of cotton germplasm (seed breeding material and seed varieties) would only be slightly enhanced by the addition of a different transformation event for glyphosate tolerant cotton should the petition for non-regulated status be granted.

2. Raw or Processed Agricultural Commodities

APHIS analysis of data on agronomic performance, disease and insect susceptibility, and compositional profiles of GlyTol™ cotton indicate no differences between this cotton and non-transgenic counterparts that would be expected to cause either a direct or indirect plant pest effect on any raw or processed plant commodity from deregulation of GlyTol™ cotton.

APHIS generally analyzes the transgenic line in comparison to the line or variety from which it was derived and/or to a range of conventional varieties. APHIS analyzes these comparisons to determine if GlyTol™ cotton has any pest characteristics greater than the recipient line or other conventional varieties and to determine if there may be any unintended effects from placing the transgene into GlyTol™ cotton. In the petition (06-332-01p, Section VIII and Appendixes 1-4), different comparisons were presented that ranged from plant growth, lodging, seed moisture content, seed weight, interactions with symbiotic nitrogen-fixing bacteria, response to naturally occurring abiotic stresses, and susceptibility to diseases and insects, and nutritional and anti-nutritional components. None of these comparisons provided any indication of increased pest characteristics or a possibility of an unintended effect that would have a bearing on the health or quality of any raw or processed agricultural commodity. A study comparing the seed composition between conventional soybeans and glyphosate-tolerant soybean found no differences between the two varieties (Padgette, Taylor et al. 1995). These types of studies and the comparator compositional analysis required by FDA and USDA have established that there are no differences between conventional crops and glyphosate-tolerant crops in the 11-year history of use. APHIS is not aware of any additional data that can provide appropriate information for making a proper and reasonable comparison to determine whether GlyTol™ cotton has the potential to impact the human environment.

While FDA is the agency responsible for determining food and feed safety, APHIS analyzed and considered the effects of the action alternatives on food safety as one aspect of public health consistent with APHIS' requirements under NEPA. APHIS reviewed the compositional test results of GlyTol™ cotton in comparison to the non-transformed recipient line and to conventional varieties as presented on p127 of the petition and found no differences between the transformed and non-transformed varieties. Food and feed from GlyTol™ cotton are the subject of a consultation under FDA's consultation procedures for foods derived from new plant varieties (http://www.cfsan.fda.gov). BCS has also applied for approval from Canadian and Mexican markets that would use herbicide-resistant cotton for food, feed or fiber. BCS will be applying for approval in the EU and Japan markets after U.S. approval. Currently, Monsanto's sister product has regulatory food and feed approval in Canada (although not grown in Canada), Australia (planting restricted south of 22^{o}S latitude), Japan, Korea, Mexico, Philippines, and the United States. Since this product is not new or novel and will be marketed as a consumer option, no new impacts from its raw or processed agricultural commodities are expected.

Based on APHIS' analysis, there is no apparent potential for impact to raw or processed agricultural commodities, and therefore there is unlikely to be an impact to public health through direct or indirect consumption of such products, if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no impact to raw or processed agricultural commodities since most of the present area of cotton production in the United States is already glyphosate tolerant varieties.

3. Current agricultural practices including organic farming

Use of glyphosate-tolerant cotton can provide positive impacts on agricultural practices. These positive impacts have been detailed in a study by Brookes and Barfoot (Brookes and Barfoot 2006) and include:

a) Improved weed control which reduces harvesting costs – cleaner crops have resulted in reduced times for harvesting.

b) Facilitates the use of no-till or reduced-till plowing.

c) Reduced fuel use from less frequent herbicide applications and a reduction in the energy use in soil cultivation.

GE crop technology has provided an additional tool for growers to control competing weeds, reducing the need to rely on soil cultivation and seed-bed preparation as means to getting good levels of weed control. The use of GE crop technology has also reduced the potential damage caused by soil-incorporated residual herbicides in follow-up crops. Under traditional herbicide applications with conventional crops, a post-emergent herbicide application may result in ‘knock-back’ (crop damage from the residual herbicide application); this problem is less likely to occur in GE herbicide-tolerant crops (Brookes and Barfoot 2006).

The adaptation of no-till or reduced till systems results in time savings and equipment usage. While no- or reduced-till systems are not new, the resultant weed control of GE herbicide-tolerant crops allows the farmer to continue with the no-till/reduced-till systems long after conventional crops necessitate going back to full plowing due to excessive weeds (Brookes and Barfoot 2006).

There are beneficial fuel savings associated with making fewer herbicide applications (relative to conventional crops) and the switch to reduced- and no-till farming systems. Brookes and Barfoot (Brookes and Barfoot 2006) determined that the fuel savings has also resulted in permanent savings in carbon dioxide emissions. In 2005 this amounted to about 2.1 billion pounds (arising from reduced fuel use of 94 million gallons).

> “Over the period 1996 to 2005 the cumulative permanent reduction in fuel use is estimated at 4,613 million kg [10.2 billion lbs] of carbon dioxide (arising from reduced fuel use of 1,679 million litres [443.5 million gallons]; the use of ‘no-till’ and ‘reduced-till’ farming systems. As a result, tractor fuel use for tillage is reduced, soil quality is enhanced and levels of soil erosion cut. In turn more carbon remains in the soil and this leads to lower GHG [greenhouse gas] emissions. In 2005, the permanent carbon dioxide savings from reduced fuel use were the equivalent of removing nearly 0.43 million cars from the road; Cumulatively since 1996, the permanent carbon dioxide savings from reduced fuel consumption since the introduction of GM crops are equal to removing 2.05 million cars from the road for one year. In total, the combined GM crop-related carbon dioxide emission savings from reduced fuel use and additional soil carbon sequestration in 2005 were equal to the removal from the roads of nearly 4 million cars” (Brookes and Barfoot 2006)

New data from Sainju, et. al (Sainju, Jabro et al. 2008) support Brookes and Barfoot that tillage or irrigation sharply increased the CO2 flux during the crop growing season and CO2 fluxes from croplands can be minimized by adopting no-tilled continuous crops with reduced N fertilization rate compared with other management practices.

According to Sankula (Sankula, Marmon et al. 2005), no-till cotton acres increased 371% from 1996 to 2004, while corn and soybeans increased no-till acreage by 20 and 64%, respectively. The availability of glyphosate and glufosinate-tolerant cotton systems serve as valuable tools in managing weed resistance and population shifts due to their diverse mechanisms of action (Sankula, Marmon et al. 2005). Quantification of the impacts of biotechnology-derived crops planted in 2006 can be found in the NCFAP report (NCFAP 2007) cited at the end of this document. In brief, production volumes were measured based on yield changes that occurred when the GE crops replaced existing crop production practices with adoption costs associated with the use of the technology taken into account and the changes in pesticide use were also considered. The report concluded that the average cost for weed control was $46.20 per acre. Weed management costs for the glyphosate-tolerant cotton averaged $31.66 per acre. The national impact of glyphosate-tolerant cotton weed management programs reduced the total cost of active ingredient used by $14.54 per acre; a savings of $228,934,000 for the total cost of weed control for all states. Similar data was complied for glufosinate-tolerant cotton (NCFAP 2007).

This same report also included reduction of tillage costs for all states by $74,551,000 for all states, citing the adoption of no-till or strip-tilling in recent years. Soil conservation saves approximately 1 billion tons of soil per year in the U.S. and 306 million gallons of tractor fuel and its related emissions. According to *Cotton Incorporated* researchers, conservation tillage practices as adopted in the U.S. from 1996-2004 have an effect on carbon dioxide reduction that is equivalent to removing 27,111 cars from the road. The *Environmental Impact Quotien*t (EIQ) developed at Cornell University can be used as a robust measure of environmental impact of technologies, as it incorporates key toxicity and environmental exposure data related to individual products (Kovach, Petzoldt et al. 2008). The EIQ has decreased by 17% in the U.S., largely due to advances in genetically modified cotton as it relates to pesticide use reduction along with air, water, and soil conservation; at the same time, yields have increased 25% from 1994-2004.

Clewis and Wilcut (Clewis and Wilcut 2007) researched the economic returns of transgenic and nontransgenic cotton systems and found that while effective weed management was obtained in both conventional and strip-tillage cotton production systems, glyphosate-tolerant system showed higher cotton yields and net returns while requiring minimal inputs of soil-applied herbicides.

The National Organic Program administered by USDA's Agricultural Marketing Service requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. Excluded methods include a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes. Organic certification involves oversight by an accredited certifying agent of the materials and practices used to produce or handle an organic agricultural product. This oversight includes an annual review of the certified operation's organic system plan and on-site inspections of the certified operation and its records. 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. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan. Organic certification of a production or handling operation is a process claim, not a product claim.

It is not likely that farmers, including organic farmers, who choose not to plant transgenic cotton varieties or sell transgenic cotton, will be significantly impacted by the expected commercial use of this product. Non-transgenic cotton will likely still be sold and will be readily available to those who wish to plant it. If BCS receives regulatory approval from all appropriate agencies, it will make the GlyTol™ cotton available to growers or breeders. As with other varieties of cotton, growers or breeders will inquire about the genetic background of this cotton variety and therefore know that this product is a transgenic glyphosate-resistant cotton.

In 2005, of the 13.7 million acres of cotton was grown in the United States (USDA-ERS 2005a), 9,537 acres (0.07%) were certified organic cotton (USDA-ERS 2005b). USDA-ERS organic cotton data for 2006-2008 were unavailable at this time of writing this EA. The Organic Trade Association (OTC) has the estimates for U.S. certified organic cotton acreage in 2006 as 5,971 acres and 2007 as 7,473 acres (http://www.ota.com/organic/environment/cotton_environment.html). In a 2007 study (Swezey, Goldman et al. 2007), it was estimated that over a 6-year period that cost per production of organic cotton per bale was 37% higher than conventional cotton due to greater hand-weeding costs and lower yields. There was also a lower lint quality due to coloration of the lint in organic cotton. The production prices and lower yields combined with lower prices for cotton were considered the primary obstacles for continued organic production in the study area (Northern San Joaquin Valley, CA).

It is not likely that organic farmers or other farmers who choose not to plant or sell GlyTol™ cotton or other transgenic cotton will be significantly impacted by the expected commercial use of this product as: (a) non-transgenic cotton will likely still be sold and will be readily available to those who wish to plant it; (b) cotton is a highly self-pollinated plant and therefore buffer requirements would be minimal in the absence of pollinators (Van Deynze, Sunderstrom et al. 2005); and (c) 87% of the 2007 cotton acreage in the United States is already planted with transgenic glyphosate-tolerant varieties (USDA-AMS 2008), (d) APHIS expects GlyTol™ cotton to replace some of the presently available glyphosate tolerant cotton varieties without affecting the overall total cotton acreage or glyphosate-tolerant cotton acreage so organic farmers will be able to coexist with biotech cotton producers as they do now. Based on this reasoning, there is no apparent potential for significant impact to organic farming if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no impact to organic farming since most of the present area of cotton production in the United States already consists of glyphosate tolerant varieties. This particular product should not present new and different issues than those associated with non-transgenic cotton, with respect to impacts on conventional or organic farming. No additional acreage is anticipated to be planted because of the deregulation of this product since glyphosate-resistant cotton is already available on the market and has been available for 11 years.

4. Executive Orders

Executive Order (EO) 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.

EO 13045, “Protection of Children from Environmental Health Risks and Safety Risks,” acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency’s mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children. Each alternative was analyzed with respect to EO 12898 and 13045. None of the alternatives are expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

Each alternative was analyzed with respect to the above **EO 12898** and **13045**. The human health and environmental impacts of the action alternatives are presented in pages 30-32 of the submitted petition. No human health or environmental effects were identified in the data on pages 30-32 of the submitted petition for any of the action alternatives that would have a disproportionate adverse effect or that would exclude a particular group of persons or populations, including minority and low-income populations, or children, from expected benefits. No change is expected in herbicide (or other pesticide applications) or the rate of development of glyphosate-resistant weeds regardless of the alternative chosen. The selection of glyphosate resistance does not disproportionately affect minority and low-income populations or children. Additional analyses provided here indicate that glyphosate resistant cotton technology can provide environmental and economic value to rural agricultural communities. Comparisons of weed management programs for conventional and herbicide resistant cotton were evaluated in a two year (1996-1997) study in across Alabama. Glyphosate resistant cotton was shown to have lower herbicide injury levels and higher weed control levels in a total post-emergence herbicide program, while maintaining high yield and greater net returns. Net returns were determined more by weed control and variety yield potential than by treatment cost. The economic and environmental impacts of glyphosate-resistant crops were reviewed by Gianessi (Gianessi 2005). It was estimated in the year 2000 that use of glyphosate-tolerant cotton has saved the industry approximately $132 million dollars per year by reducing herbicide applications, tillage and hand-weeding (Gianessi 2005). Crop safety is also a concern for the farmer, as well as to their children and pesticide applicators. Of 182 alternative herbicide treatment programs available for use on cotton, glyphosate was among the 47 with the highest crop safety rating in the weed control guides (Gianessi 2005). In another simulation study, researchers have looked at the effect of switching from glyphosate-resistant crops to conventional seeds with other herbicides, and they found that the switch would require farmers to increase the LD_{50} dose applied to the average U.S. farm by 25% per hectare in cotton (Service 2007). The LD_{50} dose is a mammalian toxicity measure for the volume of pesticide needed to kill 50% of a test population of rats. Even with conventional tillage, the use of glyphosate resistant crops reduces the number of LD_{50} doses applied per hectare (Service 2007). Under the "no action" alternative these benefits would presumably continue. If the petition is granted in whole, these benefits would also presumably continue and may be even greater if the varieties developed from GlyTol™ cotton are higher yielding as anticipated by the developer.

EO 13112, "Invasive Species", states that federal agencies take action to prevent the introduction of invasive species and provide for their control and to minimize the economic, ecological, and human health impacts that invasive species cause. Cotton is not considered an invasive species, is readily out-grown by weeds and does not establish itself without human intervention (as described in on page 21, Appendix I). Based on historical experience with cotton and the agronomic data submitted by the applicant (pages 121-132, petition data) and reviewed by APHIS, the engineered plant is sufficiently similar in fitness characteristics to other cotton varieties currently grown and it is not expected to have an increased invasive potential.

Executive Order 12114, "Environmental Effects Abroad of Major Federal Actions" requires Federal officials to take into consideration any potential environmental effects outside the U.S., its territories and possessions that result from actions being taken. APHIS has given this due consideration and does not expect an environmental impact outside the United States should APHIS choose any of the listed alternatives to petition #06-332-01p. It should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new cotton cultivars internationally, apply equally to those covered by an APHIS determination of non-regulated status under 7 CFR part 340. Any international traffic of genetically engineered cotton subsequent to a determination of regulated status for GE cotton would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC).

The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (https://www.ippc.int/IPP/En/default.jsp). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention 153 countries as of February 2009). In April, 2004, a standard for pest risk analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11; Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk, and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for bioengineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The Cartagena Protocol on Biosafety is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which includes those modified through biotechnology. The Protocol came into force on September 11, 2003 and 153 countries are Parties (103 signatures) to it as of February 27, 2009 (see http://www.cbd.int/biosafety/). Although the United States is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, US exporters will still need to comply with domestic regulations that importing countries that are Parties to the Protocol have put in place to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol, and the required documentation. LMOs imported for food, feed or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11 Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the US Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (http://usbiotechreg.nbii.gov). This data will be available to the Biosafety Clearinghouse.

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the United States and in the Organization for Economic Cooperation and Development. NAPPO has completed three modules of a standard for the *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (see http://www.nappo.org/Standards/Std-e.html). APHIS also participates in the North American Biotechnology Initiative (NABI), a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including: Argentina, Brazil, Japan, China, and Korea.

EO 13175, "Consultation and Coordination with Indian Tribal Governments", requires regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications. USDA is the lead agency of the Federal Government for providing effective and efficient coordination of Federal agricultural and rural development programs. Consistent with applicable law, USDA officials consult with tribal governments and Alaskan Native Corporations (ANC) regarding the influence of USDA activities on water, land, forest, air, and other natural resources of tribal governments and ANCs. USDA-APHIS responded to EO 13175 by establishing the APHIS Native American Working Group (ANAWG), which has representatives from all APHIS program areas. The group advises the agency's top management about ways to enhance program delivery and accessibility to tribes, intertribal committees, and related organizations, such as the Intertribal Agriculture Council. APHIS, BRS has an active representative in the ANAWG and works in partnership with both Indian Tribal Governments and the APHIS Management Team (AMT) during permitting and deregulation of plants that can affect any tribal areas. The deregulation of GlyTol™ cotton does not have any tribal land impacts as it is to be marketed as a consumer option to a product that has already existed in the market for the past 11 years.

EO 13186, "Responsibilities of Federal Agencies to Protect Migratory Birds" requires an agency to have a Memorandum of Understanding (MOU) with the Fish and Wildlife Service (FWS) that shall promote the conservation of migratory bird populations. The Migratory Bird Treaty Act of 1918 as amended and Executive Order 13186 states that migratory birds include all native wild birds found in the United States except the house sparrow, starling, feral pigeon, and resident game birds such as pheasant, grouse, quail, and wild turkeys. A reference list of migratory game birds is found in Title 50, CFR, part 10. The Migratory Bird Treaty Act makes it unlawful for anyone to kill, capture, collect, possess, buy, sell, trade, ship, import, or export any migratory bird, including feathers, parts, nests, or eggs. Executive Order 13186 "Responsibilities of Federal Agencies to Protect Migratory Birds" requires Federal officials to consider the impacts of planned actions on migratory bird populations and habitats for all planning activities. APHIS has determined that it is reasonable to assume that the deregulation of GlyTol™ cotton should have no impact on migratory birds since glyphosate tolerant cotton already exists in the marketplace and no adverse effects have been noted on any bird species within the Cotton Belt.

V. Listing of Agencies and Persons Consulted

Biotechnology Regulatory Services
Mike Gregoire, Deputy Administrator

Permits and Risk Assessment Staff
Neil Hoffman, Ph.D., Division Director (Reviewer)
Aimee Hyten, PhD. Biotechnologist (Reviewer)
Michael Watson, PhD. Plants Branch Chief (Reviewer)

BRS, Policy and Coordination Division
John Turner, Ph.D., Director
Patricia Beetham, Ph.D. Biotechnologist (EA Preparer)

Environmental Services
Rhonda Solomon, Ph.D. Reviewer

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VII. SELECTED RESOURCE MATERIALS

USDA-APHIS documents:
Petition submitted by the developer

Environmental Protection Agency documents:
June 2003. EPA's Regulation of Biotechnology for Use in Pest Management. (http://www.epa.gov/pesticides/biopesticides/reg_of_biotech/eparegofbiotech.htm)

Food and Drug Administration documents:
March 2007. CFSAN/Office of Food Additive Safety. List of Completed Consultations on Bioengineered Foods (http://www.cfsan.fda.gov/~lrd/biocon.html)

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USDA-ERS Organic Handler Database information:
from http://www.ers.usda.gov/Data/OrganicHandlers/ :
“The ERS organic handler database contains select results from the 2004 Nationwide Survey of Organic Manufacturers, Processors, and Distributors, administered by Washington State University, Social and Economic Sciences Research Center. The survey covered a variety of topics related to the procurement and contracting of organic products and ingredients. Data are available on 9 commodity groups, such as fruit and nuts, and 45 commodities, such as berries

and citrus. The procurement data include information from 1,038 facilities; the contracts data include information from 686 facilities that use contracts."

Appendix A: Pest Risk Assessment

In evaluating plant pest risk, APHIS reviews the petition along with scientific evidence to determine if there are differences between GlyTol™ cotton and traditional Upland cotton with regard to plant pest risk. APHIS regulations 7 CFR part 340 defines a plant pest as:

> "Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants."

Plant pest risk evaluation by APHIS includes comparing the GE plant and unmodified plant to determine if the inserted gene affects weediness, the impact on the weediness of another other plant with which it can interbreed, transfer of genetic information to organisms with which it cannot interbreed and differences in disease and pest susceptibilities. APHIS made these evaluations by comparing monitored agronomic properties in prior field tests done by the applicant. Field test reports can be found in the BCS GlyTol™ cotton petition in Appendix 1 (petition# 06-332-01p, p.86-105). Agronomic, gene expression and protein characterization data from the field tests can be found in the submitted petition (petition# 06-332-01p, p.108-173).

A. Weeds and Resistance

1. Upland Cotton

In the United States, Upland cotton (*Gossypium hirsutum*) is not a weed pest (Crockett 1977; Holm, Pancho et al. 1979; Muenscher 1980). Upland cotton is a domesticated crop that requires human intervention to survive in non-cotton production areas.

In the United States, cotton is not listed as a weed in the major weed references (Crockett 1977; Holm, Pancho et al. 1979; Muenscher 1980), nor is it present on the lists of noxious weed species distributed by the Federal Government (USDA-APHIS 2006). Furthermore, cotton has been grown throughout the world without any report that it is a serious weed. Cotton is unlikely to become a weed. It is not persistent in undisturbed environments without human intervention. In the year following cultivation, cotton may grow as a volunteer only under specific conditions (disturbed or cultivated soil that had cotton grown in the last growing season) and can be easily controlled by herbicides (see Table 2 for pre-emergent herbicides) or mechanical means. It does not compete effectively with cultivated plants or primary colonizers (OECD 2004).

2. Glyphosate resistant cotton

The addition of herbicide tolerance in BCS' GE cotton does not confer any additional weediness potential. Eleven years experience with Roundup Ready® cotton has demonstrated that it is an additional tool in integrated weed management systems (http://www.weedresistancemanagement.com/layout/default.asp). Glyphosate-tolerant plants are susceptible to many other herbicides other than glyphosate (see Table 1). Volunteer plants can easily be controlled by pre- or post-emergence herbicides as indicated in the University of California's website on integrated weed management (http://www.ipm.ucdavis.edu/PMG/r114700111.html).

APHIS believes there will be no plant pest risk impacts due to increased weediness from this GE cotton based on the absence of such weediness observed during the prior commercial use of herbicide-tolerant cotton grown on an accumulated 78.5 million acres over the last 11 years (data compiled from NASS and ERS data sets; http://www.nass.usda.gov and http://www.ers.usda.gov/Data/biotechcrops/). Because glyphosate tolerant cotton has already been highly adopted by U.S. cotton growers, this new product is not expected to lead to an increase in the US acreage of glyphosate tolerant cotton. APHIS believes the deregulation of this product will not cause an increase in the US acreage of glyphosate tolerant cotton, but simply provide an additional consumer choice. APHIS also believes that there is no apparent potential for significant impact to plant pest risk from stacking of herbicide resistance traits if APHIS were to grant the petition for non-regulated status.

The potential impacts of stacking of herbicide resistance traits (e.g. combining two or more traits through crossing of different genetically engineered plants) are the availability of deregulated herbicide resistance events, the effect of stacked traits on the plant and on herbicide use, the number of effective alternative herbicides for cotton production, the probability of developing weeds with multiple resistance to various herbicide modes of action and the probability of a stacked cotton becoming a weed. APHIS has previously deregulated other herbicide tolerance gene/events in cotton. The first herbicide tolerant cotton to be deregulated was the glyphosate-tolerance cotton based on the *cp4 EPSPS* gene by Monsanto in 1995. The second herbicide tolerance trait to be deregulated in cotton was tolerance to the phosphinothricin class of herbicides based on expression of phosphinothricin-N-acetyl transferase (PAT) enzyme, which catalyzes the conversion of the active herbicidal ingredient glufosinate ammonium to an inactive form. There are two types of genes that encode similar PAT enzymes; i.e. the *bar* gene from *Streptomyces hygroscopicus* and a synthetic *pat* gene derived from *Streptomyces viridochromogenes.*

Based on all of the genetically engineered herbicide tolerant traits in all of the crops deregulated to-date by APHIS, herbicide tolerant traits that have been deregulated for cotton have no effect on any other plant characteristic (see agronomic data petition# 06-332-01p, p.105-173) so the stacking of two or more herbicide tolerant traits into one plant should have no effect on making the plant more weedy or changing the level of other herbicide tolerances in the plant. As noted above in Section II (Affected Environment), several alternative herbicides are necessary to use in cotton for controlling a wide array of weeds. The development of herbicide resistant weeds is generally due to frequent use of the same herbicide over a period of time on the same area. Alternating herbicides with different modes of actions to control weeds generally is recommended to help avoid the development of herbicide resistant weeds, and successful cotton producers incorporate this into their agricultural and cultivation practices. Therefore incorporating tolerance to two or more herbicides into the same plant may be useful in avoiding the development of herbicide resistant weeds. Cotton has never been considered a weed other than as an occasional volunteer in subsequent crops.

B. Gene introgression[6] from GE cotton into its sexually compatible relatives

Potential impacts to be addressed are those that pertain to the use of GlyTol™ cotton and its progeny in the absence of confinement. Does the presence of the 2mEPSPS protein in GlyTol™ cotton confer any advantage over the unmodified cotton plant?

In assessing the risk of gene introgression from BCS' glyphosate-resistant cotton into its sexually compatible relatives, APHIS considers two primary issues: 1) the potential for gene flow and introgression via pollen movement and horizontal gene transfer[7]; and 2) the potential plant pest risk of introgression.

1. Gene Flow via Pollen Movement

Movement of genetic material by pollen is possible only to those plants with the proper chromosomal type. In the United States, this would only include *G. hirsutum*, *G. barbadense*, and *G. tomentosum*. *G. barbadense* is only found in Hawaii, Virgin Islands and Puerto Rico, while *G. tomentosum* is only found in Hawaii (Fryxell 1979). *G. hirsutum* is generally self-pollinating but some cross-pollination can occur, albeit at relatively low incidence through activity of pollinating insects (Fryxell 1979). Gene movement between *G. hirsutum* and *G. barbadense* is possible if suitable insect pollinators are present, and if there is a short distance from host plants to recipient plants (Fryxell 1979). Physical barriers, intermediate pollinator-attractive plants, and other temporal (like only pollinating at night as in the case of *G. tomentosum*) or biological impediments (geography or absence of pollinators) reduce the potential for pollen movement (Fryxell 1979). Table 4 outlines the compatibility of all species on an international level.

Table 4. Cotton Species

Species	Common Name	Native location	Comments
G. hirsutum	Upland cotton	Central America, Mexico, Caribbean and southern Florida.	Commercial Species, Grown in U.S.A. and comprises 97% of U.S.A cotton crop. Sexually compatible with *G. barbadense* and *G. tomentosum*.
G. barbadense	Pima, Creole, Egyptian or Sea Island cotton	S. America	Commercial species, grown in U.S.A. Grown in Hawaii, Virgin Islands and Puerto Rico. Sexually compatible with *G. hirsutum* and *G. tomentosum*.

[6] Introgression is the introduction of genes from one species into the gene pool of another via sexual crossing. The process begins with hybridization between the two species, followed by repeated backcrossing to one of the parent species.
[7] Horizontal gene transfer is any process in which an organism transfers genetic material to another cell that is not its offspring.

G. tomentosum	Ma'o or Hawaiian cotton	Hawaii	Non-commercial species. Pollinated by moths when the flowers open at night. Only found in Hawaii. Sexually compatible with *G. hirsutum* and *G. barbadense*.
G. arboreum	Asiatic tree or tree cotton	Pakistan, India	Commercial species, grown in Europe, Africa and eastern countries. Sexually compatible with *G. herbaceum*.
G. herbaceum	Levant cotton	Africa, Arabia	Commercial species, grown in Europe, Africa and eastern countries. Sexually compatible with *G. arboreum*.
G. thurberi	Thurber's, Desert or Arizona desert cotton	Mexico, Arizona	Non-commercial species. Sexually compatible with *G. arboreum* and *G. herbaceum*.

Cross-pollination between *G. tomentosum* and *G. hirsutum* is unlikely because they use different insect pollinators and are receptive to pollination at different times of the day. Flowers of *G. tomentosum* are pollinated by moths at night unlike flowers of *G. hirsutum* which are pollinated by bees during the day (McGregor 1976). Concentration of suitable pollinators varies from location to location and by season, and is considerably suppressed by insecticide use.

In farm scale studies using traditional Upland cotton in California, it was found that the out-crossing distance was strongly dependent on the presence of bee colonies. When only native pollinators were present in the field, 1% out-crossing was detectable over a distance of 1 meter (approximately 3 ft) and 9 m (29.5 ft) when there was high pollinator activity (Van Deynze, Sunderstrom et al. 2005). Out-crossing declined exponentially with increasing distance from the source plot (Van Deynze, Sunderstrom et al. 2005). Current cultivation practices to prevent out-crossing (distance being primarily used) have been deemed sufficient to prevent unwanted gene flow. For Upland cotton, the Association of Official Seed Certifying Agencies (AOSCA) mandates an isolation distance being a nature barrier or crop boundary with a minimal isolation distance of 100 ft "if the contaminating source differs by easily observed morphological characteristics from the field to be inspected". For Pima or Egyptian type cotton "the isolation shall be 1320 feet from any other type of cotton for Foundation and Registered and 660 feet for Certified seed"[8]. Since GlyTol™ cotton is not morphologically distinguishable from traditional Upland cotton much like Pima or Egyptian type cotton, cultivation practices using AOSCA standards of 1320 ft for Foundation and Registered and 660 ft for Certified seed are used.

Wind is rarely seen as a means for cross-pollination of cotton pollen because of its adherent properties and large size (mean diameter of 53-56 µm). The pollen of cultivated *Gossypium* species is described as being sticky and having pronounced spines, with a marked tendency for groups of pollen grains to clump together (Humacher and Wright 2006).

[8] From AOSCA "Yellow Books" 2003 OPERATIONAL PROCEDURES, CROP STANDARDS AND SERVICE PROGRAMS PUBLICATION (Genetic and Crop Standards), pg 194.

2. Gene Flow via Horizontal Gene Transfer[9]

Transfer and expression of DNA from GlyTol™ cotton to soil bacteria is unlikely to occur. Gebhard and Smalla (Gebhard and Smalla 1999) and Schlüter *et al.* (Schlüter, Fütterer et al. 1995) have studied transgenic DNA movement to bacteria, and although theoretically possible, determined mathematically it would occur at extremely low rates (approximately 1 in 10^{-14}). Many genomes (or parts thereof) have been sequenced from bacteria that are closely associated with plants including *Agrobacterium* and *Rhizobium* (Kaneko, Nakamura et al. 2000) and there is no evidence for recent horizontal transfer. Koonin *et al.* (Koonin, Makarova et al. 2001) and Brown (Brown 2003) presented reviews based on sequencing data that revealed horizontal gene transfer occurs occasionally on an evolutionary time scale of millions of years. Even in the unlikely event transfer were to occur, the gene would be poorly expressed at best because transgene promoters and coding sequences are optimized for plant expression and function poorly in prokaryotic cells.

3. Summary

APHIS believes that natural gene transfer in cotton is such an unlikely event that there is minimal risk for gene introgression via gene transfer. If gene introgression were to occur via pollen flow, cotton is not considered a weed and the gene event would not confer any additional survival advantage over non-GE cotton. There would also be no impact from introgression since over 90% of the present area of cotton production in the United States is already planted with herbicide tolerant varieties (herbicide-tolerant or herbicide-tolerant stacked with insect-resistance) (USDA-NASS 2008).

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[9] Horizontal gene transfer is any process in which an organism transfers genetic material to another cell that is not its offspring.

Appendix B: Technical Information about Glyphosate and *EPSPS* Gene

A. Glyphosate

The glyphosate herbicide (N-phosphonomethyl-glycine) is registered for non-selective weed control on both non-food use and food use plants. Glyphosate is a systemic herbicide that has a relatively slow mode of action allowing for the movement of the herbicide throughout the plant before symptoms occur. It has been found to be biodegradable and acute toxicity studies have demonstrated the lack of toxic effects in humans and wild fauna (Malik, Barry et al. 1989).

Glyphosate works by interfering with normal plant metabolism by competing with the naturally present enzyme, 5-enolpyruvyl-3-phosphoshikimate acid synthase (EPSPS). EPSPS is involved in the biosynthesis of the aromatic amino acids, phenylalanine, tryptophan, and tyrosine (as well as some secondary metabolites) through the shikimate pathway. These aromatic amino acids are essential building blocks of proteins in all species. The herbicide glyphosate resembles the structure of the substrate for EPSPS, phosphoenolpyruvate (PEP). Therefore, glyphosate competes with PEP for the enzyme's active site and prevents the conversation of PEP to the molecule that is required for the synthesis of aromatic amino acids. As a consequence of interfering with aromatic amino acid biosynthesis, plant cells cannot complete the synthesis of proteins and the plant dies (Kishore and Shah 1988). EPSPS is found naturally in all plants, fungi and some bacteria but is not present in animals (including humans). For animals, aromatic amino acids must be obtained through the diet (Steinrucken and Amrhein 1980). Consequently, all animals are naturally exposed to sources of EPSPS through their normal diets.

B. Use of an *EPSPS* gene

To create a plant that is resistant to glyphosate herbicide, the EPSPS enzyme must be mutated, but not inactivated. It still must be able to function in the shikimate pathway to produce essential amino acids, but not be able to bind glyphosate herbicide. The first mutated EPSPS enzyme that was placed into corn came from the *Agrobacterium* C4 gene. This gene was identical to the naturally occurring EPSPS protein in corn with the exception of two amino acid mutations. These two amino acid mutations allowed the corn plant to continue to make aromatic amino acids, but did not readily bind to the glyphosate herbicide, allowing the plant's survival in the presence of the herbicide.

The *EPSPS* gene inserted in GlyTol™ cotton is from corn (*Zea mays*) and its protein differs from the native protein by only two amino acids (Table 8, p.40 of submitted petition). BCS has conducted a safety evaluation of the 2mEPSPS protein produced in GlyTol™ cotton including homology searches for allergenicity and toxins, as well as *in vitro* digestibility assays. In keeping with historical data (demonstrated with both *Agrobacterium* EPSPS and corn event GA21 (mEPSPS), BCS' data demonstrates the 2mEPSPS protein is not resistant to *in vitro* digestion and shows no homology with allergens or toxins. Expression data for the protein during plant growth and the verification of biochemical properties and function can be found in BCS' submitted petition on pages 30-40.

Determination of nonregulated status for GlyTol™ cotton

In response to the petition 06-332-01p from Bayer CropScience, APHIS has determined GlyTol™ cotton and progeny derived from it are no longer regulated articles under APHIS regulations at 7 CFR part 340, as APHIS has no authority under the Plant Protection Act to regulate articles that are not deemed plant pests. Permits or acknowledged notifications that were previously required for environmental release, importation, or interstate movement under those regulations will no longer be required for GlyTol™ cotton and its progeny. Importation of seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and the Federal Seed Act regulations at 7 CFR part 201. This determination is based on APHIS' analysis of field, greenhouse and laboratory data, references provided in the petition, and other relevant information as described in this environmental assessment that indication that GlyTol™ cotton is unlikely to pose a plant pest risk. The transgenic event found in GlyTol™ cotton will not post a plant pest risk for the following reasons: (1) gene introgression from GlyTol™ cotton into wild relatives in the United States and its territories is extremely unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect genetic diversity of related plants any more than would introgression from traditional cotton varieties; (2) it exhibits no characteristics that would cause it to be weedier than the non-genetically engineered parent cotton line or any other cultivated cotton; (3) horizontal gene flow is unlikely to occur between GlyTol™ cotton and soil bacteria (4) it does not pose a threat to biodiversity as it does not exhibit traits that increase its weediness, and its unconfined cultivation should not lead to increased weediness of other cultivated cotton and it exhibits no changes in disease susceptibility (5) compared to current cotton pest and weed management practices, cultivation of GlyTol™ cotton should not impact standard agricultural practices in cotton cultivation including those for organic farmers; and (6) disease susceptibility and compositional profiles of GlyTol™ cotton are similar to those of its parent line and other cotton cultivars grown in the United States, therefore no direct or indirect plant pest effects on raw or processed plant commodities are expected.

In addition to our finding that GlyTol™ is unlikely to pose a plant pest risk, there will likely be no effect on federally listed threatened or endangered species, species proposed for listing, or their designated critical habitat resulting from a determination of nonregulated status for GlyTol™ cotton and its progeny. APHIS also concludes that new varieties bred from GlyTol™ cotton are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for GlyTol™ cotton, or those observed for other cotton varieties not considered regulated articles under CFR 7 part 340.

Michael C. Gregoire

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