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 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. 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. The promoter for MON 89788 is a chimeric promoter P-FMV/TSF1 from Figwort Mosaic Virus and *Arabidopsis thaliana*, and the promoter for MON-04032-6 is P-E35S from Cauliflower Mosaic Virus. 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 the yield potential of A3244 versus other soybean lines. The recipient line for MON-04032-6 was A5403. The DNA regulatory sequences derived from the plant pathogens *Agrobacterium tumefaciens* and Figwort Mosaic Virus cannot cause plant disease by themselves or in conjunction with the genes that they regulate in the MON 89788 soybean.

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 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 Mon-04032-6, 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. A final FDA decision is pending.

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 Part 340.6 (d) (3) (I) state that APHIS may "approve the petition in whole or in part." APHIS might approve a petition in part if this partial approval would mitigate 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**.**

D. Preferred Alternative

APHIS has chosen Alternative B as the preferred alternative. This 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. 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 Organization 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). As 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 Mon-04032-6 event.

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, manual 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 (87% of all soybeans planted in the United States in 2005 were herbicide tolerant) 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). Weed scientists are developing management strategies to help ensure consistent control of these weeds (Loux et al. 2004; Loux and Stachler 2006).

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.

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

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 United States 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 essentially zero 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 planted with glyphosate tolerant varieties.

2. 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 planted to glyphosate tolerant varieties.

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

APHIS evaluated the potential for deleterious effects or significant impacts on non-target organisms, including those federally-listed or proposed as Threatened and Endangered Species (TES) by the U.S. Fish and Wildlife Service (http://endangered.fws.gov/wildlife.html#Species), from cultivation of MON 89788 soybean and its progeny.

Data supplied in the petition and reviewed by APHIS (Sections IV-VI, pp 31- 60) support the conclusion that MON 89788 contains the following sequences: 1) the P-*FMV/Tsf1* transcriptional promoter containing the enhancer sequences from the figwort mosaic virus 35S promoter and the promoter from the *Tsf1* gene from *Arabidopsis thaliana*, followed by its 5' non-translated leader (exon 1) and intron, 2) coding sequence for a chloroplast transit peptide from *Arabidopsis thaliana*, 3) the codon-optimized 5-enolpyruvylshikimate-3-phosphate synthase (*epsps*) gene 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. The EPSPS protein has been shown to have very low to no mammalian toxicity and its potential to be a food allergen is minimal (OECD 1999). The data on mammalian toxicity allow APHIS to reach a "no effect" determination for the 358 mammals on the TES list plus the Proposed mammals for the TES list. For those mammals, such as the Federal Endangered Delmarva Peninsula Fox

Squirrel, that are known to feed on soybeans, this level of toxicity and allergenicity would have no effect. In addition, 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. TES generally are found outside of agricultural fields. Combining all of the above information, cultivation of Mon 89788 soybeans and its progeny is expected to have no effect on TES nor is it expected to adversely modify 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 threatened or endangered species, 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 non-target organisms, including beneficial organisms and threatened or endangered species, since most of the present area of soybean production in the United States is already planted to glyphosate tolerant varieties.

4. 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 threatened or endangered species recognized by the U.S. Fish and Wildlife Service. Based on this analysis, there is no apparent potential for significant impact to biodiversity 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 biodiversity since most of the present area of soybean production in the United States is already planted to glyphosate tolerant varieties.

5. Potential impacts on commercial use

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 to be 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. 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 is already planted to glyphosate tolerant varieties.

6. 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 with the deregulation and commercial release of MON 89788 soybean. However, since 87% of the area devoted to soybean production in the United States during 2005 is the previously deregulated glyphosate tolerant MON 04032-6 soybean and since MON 04032-6 soybean and MON 89788 soybean have the same gene for glyphosate tolerance, 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 analysis, 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 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 glufosinate tolerance based on the *pat* gene. Five *pat* events 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 98-173-01p. (2) APHIS believes there is very little, if any, commercial production of the glufosinate tolerant soybeans in the United States based on the lack of the use of the herbicide glufosinate 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 crop plant may be considered useful in avoiding the development of herbicide resistant weeds provided that the crop plant is not sexually-compatible with 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. Based on this analysis, there is no apparent potential for significant impact of 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 is already planted to 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 since: (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 and 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. 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 is already planted to glyphosate tolerant varieties.

7. 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. MON 89788 soybean is also undergoing review by the FDA for use in food and feed (http://www.cfsan.fda.gov). Based on this analysis, there is no apparent potential for significant impact to raw or processed agricultural commodities 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 planted to glyphosate tolerant varieties.

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 EO 12898 and 13045. None of the alternatives are expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

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 is widely grown in the United States. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, 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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