Finding of No Significant Impact
Animal and Plant Health Inspection Service
Petition for Nonregulated Status for Pioneer Corn DP-098140-6
(APHIS 07-152-01p)

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, under APHIS regulations in 7 Code of Federal Regulations (CFR) part 340, of whether or not to approve a petition (APHIS number 07-152-01p) for a determination of nonregulated status received from Pioneer Hi-Bred International (Pioneer). The subject of this petition, corn (*Zea Mays*) line DP-098140-6 (referred to herein after as Pioneer HT corn), is genetically engineered (GE) to express a modified glyphosate acetyltransferase (GAT4621) enzyme and an acetolactate synthase (ZM-HRA) enzyme which allow the plant to tolerate applications of glyphosate and acetolactate synthase-inhibiting (ALS-inhibiting) herbicides, respectively. On December 8, 2008, APHIS published a notice in the *Federal Register* (73 *FR* 74453-74454, Docket no. 2008-0094) announcing the availability of the draft EA for public review and comment for a 60-day period, ending February 6, 2009. APHIS received 31 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 Pioneer HT corn is No Longer a Regulated Article. APHIS proposed Alternative B as its preferred alternative because of the lack of plant pest characteristics of Pioneer HT corn. APHIS has not identified any greater plant pest risk characteristics in this transformed corn than in non-transformed or other nonregulated corn 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. Relative Weediness and/or Invasiveness
In the U.S., corn is not listed as a weed in the major weed references nor is it listed as a noxious weed species by the Federal Government, and corn has been grown throughout the world without any report that it is a serious weed. Cultivated corn is unlikely to become a weed because it generally does not persist in undisturbed environments without human intervention. In the year following cultivation, corn may grow as a volunteer only under specific conditions and can be easily controlled by herbicides or mechanical means. No data of which APHIS is aware indicate that the presence of the *gat4621* and *zm-hra* genes improve the ability of this transformed corn to survive without human intervention, nor is there any foreseeable reason to conclude that these genes would affect this line's survival in the wild. APHIS has reviewed field performance data submitted by the petitioner, and these data indicate that Pioneer HT corn is not different in any fitness characteristics from its parent that might cause it to become invasive. Therefore, corn is unlikely to become a weed through the introduction of the glyphosate and ALS-inhibiting

herbicide tolerant traits. For these reasons a determination to grant nonregulated status to this GE line (Alternative B) and its subsequent release should not increase its weediness or invasiveness potential relative to the release of any conventional corn line.

2. Gene Flow and Gene Introgression into Sexually-Compatible Relatives

There should be no significant environmental impact as a result of gene introgression from this transformed corn to other corn or corn relatives with which it can interbreed. In assessing the potential risks associated with gene introgression from Pioneer HT corn 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. Cultivated corn is sexually compatible with other members of the genus *Zea* and to a much lower degree with members of the genus *Tripsacum*. Wild *Zea* (teosinte) are normally confined to the tropical and subtropical regions of Mexico, Guatemala, and Nicaragua. Although in the past, a few small isolated populations of *Z. mexicana* and *Z. perennis* have been reported to exist in some states in the U.S., neither of these teosinte species has been shown to be aggressive weeds in their native or introduced habitats. Cultivated corn can hybridize with *Z. Mexicana*; however, it rarely crosses with *Z. perennis*. If hybrids from the latter were produced, they would be sterile. Pioneer HT corn has been shown to have no agronomic differences from those of conventional corn. Therefore, although the potential for cross pollination between Pioneer HT corn and teosinte is present, it would be no different than the potential cross between teosinte and conventional corn. In addition, a number of factors such as distance between plants, pollen viability and travel ability, plant morphology, and reproductive timing significantly reduce the likelihood that cross-pollination between any corn crop and teosinte would produce successful hybrids, and if formed, that those hybrids would become aggressive weeds. Most species in the genus *Tripsacum* are native to Mexico, Central and South America, with three occurring in the U.S. Many species of *Tripsacum* can cross with *Zea*, but with difficulty and with resulting hybrids being primarily male and female sterile. Although, some *Tripsacum* species may be found in areas where corn is cultivated, gene introgression from corn under natural conditions has been shown to be highly unlikely, if not impossible. Seed obtained from crosses between *Tripsacum* and corn is often sterile or progeny have greatly reduced fertility. Therefore, introgression from Pioneer HT corn to *Tripsacum* species would be no different from that of other cultivated corn varieties and also unlikely to occur. Therefore, there should be no significant environmental impact related to out-crossing by deregulating this line.

3. Impacts on Biodiversity

APHIS evaluated the potential for significant impacts to biodiversity from the cultivation of Pioneer HT corn. Analysis of available information demonstrates that Pioneer HT corn exhibits no traits that should cause increased weediness, and that its unconfined cultivation should not lead to increased weediness of other sexually compatible relatives. Pioneer HT corn has no effect on non-target organisms common to the agricultural ecosystem or federally listed threatened and endangered species (TES) or species proposed for listing. Glyphosate use and crop production practices are not expected to change significantly, therefore there should be no indirect or cumulative impact on biodiversity related to these practices. Use of ALS-inhibiting herbicides will likely increase to manage glyphosate resistant weed populations, but the use of glyphosate and ALS-inhibiting herbicides on Pioneer HT corn according to product labels is not expected to cause significant impacts on biodiversity outside the agroecosystems based on the chemical and toxicological properties of these products. The herbicides are not considered to be a significant soil or water contaminant and in general, there is little effect on soil microflora, aquatic organisms, arthropods, and mammals when the herbicides are used in recommended doses and according to label instructions. Based on these conclusions, there should be no significant impact to biodiversity by deregulating this line.

4. Transfer of Genetic Information to other Organisms
Transfer and expression of DNA from Pioneer HT corn 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*. There is no evidence for horizontal gene transfer. Even in the unlikely event that transfer was to occur, the genes would be poorly expressed 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 environmental impact of horizontal gene transfer by deregulating this line.

5. Effect on Non-target and Beneficial Organisms
APHIS does not expect Pioneer HT corn to have any impacts on non-target organisms, including beneficial organisms and TE species because the GAT4621 and ZM-HRA proteins are not known to have any toxic or allergenic properties. Pioneer conducted extensive compositional analysis on Pioneer HT corn and noted minor compositional differences compared to non-transgenic control corn. Pioneer conducted three separate acute toxicity studies with individual Pioneer HT corn components (GAT4621, ZM-HRA, and N-acetylaspartate) and noted no toxicities at the levels tested. Pioneer also conducted a poultry study to assess wholesomeness/nutrition of corn meal. This study showed the nutritional comparability of diets made from Pioneer HT corn to those made from control corn. In addition, as of September, 2008, and based on the information submitted by Pioneer, the FDA completed the voluntary biotechnology consultation for Pioneer HT corn (food and feed) (BNF No. 000111). FDA concluded its food and feed analysis of this product and indicated to the developer that it had no further questions about this corn. Therefore, there should be no significant impact to non-target organisms, including beneficial organisms, and no effect is expected on federally listed TES, species proposed for listing, or their designated or proposed critical habitat from exposure to the GAT4621 and ZM-HRA proteins expressed in Pioneer HT corn as a result of deregulating this line.

6. Effect from Cultivation on Non-target and Beneficial Organisms
APHIS evaluated the potential for significant impacts from cultivation of Pioneer HT corn and its progeny on non-target organisms, including those species federally listed TE species, or species proposed for listing, and their proposed and designated critical habitat. APHIS does not expect Pioneer HT corn to have significant impacts on such species

because the GAT4621 and ZM-HRA are not known to have toxic or allergenic properties. Similar acetyltransferase (similar to GAT4621) and ZM-HRA proteins are found in plants and microorganisms and data collected by Pioneer noted no significant differences in non-target organism impacts over several years of study (i.e., abundance and diversity of organisms in fields of Pioneer HT corn were the same as in control corn fields). In addition, APHIS reviewed the expected use of glyphosate and ALS-inhibiting herbicides on Pioneer HT corn. Glyphosate tolerant corn has been grown commercially and treated with glyphosate for a number of years. Similarly, ALS-inhibiting herbicides have been registered by EPA for use on corn for many years. EPA has not identified any significant issue related to label changes or metabolites from the use of glyphosate and registered ALS-inhibiting herbicides on Pioneer HT corn. Therefore, there should be no significant impact to non-target organisms or TES, or their designated or proposed critical habitat from exposure to Pioneer HT corn or from exposure to label rates of glyphosate and/or ALS-inhibiting herbicides expected to be used in conjunction with Pioneer HT corn as a result of deregulating this line.

7. Effect on Agricultural Practices

If Pioneer HT corn was to be grown commercially, the effect on agricultural practices (e.g., cultivation, spray programs, crop rotation practices, planting rates, etc.) from its introduction into the environment should not be significantly different than for the previously deregulated herbicide tolerant corn lines. APHIS has evaluated field trial data reports on Pioneer HT corn and its progeny and no significant adverse effects have been noted on non-target organisms, no increase in fitness or weediness characteristics, and no effect on the health of other plants. In addition, herbicide use and cultivation practices due to the commercial availability of Pioneer HT corn are expected to be no different from other corn based on levels of herbicide tolerance, other agronomic characteristics, and approved and recommended applications rates for glyphosate and ALS-inhibiting herbicides. Based on these conclusions, there should be no significant impact on commercial use by deregulating this line.

8. Effect on Organic Farming

If Pioneer HT corn were to be grown commercially, APHIS expects the variety will be used to breed corn varieties suitable to a range of environments and maturity zones and replace some of the older, less effective herbicide tolerant corn varieties. This product could also be expected to result in a small increase in overall herbicide tolerant corn acreage, depending upon new demand for such corn. However, based upon the past planting trends, any potential increase would be expected to be small. The potential impact on organic farming should not change from the current situation and organic or other growers who choose not to plant or sell glyphosate/ALS or other transgenic corn (a) will still be able to purchase and grow non-transgenic corn and (b) will be able to coexist with biotechnology corn producers as they do now. A number of techniques have been developed in order to maintain the concept of coexistence and to prevent cross-pollination. Isolation distances between fields help to minimize the effects of pollen flow. In addition to spatial isolation, growers can use reproductive isolation to minimize or eliminate cross-pollination (i.e. plant varieties with different maturity dates) or stagger

planting dates (to obtain different flowering stages), with a minimum of three to four weeks difference between the planting of their crop and neighboring crop.
Based on these considerations, there should be no potential for a significant impact on organic farming by deregulating this line.

9. Development of Herbicide Resistant Weeds
APHIS does not expect Pioneer HT corn to cause significant impacts on the development of herbicide resistant weeds or significant cumulative impacts when combined with other available glyphosate or ALS tolerant crops. Data show that the acres of corn planted to biotechnology herbicide tolerant varieties dropped in 2008 and although it may be difficult to predict the corn market, experts anticipate that the planted acres of corn will stabilize at 89-90 million acres in 2008 and will remain at that level through 2016. Data also show that corn varieties containing the Bt (*Bacillus thuringiensis*) trait (conferring insect resistance), whether alone or stacked with an herbicide resistant trait, are more readily planted than those varieties conferring resistance to herbicides alone. In addition, Pioneer HT corn is likely to be used by growers as a replacement crop to other herbicide tolerant corn varieties. The introduction of alternative tools, such as Pioneer HT corn, provide a wider range of options for growers to minimize the development of glyphosate or ALS tolerant weeds, essentially extending the usefulness of both types of herbicides. Therefore, APHIS reasonably concludes that Pioneer HT corn should not have any significant impact on rate of the development of herbicide resistant weeds.

10. Impact of Stacking Herbicide Tolerant Traits
APHIS considered the potential impact from the stacking of herbicide tolerant traits that could result if Pioneer HT corn was 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 corn 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 corn becoming a weed. Based on these considerations as analyzed in the EA and the attached response to comments, there should be no significant impact from the stacking of herbicide resistant traits by deregulating this line.

11. Impact on Field Performance
APHIS has reviewed the field performance data submitted by the petitioner, and these data indicate that Pioneer HT corn shows no difference in any fitness characteristic from its parent that might cause it to become invasive. Therefore, there should be no impact on field performance from deregulating this line.

12. Impact on Altered Disease and Pest Susceptibilities
Data on agronomic performance, disease and insect susceptibility, and compositional profiles of Pioneer HT corn and its non-GE counterpart indicate 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. Based on APHIS'

analysis, there should be no direct or indirect plant pest effects on raw or processed plant commodities by deregulating this line.

13. Cumulative Impacts
When considered in light of other past, present, and reasonably foreseeable future actions, and considering potential environmental effects associated with the adoption of Pioneer HT corn, APHIS could not identify significant environmental impacts that would result from the determination of nonregulated status for the corn. Neither of the alternatives is 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 effects on the human environment 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 herbicide tolerant corn varieties and to those observed for the use of glyphosate and several ALS-inhibiting herbicides in agriculture production systems. None of the proposed alternatives are expected to threaten or violate Federal, State, or local law requirements.

Based on all of the analyses and reasons above, I have determined that there would be no significant impact to the quality of the human environment from the implementation of the chosen alternative (Alternative B) and, therefore, no EIS needs to be prepared.

Michael C. Gregoire

Michael Gregoire
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: 10-9-09

Response to Comments
Petition 07-152-01p

On December 8, 2008, APHIS published a notice in the Federal Register (73 *FR* 74453-74454, Docket no. 2008-0094) announcing the availability of the Pioneer petition to deregulate 98140 corn and of a draft environmental assessment (EA) for public review and comment for a 60-day period, ending February 6, 2009.

APHIS reviews a petition for nonregulated status to determine if the genetically engineered (GE) organism should no longer be considered a regulated article under APHIS biotechnology regulations (7 Code of Federal Regulations (CFR) part 340). Prior to reaching a decision whether to grant a determination of nonregulated status for Pioneer HT corn, APHIS prepared a plant pest risk assessment to evaluate whether Pioneer HT corn is likely to pose a plant pest risk. After finding that Pioneer HT corn is unlikely to pose a plant pest risk, and is eligible for nonregulated status, APHIS prepared an EA to evaluate whether there could be significant impacts on the environment arising from a decision to grant a determination of nonregulated status to the corn line. APHIS prepared the EA as part of its obligation, like other Federal agencies, to meet the requirements of the National Environmental Policy Act (NEPA) of 1969. As part of this process, APHIS considered public comments on the petition for deregulation, as well as on the prepared EA.

APHIS received 31 comments during the comment period. There were 12 comments from groups or individuals who supported deregulation and 19 from those who opposed deregulation; attached to one of these comments were 13,255 form letters (same letter, different submitters). In addition, APHIS received a number of documents attached to 12 blank comments.

Individuals who wrote in support of granting a determination of nonregulated status included weed science/crop management and agronomy professors and state and national corn grower association representatives. Supporters for deregulation cited a number of benefits associated with having this product available for use: increased options for weed control in corn fields, the ability to combat an increasing number of glyphosate tolerant weed populations, longer-lasting broad spectrum weed control, increased marketplace choice of seeds, increased market competition, benefits to the environment from decreased tillage and use of fewer environmentally hazardous pesticides, reduced fuel usage, improved productivity, improving the availability of a safe, affordable food supply, and preserving the utility of herbicide tolerant traits. Several comments also focused on Pioneer/Dupont’s history of effective product stewardship programs.

Many individuals opposed the deregulation based on a general disagreement to the development and use of GE plants. These comments did not cite any specific issues with the EA or the petition. Other comments raised specific issues with this GE product and the EA and/or petition. Responses to these comments are below.

1. **Comment:** A comment indicated that APHIS failed to adequately analyze the impacts on the public's right to choose not to eat GE food. The commenter indicated that the public has the right to know if GE is present in the food they purchase at the grocery store. The commenter quoted that "60 percent of Americans would avoid GE foods if they were appropriately labeled, and up to 90 percent of Americans support such labeling".

   Response: No requirement has been placed on any developer or grower of herbicide tolerant corn in the U.S., or on any food company which utilizes such corn, to label the corn crop and/or product; this is the case for all herbicide tolerant corn, whether made through conventional or GE means. Once Pioneer HT corn is deemed not be a plant pest, it can be sold and grown anywhere in the U.S. as any other variety of corn available in the market today. In reference to the quote regarding the number of Americans who support labeling, the commenter neglected to provide all of the information gathered and analyzed by those who conducted the survey. According to the study, out of the 1,201 people surveyed, 89% said that GE foods should be labeled and the following, was the conclusion drawn by the writers: "Though it appears that most Americans want GM foods labeled, it is possible that their stated preference for such a label could stem from a more general desire for more information about the foods they eat". In order to test this, the developers asked the participants to rate how important it was that food labels indicate certain information (Hallman et al., 2004). The conclusions from that test indicated that the information rated as most important to put on a label was "whether pesticides were used in the process of growing the food." Next in importance was information concerning "whether the food contains GE ingredients" and "if the food was grown or raised organically," which were rated as equally important. These results imply that consumers want a variety of additional information on food labels and as concluded by the writers, "the support of such labels may be more an issue of 'consumer sovereignty' rather than simple avoidance" (Hallman, et al., 2004).

   In addition, if in the future such labels are required, they would likely fall under the authority of the Food and Drug Administration's (FDA) Office of Nutrition, Labeling and Dietary Supplements, not APHIS.

   References

   Hallman, W. K., W. C. Hebden, C. L. Cuite, H. L. Aquino, and J. T. Lang. 2004. Americans and GM Food: Knowledge, Opinion, and Interest in 2004. Food Policy Institute RR-1104-007 (http://www.foodprocessing.com/Media/MediaManager /RutgersGMFoodStudy.pdf)

2. **Comment:** Several comments indicated that APHIS did not adequately analyze the economic and human health impacts of gene flow from Pioneer HT corn to organic and conventional corn growers and exporters, and stated that coexistence and other methods used to prevent such gene flow are not sufficient. Commenters discussed the issue of StarLink as an example of such gene flow.

   Response: As described in the Plant Pest Risk Assessment (Appendix A of the EA), the applicant has demonstrated that Pioneer HT corn does not exhibit any differences in agronomic properties from other cultivated corn. Therefore, the presence of Pioneer HT corn in the environment is not different, than the presence of other herbicide tolerant corn (e.g., Clearfield® Corn) developed through conventional, non-GE means. APHIS recommends the use of isolation distances, among other means, to minimize the effects of pollen flow from GE corn into non-GE corn and therefore, minimize economic impacts due to gene flow. Growers can obtain the Association of Official Seed Certifying Agencies' (AOSCA) reference material which describes isolation distance requirements for the certification of corn seed (AOSCA, 2003). Instead of, or in addition to, spatial isolation, growers can use reproductive isolation to minimize or eliminate cross-pollination. In those instances, growers can plant varieties with different maturity dates (Ronald and Fouche, 2006) or stagger planting dates (to obtain different flowering stages), with a minimum of three to four weeks difference between the planting of their crop and neighboring crop (Fernandez and Polansky, 2006). In regard to human health issues, this corn has already been through the FDA consultation process and based on the nutritional data provided by the applicant, Pioneer HT corn has been shown to be no different from control non-GE corn.

The USDA believes that all methods of agricultural production (conventional, organic, or the use of GE varieties) can provide benefits to the environment, consumers, and the agricultural economy. The role of BRS within APHIS is to provide plant health regulatory oversight that allows for the safe development and use of GE organisms in agriculture and the environment. Once a new biotech variety has been granted a determination of nonregulated status by APHIS, any decisions to produce or market that product are made by the technology providers and producers and are driven by market demand. USDA encourages the developers of new biotech varieties to seek regulatory approvals for these new products in our major export markets at the same time nonregulated status is sought within the U.S.

Agricultural seed producers are free to develop and produce crop seed varieties whether they are conventional, GE, or organic. Growers are free to cultivate the crops and crop varieties of their choice using the production systems they prefer. Growers are likewise free to market their GE or non-GE corn varieties and obtain price premiums for growing varieties of corn for particular markets (e.g., using organic methods for corn production or producing a specialty corn variety for particular processing needs). Consumers are likewise free to choose the type of agricultural products they consume. Market impacts result from and are affected by these various decisions and choices.

Although the commenters do not agree that the use of coexistence and other methods used to prevent or minimize biological contamination are sufficient, the data collected by APHIS suggest otherwise. Growers have, for decades, been successfully growing crops bearing different traits and often on adjoining fields; whether such traits were introduced into the crops by conventional means or genetic engineering. Growers have always had the choice of what crops to grow, and have had to contend with commingling, admixtures, and other contaminants in their crops (Ronald and Fouche, 2006). Studies of coexistence of major GE and non-GE crops in North America and the European Union (E.U.) have demonstrated that there has been no significant introgression of GE genes, and that GE and non-GE crops are coexisting with minimal economic effects (Gealy et.al, 2007; Brookes and Barfoot, 2003; Brookes and Barfoot, 2004(a) and (b)).

There are millions of acres planted to corn and other crops throughout the U.S. each year, and yet instances such as those mentioned by the commenter (e.g., StarLink), are rare. Therefore, it is logical to assume that coexistence practices can be sufficient to maintain the integrity of a crop and the purity of seed, especially if there are economic/market motivations to implement coexistence practices, e.g., for organic farmers who receive higher price premiums for their crop (Ronald and Fouche, 2006). In terms of purity, for example, a bag of "pure" seed corn will cost $100 per bag, whereas one that exceeds the 5%[1] tolerance is worth $2 per bag (Fernandez and Polansky, 2006). The concept of successful coexistence and organic farming is also validated by data obtained from the Economic Research Service (ERS). According to the USDA-ERS, organic farming has been one of the fastest growing segments of U.S. agriculture. The U.S. had under a million acres of certified organic farmland when Congress passed the Organic Foods Production Act of 1990. By the time USDA implemented national organic standards in 2002, certified organic farmland had doubled, and doubled again between 2002 and 2005 (USDA-ERS, 2009). The U.S. total number of certified organic producers in 2000 was 6,592; this number increased to 10,159 in 2007 (USDA-ERS, 2009). This data shows that despite the availability and presence of GE crops in the U.S., organic farmland and organic producers continue to increase.

Based on the environmental analysis in the EA and the information above, APHIS believes that a determination of nonregulated status for Pioneer HT corn would not have significant impacts on human health and the environment due to pollen flow.

References

AOSCA. 2003. "Yellow Books" – Operation Procedures, Crop Standards, and Service Programs Publication. Association of Official Seed Certifying Agencies, Meridian, Idaho.

Brookes, G. and P. Barfoot. 2003. Co-existence of GM and Non-GM crops: Case Study of Maize Grown in Spain. PG Economics, Dorchester, United Kingdom.

Brookes, G. and P. Barfoot. 2004(a). Co-existence of GM and Non-GM Arable Crops: The Non-GM and Organic Context in the EU. PG Economics, Dorchester, United Kingdom.

Brookes, G. and P. Barfoot. 2004(b). Co-existence in North American Agriculture: Can GM Crops Be Grown with Conventional and Organic Crops? PG Economics, Dorchester, United Kingdom.

[1]The law states that if a batch of seed contains less than 5% adventitious presence (low-level, unavoidable, naturally occurring presence of foreign material in any product) of the same kind of crop seed, that portion of the batch does not need to be labeled as a unique genetic identification (Fernandez and Polansky, 2006).

Fernandez, M. and A. Polansky. 2006. Peaceful Coexistence Among Growers of: Genetically Engineered, Conventional, and Organic Crops. Summary of a Multi-Stakeholder Workshop Sponsored by the National Association of State Departments of Agriculture and The Pew Initiative on Food and Biotechnology, Boulder, Colorado (http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Summaries_-_reports_and_pubs/PIFB_Peaceful_Coexistence_Workshop_Report.pdf).

Gealy, D. R., K. J. Bradford, L. Hall, R. Hellmich, A. Raybould, J. Wolt, and D. Zilberman. 2007. Implications of Gene Flow in the Scale-up and Commercial Use of Biotechnology-derived Crops: Economic and Policy Considerations. Council for Agricultural Science and Technology (CAST, Issue Paper) 37:1-24.

Ronald, P. and B. Fouche. 2006. Genetic Engineering and Organic Production Systems. Agricultural Biotechnology in California Series, Publication 8188. University of California, Agriculture and Natural Resources (UCANR) (http://ucanr.org/freepubs/docs/8188.pdf).

USDA-ERS. 2009. Organic Production (Data Sets). United States Department of Agriculture, Economic Research Service, Washington, D.C. (http://www.ers.usda.gov/Data/Organic/index.htm#tables). Accessed on April 20, 2009.

3. **Comment:** One comment indicated that Pioneer HT corn will be dependent upon pesticide use to grow.

   Response: APHIS concludes that Pioneer HT corn is resistant to herbicides, but the absence of herbicide does not prevent its growth. The absence of herbicides promotes the growth of weeds, which in turn, can have significant negative impacts on the corn, including impacts on quality and yield. The environmental impacts associated with pesticide use on Pioneer HT corn are addressed in the EA and in response to other comments below.

4. **Comment:** Several comments indicated that APHIS should extend the comment period on this EA. In addition, the commenters believe that APHIS should prepare an EIS to more thoroughly analyze the environmental and potential human health hazards of deregulating Pioneer HT corn.

   Response: APHIS' 7 CFR part 340 regulations specify that comments on a petition for deregulation will be accepted from the public during a 60-day period. In this case, APHIS has determined that Pioneer HT corn is not a plant pest (Appendix A of the EA) and therefore, believes that 60 days is sufficient for the public to submit comments in support or against the deregulation of this product. In addition, APHIS has conducted an environmental assessment and determined that the deregulation of Pioneer HT corn will not have a significant impact on the quality of the human environment. Therefore, APHIS does not need to prepare an EIS before deregulating the product. APHIS considers its analysis on the environmental and potential human health hazards addressed in the EA and in response to other comments below to be adequate.

5. **Comment:** A comment indicated that crop varieties, such as Pioneer HT corn, are harmful to wildlife habitat (e.g., due to chemical pollution and increase in soil erosion), degrading the biodiversity of the North American landscape. In addition, the comment states that crop varieties, such as Pioneer HT corn, are likely to be exported and therefore, will spread their harmful effects worldwide.

   Response: APHIS promulgated biotechnology regulations pursuant to its authority under the Plant Protection Act (PPA). The PPA is the plant health statute, intended to protect plant health in the U.S. As long as Pioneer HT corn is a regulated article under APHIS regulations (7 CFR part 340), it is subject to the provisions of the regulations under the PPA. In this case, APHIS has concluded that Pioneer HT corn does not present a plant pest risk in the U.S. and should, therefore, be deregulated. A discussion on chemical use and soil erosion has been included in the response to comments #9 and 14, respectively. In summary, data over the past 15 years has demonstrated that the availability of herbicide tolerant crops has both lowered the amount of chemicals used by growers and decreased soil erosion due to the increased use of conservation tillage. In terms of wildlife and food safety, as of September, 2008, and based on the information submitted by Pioneer, the FDA completed the voluntary biotechnology consultation for Pioneer HT corn for food and animal feed (BNF No. 000111). FDA has no further questions about this corn (US-FDA, 2008). The overall impacts of U.S. agriculture on the North American landscape are beyond the scope of the E.A. and this response to comments.

   In terms of the effects of Pioneer HT corn worldwide, although APHIS engages in technical dialogs with its regulatory counterparts in other countries, the decisions in the other countries whether or not to regulate Pioneer HT corn are sovereign decisions of those countries. Other countries may conduct risk assessments for Pioneer HT corn in order to make their own determinations and in accordance with their own regulatory statutes.

   US-FDA. 2008. Biotechnology Consultation, Agency Response Letter (BNF No. 000111). United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, College Park, Maryland (http://www.cfsan.fda.gov/~rdb/bnfl111.html). Accessed on November 18, 2008.

6. **Comment:** One comment indicated that APHIS did not properly analyze alternatives to the proposed action.

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

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

7. **Comment:** One comment raised food safety concerns with Pioneer HT corn due to the presence of poorly characterized acetylated amino acids that have the potential to adversely affect the health of humans and animals. In addition, the commenter noted that Pioneer failed to conduct long-term animal feeding studies with this corn. Other commenters stated that APHIS did not adequately analyze the risks (e.g. amplification of toxins and reduced levels of nutrients in the GE corn) to human and animal health.

   Response: Regulation of biotechnology is a responsibility that APHIS shares with the Environmental Protection Agency (EPA) and the FDA. EPA regulates pesticides, including crops with plant-incorporated protectants (pesticides intended to be produced and used in a living plant) to ensure public safety from their use, including pesticide residue on food and animal feed. FDA has primary responsibility for ensuring the safety of food and animal feed. This coordinated federal biotechnology regulatory effort is critical for reassuring industry, consumers, and other groups that biotechnology-derived crops and other biotech products are rigorously regulated for safety.

   Acetylated amino acids are not poorly characterized because they have a history of safe consumption based on their presence in commonly consumed foods. The applicant tested and found acetylated amino acids in a number of foods (pg. 173 of the petition) including: ground beef, ground turkey, ground chicken, and whole egg. In fact, N-acetyl-L-methionine has been approved by FDA as a food additive (US-FDA, 2008(b)) and an online search revealed that N-acetyl-L-cysteine and N-acetyltyrosine are readily available as dietary supplements from a wide variety of retailers (Advance Physician Formulas, 2009; Health Superstore, 2009). In addition, as of September, 2008, and based on the information submitted by Pioneer, the FDA completed the voluntary biotechnology consultation for Pioneer HT corn (food and feed) (BNF No. 000111). FDA has no further questions about this corn (US-FDA, 2008(a)).

The response to question #13 of this document summarizes the experiments conducted in order to address the food safety concerns associated with Pioneer HT corn (including animal studies), those experiments include a 42-day broiler and a mice feeding study. In response to the risks associated with consumption of Pioneer HT corn and the development of toxins or the presence of reduced levels of nutrients in the corn, the data show that the proteins expressed in Pioneer HT corn lack amino acid identity with known protein allergens and toxins. Pioneer HT corn was also found to be equivalent to the control corn, in terms of composition (e.g. nutrient levels), in both food and forage samples.

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US-FDA. 2008(b). Food Additives Permitted for Direct Addition to Food for Human Consumption, Special Dietary and Nutritional Additives, Section 172.372 – N-Acetyl-L-methionine. United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, College Park, Maryland (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.372). Accessed on March 16, 2009.

8. **Comment:** One comment indicated that Pioneer HT corn would not be a replacement product to other herbicide tolerant corn varieties available on the market today and its deregulation will in turn, increase the acreage planted to GE corn.

   Response: The commenter did not submit any type of evidence to validate the claim that the deregulation of Pioneer HT corn would increase the acres planted to GE corn across the U.S. The commenter's speculations are based on personal opinion and are not substantiated by any data. As discussed in the EA, growers can choose to plant seed from a wide range of crop varieties available in the market today. As stated by the commenter, growers with weed resistance problems could choose to plant Pioneer HT corn in order to better manage weed resistance. But this is the case for any grower with any weed problem, not only weed resistance. Several varieties of corn have been produced, through genetic engineering or traditional means, to be tolerant to a number of pesticides, including glyphosate and those are readily available to growers today. In addition to the varieties provided in Appendix B of the EA, the list below provides some of the dual herbicide resistant corn varieties available in the market today. Therefore, growers have, and will continue to have, herbicide tolerant corn varieties available for planting with or without the deregulation of Pioneer HT corn. Also, as mentioned in the EA (pg. 28), growers have access to other crops resistant to glyphosate and ALS-inhibiting herbicides, not only corn. Despite the number of GE herbicide tolerant corn varieties available to growers, data shows that the acres of corn planted to biotech herbicide tolerant varieties, (non-stacked with insect resistant traits), dropped in 2008 and again in 2009, (USDA-NASS, 2008; USDA-NASS, 2009) and although it may be difficult to predict the corn market, experts anticipate that the planted acres of corn will stabilize at 89-90 million acres in 2008 and will remain at that level through 2016 (USDA-OCE, 2007). In addition, data shows that corn varieties containing the Bt (*Bacillus thuringiensis*) trait (conferring insect resistance), whether alone or stacked with an herbicide resistant trait, are more readily planted than those varieties conferring resistance to herbicides alone (USDA-NASS, 2008). Despite the corn market's "ethanol bloom" as stated by the commenter, data from 2008 shows that acres planted to corn dropped by 7% from 2007 (USDA-NASS, 2008) and data from production and use of corn in the U.S. shows that 1 billion more bushels of corn are used for animal feed than for ethanol production (ICPB-ICGA, 2009).

References

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Links to Some Corn Varieties Available on the Market Today:

- Agrigold A6391 (glyphosate, glufosinate) (http://www.agrigold.com/hybrids/pdfs/A63911.pdf)
- Pfister 2730 Triple (insect, glyphosate, glufosinate) (http://www.pfisterhybrid.com/hybrids/details.cfm?hybridID=27)
- 7916Hx1CL (insect, ALS inhibitors, glufosinate) (http://www.beckshybrids.com/Media/pdf/single_double_stack_corn.pdf)
- Agrisure GT/CB/LL (insect, glyphosate, glufosinate) (http://www.kussmaulseeds.com/technology/AvailableTraitsforCorn.htmlhttp://www.kussmaulseeds.com/technology/Agrisure.html_)

9. **Comment:** One commenter was concerned with herbicide use and the increased buildup of residues in the soil. Another commenter was concerned that more chemical use contaminates the environment and places animals, plants, and people at risk.

   Response: Under the PPA, APHIS has no regulatory authority to restrict the use of herbicides on crops, whether they are GE or non-GE crops. The EPA is responsible for the regulation of pesticides, including herbicides; in this case, the safe use of glyphosate (EPA, 1993) and a number of ALS–inhibiting herbicides (EPA, 2008) has been established by the EPA through their registration for use on corn and the setting of tolerances. Glyphosate and many ALS-inhibiting herbicides, when used according to the label, have been shown not to have unreasonable adverse effects on plants, animals, humans, and the environment. To make such determinations, EPA reviews a large number of scientific studies and tests conducted by applicants (EPA, 2009). 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 species. In considering whether to register a pesticide, EPA reviews data from ecological, dietary, and exposure experiments 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 by EPA's Office of Pesticide Programs. EPA has already concluded that glyphosate and registered ALS-inhibiting herbicides pose no unreasonable risks to humans, wildlife, and the environment (EPA, 2008).

   References

EPA. 1993. Reregistration Eligibility Decision (RED) – Glyphosate (738-R-93-014). Office of Prevention, Pesticides and Toxic Substances. United States Environmental Protection Agency, Washington, D. C. (http://www.epa.gov/oppsrrd1/REDs/old_reds/glyphosate.pdf).

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EPA. 2009. Pesticides: Regulating Pesticides. United States Environmental Protection Agency, Washington, D.C. (http://www.epa.gov/pesticides/regulating/). Accessed on March 16, 2009.

10. **Comment:** One commenter was concerned that because weeds give a picture of the fertility of the soil and bring essential elements to plants, killing the weeds with herbicides would change the fertility of the soil.

    Response: Although some weeds can be indicators of the growing conditions in a field and may help to conserve moisture and nutrients, corn and other crop growers had, and continue to have, management practices in place to control the presence of weeds in their fields. As described in the EA (pg. 6), growers choose from a wide range of agronomic practices in order to control weeds; which, if left uncontrolled, can cause significant losses in yield (Bosnic and Swanton, 1997; Fausay et al., 1997). Weeds compete with crops for water, nutrients, light, and other growth factors. Among U.S. crops, corn is one of two crops that suffer the greatest aggregate production losses due to weeds (Swinton et al., 1994). Therefore, because growers already have agronomic practices in place to control weeds, any widespread planting of Pioneer HT corn will not significantly affect growers' efforts to manage weeds. In this case, glyphosate and ALS-inhibiting herbicides are post-emergence herbicides that will be applied after Pioneer HT corn, and weeds, have emerged.

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11. **Comment:** One commenter was concerned that once applied, pesticides or herbicides become a part of the GE plant and the seed. The commenter was worried that the GE seeds cannot be properly digested and that the pesticide or herbicide stays in the body and "continues to grow."

    Response: Pioneer HT corn is resistant to glyphosate and ALS-inhibiting herbicides. Considering the long list of ALS herbicides available in the market today, BRS has chosen glyphosate in order to provide a clear and concise answer to this comment. According to the EPA, the nature of glyphosate residue in plants and animals is adequately understood (EPA, 1993). Studies with a variety of plants indicate that uptake of glyphosate from soil is limited. The material which is taken up is readily translocated throughout the plant. Foliarly applied glyphosate is also readily absorbed and translocated. The primary degradation product of glyphosate in plants, soil, and water, is aminomethylphosphonic acid (AMPA), whose chemical structure is very similar to that of glyphosate. AMPA itself has no commercial use. Metabolic studies in GE plants developed to be resistant to glyphosate show that the metabolism is the same as in susceptible plants. Glyphosate is metabolized to AMPA, which is either non-selectively bound to natural plant constituents, further degraded to one-carbon fragments that are incorporated into natural products, or conjugated with naturally-occurring organic acids to give trace-level metabolites. The metabolites are the same in resistant and susceptible crops but their relative distribution depends on the speed and extent of conversion to AMPA (FAO, 1997). EPA conducted a dietary risk assessment for glyphosate based on a worst-case risk scenario, that is, assuming that 100 percent of all possible commodities/acreage were treated, and assuming that tolerance-level residues remained in/on all treated commodities. The Agency concluded that the chronic dietary risk posed by glyphosate food uses is minimal. More information on glyphosate and other herbicides can be found on EPA's website (EPA, 2009).

In terms of seed and pesticide digestion, APHIS assumes that the commenter referred to the potential of seeds growing in our bodies and not pesticides, as it would be impossible for any pesticide to grow (under any condition). As discussed in the EA, in terms of composition and nutrition, Pioneer HT corn was found to be no different than control (non-GE) corn and aforementioned, the FDA completed the biotechnology consultation for Pioneer HT corn (BNF No. 000111) and has no further questions about Pioneer HT corn in food and feed (US-FDA, 2008). In addition, and based on the results of the 42-day chicken study conducted by Pioneer, it was concluded that Pioneer HT corn, unsprayed or sprayed with an herbicide mixture, was nutritionally equivalent to non-GE control grain (McNaughton et al., 2008). Besides the studies conducted by Pioneer, other feeding studies have shown that GE corn is as safe and nutritious as other existing commercial corn varieties (Van Eenennaam, 2005; Hammond et al., 2004; Donkin et al., 2003). In terms of GE crops in general, over 100 digestion and feeding studies examining the effects of feeding GE crops to animals have been reported in the scientific literature. The results of such studies have shown no significant differences in the nutritional value of feed derived from GE crops compared to their conventional counterparts, nor have they shown any indication of a disturbance to animal health or the quality of resulting animal products (Van Eenennaam, 2005). In addition, if seeds were not properly devitalized (devoid of life) by chewing and the initial process of digestion, the extreme low pH of the stomach (gastric juice keeps the acidity of the stomach at a pH between 1 and 3) and the subsequent environment of the digestive tract would surely prevent the germination of any seed and therefore, the growth of a plant.

References

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Hammond, B, R. Dudek, J. Lemen, and M. Nemeth. 2004. Results of a 13 Week Safety Assurance Study with Rats Fed Grain from Glyphosate Tolerant Corn
Food and Chemical Toxicology 42:1003–1014.

McNaughton, J., M. Roberts, B. Smith, D. Rice, M. Hinds, T. Rood, R. Layton, Lamb, and B. Delaney. 2008. Comparison of Broiler Performance and Carcass Yields When Fed Diets Containing Transgenic Maize Grains from Event DP-Ø9814Ø-6 (Optimum GAT), Near-Isogenic Control Maize Grain, or Commercial Reference Maize Grains. Poultry Science 87:2562–2572.

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Van Eenennaam, A. L. 2005. Do Genetically Engineered (GE) Crops Impact Animal Health and Food Products? Proceedings, California Alfalfa and Forage Symposium, Visalia, California. UC Cooperative Extension, Agronomy Research and Extension Center, Plant Sciences Department, University of California, Davis, California (http://alfalfa.ucdavis.edu/+symposium/proceedings/asdf/alf_symp /2005/05-273.pdf).

12. **Comment:** Several comments indicated that the deregulation of Pioneer HT corn will increase the use of glyphosate and ALS inhibitors due to the increase in acreage of herbicide tolerant corn to be planted. One commenter stated that APHIS falsely assumes that corn acreage in the U.S. has leveled out and will not dramatically increase in the future; in addition, the commenter accuses APHIS of reporting false acreage data in the EA. Comments also indicated that the availability of Pioneer HT corn will increase weed resistance to both herbicides and this increase in weed resistance will in turn, lead to greater use of other toxic chemical weedkillers.

Response: APHIS believes that the availability of Pioneer HT corn is not going to significantly increase the number of acres planted to herbicide tolerant corn (see response to comment #8) and therefore, should not considerably increase the number of acres to be sprayed with glyphosate and ALS-inhibiting herbicides. Furthermore, if the prediction is correct that the corn acreage in the U.S. is likely to stabilize at 89-90 million acres through 2016 (see response to comment #8), then corn acreage in the U.S. planted to glyphosate/ALS-inhibiting herbicides tolerant corn varieties is not expected to increase due to the availability of Pioneer HT corn because: 1) a certain percentage of corn growers choose to grow organic corn, and GE corn varieties cannot be grown and certified as organic, 2) some growers will choose to grow non-GE corn for other marketing reasons, 3) a certain percentage of corn growers each year may choose to rotate out of glyphosate and/or ALS resistant corn and use herbicides with alternate modes of action and/or tillage as recommended to avoid weed shifts or the selection of glyphosate and/or ALS resistant weeds, and 4) they may simply choose another variety without the glyphosate/ALS tolerance trait that is better suited to their specific growing conditions.

One commenter accuses APHIS of falsely stating that “approximately 24% of the corn planted in 2007 was herbicide tolerant” and that APHIS stated that the number would be higher if stacked varieties were included in that percentage. APHIS analyzed data from the USDA’s Economic Research Service and stated in the EA that the number would be higher if all varieties were taken into consideration. In the EA, APHIS considered only the herbicide tolerant varieties that Pioneer HT corn would replace. Bt stacked varieties were excluded because it would be reasonable to assume that a grower planting a Bt resistant crop would continue to plant that variety, or a similar replacement product, if they found that there was an advantage to having the added insect resistance in the corn variety they planted. In response to this comment, APHIS has added language to clarify the scope of the data in Table 5 of the EA

APHIS acknowledges the occurrence of herbicide resistant weeds in the U.S. and discusses management strategies to deal with the issue in the EA (pgs. 9-11). APHIS also points out that farm press publications, scientific articles, Universities/Cooperative Extension Services, and other sources are available for growers (see below) as educational and guidance tools. Weed scientists constantly provide information, through these resources, about the importance and existence of resistant weeds. They also provide management strategies for controlling resistant weeds as well as tactics for preventing the development of more resistant biotypes. The use of multiple herbicides with different modes-of-action on crops (whether tank-mixed or applied sequentially) is already a common agricultural practice in order to manage weeds. Growers already spray either glyphosate or ALS-inhibiting herbicides on their corn fields. In this case, Pioneer HT corn will enable growers to control weeds using ALS-inhibiting herbicides where, for example, glyphosate resistant weeds are present, or conversely, use glyphosate where ALS resistant weeds are present. This, in turn, should both delay the development of resistant weeds and prevent the use of more toxic chemical herbicides.

In 2007, the area planted to four major crops (wheat, corn, soybean, and cotton) in the U.S. was estimated at over 225 million acres (USDA-NASS, 2007). If one considers that the estimated acreage that may have contained glyphosate tolerant weeds ranged from approximately 230,000 to 2.49 million acres (acreages are reported in ranges only and therefore lack some accuracy) (Weed Science, 2008(a)), the total acreage of land that harbored glyphosate tolerant weeds was relatively small (somewhere between approximately 0.1 and 1%). This number does not take into account the acres planted to other crops such as sorghum, rice, canola, safflower, potatoes, etc. It is reasonable to expect that growers who find it necessary to address glyphosate tolerant weeds in their fields may choose to adopt Pioneer HT corn or another similar variety with dual herbicide resistance. If either of these options is not sufficient, it can be expected that a grower will utilize another means of weed control (e.g., tillage, use of a different mode-of-action herbicide, etc.). It can further be expected that growers will rotate between methods of weed control over time as they see fit based on the presence or absence of herbicide tolerant weeds in their fields. What this means is that usage of various herbicides will fluctuate over time (as has happened in the past and is documented in the EA, pg. 8). APHIS is not aware of significant environmental impacts resulting from these fluctuations in herbicide use in the past and would not expect significant impacts to occur in the future. APHIS also notes the appearance of ALS tolerant weeds (Weed Science, 2008(a)) dating back as far as 1987. Subject to the same limitations in the accuracy of data noted above, range estimates of affected acreage by ALS tolerant weeds is relatively small when compared to the 225 million acres of land planted to the four aforementioned crops. One also needs to consider that there are numerous ALS inhibitor herbicides (Weed Science, 2008(b)) and noted tolerant weeds may not be tolerant to all such herbicides (i.e., other ALS inhibitors may still be effective for significant weed control in corn).

One commenter believes that a factor that promotes the development of glyphosate resistant weeds, due to the availability of HT crops, is the delayed application of glyphosate because delaying application increases the potential for weeds, including resistant ones, to survive and propagate. The commenter stated: “Many growers delay application of glyphosate until many weeds are large in the hope that all weeds will have emerged and only one application would be needed.” Although a page later, the same commenter contradicted this by stating that: “The stacking [of genes] would allow for more frequent applications of higher doses of glyphosate, perhaps over the entire growing season of the crop.” Although it is difficult to discern whether the commenter is in support or against more than one application of the herbicide, APHIS’ response is that when applying an herbicide to their fields, growers must follow label application rates;“higher doses” would have to be reviewed and approved by the EPA (see response to comment #10). EPA includes instructions and restrictions on how glyphosate, and other herbicides, can be applied, and has determined that there is no unreasonable environmental risk if the user adheres to the directions. Violators of the label restrictions are liable for all negative consequences of their actions; therefore, growers who use glyphosate and other herbicides, are very likely to follow the label restrictions, and adverse impacts from an increase in herbicide use should be minimized. In addition, APHIS has no regulatory authority over the use of any herbicides; herbicide use is regulated by the EPA.

In regard to weed resistance to ALS herbicides, the commenter states that weed resistance in corn and soybean explains the reduction in ALS herbicide use over the years, as growers switched to other mode-of-action herbicides. As already discussed, APHIS acknowledges the occurrence of weed resistance and the issues associated with it and includes in the EA and this document sources of information and educational material for growers to use to manage weeds and to prevent the development of resistant ones. This commenter emphasizes the point that APHIS has been trying to make: when and if resistance occurs, growers are encouraged to and do switch to herbicides with different modes of action (also an integrated weed management practice). The availability of Pioneer HT corn will allow growers to do exactly as described by the commenter.

As already discussed, APHIS believes that Pioneer HT corn will likely be a replacement product to other similar products available in the market today. In the EA, APHIS does not discount the potential increase in glyphosate and ALS-inhibiting herbicides due to the deregulation of Pioneer HT corn. Nevertheless, in terms of glyphosate, this increase would likely be negligible relative to the large number of acreage already being sprayed with the herbicide. A discussion on the impacts of the potential increase in the use of ALS herbicides is included on pg. 30 of the EA. One comment stated that herbicide use continues to increase despite the availability of products such as Pioneer HT corn. Although one study, as provided by the commenter, has claimed that the volume of herbicide use is greater due to glyphosate tolerant crops (Benbrook, 2004), other studies demonstrate a decrease in overall herbicide usage related to the increase adoption of herbicide resistant crops (Johnson et al., 2008; Fernandez-Cornejo, 2006; Gianessi and Reigner, 2006; Sankula, 2006; Heimlich et al., 2000). The commenter accuses APHIS of relying on erroneous and outdated literature to show this decrease, such as using papers by authors Gianessi (2005) and Brookes and Barfoot (2006). According to the commenter, these authors are “unscrupulous contractors for the biotech industry who put out misleading studies.” These accusations are based on the personal opinion of the commenter and will not be addressed by APHIS. However, APHIS does emphasize that the scientists writing biological assessments such as this EA, use the most up-to-date information available, scientific studies, and peer-reviewed literature. This is shown above, where five citations validate the claims made by authors Gianessi in 2005 and Brookes and Barfoot in 2006. Although, as already discussed above, APHIS believes that Pioneer HT corn would replace similar products available in the market, it does not discount the possibility that acres planted to GE corn could increase following its deregulation. This would mean an increase in the use of glyphosate and ALS-inhibiting herbicides. But as described in the EA under the “no action” alternative, the availability of products such as Pioneer HT corn help reduce the use of more harmful herbicides such as atrazine and dicamba. Glyphosate has been shown to replace the use of herbicides that are more toxic and persist longer in the environment (Gianessi and Carpenter, 2000; Heimlich et al., 2000)). In this case, the comment indicated that glyphosate use has greatly increased over the years but excludes any information on the number of herbicides that have decreased. As shown in Table 4 of the EA (pg. 8), consistently from

1995 to 2005, the use of the following herbicides has decreased: alachlor, bromoxynil, dicamba, dimethenamid, metolachlor, nicosulfuron, and pendimethalin; while the acreage planted to corn increased (72 million acres in 1995, 79.6 in 2000, and 81.6 in 2005) (USDA-NASS, 1995; USDA-NASS, 2000; USDA-NASS, 2005).

Although the commenter agrees that glyphosate is a popular herbicide and that herbicide tolerant crop plantings have increased in the past decade, he/she fails to point out any of the positive attributes associated with herbicide tolerant varieties. As many comments in support of the deregulation described, growers rely on products, such as Pioneer HT corn, for weed resistance management, for soil and water conservation by facilitating conservation tillage practices, for the continued use of herbicides with favorable environmental profiles, to rotate herbicide modes of action, for marketplace competition, and for the delivery of an abundant, high quality, and economically and efficiently produced corn crop (Bill Chase, President, South Dakota Corn Growers Association; Bill Johnson, Associate Professor of Weed Science, Purdue University; Bryan Young, Professor of Weed Science, Southern Illinois University; F. Jon Holzfaster, Chairman, Nebraska Corn Board; Brandon Hunnicutt, President, Nebraska Corn Growers Association; Philip Westra, Professor of Weed Science, Colorado State University; Bob Dickey, President, National Corn Growers Association; Rob Elliott, Illinois Corn Growers Association; Mark VanGessel, Professor and Extension Specialist of Weed/Crop Management, University of Delaware; Jere White, Executive Director, Kansas Corn Growers Association).

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Links to examples of information sources available to growers:

- Provides links for more information, talks about rotating modes of actions, scouting, targeting, etc. (http://farmindustrynews.com/crop-protection/herbicides/weeds-rebound/)
- Provides link to Syngenta's Resistance Fighter site, which offers customized weed management solutions (http://deltafarmpress.com/mag/farming_syngenta_module_helps/)
- Discusses methods to delay resistance, including crop rotation, alternating chemistries, tillage, and cleaning equipment (http://southwestfarmpress.com/news/012407-weed-resistance/)
- University of Wisconsin-Madison, glyphosate resistant weeds (http://news.cals.wisc.edu/newsDisplay.asp?id=1816)
- Iowa State Weed Science, integrated weed management, glyphosate resistant weeds, etc. (http://www.weeds.iastate.edu/)

13. **Comment:** Two comments indicated that APHIS failed to consider the impacts to threatened and endangered, non-target, and beneficial species. One commenter provided references for a number of studies showing the effect of herbicides to support the claim that the deregulation of Pioneer HT corn would have adverse effects on aquatic ferns and other aquatic species. The second commenter referenced a peer-reviewed paper as part of the comment and submitted two papers with no comment to validate the need for APHIS to address competition between invasive earthworms and the American burying beetle. One paper on amphibians was also submitted by the same individual with no comment; the response below encompasses all non-target species.

    Response: BRS has reviewed the data in the petition to determine if a consultation, as required under Section 7 of the Endangered Species Act is required. APHIS has reached a determination that the deregulation of Pioneer HT corn would have no effects on listed threatened and endangered species and consequently a written concurrence or formal consultation with FWS is not required for this EA. In turn, APHIS does not need to write a biological assessment for the proposed action.

    As described in Appendix D of the EA, data obtained for the GAT protein (confers resistance to glyphosate) indicate the lack of amino acid identity and of immunologically significant similarities between the GAT protein in Pioneer HT corn and known protein allergens or toxins. Pioneer’s assessment of ZM-HRA protein (confers resistance to ALS-inhibiting herbicides) noted high similarity of this protein with ALS proteins found in bacteria, fungi, algae, and plants; Pioneer also analyzed protein sequence similarities with known and putative protein allergens and toxins and found no similarity that would indicate either allergenicity or toxicity of ZM-HRA protein. Pioneer also conducted a study to assess the wholesomeness/nutrition (poultry study) of Pioneer HT corn (Appendix A) and an acute and repeated dose study of N-acetylaspartate (NAAsp), an acetylated amino acid, in rats (Appendix D). In both studies, no differences were observed in any of the treatment groups. In addition, Pioneer found no evidence of acute toxicity in mice, for each protein, at a target dose of 2,000 milligram purified protein preparation per kilogram of body weight (equivalent to approximately 1,640 mg of the full-length GAT4621 protein per kg of body weight and 1,236 mg of full-length ZM-

HRA protein per kg of body weight) (Appendix D of the EA). Pioneer also conducted extensive analyses to assess compositional differences between Pioneer HT corn and the comparator corn varieties. Pioneer found no statistically significant differences between the Pioneer HT corn and control corn mean values for an extensive number of nutrients (e.g., protein and fat) (Section VIII, pg. 84-92 of the petition), vitamins, minerals, and other compounds (Section VIII, pg. 96-99 of the petition). Compositional analyses data comparison between Pioneer HT corn and control corn for the forage samples also showed no statistically significant differences (Section VIII, pg. 101-106 of the petition). Pioneer HT corn comparisons to the non-GE control corn and other corn varieties indicated no significant differences in its growth habit, other agronomic properties, and interactions with pests and non-pest organisms. In addition, as of September, 2008, and based on the information submitted by Pioneer, FDA has completed the voluntary biotechnology consultation for Pioneer HT corn (BNF No. 000111) and has no further questions (US-FDA, 2008). The above information supports the conclusion that Pioneer HT corn is no different than any other corn variety available in the market today.

APHIS made a no effects determination on listed and proposed threatened or endangered species for Pioneer HT corn based on its plant and plant pest characteristics (above). Because the preferred alternative of deregulation in whole of Pioneer HT corn is not expected to change land use patterns or cultivation practices relevant to current practices, APHIS also concluded that granting a determination of nonregulated status to Pioneer HT corn would not affect designated or proposed critical habitat.

APHIS has no regulatory authority over the use of herbicides. EPA regulates the use of herbicides and is responsible for determining the effects of herbicides on TES species. Pioneer HT corn is expected only to be a partial or complete replacement for the herbicide tolerant varieties already available on the market today. The amount of glyphosate to be used on Pioneer HT corn is expected to be similar to the amount of glyphosate used on other corn varieties. Although a shift to planting Pioneer HT corn could result in an increase in the use of ALS-inhibiting herbicides, these are very low use rate herbicides (ounces/acre) (EPA, 2008) and their existing combined use in corn is low. In regard to the combined effect of glyphosate and ALS-inhibiting herbicides, the use of multiple herbicides with different modes-of-action on crops (whether tank-mixed or applied sequentially) is already a common agricultural practice. In addition, the EPA is responsible for the regulation of pesticides, including herbicides; in this case, the safe use of glyphosate (EPA, 1993) and a number of (ALS)–inhibiting herbicides (EPA, 2008) has been established by the EPA through their registration for use on corn and the setting of tolerances.

Glyphosate and many ALS-inhibiting herbicides, when used according to the label, have been shown not to have unreasonable adverse effects on species and the environment. To make such determinations, EPA reviews a large number of scientific studies and tests from applicants (EPA, 2009). 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. EPA has already concluded that glyphosate and registered ALS-inhibiting herbicides pose no unreasonable risks to wildlife and the environment (EPA, 2008).

The studies referenced by the commenter focus on aquatic species. Pioneer HT corn has not been modified in a way that would allow it to be grown in wetter or aquatic environments. Therefore, the potential exposure of aquatic organisms to glyphosate and ALS-inhibiting herbicides should not increase because of the determination of nonregulated status for Pioneer HT corn. In addition, in the study cited by the commenter, Aida et al. (2004), the research was focused on rice patty herbicides, specifically, Bensulfuron Methyl (BSM). BSM has been registered for use in rice patties, not on corn fields. In addition, the agricultural environment of a rice patty is significantly different from that of corn. Many of these tests have also been conducted in pots or micro-plates and not in agricultural fields or under field experimental conditions. As discussed in the EA (pg. 11), agricultural ecosystems are highly diverse and complex. Several processes and factors affect the environmental fate of herbicides in soils (Kenna, 1995; Sims and Cupples, 1999; Soulas and Lagacherie, 2001); many should be taken into account in order to properly assess the effect of herbicides on non-target species, the soil, and the environment. The authors in a scientific paper referenced by the commenter explain that: “the toxicity of sulfonylurea herbicides could be modified by several environmental factors; among these could be the occurrence of dissolved amino acids in natural waters” (Nyström et. al, 1999). This is important because, as later the authors add, “Dissolved amino acids at natural concentrations can support algal (Rivkin and Putt, 1987) as well as bacterial (Coffin, 1989) growth.” Based on this information, APHIS does not believe that these studies validate the commenter’s claims that Pioneer HT corn would have adverse effects on non-target aquatic species.

In terms of competition between invasive earthworms and the burying American beetle, the commenter utilized the EA written for MIR604 corn (72 *FR* 13736-13737, Docket no. 2006-0157) and two references, to indicate the need for APHIS to further analyze the impact of the deregulation of Pioneer HT corn on soil organisms. The commenter was concerned that the deregulation of Pioneer HT corn might disrupt the competition among soil organisms.

First, the EA for MIR604 addressed the issue of endangered beetles because the product conferred resistance to Coleopteran species (corn rootworm). It would be expected that the NEPA analysis for such a product would involve an evaluation on the effects of deregulation on threatened and endangered Coleopteran species. This is not the case for Pioneer HT corn, as the product is herbicide tolerant and as discussed in the plant pest risk assessment (EA, pg. 45), other than expressing the herbicide tolerance genes, the product is not different from the unmodified organism from which it was derived.

Second, the references utilized by the commenter examined the issues related to colonization of hardwood forests in North America by non-native earthworms. The references do not indicate that this is a problem in corn fields, where clearly, Pioneer HT corn would be grown. The reference does not involve GE varieties of hardwood trees or any other type of GE tree. One of the references examined the problems associated with nightcrawlers (*Lumbricus terrestris*); these earthworms may be at least partly responsible for the occasional rapid movement of liquid animal manure and chemicals through soil to underground drainage pipes (Comis, 2005). It is difficult to respond to a reference without a corresponding comment explaining the commenter's reasons for submitting it. In addition, the paper never mentions competition between earthworms and beetles (or any organism); therefore, it is unclear what the commenter's position is. APHIS notes that the paper includes solutions for growers to avoid the presence of liquid manure and chemicals in drainage pipes. In addition, APHIS emphasizes, as in the EA, that the soil is a complex environment of organisms. Population differences among locations will vary due to a complex array of factors including soil type, tillage and crop history, chemical use history, climate history, weather changes, etc. (Kladivko, et. al, 1997). Therefore, what may be true in a hardwood forest will not necessarily be true in a corn field.

Although no comment was included on the paper on amphibians, APHIS assumes the commenter believes APHIS did not adequately analyze the impacts of glyphosate on amphibians. Glyphosate is slightly toxic to amphibians; however, some formulations of glyphosate with the surfactant polyethoxylated tallowamine POEA can be toxic to amphibians. POEA is a non-ionic surfactant used in many herbicide formulations to increase the ability of active ingredients to penetrate leaf cuticles. POEA has been found to be more toxic to amphibians and other aquatic animals than the herbicide itself (Lajmanovich, 2003). EPA has already determined that, when used according to the label, glyphosate does not pose any unreasonable risks to wildlife and the environment. Estimated and measured concentrations of glyphosate use in wetlands and different bodies of water has shown that the risk to aquatic organisms is negligible or small at application rates less than 4 kg/ha (kilogram/hectare) and only slightly greater at application rates of 8 kg/ha (rates at, or significantly above, the recommended application rates of 0.21 to 4.2 kg/ha for glyphosate) (Solomon and Thompson, 2003; Cerdeira and Duke, 2006).

All of the above reasons allow APHIS to conclude that the deregulation of Pioneer HT corn will have no adverse effects on federally threatened and endangered, non-target, and beneficial species.

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14. **Comment:** One comment indicated that the EA's analysis of tillage and climate change was inadequate and required an EIS because APHIS did not provide enough evidence that growing herbicide tolerant crops increases the use of conservation tillage and therefore, causes less climate changes. The commenter asked APHIS how the deregulation of Pioneer HT corn can provide additional stimulus for conservation tillage if Pioneer HT corn will replace other herbicide tolerant varieties. The comment also discussed the problem of the increased number of earthworms found in no-till fields.

    Response: The EA's analysis of how deregulation of Pioneer HT corn may affect tillage and climate change was adequate. The commenter states that the availability of HT crops has not increased the use of conservation tillage. However, the EA made clear that growers will utilize the most effective and economical means of weed control at their disposal. While mechanical tillage is one recommended practice for controlling herbicide tolerant weeds and an important part of an Integrated Weed Management (IWM) program, the availability of dual herbicide tolerant crops such as Pioneer HT corn, give growers the option to use different herbicides to control weeds in addition to or instead of tilling. Table 6 of the EA provides an overview of the national use of tillage systems from 1989 to 2000; updated national information has not yet been released by the National Agricultural Statistics Service (NASS) and as indicated in the EA, the table clearly shows that the use of no-till increased over that time period. More recent data also indicate that conservation tillage has increased over the years. In Tennessee (TN), for example, data collected by the NASS Tennessee Field Office show that conservation tillage (primarily no-till) increased for five crops (soybeans, corn, sorghum, cotton, and wheat) in six districts in 2008. The data compiled by NASS in TN also showed the same trend when comparing conservation tillage to conventional tillage use over a five year period (2004-2008) (USDA-NASS, 2008(a)).

    The commenter is concerned that the availability of herbicide tolerant crops has not reduced growers' use of tillage to control weeds. As discussed in the EA, although APHIS believes that Pioneer HT corn will likely be a replacement product to other similar products available in the market today, it does not discount the possibility that acres planted to GE corn could increase following its deregulation. As discussed in response #12 supporters of this deregulation, have seen the positive attributes of the availability of products such as Pioneer HT corn; one of those attributes is soil and water conservation by facilitating conservation tillage. USDA data published in 2006 shows that about 60 percent of the area planted with HT soybeans was under conservation tillage in 1997, compared with only 40 percent of the acres planted to conventional soybeans (Fernandez-Cornejo and Caswell, 2006). It would be logical to assume that this link would be clearer and more pronounced for soybeans, when considering the high adoption and higher rate of adoption of HT soybeans versus HT corn over the past decade. (Data published by NASS in 2008(b), and for the states surveyed, showed that 92% of the acres planted to GE varieties were planted to herbicide tolerant soybeans in comparison to only 23% for corn). Brookes and Barfoot (2006(a)), in their analysis of GE crop impact, stated: "[the use of no-till and reduced-till] have increased significantly with the adoption of GM HT crops because the GM HT technology has improved growers' ability to control competing weeds, reducing the need to rely on soil cultivation and seed-bed preparation as means to getting good levels of weed control." In a review of organic farming and the benefits of no-till agriculture in the United Kingdom, the author stated: "GM herbicide-tolerant crops in the USA are responsible for the considerable USA take-up of no-till agriculture" (Trewavas, 2004).

In terms of tillage and climate change, APHIS understands that human activities such as agriculture contribute to the release of atmospheric gases that may lead to climate change and global warming, but in this case, the EA was written for the deregulation of Pioneer HT corn and not to address the effects of agriculture on the world. Brookes and Barfoot (2006(a)) described that based on the savings arising from the adoption of conservation tillage in North and South America, an extra 2,929 million kilograms of soil carbon is estimated to have been sequestered in 2005 (equivalent to 8,053 million tonnes of carbon dioxide not released into the atmosphere). To put these numbers into context, GE crop-related savings in 2005 were equal to the removal of nearly four million cars from the road (Brookes and Barfoot, 2006(a)). Trewavas (2004) summarized the advantages of no-till agriculture compared to tilled organic and conventional fields in his review; some of those advantages included: farm fossil fuel use reduction, soil erosion reduction, run-off of fertilizers and herbicides greatly diminished, free oxidized nitrogen compounds (e.g., nitrate) reduction, better balance of soil moisture during a drought, and soil carbon sequestration. In another peer-reviewed paper, Brookes and Barfoot (2006(b)) stated: "GM crops contribute to a reduction in fuel use due to less frequent herbicide or insecticide applications and a reduction in the energy use in soil cultivation." Using Smith's calculations (Smith, 2009) on the fuel costs of tillage and herbicide application, and to put fuel use into context, fuel (diesel at $3.00/gallon) cost for moldboard plowing is approximately $11.70/acre in comparison to $0.54/acre for no tillage (herbicide application only).

One reference provided by the commenter involved a study of nightcrawlers (*Lumbricus terrestris*) in northwestern Ohio. As discussed in the response to comment #13, these earthworms may be at least partly responsible for the occasional rapid movement of liquid animal manure and chemicals through soil to underground drainage pipes (Comis, 2005). The paper specifically described an issue that occasionally occurs in poorly drained areas fertilized with liquid manure and not tilled. Again, APHIS points out that the authors included suggestions in the paper for growers to avoid the presence of liquid manure in drainage pipes. APHIS also emphasizes that the soil is a complex environment of organisms. Population differences and the benefits and risks associated with the presence/absence of certain flora and fauna among locations will vary due to a complex array of factors including soil type, tillage and crop history, chemical use history, climate history, weather changes, etc. (Kladivko, et. al, 1997). For example, Trewavas (2004) described the increase numbers of large earthworms (up to 6-fold in no-till versus tilled fields (House and Parmalee, 1985) as an advantage of no-till agriculture compared to tilled organic and conventional fields, not a risk. He further explained that the increase in large earthworms “greatly improves drainage by leaving open channels in the soil. In ploughed soils only much smaller worms predominate.” House and Parmalee (1985) explained that the increase in these soil fauna helped in crop-residue decomposition and this in turn helped with nutrient release and turnover.

The comment also provided information regarding runoff and conservation tillage. The commenter indicated that: “While no-till systems had the lowest volume of runoff, the concentrations of atrazine and cyanazine in runoff water were always greater in no-till systems than for the other tillage regimes.” APHIS is aware that runoff is a problem when using atrazine and emphasizes the point made in the EA that the deregulation of Pioneer HT corn would increase the use of an environmentally-friendly herbicide, such as glyphosate, and the decreased use of more harmful herbicides, such as atrazine (pg. 18 of the EA). Lastly, the other references provided in the comment examined the issues related to colonization of hardwood forests in North America by non-native earthworms. The references do not indicate that this is a problem in corn fields, where Pioneer HT corn would be grown.

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15. **Comment:** One comment indicated that APHIS did not adequately analyze cumulative impacts. The commenter mentioned two issues that have already been addressed in other parts of this document: climate change (comment #14) and the increase use of herbicides and development of resistant weeds (comment #12). Cumulative impacts and the issue of gene stacking and contamination (APHIS assumes the commenter is referring to gene flow) due to stacking, are addressed in this response.

    Response: APHIS considered the potential cumulative impacts of Pioneer HT corn and other herbicide tolerant crops, increased use of glyphosate and ALS-inhibiting herbicides, herbicide resistant weeds, and reasonably foreseeable future actions in the EA (pgs. 27-31). APHIS does not agree that more extensive analysis is warranted. No significant rise in acres planted to herbicide tolerant corn is expected due to the availability of Pioneer HT corn (see response to comment #8 and #12).

    The commenter mentioned the issue of stacking Pioneer HT corn with other traits, but failed to describe his/her exact concerns. APHIS assumes the commenter is concerned that stacking of traits may lead to the availability of more products for growers and this, in turn, will lead to greater cumulative impacts. As discussed in the EA, growers in the U.S. have been looking for ways to defend crop plants from the negative effects of pests for more than 100 years, (Kogan, 1998), long before the introduction of genetic engineering. The industry, whether through genetic or conventional means, will continue to develop new products to deal with pests; in turn, growers will continue to search for techniques and products to help them better manage their fields and obtain the best yields for their crop. The potential therefore exists, for Pioneer HT corn to be stacked with another corn variety. It is also likely Pioneer HT corn would be replaced by the new variety, as it often happens when products are phased-out, intentionally or not, by a loss in popularity or displacement by another product. Discontinuation is a normal and predictable part of any product life cycle. For example, there are many reasons a company may decide to discontinue a product; such as commercial reasons due to declining sales or product replacement by a new and improved variety. In some cases, a product may be discontinued in order to optimize resources, for example to simplify inventory management. For some products, there may also be legal obligations to consider, such as the expiration of country approvals or licensing agreements. Sethoxydim (Poast) (SR or Poast Preferred) herbicide tolerant varieties, for example were available for a few years; however, poor yield performance resulted in discontinued planting of this corn (Kremer, 2004).

As discussed above and in pg. 29 of the EA, if Pioneer HT corn were stacked with another variety, it is very likely that the new variety would replace Pioneer HT corn. Therefore, any increase in glyphosate use from the adoption of the new variety is likely to be negligible when combined with the past, current, and future use of the herbicide on glyphosate tolerant varieties of corn and other major crops. As discussed in the EA, glyphosate is one of the most popular herbicides available to growers and it is not likely that its popularity will change in the near future (e.g., the majority of the 92% acres of soybean in 2008 were planted to a glyphosate tolerant variety) (USDA-NASS, 2008). Glyphosate has been deemed one of the safer herbicides for the environment. Studies have shown that glyphosate has little or no activity in the soil, it strongly absorbs to soil particles, and it is rapidly degraded by soil microbes (Cerdeira and Duke, 2006). In addition, glyphosate is considered to be a low risk herbicide in terms of toxicity and environmental effects. Although today there is a long list of herbicides available to growers for the treatment of weeds, glyphosate replaces the use of other synthetic herbicides that are at least three times more toxic and that persist in the environment nearly twice as long as glyphosate (Heimlich et al., 2000; Gianessi and Carpenter, 2000).

In addition to the aforementioned issues, the commenter mentioned the development of "super-glyphosate tolerant" corn. The commenter fears that seed companies will stack different herbicide tolerant genes (e.g., *gat* gene) into a plant to create one tolerant to "six times the dose of glyphosate normally applied." The commenter failed to understand that the enzyme activity displayed by the GAT protein (expressed from the *gat* gene) published in the paper by Castle et al., 2004, is the same as the one in Pioneer HT corn. Although Pioneer HT corn may harbor this "super-glyphosate tolerance", it is not being marketed as such. An enhanced glyphosate tolerant variety, to be marketed in this manner, would require Pioneer to conduct more extensive data collection and the assessment of additional environmental impacts. The product would also require an extensive review of the data by the EPA, the establishment of residue tolerances by EPA, and glyphosate label changes by EPA. APHIS has no regulatory authority over the use of herbicides on GE crops.

Lastly, the commenter was concerned that gene stacking of GE varieties would lead to an increase in the likelihood of contamination by from the GE crop to non-GE crops. Stacking a gene to an existing GE and/or non-GE corn variety does not increase the likelihood of the presence of GE gene in non-GE crops by means of pollen flow. A GE crop product undergoes many years of testing (e.g., agronomic and nutritional) before it is deregulated. One of the key elements is that the GE herbicide tolerant variety is identical to the non-GE control parent, with the exception of the gene that conferred the tolerance to the herbicide. This means that the plant and plant parts, including the pollen, are essentially identical in both the GE and the non-GE plants. Pioneer HT corn was tested and found to be no different than the control corn. Therefore, the pollen of a non-GE corn plant will travel the same distance as the pollen of a plant carrying one, or in the case of Pioneer HT corn, two, transgenic genes.

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16. **Comment:** One comment indicated that APHIS improperly relied upon stewardship measures as a way to mitigate potentially significant impacts.

    Response: As discussed in the EA, APHIS cannot predict the number of growers who will follow stewardship measures, such as the integrated weed management (IWM) guidelines discussed on pg. 10 of the EA. Nevertheless, APHIS believes that the adoption of these programs has helped prevent the development of herbicide resistant weeds over the past decades. Growers have adapted to the development of herbicide, and dual herbicide, resistant weed populations in the past and it is reasonably foreseeable that they will continue to do so in the future. As already mentioned, many weed scientists, companies, and university scientists are constantly working to develop management strategies and new products to help ensure consistent control of weeds. Pioneer has shown strong support for IWM programs in the past and it is likely that they will continue to do so in the future. In a comment in support of the deregulation of Pioneer HT corn, a professor of weed science at Purdue University explained: "In my experience, DuPont has consistently demonstrated its commitment to sound product stewardship through communication and education and I expect they will continue to do so." One would expect that it would be to a company's best interest to sponsor reliable and effective stewardship programs in order to maintain the usefulness and marketability of their products. In this case, in the petition for deregulation, the company states that DuPont's Pioneer Hi-Bred International, Inc. and Crop Protection Chemicals businesses both have long histories of product stewardship and because of the unique nature of the dual herbicide tolerance in Pioneer HT corn, stewardship efforts for this product will be a joint collaboration between the two businesses. It is further explained that stewardship principles will be incorporated into marketing, positioning, promotional, and communication strategies for this product. Examples of those efforts include: local weed management (presentations to local audiences about resistant weeds and best management practices; assistance in making crop management decisions, including options for managing weeds); product labeling (for at least 20 years, all DuPont herbicide labels have carried voluntary statements regarding resistant weed management, for an example, see pg. 178 of the petition); training and education of sales representatives and agronomists (see pg. 179 of the petition for specific information on training programs); technical bulletins provided to seed customers and the public (direct mail and information on websites); involvement in industry and academic groups (e.g., Herbicide Resistance Action Committee (HRAC)); customer satisfaction and weed resistance management plan (maintain contact with customers, track and respond to complains, and provide tools and processes).

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and
Plant Health
Inspection
Service

Pioneer Hi-Bred International, Inc. Herbicide Tolerant 98140 Corn

OECD Unique Identifier DP-098140-6

Environmental Assessment October 8, 2009

<u>Biotechnology Regulatory Services</u>

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TABLE OF CONTENTS

I. Purpose and Need

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services' (BRS) mission is to protect America's agriculture and the environment using a dynamic and science-based regulatory framework that allows for the safe development and use of genetically engineered (GE) organisms. 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 U.S.: USDA's 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 enforce agency-specific regulations to products of biotechnology that are based on the specific nature of each GE organism.

APHIS' 7 Code of Federal Regulations part 340 (7 CFR part 340), which was promulgated pursuant to authority granted by the Plant Protection Act, as amended, (7 United States Code (U.S.C.) 7701–7772), regulates the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 when it has been demonstrated, and the Administrator has determined, that it does not present a plant pest[1] risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR § 340.2) and is also considered a plant pest or the Administrator has reason to believe is a plant pest. A person may petition the agency to evaluate submitted data and determine that a particular regulated article does not present a plant pest risk, 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 from which it was derived. 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.

APHIS has received a petition from Pioneer Hi-Bred International, Inc. (referred to hereafter as Pioneer) for a determination of nonregulated status for GE herbicide tolerant (HT) 98140 corn (*Zea Mays*) derived from their transformation event 98140 (the article will be referred to hereafter as Pioneer HT corn). Pioneer developed the HT corn to tolerate glyphosate and acetolactate synthase (ALS)–inhibiting herbicides (e.g. herbicides under the sulfonylureas and imidazolinones chemical families). HT Pioneer corn will be the first GE commercial corn product to contain both traits. The availability of this corn will enable growers to control weeds

[1] 7 CFR part 340.1 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" (USDA-APHIS-BRS, 2008(b)).

using an ALS-inhibitor herbicide where, for example, glyphosate resistant weeds are present, or conversely, use glyphosate where ALS resistant weeds are present. Growers will be able to choose an optimal combination of the two herbicides, and other complementary herbicides, to best manage their individual weed populations.

Pioneer HT corn has been field tested in the U.S. since 2005 as authorized by USDA notifications and permits listed in Appendix 6, on page 168 of the petition. The list includes a number of test sites in diverse regions of the U.S. including the major corn growing areas of the Midwest. Field tests conducted under APHIS oversight allow for evaluation in a natural agricultural setting while imposing measures to prevent persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These in turn, are used by APHIS to determine if the new variety poses a plant pest risk. Pioneer has petitioned APHIS to make a determination that Pioneer HT corn and the progeny derived from its crosses with other nonregulated corn shall no longer be considered regulated articles under 7 CFR part 340.

As a Federal agency subject to compliance with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), APHIS has prepared this environmental assessment (EA) to consider the potential environmental effects of this proposed action (deregulation) and the reasonable alternative to that action (no action) consistent with NEPA regulations (40 CFR parts 1500-1508, 7 CFR 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment[2] that may result from the deregulation of Pioneer HT corn. APHIS' plant pest risk assessment for Pioneer HT corn can be found in Appendix A of this EA.

The EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, 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) (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 the requirement of a tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA; the FDA enforces the tolerances set by EPA. Pioneer submitted the appropriate regulatory package to EPA in 2007 to amend the corn tolerance for glyphosate to include the degradation by-product of glyphosate, N-acetylglyphosate; the assessment is currently under review. Safe use of glyphosate (EPA, 1993) and a number of (ALS)–inhibiting herbicides (EPA, 2008(a)) has been established by the EPA through their registration for use on corn and the setting of tolerances.

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 commercialization and distribution of bioengineered food and

[2] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR § 1508.14).

feed. Pioneer submitted a food and feed safety and nutritional assessment summary to FDA for Pioneer HT corn in 2007. Based on the information that Pioneer submitted, and as of September, 2008 (BNF No. 000111), FDA has no further questions concerning the new corn variety, Pioneer HT corn (US-FDA, 2008).

Public Involvement

APHIS-BRS routinely seeks public comment on draft environmental assessments. APHIS-BRS does this through a notice published in the Federal Register. This EA, the petition submitted by Pioneer, and APHIS' plant pest risk assessment, will be available for public comment for a period of 60 days. Comments received by the end of the 60-day period will be analyzed and used to inform APHIS to grant nonregulated status, to not grant nonregulated status, or to conduct an Environmental Impact Statement for the deregulation of Pioneer HT corn.

II. Affected Environment

A. Corn

Zea mays L. subsp. *mays* (corn or maize) is a member of the *Maydeae* tribe of the grass family, *Poaceae*. Corn is an annual plant (completes an entire life cycle in one year) and the duration of the life cycle depends on the variety and on the environments in which the variety is grown (Hanway, 1966). Corn cannot survive temperatures below 0°C for more than 6 to 8 hours at around leaf stage 6 (when the growing point is above ground); although damage from freezing temperatures depend on the extent of temperatures below 0° C, soil condition, residue, length of time, wind movement, relative humidity, and stage of plant development. In the U.S., corn is primarily grown in the warm temperate climate of the Midwest 'Corn Belt'; however, it can be found in various other regions of the country.

In 2006, 78 million acres of corn were planted in 48 states across the U.S.; of those 78 million acres, over 65 million were grown in the Midwest states of Iowa, Indiana, Illinois, Ohio, South Dakota, Nebraska, Kansas, Minnesota, Wisconsin, Michigan, Missouri, and Kentucky. In 2007, there were approximately 92.9 million acres of corn grown (for all purposes), up 19% from 2006; of the acres planted in 2007, 73% were GE varieties (USDA-NASS, 2007), up from 61% in 2006. Data for organic corn acreage was last published in 2005 (USDA-ERS, 2005(a)); extrapolating from the 130,672 acres (0.16% of the total corn acreage planted) in 2005 and using the 30% increase in organic corn acreage between 2004 and 2005, organic corn may exceed 220,000 acres, representing approximately 0.26% of the total acreage in the U.S.

1. Corn Varieties

As previously noted, corn is grown as a commercial crop on over 90 million acres in at least 45 states in the U.S. (USDA-NASS, 2007). In 2007, 24% of the corn acreage in the U.S. was herbicide tolerant (USDA-NASS, 2007). This number may actually be higher as not all states were surveyed and it does not include stacked[3] varieties. In 2009, out of 85% of all of the corn planted in the U.S., 85% was GE (including both stacked and non-stacked varieties). Growers make choices to plant certain corn varieties based on factors such as yield, weed and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Gianessi, 2005; Olson and Sander, 1988). Therefore, when taking into account these factors, growers will ultimately base their seed choice on individual wants and needs.

APHIS notes that one commercially-available product is ALS herbicide tolerant and several products are glyphosate tolerant; two of those products include Clearfield® Corn (BASF, 2005) and Roundup Ready® Corn 2 (Monsanto, 2006), respectively. Some have been produced via genetic engineering while others are a result of traditional breeding. There are currently no commercially available corn products that are both glyphosate and ALS herbicide tolerant. HT Pioneer corn will be the first GE commercial corn product to contain both traits. Many GE varieties previously deregulated by APHIS have been used in traditional breeding programs to obtain new varieties. One common product obtained from such crosses is MonsantoYieldGard® Plus with Roundup Ready® 2 (corn borer and rootworm protection, and glyphosate herbicide

[3] Two or more traits (e.g. herbicide tolerance and insect resistance) in one plant.

tolerance) (Monsanto, 2008). For a list of biotech corn seed products tolerant to glyphosate, alone or in combination with other traits, available for the 2008 planting season, refer to Appendix B. Clearfield® Corn (made through traditional breeding) is the only corn variety tolerant to ALS-inhibiting herbicides available in the market today.

2. Uses of Corn

There are approximately 3,500 different uses for corn products. Corn components can be found in a vast number of goods including food, cosmetics, pharmaceuticals, and cleansers (ICPB-ICGA, 2008). The USDA breaks corn usage into three major categories: feed/residual (45.9% of total U.S. corn usage in 2007-2008), food/seed/industrial (35.2%), and export (18.9%). As an example, Table 1 provides data from Nebraska, a major Midwest State corn producer, on the products that make up the food/feed/industrial category. Table 2, provides data from Iowa, the major Midwest State corn producer, on the main final uses of corn and volumes (bushels) of each type. Refer to Appendix C for a general breakdown of corn consumption in the U.S. from 2005-2006.

Table 1. Products that Make Up the Food, Feed, and Industrial Category and their Corresponding Percentage of Total Corn Usage in Nebraska.

Category	Percentage of Total U.S. Corn Usage (2006-2007)*
Ethanol	24.7
High Fructose Corn Syrup	3.9
Starch	2.1
Sweeteners	1.8
Cereal/Other	1.5
Alcohol	1.0
Seed	0.2

* Data collected from September to August of the following year (NCB, 2008).

Table 2. Breakdown of the Major Uses of Iowa's Corn Crop in 2006 and 2007.

	Statistics	
	2005/2006*	2006/2007*
Animal Feed	6.1 billion bushels[a]	5.6 billion bushels[b]
Exports	More than 2.1 billion bushels[c]	More than 2.1 billion bushels[c]
Corn Sweeteners	755 million bushels[d]	753 million bushels[d]
Ethanol	1.6 billion bushels[e]	2.1 billion bushels[e]
Other Uses	600 million bushels[f]	599 million bushels[g]

* Data collected from September to August of the following year (USDA-ERS, 2008; ICPB-ICGA, 2008)
[a] Livestock in IA consumed approximately 550 million bushels of IA's crop (53% hogs, 29% beef cattle, 12% poultry, and 5% dairy cattle).
[b] Livestock in IA consumed approximately 510 million bushels of IA's crop (47% hogs, 29% beef cattle, 18% poultry, and 6% dairy cattle).
[c] The 10 largest customers for U.S. corn (for food and feed) were: Japan, Mexico, Taiwan, South Korea, Egypt, Colombia, Algeria, Canada, Israel, and the Dominican Republic.
[d] Corn refined into sweeteners are used in colas, cakes, cookies, lunch meats, jams, jellies, snack foods, salad

dressings, and ice cream.
[e] Fermented into fuel alcohol.
[f] 275 million bushels processed into starch for food and industrial uses (paper, textiles, adhesives, plastics, baked goods, condiments, candies, soups, etc.); 190 million bushels processed into breakfast cereals, snack chips, tortillas, and other corn foods; 135 million bushels fermented into alcoholic beverages.
[g] 272 million bushels processed into starch for food and industrial uses (see f); 190 million bushels processed into breakfast cereals, snack chips, tortillas, and other corn foods; 137 million bushels fermented into alcoholic beverages.

3. Weeds in Corn

In general, the agronomic practices described in the section below are the same for conventional and GE corn production for food or feed. In both cases, the primary emphasis is placed on obtaining the best yield (Ransom et al., 2004). Growers choose from a wide range of agronomic practices in order to control weeds; which, if left uncontrolled, can cause significant losses in yield (Bosnic and Swanton, 1997; Fausay et al., 1997). Weeds compete with crops for water, nutrients, light, and other growth factors. Weed control in corn is especially critical during the first 3 to 5 weeks following crop emergence, before weeds reach a height of approximately 6 to 8 inches, which is when they begin to impact corn yields (UC-IMP, 2008). Weed species such as giant foxtail and barnyardgrass have been shown to reduce corn yields by up to 13 and 35%, respectively (Bosnic and Swanton, 1997; Fausay et al., 1997). Each year in the U.S., corn yields are threatened by more than 200 weed species (Weed Science, 2008). Common weeds that cause problems in corn fields include velvetleaf, common cocklebur, common lambsquarters (annuals) and quackgrass and Johnsongrass (perennials). Perennials are extremely competitive and difficult to control as they re-grow each year from rhizomes or root systems (Olson and Sander, 1988). Weed infestations that occur later in the season do not have such a negative impact on yields, but they can harbor diseases and insect pests such as thrips and armyworm. Late-season weeds can also reduce silage feed quality, slow mechanical harvest, raise grain moisture content, and be a seed source that will infect subsequent crops (UC-IMP, 2008). For a list of some difficult-to-control weeds in corn, see Table 31, pg. 116 of the petition.

B. Agronomic Practices for Corn

Today, growers can choose from hundreds of corn hybrids marketed by companies that produce seed (refer to Appendix B for examples of available varieties). Hybrids differ generally in agronomic characteristics, including disease and pest resistance and length of growing period (Olson and Sander, 1988). The optimum planting date for corn is influenced by factors such as the locality, environmental conditions, seed growing period, and seed variety, and it usually occurs in April or May. Several tillage methods are currently available to help prepare the seedbed for a given crop; these types are explained in more detail in Table 3. Harvesting generally occurs from mid-to-late September through November; the use of a combine (mechanical harvesting) is the standard practice for grain production. Weed control methods differ depending on a number of factors including locality, grower resources, and crop trait; the techniques may be direct (e.g. mechanical[4] and chemical[5]) or indirect (e.g. cultural[6]) (Olson and Sander, 1988).

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[4] Includes tillage (Table 1) and mowing.
[5] Herbicide application.
[6] Crop rotation/spot spraying of herbicide/hand removal of weeds.

As already discussed, weed control in corn production is essential in order to obtain good crop yield. Generally, growers will manage a range of weeds simultaneously. Therefore, growers will likely chose from a number of techniques to effectively and efficiently manage weeds in their fields. In 2005, the most prevalent weed management practice was herbicide use (USDA-ERS, 2005(b)). Ultimately, the weed management practice utilized by a grower will depend on the types of weeds in their field, the level of infestation, the cropping system, the type of soil, cost, weather, time, and labor.

1. Tillage

Tillage is the mechanical treatment of the soil and crop residue (plant parts left on the field after harvest) to prepare a seedbed for planting. Tillage is also an integral part of weed management, as digging up the soil helps to remove unwanted vegetation from the corn field. The types of tillage utilized by growers are described in more detail in Table 3; these types include conservation tillage (no-till, ridge-till, and mulch-till), reduced tillage, and intensive or conventional tillage.

Table 3. Tillage practices.

[a] The amount of crop residue (e.g. leaves, stalks, etc.) left in the field following harvest. The advantages of crop residue cover are discussed in section IV (Environmental Consequences) (USDA-ERS, 2002).

Type of Tillage	Definition	Tillage Tools	Percent Crop Residue Cover Remaining in Field[a]
Intensive or Conventional	Full tillage - combines primary and secondary tillage operations	Primary tillage is performed in the fall (or spring) with a moldboard plow followed in the spring by secondary tillage (disking (twice) or disking and using a soil finisher or other such equipment); followed by planting	Less than 15%
Reduced	Intensity of tillage reduced (no use of moldboard)	Tillage performed with a chisel plow, field cultivator, or other such equipment; followed by planting	15-30%
Conservation			
No-till	The soil is left undisturbed from harvest to planting except for nutrient injection	Planting accomplished in a narrow seedbed or slot created by coulters, row cleaners, disk openers, or other such equipment	30% or more
Ridge-till	The soil is left undisturbed from harvest to planting except for nutrient injection	Planting is completed in a seedbed prepared on ridges with sweeps, disk openers, coulters, or row cleaners (residue is left between ridges)	30% or more
Mulch-till	The soil is disturbed prior to planting	Tillage performed with chisels, field cultivators, disks, sweeps, or blades; followed by planting	30% or more

2. Herbicides

Data from the Agricultural Resource Management Survey indicated that in 2005, out of the 76 million acres of corn that were planted, approximately 214 million acres were treated with herbicide (USDA-ERS, 2005(b)), indicating that most acres were treated multiple times. Depending on the type, herbicides can be applied to the corn fields pre-plant[7], pre-emergence[8], and post-emergence[9] of the crop. Corn typically receives a soil applied herbicide followed by a post-emergence herbicide application. In the 2005 Survey, data showed that 18.6% of planted corn acres received a burn down herbicide[10], while 61.3% received a pre-emergence and 66.5% received a post-emergence (USDA-ERS, 2005(b)). Table 4 provides a list of herbicides and the percent of U.S. corn acres treated with each, in the years 1995, 2000, and 2005. Atrazine was the most widely applied herbicide, with 66% of the planted acreage being treated. Glyphosate was applied to 33% of planted acres, followed by Acetochlor at 23% (USDA-NASS, 2006(a)). Refer to Table 30, pg. 115 of the petition for a list of the most commonly used ALS-inhibiting herbicides currently registered for use on corn (the table includes their general use rate, residual activity, and re-cropping restrictions).

Table 4. Percent of U.S. Corn Acres Treated in 1995, 2000, and 2005 with the Following Herbicides.

Active Ingredient	**1995[a]**	**2000[b]**	**20005[c]**
2 4-D (all)	13	8	7
Acetamide		2	
Acetochlor	18	25	23
Alachlor	8	4	1
Atrazine	65	68	66
Bentazon	2	2	
Bromoxynil	8	4	1
Carfentrazone-ethyl		1	*
Clopyralid		9	5
Cyanazine	17	*	*
Dicamba (all)	27	29	12
Diflufenzopyr-sodium		3	4
Dimethenamid	3	7	1
Dimethenamid-P			4
EPTC	3	1	
Flufenacet			3
Flumetsulam	1	10	6
Foramsulfuron			2
Glufosinate-ammonium		2	5
Glyphosate (all)	6	9	33

[7] Applied several weeks or just before crop planting.
[8] Applied immediately after crop planting, but before crop (and weed) emergence.
[9] Applied after the crop (and weeds) have emerged.
[10] Usually applied pre-plant, non-selective (controls all types of weeds); can also be foliar active (absorbed by the leaves, stems, etc. of emerged weeds).

Halosulfuron	1	*	1
Imazapyr		2	1
Imazethapyr	1	3	1
Isoxaflutole		3	6
Mesotrione			20
Metolachlor	29	28	25
Metribuzin	1	2	*
Nicosulfuron	13	15	10
Paraquat	1	1	1
Pendimethalin	4	3	2
Primisulfuron	3	9	2
Prosulfuron		4	1
Pyridate		5	
Rimsulfuron	1	9	8
Simazine	3	2	3
Sulfosate		*	1
Thifensulfuron	1	*	*
Trifluralin		*	1

* Area applied is less than 1%; herbicides in bold and italics are further described in section IV (Environmental Consequences)
[a] 64.1 million acres (90% of the total for the U.S.) planted in 1995 for 17 major States (DE, GA, IL, IN, IA, KS, KY, MI, MN, MO, NE, NC, OH, PA, SD, TX, and WI) (USDA-ESMIS-NASS, 1996).
[b] 73.8 million acres (93% of the total for the U.S.) planted in 2000 for 18 States surveyed (CO, IL, IN, IA, KS, KY, MI, MN, MO, NE, NY, NC, ND, OH, PA< SK, TX, and WI) (USDA-NASS, 2001).
[c] 76.5 million acres (93% of the total for the U.S.) planted in 2005 for 19 Program States (CO, GA, IL, IN, IA, KS, KY, MI, MN, MO, NE, NY, NC, ND, OH, PA, SD, TX, and WI) (USDA-NASS, 2006(a)).

3. Crop Rotation

Crop rotation (successive planting of different crops on the same land) helps to reduce weeds in corn and the next year's crop. Crop rotation is an integrated weed management (IWM) technique that is often used along with other weed management systems, such as conservation tillage, to control weeds. For example, a cereal grain, such as wheat (seeded in the fall), is very competitive against summer annual weeds common in corn (Curran et al., 1996); planting wheat would therefore, interrupt the weeds' lifecycle.

4. Weed Management

As aforementioned, uncontrolled weed populations can cause significant yield losses in corn. Among U.S. crops, corn is one of two crops that suffer the greatest aggregate production losses due to weeds (Swinton et al., 1994). Before the development of effective herbicides for the selective control of weeds, numerous mechanical and cultural tactics were available for the management of weed populations. Although the feasibility, effectiveness, and economics of adopting certain weed management practices is highly site dependent, for the past several decades, reliance on herbicides for weed management has continued to increase (Bridges, 1994). The repeated use of herbicides, over the course of time, has led to the development of resistant weeds. Cases of weed resistance date back as far as the 1950's. By the 1990's, 81 weed species contained individuals (or biotypes) that were resistant to one or more herbicides. Today, that list includes approximately 319 biotypes distributed across the globe (Weed Science, 2008). Herbicide resistance may be defined as the ability of a weed to survive and reproduce following exposure to a dose of the herbicide that would normally be lethal to the wild type (Boerboom and Owen, 2006). Resistance may occur in weeds by random and infrequent mutations, including mutation induced by herbicide exposure (Powles and Preston, 2006). If an herbicide is continually used on a population of weeds, a resistant biotype may successfully reproduce and become dominant in the population.

In 2004, a study was conducted on the ecological impact of glyphosate on weed resistance; the research assessed the fitness costs and benefits of herbicide tolerance of glyphosate tolerant *Ipomoea purpurea* (tall morning glory) (Baucom and Mauricio, 2004). In an agricultural field in Georgia, 32 random *I. purpurea* plants which had been sprayed with Roundup® for approximately 8 years were chosen for this evaluation. All seeds collected from each plant shared the maternal genetic contributions which were then used as the unit for the genetic analysis. Seeds from each of the 32 lines were self-pollinated for one generation; the seeds from the F2 generation were grouped according to each maternal line and planted in five spatial blocks to account for habitat heterogeneity[11]. All plants were sprayed with amounts of Roundup® previously shown to reduce biomass production by 90%. Results demonstrated that the tolerant line produced 35% fewer seeds in the absence of Roundup® than the most susceptible lines. These results suggest that in the absence of herbicide selection (e.g., spraying with Roundup®), herbicide tolerance would be lost in subsequent generations due to higher metabolic costs to resistant weeds. Therefore, it is possible that weeds may lose their resistance trait if herbicide use is discontinued (Baucom and Mauricio, 2004).

Weed scientists, companies, and university scientists are constantly working to design management strategies/practices to help control weeds and to develop alternative herbicide tolerant crops for growers (Service, 2007; Purdue Weed Science, 2008). In order to minimize the development of herbicide resistant weeds, growers can adopt Integrated Weed Management (IWM) programs through communication, research, education, and participation in industry coalitions such as the Herbicide Resistance Action Committee (HRAC). The HRAC is an industry-based group whose mission is to support a cooperative approach to the management of herbicide resistance by facilitating communication and cooperation between industry, government researchers, advisors, and growers (HRAC, 2008). IWM uses all available strategies to manage weed populations in an economically and environmentally sound manner; such strategies include cultural, mechanical, chemical, and biological methods (see footnotes on pg. 6 for examples).

Specific recommendations include:

- Using alternative weed management practices, such as mechanical cultivation, delayed planting, and weed-free crop seeds.
- Cleaning equipment before leaving fields suspected to have resistant weeds to minimize the spread of weed seed.
- Scouting fields prior to the application of any herbicide to determine the species and the need for an herbicide application.
- Scouting fields after application to detect weed escapes or shifts and applying alternative

[11] Diverse characteristics of the environment.

control methods to avoid seed deposition in the field.

- When using herbicides, use full label rates and tank mix partners.
- Using mixtures or sequential treatments of the herbicides having a different mode of action.
- Limiting the number of applications of a single herbicide(s) with the same mode of action in a single growing season and in successive years.
- Rotating crops with an accompanying rotation of herbicides to avoid using herbicides with the same mode of action of the same field.
- Where practical, use cover crops and other methods to reduce weed seeds in the soil.

IWM is a form of Integrated Pest Management (IPM) (subsumes weeds, pathogens, and insects) which was first advocated by President Nixon's Council on environmental quality in 1972 and in 1979 by President Carter. President Clinton's Administration set a goal of implementing IPM programs on 75% of managed acres in the U.S. by the year 2000. Over the years, the challenge has been how to measure IPM adoption. This has been and continues to be problematic because an IPM system for a given crop will vary with growing region and season, the emergence of new pests, and changes in production practices (Shennan et. al, 2001). Because the development of IPM programs has not been uniform across the types of pests (weeds, pathogens, and insects), crops, and regions, it has been difficult to develop a general measure for use. Although in recent years there has been advances in methodology, a complete, practical, and accepted method to measure IPM adoption is not yet available (Fernandez-Conejo and Jans, 1999). In 1989, the National Academy of Sciences estimated that 14% of the soybeans [*Glycine max* (L.) Merr.] and 20% of the corn (*Zea mays* L.) in the U.S. were under some form of IPM (National Research Council, 1989). A report by Vandeman et al., in 1994, found that 69% of the soybean acres and 65% of the corn acres were "scouted" (systematic collection of pest and crop data from the field (e.g. weed distribution, growth stage, population, crop stage, etc.)) for weeds, diseases, and insects. (Scouting is an IWM practice). Data from a 1996 survey published by Fernandez-Cornejo and Jans in an Economic Research Service Report (1999) indicated that soybean and corn farmers reported scouting for weeds on 79% and 78% of their acreage respectively. In a more recent survey conducted in Wisconsin, Hammond et al. (2006) reported that 71% of the farmers who participated in the survey reported scouting for weeds, insects, and diseases on a regular basis. Survey participants indicated that the most frequently used weed management practices were: broadspectrum herbicides (84%); crop rotation (55%); and mechanical cultivation (35%).

APHIS cannot predict the number of growers who will follow IWM programs with a Pioneer HT corn crop or the likelihood that those growers will be successful in preventing the development of herbicide resistant weeds if they were to adopt such programs. Although in theory, IWM programs offer a number of advantages to those who adopt them, there is no data available to support their effectiveness. Nevertheless, APHIS believes that the adoption of these programs has helped prevent the development of herbicide resistant weeds over the past decades. If such programs were not successful, growers, universities, and companies would not continue to spend the time, money, and effort to adopt and promote them.

C. Non-target Species and Agricultural Ecosystems

The landscape surrounding a corn field varies depending on the region. In certain areas, corn fields may be bordered by other corn (or any other crop); fields may also be surrounded by wooden and/or pasture/grassland areas. Therefore, the types of vegetation around a corn field depend on the area where the corn is planted. A variety of weeds dwell in and around corn fields; those species will also vary depending on the region where the corn is planted.

Corn fields have been known to be visited by birds, deer and small mammals (e.g. deer mice), and other types of wildlife species. Although many birds visit row-crop fields such as corn, numbers are low and few nest there (Patterson and Best, 1996). The corn red-winged blackbird (*Agelaius phoeniceus*) is the most abundant bird in North America; they are often initially attracted to corn fields to feed on insect pests but then feed on the corn. Annually, this bird destroys over 360,000 tons of field corn and substantial amounts of sweet corn (Dolbeer, 1990); other abundant species of birds that forage and/or nest on and around corn include the horned lark (*Eremophila alpestris*), the brown-headed cowbird (*Molothrus ater*), and the vesper sparrow (*Pooecetes gramineus*) (Patterson and Best, 1996). Deer, such as the white-tailed (*Odocoileus virginianus*), find field corn attractive because it functions both as food and cover throughout the latter half of the growing season (Vercauteren, 1993). Deer can significantly damage or completely destroy small corn fields that are surrounded by woody or brushy areas; however, deer damage to large corn fields is often limited to a few rows closest to the wooded areas (Nielsen, 2005). The deer mouse (*Peromyscus maniculatus*) is the most common small mammal in almost any agricultural field (Stallman and Best, 1996; Sterner et al., 2003). The deer mouse feeds on a wide variety of plant and animal matter depending on availability, but primarily feeds on seeds and insects. The deer mouse has been considered beneficial in agroecosystems because it consumes both weed and pest insect species (Smith, 2005). The meadow vole (*Microtus pennsylvanicus*) feeds primarily on fresh grass, sedges, and herbs, but also on seeds and grains. The meadow vole may also be considered beneficial for its role in the consumption of weeds, but can be a significant agricultural pest where abundant as they rely on cover absent from tilled agriculture (Smith, 2005). The lined ground squirrel (*Spermophilus tridecemlineatus*) feeds primarily on seeds of weeds and available crops, such as corn and wheat. This species has the potential to damage agricultural crops, although it can also be considered beneficial when eating pest insects, such as grasshoppers and cutworms (Smith, 2005).

The soil is a complex environment rich in microorganisms and arthropods. The corn root system acts as a soil modifier due to its association with several microbial groups such as bacteria, fungi, protozoa, and mites. The highest microbial population usually is bacteria, followed by fungi. These microbial groups play an important and particular role in the ecology of the soil, including nutrimental cycling and the availability of nutrients for plant growth. In addition, certain microbial organisms may contribute to the protection of the root system against soil pathogens (OECD, 2003). Although many of the organisms found in corn-producing areas are considered pests, such as the European corn borer (*Ostrinia nubilalis*) and the corn rootworm (*Diabrotica* spp.), many others are considered beneficial. Numerous insects and related arthropods perform valuable functions; they pollinate plants, contribute to the decay of organic matter, cycle soil nutrients, and attack other insects and mites that are considered to be pests. Some of these beneficial species include the convergent lady beetle (*Hippodamia convergens*) and the predatory mite (*Phytoseiulus persimilis*) (Weeden et al., 2008).

D. Agriculture and Climate change

Overall, four basic issues of global concern surround agricultural production today: the limitations of land resources, the impact of agriculture practices on the environment (greenhouse effect), the use of residue management and conservation tillage, and the enhancement of soil quality (Lal, 1997). An extensive look into the causes and effects of each core issue is beyond the scope of this EA, but some discussion on the issues, as they relate to Pioneer HT corn, is warranted.

Research shows that crop soils are prone to degradation due to the disturbance and exposure of the top surface layer by certain agronomic practices. Two environmental impacts of soil degradation (discussed further under section IV) are the decline in water quality and the contribution to the greenhouse effect (Lal and Bruce, 1999). It has been shown that a decline in soil quality and soil resilience[12] enhances the greenhouse effect through emissions of radiatively-active gases[13] (CO_2, N_2O) and depletion of the soil carbon pool (Lal, 2003). In turn, a decrease in carbon aggregation and sequestration in the soil leads to increase runoff and soil erosion.

Among other human activities that contribute to the greenhouse effect, is fossil fuel combustion. Increasing evidence has demonstrated that additions to the greenhouse effect can cause changes to the atmosphere that contribute to climate change and global warming (EPA, 2008(b)).

[12] The ability of a soil to restore itself.
[13] Gases that absorb incoming solar radiation or outgoing infrared in turn, affecting the temperature of the atmosphere.

III. Alternatives

This draft EA analyzes the potential environmental consequences of a proposal to deregulate Pioneer HT corn. Two alternatives are considered in this EA: (1) no action and (2) to grant deregulated status for Pioneer HT corn. A third alternative was considered and dismissed: approval of the petition with geographic restrictions. The third alternative was considered and dismissed based on the determination that Pioneer HT corn does not pose a greater plant pest risk in a specific geographic location. This alternative would hinder the purpose and need of the action to allow for the safe development and use of GE organisms given that Pioneer HT corn has been determined by APHIS not to be a plant pest in any region of the United States (Appendix A).

A. No Action: Continuation as a Regulated Article

Under the Federal "no action" alternative, APHIS would deny the petition and continue to regulate Pioneer HT corn under 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of Pioneer HT corn. This alternative is not the preferred alternative because APHIS has already determined through a plant pest risk assessment (Appendix A) that Pioneer HT corn does not pose a plant pest risk. APHIS does not have the authority to regulate Pioneer HT corn if APHIS determines it does not pose a plant pest risk.

As described in the "Affected Environment" section of this EA, today, there are a number of agronomic practices that growers may choose to adapt and a wide range of corn seed varieties that they may opt to plant. Under the APHIS "no action" alternative, growers will not have access to Pioneer HT corn to utilize in weed management; although other GE and conventional herbicide tolerant corn varieties are available to the public today, this is the first variety of its kind.

B. Preferred Alternative: Determination that Pioneer HT Corn is No Longer a Regulated Article, in Whole

Under this alternative, Pioneer HT corn would no longer be a regulated article under 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of Pioneer HT corn. Upon review of the petition and scientific literature, APHIS has chosen the preferred alternative for the proposed action. This is based on the lack of plant pest characteristics of Pioneer HT corn (appendix A). By deregulating Pioneer HT corn, the purpose and need to allow the safe development and use of GE organisms is met.

Pioneer must receive regulatory approval from all appropriate agencies before it is available to growers and breeders. If Pioneer receives all approvals, it is likely that Pioneer HT corn will be a replacement product to other herbicide tolerant corn products on the market today (see discussion on pg. 28). Pioneer HT corn is the first corn product to combine glyphosate and ALS-inhibitor tolerance; its availability will allow growers a greater ability to manage weeds and weed resistance. Growers and other parties who choose not to plant transgenic corn varieties or sell transgenic corn should not be significantly impacted by the expected commercial use of this product. Non-transgenic corn will still be sold and readily available to those who wish to plant them (see discussion on pgs. 26-27).

IV. Environmental Consequences

Potential environmental concerns from the “no action” alternative and the “preferred” alternative for Pioneer HT corn are described in detail throughout this section. Certain aspects of this product and its cultivation would be no different under each alternative; those are described below. Corn practices that may be affected under the different alternatives include tillage and herbicide use.

Neither action is expected to significantly alter the range of corn cultivation (see discussion on pg. 28) or the final uses of corn; therefore, no differences in environmental consequences are expected under each alternative. In terms of agronomic practices, many annual broadleaf weeds can be easily controlled and/or economically managed in corn by using crop rotation. The adoption of this system has been shown to be very advantageous and although it has become an important component of weed management, no differences among the two alternatives are expected with or without the availability of Pioneer HT corn. The type of rotation crop and the specific herbicide needs of the rotational crop will not be impacted, as growers will continue to choose rotational crops based on market needs and cultural practices. Recommendations for specific ALS inhibitor products for a grower planting Pioneer HT corn will take into account existing crop rotation practices (corn/soybean, corn/wheat, corn/cotton, etc.), just as they do currently for conventional, glyphosate tolerant, or other corn varieties. Glyphosate has no residual activity and therefore no re-cropping restrictions, so if growers choose to spray only glyphosate (and not ALS inhibitors or other herbicides labeled for corn) on their Pioneer HT corn, there will be no re-cropping constraints.

A. No Action

Under the Federal “no action” alternative, growers would not be able to plant Pioneer HT corn, which has been developed as an alternative to products available in the market today. The use of Pioneer HT corn may help growers reduce costs (e.g. fuel and equipment needed for tillage) and some of the negative impacts of agriculture on the environment (e.g. soil degradation). In addition, if resistant weeds to an herbicide should develop in a grower’s corn field, Pioneer HT corn would not be available as an option that allows for the alternate use of two different classes of herbicides.

APHIS has determined that Pioneer HT corn does not pose a plant pest risk (appendix A). Once APHIS makes the determination that a regulated GE organism does not pose a plant pest risk, then APHIS has no regulatory authority to continue to regulate that particular GE organism. Therefore, in this case, APHIS can not continue to regulate Pioneer HT corn and must reject the “no action” alternative.

A. Corn

1. Corn Varieties

As shown in Appendix B, whether through genetic engineering or traditional breeding, many corn varieties are commercially available and new corn varieties continue to be developed. Table 5 shows the amount of non-stacked, with an insect resistant trait, varieties of herbicide tolerant GE corn planted as a percentage of all of the corn planted in the U.S. from 2000 to 2008. Although the percent of non-stacked varieties of herbicide tolerant GE corn has been increasing since 2000, the percentage dropped from 24% in 2007 to 23% in 2008 to 22% in 2009. The total for all biotech varieties planted was 73% in 2007, 80% in 2008, and 85% in 2009 (USDA-NASS, 2007; USDA-NASS, 2008; USDA-NASS, 2009). These numbers indicate that the adoption of non-stacked, with an insect resistant trait, herbicide tolerant GE corn varieties in the U.S. has not increased to the dramatic extent that it has, for example, for soybean (91% in 2007 and 92% in 2008, out of all soybean acres planted) and that growers have chosen to plant other GE corn available varieties (e.g. insect resistant corn, or herbicide tolerant corn stacked with insect resistance). Although it is difficult to predict adoption rates of herbicide tolerant GE corn in the U.S., it is not likely that the availability of Pioneer HT corn would cause the number of acres of GE corn to increase dramatically because it is expected to be a replacement product for growers already using GE varieties. It is likely that if an existing herbicide tolerant corn grower is experiencing a problem with herbicide resistant weeds, for example, she or he may chose to plant a dual herbicide tolerant GE variety in order to adequately manage the weed problem. Under the "no action" alternative, Pioneer HT corn would not be available to growers, in light of the fact that this product offers the advantage of having dual herbicide tolerance, as a replacement product to other glyphosate tolerant or ALS-inhibiting herbicide tolerant corn.

Table 5. Non-stacked, with Insect Resistance, Herbicide Tolerant Biotechnology Varieties of Corn in the U.S., Percent of All Corn Planted, 2000-2008

Year	Herbicide Tolerant
2000	6%
2001	7%
2002	9%
2003	11%
2004	13%
2005	17%
2006	21%
2007	24%
2008	23%
2009	22%

B. Agronomic Practices

1. Tillage

One of the most important benefits of tillage is weed control. In conventional tillage agriculture, the grower relies on extensive tillage operations to manage weeds in the field. Although intensive tillage is still the most common form of tillage, the use of conservation tillage has been increasing since the 1990s (Table 6). The ability of growers to utilize herbicides to control weeds without crop damage has greatly contributed to this shift. In conservation tillage, the grower uses similar weed management practices as in conventional tillage, but eliminates most or all of the tillage operations.

Table 6. National Use of Various Tillage Systems, 1989-2000[a].

Tillage System	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	2000
	Million Acres										
Conservation tillage											
No-till	14.1	16.9	20.6	28.1	34.8	39.0	40.9	42.9	46.0	47.8	52.2
Ridge-till	2.7	3.0	3.2	3.4	3.5	3.6	3.4	3.4	3.8	3.5	3.3
Mulch-till	54.9	53.3	55.3	57.3	58.9	56.8	54.6	57.5	60.0	57.9	52.6
Reduced-till	70.6	71.0	72.3	73.4	73.2	73.1	70.1	74.8	77.3	78.1	65.2
Intensive-till	137.3	136.7	129.8	120.8	107.9	111.4	109.7	111.6	107.6	106.1	124.4

[a] Data not available for 1999 (USDA-ERS, 2002).

Tillage is predominantly achieved by inverting the surface layer of soil using tools such as the plow. Continuously inverting the soil can degrade the soil structure and lead to compacted soil that is composed of fine particles with low levels of organic matter. In such cases, the land is more prone to soil loss through water and wind erosion (Holland, 2004; Montgomery, 2007). Techniques such as conservation tillage (reduction or elimination of plowing), have been developed to combat soil deterioration. Conservation tillage involves management practices that minimize disruption of the soil's structure, composition, and natural biodiversity; therefore minimizing erosion and degradation (Holland, 2004). Although by eliminating some or all of the tillage practices under conservation tillage, growers may rely more heavily on the use of herbicides for weed control (Curran et al., 1996).

Reduced and conservation tillage are techniques found in Crop Residue Management[14] (CRM). Of the two, conservation tillage results in the highest amount of crop residue cover (Table 3). Post-harvest residues provide a critical source of soil carbon, protection to the soil surface against erosion, and assist in improvement of soil quality (e.g. biodiversity). Intensive tillage, along with residue removal, can have a significant impact on degradation of soil organic matter, increase CO_2 release, and potential water quality problems (increase runoff and pollution of surface waters) (Al-Kaisi and Guzman, 2007).

<u>Non-target Effects</u>

The purpose of tilling is to remove unwanted vegetation that may compete with the corn crop. Regardless of the type of system utilized by a grower, the plants affected by tillage are generally targeted weeds that would interfere with crop growth.

Conventional agricultural practices, such as intensive tillage, have been shown to have a negative impact on wildlife. The use of intensive tillage may reduce the availability of food, cover, and nesting ground for certain species (e.g. birds). In addition, the erosion associated with intensive tillage has contributed to runoffs that contaminate off-site ecosystems (e.g. aquatic) with agricultural chemicals transported in the sediment (Dimmick et al., 1988).

[14] Year-round conservation system that usually involves a reduction in the number of times tillage equipment is passed over the field and/or the intensity of the tillage operations.

Different tillage systems disturb the soil to different degrees; therefore, having different impacts on soil microorganisms. Intermediate forms of tillage (e.g. reduced tillage) are likely to have intermediate effects on soil ecology. Studies have shown that intensive tillage can have significant impacts on microbial populations and activity (Young and Ritz, 2000). In general, tillage has more negative impacts on larger organisms such as earthworms and beetles than on smaller ones. This is due to the physical disruption of the soil, the burial of crop residue, and the changes in water and temperature that occur due to residue integration (Kladivko, 2001). In addition, soil biodiversity has been shown to be affected by the increase in soil erosion associated with intensive tillage.

Under the "no action" alternative, Pioneer HT corn would not be available to growers as an option to help increase the use of conservation tillage and to reduce the damaging impacts to soil, soil organisms, and wildlife.

2. Herbicides

Herbicides are used alone or in combination and selected on the basis of their effectiveness on the different weed species in the corn field. Different herbicides have different modes of action; the correct herbicide rate must be used for each in order to obtain good weed control results and to minimize corn injury. Sprayed herbicides can pollute the air by drift (movement via spray droplets) or volatility (drift of vapor or fumes), and bodies of water by runoff. Refer to Table 4 for a list of herbicides used for corn during 1995, 2000, and 2005.

Glyphosate is a broadspectrum herbicide and in general, considered "environmentally friendly" when compared to other herbicides (Knezevic and Cassman, 2003). Although glyphosate may be applied to non-tolerant corn varieties during the initial growth stage, it should not be applied post-emergence because it can cause crop injury. The development of glyphosate tolerant corn varieties has allowed farmers to use glyphosate in place of other herbicides that are used post-emergence.

Although APHIS believes that Pioneer HT corn would replace similar products available in the market, it does not discount the possibility that acres planted to GE corn could increase following its deregulation. This would mean an increase in the use of glyphosate and ALS-inhibiting herbicides, although over time, research has shown that the availability of products such as Pioneer HT corn help reduce the use of more harmful herbicides. Under this "no action" alternative, products such as atrazine and dicamba, which can be sprayed post-emergence and can control many annual and perennial weeds, are likely to be used instead of glyphosate. The environmental effects of both atrazine and dicamba (trade name in parenthesis) are discussed below.

<u>Atrazine (Atrazine)</u>

Atrazine is a selective herbicide registered for the control of broadleaf weeds and some grassy weeds and can be applied pre- or post-emergence. Atrazine is the most widely used agricultural pesticide for corn in the U.S. (Table 4), partly because it causes no injury to corn. Atrazine is a restricted use pesticide (several risk reduction measures have been instituted for its use) and EPA has classified it as toxicity category III[15] for acute oral toxicity. It is toxicity category IV for acute inhalation, dermal, and eye irritation. Atrazine is highly persistent in the soil; most of its breakdown occurs chemically, followed by degradation by soil microorganisms. It is moderately soluble in water, but because it does not absorb strongly to soil particles and can persist in the soil, it has a high potential for water contamination. Non-target plants are susceptible to the herbicide, especially aquatic species, due to runoff. Terrestrial plants living in wetter habitats are at greater risk than ones living in drier areas. Atrazine is nontoxic to birds and bees, slightly toxic to fish and other aquatic life, and slightly to moderately toxic to humans and other animals (can be absorbed orally, dermally, and by inhalation). Atrazine is readily absorbed through the gastrointestinal tract; it is not mutagenic and carcinogenic only following lifetime administration of high doses (EPA, 2008(a); Extoxnet, 1998).

<u>Dicamba (Dicamba, Clarity)</u>

Dicamba is a selective herbicide registered for the control of certain broadleaf weeds and woody plants and it can be applied pre- or post-emergence. Dicamba is the fifth most widely used agricultural pesticide for corn in the U.S. (Table 4). It has been classified by the EPA as toxicity category III for acute oral and dermal toxicity and category II for primary eye irritation. Dicamba is moderately persistent in soil and most of its breakdown is dependent on soil microorganisms. It is highly soluble in water, but does not bind to soil particles and it is highly mobile in the soil; therefore, it may contaminate groundwater. Dicamba is nontoxic to most aquatic vascular plants (e.g. flowering plants), but it can have adverse effects on growth and development of non-vascular aquatic plants (e.g. algae) and terrestrial plants. Dicamba is practically nontoxic to birds, slightly toxic to fish, and nontoxic to bees. Dicamba is excreted rapidly and it does not accumulate in mammalian tissues; it is not mutagenic or carcinogenic (EPA, 2008(a); Extoxnet, 1998).

<u>ALS-inhibiting Herbicides</u>

The environmental impacts of three ALS-inhibiting herbicides are described in more detail under the “preferred” alternative. Many ALS-inhibiting herbicides are used in tank mixes[16] and are spot sprayed or applied pre-emergence to avoid corn injury. It is unlikely that the “no action” alternative for Pioneer HT corn would significantly affect the use of ALS-inhibiting herbicides by growers.

<u>Herbicide Resistant Weeds</u>

Weeds are commonly found in and around agroecosystems and for ages, control of their growth through various means has been a human concern. Some of the agronomic reasons to control weeds in crops include: improve the crop yield, enhance product quality, and decrease production costs. A number of methods, including tillage and herbicide application, are available to help manage weeds in croplands (Timmons, 2005).

The use of herbicides to control weeds has increased in popularity in the U.S. since the 1950s (Timmons, 2005). Advantages leading to increased effectiveness and convenience and lower

[15] Toxicity categories as established by the EPA under “precautionary statements (I indicates the highest degree of acute toxicity and IV the lowest) (EPA, 2007(a)).
[16] Two or more chemical pesticides or formulations mixed in the spray tank at the time of herbicide application.

costs have been partially attributed to such herbicide usage. Over the years, the extensive use of certain types of herbicides to control weeds has led to the development of resistance (Appleby, 2005). Herbicide resistance was first reported in 1957 (Hilton, 1957; Switzer, 1957). The development and use of herbicides considered to be less toxic to people and the environment has steadily increased over the past decade. This increase has been partially attributed to the adoption of herbicide-tolerant crops produced via conventional breeding or genetic engineering methods (Tan et al., 2005; Cerdeira and Duke, 2006). The presence of resistant weeds will force a grower to utilize other herbicides and/or other weed management practices in order to combat such weeds.

Overall, under the “no action” alternative, Pioneer HT corn would not be available to growers as an option to decrease the use of more toxic chemicals, such as atrazine, and replace them with glyphosate, a more “environmentally friendly” herbicide, without affecting yield. Also under this alternative, if the development of resistant weeds to an herbicide should occur, Pioneer HT corn would not be available as an option to alternate herbicides to control weeds without damage to the corn.

C. Agriculture and Climate Change

The use of tillage and the removal of soil residue are considered agriculture practices that accentuate loss of soil organic carbon (Lal and Bruce, 1999). As described in section II, this loss has negative impacts on the atmosphere and increases soil erosion, among others. The use of equipment for tillage and herbicide application also contributes to these environmental impacts by increasing fossil fuel emissions. However, energy input for tillage is higher than that used with herbicide spraying (Cerdeira and Duke, 2006). The ability of growers to utilize herbicides to control weeds without crop damage has been linked to a decrease in the use of intensive tillage. Under the “no action” alternative, Pioneer HT corn would not be available to growers, and it is likely that there would be more use of tillage as a means of weed management.

B. Preferred Alternative

Under this alternative, Pioneer HT corn would no longer be a regulated article under 7 CFR part 340. Permits and/or notifications by APHIS would no longer be required for introductions of Pioneer HT corn. Based on APHIS’ evaluation, it has been determined that Pioneer HT corn’s agronomic performance in the field is not significantly different than its non-GE counterpart. APHIS has chosen the preferred alternative for the proposed action because APHIS determined that Pioneer HT corn is not a plant pest. The determination that this product lacks plant pest characteristics is found in Appendix A; APHIS’ assessment of environmental impacts is described below.

A. Corn

1. Corn Varieties

Under this alternative, Pioneer HT corn would be available to growers as a replacement product to other glyphosate or ALS-inhibiting herbicide tolerant corn varieties. Growers having trouble with glyphosate or ALS-inhibiting herbicide tolerant weeds could alternate herbicides in order to better manage their weeds. A potential environmental impact to consider as a result of planting this corn variety, as with any other commercially-available variety, is the potential for gene flow (the transfer of genetic information between different individuals and/or populations). Based on the plant pest risk assessment (Appendix A), APHIS has already determined that Pioneer HT corn is not a plant pest and that gene flow between this product and weedy and wild relatives is not likely to occur. APHIS does note that gene flow can take place between a field planted with Pioneer HT corn and a neighboring corn crop. Although the biology of the crop (See Appendix A, Potential Impacts from Gene Flow and Gene Introgression from Pioneer HT Corn into its Sexually-Compatible Relatives) limits the amount of gene flow that may occur between two corn plants, certain measures can be taken to minimize such flow (e.g. isolation distance).

Coexistence in agriculture is not a new concept. Coexistence is the practice of growing various crops in the same area without commingling and potentially compromising the economic value of all crops involved. As practiced by growers and guided by national and international seed associations from several countries over many years, coexistence principles have been key to the successful diversification and production of plant varieties for food and seed (Van Deynze et al., 2008; CropLife, 2008; PG Economics, 2004). Whether the crop is produced via conventional, GE, or organic methods, coexistence is based on the concept that growers should be free to cultivate the crops of their choice using the production systems they prefer. The foundation of this concept is good communication among all parties (growers, handlers, shippers, and marketers), shared responsibilities (e.g., implementing appropriate management practices), and respect for each others' practices and requirements (PG Economics, 2004; Van Deynze et al., 2008). Due to the inevitable drift of pollen between two crops, there is a general agreement in agriculture that a 100% purity standard is not practical in field production systems, but tolerances and thresholds for the presence of low levels of undesirable materials allow efficient marketing while still reaching quality and safety criteria (US-FDA, 1998). Traditionally, the primary responsibility for meeting market standards has largely rested on the party who is economically benefiting from it, usually the grower who is compensated for higher quality products (CropLife, 2008; Fernandez and Polansky, 2006; SCIMAC, 2008). In this case, growers involved in the production of corn seed (e.g., 0.2% in NE, Table 1), who want/need to produce a higher quality product, should attempt to follow the co-existence principles in order to maintain the purity of their crop and minimize gene flow from neighboring fields planted to herbicide tolerant varieties (or other corn varieties); again, regardless whether the variety was made through genetic engineering or conventional breeding.

Given the diversity of U.S. Agriculture, the USDA Advisory Committee on Biotechnology and 21st Century Agriculture published a consensus report in 2008 to address the issues to consider regarding coexistence among diverse agricultural systems (USDA ACB and 21st CA, 2008). In that report, the committee stated that the term "coexistence", refers to the concurrent cultivation of conventional, organic, and GE crops consistent with underlying consumer preferences and choices. The committee noted that "the success of coexistence assumes that market demand for organic, identity-preserved conventional, and GE products continues and that the government will support different agricultural production systems. That support plays an important role in ensuring that production systems in the U.S. for these three classes of crops will continue to thrive, prosper, and meet the needs of the marketplace." The paper stated that a number of factors may interact to either enhance or inhibit coexistence of production systems in the U.S., including new developments in technology, changes in laws and regulation, lawsuits and judicial decisions, domestic and global market factors, and initiatives undertaken by participants in the food and feed agricultural production system.

In agricultural systems, growers may choose to grow GE or non-GE corn, and obtain price premiums for growing varieties of corn for particular markets (e.g., using organic methods for corn production or producing a specialty corn variety for particular processing needs). The USDA asserts that agricultural practices that use conventional means, organic production systems, or GE varieties can all provide benefits to the environment, consumers, and farm income. Gene flow into and out of these specialized corn production systems has been managed using various types of buffer zones or isolation practices, such as differences in planting dates (which results in differences in flowering) or making sure fields are at an appropriate distance from other compatible crops (such as using isolation distances).

Pioneer HT Corn

The food/feed nutritional and safety assessment for Pioneer HT corn is being reviewed by the FDA (Section I, Purpose and Need). Under FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from Pioneer HT corn must be in compliance with all applicable legal and regulatory requirements. FDA's final review for this product is pending. Pioneer has indicated that it would not commercialize Pioneer HT corn without a review by the FDA. APHIS assessment of the safety of this product for humans and animals focuses on plant pest risk, and that analysis, is based on the comparison of the GE-corn to its non-GE counterpart (Appendix A).

In the petition, Pioneer noted the increased levels of five acetylated amino acids (N-acetylaspartate (NAAsp), N-acetylglutamate (NAGlu), N-acetylserine (NASer), N-acetylthreonine (NAThr), and N-acetylglycine (NAGly) from the compositional analysis of Pioneer HT corn (Table A, addendum to petition, 03/12/08). N-acetylated amino acids are widely found throughout the plant and animal kingdom and are therefore, present in many food sources (Appendix 8, pg. 172 of the petition). Pioneer analyzed eggs, yeast, ground turkey, chicken, and beef and found amounts of both NAAsp and NAGlu at various levels (Appendix 8, pg. 171-173 of petition). The levels of NASer, NAThr, and NAGly detected in Pioneer HT corn were 100 times lower than those for NAAsp and NAGlu. Pioneer also conducted a study to assess the wholesomeness/nutrition (poultry study) of Pioneer HT corn (Appendix A) and an acute and repeated dose study of NAAsp in rats (Appendix D). On both studies, no differences were observed in any of the treatment groups. Based on this data, it appears that some of these amino acids are normal components of the human diet. Also, acetylation of proteins (which are made up of amino acids) is employed in the food industry to alter properties of protein concentrates to be added to food (El-Adawy, 2000; Ramos and Bora, 2004).

Based on the assessment of the laboratory-based evidence provided by Pioneer and scientific literature (Appendix D), APHIS has concluded that under this alternative, the proposed action to deregulate Pioneer HT corn would have no significant impacts on human or animal health.

B. Agronomic Practices

1. Tillage

Before herbicides, the primary means to manage weeds involved extensive tillage and manual weeding (Cerdeira and Duke, 2006). Although conventional tillage is today the most commonly used form of tillage (Table 6), the availability of herbicide tolerant crops has promoted the use of conservation tillage because herbicides can be sprayed to control weeds as needed without affecting crop yield (Cerdeira and Duke, 2006). Under conservation tillage, crops are grown with minimal cultivation of the soil; most or all of the plant residues (crop residue) remain on top rather than being plowed or disked into the soil (Table 1). The new crop is then planted into the stubble or into small strips of tilled soil (Peet, 2001). Under the "preferred" alternative, growers will have access to Pioneer HT corn as an herbicide tolerant corn option that will require less tillage than that required for non-herbicide tolerant corn varieties.

Non-target Effects

As described in the "no action" alternative, regardless of the type of tillage utilized by growers, the plants mostly affected are weeds.

Conservation tillage is increasingly being viewed as a technology to help reduce the negative impacts of conventional agriculture on natural ecosystems. The potential benefits of conservation tillage to wildlife include on-site benefits, which are often in the form of increased food and cover; and off-site benefits, particularly to aquatic ecosystems, which may be cumulative over longer time spans as a result of, for example, a reduction in soil erosion (reducing herbicide runoff). Residue provides (1) food in the form of waste grain on the soil surface, (2) diverse structure for protective cover, and (3) residual vegetation used for constructing nests. Conservation tillage may provide food and security unavailable in disked or plowed fields (Dimmick, 1988) due to the high percentage of crop cover that remains on the field.

The increasing use of conservation tillage has also contributed to reductions in soil erosion from water and wind, loss of soil moisture, and soil compaction (Holland, 2004; Cerdeira and Duke, 2006, Olson and Sander, 1988). Many organisms, such as earthworms and termites, contribute to organic and nutrient cycling. Intensive physical disruption of the soil causes numbers of such organisms to decrease, as nests and burrows are destroyed. The removal of residue cover takes away moisture and temperature conditions for larvae stages of certain beetles and food and cover for other organisms (Kladivko, 2001). Conservation tillage, primarily no-till operations, minimizes the disruption of the soil and leaves behind the most amount of residue.

Under the "preferred" alternative, Pioneer HT corn would be available to growers as an option to help to increase the use of conservation tillage and reduce the damaging impacts of intensive tillage.

2. Herbicides

The successful control of weeds is essential for the economical production of corn. As already described, weeds reduce crop yields by competing for nutrients, water, and light during the growing season and by interfering with harvest. A corn plant that emerges rapidly and uniformly will have the competitive advantage. Therefore, it is important to utilize good management practices in order to prevent weeds from emerging or growing along with the crop. Late season weeds can cause inefficient equipment operation and be a source of weed seed for the next planting season (UF/IFAS, 2008). Although growers may use a number of techniques, or combinations of them, to control weeds, herbicides have been shown to be the most popular and most effective tools for successful weed control in corn (UF/IFAS, 2008).

Under the “preferred” alternative, Pioneer HT corn would be available to growers as an alternative to commercially-available glyphosate tolerant products. APHIS notes that the number of acres planted to herbicide tolerant varieties has been slowly increasing over the past few years (USDA-NASS, 2007) and that this trend may continue; although as previously discussed, the number of acres of non-stacked, with an insect resistant trait, varieties of GE HT corn planted in 2007 decreased in 2008 and 2009 (Table 5). If the number of acres of herbicide-tolerant corn were to continue to increase, due or not to the availability of Pioneer HT corn[17], it is expected that the use of herbicides, including glyphosate, may continue to increase (exact amounts are hard to predict). In this case, the availability of Pioneer HT corn would allow growers to use a more “environmentally-friendly” herbicide (non-target effects described below). (Though any increase due to the deregulation of Pioneer HT corn is likely to be negligible, see pg. 28). Also, although not as widely used (Table 4), the deregulation of Pioneer HT corn may also cause an increase in the use of ALS-inhibiting herbicides (again, hard to predict exact amounts). A more detailed look at the three most widely used ALS-inhibiting herbicides as shown in Table 4 (*italics*), is provided below. For each herbicide, the analysis has been combined for its effects on plants, animals, soil microorganisms, and humans. Even if the deregulation of Pioneer HT corn caused an increase in the use of glyphosate and ALS-inhibiting herbicides, such increase would not significantly affect the quality of the human environment, as described below.

Glyphosate (Roundup)

It has been estimated, that the adoption of glyphosate tolerant crops has reduced overall herbicide use by 37.5 million pounds per year in the U.S. (Gianessi, 2005). Glyphosate is considered to be a low risk herbicide in terms of toxicity and environmental effects. Although today, there is a long list of herbicides available to growers for the treatment of weeds, glyphosate replaces the use of other synthetic herbicides that are at least three times more toxic and that persist in the environment nearly twice as long as glyphosate (Heimlich et al., 2000; Gianessi and Carpenter, 2000). Therefore, under the “preferred” alternative, Pioneer HT corn would be available to growers, if they are not already growing a glyphosate-tolerant variety, as an option to utilize a more “environmentally” friendly herbicide for weed control.

Non-target Effects

The goal of using glyphosate, or any other herbicide, is to destroy the unwanted vegetation that may harbor pests and compete with the crop for resources, thus lowering yield, without damage to the crop itself. It is common for growers to also want to reduce the vegetation within a few meters of the crop to prevent the spread of seeds or any plant parts that may further propagate the weeds into the field. Glyphosate can be metabolized (broken down) by some plants, but this ability is not universal (Carlisle and Trevors, 1988). Some plants carry inherent resistance and can grow normally in the presence of glyphosate. In others, glyphosate may affect their germination and/or growth characteristics and in some cases, glyphosate may stimulate their growth (Wagner, et al., 2003; Schabenberger et al., 1999; Cerdeira and Duke, 2006). Because of the potential for unintended damage, measures should be taken to avoid contact with desirable

[17] As described on pg. 28. Pioneer HT corn is likely to be adopted by growers already growing herbicide tolerant varieties.

vegetation.

Glyphosate is highly soluble in water; in most soils, it does not leach into ground water, and it has been shown to dissipate more rapidly than other herbicides on surface water (Cerdeira and Duke, 2006; Carpenter et al., 2002). Glyphosate is no more than slightly toxic to wild birds and some aquatic invertebrates; it is nontoxic to fish and honeybees (EPA, 2008(a)). Glyphosate has not been reported as an atmospheric contaminant and is not volatile at 25ºC (Van Dijk and Guicherit, 1999; Giesy et al., 2000). Estimated and measured concentrations of glyphosate use in wetlands and different bodies of water has shown that the risk to aquatic organisms is negligible or small at application rates less than 4 kg/ha (kilogram/hectare) and only slightly greater at application rates of 8 kg/ha (rates at, or significantly above, the recommended application rates of 0.21 to 4.2 kg/ha for glyphosate) (Solomon and Thompson, 2003; Cerdeira and Duke, 2006).

Glyphosate has little or no activity in the soil (Cerdeira and Duke, 2006). It strongly absorbs to soil particles, it is rapidly degraded by soil microbes. Glyphosate applied at recommended field rates has been shown to have no effect on the growth and survival of many soil organisms, including arthropods (e.g. spiders) and earthworms. In general, glyphosate has been shown to have little effect on soil microflora (Haney et al., 2000; Cerdeira and Duke, 2006).

Glyphosate has been classified by the EPA as toxicity category III and has relatively low oral and dermal acute toxicity. The acute inhalation toxicity study was waived by the EPA because glyphosate is non-volatile and because adequate inhalation studies show low toxicity (EPA, 2008(a)). Glyphosate is poorly absorbed through the digestive tract and largely excreted unchanged by mammals; it is not mutagenic or carcinogenic (EPA, 2008(a); Extoxnet, 1998).

<u>ALS-Inhibiting Herbicides (Trade Name)</u>

<u>*Nicosulfuron (Accent)*</u>

Nicosulfuron is a broad spectrum herbicide registered for the control of annual and perennial grasses and broadleaf weeds and it is usually applied post-emergence. Nicosulfuron has been classified by the EPA as toxicity category IV for acute oral, dermal, inhalation toxicity and category III for acute eye irritation. Nicosulfuron has low to intermediate soil mobility, with minimal risk of runoff. Nicosulfuron is slightly toxic to birds, practically nontoxic to freshwater fish and invertebrates, and nontoxic to honey bees. Nicosulfuron is not mutagenic or carcinogenic (EPA, 2008(a); Extoxnet, 1998).

<u>*Rimsulfuron (Matrix)*</u>

Rimsulfuron is a broad spectrum herbicide registered for the control of a wide variety of grasses and broadleaf weeds and it can be applied pre- or post-emergence. Rimsulfuron has been classified by the EPA as toxicity category IV for acute oral, dermal, and inhalation toxicity and category III for primary eye irritation. Rimsulfuron degrades rapidly in soil and water and has low soil mobility; therefore, low potential of water contamination. Rimsulfuron is not mutagenic or carcinogenic (Schneiders, 1993; EPA, 2008(a)).

<u>*Flumetsulam (Python)*</u>

Flumetsulam is an herbicide registered for the control of grasses and broadleaf weeds and it can be applied pre- or post-emergence. Flumetsulam has been classified by the EPA as toxicity category III for acute oral, dermal, and inhalation toxicity and category IV for eye irritation. Flumetsulam has low mobility in soils. Although it absorbs to soil and it is soluble in water, some runoff to drinking water occurs. Flumetsulam is rapidly excreted, mainly in urine, unchanged. Flumetsulam is not mutagenic or carcinogenic (Rouchaud, 2002; EPA, 2008(a))

Herbicide Resistant Weeds

As previously discussed, the potential environmental impacts associated with weed control also include the development of dual herbicide resistant weeds through continued use of glyphosate and ALS-inhibiting herbicides on current products available to growers for planting; this includes varieties with stacked herbicide resistant traits from previously deregulated and non-GE herbicide tolerant corn lines (Appendix B). APHIS notes two reports of weeds that have developed tolerance to both glyphosate and ALS-inhibitors. Common waterhemp (*Amaranthus rudis*) in Missouri and Illinois and horseweed (*Conyza canadensis*) in Ohio (Weed Science, 2008). Growers have adapted to the development of herbicide, and dual herbicide, resistant weed populations in the past and it is reasonably foreseeable that they will continue to do so in the future. As already mentioned, many weed scientists, companies, and university scientists are constantly working to develop management strategies, and new products, to help ensure consistent control of weeds. Pioneer has shown strong support for IWM programs in the past and it is likely that they will continue to do so in the future.

The use of Pioneer HT corn is amenable to the aforementioned integrated weed management program. By having herbicide resistance to two different modes of action, the use of Pioneer HT corn, in conjunction with an herbicide resistance management strategy, should facilitate practices that allow the application of more than one herbicide mode of action within a season and in successive years. In turn, this should allow growers to better manage resistant and non-resistant weeds in their corn fields. Pioneer HT corn was developed to confer tolerance to representative members of each of the five classes of herbicides in the ALS-inhibitor family; therefore, if the development of dual herbicide resistant weeds to glyphosate and certain ALS-inhibiting herbicides should occur, or if such weeds were currently present in the field, growers would have a variety of herbicides available to help them manage resistant weeds in their fields.

C. Agriculture and Climate Change

The use of conservation tillage and residue cover has been shown to increase soil organic carbon content. As described above, reducing the disturbance to the soil and maintaining high amounts of residue cover contribute to the increase in soil carbon. Preventing soil erosion enhances soil quality (biodiversity) and resilience, and improves water quality by reducing runoff. In addition, the soil carbon sequestration gains resulting from reduced tillage greatly decrease carbon dioxide emissions (Brookes and Barfoot, 2006). The adoption of glyphosate herbicide tolerant crops has also contributed to a reduction in the number of herbicide applications (Gianessi, 2005); this has resulted in carbon dioxide savings from reduced fuel use. In their study, Brookes and Barfoot, indicated that GE technology has resulted in 224 million kg less pesticide use by growers. They also indicated that planting GE crops have facilitated a reduction in greenhouse gas emissions of 9 billion kg in 2005; this is equivalent to removing 4 million cars from the roads for a year (Brookes and Barfoot, 2006).

D. Conventional and Organic Farming

Organic farming operations as described by the National Organic Program, which is 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.

Corn produced using organic methods is increasing at approximately 30% a year (USGC, 2006). In 2005, of the total 81.6 million acres of corn cropland in the U.S., 130,672 acres (0.16%) were certified organic corn (USDA-ERS, 2005(a)). Out of the states surveyed, 52% of the total acreage was planted with GE varieties (17% of which were planted to non-stacked, with an insect resistant trait, herbicide tolerant varieties) and, thus, approximately 48% of the total corn cropland acreage in 2005 was planted with nontransgenic corn (USDA-NASS, 2005). In 2008 and 2009, of the States surveyed, approximately 80% and 85%, respectively, of the total acreage in those States was planted with GE varieties (USDA-NASS, 2008; USDA-NASS, 2009).

It is not likely that growers, including organic and conventional growers, who choose not to plant transgenic corn varieties or sell transgenic corn, will be significantly impacted by the commercial use of this product. Non-transgenic corn will likely still be sold and will be readily available to those who wish to plant it. An internet search of "corn seed company" identified vendors that offered all types of conventional and transgenic corn seeds for purchase. A few of the many searchable sites available included http://www.bo-jac.com (Bo-Jac, 2008) and http://www.lathamhybrids.com (Latham, 2008). If Pioneer receives regulatory approval from all appropriate agencies, it will make Pioneer HT corn available to growers and breeders. It is not likely that other growers who choose not to plant or sell Pioneer HT corn or other transgenic corn will be significantly impacted by the expected commercial use of this product as (a) non-transgenic corn will likely still be sold and readily available since between 2005 and 2008, and based on the States surveyed, approximately 20 to 48% of the total corn acreage was planted with nontransgenic corn (USDA-NASS, 2005-2008); (b) isolation distances can be maintained to prevent cross-pollination; and (c) APHIS expects that Pioneer HT corn will replace some of the presently available glyphosate tolerant corn varieties, see pg. 28, without significantly affecting the existing glyphosate tolerant corn acreage or the overall total corn acreage; therefore, organic farmers will be able to coexist with biotech corn producers as they do now (see discussion on co-existence under *Corn varieties,* **Preferred Alternative** (pg. 20)).

C. Cumulative Effects

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

These actions include previous determinations of nonregulated status for glyphosate tolerant varieties (there are no GE ALS-inhibiting herbicide tolerant corn varieties on the market today). This includes non-GE glyphosate tolerant and ALS-inhibiting herbicide tolerant varieties and stacked gene varieties made through conventional breeding (Appendix B) tolerant to either on the two herbicides.

In 2005, the vast majority of the herbicide tolerant corn planted was glyphosate resistant (approximately 30% of total corn acreage) (Monsanto, 2006). In 2000, approximately 7% of the U.S. corn was planted to Clearfield® corn (Stapleton, 2001). Those percentages are exceedingly higher when taking into account all of the available glyphosate, ALS-inhibiting herbicide, and stacked varieties for each crop available in the market today (e.g., Roundup ready® soybean, corn, sorghum, canola, cotton and sugar beet; Clearfield® corn, wheat, rice, sunflower, canola, and lentils; STS™ soybeans; other varieties found in Appendix B). In 2006, alone, glyphosate tolerant varieties of soybean were planted on approximately 89% of total soybean acreage in the U.S. (USDA-NASS, 2006(b)).

In 2007, APHIS published a determination of nonregulated status for Monsanto 89788 soybean (petition 06-178-01p) (USDA-APHIS-BRS, 2008(a)) which is tolerant to glyphosate. This new line was developed to replace the original 40-3-2 event. It is expected that the new Monsanto 89788 varieties will replace the older 40-3-2 varieties over time. In July, 2008, APHIS reached a determination of nonregulated status for Pioneer 356043 soybean (petition 06-271-01p) (USDA-APHIS-BRS, 2008(a)). This is the first glyphosate and ALS-inhibitor tolerant soybean available to growers. It is possible that growers would choose to rotate 356043 soybean (or other glyphosate tolerant varieties) with Pioneer HT corn. This rotation pattern is not likely to cause an increase in the number of herbicide resistant weeds, as growers will be able to utilize both glyphosate and ALS-inhibitor herbicides. The availability of this corn will enable growers to control weeds using an ALS-inhibitor herbicide where, for example, glyphosate resistant weeds are present, or conversely, use glyphosate where ALS resistant weeds are present. If a grower plants 356043 soybean and/or Pioneer HT corn, it does not mean they will need to use both glyphosate and ALS-inhibitors; they may only need to use one, or they may use herbicides with other modes of action registered for the crop. Many herbicides are currently available to use on corn and soybeans. Growers who apply recommended principles of IWM (such as herbicide rotations using different chemistries) will best be able to delay the onset of resistant weeds (UW-IPCM, 2008).

Possible future actions from APHIS also include deregulation of glyphosate tolerant cotton (06-332-01p), alfalfa (04-110-01p), and creeping bentgrass (03-104-01p). Only cotton and alfalfa are sometimes rotated with corn. If growers choose to rotate from either 356043 soybean or Pioneer HT corn to a crop that does not have dual herbicide tolerance, there may be re-cropping issues to consider because of the residual re-plant restrictions (herbicide label restrictions that prevent a grower from planting any crop of their choice) for some of the ALS inhibitor herbicides. These issues are similar to re-cropping considerations that growers currently need to consider.

Corn cultivation occurs on land that is dedicated to crop production. Most corn is planted in fields that have been in crop production for years. As with most agricultural practices, continuous production of corn would normally include the use of tillage and herbicides to limit the growth of weeds, limit the potential impact caused by insects, animals, disease, and to maximize production. Introduction of Pioneer HT corn is not expected to significantly alter the range of corn cultivation. This corn will likely be introduced in an area where corn is currently grown. The USDA predicts that in general, the planted acres of corn will stabilize at 89-90 million acres in 2008 and will remain at that level through 2016 (USDA-OCE, 2007) and although it is possible that the adoption of GE corn could increase, when specifically looking at non-stacked, with an insect resistant trait, herbicide tolerant varieties, percentages indicate non-stacked GE herbicide tolerant corn planted in 2009 and 2008 was lower than that planted in 2007 (see Table 5). In 2009, out of 85% of all corn planted acres, 85% were biotechnology varieties; this included stacked (herbicide and insect resistant) and non-stacked varieties (herbicide resistant or insect resistant) (USDA-NASS, 2009). The data indicate that a great portion of the acres planted to corn in the U.S. are already GE.

Furthermore, Pioneer HT corn is likely to be used by growers as a replacement crop to other non-stacked, with an insect resistant trait, herbicide tolerant corn varieties. APHIS bases this conclusion on a variety of factors, including that the rate of adoption of non-stacked, with an insect resistant trait, herbicide tolerant crops is not expected to dramatically increase and on the fact that Pioneer, based on its knowledge of the corn market, characterizes Pioneer HT corn as a 'replacement product' (pg. 119 of the petition).

Any increase in glyphosate use from the adoption of Pioneer HT corn is likely to be negligible and, when combined with the past, current, and future use of the herbicide on glyphosate tolerant varieties (e.g. herbicide tolerant soybeans) will not significantly impact the quality of the human environment. In the future, there is the potential of stacking Pioneer HT corn with, for example, an insect resistant variety. In that case, it is likely that Pioneer HT corn would be replaced by the new variety, if growers feel there is an advantage to having the added insect resistance in their corn field. APHIS, however, does not discount the possibility that acres planted to GE corn could increase if Pioneer HT corn was stacked and adoption rates changed. This could potentially mean an increase in the use of glyphosate and ALS-inhibiting herbicides. In terms of the environmental effects of the past, present, and future use of glyphosate, studies have shown that glyphosate has little or no activity in the soil, it strongly absorbs to soil particles, and it is rapidly degraded by soil microbes (Cerdeira and Duke, 2006). In addition, glyphosate is considered to be a low risk herbicide in terms of toxicity and environmental effects. Although today there is a long list of herbicides available to growers for the treatment of weeds, glyphosate replaces the use of other synthetic herbicides that are at least three times more toxic and that persist in the environment nearly twice as long as glyphosate (Heimlich et al., 2000; Gianessi and Carpenter, 2000).

Although there is uncertainty as to the adoption rate of Pioneer HT corn, there are a number of possible scenarios to consider. For a grower, the decision to purchase Pioneer HT corn will be largely economic, as most of the costs associated with growing and selling a crop are usually factored into which seed to purchase. Growers will only buy Pioneer HT corn if they can derive an economic benefit. Buyers of Pioneer HT corn are likely to have had experience with herbicide tolerant corn and will mainly replace their existing HT corn with Pioneer's. Pioneer HT corn will provide an extra weed control option since this product will allow use of ALS-inhibiting herbicides that will help a grower manage glyphosate tolerant weeds, if present.

Researchers at Cornell University have developed a method to assess the environmental impacts of herbicides using a variety of environmental toxicity parameters (Kovach et al., 1992). This compilation indicates that ALS-inhibiting herbicides and glyphosate have comparable environmental impacts within agricultural production systems. Growers of currently available non-GE corn are currently able to apply both glyphosate and ALS-inhibitors to their corn. Since Pioneer HT corn will most likely be used by growers that are presently using glyphosate tolerant corn, and there are no significant environmental impacts from use of these two types of herbicides, cumulative impacts are likely to be similarly insignificant.

APHIS notes that the use of herbicides with different modes-of-action on crops is already a common agricultural practice. As part of its ongoing responsibilities for regulation of pesticides, EPA has assessed the impacts of application of glyphosate and ALS-inhibitors on corn, and other herbicide tolerant crops, and approved the appropriate pesticide label amendments and/or tolerances for those uses. In addition, EPA has reviewed aggregate dietary exposures of glyphosate and ALS-inhibitors in making its food safety determinations for these products under the Federal Food, Drug, and Cosmetic Act (EPA, 1993; EPA 2008(a)). ALS-inhibiting herbicides reached their peak use on corn in the late 1990s. But their widespread use in a number of major crops over the past two decades contributed to the development of several resistant weed species (Brenly-Bultemeier et al., 2002). Since then, the use of ALS-inhibiting herbicides has significantly decreased (Table 4). The commercialization of Pioneer HT corn may lead to an increase in the use of ALS-inhibitors, but the amounts are not expected to reach the historic high levels (Figure 30, pg. 119 of the petition). Although some of the acres that will be treated represent new markets, the majority of the Pioneer HT corn acres treated will be replacement acres for those already being treated with ALS inhibiting herbicides. APHIS believes that if a grower is already planting an ALS tolerant product, that grower will replace their product with Pioneer HT corn in order to utilize glyphosate whenever ALS does not work (and vice versa). Also, not all growers who plant Pioneer HT corn will choose to use ALS-inhibitor herbicides. Thus, deregulation of Pioneer HT corn does not significantly change current agricultural practice, and no significant cumulative impacts would be expected.

Low use-rate herbicides such as ALS-inhibitors can cumulatively lessen impact on the environment by decreasing the amount of herbicide used, diminishing waste generation and energy use, while allowing easier handling, storage, and transport. Growers using low-use rate ALS-inhibitors would apply 95-99% less herbicide (active ingredient) to their crops, releasing much less into the environment. A significant reduction in energy input and waste generation is also expected during the chemical manufacturing of low-use rate herbicides. For example, the energy (gas, oil, electricity, etc.) needed to produce high use-rate herbicides (e.g., 2,4-D or dicamba) is 7 to 9-fold more than that required for a sulfonylurea (Pioneer, 2008). Waste streams of 10-100 kg of waste per kg final active ingredient are typical in agricultural chemical production (Brown, 1995). Waste streams for ALS-inhibitors are typically on the low end of this range. Coupled with the low-use rates needed, these result in lower energy use and waste generated per acre of treatment than for other herbicides.

Pioneer HT corn does not produce any other substance that is not normally produced by conventional corn, nor is the composition of the seed produced by the corn significantly different from unmodified counterpart (conventional corn). Data supplied by the applicant, including results of 3 years of field tests in various environments, indicate that Pioneer HT corn has not had observable or measurable impacts on ecosystems in which it has been grown (Section VII, pg. 81 of the petition). Therefore, APHIS does not expect accumulation of a novel substance in soil, nor does APHIS expect significant impacts on organisms living in and around these agricultural fields, when compared to corn currently planted, because of exposure to Pioneer HT corn. Also, as discussed in Appendix A, Pioneer HT corn shows no difference in agronomic performance, disease, and phenotypic assessments to conventional corn; therefore, neither presently nor in the future, is Pioneer HT corn any more likely than conventional corn to form successful crosses with wild and weedy relatives.

Based on this 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 that would significantly affect the quality of the human environment 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 Pioneer HT corn is planted. However, as previously discussed, APHIS suggests that growers follow IWM practices, for any type of crop, in order to minimize the environmental impacts of agriculture and prevent cumulative impacts.

D. Threatened and Endangered Species

APHIS considered the potential impact on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. In this analysis, APHIS considered the biology of Pioneer HT corn, as well as the classic agricultural practices associated with the cultivation of corn. As discussed in Appendix A, Pioneer HT corn differs from non-transgenic corn only in the expression of the two genes responsible for the herbicide tolerance to glyphosate and ALS-inhibiting herbicides. The proteins produced by the inserted genes and the increase in the amino acids N-acetylaspartate (NAAsp), N-acetylglutamate (NAGlu), N-acetylserine (NASer), N-acetylthreonine (NAThr), and N-acetylglycine (NAGly) (Appendix D), do not raise safety issues. Pioneer HT corn does not express additional proteins, natural toxicants, allelochemicals, pheromones, hormones, etc. that could directly or indirectly affect a listed TES or species proposed for listing. Data submitted on the composition of Pioneer HT corn indicate that this corn is not significantly different from non-transgenic corn and would not be expected to have any impact on TES that would be any different from non-transgenic corn. Given all these factors, and the lack of noted adverse effects on chickens (Section VIII-E, pg. 109 of the petition), consumption of Pioneer HT corn should have no effect on threatened and endangered species. Finally, Pioneer HT corn is not sexually compatible with a federally listed TES or a species proposed for listing.

Cultivation of Pioneer HT corn is not expected to differ from typical corn cultivation. Although the extent to which Pioneer HT corn will be grown is unknown, this product is expected to replace the existing glyphosate tolerant corn varieties available in the market, and used in areas where glyphosate tolerant corn is already present. Although a shift to planting Pioneer HT corn could result in an increase in the use of ALS-inhibiting herbicides, these are very low use rate herbicides (ounces/acre) (EPA, 2008(a)) and their existing combined used in corn is low. After reviewing the possible effects of deregulating Pioneer HT corn, APHIS has not identified any stressor caused directly by this product, that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. The potential environmental impacts on TES of this product are those associated with typical agriculture. The effect of agricultural practices (tillage and herbicide use) on plants, animals, and soil microorganisms was discussed in Section IV. It is expected that some of those agricultural practices would also have an impact on TE species and those proposed for listing, just as they did for non-TE species. Growers planting Pioneer HT corn, as with any other corn variety, genetically engineered or not, should consider the environmental impacts of agronomic practices on those TE species found in and around their corn field.

Although a shift to planting Pioneer HT corn may result in an increase in the use of ALS-inhibiting herbicides, this increase may likely occur anyway because of the availability of other such corn varieties. The ALS inhibitors currently registered for use on corn can also be used on Pioneer HT corn, with no change in label rates. In order to be registered as a pesticide by EPA under FIFRA, it must be demonstrated that when used with common practices, a pesticide will not cause unreasonable adverse effects in the environment, including effects on wildlife and TES (EPA, 2007(b)). Thus, ALS-inhibitor herbicides currently registered for use on corn varieties are not expected to pose any unreasonable risks to wildlife and the environment. Several of the ALS-inhibitor herbicides have comparable environmental impacts (as calculated by a Cornell University publication (Kovach et al., 1992) as glyphosate, which will likely continue to be used on large acreages across the U.S. Additionally, as noted in Table 4, ALS inhibitors continue to be used and have been used effectively on corn in the past (e.g., Nicosulfuron, Flumetsulam, Rimsulfuron, and others). As these herbicides have been used effectively and safely for many years on corn as well as other crops, there is no indication that their use on a higher percentage of acres would be associated with significant environmental impacts. Periodic registration review by EPA for these herbicides ensures that these products do not present unreasonable risks to humans, wildlife, fish, and plants (EPA, 2007(c)). It is uncertain exactly which ALS-inhibiting herbicide(s) would be recommended for use on Pioneer HT corn, but growers will have several options and be able to choose based on their needs.

After reviewing possible effects of deregulating Pioneer HT corn, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. Consequently, an exposure analysis for individual species is not necessary. APHIS expects Pioneer HT corn to replace some of the presently available glyphosate tolerant and ALS-inhibiting herbicide tolerant corn varieties, but APHIS does not expect that Pioneer HT corn will cause new corn acres to be planted in areas that are not already devoted to agriculture. As noted previously, 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 a pesticide poses and whether changes to the use or proposed use are necessary to protect the environment. APHIS has considered the effect of Pioneer HT corn production on critical habitat (which is a subset of the environment and therefore also considered by EPA) and could identify no difference from affects that would occur from the production of other corn varieties. Therefore, APHIS has determined that granting a petition of non-regulated status for Pioneer HT corn will have no effect on federally listed threatened or endangered species and species proposed for listing, or on designated critical habitat or habitat proposed for designation. Consequently, a written concurrence or formal consultation with the USFWS is not required for this action.

E. Other Considerations

Executive Order (EO) 12898 (US-NARA, 2008), “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 or low-income communities from being subjected to disproportionately high and adverse human health or environmental effects. EO 13045 (US-NARA, 2008), “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) required 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. Based on the information submitted by the applicant, Pioneer HT corn is not significantly different than conventional corn and it is therefore, not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

EO 13112 (US-NARA, 2008), “Invasive Species”, states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause. Both non-GE and deregulated GE glyphosate tolerant corn varieties are widely grown in the U.S. Based on historical experience with corn and the data submitted by the applicant and reviewed by APHIS, Pioneer HT corn plants are very similar in fitness characteristics to other corn varieties currently grown and are not expected to become weedy or invasive.

EO 13186 (US-NARA, 2008), “Responsibilities of Federal Agencies to Protect Migratory Birds”, states that Federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within 2 years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations. Data submitted by the applicant has shown that Pioneer HT corn has the same agronomic characteristics as conventional corn. The only difference found between Pioneer HT corn and control corn was in the elevated concentrations of acetylated amino acids. APHIS’ review of that information is provided in Appendix D. Based on this review, it is not likely that the deregulation of Pioneer HT corn can, or will, have a negative effect on migratory bird populations.

EO 12114 (US-NARA, 2008), “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 a significant environmental impact outside the U.S. should nonregulated status be determined for Pioneer HT corn. It should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new corn cultivars internationally, apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340. Any international traffic of Pioneer HT corn subsequent to a determination of nonregulated status for the product 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" (IPP, 2008); the protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (157 countries as of October 2006). 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 138 countries are Parties to it as of January 5, 2007 (CBD, 2008). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. 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 U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII, 2008). These 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 U.S., and within 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* (NAPPO, 2008). 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.

V. Listing of Agencies and Persons Consulted

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Appendix A: Plant Pest Risk Assessment

Plant Pest Risk Evaluation

Potential impacts to be addressed in this risk assessment are those that pertain to the use of Pioneer's herbicide tolerant 98140 corn (hereafter referred to as Pioneer HT corn) and its progeny in the absence of confinement. APHIS utilizes data and information submitted by the applicant, in addition to current literature, to determine if Pioneer HT corn is unlikely to pose a plant pest[18] risk. If APHIS determines that a GE organism is not a plant pest, then APHIS has no regulatory authority over that organism.

Based on the information requested by APHIS for submission of a petition for nonregulated status (§ 340.6(c)(4)) (USDA-APHIS-BRS, 2008), and in order to determine whether Pioneer HT corn is unlikely to pose a plant pest risk, BRS considered information such as: plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on non-target organisms, and transfer of genetic information to organisms with which it cannot interbreed.

An analysis on agricultural or cultivation practices was included in the Environmental Assessment (EA). Effects of the deregulation of Pioneer HT corn (e.g. use of herbicides, tillage, etc.) on non-target organisms was also included in the EA. Potential impacts addressed in this risk assessment are those that pertain to plant pest risk characteristics. The genetically engineered (GE) construct inserted in Pioneer HT corn was evaluated to determine if those sequences in the corn caused plant disease. In addition, morphological characteristics of this corn were analyzed to determine if this variety would become weedy or invasive. Gene flow and introgression of the inserted genes into weedy and wild relatives was evaluated to determine the potential of increased weedy or invasive characteristics; also, the potential to transfer genetic information to organisms with which corn cannot interbreed. Finally, APHIS evaluated and compared Pioneer HT corn to conventional corn in regards to disease and pests susceptibility and conducted an analysis of the effects of the regulated article on non-target organisms.

Development of Herbicide Tolerant 98140 Corn

Pioneer has developed HT corn to tolerate glyphosate and acetolactate synthase (ALS)–inhibiting herbicides (e.g. sulfonylureas and imidazolinones). Pioneer HT corn will be the

[18] 7 CFR part 340.1 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" (USDA-APHIS-BRS).

first GE commercial corn product to contain both traits. The availability of this corn will enable growers to control weeds using an ALS-inhibitor herbicide where, for example, glyphosate tolerant weeds are present, or conversely, glyphosate can be used on ALS tolerant weeds. Growers will be able to choose an optimal combination of the two herbicides, and other complementary weed controls, to best manage their individual weed populations.

Expression of the Gene Product

Pioneer HT corn has been genetically engineered to express modified GAT4621[19] (glyphosate acetyltransferase) and ZM-HRA[20] (modified version of a maize acetolactate synthase) proteins. The GAT4621 protein, encoded by the *gat4621*[21] gene, confers tolerance to glyphosate-containing herbicides by acetylating glyphosate and thus rendering it non-phytotoxic. The ZM-HRA protein, encoded by the *zm-hra*[22] gene, confers tolerance to the ALS-inhibiting class of herbicides (e.g., sulfonylureas and imidazolinones). Expression of the *zm-hra* gene is controlled by the maize ALS (acetolactate synthase) promoter. ALS[23] is the enzyme required for the production of essential branched-chain amino acids such as valine, leucine, and isoleucine. The *gat4621* gene is based on the sequences of three *gat* genes from *Bacillus licheniformis*, a common soil bacterium. Expression of the *gat4621* gene is driven by the corn ubiquitin promoter[24] (*ubi*ZM1). The *zm-hra* gene was made by isolating the herbicide sensitive maize *als*[25] gene and introducing two specific changes known to confer herbicide tolerance to tobacco ALS.

The genetic insert also contains the terminator sequence from *Solanum tuberosum* (potato) and two sequences from two prevalent plant pests, cauliflower mosaic virus (enhancer) and *Agrobacterium tumefaciens* (border region). All of these sequences are well-characterized and are non-coding regulatory regions only. Therefore, these sequences will not cause Pioneer HT corn to promote plant disease.

A single copy of these genes and other DNA regulatory sequences were introduced into the corn genome with the transformation vector PHP24279 using disarmed (non-plant pest causing) *A. tumefaciens* transformation[26] of immature embryos. Plant cells containing the introduced DNA were selected by culturing in the presence of glyphosate. After the initial transformation, the antibiotic carbenicillin was included in the culture medium to kill any remaining Agrobacterium. Therefore, no part of the plant pest *A. tumefaciens* remained in Pioneer HT corn due to the transformation method. Samples were then taken from growing calli (undifferentiated plant cells) to verify the presence of both transgenes. The plants regenerated from the calli were evaluated for glyphosate and ALS inhibitor herbicide tolerance.

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[19] GAT4621 refers to the specific protein
[20] ZM-HRA refers to the specific protein
[21] *gat4621* refers to the specific gene
[22] *zm-hra* refers to the specific gene
[23] ALS refers to the specific protein
[24] A promoter is a region of DNA that controls expression of a gene.
[25] By convention, *als* refers to the specific gene
[26] A method of introducing DNA into cells by infecting them with disarmed Agrobacterium tumefaciens, which contain a plasmid carrying the gene(s) of interest.

Data from Southern Blot analyses demonstrate that Pioneer HT corn plants: (1) contain a single copy of both *gat4621* (Figure 8, pg. 37 of the petition) and *zm-hra* (Figure 9, pg. 38 of the petition) genes; (2) contain a single copy of both the *ubi*ZM1 (Figure 8, pg. 37 of the petition) and ALS (Figure 9, pg. 38 of the petition) promoters; and (3) do not contain sequences ('backbone sequences') from the transformation plasmid PHP24279 (Figures 18-22, pg. 47-51 of the petition) that were not intended to be transferred. Data also demonstrated that the overall integrity of the insert was complete and intact (Figures 11-13, pg. 40-42 of the petition). Statistical analysis of genetic segregation data collected over time confirmed that the *gat4621* and *zm-hra* genes were stably integrated into the corn genome and stably inherited over four generations in the expected fashion (Table 6, pg. 52 of the petition). Therefore, only the expected genetic material was stably inserted into Pioneer HT corn and no expectation exists that plant disease will result due to the presence of the genetic construct in the corn.

A detailed analysis of the composition of Pioneer HT corn compared to conventional corn can be found in Appendix D.

Relative Weediness and/or Invasiveness of Pioneer HT Corn

APHIS has assessed whether Pioneer HT corn is any more likely to become a weed than the non-transgenic recipient corn line or any other currently cultivated corn.

Based upon information provided in the major weed references, corn is not listed as a weed in the United States (Muenscher, 1980; Holm et al., 1991; Holm et al., 1997) nor is it listed as a noxious weed species by the U. S. Federal Government (7 CFR part 360) (USDA-APHIS, 2006). Cultivated corn is unlikely to become a weed because it generally does not persist in undisturbed environments without human intervention. Although corn volunteers in agricultural fields are not uncommon, they are easily controlled by herbicides or mechanical means and not likely to appear in the second season. Furthermore, corn possesses few of the characteristics of plants that are notably successful weeds (Baker, 1965; Keeler, 1989).

The applicant has field tested Pioneer HT corn since 2005. Agronomic performance, disease, and phenotypic assessments were conducted in trials at over 40 different locations across 17 states in the U.S. and the Commonwealth of Puerto Rico. These field tests were authorized by APHIS under the permit numbers noted in Appendix 6, pg. 168 of the petition. The trials were conducted in agricultural settings under physical and reproductive confinement conditions. Agronomic evaluations were conducted to assess the comparability of Pioneer HT corn to conventional corn. During these field trials, Pioneer evaluated seed germination, seed dormancy, abiotic stresses response, plant growth, yield, days to maturity, disease incidence, insect damage, and a number of other agronomic parameters (pg. 67-81 of the petition). Pioneer HT corn plants were also evaluated to confirm that they exhibited tolerance to glyphosate and ALS-inhibitors and that these traits were genetically stable under field conditions.

Agronomic field trial data showed no biologically significant differences between Pioneer

HT corn and control corn with respect to germination/emergence, vegetative growth, reproductive parameters, yield, and ecological interactions. Also, no significant difference in the agronomic performance between the pollen from Pioneer HT corn and the pollen from control corn (Table 14, pg. 80 of the petition) was found. The data support the conclusion that Pioneer HT corn compares to conventional corn in agronomic characteristics. There is no evidence to suggest the herbicide tolerance traits in this corn would cause it to be weedier or more invasive than the control corn line. In addition, Pioneer HT corn, as with conventional corn, is susceptible to a number of available herbicides and can be easily controlled. Therefore, Pioneer HT corn is unlikely to present a greater plant pest risk than conventional corn.

Gene Flow and Gene Introgression from Pioneer HT Corn into its Sexually-Compatible Relatives

Zea mays L. subsp. *mays* (corn) is a member of the *Maydeae* tribe of the grass family, *Poaceae*. It is a monoecious annual plant that requires human intervention for its seed dispersal and propagation. The species is open-pollinated through the movement of pollen by wind. Additional information on the biology of corn is available in the OECD (Organization for Economic Co-Operation and Development) *Zea mays* consensus document (OECD, 2003).

In assessing the risk of gene introgression from Pioneer HT corn to its sexually compatible relatives, APHIS considered two primary issues: 1) the potential for gene flow and introgression, and 2) the potential impact of introgression. This assessment covers only wild and weedy relatives of corn and the possibility that increased weediness could result from gene flow and introgression from Pioneer HT corn into such relatives. Although general information on pollen flow is given, this evaluation does not directly look at gene flow between a GE corn crop and a conventional and/or organic corn crop; some information on gene flow from Pioneer HT corn to conventional/organic corn crops is covered in the EA on pg. 20.

The phenomenon of gene flow (the transfer of genetic information between different individuals and/or populations) is a normal occurrence in the biological world. Gene flow has been shown to maintain the diversity necessary for long-term survival of certain populations in ever changing environments (Gealy et al., 2007). Gene flow from cultivated agricultural crops to sexually compatible relatives (domesticated or wild/weedy) has most likely occurred since domestication began. In most plants, including corn, genetic information is usually exchanged by pollen dispersal (Gealy et al., 2007). On the other hand, the process of introgression occurs when genes are retained, spread, and potentially incorporated into the gene pool of the recipient species; this is usually based on a selective or reproductive advantage for the population (Gealy et al., 2007). The process of introgression is not simple and it occurs in several steps that involve many hybrid generations. Based upon currently available data, there have been a relatively low number of confirmed cases of introgression (Stewart et al., 2003).

APHIS evaluated the potential for gene flow and gene introgression from Pioneer HT corn to sexually compatible wild relatives and considered whether introgression would result in increased weediness. Cultivated corn is sexually compatible with other members of the genus *Zea* and to a much lower degree with members of the genus *Tripsacum*.

Corn pollen is among the largest and heaviest of the wind-dispersed pollen grains and because of it, corn pollen has a rapid settling rate (Raynor et al., 1972). These characteristics limit the distance that corn pollen can travel. In terms of viability, under conditions of high temperature or low humidity, corn pollen may only survive for a few minutes. Under controlled handling in the laboratory or more favorable conditions in the environment, pollen may be viable for several hours (EPA, 2000). Studies have shown that gene flow decreases with distance. In one study, levels decrease rapidly within the first 66 feet of the source and thereafter at a diminished rate (Henry et al., 2003). A study conducted in 2000 indicated that cross-pollination of commercial corn cultivars at 100 ft downwind from the source of GE corn was 1 % and that this proportion declined exponentially to 0.1 % at 130 ft and to 0.03 % at 160 ft. At the farthest distance measured (1000 ft), no cross-pollination was detected (Jemison and Vayda, 2000). Additional factors affect the likelihood of cross-pollination in corn, including: size of pollen source, size of recipient population, wind direction and velocity, rain, silk receptivity, flowering times, pollen competition, and physical barriers (Devos et al., 2005).

Wild diploid and tetraploid members of *Zea*, collectively referred to as teosinte, are normally confined to the tropical and subtropical regions of Mexico, Guatemala, and Nicaragua. Although in the past, a few small isolated populations of the annual *Zea mexicana* and the perennial *Zea perennis* have been reported to exist in Alabama, Florida, Maryland and South Carolina, respectively (USDA-NRCS, 2007). Neither of these teosinte species has been shown to be aggressive weeds in their native or introduced habitats. Cultivated corn can hybridize with *Zea Mexicana*; however, it rarely crosses with *Zea perennis*. If hybrids from the latter were produced, they would be triploids and therefore, sterile (USDA, 2007). Pioneer HT corn has been shown to have no agronomic differences from those of conventional corn. Therefore, although the potential for cross pollination between Pioneer HT corn and teosinte is present, it would be no different than the potential cross between teosinte and conventional corn. Moreover, the factors described above (pollen, distance, plant morphology, reproductive timing, etc.) significantly reduce the likelihood that cross-pollination between any corn crop and teosinte would produce successful hybrids, and if formed, that those hybrids would become aggressive weeds.

Introgression from corn to teosinte in the wild is limited by a number of factors including, differing degrees of genetic incompatibility, temporal separation in flowering time, differences in developmental morphology, variations in dissemination methods, and disparities in seed dormancy (Galinat, 1998; Doebley 1990(a), 1990(b)). Gene introgression, again, occurs over many steps that require several hybrid generations; and first generation hybrids are generally less fit for survival and dissemination in the environment, and show reduced or no reproductive capacity. Teosinte has coexisted and coevolved in close proximity to corn in the Americas over thousands of years, but they each maintain a distinctive genetic make-up despite sporadic introgression (Doebley 1990(a)). The applicant has shown that Pioneer HT corn does not exhibit any differences in agronomic properties from other cultivated corn. Introgression and the impact of introgression from Pioneer HT corn to teosinte would therefore be no different from that of other cultivated corn varieties.

The genus *Tripsacum* contains up to 16 recognized species worldwide; most are native to Mexico, Central and South America, but three occur in the U.S. (*T. dactyloides*, *T. floridanum* and *T. lanceolatum*) (EPA, 2000). Many species of *Tripsacum* can cross with *Zea*, but with difficulty and with resulting hybrids being primarily male and female sterile (Galinat, 1988; Wilkes, 1967). The *Tripsacum* and corn hybrids have not been observed in the field, but have been obtained in the laboratory using specific techniques under controlled conditions. In most cases, these progeny have been sterile or viable only by culturing "embryo rescue" techniques (EPA, 2000). Although, some *Tripsacum* species may be found in areas where corn is cultivated, gene introgression from corn under natural conditions is highly unlikely, if not impossible (Beadle, 1980). Seed obtained from crosses between *Tripsacum* and corn is often sterile or progeny have greatly reduced fertility. Therefore, introgression from Pioneer HT corn to *Tripsacum* species would be no different from that of other cultivated corn varieties and also unlikely to occur.

Transfer of Genetic Information to Organisms to which Pioneer HT corn cannot Interbreed

Horizontal gene transfer (HGT) (transmission of DNA between species) from Pioneer HT corn to bacteria (chosen for this analysis) is unlikely to occur. First, many genomes from bacteria closely associated with plants (e.g. *Agrobacterium* and *Rhizobium*) have been completely or partially sequenced (Wood et al., 2001; Kaneko et al., 2000;), and no evidence has been found that these organisms contain gene derived from plants. Second, in cases where review of sequence data implied that HGT occurred, the events were inferred to occur on an evolutionary time scale on the order of millions of years (Kurland et al, 2003; Brown, 2003). Third, transgene DNA promoters and coding sequences are optimized for plant expression, not prokaryotic bacterial expression. Thus, even if HGT occurred, proteins corresponding to the transgenes are not likely to be produced. Fourth, the FDA has evaluated HGT and the use of antibiotic resistance marker genes, and has concluded that the likelihood of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is remote (US-FDA, 1998). Therefore APHIS concludes that horizontal gene transfer from Pioneer HT corn to other species is unlikely to occur and thus poses no significant environmental or plant pest risk.

Disease and Pest Susceptibilities

The ecological data submitted by Pioneer indicated no significant difference between Pioneer HT corn and the non-transgenic control corn for pest susceptibility (as measured, for example, by European corn borer and corn earworm damage) (Appendix 5, Table 1, pg. 160-164 of the petition) and disease (as measure, for example, by northern corn leaf blight and southern corn rust damage) (Appendix 5, Table 2, pg. 165-167). The data in the petition also indicated no difference in the compositional and nutritional quality of Pioneer HT corn compared to conventional corn. Thus, Pioneer HT corn is susceptible to the same insect and disease stressors as conventional corn.

Effect on Non-target and Beneficial Organisms

Based on the data provided by the applicant and existing literature, APHIS evaluated the potential for deleterious effects or significant impacts of Pioneer HT corn on non-target and beneficial organisms. First, APHIS notes that neither GAT nor ZM-HRA proteins are known to have toxic properties. The GAT protein sequence, which is derived from the bacterium *Bacillus licheniformis*, has been considered safe for food and feed in the U.S., Canada, and Europe (European Commission, 2000; US-FDA, 2001). ZM-HRA protein is a modified form of the ALS protein. Similar proteins have been commercialized in Clearfield® (BASF, 2005) and STS® (Deltapine, 2006), which are grown on millions of acres in the U.S. every year. As such, ALS (the protein nearly identical to GM-HRA) is consumed regularly by anything that feeds on any Clearfield® or STS™ products (e.g., corn, rice, sunflower, canola, wheat, and soybean).

Pioneer collected extensive data on the possible effects of Pioneer HT corn on non-target organisms in the field. They made observations on organisms such as beetles, spiders, ants, aphids, mites, and leafhoppers (Appendix 5, pg. 160-167 of the petition). Data was compiled at all locations in 2005 and 2006. Pioneer assessed insect damage across all locations in 2006 (pg. 76-80 of the petition) and response to disease stressors (pg. 165-167 of the petition). No significant differences were identified between Pioneer HT corn and control corn in any instance.

In the U.S., corn plays a significant role in animal feed (Appendix C). In order to compare the wholesomeness and nutrition of Pioneer HT corn with control corn, when used in animal feed, Pioneer conducted a chicken feeding study (a recognized model for assessing the wholesomeness of feeds) where Pioneer HT corn made up a large part of the chicken diet (Section VIII-E, pg. 109 of the petition). The study assessed mortality, weight gain, and feed efficiency parameters over a 42-day period as well as various carcass and organ data at the end of the period. Pioneer did not observe any adverse effect on the chickens or significant differences in the parameters analyzed.

The data submitted by the applicant indicated that the ecological interactions between Pioneer HT corn and the control lines were similar. Considering all the data noted from field observations and the chicken feeding study, APHIS concluded that Pioneer HT corn is unlikely to pose a safety risk to non-target and beneficial organisms.

Conclusion

APHIS has prepared this plant pest risk assessment in order to determine if Pioneer HT corn is unlikely to pose a plant pest risk. Based on the information provided by the applicant and the lack of: plant pest risk from the inserted genetic material, weedy characteristics, atypical responses to disease or plant pests in the field, deleterious effects on non-targets or beneficial organisms in the agro-ecosystem, and horizontal gene transfer, APHIS has concluded that Pioneer HT corn is unlikely to pose a plant pest risk.

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Appendix B: Biotech Seed Products Available for the 2008 Planting Season[1,2,3]

Product Registrant Trade Name	Characteristic
MonsantoYieldGard Roundup Ready 2	Cry1Ab corn borer protection Glyphosate herbicide tolerance
YieldGard Corn Rootworm Protection Roundup Ready 2	Corn rootworm protection Glyphosate herbicide tolerance
Monsanto Roundup Ready 2	Glyphosate herbicide tolerance
MonsantoYieldGard Plus with Roundup Ready 2	Cry1Ab corn borer and corn rootworm protection Glyphosate herbicide tolerance
Herculex I Roundup Ready 2	Cry1F western bean cutworm, corn borer, black cutworm and fall armyworm protection Glyphosate herbicide tolerance Glufosinate herbicide tolerance
Syngenta Agrisure GT	Glyphosate herbicide tolerance
Syngenta Agrisure GT/CB/LL	Cry1Ab corn borer protection Glyphosate herbicide tolerance Glufosinate herbicide tolerance
MonsantoYieldGard Roundup Ready	Cry1Ab corn borer protection Glyphosate herbicide tolerance
Dow AgroSciences Pioneer Hi-Bred Herculex Rootworm Monsanto Roundup Ready 2	Cry34/35Ab1 western, northern, and Mexican corn rootworm protection Glyphosate herbicide tolerance
Dow AgroSciences Pioneer Hi-Bred Herculex Xtra Monsanto Roundup Ready 2	Cry1F western bean cutworm, corn borer, black cutworm, and fall armyworm protection Glufosinate herbicide tolerance Cry34/35Ab1 western, northern, and Mexican corn rootworm protection Glyphosate herbicide tolerance
YieldGard VT™	Corn rootworm protection

Rootworm/RR2	Glyphosate herbicide tolerance
YieldGard VT™ Triple	Cry1Ab corn borer and corn rootworm protection Glyphosate herbicide tolerance
Syngenta Agrisure GT/RW	Modified Cry3A, western, northern, and Mexican corn rootworm protection Glyphosate herbicide tolerance

[1] The list is representative of available glyphosate tolerant products, alone and in combination with other traits, but may not include all corn biotechnology hybrids currently available with such traits (NCGA, 2008).
[2] All of the hybrids listed have full food and feed approval in the United States.
[3] Not all varieties are approved for all export market uses.

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Appendix C: General Breakdown of Corn Uses in the United States from 2005-2006

Total Corn: 11,270 Million Bushels[1]		
Purpose	**Bushels**	**Overall Percentage**
Export[1]	2,147 Million	19%
Domestic Use[1]	9,122 Million	81%
Breakdown of Domestic Use		
Feed/Residual[1]	67.3%	
Food/Industrial[1]	32.7%	
Ethanol[1]		53.5%
Sweeteners[3] - High Fructose Corn Syrup[3]: 69.7% - Glucose/Dextrose[3]: 30.3%		25.4%
Seed[4]		8%
Starch[3] - Food Use[2]: 13% - Non-Food Use[2]: 87%		9%
Beverage/Manufacturing[3]		4.5%
Cereals/Other Products[4]		<1%

[1] (USDA-ESMIS, 2007)
[2] (Johnson et al., 1999)
[3] (USDA-ERS, 2007)
[4] (NAMA, 2006)

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Appendix D: Pioneer HT Corn (Compositional Analysis)

As described in Appendix A, data collected and supplied by Pioneer in the petition and reviewed by APHIS (Chapter V, pg. 25-53 of the petition) support the conclusion that Pioneer HT corn contains the introduced genes *gat4621* (glyphosate acetyltransferase from *Bacillus licheniformis*, a common soil bacterium) and *zm-hra* (modified acetolactate synthase from corn). In addition, other DNA sequences were introduced that serve to control gene expression. Section IV (pg. 21-24) of the petition describes the genes and gene regulatory sequences introduced into Pioneer HT corn. Several of the additional gene sequences originate from corn itself while others come from another plant and from a common plant virus (Appendix A). The intended changes to Pioneer HT corn result in the production of the proteins glyphosate acetyltransferase and a slightly modified acetolactate synthase that impart tolerance to glyphosate and ALS-inhibiting herbicides, respectively.

The GAT4621 and ZM-HRA (modified ALS) proteins were assessed for possible allergenicity and toxicity using internationally accepted guidance from the Codex Alimentarius Commission. Complete summaries of the food and feed safety assessments for the GAT4621 and ZM-HRA proteins are found in section VI (pg. 65-66) of the petition. The data obtained for the GAT protein indicate the lack of amino acid identity and of immunologically significant similarities between the GAT4621 protein and known protein allergens. Pioneer's assessment of ZM-HRA protein noted high similarity of this protein with ALS proteins found in bacteria, fungi, algae, and plants. Pioneer also analyzed protein sequence similarities with known and putative protein allergens and toxins and found no similarity that would indicate either allergenicity or toxicity of ZM-HRA protein. ALS proteins have been the subject of previous FDA consultations in GE flax (BNF No. 50) and GE cotton (BNF No. 30) (US-FDA, 2008). In both of these cases, the FDA indicated that they had no further questions regarding the safety and nutritional assessments submitted by the respective companies. A nearly identical ALS protein is found in two non-GE plant varieties that were developed in the 1980s and 1990s; Clearfield® (BASF, 2005) and STS™ (Deltapine, 2006) are grown widely across the world and have a history of safe use. In addition, Pioneer conducted an acute toxicity study of each protein in mice, at a target dose of 2,000 milligram purified protein preparation per kilogram of body weight (Section VI-E, pg. 65 of the petition) (equivalent to approximately 1,640 mg of the full-length GAT4621 protein per kg of body weight and 1,236 mg of full-length ZM-HRA protein per kg of body weight). Based on expression levels of GAT4621 and ZM-HRA proteins in Pioneer HT corn, a child weighing 10 kg would have to consume 2,076 kg (for GAT) and 36,353 kg (for ZM-HRA) of Pioneer HT corn in order to match the dose used in the mouse acute toxicity test. In turn, an adult weighing 60 kg would have to consume 12,456 kg (for GAT) and 218,118 kg (for ZM-HRA) of Pioneer HT corn.

In addition, Pioneer conducted extensive analyses to assess compositional differences between Pioneer HT corn and the comparator corn varieties (Section VIII, pg. 82 of the petition). Two types of corn lines, control corn and reference corn, were used. The control plants had a genetic background similar to that of Pioneer HT corn but lacked the transgenic insert. The other comparator consisted of non-transgenic commercial corn reference hybrids. The compositional analyses was conducted with Pioneer HT and control corn that had not been sprayed with herbicides, in order to isolate the potential impact of the transgenes on the nutritional composition of the corn. The compositional assessment was conducted in accordance with the OECD consensus document on compositional considerations for new varieties of corn (OECD, 2002). The analyses of grain samples included protein, fat, acid detergent fiber (ADF), neutral detergent fiber (NDF), ash, carbohydrates, fatty acids, amino acids, vitamins and minerals, key anti-nutrients (raffinose, phytic acid, and trypsin inhibitor) and key secondary metabolites (furfural, ferulic acid, and *p*-coumaric acid). Compositional analyses of forage samples included protein, fat, ADF, NDF, ash, carbohydrates, calcium, phosphorus and amino acids.

Pioneer found no statistically significant differences between the Pioneer HT corn and control corn mean values for protein, fat, ADF, NDF, ash, carbohydrates, fatty acids, and total and free amino acids (adjusted P-values were > 0.05) (Section VIII, pg. 84-92 of the petition). Also, no statistically significant differences were observed between Pioneer HT corn and control corn mean values for any of the vitamins, minerals, anti-nutrients, and key secondary metabolites analyzed (Section VIII, pg. 96-99 of the petition). Compositional analyses data comparison between Pioneer HT corn and control corn for the forage samples also showed no statistical significant differences (Section VIII, pg. 101-106 of the petition).

Pioneer noted in the petition, and later in the form of an addendum to the petition (dated 03/12/2008), the increased level of five acetylated amino acids from the compositional analyses of Pioneer HT corn (Section VIII, pg. 93 for grain; Section VIII, pg. 107 for forage of the petition). The GAT enzyme preferentially targets glyphosate as a substrate. However, this enzyme also acetylates the amino acids aspartate, glutamate, serine, threonine, and glycine. Consequently, levels of N-acetylaspartate (NAAsp), N-acetylglutamate (NAGlu), N-acetylserine (NASer), N-acetylthreonine (NAThr), and N-acetylglycine (NAGly) in Pioneer HT corn were higher than those found in the control corn (Table A, addendum to the petition, 03/12/2008).

N-acetylated amino acids are widely found throughout the plant and animal kingdom and are therefore, present in many food sources (Appendix 8, pg. 172 of the petition). Acetylation of proteins (which are made up of amino acids) is employed in the food industry to alter properties of protein concentrates to be added to food (El-Adawy, 2000; Ramos and Bora, 2004). Pioneer analyzed eggs, yeast, ground turkey, chicken, and beef and found amounts of both NAAsp and NAGlu at various levels (Appendix 8, pg. 171-173 of the petition). Based on that data, it appears that some of these amino acids are normal components of the human diet. The levels of NASer, NAThr, and NAGly detected in Pioneer HT corn are 100 times lower than those for NAAsp and NAGlu.

NAAsp is an abundant amino acid in the central nervous system (CNS) (Demougeot et al., 2004) but its biological function is not exactly clear. It is, however, essential for the formation and/or maintenance of myelin in the CNS (Chakraborty et al., 2001). In mammals, NAGlu is found in the brain, and at high concentrations in the liver and small intestine (Caldovic and Tuchman, 2003). Levels of NAGlu in the liver increase with increased protein consumption and are also affected by growth hormone levels (Caldovic and Tuchman, 2003).

A rare human condition called Canavan's disease (CD) is caused by an inherited mutation in the aspartoacylase gene (aspartoacylase converts NAAsp into aspartate and acetate). This condition results in the inability to transform NAAsp to the free amino acid, aspartic acid, and leads to an accumulation of excess NAAsp in the brain. The resulting deficiency in metabolism of NAA leads to inadequate myelin formation in the brain and severe developmental abnormalities (Kirmani et al., 2002; Madhavarao et al., 2005; Mehta and Namboodiri, 1995).

Pioneer submitted, as part of a petition (06-271-01p) seeking a 'determination of nonregulated status for herbicide tolerant 356043 soybeans' (USDA-APHIS-BRS, 2008), information on the potential impact of dietary exposure of NAAsp on individuals with CD. Pioneer 356043 soybeans express the same two proteins as Pioneer HT corn, also conferring tolerance to glyphosate and ALS-inhibiting herbicides. Analysis of the amounts of NAAsp excreted by healthy individuals compared to those with CD indicated that the vast majority of NAAsp within the body is produced endogenously (within the body) and does not result from dietary exposure (Addendum 2 to the petition). Because the levels of NAAsp and NAGlu are negligible from dietary sources compared to the amounts produced endogenously by people with CD, those individuals affected by the disease are not expected to have adverse effects from consuming 356043 soybeans. Pioneer HT corn has been shown to contain comparable concentrations of NAAsp and NAGlu to 356043 soybeans. When comparing the percent of the two amino acids from the total in each product, the percentage in Pioneer HT corn is considerable higher (0.5%) than in 356043 soybeans (0.15%) this is because there are approximately four times more (total) amino acids in soybeans than in corn. NAAsp levels in individuals with CD increase because the enzyme needed to transform NAAsp is inactive due to a genetic defect. No correlation has been found between the increase consumption of acetylated amino acids and the development of CD, or between the avoidance of acetylated amino acids in foods and the cure for it. In July, 2008, APHIS reached a determination of nonregulated status for Pioneer 356043 soybean (USDA-APHIS-BRS, 2008). In addition, FDA's final review for 356043 soybean was completed on September 21, 2007. FDA indicated that it had no further questions regarding the safety and nutritional assessment of 356043 for use in food and feed (BNF No. 108) (US-FDA, 2008).

As part of the corn petition, Pioneer also conducted an acute and repeated dose study of NAAsp in rats (Delaney et al., 2008). In this study, no mortalities or evidence of adverse effects were observed in rats following an acute oral administration of NAAsp. In a separate experiment, NAAsp was added to the diets of the rats at several concentrations and for a number of days. No biologically significant differences were observed in functional observational battery (FOB), motor activity evaluations, ophthalmologic examinations, hematology, coagulation, clinical chemistry, or organ weights of any of the NAAsp treatment groups. No differences in body weights, feed consumption values, or clinical signs were observed in any of the treatment groups.

In the U.S., corn is a major component of animal feed, particularly for chickens, cattle, and pigs; it is possible, that animal exposure to the acetylated amino acids would also increase should APHIS deregulate Pioneer HT corn. APHIS has reviewed the information submitted by Pioneer relating to the safety of the acetylated amino acids and noted several points in their assessment:

- Acetylated amino acids are naturally occurring compounds that are found in many biological systems, including plants and animals. NASer, NAThr, and NAGly were present in the control corn, demonstrating these are not novel substances.
- Up to 80% of cellular proteins in mammalian systems are estimated to be acetylated (Brown and Roberts, 1976; Driessen et al., 1985).
- No toxicological or safety issues associated with NASer, NAThr, and NAGly were found in a literature search.
- Acetylation of proteins is used in the food and feed industries (El-Adawy, 2000) (e.g., use of N-acetyl-L-methionine in place of free L-methionine for livestock).
- Metabolism studies of other acetylated amino acids on rats, pigs, and humans have not raised safety issues (Magnusson et al., 1989; Arnaud et al., 2004; Boggs, 1978; Boggs et al., 1975; Stegink et al., 1982 and 1980).
- NAAsp and NAGlu are components of human and animal diets and there is no indication that they are associated with adverse effects when consumed.
- The small increase in exposure to N-acetylated amino acids predicted to occur from consuming Pioneer HT corn is not expected to have any adverse effects on animals as they have the enzymes in various tissues that deacetylate N-acetylated amino acids (Gade and Brown, 1981; Endo, 1980).
- A poultry study (section VIII, pg. 109) demonstrated the nutritional comparability of diets made from Pioneer HT corn to those made from control corn.

Considering all the information noted above on compositional similarities and differences between Pioneer HT corn and control corn, no significant impacts are likely to occur should APHIS choose the proposed action to deregulate Pioneer HT corn.

Finally, APHIS/BRS has consulted with FDA regarding its food/feed nutritional and safety assessments for this corn. The safety of food and feed derived from Pioneer HT corn falls within the regulatory purview of the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (FFDCA). Under FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from Pioneer HT corn must be in compliance with all applicable legal and regulatory requirements. FDA's final review for Pioneer HT corn is pending. Pioneer has indicated that it would not commercialize this corn without review by FDA.

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Determination of Nonregulated Status for Pioneer DP-098140-6 Corn (Pioneer HT Corn)

In response to petition 07-152-01p from Pioneer Hi-Bred, APHIS has determined that Pioneer HT corn and progeny derived from it do not pose a plant pest risk and are no longer to be considered regulated articles under APHIS' biotechnology regulations (7 Code of Federal Regulations (CFR) part 340), as APHIS has no authority to continue to regulate a GE organism once APHIS has determined that the GE organism does not pose a plant pest risk. Permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation under those regulations will no longer be required for Pioneer HT corn and its progeny. Importation of seeds and other propagative material will still be subject to APHIS foreign quarantine notices in 7 CFR part 319 and Federal Seed Act regulations in 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 the environmental assessment and APHIS' response to public comments that indicate that Pioneer HT corn is unlikely to pose a plant pest risk. The transgenic event found in Pioneer HT corn will not post a plant pest risk and transformation event 98140 should be granted nonregulated status for the following reasons: (1) gene introgression from Pioneer HT corn 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 corn varieties; (2) it exhibits no characteristics that would cause it to be weedier than the non-genetically engineered parent corn line or any other cultivated corn; (3) horizontal gene transfer is unlikely to occur between Pioneer HT corn and soil bacteria; (4) based on its lack of toxicity and allergenicity, it does not pose a risk to non-target organisms, including beneficial organisms and federally listed threatened or endangered species, and species proposed for listing; (5) considering its cultivation in the agroecosystem, it does not pose a risk to non-target organisms, including threatened and endangered species, or designated critical habitat as a result of the use of EPA-registered glyphosate and ALS-inhibiting herbicides, as these have been safely used in corn for many years; (6) it does not pose a threat to biodiversity as it does not exhibit traits that increase its weediness, its unconfined cultivation should not lead to increased weediness of other cultivated corn, and it exhibits no changes in disease susceptibility ; (7) its commercial use should not have significant effects on agricultural practices; (8) compared to current corn pest and weed management practices, cultivation of Pioneer HT corn should not impact standard agricultural practices in corn cultivation including those for organic growers; (9) it should not cause significant impacts on the development of herbicide resistant weeds or cumulative impacts in combination with other herbicide tolerant crops; (10) agronomic performance, disease and insect susceptibility, and compositional profiles of Pioneer HT corn are similar to those of its parent line and other corn cultivars grown in the U.S., therefore no direct or indirect plant pest effects on raw or processed plant commodities are expected; (11) when considered in light of other actions, APHIS identified no significant environmental impacts that would result from a determination to grant nonregulated status to Pioneer HT corn.

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

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