Finding of No Significant Impact

Animal and Plant Health Inspection Service

Petition for Non-regulated Status for Soybean Line MON 89788 (APHIS 06-178-01p)

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has prepared an environmental assessment (EA) prior to making its determination of whether or not to approve a petition (APHIS number 06-178-01p) for a determination of nonregulated status received from Monsanto Company, under APHIS regulations at 7 CFR part 340. The subject of this petition, soybean (*Glycine max*) line MON 89788, is genetically engineered to express the enzyme 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium* sp. Strain CP4 (CP4 EPSPS) that allows the plant to tolerate application of the broad spectrum herbicide glyphosate. On February 5, 2007, APHIS published a notice in the *Federal Register* (72 *FR* 5261-5263, Docket no. 2006-0195) announcing the availability of the draft EA for public review and comment for a 60-day comment period, ending April 6, 2007. APHIS received 23 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 three alternatives: Alternative A – No Action: Continuation as a Regulated Article; Alternative B – Determination that MON 89788 soybean is No Longer a Regulated Article, in Whole; Alternative C – Determination that MON 89788 soybean is No Longer a Regulated Article, in Part. APHIS proposed Alternative B as its preferred alternative because of the lack of plant pest characteristics displayed by the MON 89788 soybean. APHIS has not identified any greater plant pest risk characteristics in this transformed soybean than non-transformed or other non-regulated glyphosate tolerant soybeans that would warrant denying the petition or granting deregulation in part for MON 89788 soybeans.

Based upon analysis described in the final EA and in APHIS' response to comments, APHIS has determined that the preferred alternative, to grant the petition in whole, will not have a significant impact on the quality of the human environment for the following reasons.

1. There should be no significant environmental impact as a result of gene introgression from this soybean line. In assessing the potential risks associated with gene introgression from MON 89788 soybean into its sexually compatible relatives, APHIS considered two primary issues: a) the potential for gene flow and introgression; and b) the potential impact of introgression. The genus *Glycine* has approximately 9 species with *G. max* being placed in the subgenus *Soja* along with one other species, *G. soja* (previously *G. ussuriensis*). *G. max* is sexually compatible with only *G. soja* and no other *Glycine* species. *G. max* is the only *Glycine* species located in the USA other than a few *G. soja* plants in research plots. *G. max* has never been found in the wild. Therefore the probability of gene flow and introgression of MON 89788 soybeans into other species is

essentially zero and consequently the potential impact of introgression is not foreseeable. Therefore, there should be no impact related to outcrossing by deregulating this line in whole (Alternative B). There should also be no impact from continuing to regulate the line (Alternative A).

2. *G. max* is not considered to be a weed and it does not persist in unmanaged ecosystems. In the United States, soybean is not listed as a weed in the major weed references, it is not present on the lists of noxious weed species distributed by the Federal Government, and soybean has been grown throughout the world without any report that it is a serious weed. It is not generally persistent in undisturbed environments without human intervention. In the year following cultivation, soybean may grow as a volunteer only under specific conditions and can be easily controlled by herbicides or mechanical means. It does not compete effectively with cultivated plants or primary colonizers. *G. max* has never been found in the wild. No data of which APHIS is aware indicate that the presence of the *cp4 epsps* gene improves the ability of this soybean line to survive without human intervention, nor is there any foreseeable reason to conclude that this gene would affect this line's survival in the wild. APHIS has reviewed field performance data submitted by the petitioner, and these data indicate that the engineered plant is not different in any fitness characteristics from its parent that might cause MON 89788 to become invasive. Therefore, soybean is unlikely to become a weed through the introduction of the glyphosate resistance trait. For these reasons granting nonregulated status in whole to this genetically engineered line (Alternative B) and its subsequent release should not increase the weediness or invasiveness potential of this line relative to the release of any conventional soybean line. There should also be no impact from continuing to regulate the line (Alternative A).

3. APHIS does not expect MON 89788 to have any impacts on non-target organisms, including beneficial organisms and threatened or endangered species because the CP4 EPSPS protein is not known to have any toxic properties and has minimal potential to be a food allergen. This protein has over a 10 year history of safe use in several crops – including soybeans, corn, canola, and cotton. APHIS evaluated the potential for effects or significant impacts from cultivation of MON 89788 soybean and its progeny on non-target organisms, including effects on those species federally listed as threatened or endangered species (TES), or species proposed for listing, and their proposed and designated critical habitat (http://endangered.fws.gov/wildlife.html#Species). In addition to evaluating the toxicity and allergenicity of the CP4 EPSPS protein, APHIS reviewed the expected use of glyphosate on this glyphosate tolerant soybean line. Glyphosate tolerant soybeans have been grown commercially for over ten years and have been treated with glyphosate for over ten years. EPA communicated to APHIS that it has not received any reported adverse effects on threatened or endangered species or their critical habitats from the use of glyphosate on glyphosate tolerant soybeans. 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 listed, or their designated or proposed critical habitat from exposure to the EPSPS protein expressed in MON 89788 or from exposure to label rates of glyphosate expected to be used in conjunction with this MON 89788 soybean as a result of deregulating this line in

whole (Alternative B). There should also be no impact or effect from continuing to regulate the line (Alternative A).

4. Analysis of available information indicates that MON 89788 exhibits no traits that should cause increased weediness, and that its unconfined cultivation should not lead to increased weediness of other sexually compatible relatives (of which there are none in the United States). MON 89788 has no effect on non-target organisms common to the agricultural ecosystem or federally listed TES or species proposed for listing. Glyphosate use and crop production practices are not expected to change regardless of the alternative chosen (see below), therefore there should be no indirect or cumulative impacts on biodiversity related to these practices. Use of glyphosate in glyphosate resistant soybeans (MON 89788 or Roundup Ready 40-3-2 soybean as recommended and according to product labels is not expected to cause significant impacts on biodiversity outside the agroecosystem based on the chemical and toxicological properties of glyphosate. It is not considered to be a significant soil or water contaminant when used in recommended doses according to label instructions; in general, there is little effect of glyphosate on soil microflora, aquatic organisms, arthropods, and mammals. Based on these conclusions, there should be no significant impact to biodiversity by deregulating this line in whole (Alternative B). There should also be no impact from continuing to regulate the line (Alternative A).

5. If MON 89788 were to be grown commercially, the effect on agricultural practices from introducing MON 89788 into the environment should be no different than for the previously deregulated Roundup Ready 40-3-2 soybean line expressing the same CP4 EPSPS protein from *Agrobacterium* sp. Strain CP4, with which APHIS has over 10 years of experience. APHIS has evaluated field trial data reports submitted on the MON 89788 event and progeny, and the previously deregulated Roundup Ready 40-3-2 soybean line has been grown commercially for over 10 years on approximately 89% of the 2006 soybean acreage, but 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. Herbicide and other cultivation practices with MON 89788 are expected to be no different from those of previously deregulated Roundup Ready 40-3-2 soybean based on its level of herbicide resistance and other agronomic characteristics and approved and recommended application rates for glyphosate herbicides. Based on these conclusions, there should be no significant impact on commercial use by deregulating this line in whole (Alternative B). There should also be no impact from continuing to regulate the line (Alternative A).

6. APHIS does not expect MON 89788 to have any impacts on the development of herbicide resistant weeds or a cumulative impact in combination with other glyphosate tolerant crops. This is because the soybean production in the U.S is already saturated with Roundup Ready soybean where close to 90% of U.S. soybean production is already Roundup Ready 40-3-2 soybean. Furthermore soybean acreage is not expected to increase as estimates of the 2007 soybean crop indicate that planting will be the lowest level since 1996 reflecting an 11% decrease in acreage compared to 2006. (http://www.nass.usda.gov/Newsroom/2007/03_30_2007.asp) and in the prior five years,

soybean production was relatively steady varying from 72 million acres to 75.5 million acres (http://www.nass.usda.gov/QuickStats/index2.jsp). Lastly, MON89788, which has the same glyphosate resistance trait as Roundup Ready 40-3-2 soybeans, is expected eventually to merely replace this product. Because the amount of Roundup Ready soybean planted in the U.S. is unlikely to increase based on whether or not MON89788 is deregulated, and the development of glyphosate resistant weeds is related to the amount of glyphosate used which is directly influenced by the acreage planted to glyphosate resistant crops, including Roundup Ready soybeans, APHIS reasonably concludes that MON89788 should not have any impacts on rate of the development of herbicide resistant weeds whether it is deregulated (Alternative B) or remains a regulated article (Alternative A).

7. If MON 89788 were to be grown commercially, the potential impact of stacking of herbicide resistance traits was considered. 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 soybean 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 soybean becoming a weed. Based on these considerations as analyzed in the EA, there should be no significant impact from the stacking of herbicide resistant traits by deregulating this line in whole (Alternative B). There should also be no impact from continuing to regulate the line (Alternative A).

8. If MON 89788 were to be grown commercially, APHIS expects MON 89788 soybean will be used to breed varieties suitable to a range of environments and maturity zones and replace some to all of the presently available glyphosate tolerant soybean. The potential impact on organic farming should not change from the current situation where close to 90% of soybeans produced are Roundup Ready and organic farmers or other farmers who choose not to plant or sell Roundup Ready soybean or other transgenic soybeans (a) will still be able to purchase and grow nontransgenic soybeans and (b) will be able to coexist with biotech soybean producers as they do now. Soybean is a highly self pollinated plant with large, heavy seeds that are not easily dispersed; thus minimal buffer zones are needed to prevent cross-pollination to other soybeans or seed contamination of adjacent agricultural land. Based on these considerations, there should be no apparent potential for a significant impact on organic farming by deregulating this line in whole (Alternative B). There should also be no impact from continuing to regulate the line (Alternative A).

9. APHIS' analysis of data on agronomic performance, disease and insect susceptibility, and compositional profiles of MON 89788 and its non-genetically engineered counterpart indicates no significant differences between the two that would be expected to cause either a direct or indirect plant pest effect on raw or processed plant commodities from the deregulation of MON 89788. Based on the analysis, there should be no direct or indirect plant pest effects on raw or processed plant commodities by deregulating this line

in whole (Alternative B). There should also be no impact from continuing to regulate the line (Alternative A).

10. APHIS has reviewed field performance data submitted by the petitioner, and these data indicate that the engineered plant is not different in any fitness characteristics from its parent that might cause MON 89788 to become invasive.

11. None of the alternatives are expected to have significant human health or environmental effects, nor are they expected to establish a precedent for future actions with potentially significant effects. None of the 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 Roundup Ready soybean varieties and to those observed for the use of glyphosate and several other herbicides in agriculture production systems. None of the proposed alternatives are expected to threaten or violate Federal, State, or local law requirements.

Because APHIS has reached a finding of no significant impact, no Environmental Impact Statement will be prepared regarding this decision.

/s/

for Rebecca Bech
Acting Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: JUL 23 2007

Attachment
Finding of no significant impact
Response to comments
APHIS No. 06-178-01p

On February 5, 2007, APHIS published a notice in the *Federal Register* (72 *FR* 5261-5263, Docket no. 2007-0195) announcing the availability of the draft EA for public review and comment for a 60-day period, ending April 6, 2007. APHIS reviews the petition to determine if the genetically engineered (GE) organism should continue to be considered a regulated article under the APHIS biotechnology regulations found at 7 CFR part 340. In order for a GE organism to be considered a regulated article under these regulations, the organism must pose a plant pest risk and be modified by recombinant DNA techniques (genetic engineering under the definition of the regulation). Prior to making a decision on a petition for APHIS to grant nonregulated status for a GE organism, APHIS prepares an EA to evaluate the significance of impacts on the environment arising from a decision to grant nonregulated status. APHIS prepares the EA as part of its obligation, like other Federal agencies, to meet the requirements of the National Environmental Policy Act of 1969 (NEPA). As part of a petition, APHIS considers public comments on the proposed deregulation as well as the EA that APHIS prepares under NEPA.

APHIS received 23 comments regarding the EA. APHIS' responses to the issues raised during the comment period are included below. The EA was updated to include or clarify relevant analysis, including that related to effects of glyphosate.

There were 12 comments from groups or individuals that supported deregulation and 11 comments that opposed the deregulation.

Comments supporting the deregulation came from eight farm industry organizations, three weed scientists, and one from the petitioner. Comments from the farm industry supporting the deregulation focused on the benefits of the more than10 year history of safety of Roundup Ready soybeans: improving profit opportunities through improved yields without increasing herbicide use; providing growers with consistent weed control; continuing to have timely advancement of new genetics/traits that enable American farmers to produce soybeans economically and safely and to meet the growing demand for food, feed and fuel without a proportional increase in acreage; continuing the widespread adoption of conservation tillage crop production methods that have decreased soil erosion, reduced fuel consumption, increased the earthworm population, helped remove carbon dioxide from the Earth's atmosphere and sequestered the carbon within the soil, and increased the absorption of rainfall with less runoff. Comments from the weed scientists, each of whom have a research focus on herbicide resistant weeds and supported the deregulation, focused on the development of herbicide resistant weeds. Their general consensus was that the development of glyphosate resistant weeds are the result of the over dependence on one mode of action for weed management, a possible limitation of the number of residual herbicides for the producers to purchase, and that

farm coops and farmers share a large amount of responsibility in the development of resistant weeds. They also generally agreed that the most effective method for combating resistance is to prevent the selection environment that allows resistant weeds to proliferate. Preventive management strategies include: crop rotation; rotation of herbicide modes of action or multiple modes of action in the same year; optimum crop competition with the weeds through cultural practices such as proper fertility and soil pH, uniform stands and narrow rows; and tillage. Extension personnel across the country are actively promoting resistance management strategies. The weed scientists also agreed that glyphosate tolerant soybeans have tremendous value, this trait is necessary for farmers to remain competitive in the global commodity market, and the release of MON 89788 soybean should have no impact on the rate of resistance evolution relative to cultivars based on Roundup Ready Soybean 40-3-2 as described in the EA (pp. 13-14).

Comments from those opposed to the deregulation came from 10 individuals and one public interest group, and they are addressed below.

Comment: One comment indicated that APHIS failed to analyze MON 89788 in comparison to the conventional soybean line from which it was derived.

Response: APHIS generally analyzes the transgenic line in comparison to the line or variety from which it was derived and/or to a range of conventional varieties. In the case of MON 89788, APHIS evaluated comparisons to the nontransgenic recipient line, A3244; to the ranges of several conventional soybean varieties; and to Roundup Ready soybean line 40-3-2, also designated MON-04032-6. The appropriateness of these comparisons is described on page 28 of the petition. A3244 is a non-transgenic elite maturity group III soybean variety developed by Asgrow Seed Company that was developed and selected based on its superior agronomic performance over other soybean lines. APHIS analyzes these comparisons to determine if MON 89788 has any pest characteristics greater than the recipient line or other conventional varieties and to determine if there may be any unintended effects from placing the transgene into A3244. In the petition (06-178-01p, Sections VII and VIII, and Appendixes E, F, G, H, and I), 151 different comparisons were presented that ranged from plant growth, pollen, seed germination and interactions with symbiotic nitrogen-fixing bacteria, to abiotic stresses, to susceptibility to diseases and insects, and to nutritional and anti-nutritional components. None of these comparisons provided any indication of increased pest characteristics or a possibility of an unintended effect. APHIS is not aware of any additional data that can provide appropriate information for making a proper and reasonable comparison to determine whether MON 89788 has the potential to significantly impact the human environment, threatened and endangered species, and/or unintended organisms. In addition, MON 89788 was compared to Roundup Ready soybean line 40-3-2, which is the very widely grown Roundup Ready (glyphosate tolerant) event in the United States. In 2006 approximately 90% of the United States soybean acreage was devoted to Roundup Ready soybean varieties. Since MON 89788 and deregulated Roundup Ready soybean line 40-3-2 have the same CP4 EPSPS protein, which is insensitive to glyphosate and imparts glyphosate tolerance to the entire plant, the comparison of these two events provides a valid reason for making inferences on the

performance of MON 89788 based on the past performance of the deregulated Roundup Ready soybean event 40-3-2 that has been extensively grown over 10 years.

Comment: One comment pointed out that by assuming Roundup Ready Soybean 40-3-2 as an unproblematic baseline for its assessment of MON 89788, APHIS virtually ignores over a decade of research pointing to substantial agronomic and environmental problems with the Roundup Ready soybean system.

Response: APHIS disagrees that there are substantial agronomic and environmental problems with the Roundup Ready soybean system. Soybean farmers make their choices of soybean varieties and weed control systems based on several factors: 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). American soybean farmers decided to devote 89% of their 2006 soybean acreage to varieties based on Roundup Ready Soybean 40-3-2 despite the availability of other soybean varieties lacking the trait. There are many soybean varieties both containing and lacking the Roundup Ready Soybean trait available for each of the major soybean growing regions varying from each other over numerous characteristics, some of which may be more or less important to individual farmers (Reddy 2001). For example, two lines A and B may vary in their yields under drought and optimal water conditions. Line A may produce better yields under stress than Line B while yielding less than Line B under optimal conditions. One farmer may choose to grow Line A without irrigation while another may choose to grow Line B and irrigate. The fact that Roundup Ready varieties do not outperform conventional varieties under all circumstances is to be expected. As noted in some of the comments and responses below, some potential deficiencies such as reduced micronutrient uptake and increased disease susceptibility were noted in a very limited number of varieties based on Roundup Ready Soybean 40-3-2. However, the apparent deficiencies did not appear to affect yield significantly, especially if managed correctly. Compared to the benefits of effective weed control, these agronomic problems alluded to by the commenter are insignificant. Yield reductions because of glyphosate applications to glyphosate resistant soybean have not been observed in extensive field trials (Delannay *et al.* 1995; Reddy & Whiting 2000; Elmore *et al.* 2001a; Reddy 2001). Several university soybean performance trials conducted earlier (from about 1997-2000) suggested that a yield suppression may be associated with the glyphosate resistance trait in soybean, and Elmore et al. (2001b) compared backcrossed derived glyphosate resistant and non glyphosate resistant sister lines in 4 years and 2 locations and demonstrated that glyphosate resistant sister lines yielded 5% less than the non-glyphosate resistant sister lines. Nonetheless, based on nationwide average yields, in 1995-1997 when the adoption rate of Roundup Ready soybean was 0, 1%, and 13% respectively (http://www.isaaa.org/resources/publications/briefs/08/download/isaaa-brief-08-1998.pdf), the average yields were 35.3-38.9 bushels per acre, whereas in 2004-2006 when glyphosate tolerant soybeans were planted in excess of 80% of all soybean acres in the United States, average yields were 42.2- 43.0 bushels per acre (http://usda.mannlib.cornell.edu/ers/89002/Table02.xls). Although yields vary considerably from year to year due to differing management practices, weather, and

soybean genetics, it is apparent that soybean yields have not decreased due to "substantial agronomic and environmental problems with the Roundup Ready soybean system", but instead the yields have tended to rise due in part to benefits gleaned from effective weed control in the Roundup Ready system.

Comment: One comment indicated that the compositional analysis of MON 89788 and APHIS' analysis of it were deficient. The commenter indicated that APHIS should have required and analyzed data on the mineral content of forage and seed from glyphosate-treated MON 89788 and lignin levels of glyphosate-treated MON 89788 under a range of temperatures.

Response: While FDA is the agency responsible for determining food and feed safety, APHIS does analyze and consider the effects of their actions on food safety as one aspect of public health within their NEPA documents. APHIS reviewed the compositional test results of MON 89788 in comparison to A3244 (the nontransformed recipient line) and to several conventional varieties as presented in Appendix E of the petition. APHIS determined that there were no significant impacts since all of the results for MON 89788 were well within the ranges of the conventional varieties. APHIS also considers FDA's conclusion regarding their consultation with developers on the food and feed safety of plants derived from new genetically engineered varieties. The EA (pg. 5) has been updated to reflect the current status of their review.

Food and feed from MON 89788 soybean were the subject of a completed consultation under FDA's consultation procedures for foods derived from new plant varieties. Based on the information presented during the consultation, FDA did not question the crop developer's determination that food and feed derived from MON 89788 soybean are not materially different in terms of composition or safety from food and feed derived from non-transgenic soybean currently on the market. On January 19, 2007 FDA announced that "at this time, based on Monsanto's data and information, the agency considers Monsanto's consultation on glyphosate-tolerant soybean line MON 89788 to be complete." (See http://www.cfsan.fda.gov/~rdb/bnfm104.html.).

The OECD has produced several consensus documents with recommendations on the type of compositional data that should be provided to evaluate the key food and feed nutrients and antinutrients. FDA has participated in the writing and review of these documents. FDA does not have their own standard checklist of key nutrients (including micronutrients such as minerals) that is specific to different crops. The United States was the lead on the OECD Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-Nutrients No. 2, 2001, ENV/JM/MONO(2001)15. This consensus document does not include minerals and lignin specifically among the key nutritional and antinutritional parameters suggested for analysis in soybean matrices for human food or animal feed. Lignin and cellulose content are indirectly inferred from the acid detergent fiber (ADF) component which was included in Monsanto's data package. Monsanto's data package included appropriate comparators as indicated in this consensus document.

While application of glyphosate may have an impact on binding and uptake of certain minerals or micronutrients (see below), there is not a clear consensus that micronutrient analysis of herbicide tolerant soybeans with and without herbicide treatment is necessary, and results of such analyses would be highly influenced by a number of factors including past herbicide use practices and local soil conditions.

Comment: Several comments indicated that glyphosate application to glyphosate tolerant soybeans (referring to Roundup Ready soybean line 40-3-2 and not to MON 89788) and other glyphosate tolerant crops can inhibit uptake of micronutrients and increase plant susceptibility to disease.

Response: APHIS reviewed the literature (Gordon, 2005, Ebelhar et al. 2005) and agrees that preliminary information indicates that glyphosate application to glyphosate tolerant soybeans (referring to Roundup Ready soybean line 40-3-2 and not to MON 89788) may affect manganese uptake or metabolism especially in soils with low levels of manganese, that are on bottomlands, are sandy, and/or that have high pH levels (pH 6.5 or more). Whether these apparent micronutrient deficiencies affect all glyphosate tolerant varieties or just a few varieties still remains to be determined. These deficiency effects may cause lower yields, but research has shown that these deficiencies can be corrected by the addition of manganese (5 to 7.5 lb/acre banded preplant), and result in a typical yield increase of 3 to 5 bushels/acres, but can be up to an increase of 10 bushels/acre (Gordon, 2005, and personal communication 6/1/07). According to Gordon (personal communication) very few acres are affected by this problem and it is not considered a significant problem. The problem is manifested on soils that are typically high yielding, that are sandy with high pH, or on soils with extremely low pH to which lime is applied to adjust the pH, and glyphosate application tends to enhance the deficiency problem. The cost of applying the supplemental manganese (about $2.5/acre) would be recovered about 7 fold with even a minimal yield boost of 3 bushels/acre bringing in a typical price of about $6.00- $6.50/bushel.

APHIS also reviewed the article (Kremer et al. 2005) reporting the apparent stimulation of the growth of selected rhizosphere fungi (*Fusarium* spp.) on the roots of hydroponically-grown glyphosate tolerant soybean (referring to Roundup Ready soybean line 40-3-2 and not to MON 89788) plants treated with glyphosate. In this case, no noticeable effect was observed on yield of soybeans grown in the field (Njiti et al. 2003).

As noted in the review by Cerdeira and Duke (2006), glyphosate is toxic to many microorganisms, including some plant pathogens, and its influence on plant diseases in glyphosate resistant crops is variable, sometimes reducing and other times increasing disease. In soybean, glyphosate was reported to reduce the incidence of infection with the Asian soybean rust pathogen, *Phakopsora pachyrhizi,* in glyphosate resistant soybeans in preliminary greenhouse experiments (Feng et al., 2005). The reported increased susceptibility of glyphosate resistant soybeans in Michigan to white mold disease, caused by *Sclerotinia sclerotiorum*, was demonstrated not to be linked to the resistance transgene, to glyphosate, or its formulation components (Lee et al. 2000 and 2003), nor have glyphosate resistant soybeans consistently shown more susceptibility to

root rot and damping off diseases caused by *Rhizoctonia solani* Kuehn (Harikrishnan and Yang 2002) or to *Fusarium solani*-caused sudden death syndrome (Sanogo et al., 2000, 2001, and Njiiti et al. 2003). Glyphosate-tolerant and glyphosate-sensitive cultivars had similar responses when treated with glyphosate in relation to root rot, damping-off, and sudden death syndrome.

As is the case with all plant species, various susceptibilities to pests and diseases have developed and continue to evolve over time, or greater susceptibility to an abiotic stress is discovered in isolated or unique environments for a particular variety or similar set of varieties. There are numerous soybean varieties available to farmers, and soybean breeders are continuing to develop improved varieties. Over the course of time, breeders have developed and will continue to develop varieties suited to a number of growing environments to address issues related to disease and pest resistance and tolerance to various abiotic stresses. Agricultural extension agents and seed companies make recommendations on varieties that are best suited to local growing conditions and pressures. That soybean yields continue to improve with the widespread adoption of Roundup Ready crops indicates that the effects of glyphosate on micronutrient uptake and potentially increased susceptibility to disease are insignificant relative to the benefits of flexible and effective weed control.

Comment: One comment indicated that damage to symbiotic organisms along with the associated effects of reduced nitrogen fixation, reduced yields, and related effects had not been adequately analyzed.

Response: The results of King et al. (2001) demonstrated a negative impact of glyphosate on *Bradyrhizobium japonicum*, an important nitrogen-fixing symbiont that colonizes soybean roots. As nitrogen-fixation is critical for soybean yield, if this effect were significant, soybean yields would be expected to show a decline with glyphosate use. An investigation into the impact of using glyphosate on glyphosate tolerant-soybeans concluded that there is no significant reduction in yield when glyphosate is used at label rates (Zablotowicz and Reddy, 2004). Similarly, NASS statistics cited above indicate that the average nationwide yield of soybeans continues to increase with the adoption of Roundup Ready soybeans. Based on the yield data, APHIS reasonably concludes that deregulation of MON 89788 and the continued use of glyphosate on MON 897988 should have no significant impact on symbiont organisms.

Comment: One comment indicated that APHIS did not satisfactorily address concerns on the cumulative impacts of the development of glyphosate resistant weeds resulting from the adoption of glyphosate tolerant soybeans, alone and in combination with other glyphosate tolerant crops. The commenter also provided numerous articles to stress the seriousness of glyphosate resistant weeds.

Response: APHIS acknowledges and addresses the occurrence of glyphosate resistant weeds as a result of the widespread adoption of glyphosate tolerant soybeans in the United States and includes management strategies to deal with the issue in the EA (pp. 8-9 and 13-15). The commenter failed to mention that in each of the articles submitted to

emphasize the importance and existence of glyphosate resistant weeds, that the weed scientists also provided recommended management strategies for controlling these weeds as well as strategies for preventing the development of glyphosate resistant weeds. The development of herbicide resistant weeds is well understood by weed scientists. Although weed scientists cannot predict which weeds will gain resistance to a particular herbicide, several weed scientists provided comments on management procedures to mitigate the development of herbicide resistant weeds. APHIS considers the potential cumulative impacts of other glyphosate tolerant crops, increased use of glyphosate, glyphosate resistant weeds, and reasonably foreseeable future actions in the EA (pp. 13-14 and 17-20). APHIS does not agree that more extensive analysis is warranted. No increased soybean acreage is expected because approximately 90% of the present soybean acreage is already devoted to GT varieties, estimates of the 2007 soybean crop indicate that planting will be the lowest level since 1996 reflecting an 11% decrease in acreage compared to 2006. (http://www.nass.usda.gov/Newsroom/2007/03_30_2007.asp) and in the prior five years, soybean production was relatively steady varying from 72 million acres to 75.5 million acres (http://www.nass.usda.gov/QuickStats/index2.jsp). Furthermore, the percentage of soybean acreage in the United States planted to Roundup Ready soybean varieties is not expected to dramatically increase beyond current levels for the following reasons: 1) a certain small percentage (<1%) of soybean growers choose to grow organic soybeans, and genetically engineered soybean varieties can not be grown and certified as organic, 2) some growers will choose to grow non genetically-engineered soybeans for other marketing reasons, 3) a certain percentage of soybean growers each year may choose to rotate out of glyphosate resistant soybeans and use herbicides with alternate modes of action and/or tillage as recommended to avoid weed shifts or the selection of glyphosate resistant or tolerant weeds, and 4) they may simply choose another variety without the glyphosate tolerance trait that is better suited to their specific growing conditions. Based on this analysis, there should not be any significant cumulative impact because there should not be any incremental increase in acreage of GT soybeans if APHIS were to grant the petition for non-regulated status in whole. Furthermore, no change in the label rate of glyphosate use is anticipated for the MON 89788 soybean. If APHIS chooses the no action alternative, there would also be no significant cumulative impact due to increased acreage of GT soybeans since most of the present area of soybean production in the United States is already glyphosate tolerant varieties.

Comment: One comment indicated that the environmental assessment failed to adequately analyze potential harm to wildlife, including endangered wildlife, in violation of NEPA and the Endangered Species Act.

Response: APHIS disagrees with this comment. On page 11 of the environmental assessment, information was provided on the CP4 EPSPS protein, which has been shown to have very low or no toxicity based on several sources of information. Additional information documenting APHIS' analysis of the potential for effects on listed or proposed threatened or endangered animals is included in the EA (pp. 10-12). MON 89788 comparisons to the nontransgenic recipient soybean plant and a range of conventional varieties indicated no significant differences in its growth habit, other

agronomic properties, interactions with pests and non-pest organisms. The CP4 EPSPS protein in MON 89788 and Roundup Ready Soybean 40-3-2 are identical, and therefore the experiences and information gained on Roundup Ready Soybean 40-3-2 can be used to make additional inferences on the effects of MON 89788 on threatened and endangered species as well as non-target and beneficial organisms. APHIS made a no effects determination on listed and proposed threatened or endangered species and proposed and designated critical habitat for MON 89788 based on its plant characteristics and expected use of glyphosate. The following facts were relevant to this determination. MON 89788 is expected only to be a partial or complete replacement for the varieties based on Roundup Ready Soybean 40-3-2. Roundup Ready Soybean 40-3-2 is grown on approximately 90% of the United States soybean acreage. The amount of glyphosate to be used on MON 89788 is expected to be similar to the amount of glyphosate used on Roundup Ready Soybean 40-3-2 and no effects on threatened or endangered species have been noted for Roundup Ready Soybean 40-3-2 in combination with the glyphosate used on Roundup Ready Soybean 40-3-2. Furthermore, the preferred alternative of deregulation in whole of MON 89788 does not specifically authorize activities on designated or proposed critical habitat and is not expected to change land use patterns or cultivation practices relevant to current practices, and so will not effect critical habitat.

The commenter raises the point that the surfactant in Roundup is toxic to tadpoles and juvenile frogs. However EPA registration does not permit glyphosate formulated with surfactant for use in or near fresh water. When used according to the label, glyphosate does not have unreasonable adverse effects. To make such determinations, EPA requires more than 100 different scientific studies and tests from applicants (http://www.epa.gov/pesticides/regulating/). Many plant and wildlife species can be found near or in cities, agricultural fields, and recreational areas. Before allowing a pesticide product to be sold on the market, EPA ensures that the pesticide will not pose any unreasonable risks to wildlife and the environment. EPA does this by evaluating data submitted in support of registration regarding the potential hazard that a pesticide may pose to non-target fish and wildlife species. In considering whether to register a pesticide, EPA conducts ecological risk assessments to determine what risks are posed by a pesticide and whether changes to the use or proposed use are necessary to protect the environment. A pesticide cannot be legally used if it has not been registered with EPA's Office of Pesticide Programs. EPA has already concluded that glyphosate use on Roundup Ready soybean 40-3-2 varieties will not pose any unreasonable risks to wildlife and the environment. Commercialization of MON 89788 should not lead to increased use of glyphosate because nearly all soybean produced in the U.S. is already sprayed with glyphosate, EPA registration does not change the maximum glyphosate application rate for MON 89788 compared to 40-3-2, and MON 89788 is expected to be a replacement for 40-3-2 varieties. Furthermore, MON 89788 is not modified in a way that would allow it to be grown in wetter environments; therefore, it should not increase the exposure of amphibians to glyphosate herbicides containing harmful surfactants. For these reasons, APHIS reasonably concludes that the deregulation of MON 89788 should not have any significant impact on wildlife and should have no effect on species federally listed as threatened or endangered, or species proposed for listing, or their proposed or designated critical habitat.

Comment: One comment indicated the analysis of impacts on agricultural commodities and organic farming is inadequate.

Response: APHIS addressed these issues in the EA (pp. 13-16). Even with the high adoption rates of Roundy Ready soybeans, organic and conventional soybeans remain a viable option for those farmers who choose to grow them. According to data compiled by the U.S. Economic Research Service (http://www.ers.usda.gov/data/organic/), the U.S. organic soybean acreage was 82,143 in 1997 and increased to 174,467 in 2001 (1 year prior to the adoption of national organic standards by the USDA) and from 2002 to 2005 has varied only slightly, with acreages of 126,540, 122,403, 114,239, and 122,217, respectively. The fact that organic soybean production acreage remained stable from 2002 to 2005 despite the high rates of adoption of glyphosate resistant soybeans by conventional soybean growers during this period, indicates that organic growers are still able to locate and buy organic or conventional untreated, non-genetically engineered seed to meet their needs. The National Sustainable Agriculture Information Service website provides a link to a searchable database of organic seed suppliers that includes numerous suppliers of organic soybean seed in the United States (see http://www.attra.ncat.org/attra-pub/altseed_search.php). Furthermore, U.S. organic soybean crops continued to carry a substantial premium (2 to 3 fold greater price) over conventional crops from 1995 to 2003 (Streff and Dobbs 2004) while glyphosate tolerant soybeans have made up an increasingly large part of the non-organic soybean acreage in the U.S. As MON 89788 is only expected to be a partial or complete replacement for Roundup Ready Soybean 40-3-2, APHIS expects organic and conventional soybeans to remain a viable option for those farmers who choose to grow them, and therefore APHIS expects that deregulation of MON 89788 soybeans should have no significant impact on organic and conventional soybean production.

Comment: One comment indicated that APHIS failed to adequately assess the impacts of stacking MON 89788 with other genetically engineered soybean varieties.

Response: APHIS addressed the stacking of additional herbicide tolerant traits with MON 89788. 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 soybean 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 soybean becoming a weed. Based on the analysis in the EA (pp. 14-15), APHIS concludes there is no significant impact from stacking glyphosate with other herbicide resistance traits. It is not possible to assess the impacts of combining the glyphosate tolerance trait with any other genetically engineered traits that have yet to be developed. APHIS will assess these new traits in combination with glyphosate tolerance traits as they are proposed for deregulation.

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USDA-APHIS
Environmental Assessment

In response to Monsanto Petition 06-178-01p seeking a Determination of Non-regulated Status for Roundup RReady2Yield Soybean MON 89788

OECD Unique Identifier MON-89788-1

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

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I. SUMMARY

The Animal and Plant Health Inspection Service of the United States Department of Agriculture (USDA-APHIS), has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 06-178-01p) from Monsanto Company for a determination of non-regulated status for genetically engineered (transformed) Roundup RReady2Yield Soybean (*Glycine max*) derived from their transformation event MON 89788 (referred to hereafter as MON 89788). The genetically engineered Roundup RReady2Yield Soybean was developed to tolerate the herbicide glyphosate. MON 89788 soybean is currently a regulated article under USDA regulations at 7 CFR part 340, and as such, interstate movements, importations, and field tests of MON 89788 soybean have been conducted under notifications issued by APHIS. Monsanto petitioned APHIS requesting a determination that MON 89788 soybean does not present a plant pest risk, and therefore MON 89788 soybean and its progeny derived from crosses with other non-regulated soybean should no longer be regulated articles under these APHIS regulations.

II. INTRODUCTION

The first glyphosate tolerant soybean to be deregulated by APHIS was Roundup Ready soybean 40-3-2 (OECD Unique Identifier MON-04032-6) which was submitted as Petition 93-258-01p by Monsanto (Petition 1993) and deregulated by APHIS in May, 1994 (EA 1994). This event was the result of incorporating the *cp4 epsps* gene derived from *Agrobacterium* sp. strain CP4, a common soil bacterium. Since the 1994 deregulation, Roundup Ready soybeans have gained in market share such that in 2005 Roundup Ready soybeans were planted on approximately 87% of the soybean acreage in the United States (USDA-NASS 2005) and 60% of the global area planted to genetically engineered crops (James 2005). The utilization of glyphosate herbicide plus Roundup Ready soybeans has provided significant convenience in weed control, encouraged the use of conservation-tillage, and provided positive economic impact to farmers (revised petition 06-178-01p page 4, Gianessi et al. 2002).

MON 89788 is very similar to MON-04032-6. Both plants were genetically engineered to be glyphosate tolerant by inserting a gene (from *Agrobacterium* sp. strain CP4) coding for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) into the soybean genome. The CP4 EPSPS protein allows the plant to tolerate applications of the broad spectrum herbicide glyphosate. The major differences between MON 89788 and MON-04032-6 are the promoter for the *cp4 epsps* gene, the transformation method, and the recipient variety. A promoter is a region of DNA that is located upstream of the protein coding region of the gene that permits the proper activation or repression of the gene which it controls. The promoter (P-FMV/TSF1) for MON 89788 is a chimeric promoter (e.g. one that includes sequences from different sources) consisting of enhancer sequences from the 35S promoter of the figwort mosaic virus (FMV) and the promoter from the *Tsf1*gene of the plant *Arabidopsis thaliana* encoding elongation factor EF-1 alpha. In contrast, the promoter for MON-04032-6 is P-E35S from cauliflower mosaic

virus (CMV). The DNA regulatory sequences derived from the plant pathogens *Agrobacterium tumefaciens* and FMV cannot cause plant disease by themselves or in conjunction with the genes that they regulate in the MON 89788 soybean. The transformation method is the method by which the new gene constructs are introduced and integrated into the existing DNA of the recipient. The transformation method for MON 89788 was based on a new technique of *Agrobacterium*-mediated gene delivery to soybean meristem where cells were induced directly to form shoots and give rise to transgenic plants. Incorporation of the *cp4 epsps* gene into the soybean via *Agrobacterium*-mediated transformation does not cause plant disease. The transformation method for MON-04032-6 was particle acceleration using plant tissue culture cells as the recipient plant material. The recipient parental line for MON 89788 was A3244. According to the applicant, A3244 has superior agronomic characteristics and high yielding properties which will be an excellent base for future breeding improvements. APHIS did not evaluate data directly comparing the yield potential of A3244 versus other soybean lines. The recipient line for MON-04032-6 was A5403.

APHIS authorized the first field testing of the MON 89788 soybean plants starting in 2001, and they have been field tested in the United States under the APHIS authorization numbers noted in Table A-1, pages 155-157, of the revised petition 06-178-01p. MON 89788 soybean plants have been evaluated extensively to confirm that they exhibit the desired agronomic characteristics, that tolerance to glyphosate is stable under field conditions, and that they do not present a plant pest risk. The field tests have been conducted in agricultural settings under physical and reproductive confinement conditions.

In accordance with APHIS procedures for implementing the National Environmental Policy Act (NEPA) (7 CFR part 372), this EA has been prepared for MON 89788 soybean in order to specifically address the potential for impact to the human environment through the unconfined cultivation and use in agriculture of the regulated article. Plant pest risks are also considered in the context of this EA.

A. USDA Regulatory Authority

APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the Plant Protection Act (7 U.S.C. 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. An organism is no longer subject to the regulatory requirements of 7 CFR part 340 when it is demonstrated not to present a plant pest risk. A genetically engineered organism is considered a regulated article if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest, or if there is reason to believe that it is a plant pest. These soybean plants have been considered regulated articles because they contain non-coding DNA regulatory sequences derived from plant pathogens and the vector agent used to deliver the transforming DNA is a plant pathogen.

Section 340.6 of the regulations, entitled "Petition for Determination of Nonregulated Status", provides that a person may petition APHIS 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. If APHIS determines that the regulated article is unlikely to present a greater plant pest risk than the unmodified organism, APHIS can grant the petition in whole or in part. In such a case, APHIS authorizations (i.e., permits or notifications) would no longer be required for field testing, importation, or interstate movement of the non-regulated article or its progeny.

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

The genetically engineered soybean is also subject to regulation by other agencies. The EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), pesticides added to (or contained in) raw agricultural commodities generally are **considered** to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA, and the FDA enforces the tolerances set by the EPA. Because of the similarity in tolerance to glyphosate for MON 89788 and the previously deregulated event 40-3-2, Monsanto has not requested a label change for the application of glyphosate to MON 89788 soybeans (Russell Schneider, Monsanto, Personal communication, 12/19/06).

The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992, and appears at 57 FR 22984-23005. Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food. Monsanto submitted a food and feed safety and nutritional assessment summary to FDA for the MON 89788 soybean. On January 19, 2007, FDA announced that “at this time, based on Monsanto's data and information, the agency considers Monsanto's consultation on glyphosate-tolerant soybean line MON 89788 to be complete.” (See http://www.cfsan.fda.gov/~rdb/bnfm104.html.)

III. PURPOSE and NEED

APHIS has prepared this EA before making a determination on the status of MON 89788 soybean as regulated articles under APHIS regulations. The developer of these soybean plants, Monsanto, submitted a petition to USDA-APHIS requesting that APHIS make a determination that these soybean plants shall no longer be considered regulated articles under 7 CFR part 340. Under regulations in 7 CFR part 340, APHIS is required to give a determination on the petition for nonregulated status. This EA was prepared in

compliance with the National Environmental Policy Act (NEPA) of 1969 as amended, (42 USC 4321 *et seq.*) and the pursuant implementing regulations (40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372).

IV. ALTERNATIVES

A. No Action: Continuation as a Regulated Article

Under the Federal "no action" alternative, APHIS would deny the petition. Under this alternative, MON 89788 soybeans would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of MON 89788 soybeans. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of glyphosate tolerant soybeans.

B. Determination that MON 89788 soybeans are No Longer Regulated Articles, in Whole

Under this alternative, MON 89788 soybeans would no longer be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of glyphosate tolerant soybeans derived from this event. APHIS might choose this alternative if there were sufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of glyphosate tolerant soybeans derived from this event.

C. Determination that MON 89788 soybeans are No Longer Regulated Articles, in Part

The regulations at 7 CFR § 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." APHIS might approve a petition in part if this partial approval would mitigate a potential plant pest risk. APHIS has not identified any greater plant pest risk characteristics in this transformed soybean than non-transformed or other non-regulated glyphosate tolerant soybeans that would warrant deregulation in part of MON 89788 soybeans. Therefore, deregulation in part is not a viable alternative and the specific impacts of this alternative will not be analyzed any further.

D. Preferred Alternative

APHIS has chosen Alternative B as the preferred alternative. This decision is based upon the lack of plant pest characteristics in the MON 89788 soybeans.

V. AFFECTED ENVIRONMENT

A. Soybean

Glycine max L. is a member of the Phaseoleae tribe of the Leguminosae family with its Center of Origin in eastern Asia The plants are not frost tolerant and do not survive freezing winter conditions. Soybean is a highly self-pollinated species with a cross-pollination rate of usually less than one percent (Caviness 1966). It is not weedy, is not found outside of cultivated areas and does not compete well with other cultivated plants. It has never been found in the wild (Hymowitz and Singh 1987).Volunteer plants that might grow under certain environmental conditions can be easily controlled mechanically or with herbicides. Additional information on the biology of soybean can be found within the Organisation for Economic Co-Operation and Development (OECD) consensus document (OECD, 2000). Soybean is grown as a commercial crop in over 35 countries. In the United States it is grown on over 70 million acres in at least 31 states with over a million acres grown in each of the following states: IA, IL, MN, IN, MO, NE, OH, SD, AR, ND, KS, MI, MS, WI, NC, KY, TN (USDA-NASS 2006). Since 87% of the 2005 soybean acreage in the United States was planted to glyphosate tolerant varieties, the introduction of MON 89788 soybeans is not likely to alter the range of soybeans since MON 89788 closely resembles the presently deregulated 40-3-2 event.

Soybean farmers make their choices of soybean varieties and weed control systems based on several factors: 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). American soybean farmers decided to devote 89% of their 2006 soybean acreage to varieties based on Roundup Ready Soybean 40-3-2 despite the availability of other soybean varieties lacking the trait. There are many soybean varieties both containing and lacking the Roundup Ready Soybean trait available for each of the major soybean growing regions varying from each other over numerous characteristics, some of which may be more or less important to individual farmers (Reddy 2001). Roundup Ready varieties may not outperform conventional varieties under all circumstances. Monsanto claims (see pp. 18-21 and pg. 111 of the petition) that MON 89788 was developed in a genetic background, Asgrow soybean variety A3244, which is "known for its superior agronomic characteristics and high yielding property" and that "using elite germplasm as the base genetics, the superior agronomic characteristic of A3244 can be introgressed to other soybean varieties through crosses with MON 89788". They claim that "In general, MON 89788 has been found to have a 4 to 7% yield advantage compared to Roundup Ready soybeans in the same elite genetic background (A3244) while maintaining the weed control and crop safety benefits of the Roundup Ready soybean system." Therefore APHIS expects that growers who currently use Roundup Ready soybeans will gradually move to varieties bred for their region that are derived from MON 89788, provided that the yield benefits are realized. However, it is unlikely that the percentage of soybean acreage in the United States planted to Roundup Ready soybean varieties would dramatically increase beyond current levels for the following reasons: 1) a certain small percentage (<1%) of soybean growers choose to grow organic soybeans, and genetically engineered soybean varieties can not be grown and certified as organic, 2) some growers will choose to grow non genetically-engineered soybeans for other marketing reasons, 3) a certain percentage of soybean growers each year may choose to rotate out of glyphosate resistant soybeans and use herbicides with alternate modes of action and/or tillage as recommended to avoid weed shifts or the

selection of glyphosate resistant or tolerant weeds, and 4) they may simply choose another variety without the glyphosate tolerance trait that is better suited to their specific growing conditions. Furthermore soybean acreage is not expected to increase as estimates of the 2007 soybean crop indicate that planting will be the lowest level since 1996, reflecting an 11% decrease in acreage compared to 2006 (http://www.nass.usda.gov/Newsroom/2007/03_30_2007.asp), and in the prior five years, soybean production was relatively steady varying from 72 million acres to 75.5 million acres (http://www.nass.usda.gov/QuickStats/index2.jsp).

B. Weed Competition and Control

In most soybean fields, weed populations are high enough to cause major yield losses of up to 50-90% if left uncontrolled. Before the development of effective herbicides for the selective control of weeds in soybeans in the early 1960's, cultural practices, mainly tillage, using weed free seed, row spacing and crop rotation, were the only way to control weeds (Wax 1973). By 1987 there were over 30 herbicides used on soybean (Jordan et al. 1987). By the early 1990's, there were over 70 individual herbicides or combination products registered for weed control in soybeans (Gianessi et al. 2002). Along with the increased use of herbicides, biotypes of various plant species developed resistance to certain herbicide modes of action (Heap 2006). With the 1996 commercial introduction of glyphosate tolerant soybeans, a major shift occurred with an increased use of glyphosate concurrent with the increased planting of glyphosate tolerant soybeans (increased to 87% of all soybeans planted in the United States in 2005) and a decrease in use of other soybean herbicides as noted in the following table (Gianessi et al. 2002).

Percent of United States soybean acres treated with the following herbicides in 1995 vs. 2001

	1995	vs 2001		1995	vs 2001
2,4-D	10	4	**Glyphosate**	20	76*
2,4-DB	1		**Imazamox**		5
Acifluorfen	12	3	**Imazaquin**	15	2
Alachlor	4	<1	**Imazethapyr**	44	9
Bentazon	12	1	**Lactofen**	5	1
Chlorimuron	16	5	**Linuron**	2	
Clethodim	5	4	**Metolachlor**	7	
Clomazone	4	<1	**Metribuzin**	11	2
Cloransulam		5	**Paraquat**	2	
Dimethenamid	1		**Pendimethalin**	26	10
Ethalfluralin	1		**Quizalofop**	6	<1
Fenoxaprop	6	3	**S-Metolachlor**		<1
Fluazifop	10	3	**Sethoxydim**	7	1
Flumetsulam	2	<1	**Sulfentrazone**		5
Flumiclorac		<1	**Thifensulfuron**	12	2
Fomesafen	4	7	**Trifluralin**	20	7

* In 2001, 68 percent of U.S. soybeans were glyphosate tolerant (Pew 2001)

The reasons for growers rapidly switching to the glyphosate tolerant varieties that allowed post emergence treatment with glyphosate include the effectiveness of glyphosate on a broad spectrum of weeds, flexibility in time of application, total lower costs of the glyphosate treatment vs. alternative programs, reduced tillage costs, and reduced costs of fewer herbicide applications (Gianessi et al. 2002). As has happened with other herbicides to which weeds have developed resistance to their modes of action, some weeds in soybeans have developed resistance to glyphosate, namely horseweed (*Conyza canadensis)*, common waterhemp (*Amaranthus rudis*), common ragweed (*Ambrosia artemisiifolia*), and giant ragweed (*Ambrosia trifida*) (Heap 2006). Although the selection of glyphosate resistant weeds as a result of the adoption of glyphosate resistant crops can limit the effectiveness of glyphosate weed control, according to a recent survey only 8% of farmers say it's a problem across all of their acreage (Service 2007a). Weed scientists are developing management strategies to help ensure consistent control of these weeds (Loux et al. 2004, Loux and Stachler 2006), and companies and university scientists have developed and are developing alternative herbicide resistant crop strategies (e.g. Service 2007a).

VI. POTENTIAL ENVIRONMENTAL IMPACTS.

Potential impacts to be addressed in this EA are those that pertain to the use of MON 89788 soybeans and its progeny in the absence of confinement.

A. Potential impacts from gene introgression from MON 89788 soybeans into its sexually compatible relatives.

Introgression is the infiltration of the genes of one species into the gene pool of another, e.g. through repeated backcrossing of an interspecific hybrid to one of the parental species or to a different species. In assessing the risk of gene introgression from MON 89788 soybeans into its sexually compatible relatives, APHIS considers two primary issues: 1) the potential for gene flow and introgression; and 2) the potential impact of introgression.

The genus *Glycine* has approximately 9 species with *G. max* being placed in the subgenus *Soja* along with one other species, *G. soja* (previously *G. ussuriensis*). *G. max* is sexually compatible with only *G. soja* and no other *Glycine* species. *G. max* is the only *Glycine* species located in the USA other than a few *G. soja* plants in research plots. *G. max* has never been found in the wild (Hymowitz and Singh 1987). Therefore the probability of gene flow and introgression of MON 89788 soybeans into other species is not foreseeable and the potential impact of introgression is nonexistent if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no impact from introgression since most of the present area of soybean production in the United States is already glyphosate tolerant varieties.

B. Potential impacts based on the relative weediness of MON 89788 soybean.

APHIS assessed whether MON 89788 soybean is any more likely to become a weed than the nontransgenic recipient soybean line, or other soybean currently cultivated. The assessment encompasses a thorough consideration of the basic biology of soybean and an evaluation of unique characteristics of MON 89788 soybean.

In the United States, soybean is not listed as a weed in the major weed references (Crockett 1977; Holm *et al.* 1979; Muenscher 1980), nor is it present on the lists of noxious weed species distributed by the Federal Government (APHIS-USDA 2006). Furthermore, soybean has been grown throughout the world without any report that it is a serious weed. Soybean is unlikely to become a weed. It is not persistent in undisturbed environments without human intervention. In the year following cultivation, soybean may grow as a volunteer only under specific conditions and can be easily controlled by herbicides or mechanical means. It does not compete effectively with cultivated plants or primary colonizers (OECD 2000). *G. max* has never been found in the wild (Hadley and Hymowitz 1973).

Monsanto conducted field trials to evaluate phenotypic characteristics comparing MON 89788 to A3244, the recipient parental line, at a total of 17 field trial locations in soybean growing regions of the United States in 2005. Table VIII-5 (revised petition, page 79) identifies the traits assessed in these field trials. There were no statistically significant differences between MON 89788 and A3244 for any of the assessed traits except for plant height. Plant height for MON 89788 was approximately 5% smaller than for A3244, but was well within the range of plant heights observed for the other commercial varieties in the trials. A decreased plant height is not expected to increase the weed potential for MON 89788. Based on this analysis, there is no apparent potential for significant impact on weediness if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no impact on weediness since most of the present area of soybean production in the United States is already glyphosate tolerant varieties.

C. Potential impact on non-target organisms, including beneficial organisms, and effects on threatened or endangered species

APHIS evaluated the potential for deleterious effects or significant impacts on non-target organisms from cultivation of MON 89788 soybean and its progeny as part of its responsibilities under APHIS regulations at 7 CFR 340 and under NEPA. APHIS also evaluated the potential for effects on federally listed Threatened or Endangered Species (TES), those proposed for listing, and their designated or proposed critical habitat in compliance with the Endangered Species Act (species lists available at http://endangered.fws.gov/wildlife.html#Species).

Data supplied in the petition (Sections IV-VI, pp 31- 60) and reviewed by APHIS support the conclusion that MON 89788 contains the following sequences: 1) the P-*FMV/Tsf1* transcriptional promoter containing the *Arabidopsis thaliana Tsf1* gene

promoter and enhancer sequences from the figwort mosaic virus 35S promoter, 2) coding sequence for a chloroplast transit peptide from *Arabidopsis thaliana*, 3) the 5-enolpyruvylshikimate-3-phosphate synthase gene (*epsps*) from *Agrobacterium* sp. strain CP4, and 4) DNA containing polyadenylation sequences from the 3' non-translated region of the *Pisum sativum* (pea) *rbc*S E9 gene. The non-coding 35S promoter from the plant pathogen figwort mosaic virus cannot cause plant disease and serves a purely regulatory function for the *epsps* gene. The FMV promoter has a history of safe use in transgenic plants, e.g. canola event RT73 (petition 98-21-01p), cotton MON 88913 (petition 95-023-01p), alfalfa J101 and J163 (petition 04-110-01p), and sugar beet TSB77 (petition 98-173-01p) (USDA-APHIS 2006). The *epsps* gene is from the soil-inhabiting bacterial plant pathogen, *Agrobacterium* sp. strain CP4. It encodes the EPSPS protein which functions to impart tolerance to the broad spectrum herbicide glyphosate. It does not cause disease and has a history of safe use in a number of deregulated genetically engineered plants (e.g., corn, cotton, canola, and soybean varieties). The amino acid sequence of the CP4 EPSPS protein in MON 89788 is identical to the CP4 EPSPS protein in the present Roundup Ready soybean that has been deregulated since 1994 and planted on 87% of the 2005 soybean acres in the United States with no reported negative effects on non-target organisms or on any TES.

As noted in the petition (pg. 57) EPSPS proteins are already found in a variety of animals (mammals, fish, birds, reptiles and insects). CP4 EPSPS is nontoxic to mammals and birds and its potential to be a food allergen is minimal (OECD 1999). The CP4 EPSPS protein has been shown to have no observable adverse effects in acute oral toxicity studies on mice at doses as high as 572 mg/kg of body weight. (To consume this dose, a typical 25 g mouse would have to consume about 4 times its weight in MON 89788 grain, based on measured expression levels of 150 µg/g dry weight of CP4 EPSPS in MON 89788 grain as reported in the petition. The level of CP4 EPSPS in MON 89788 grain (140 µg/g fresh weight) is lower than that measured in the previously deregulated Roundup Ready soybean (239 µg/g fresh weight as reported in Petition 93-258-01p). The data on mammalian toxicity are directly applicable to the 358 mammals on the TES list plus the proposed mammals for the TES list. APHIS conducted an analysis of all of the animals federally listed or proposed as threatened or endangered to determine if they have any association with soybean fields as habitats and/or whether they consume soybeans. The only animal listed that occupies habitat that is likely to include soybean fields and that would be expected to potentially feed on soybeans is the federally Endangered Delmarva Peninsula Fox Squirrel. It is known to utilize certain agricultural lands readily, but its diet includes acorns, nuts/seeds of hickory, beech, walnut, and loblolly pine; buds and flowers of trees, fungi, insects, fruit, and an occasional bird egg (NatureServe 2007). Therefore it is not expected to consume many soybeans or be exposed to doses of CP4 EPSPS from MON 89788 that would exceed 572 mg/kg of body weight.

APHIS also considered the potential for effects from use of glyphosate in varieties derived from MON 89788 compared to current agricultural practices. There is some debate about the significance of the toxicity to tadpoles and juvenile frogs of the surfactant (polyethoxylated tallowamine; POEA) that is included in some formulations of

glyphosate (including Roundup) to allow glyphosate to permeate the waxy cuticle of plant leaves (cf. Relyea 2006 and references therein). However EPA registration does not permit glyphosate formulated with surfactant for use in or near fresh water. The EPA has concluded that when used according to the label, glyphosate does not have unreasonable adverse effects to human health or the environment. To make such determinations, EPA requires more than 100 different scientific studies and tests from applicants (http://www.epa.gov/pesticides/regulating/). Many plant and wildlife species can be found near or in cities, agricultural fields, and recreational areas. Before allowing a pesticide product to be sold on the market, EPA ensures that the pesticide will not pose any unreasonable risks to wildlife and the environment. EPA does this by evaluating data submitted in support of registration regarding the potential hazard that a pesticide may pose to non-target fish and wildlife species. In considering whether to register a pesticide, EPA conducts ecological risk assessments to determine what risks are posed by a pesticide and whether changes to the use or proposed use are necessary to protect the environment. A pesticide cannot be legally used if it has not been registered with EPA's Office of Pesticide Programs. EPA has already concluded that glyphosate use on Roundup Ready soybean 40-3-2 varieties will not pose any unreasonable risks to wildlife and the environment. Commercialization of MON 89788 should not lead to increased use of glyphosate because nearly all soybean produced in the U.S. is already sprayed with glyphosate, EPA registration does not change the maximum glyphosate application rate for MON 89788 compared to 40-3-2, and MON 89788 is expected to be a replacement for 40-3-2 varieties. Furthermore, MON 89788 is not modified in a way that would allow it to be grown in wetter environments; therefore, it should not increase the exposure of amphibians to glyphosate herbicides containing harmful surfactants. The reregistration eligibility document for glyphosate completed in 1993 includes a summary of EPA's conclusions regarding potential effects on endangered species (see http://www.epa.gov/REDs/old_reds/glyphosate.pdf). Potential concerns were raised for endangered plants and for the Houston toad, and the agency indicated how they intend to address those concerns. TES generally are found outside of agricultural fields. Thus far, there have been no reported adverse effects on TES or their critical habitats with the use of glyphosate on glyphosate tolerant soybeans since the deregulation of the first glyphosate tolerant soybean (James Thompkins, EPA-Pesticide Programs, Personal communication 12/5/06). APHIS expects MON 89788 soybean to replace some to all of the presently available glyphosate tolerant soybean varieties, but APHIS does not expect that MON 89788 will cause new soybean acres to be planted in areas that are not already devoted to agriculture. Combining all of the above information, cultivation of MON 89788 soybeans and its progeny is expected to have no effect on listed TES, species proposed for listing, or their proposed or designated critical habitat compared to current agricultural practices. Based on this analysis, there is no apparent potential for significant impact on non-target organisms, including beneficial organisms and no effect is expected on listed TES, species proposed for listing, or their proposed or designated critical habitat, if APHIS were to grant the petition for non-regulated status in whole. The same is true if APHIS chooses the no action alternative, since most of the present area of soybean production in the United States is already glyphosate tolerant varieties.

D. Potential impacts on biodiversity

Analysis of available information indicates that MON 89788 exhibits no traits that would cause increased weediness, that its unconfined cultivation should not lead to increased weediness of other sexually compatible relatives (of which there are none in the United States), and it is likely to have no effect on non-target organisms common to the agricultural ecosystem or federally listed threatened or endangered species or species proposed for listing. Based on this reasoning, there is no apparent potential for significant impact to biodiversity if APHIS were to grant the petition for non-regulated status in whole. The biodiversity of soybean germplasm (seed breeding material and seed varieties) would only be slightly enhanced by the addition of a different transformation event for glyphosate tolerant soybeans should the petition for non-regulated status be granted in whole. If APHIS chooses the no action alternative, there would also be no significant impact on biodiversity since most of the present area of soybean production in the United States is already glyphosate tolerant varieties.

E. Potential impacts on commercial use and availability of glyphosate tolerant soybean varieties.

If APHIS takes no action, commercial scale production of MON 89788 soybean and its progeny is effectively precluded and the presently deregulated and commercially available glyphosate tolerant soybean varieties would be the only available choice of glyphosate tolerant varieties. MON 89788 soybean plants could still be grown under APHIS permit as they have been for the past several years. However, widespread, unconfined plantings of MON 89788 soybean would not be allowed as long as these soybean plants are considered regulated articles. APHIS has evaluated field trial data reports submitted on this event and progeny, and has noted no significant adverse effects on non-target organisms, no increase in fitness or weediness characteristics, and no effect on the health of other plants. APHIS expects that if these plants were grown under permit in the future, that they would perform similarly. If APHIS were to grant the petition for non-regulated status in whole, MON 89788 soybean and its progeny would no longer be considered regulated articles. The unrestricted cultivation and distribution of MON 89788 soybean would be allowed and would not be subject to regulation by APHIS under 7 CFR part 340. New varieties based on the MON 89788 event would eventually be bred into commercial varieties with different genetic backgrounds and maturity groups for different soybean growing regions of the US and be placed on the market, as occurred with the previously deregulated Roundup Ready soybean 40-3-2 varieties. Based on this analysis, there is no apparent potential for significant impact on commercial use if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no impact on commercial use since most of the present area of soybean production in the United States already consists of glyphosate tolerant varieties.

F. Potential impacts on agricultural practices including organic farming

APHIS considered potential impacts associated with the cultivation of glyphosate tolerant MON 89788 soybeans on current agricultural practices, in particular, those associated with weed control. Potential impacts include the development of herbicide resistant

weeds through the continued use of the herbicide and the stacking of herbicide resistance traits from previously deregulated soybean lines.

Potential impact of the development of herbicide resistant weeds
The development of glyphosate resistant weeds is most likely to continue at the same rate with the deregulation and commercial release of MON 89788 soybean. As 87% of the area devoted to soybean production in the United States during 2005 was planted to varieties derived from the previously deregulated glyphosate tolerant 40-3-2 soybean and as 40-3-2 soybean and MON 89788 soybean have the same gene for glyphosate tolerance, and no change in the label rate for glyphosate use on these soybeans is anticipated, it is highly unlikely the deregulation and commercial release of MON 89788 will have any impact on the development rate of glyphosate resistant weeds. Based on this reasoning, there is no apparent potential for significant impact on development of herbicide resistant weeds if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no impact on development of herbicide resistant weeds since most of the present area of soybean production in the United States is already glyphosate tolerant varieties.

Potential impact of stacking of herbicide resistance traits
Factors that need to be considered in evaluating the potential impact of stacking of herbicide resistance traits (e.g. combining two or more traits through crossing of different genetically engineered plants) are: (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 soybean 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 soybean becoming a weed.

Each of the above factors will be addressed: (1) In addition to the *cp4 epsps* gene for glyphosate tolerance, which is the subject of the present petition, APHIS has previously deregulated other herbicide tolerance gene/events in soybean. The first herbicide tolerant soybean to be deregulated was the glyphosate tolerance soybean based on the *cp4 epsps* gene in Petition 93-258-01p. The second herbicide tolerance trait to be deregulated in soybean was tolerance to the phosphinothricin class of herbicides based on expression of the PAT enzyme, phosphinothricin-N-acetyl transferase, which catalyzes the conversion of the active herbicidal ingredient glufosinate ammonium to an inactive form. Two types of genes encode similar PAT enzymes; i.e. the *bar* gene from *Streptomyces hygroscopicus* and a synthetic *pat* gene derived from *Streptomyces viridochromogenes*. Five transformation events (two with the *bar* gene and 3 with the *pat* gene) were deregulated for Petition 96-068-01p, one *pat* event was deregulated for Petition 98-014-01p and one *pat* event was deregulated for Petition 98-238-01p. (2) APHIS believes there is very little, if any, commercial production of the glufosinate ammonium tolerant soybeans in the United States based on the lack of the use of the herbicide glufosinate ammonium in soybean production as noted above in Section V. B. For the presently deregulated glyphosate tolerant event in Petition 93-258-01p, approximately 63 million acres were planted in 2005. (3) Based on all of the genetically engineered herbicide tolerant traits in all of the crops deregulated to-date by APHIS, the herbicide tolerant trait

has no effect on any other plant characteristic so the stacking of two or more herbicide tolerant traits into one plant should have no effect on making the plant more weedy or changing the level of herbicide tolerance in the plant. (4) As noted above in Section V. B., several effective alternative herbicides are available for use in soybean for controlling a wide array of weeds. (5) The development of herbicide resistant weeds is generally due to frequent use of the same herbicide over a period of time on the same area. Alternating herbicides with different modes of actions to control weeds generally is recommended to help avoid the development of herbicide resistant weeds. Therefore incorporating tolerance to two or more herbicides into the same plant may be considered useful in avoiding the development of herbicide resistant weeds. (6) Soybean is a highly self-pollinated crop with cross-pollination occurring at a rate of less than 1%. (7) Soybean has never been considered a weed other than as an occasional volunteer in subsequent crops. Based on this analysis, there is no apparent potential for significant impact from stacking of herbicide resistance traits if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no impact of stacking of herbicide resistance traits since most of the present area of soybean production in the United States already consists of glyphosate tolerant varieties.

Potential impacts on organic farming

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

In 2003, of the 73.4 million acres of soybeans in the United States (USDA-ERS 2006), 122,403 acres (0.17%) were certified organic soybeans (USDA-ERS 2005).

It is not likely that organic farmers or other farmers who choose not to plant or sell MON 89788 soybean or other transgenic soybeans will be significantly impacted by the

expected commercial use of this product as: (a) nontransgenic soybeans will likely still be sold and will be readily available to those who wish to plant it; (b) soybean is a highly self pollinated plant and therefore buffer requirements would be minimal; and (c) 87% of the 2005 soybean acreage in the United States is already planted to transgenic glyphosate tolerant varieties, (d) APHIS expects MON 89788 soybean to replace some to all of the presently available glyphosate tolerant soybean varieties without significantly affecting the overall total soybean acreage or glyphosate tolerant soybean acreage so organic farmers will be able to coexist with biotech soybean producers as they do now. Based on this analysis, there is no apparent potential for significant impact to organic farming if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no impact to organic farming since most of the present area of soybean production in the United States already consists of glyphosate tolerant varieties.

G. Potential impacts on raw or processed agricultural commodities

APHIS analysis of data on agronomic performance, disease and insect susceptibility, and compositional profiles of soybean indicate no significant differences between MON 89788 soybean and non-transgenic or previously deregulated transgenic glyphosate tolerant counterparts that would be expected to cause either a direct or indirect plant pest effect on any raw or processed plant commodity from deregulation of MON 89788 soybean. APHIS generally analyzes the transgenic line in comparison to the line or variety from which it was derived and/or to a range of conventional varieties. In the case of MON 89788, APHIS evaluated comparisons to the nontransgenic recipient line, A3244; to the ranges of several conventional soybean varieties; and to Roundup Ready soybean line 40-3-2, also designated MON-04032-6. The appropriateness of these comparisons is described on page 28 of the petition. A3244 is a non-transgenic elite maturity group III soybean variety developed by Asgrow Seed Company that was developed and selected based on its superior agronomic performance over other soybean lines. APHIS analyzes these comparisons to determine if MON 89788 has any pest characteristics greater than the recipient line or other conventional varieties and to determine if there may be any unintended effects from placing the transgene into A3244. In the petition (06-178-01p, Sections VII and VIII, and Appendixes E, G, and I), numerous different comparisons were presented that ranged from plant growth, lodging, seed moisture content, seed weight, interactions with symbiotic nitrogen-fixing bacteria, response to naturally occurring abiotic stresses, and susceptibility to diseases and insects, and nutritional and anti-nutritional components. None of these comparisons provided any indication of increased pest characteristics or a possibility of an unintended effect that would have a bearing on the health or quality of any raw or processed agricultural commodity. APHIS is not aware of any additional data that can provide appropriate information for making a proper and reasonable comparison to determine whether MON 89788 has the potential to significantly impact the human environment. In addition, MON 89788 was compared to Roundup Ready soybean line 40-3-2, which is the very widely grown Roundup Ready (glyphosate tolerant) event in the United States.

While FDA is the agency responsible for determining food and feed safety, APHIS analyzed and considered the effects of their action alternatives on food safety as one aspect of public health consistent with their requirements under NEPA. APHIS reviewed the compositional test results of MON 89788 in comparison to A3244 (the nontransformed recipient line) and to several conventional varieties as presented in Appendix E of the petition. Food and feed from MON 89788 soybean were the subject of a completed consultation under FDA's consultation procedures for foods derived from new plant varieties. Based on the information presented during the consultation, FDA did not question the crop developer's determination that food and feed derived from MON 89788 soybean are not materially different in terms of composition or safety from food and feed derived from non-transgenic soybean currently on the market. On January 19, 2007 FDA announced that "at this time, based on Monsanto's data and information, the agency considers Monsanto's consultation on glyphosate-tolerant soybean line MON 89788 to be complete." (See http://www.cfsan.fda.gov/~rdb/bnfm104.html.)

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

H. Precedent setting and cumulative impacts

APHIS considered the degree to which the proposed action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration (40 CFR § 1508.27(b)(6)) and 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 undertakes such actions (40 CFR § 1508.27(b)(7)).

APHIS' determination regarding the regulated status of MON 89788 does not set a precedent for other genetically engineered herbicide tolerant soybeans, since APHIS has previously deregulated another Roundup Ready soybean and soybeans engineered for tolerance to another herbicide, glufosinate ammonium. It also does not set a precedent for actions by other agencies, since Monsanto has not requested a label change for the application of glyphosate to MON 89788 soybeans.

For MON 89788, potential cumulative effects largely revolve around the increasing acreage of glyphosate tolerant (GT) crops and the associated total increased usage of glyphosate herbicide on these crops. As noted above, the first GT crop, GT soybeans based on the Roundup Ready soybean 40-3-2 event, was first commercialized in 1996. Since then, approximately 89% of the 75 million acres of soybeans were planted to GT varieties based on the Roundup Ready soybean 40-3-2 event (USDA- NASS 2006). In 2005, 87% of the soybean acreage was planted to GT varieties, about 60% of the cotton

acreage was planted to GT varieties, and about 25% of the corn acreage was planted to GT varieties.

There is some debate about the effects of glyphosate in the glyphosate tolerant soybean system. Preliminary information (Gordon, 2005 and Ebelhar et al. 2005) indicates that glyphosate application to glyphosate tolerant soybeans (referring to Roundup Ready soybean line 40-3-2) may affect manganese uptake or metabolism especially in soils with low levels of manganese, that are on bottomlands, are sandy, and/or that have high pH levels (pH 6.5 or more). Whether these apparent micronutrient deficiencies affect all glyphosate tolerant varieties or just a few varieties still remains to be determined. These deficiency effects may cause lower yields, but research has shown that these deficiencies can be corrected by the addition of manganese (5 to 7.5 lb/acre banded preplant), and result in a typical yield increase of 3 to 5 bushels/acres (Gordon, 2005).

As noted in the review by Cerdeira and Duke (2006), glyphosate is toxic to many microorganisms, including some plant pathogens, and its influence on plant diseases in glyphosate resistant crops is variable, sometimes reducing and other times increasing disease. In soybean, glyphosate was reported to reduce the incidence of infection with the Asian soybean rust pathogen *Phakopsora pachyrhizi* in glyphosate resistant soybeans in preliminary greenhouse experiments (Feng et al. 2005). The reported increased susceptibility of glyphosate resistant soybeans in Michigan to white mold disease (also called Sclerotinia stem rot) caused by *Sclerotinia sclerotiorum* was demonstrated not to be linked to the resistance transgene, to glyphosate, or its formulation components (Lee et al. 2000 and 2003), nor have glyphosate resistant soybeans consistently shown more susceptibility to root rot and damping off diseases caused by *Rhizoctonia solani* Kuehn (Harikrishnan and Yang 2002) or to *Fusarium solani*-caused sudden death syndrome (Sanogo et al., 2000, 2001, and Njiiti et al. 2003). Glyphosate-tolerant and glyphosate-sensitive cultivars had, for the most part, similar responses when treated with glyphosate in relation to root rot and damping-off and sudden death syndrome.

King et al. (2001) demonstrated a negative impact of glyphosate on *Bradyrhizobium japonicum*, an important nitrogen-fixing symbiont that colonizes soybean roots. As nitrogen-fixation is critical for soybean yield, if this effect were significant, soybean yields would be expected to show a decline with glyphosate use. An investigation into the impact of using glyphosate on glyphosate tolerant-soybeans concluded that there is no significant reduction in yield when glyphosate is used at label rates (Zablotowicz and Reddy, 2004). Yield reductions because of glyphosate applications to glyphosate resistant soybean have not been observed in extensive field trials (Delannay *et al.* 1995; Reddy & Whiting 2000; Elmore *et al.* 2001a; and Reddy 2001).

Over the ten years from 1996 to 2005, average U.S. soybean yields have varied from 33.9 to 43.3 bushels per acre (with 2005 producing the highest yield on record) and soybean production ranged from 2.38 to 3.12 billion bushels (with 2004 being the largest production year on record) (data summarized on pp. 92-93 of the petition). That soybean yields continue to improve with the widespread adoption of Roundup Ready crops indicates that the effects of glyphosate on micronutrient uptake and potentially increased

susceptibility to disease are insignificant relative to the benefits of flexible and effective weed control. An effect expected from adoption of soybean varieties developed from MON 89788 over previous Roundup Ready soybean varieties is a potential enhancement of yield. APHIS evaluated field trial data collected during 2005 comparing MON 89788 with the recipient plant variety and reference varieties representing conventional and Roundup Ready Soybeans at 17 locations. Typical production practices for soybean in each area were employed, however glyphosate was not used in order to be able to compare the non glyphosate tolerant varieties. The 17 locations have a range of environmental and agronomic conditions representative of major U. S. soybean-growing regions where the majority of commercial production of MON 89788 is expected to occur. These trials indicated that MON 89788 does not confer any increased susceptibility or tolerance to specific disease, insect, or abiotic stressors, and the average, minimum and maximum yields over the 17 locations for MON 89788 (48.4, 21.9 and 75.6 bu/ac respectively) were comparable to those of the recipient line A3244 (49.9, 20.6, and 76.8 bu/ac respectively) (see pg. 83 and Appendix G of the petition). Yield data for the other conventional non glyphosate tolerant and previous Roundup Ready lines were not reported, however APHIS notes that the average yields for MON 89788 and A3244 were higher than the average soybean yields (43.3 bu/ac) reported in the US for 2005.

In the reasonably foreseeable future, one additional GT soybean, Pioneer 356043 soybean, could be deregulated in addition to MON 89788 and the previously deregulated Roundup Ready soybean 40-3-2 event. Pioneer 356043 soybean is also engineered for tolerance to the ALS inhibitor class of herbicides, and a petition for deregulation (06-271-01p) is pending. APHIS expects that varieties based on the MON 89788 event will replace some or all of the GT soybean varieties based on the Roundup Ready soybean 40-3-2 event. If the GT Pioneer 356043 soybean is deregulated, APHIS would expect the varieties based on Pioneer 356043 to only partially replace the existing GT soybeans and still expect no significant increase in the percentage of GT soybean acreage. No increased soybean acreage is expected because, as stated above, approximately 90% of the present soybean acreage is already devoted to GT varieties, estimates of the 2007 soybean crop indicate that planting will be the lowest level since 1996 reflecting an 11% decrease in acreage compared to 2006, (http://www.nass.usda.gov/Newsroom/2007/03_30_2007.asp). In the prior five years, soybean production was relatively steady varying from 72 million acres to 75.5 million acres (http://www.nass.usda.gov/QuickStats/index2.jsp). Furthermore, as noted elsewhere in this EA, some growers may choose to plant non genetically engineered soybean, or may choose to rotate to non-glyphosate tolerant soybeans to avoid selection of glyphosate resistant or tolerant weeds or weed shifts associated with the use of glyphosate (as discussed below). Based on this analysis, there should not be any significant cumulative impact because there should not be any incremental increase in acreage of GT soybeans if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no significant cumulative impact due to increase acreage of GT soybeans since most of the present area of soybean production in the United States is already glyphosate tolerant varieties.

Along with the increasing adoption of these GT crops have come the increasing use of the herbicide glyphosate and the associated decreasing use of other herbicides. Compared to the herbicides it replaces, the glyphosate used on these crops is less toxic to humans and not as likely to persist in the environment as the herbicides it replaces (USDA-ERS. 2006a). APHIS expects no change in the recommended rate of glyphosate to be used on GT soybeans, no matter if the GT soybean is based on the Roundup Ready soybean 40-3-2 event, the MON 89788 event, or the Pioneer 356043 event (no rate change is expected for the label for glyphosate for use on Pioneer 356043 event according to personal communication with Pioneer, 7/18/07). Therefore, the total amount of glyphosate used on GT soybeans is not expected to significantly increase with the deregulation of MON 89788. Based on this analysis, there is unlikely to be a significant cumulative impact due to an increase in the use of glyphosate in soybean production if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no significant cumulative impact due to increased acreage of GT soybeans since most of the present area of soybean production in the United States is already planted to glyphosate tolerant varieties.

As has happened with most widely used herbicides to which weeds have developed resistance, various weeds have developed biotypes that are resistant to glyphosate (http://www.weedscience.org/in.asp). To date, weeds have been slow to evolve resistance to glyphosate compared to herbicides with other modes of action, and very few have developed in glyphosate resistant cropping systems in the United States. At the present, 183 weed species world-wide are noted to be resistant to herbicides to which they were once thought to be susceptible. Of these 183, twelve are noted to be resistant to glyphosate. Of these twelve, four to five (common waterhemp, common ragweed, giant ragweed, horseweed and possibly Palmer amaranth) are found in glyphosate tolerant soybeans in the United States. Palmer amaranth is common in cotton and soybeans, but glyphosate was never considered to be a control for Palmer amaranth. Therefore, it may not be considered a true glyphosate resistant weed, though from a practical standpoint, Palmer amaranth is a problem in soybean and cotton fields treated only with glyphosate. In comparison to glyphosate, of the herbicides used in soybeans as noted above, the acetolactate synthase (ALS) inhibitor class of herbicides has 95 resistant weeds, the dinitroanilines class of herbicides has 10 resistant weeds, the acetyl coenzyme A carboxylase (ACCase) inhibitor class of herbicides has 35 resistant weeds, the synthetic auxins class of herbicides has 25 resistant weeds, and the photosystem II inhibitors class of herbicides has 66 resistant weeds. APHIS expects that if GT soybeans continue to be a large proportion of the total plantings of soybeans, glyphosate will continue to be used on these plantings and as a result the number of glyphosate resistant weeds will most likely increase. However, as noted above, since MON 89788 will only partially or completely replace varieties based on the 40-3-2 event, APHIS expects no increase in the rate of glyphosate resistant weeds. Based on this analysis, there is no apparent potential for significant cumulative impact due to the development of glyphosate resistant weeds if APHIS were to grant the petition for non-regulated status in whole. If APHIS chooses the no action alternative, there would also be no significant cumulative impact due to the development of glyphosate resistant weeds since most of

the present area of soybean production in the United States is already planted to glyphosate tolerant varieties.

I. Highly uncertain or unique or unknown risks

The NEPA implementing regulations require consideration of the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risk (40 CFR § 1508.27(b)(5)). None of the effects on the human environment identified above are highly controversial, highly uncertain, or involve unique or unknown risks. The effects are similar in kind to (and no worse than) those already observed for currently commercially available and widely grown Roundup Ready soybean varieties and to those observed for the use of glyphosate and several other herbicides in agriculture production systems. Furthermore, APHIS is not aware of any means by which the proposed action would threaten or violate Federal, State, or local law requirements.

VII. CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

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

EO 13045, “Protection of Children from Environmental Health Risks and Safety Risks,” acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency’s mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

Each alternative was analyzed with respect to the above EO 12898 and 13045. The human health and environmental impacts of the action alternatives are presented in Section VI of this EA. No human health or environmental effects were identified in Section VI of this EA for any of the action alternatives that would have a disproportionate adverse effect or that would exclude a particular group of persons or populations, including minority and low-income populations, or children, from expected benefits. Both MON 89788 and the previously deregulated Roundup Ready soybean event have completed FDA food safety consultations and no change is expected in herbicide (or other pesticide applications) or the rate of development of glyphosate-resistant weeds regardless of the alternative chosen. The selection of glyphosate resistant

weeds as a result of the adoption of glyphosate resistant crops is not one that disproportionately affects minority and low-income populations or children.

Additional analyses provided here indicate that glyphosate resistant soybean technology can provide environmental and economic value to rural agricultural communities. The efficacy and economic return on investment (EROI) for conventional and herbicide-resistant soybeans were evaluated in a two year (1999-2000) study in Illinois. Compared to varieties resistant to other herbicides (sulfonylurea and glufosinate), glyphosate resistant soybeans were shown to have lower herbicide injury levels and higher weed control levels, while maintaining high yield and high EROI (Nolte and Young, 2002 (see Table 7). EROI was determined more by weed control and variety yield potential than by treatment cost. This analysis took into consideration the technology fee assessed for these varieties. The economic and environmental impact of glyphosate-resistant crops were recently reviewed by Gianessi (2005). In an herbicide replacement simulation study, it was estimated that the average cost difference between herbicide weed-control program for soybeans that were as effective on the major weed species as the glyphosate program with no need for tillage was $20 more per acre (Gianessi 2005). Crop safety is also a concern for the farmer, as well as to their children and pesticide applicators. Of 182 alternative herbicide treatment programs available for use on soybeans, glyphosate was among the 47 with the highest crop safety rating in the weed control guides (Gianessi 2005). In another simulation study, researchers have looked at the effect of switching from glyphosate-resistant crops to conventional seeds with other herbicides, and they found that the switch would require farmers to increase the LD_{50} dose applied to the average U.S. farm by 10% per hectare in soybeans (Service 2007b). The LD_{50} dose is a mammalian toxicity measure for the volume of pesticide needed to kill 50% of a test population of rats. Even with conventional tillage, the use of glyphosate resistant crops reduces the number of LD_{50} doses applied per hectare (Sampson 2007). Under the "no action" alternative these benefits would presumably continue. If the petition is granted in whole, these benefits would also presumably continue and may be even greater if the varieties developed from MON 89788 are higher yielding as anticipated by the developer.

EO 13112, "Invasive Species", states that federal agencies take action to prevent the introduction of invasive species and provide for their control and to minimize the economic, ecological, and human health impacts that invasive species cause. Both non-engineered and deregulated engineered glyphosate tolerant soybean are widely grown in the United States. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS (see Section VI B. of this EA), the engineered plant is sufficiently similar in fitness characteristics to other soybean varieties currently grown and it is not expected to have an increased invasive potential.

Executive Order 12114, "Environmental Effects Abroad of Major Federal Actions" requires Federal officials to take into consideration any potential environmental effects outside the U.S., its territories and possessions that result from actions being taken. APHIS has given this due consideration and does not expect a significant environmental impact outside the United States should non-regulated status be determined for MON 89788 soybean or if one of the other alternatives is chosen. It should be noted that all the

considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new soybean cultivars internationally, apply equally to those covered by an APHIS determination of non-regulated status under 7 CFR part 340. Any international traffic of MON 89788 soybean subsequent to a determination of non-regulated status for MON 89788 soybean would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC).

The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control" (https://www.ippc.int/IPP/En/default.jsp). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (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 136 countries are Parties to it as of November 1, 2006 (see http://www.biodiv.org/biosafety/default.aspx). Although the United States is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, United States 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. The AIA provision 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 United States Government has developed a website that provides the status of all regulatory reviews completed for

different uses of bioengineered products (http://usbiotechreg.nbii.gov). 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 United States, and in the Organization for Economic Cooperation and Development. NAPPO has completed three modules of a standard for the *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (see http://www.nappo.org/Standards/Std-e.html). APHIS also participates in the North American Biotechnology Initiative (NABI), a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including: Argentina, Brazil, Japan, China, and Korea.

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Determination of nonregulated status for MON 89788 soybean

In response to the petition 06-178-01p from Monsanto Company, APHIS has determined that MON 89788 soybean and progeny derived from it are no longer regulated articles under APHIS regulations at 7 CFR part 340. Permits or acknowledged notifications that were previously required for environmental release, importation, or interstate movement under those regulations will no longer be required for MON 89788 soybean and its progeny. Importation of seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and the Federal Seed Act regulations at 7 CFR part 201. This determination is based on APHIS' analysis of field, greenhouse and laboratory data, references provided in the petition, and other relevant information as described in this environmental assessment that indicate that MON 89788 poses no more of a plant pest risk than its non-genetically engineered counterpart. The transgenic event found in MON 89788 will not pose a plant pest risk for the following reasons: (1) gene introgression from MON 89788 soybean 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 soybean varieties; (2) it exhibits no characteristics that would cause it to be weedier than the non-genetically engineered parent soybean line or any other cultivated soybean; (3) 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; (4) it does not pose a threat to biodiversity as it does not exhibit traits that increase its weediness, and its unconfined cultivation should not lead to increased weediness of other cultivated soybeans, it exhibits no changes in disease susceptibility, and it is unlikely to harm non-target organisms common to the agricultural ecosystem or federally listed or proposed threatened or endangered species; (5) compared to current soybean pest and weed management practices, cultivation of MON 89788 soybean should not impact standard agricultural practices in soybean cultivation including those for organic farmers; and (6) disease susceptibility and compositional profiles of MON 89788 soybean are similar to those of its parent line and other soybean cultivars grown in the United States, therefore no direct or indirect plant pest effects on raw or processed plant commodities are expected.

In addition to our finding of no plant pest risk, there will 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 MON 89788 and its progeny. APHIS also concludes that new varieties bred from MON 89788 soybean are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for MON 89788 soybean, or those observed for other soybean varieties not considered regulated articles under 7 CFR part 340.

/s/

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