# Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

**[Docket No. 98–067–1]**

### Monsanto Co.; Receipt of Petition for Determination of Nonregulated Status for Potato Lines Genetically Engineered for Insect and Virus Resistance

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** We are advising the public that the Animal and Plant Health Inspection Service has received a petition from Monsanto Company seeking a determination of nonregulated status for certain potato lines genetically engineered for resistance to the Colorado potato beetle and potato virus Y. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. In accordance with those regulations, we are soliciting public comments on whether these potato lines present a plant pest risk.

**DATES:** Written comments must be received on or before September 18, 1998.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 98–067–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 98–067–1. A copy of the petition and any comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing access to that room to inspect the petition or comments are asked to call in advance of visiting at (202) 690–2817 to facilitate entry into the reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. David Heron, Biotechnology and Biological Analysis, PPQ, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–5141. To obtain a copy of the petition, contact Ms. Kay Peterson at (301) 734–4885; e-mail: Kay.Peterson@usda.gov.

**SUPPLEMENTARY INFORMATION:** The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for determination of nonregulated status must take and the information that must be included in the petition.

On December 5, 1997, APHIS received a petition (APHIS Petition No. 97–339–01p) from Monsanto Company (Monsanto) of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for certain NewLeaf® Y potato lines. The subject potato lines include one line of Russet Burbank (RBMT15–101), two lines of Shepody (SEMT15–02 and SEMT15–15), and one line of HiLite (HLMT15–46), which have been genetically engineered for resistance to the Colorado potato beetle (CPB) and potato virus Y (PVY). The Monsanto petition states that the subject potato lines should not be regulated by APHIS because they do not present a plant pest risk.

As described in the petition, all four of the subject NewLeaf® Y potato lines have been genetically engineered to contain the *cry3A* gene from *Bacillus thuringiensis* subsp. *tenebrionis* (*Btt*), which encodes a protein that is insecticidal to CPB, and the PVY coat protein gene (*PVYcp*), which imparts resistance to PVY. In addition to the *cry3A* gene and the PVYcp gene, these potato lines contain and express the *nptII* selectable marker gene, which is used in the initial stages of plant selection. While the two Shepody lines (SEMT15–02 and SEMT15–15) and the HiLite line (HLMT15–46) also contain the aad marker gene, tests indicate that this gene is not expressed in these potato plants. The subject potato lines were developed through the use of the *Agrobacterium tumefaciens* transformation system, and expression of the introduced genes is controlled in part by gene sequences derived from the plant pathogens *A. tumefaciens* and figwort mosaic virus.

The subject potato lines have been considered regulated articles under the regulations in 7 CFR part 340 because they contain gene sequences derived from plant pathogens. These potato lines have been evaluated in field trials conducted since 1995 under APHIS notifications. In the process of reviewing the notifications for field trials of the subject potato lines, APHIS determined that the trials, which were conducted under conditions of reproductive and physical containment or isolation, would not present a risk of plant pest introduction or dissemination.

In the Federal Plant Pest Act, as amended (7 U.S.C. 150aa *et seq.*), "plant pest" is defined as "any living stage of: Any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured or other products of plants." APHIS views this definition very broadly. The definition covers direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees, rhizobia, etc.

The U.S. Environmental Protection Agency (EPA) is responsible for the

regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including insecticides, be registered prior to distribution or sale, unless exempt by EPA regulation. In this regard, EPA has issued a registration to Monsanto for full commercialization of the plant pesticide *Btt* CRY3A delta endotoxin and the genetic material necessary for its production in potato. Residue tolerances for pesticides are established by EPA under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), and the Food and Drug Administration (FDA) enforces tolerances set by EPA under the FFDCA. In addition to the registration, EPA has issued exemptions from the requirement of a tolerance for residues of the subject plant pesticide CRY3A in potatoes, for the NPTII protein as a plant pesticide inert ingredient in all plants, and for the PVY coat protein in or on all plants and raw agricultural commodities.

FDA published a statement of policy on foods derived from new plant varieties in the **Federal Register** on May 29, 1992 (57 FR 22984–23005). The FDA statement of policy includes a discussion of FDA's authority for ensuring food safety under the FFDCA, and provides guidance to industry on the scientific considerations associated with the development of foods derived from new plant varieties, including those plants developed through the techniques of genetic engineering. Monsanto has completed consultation with FDA on the subject potato lines.

In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the Petition for Determination of Nonregulated Status from any interested person for a period of 60 days from the date of this notice. The petition and any comments received are available for public review, and copies of the petition may be ordered (see the **ADDRESSES** section of this notice).

After the comment period closes, APHIS will review the data submitted by the petitioner, all written comments received during the comment period, and any other relevant information. Based on the available information, APHIS will furnish a response to the petitioner, either approving the petition in whole or in part, or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of Monsanto's NewLeaf® Y potato lines RBMT15–101, SEMT15–02, SEMT15–15, and HLMT15–46 and the availability of APHIS' written decision.

**Authority:** 7 U.S.C. 150aa–150jj, 151–167, and 1622n; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(c).

Done in Washington, DC, this 14th day of July, 1998.

**Craig A. Reed,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 98–19228 Filed 7–17–98; 8:45 am]

BILLING CODE 3410–34–P

# Monsanto Petition 97-339-01p for a Determination of Nonregulated Status for Transgenic Potato Lines Resistant to Colorado Potato Beetle and Potato Virus Y

## Environmental Assessment and Finding of No Significant Impact

February 1999

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture, has prepared an environmental assessment before issuing a determination of non-regulated status for genetically engineered potato lines designated as NewLeaf®Y lines RBMT15-101, SEMT15-02, and SEMT15-15. These lines have been engineered for resistance to the Colorado potato beetle and potato virus Y. APHIS received a petition (APHIS Number 97-339-01p) from the Monsanto Company regarding the status of these potato lines as regulated articles under APHIS regulations at 7 CFR Part 340. APHIS has conducted an extensive review of the petition, supporting documentation, and other relevant scientific information to reach its determination that these lines should no longer be considered regulated articles. APHIS concludes that these transgenic potato lines and any new potato varieties developed from crosses with these transgenic lines should be as safe to grow as potato varieties which are not subject to regulation under 7 CFR Part 340. Based on the analysis documented in this environmental assessment, APHIS has reached a finding of no significant impact (FONSI) on the environment from the uncontined cultivation and agricultural use of the subject potato lines and their progeny.

Arnold S. Foudin for.

Sally L. McCammon
Acting Associate Director
Scientific Services
Plant Protection and Quarantine
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: FEB 25 1999

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## I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 97-339-01p) from Monsanto Company (Monsanto) of St. Louis, Missouri, in which Monsanto has requested that APHIS determine that three transgenic potato lines should no longer be considered as regulated articles under APHIS regulations found at 7 CFR Part 340. These potato lines, designated by Monsanto as NewLeaf®Y lines RBMT15-101, SEMT15-02, and SEMT15-15, have been engineered with genes designed to confer resistance to Colorado potato beetle (CPB) and potato virus Y (PVY).

Specifically, the transgenic plants were developed by transforming plant tissue of either Russet Burbank or Shepody potato varieties with the *cry*3A gene of the bacterium *Bacillus thuringiensis* and the coat protein gene of PVY. In addition, the transgenic lines were engineered with the *nptII* gene which encodes the enzyme neomycin phosphotransferase and serves as a selectable marker for transformed plants. The DNA sequences were introduced via a well characterized vector system which uses the plant pathogenic bacterium *Agrobacterium tumefaciens*. Under APHIS regulations, these transgenic potato lines have been considered as regulated articles under APHIS regulations, because they were developed with DNA sequences derived from plant pathogens.

As regulated articles, the interstate movement, importation, and field testing of lines RBMT15-101, SEMT15-02, and SEMT15-15 have been conducted under authorizations from APHIS. Field tests of regulated articles are conducted under conditions which confine the plants to the test site. Monsanto's petition contains information which supports their contention that these potato lines do not present a plant pest risk and, therefore, should no longer be considered as regulated articles under these regulations.

This EA addresses the potential impacts associated with APHIS' determination that lines RBMT15-101, SEMT15-02, and SEMT15-15 and their progeny should no longer be considered as regulated articles under USDA regulations at 7 CFR Part 340. APHIS concludes that the transgenic potato lines RBMT15-101, SEMT15-02 and SEMT15-15:

(1) exhibit no plant pathogenic properties and will not pose an increased plant pest risk from the appearance of new plant viruses;

(2) are no more likely to become weeds than pest resistant potato lines developed by traditional plant breeding;

(3) are unlikely to increase the weediness potential of any other cultivated or wild species with which they can interbreed;

(4) are unlikely to harm threatened or endangered species or organisms that are recognized as beneficial to agriculture, and

(5) will not cause damage to raw or processed agricultural commodities.

Therefore, after a review of the available evidence, including that provided by Monsanto in its petition as well as other scientific data, APHIS believes that potato lines RBMT15-101, SEMT15-02, and SEMT15-15 should be just as safe to grow as potato varieties which are not subject to regulation under 7 CFR Part 340. APHIS concludes that there will be no significant impact on the human environment if these potato lines and their progeny are no longer considered regulated articles under 7 CFR Part 340.

## II. BACKGROUND

**Development of the NewLeafY potato lines .** Monsanto developed the transgenic potato lines to resist two pests of potato production in North America, Colorado potato beetle (*Leptinotarsa decemlineata*; CPB) and potato virus Y (PVY). Recombinant DNA techniques (genetic engineering) were used to transform potato tissues of the cultivars Russet Burbank and Shepody with the genes *cry3A* and *PVYcp* which confer the resistance to CPB and PVY, respectively. The gene *cry3A* is derived from the common soil bacterium *Bacillus thuringiensis* var. *tenebrionis* and encodes the protein Cry3A which is toxic when ingested by some species of insects of the Order Coleoptera (beetles and weevils). The gene *PVYcp* is derived from an isolate of PVY strain O which was obtained from an infected potato plant in Washington state. Expression of viral coat protein genes in plants can protect plants from infection by that type of plant virus.

The *cry3A* and *PVYcp* genes were introduced into the plant tissues on a piece of DNA which also included a selectable marker gene to allow researchers to readily identify those plant tissues that have been successfully transformed with the genetic construct. In the case of these transgenic potato lines, the marker gene was *nptII*, a gene derived from the bacterium *Escherichia coli*. The *nptII* gene encodes the enzyme neomycin phosphotransferase which detoxifies the antibiotics kanamycin and neomycin. Kanamycin is normally toxic to the plant tissues when grown in the laboratory. Therefore, successfully transformed plant cells and tissues can be selected by growing putative transformed plant tissues on growth media with kanamycin. Transformed tissues then were regenerated into whole plants which could be evaluated in the greenhouse and field for the desired characteristics.

APHIS received a petition from Monsanto Company (Monsanto) on December 5, 1997. The petition (assigned APHIS Number 97-339-01P) requested a determination from APHIS that the genetically engineered potato lines RBMT15-101, SEMT15-02, and SEMT15-15 do not present a plant pest risk and are therefore should no longer be considered regulated articles under the regulations at 7 CFR Part 340.

These transgenic potato lines have been characterized with respect to both their genetic modifications and their growth in field tests. APHIS has authorized field tests of these lines since 1993 (APHIS Numbers 93-357-01n, 94-067-12n, 94-298-03n, 95-023-05n, 95-041-06n, 95-041-08n, 95-041-10n, 95-061-01n, 95-061-02n, 95-121-01n, 96-038-02n, 96-040-06n,

96-071-017n, 96-072-03n, 96-079-11n, 96-079-12n, 96-086-05n, 96-086-06n, 96-260-01n, 96-278-01n, 97-020-04n, 97-020-06n, 97-040-06n 97-049-07n, 97-049-08n, 97-049-11n, 97-080-05n, 97-111-09n, 97-114-04n, 97-114-05n, 97114-06n, 97-114-08n, 98-072-14n, 98-072-15n, 98-121-07n, 98-132-08n, and 98-114-07n). In the course of these tests, Monsanto confirmed its expectation that the plants would exhibit no deleterious effects, would not exhibit weedy characteristics, and would have no effect on nontarget organisms or the general environment. All field trials were performed under conditions of physical and reproductive confinement.

**APHIS Regulatory Authority.** APHIS regulations under 7 CFR Part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act, (7 U.S.C. 150aa-150jj) as amended, and the Plant Quarantine Act, (7 U.S.C. 151-164a, 166-167) as amended, 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.

As regulated articles under APHIS regulations, introductions of the transgenic potato lines RBMT15-101, SEMT15-02, and SEMT15-15 required authorizations from APHIS prior to importation, interstate movements, or planting them in field tests. APHIS regulations seek to limit introductions of transgenic plants into the environment until it is clear that the plants pose no more risk as plant pests than other varieties of that plant which are routinely grown in plant breeding programs and in commercial production.

The APHIS regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles." The regulations in subsection 340.6(a) provide that any person may submit a petition to APHIS seeking a determination that an article should not be regulated under 7 CFR part 340.

In the Federal Plant Pest Act, as amended (7 U.S.C. 150aa et seq.), "plant pest" is defined as "any living stage of: Any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured or other products of plants." APHIS views this definition very broadly. The definition covers direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees, rhizobia, etc.

Potato lines RBMT15-101, SEMT15-02, and SEMT15-15, have been considered regulated articles under Part 340 of the regulations, in part, because they have been engineered using components from plant pests (PVY, figwort mosaic virus, and *A. tumefaciens*), and the vector system used to transfer the genes into the plants was derived from the bacterial plant pathogen, *A. tumefaciens*.

Section 340.6 of the regulations, entitled "Petition Process for Determination of Nonregulated Status," provides that a person may petition the Agency to evaluate submitted data and determine that a particular regulated article does not present a plant pest risk and should no longer be regulated. If APHIS determines that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it is derived, the Agency can grant the petition in whole or in part. Therefore, APHIS permits or notifications would no longer be required for field testing, importation, or interstate movement of that article or its progeny. Normal agronomic practices with the subject line, e.g., cultivation, propagation, movement, and cross- breeding also could be conducted without further APHIS approval.

**Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) Regulatory Authority**. The EPA is responsible for the regulation of pesticides, including herbicides, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides be registered for use on specific crops prior to distribution or sale. Residue tolerances for pesticides are established by the EPA under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*). The Food and Drug Administration (FDA) enforces tolerances set by the EPA under the FFDCA.

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. Safety concerns for human and animal consumption of products with kanamycin resistance are also specifically addressed by the FDA in 21 CFR Parts 173 and 573.

## III. PURPOSE AND NEED

APHIS has prepared this EA before making a determination on the status of these potato lines as a regulated articles under APHIS regulations cited above. This EA was prepared in compliance with the National Environmental Policy Act of 1969, as amended (NEPA)(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.

Under the Federal "no action" alternative, APHIS would not come to a determination that the potato lines are no longer regulated articles. Authorizations from APHIS would still be required for introductions of the potato lines. APHIS might choose this alternative if there were

insufficient evidence to demonstrate the lack of plant pest risk from uncontained cultivation of the potato lines.

### B. Determination that the potato lines are no longer regulated articles.

Under this alternative, these transgenic potato lines would no longer be regulated articles. Authorizations from APHIS would no longer be required for introductions of these potato lines or their progeny. A basis for this alternative would include a "Finding of No Significant Impact" under NEPA and its implementing regulations.

## V. PUBLIC COMMENTS

On July 20, 1998, APHIS announced in the Federal Register that the petition submission was available for public review and that the Agency would consider written comments received from before the close of a 60-day comment period. APHIS received a total of six comments, all in favor of the petition for nonregulated status. APHIS considers these comments in addition to the petition submission and relevant information in the scientific literature.

## VI. DESCRIPTION OF POTATO LINES RBMT15-101, SEMT15-02, and SEMT15-15

The transgenic potato lines RBMT15-101, SEMT15-02, and SEMT15-15 were developed to resist herbivory from CPB and infection by PVY. Monsanto has provided information on the molecular genetic characterization of these plants. This information describes the transformation system, the DNA sequences incorporated into the plants, and the resultant gene products which are expressed. APHIS uses this and other information in its assessment to determine if these plants pose a plant pest risk.

### A. Parent plants used to develop lines RBMT15-101, SEMT15-02, and SEMT15-15.

Line RBMT15-101 was developed from the potato (*Solanum tuberosum*) cultivar Russet Burbank. Russet Burbank is the most widely grown potato cultivar in the United States. It is a male sterile, tetraploid (2n=48) variety that is resistant to two important diseases of potato, common scab (caused by *Erwinia carotovora*) and blackleg (caused by *Streptomyces scabies*). However, Russet Burbank is susceptible to PVY and potato leafroll virus (PLRV). Russet Burbank is one of many host plants for CPB, whose larval stages eat the plant foliage.

Lines SEMT15-02, and SEMT15-15 were developed from the potato cultivar Shepody. Shepody is a male fertile tetraploid that is resistant to potato virus A and PLRV-induced net necrosis. Shepody is susceptible to common scab, PVY, and potato virus X (PVX). Shepody also is a host for CPB.

**B. Transformation system.**

Transformation via *Agrobacterium*. The transgenic potato lines RBMT15-101, SEMT15-02, and SEMT15-15 were developed by using a well characterized transformation system which uses disarmed *A. tumefaciens* to transfer DNA to the plant genome where it becomes stably integrated (Klee and Rogers , 1989; Zambryski, 1988). Although *A. tumefaciens* is a recognized plant pathogenic bacterium causing crown gall disease, the strain used for the transformation, strain ABI, is a "disarmed" strain modified so that does not contain the DNA sequences responsible for pathogenesis. Following transformation, the plant tissue is treated with an antibiotic that kills any remaining *Agrobacterium* cells associated with the transformed tissue. Monsanto confirmed that there are no *Agrobacterium* cells associated with lines RBMT15-101, SEMT15-02, and SEMT15-15.

Transformation Plasmid. A plasmid designated as PV-STMT15 was used for the transformation. This plasmid has three plant-expressible genes: the *cry3A* gene which confers resistance to CPB, the *PVYcp* gene which confers resistance to PVY, and the *nptII* gene which confers kanamycin resistance and serves as a selectable marker gene during the transformation and regeneration of transformed plant tissues in the laboratory.

In addition to the plant expressible cassettes described above, plasmid PV-STMT15 also contains the following elements:

*(1) oriV*, which is the origin of replication from plasmid RK2 isolated from Agrobacterium strain ABI (Barker et al., 1981)

*(2) ori-322:rop*, which is a segment of plasmid pBR322 which provides the origin of replication for maintenance of PV-STMT15 in E. coli [rop] and the bom site enables conjugal transfer into Agrobacterium (Bolivar et al., 1977; Sutcliffe, 1978)

*(3) aad* gene, which is derived from transposon Tn7 in the bacterium, *E. coli*. The *aad* gene encodes the enzyme aminoglycoside adenyltransferase, an enzyme which confers resistance to the antibiotics streptomycin and spectinomycin. Because the *aad* gene has prokaryotic promoter and terminator sequences, it should not be expressed in the plant.

*(4) Agrobacterium* right and left border regions (RB and LB), which facilitate integration of the introduced DNA into the plant DNA.

**C. DNA sequences incorporated into lines RBMT15-101, SEMT15-02, and SEMT15-15.**

**RBMT15-101.** The transgenic potato line RBMT15-101 contains the following:

- The *cry3A* gene expression cassette consists of the *cry3A* coding region discussed above in association with the following: the promoter region of the *Arabidopsis thaliana* ribulose-1,5- bisphosphate carboxylase small subunit gene (Almedia et al., 1989; Wong et al., 1992) and the nontranslated 3' region of the *A. tumefaciens* nopaline synthase (*nos*) gene (Depicker et al., 1982; Bevan et al., 1983).

- The *PVYcp* gene expression cassette consists of the *PVYcp* coding and nontranslated regions described above in association with the following: the 35S promoter region of figwort mosaic virus (Richins et al., 1987), the leader sequence from the *Glycine max* heat-shock protein, Hsp 17.9 (Rascke et al., 1988.), and the nontranslated 3' region of the *Pisum sativum* ribulose-1,5- bisphosphate carboxylase small subunit gene, referred to as E9 3' (Coruzzui et al., 1984).

- The *npt II* gene cassette consists of the *nptII* coding region described above in association with the following: the *A. tumefaciens* nopaline synthase (*nos*) promoter (Fraley et al., 1983) and the nontranslated 3' region of the *nos* gene (Depicker et al., 1982; Bevan et al., 1983).

**SEMT15-02 and SEMT15-15.** Lines SEMT15-02 and SEMT15-15 also contain each of the three plant-expressible gene cassettes (*cry3A*, *PVYcp*, and *nptII*) described above. In addition, lines SEMT15-02 and SEMT15-15 contain the sequences for *oriV*, *ori322*, and *aad* described above in the section for PV-STMT15.

**D. Expression of coding regions introduced into lines RBMT15-101, SEMT15-02, and SEMT15-15**

Lines RBMT15-101, SEMT15-02, and SEMT15-15 expressed the proteins encoded by the *cry3A*, *PVYcp*, and *nptII* gene cassettes. The Cry3A protein expressed in these plants was characterized and found to be equivalent to the previously characterized reference standards. The mean expression levels of Cry3A protein in the leaves of in these lines ranged from 20-63 ug/g tissue fresh weight when plants were grown in the field. Expression levels in leaves were approximately 100 times greater than levels measured in tuber tissue.

Expression of the PVYcp and NPTII proteins is below the levels of experimental detection methods. PVYcp expression levels were estimated to be less than 2 ug/g fresh leaf tissue. In comparison, Monsanto reported that the level of PVY coat protein in naturally infected potato is approximately 12- to 244-fold greater, in the range of 24-488 ug/g fresh leaf tissue. The levels of NPTII expression were less than 2.7 ng/g fresh leaf tissue, the detection limit of the enzyme-linked immuno-assay serological assay used by Monsanto.

## VII. POTENTIAL ENVIRONMENTAL IMPACTS

This EA considers the characteristics of the potato lines and the potential environmental impacts that might be associated with their unconfined cultivation when no longer considered as regulated articles. To determine if potato lines RBMT15-101, SEMT15-02, and SEMT15-15 should continue to be considered as regulated articles, APHIS considered information on the biology of potato, data presented by Monsanto, and scientific data on other topics relevant to a discussion of plant pest risk. APHIS concludes that these transgenic potato lines do not present a plant pest risk and should be just as safe to grow as potato varieties which are not subject to regulation under 7 CFR Part 340. This conclusion for the three potato lines RBMT15-101, SEMT15-02, and SEMT15-15 is based upon findings in the following sections:

### A. Potato lines RBMT15-101, SEMT15-02, and SEMT15-15 exhibit no plant pathogenic properties and should not pose a plant pest risk by increasing the appearance of new plant viruses or Cry3A-resistant CPB.

Transformation vector agent. Although the transformation process used the plant pathogen, *A. tumefaciens* (the causal agent of crown gall disease), the genes that cause crown gall disease were removed, and therefore the potato plant does not develop crown gall disease. Once inserted into the chromosome of the transformed plant, the introduced genes are maintained in the same manner as any other genes. Some regulatory sequences were derived from known the plant pests, *A. tumefaciens* and figwort mosaic virus, but these sequences do not incite disease individually or in combination.

DNA sequences introduced. The *cry3A* gene was obtained from the soil bacterium *Bacillus thuringiensis*, ssp. *tenebrionis* (Btt) strain BI 256-82 (Krieg et al., 1983) then modified in its codon usage to facilitate expression in plants while retaining the amino acid sequence of the native protein which is insecticidal to a narrow spectrum of coleopteran species (Sims, 1993; MacIntosh et al., 1990). The *cry3A* gene used in these plants encodes the Cry3A band 3 protein, one of the two insecticidal proteins expressed by the cry3A gene in Btt. In Btt, the *cry3A* gene is used to encode both a 73 kilodalton protein (644 amino acids) Cry3A protein as well as the 68 kilodalton (597 amino acids) Cry3A band 3 protein. The Cry3A band 3 protein results from an in-frame, internal translation initiation site within the *cry3A* coding sequence. Thus the band 3 protein is a truncated version of the full length Cry3A protein, lacking the first 48 amino acids, but retaining the insecticidal activity (McPherson et al., 1988, Perlak et al., 1993).

The transgenic potato lines were also engineered with *PVYcp*, the coat protein gene of PVY. Expression of the PVY coat protein in the plants does not make the plants diseased, but rather, is designed to confer resistance to PVY, an economically important pathogen of potato. The *PVYcp* gene was obtained in from a PVY strain O isolate infecting potatoes in Washington State, USA (De Bokx and Huttinga, 1981; Murphy et al., 1995). The gene sequence of the native PVY coat protein gene was modified only by adding an ATG start codon to facilitate translation of the protein (PVY has a positive-sense RNA genome that is translated as a polyprotein which is subsequently cleaved to yield, among other proteins, the viral coat protein subunits). The *PVYcp* gene construct also contains the complete 3'-untranslated region of the PVY genome directly

downstream of the coat protein coding region. This 3'-region contains the poly-A tail which was used in the initial isolation and cloning of the viral genome. This region was not excised from the *PVYcp* construct, because the developers believed at the time that the region enhanced stability of the mRNA.

The *nptII* gene. These three transgenic lines also were engineered with *nptII*, a selectable marker gene that encodes the protein neomycin phosphotransferase, an enzyme which inactivates aminoglycoside antibiotics such as kanamycin and neomycin. When the *nptII* gene is included in the cassette of genes to be engineered into the plant, successfully transformed plant cells can be selected and identified in the laboratory by growing putative transformants in the presence of kanamycin. The *nptII* gene was originally isolated from the common human colon bacterium, *E. coli* (Beck et al., 1982; Jorgensen et al., 1979). The presence of *nptII* gene in these transgenic potato lines does not mean that kanamycin will be used in the cultivation of these potatoes.

Transgenic lines will not increase the emergence of new plant viruses. APHIS evaluated whether the cultivation of lines RBMT15-101, SEMT15-02, and SEMT15-15 would be likely to increase the emergence of new plant viruses or enhance the effects of viral infections by other viruses that infect potato. APHIS considered the potential for increased pest risk arising from recombination, transencapsidation, and synergism.

**Recombination.** Recombination is defined as an exchange of nucleotide sequences between two nucleic acid molecules. Recombination between viral genomes results in heritable, permanent change. The persistence of a recombined viral genome will depend upon its fitness with respect to its ability to replicate within the original host cell, its ability to replicate in the presence of parental viruses, its ability to spread systemically within the host, or its successful transmission to other host plants.

Factors that influence recombination rates and detection of a viable recombinant include sequence and structural similarity between the nucleic acid molecules, subcellular location and concentration of the nucleic acids, and the number of recombinational events required to form a viable recombinant viral genome (Lai, 1992). The frequency of recombination between two naturally occurring viruses or two viral strains in field-grown plants in the absence of selection pressure has not been determined (Henry et al., 1995) and is difficult or impossible to measure meaningfully. In transgenic plants expressing sequences derived from either a DNA virus (Schoelz and Wintermantel, 1993) or RNA virus (Greene and Allison, 1994), it has been demonstrated that recombination between a viral transgene and a defective challenge virus can restore an functional, infective virus. These results demonstrate that recombinational events occur in plants expressing viral sequences when inoculated with defective viruses but say little about what happens when nondefective viruses replicate in resistant transgenic plants.

Recombination is hypothesized as an important mechanism for virus change over evolutionary time frames and may have been quite frequent over time (Simon and Bujarski, 1994). Recently, the nucleotide sequences of numerous viral strains from many of the known genera have been published. Sequencing data have shown that certain genes in quite different taxa probably arose from recombinational events (Gibbs, 1995; Gibbs and Cooper, 1995). Miller *et al.* (1997) noted

that based on nucleotide sequence homology two major subgroups of luteoviruses probably arose via recombination.

These transgenic lines, like most transgenic plants field tested to date in the U.S. under APHIS oversight, contain viral derived transgenes from viruses that regularly infect the host plant, because damage by those viruses poses the most constant potential for loss in the crop species. Sequences from those viruses, when available for recombination, would be unlikely to pose the potential for generating novel recombinants in comparison with natural mixed infections in the recipient plant.

In assessing these virus-resistant transgenic plants, APHIS considered several questions to address the potential impact of recombination:

1) Is the viral transgene produced in the same cells that it is normally found in during viral infection? Yes, in the case of these transgenic potato lines.

The most likely viruses to recombine with viral transgene are those viruses that naturally infect potatoes. The most widely prevalent viruses in the U.S. that infect potatoes are: potato aucuba mosaic potexvirus, potato virus A potyvirus, potato virus M carlavirus, potato virus S carlavirus, potato virus X potexvirus, potato virus Y potyvirus, and potato yellow dwarf nucleorhabdovirus (from APHIS' Widely Prevalent Viruses by State, 1998). Homologous recombination, i.e. recombination between sequences that show homology, is more likely to occur with viruses in the same taxa because they share sequence homology. For potato viruses that are in different taxa, potyviruses, potexviruses, carlaviruses, and nucleorhabdovirus all replicate in mesophyll, companion, and parenchyma cells (Matthews, 1991; Lawson *et al.* 1971; Foster 1992).

2) What factors may affect the rate of recombination, and will that rate be proportional to the concentrations to transgene RNA molecules?

With respect to the amount of transgene RNA available for recombinational event, Monsanto has provided data to support that the concentration viral mRNA in viral-infected nontransgenic plants is 12- to 244-fold greater than the concentration of transgene RNA in these lines. APHIS notes a discussion among virologists on this issue, "The implications of these low expression levels for recombination are not clear. Even assuming that the higher concentration of transgene RNA the greater the chance for recombination, we do not know what a meaningful range is; what are low and high concentrations of transgene transcript relative to unacceptable recombination rates?" (AIBS, 1995). APHIS believes that the significantly lower concentration of transgene RNA in these lines is reassuring considering recombination has not been detected in transgenic plants with nondefective viruses.

3) Are any recombinants thus formed likely to be successful in competition with parental viruses?

If a recombinant virus is formed in a cell (either in a transgenic plant or during a mixed infection) will that recombinant participate in the replication process in that cell, move systemically in the plant, or cause a new disease? The vast majority of progeny viruses do not apparently function in

the replication process. For many viruses, the newly synthesized RNA is rapidly encapsidated by coat protein. Then, viral RNA synthesis in the cell ceases or declines to undetectable levels. Unless virus is transmitted to another plant by a vector or via progeny plants, the virions are degraded when the plant cell dies (Matthews, 1991). The likelihood of a recombinant becoming established depends on many factors, including: its competitiveness with infecting virus and other viruses that naturally infect the plant and by all the additional factors that may affect selection pressure (e.g., temperature, vectors, host plants). Thus, to predict the probability of development of new virus disease resulting from recombination of two viruses or between a virus and a viral derived transgene, requires a considerable level of understanding of the population biology of viruses in cells and virus movement within plants, and a better understanding of the mechanisms of how viruses cause disease.

There is a possibility that recombination between a transgene and virus could occur, but it is likely that the recombinant virus either would not be viable or the recombinant virus would be viable but not competitive with the wild type virus. Although much of the discussion on the risk of using viral-derived transgenes has focused on the risk of recombination/recombinant virus, there is no persuasive evidence that recombinant viruses pose a greater risk to plants than any new virus or viral strain that is identified each year in potatoes.

In conclusion, based on the above points APHIS believes that because the viral transgene is derived from a virus that naturally infects the potato host, is produced in less concentration than during natural infections, and if a recombinant was formed would have to be competitive with other potato-infecting viruses, the likelihood of novel interactions and formation of recombinant virus is no more likely than its occurrence during mixed infections. APHIS believes that the recombinant would not be competitive with other potato viruses. APHIS believes that even if a recombinant virus did occur that this virus could be managed just like the numerous new viruses that are detected every year in the United States.

**Transencapsidation.** When a single plant cell is simultaneously infected by two different strains of a virus (or two viruses), it may be possible for the genome of one virus to become encapsidated by coat protein of the second virus. If the virus is encapsidated by only one of the coat proteins, it is termed genomic masking or transencapsidation. Any changes are not inherited if such transencapsidated virions move to another host, so any effects are transient and pose no plant pest risk.

**Synergism.** Occasionally, when two viruses simultaneously **naturally** infect a plant, the symptoms can be more severe than when either of the viruses infects the plant singly. This phenomenon is called synergism or synergy (Matthews, 1991). Synergistic infections can often result in severely diseased, unmarketable crops. Synergy was first described and is best studied with potato (potex)virus X (PVX) and potato (poty)virus Y (PVY). Monsanto did not observe synergistic symptoms during field testing of these lines or in artificial inoculation of the plants with PVX. This supports APHIS' belief that the appearance of synergistic symptoms with these transgenic lines is highly unlikely. APHIS believes that symptoms caused by synergistic viral interactions are an agronomic problem (not an environmental issue) in the sense that the yield of the plant is reduced or the symptoms so severe that the plant cannot be sold. A similar conclusion

regarding synergy as an agronomic problem was reached by scientists in a public meeting that discussed virus resistant transgenic plants (AIBS, 1995).

After careful consideration of the physical and biological properties of PVY, the other viruses that infect potatoes, and the properties of the *PVYcp* gene, APHIS concluded that it is unlikely that the cultivation of these transgenic lines will pose an increased plant pest risk from the appearance of new plant viruses. APHIS agrees with the conclusion of the scientists who considered these issues in the AIBS report to USDA (1995) and concluded by stating, "With or without the use of transgenic plants, new plant virus diseases will develop that will require attention." APHIS concurs with their statements. Considering all of these factors, APHIS concludes that the cultivation of these transgenic lines should not increase the emergence of new plant viruses. APHIS believes that current control measures (e.g., indexing of potatoes for viruses) are adequate to control any potential new virus that may arise in potatoes.

Insect resistance management. As stated above, EPA has authority for the registration of pesticides, and is regulating the use of the Cry3A protein in transgenic plants. In light of EPA's authority, APHIS considered the possible impact on current use of registered pesticides which are microbial formulations of the *B. thuringiensis* subsp. *tenebrionis*. If some populations of CPB develop resistance to the Cry3A being produced in the transgenic potato lines, they may be resistant to the Cry3A which is the active ingredient in the microbial pesticide formulation. As summarized above, EPA has regulatory authority for the registration of pesticides, and EPA is using Insect Resistance Management (IRM) plans to address this issue. APHIS has considered the voluntary IRM strategy that has been adopted by Monsanto and EPA to delay the development of resistant insects. APHIS concludes that a determination of nonregulated status from APHIS will not affect the oversight by EPA on this issue.

**B. Potato lines RBMT15-101, SEMT15-02, and SEMT15-15 are not likely to be more weedy than traditionally bred potato varieties.**

APHIS evaluated whether the transgenic potato lines RBMT15-101, SEMT15-02, and SEMT15-15 are any more likely to present a plant pest risk as weeds than nontransgenic potatoes. APHIS considered the wealth of experience in the cultivation with other varieties of potato and concluded that these transgenic lines are similar to other potatoes in that they are unlikely to be weed pests.

Most definitions of weediness stress the undesirable nature of weeds from the point of view of humans. From this starting point, individual definitions differ in approach and emphasis (Baker, 1965; de Wet and Harlan, 1975; Muenscher, 1980). Baker (1965) described the ideal characteristics of weeds, and although these characteristics have been criticized, no more broadly accepted set of characteristics have been defined by ecologists (Williamson, 1994). In the view of APHIS, there is no formulation that is clearly superior at this time. Keeler (1989) and Tiedje et al. (1989) have adapted and analyzed Baker's list to develop admittedly imperfect guides to the weediness potential of transgenic plants. Both authors emphasize the importance of looking at the parent plant and the nature of the specific genetic changes. Cultivated potato lacks most of these "weedy" characteristics (Keeler, 1989). Potato is not listed as a common, serious or

principal weed or a weed of current or potential importance in the United States or Canada (Holm et al., 1991; Muenscher, 1980; USDA, 1971; Weed Science Society of America, 1992).

It is unlikely that expression of the *cry3A*, *PVYcp*, and *nptII* genes in lines RBMT15-101, SEMT15-02, and SEMT15-15 will provide a competitive advantage that would cause these to become more "weedy" than nontransformed potatoes. The physical characteristics, disease susceptibility, and insect susceptibility of lines RBMT15-101, SEMT15-02, and SEMT15-15 were routinely compared to the attributes of nontransgenic potatoes during field trials. The field data reports indicated no obvious differences in the number of volunteers, emergence from seed potatoes, and disease and insect susceptibility (other than to target pests, CPB and PVY).

In addition, traditional resistance genes to CPB and PVY have been identified and used in certain potato cultivars. The USDA Germplasm Resources Information Network (GRIN, 1994) contains accessions of at least 15 different species in the genus *Solanum* L., subgenus *Potato*, section *Petota* reputed to have resistance to CPB and collected in countries (i.e., Costa Rica, Guatemala, Mexico, and the United States) where CPB is listed as a pest.

It is unlikely that expression of the Cry3A protein in these transgenic lines will provide a competitive advantage sufficient to cause these to be more "weedy" than standard or other potato cultivars. None of the characteristics of weeds described by Baker (1965) involved resistance or susceptibility to insects. Resistance to CPB does not seem to be a critical factor determining weediness in Solanaceous species. Some *Solanum* species listed as common weeds in the U.S., i.e., the nightshades, are not resistant to CPB, and in fact, some are common hosts, but they do have many of the other "weedy" characteristics described by Baker (Muenscher, 1955, USDA, 1971). Although no cultivated potato varieties are available that are resistant to CPB, varieties have been developed that are resistant to other insects. For example, the variety "Norchip" is resistant to flea beetle (Thompson, 1987) and is not known to be more "weedy" than the variety from which it was developed. The database of the USDA Germplasm Resources Information Network (GRIN, 1994) contains accessions of at least 15 different species in the genus *Solanum* L., subgenus *Potato*, section *Petota* reputed to have resistance to CPB and collected in countries (i.e., Costa Rica, Guatemala, Mexico, and the United States) where CPB is listed as a pest (C.A.B. International, 1991). None of these species is listed as a serious, principal or common weed in these countries by a leading weed compendium (Holm et al., 1991).

Traditional plant breeding has been used to introduce genes from other Solanum species into cultivated varieties of potato to confer resistance to PVY infection, but Russet Burbank and Shepody are susceptible. In their overview of potato breeding for resistance to PVY, Khurana and Garg (1998) state that many cultivars possess a high level of resistance to PVY. They cite the widespread incorporation of resistance genes, such as *Nc*, which confer resistance to PVY infection. Cockerham (1970) reported on PVY resistance genes in a number of wild Solanum species, including *S. stoloniferum*. There are no reports in the scientific literature which indicate that PVY resistance makes potatoes more likely to be weed pests. APHIS considered data and observations provided in the petition on the agronomic performance and disease and insect susceptibility of potato line evaluated in field tests. APHIS can find no indication that these potato lines should be any more "weedy" than the present potato cultivars that are the result of

traditional breeding. The observations reported in the Monsanto application further support APHIS' conclusion that these transgenic potato lines are no more likely to present a plant pest risk as a weed than nontransgenic potato cultivars which contain traditional resistance genes to CPB or PVY.

**C. Outcrossing of lines RBMT15-101, SEMT15-02, and SEMT15-15 with wild relatives is not likely to result in offspring that pose a plant pest risk as weeds.**

An analysis of the biology of cultivated potato and its relatives leads APHIS to conclude that the environmental impacts of cultivation of potato line would be no different from such impacts attributable to similar varieties produced by traditional breeding techniques. Non-cultivated, wild relatives of S. tuberosum have coexisted and co-evolved in the Americas over millennia. Even if these transgenic lines were to be cultivated in agricultural regions around centers of diversity in the Andean region of South America, there is no reason to expect impacts from the transgenic potato lines will be significantly different from the effects arising from the cultivation of any other varieties of potatoes. Neither the weediness nor the survival of the wild relative species are likely to be affected by the cultivation of the transgenic potato lines. This conclusion is based on the fact that the transgenic lines do not appear to be increased in their weediness. In addition, the transgenic lines are unlikely to successfully cross in nature with wild relative species. The Russet Burbank cultivar (parent of line RBMT15-101) does not produce viable pollen. The Shepody cultivar produces fertile pollen, but hybridization does not occur readily and requires human intervention for success. Another consideration is that the wild relative Solanum species are generally the source of traits that enhance the ability of the cultivated potato varieties to resist pathogens and insect pests. Therefore, it seems unlikely that any transfer of germplasm from the cultivated to wild plants will confer a selective advantage to the in the wild species.

**D. Potential impact on nontarget organisms, including those designated as threatened and endangered species.**

Consistent with its statutory authority and requirements under NEPA, APHIS evaluated the potential for the subject potato lines and plant products derived from them to have damaging or toxic effects directly or indirectly on nontarget organisms. This includes those that are recognized as beneficial to agriculture and those that are recognized as threatened or endangered in the United States. APHIS also considered potential impacts on other "nontarget" pests, since such impacts could have an impact on the potential for changes in agricultural practices.

APHIS can find no reason to believe that deleterious effects or significant impacts on nontarget organisms, including threatened and endangered species or beneficial organisms, would result from the *nptII* gene which confers kanamycin resistance and was used as a selectable marker during development of the transgenic potato lines. This protein has been approved for human consumption by FDA (Internet address http://vm.cfsan.fda.gov/~lrd/biotechm.html, see: Listing of final consultations under FDA's Biotechnology Policy). The application of kanamycin to these transgenic potato lines when grown on commercial scale is highly unlikely and would require additional Federal government review

APHIS concludes that the *PVYcp* gene and its gene product should not cause deleterious effects or significant impacts on nontarget organisms, including those species designated as threatened and endangered. Likewise, beneficial organisms should not be significantly impacted by the unconfined cultivation of these transgenic plants. This protein is found in all PVY-infected plants, and there are no reports of this protein (or PVY-infected plants) having any toxic effects (Matthews, 1991). EPA has granted the PVY coat protein an exemption for tolerance from FFDCA (http://www.epa.gov/fedrgstr/EPA-PEST/1997/August/Day-15/p21690.htm).

EPA has previously reviewed and approved the use of the plant-pesticide CryIIIA (synonymous with Cry3A) in several CPB- resistant potato plants. The EPA review included analysis of toxicity to mammals, allergenicity, and environmental fate. Environmental fate data included impacts on avian species, nontarget and beneficial insects, honeybees and nontarget organisms. EPA determined that CryIIIA will not affect threatened and endangered species (http://www.epa.gov/fedrgstr/EPA-PEST/1995/May/Day-03/pr-243.html; see also EPA's Pesticide Fact Sheet for Plant-Pesticide *Bacillus thuringiensis* CryIII(A) delta endotoxin and the genetic material necessary for its production in potato, Conditional Registration that is available upon request).

Based on this analysis, APHIS concludes that there is unlikely to be any significant adverse impact on the environment associated with the cultivation of these transgenic potato lines. APHIS concludes that the unconfined growth of the subject potato lines, and products derived from them, should have no deleterious effects on organisms recognized as beneficial to agriculture (e.g., earthworms, honey bees) or on other organisms, including any species recognized as threatened or endangered in the United States.

APHIS concludes that the cultivation of these lines pose no harm to threatened and endangered species and nontarget organisms. Based on this analysis, APHIS concludes that the unconfined cultivation of these transgenic lines should be equivalent to nontransgenic potato cultivars in its potential to impact biodiversity of *Solanum* species.

## E. Potential impacts on raw or processed agricultural commodities.

Consistent with its statutory authority which defines plant pests as those organisms which cause direct or indirect damage to plants and plant products, APHIS evaluated whether these transgenic potato lines might indirectly impact agricultural practices or harm plant products such as some agricultural commodities.

Based on its analysis, APHIS concludes that there is unlikely to be any significant adverse impact on agricultural practices associated with the use of these potato lines. In addition, APHIS concludes that the characteristics of these potato lines reveal no difference in any trait or characteristic that could have an indirect plant pest effect on any processed agricultural commodity.

In accordance with Executive Order 12114, January 4, 1979, entitled "Environmental effects abroad of major federal actions," APHIS has also considered potential environmental impacts

associated with the cultivation of the subject potato lines outside the United States and its territories.

Our analysis of the biology of potato leads to the conclusion that the cultivation of these transgenic potato lines either domestically or abroad would not have an adverse impact on the environment. In all analyses conducted by their developer, potato lines displayed no significant differences from its parent line, except for their resistance to CPB and PVY.

It should be noted that all the existing national and international regulatory authorities and phytosanitary protocols that currently apply to introductions of new potato varieties internationally will apply to these transgenic potato lines.

## VIII. CONCLUSIONS

APHIS has reviewed the information provided by Monsanto in its petition as well as other scientific data in evaluating the transgenic potato lines RBMT15-101, SEMT15-02 and SEMT15-15. After careful analysis of the available information, APHIS has identified no significant impact to the environment as a consequence of a determination that the subject lines should no longer be considered as regulated articles under the regulations at 7 CFR Part 340.

APHIS concludes that the transgenic potato lines RBMT15-101, SEMT15-02 and SEMT15-15:

(1) exhibit no plant pathogenic properties and will not pose an increased plant pest risk from the appearance of new plant viruses.;

(2) are no more likely to become weeds than pest resistant potato lines developed by traditional plant breeding;

(3) are unlikely to increase the weediness potential of any other cultivated or wild species with which they can interbreed;

(4) are unlikely to harm threatened or endangered species or organisms that are recognized as beneficial to agriculture, and

(5) will not cause damage to raw or processed agricultural commodities.

APHIS concludes that these potato lines and their progeny will be just as safe to grow as potato lines that are not subject to regulation under 7 CFR Part 340, and that there should be no significant impact on the human environment if these potatoes are no longer considered to be regulated articles.

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## XII. APPENDIX: DETERMINATION OF NONREGULATED STATUS FOR TRANSGENIC POTATO LINES RBMT15-101, SEMT15-02 and SEMT15-15

APHIS has reviewed the Monsanto petition (APHIS Number 97-339-01p) and other relevant information to reach a determination of nonregulated status for the transgenic potato lines RBMT15-101, SEMT15-02 and SEMT15-15. APHIS concludes that these lines do not pose a plant pest risk. Therefore, APHIS has determines that that the transgenic potato lines RBMT15-101, SEMT15-02 and SEMT15-15 will no longer be considered regulated articles under APHIS regulations at 7 CFR Part 340. Permits or notifications acknowledged under those regulations will no longer be required from APHIS for field testing, importation, or interstate movement of RBMT15-101, SEMT15-02 and SEMT15-15 or their progeny. This determination has been made based on data collected from these trials, laboratory analyses and scientific literature which support the following conclusions that these lines: exhibit no plant pathogenic properties; are no more likely to become a weed than similar pest-resistant potatoes developed by traditional breeding techniques; should not increase the weediness potential of resulting progeny or have an adverse impacts on biodiversity than similar pest-resistant potatoes which are developed by traditional breeding techniques; are substantially equivalent to nontransgenic tubers and should have no adverse impacts on raw or processed agricultural commodities; and exhibit no significant potential to either harm organisms beneficial to the agricultural ecosystem or to have an adverse impact on the ability to control nontarget insect pests, or to harm threatened and endangered species.

Sally L. McCammon
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