


USDA/APHIS Petition 94-228-01 for Determination of Nonregulated Status
for Delayed-Ripening Tomato Line 1345-4

Environmental Assessment and
Finding of No Significant Impact

January 1995

The Animal and Plant Health Inspection Service (APHIS) of the U. S. Department of Agriculture has conducted an environmental assessment prior to issuing a determination of nonregulated status for a genetically engineered delayed-ripening tomato designated line 1345-4. APHIS received a petition, from the DNA Plant Technology Corporation, regarding the status of the line 1345-4 as a regulated article under APHIS regulations at 7 CFR Part 340. APHIS has conducted an extensive review of the petition and supporting documentation, as well as other relevant scientific information. Based upon the analysis documented in this environmental assessment, APHIS has reached a finding of no significant impact on the environment from its determination that delayed-ripening tomato line 1345-4 shall no longer be a regulated article.



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native wild species with which the organism can interbreed; (4) is unlikely to harm other organisms, such as bees, that are beneficial to agriculture; and (5) will not cause damage to processed agricultural commodities. APHIS has also concluded that there is a reasonable certainty that new progeny varieties bred from tomato line 1345-4 will not exhibit new plant pest properties, i.e., properties substantially different from any observed in the field-tested tomato line, or those observed in traditional tomato breeding programs.

The effect of this determination is that tomato line 1345-4 and all other lines bred from this line by sexual or asexual reproduction involving Mendelian inheritance, are no longer considered regulated articles under APHIS' regulations in 7 CFR part 340. Therefore, the permit and notification requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of the subject tomato line or its progeny. However, the importation of the tomato line and any nursery stock or seeds capable of propagation are still subject to the restrictions found in APHIS' foreign quarantine notices in 7 CFR part 319.

National Environmental Policy Act

An environmental assessment (EA) has been prepared to examine the potential environmental impacts associated with this determination. The EA was prepared in accordance with: (1) The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500-1508), (3) USDA Regulations Implementing NEPA (7 CFR part 1b), and (4) APHIS Guidelines Implementing NEPA (44 FR 50381-50384, August 28, 1979, and 44 FR 51272-51274, August 31, 1979). Based on that EA, APHIS has reached a finding of no significant impact (FONSI) with regard to its determination that the tomato line designated as 1345-4 and other lines bred from the line by sexual or asexual reproduction involving Mendelian inheritance, are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and the FONSI are available upon request from the individual listed under FOR FURTHER INFORMATION CONTACT.

Done in Washington, DC, this 17th day of January 1995.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

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I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) prior to making a determination on the regulated status of a genetically engineered line of delayed-ripening tomato (*Lycopersicon esculentum*) designated hereafter as line 1345-4. The developer of line 1345-4, the DNA Plant Technology Corporation (DNAP), petitioned APHIS requesting a determination on the regulated status of line 1345-4 that has been a regulated article under APHIS regulations. Interstate movements and field tests of line 1345-4 have been conducted under permits issued by or notifications acknowledged by APHIS. DNAP has petitioned APHIS for a determination that line 1345-4 does not present a plant pest risk and should therefore no longer be a regulated article under the APHIS regulations found at 7 CFR Part 340.

The line 1345-4 has been developed in an effort to improve the flavor and quality of fresh market tomatoes and to make them available year-round to consumers. The genes conferring delayed ripening in line 1345-4 were introduced via genetic engineering techniques. The genetic engineering techniques enabled the developer to suppress the biosynthesis of the plant hormone ethylene that is involved in fruit ripening. Line 1345-4 was developed by inserting a truncated version of the tomato aminocyclopropane cyclase (ACC) synthase gene and a selectable marker gene neomycin phosphotransferase (*nptII*) into the genome of tomato cultivar 91103-114. The truncated ACC synthase gene does not encode a functional ACC synthase enzyme. The presence of this truncated gene inhibits the expression of the unmodified gene normally found in tomato, which is necessary for the production of ethylene. The *nptII* gene, isolated from a common bacterium, *Escherichia coli*, encodes an enzyme that confers resistance to certain antibiotics used in the selection of transformed cells. The genes were introduced via a well-characterized procedure that results in direct introduction of genes into plant genomes.

EAs were prepared before granting the permits for line 1345-4 field trials. Previous EAs addressed questions pertinent to plant pest risk issues concerning the conduct of field trials under physical and reproductive confinement, but they do not address several issues that are of relevance to the unconfined growth of line 1345-4. With respect to these new issues, APHIS concludes the following:

1. Tomato line 1345-4 exhibits no plant pathogenic properties. Although pathogenic organisms were used in the development of line 1345-4, these tomato plants are not infected nor can they incite disease in other plants.
2. Tomato line 1345-4 is no more likely to become a weed than a delayed-ripening tomato developed by traditional breeding techniques. Tomato is not a weed pest, and there is no reason to believe that a tomato plant with delayed ripening fruit will lead to this tomato becoming a weed pest.

3. Tomato line 1345-4 is unlikely to increase the weediness potential of any other cultivated or wild species with which it can interbreed.
4. Tomato line 1345-4 is unlikely to harm other organisms, such as bees, which are beneficial to agriculture.
5. Tomato line 1345-4 should not cause damage to processed agricultural commodities.

Therefore, after a review of the available evidence, APHIS believes that line 1345-4 will be just as safe to grow as traditionally-bred delayed-ripening tomato varieties not subject to regulation under 7 CFR Part 340. APHIS concludes that there will be no significant impact on the human environment if line 1345-4 were no longer considered a regulated articles under regulations at 7 CFR Part 340.

II. BACKGROUND

Development of line 1345-4. DNAP has submitted a "Petition for Determination of Non-regulated Status" to the USDA, APHIS for tomato plants that contain a gene that delays fruit ripening. DNAP requested a determination from APHIS that the line 1345-4, and any progeny derived from hybrid crosses between this line and other non-transformed tomato varieties, no longer be considered regulated articles under 7 CFR Part 340.

Using Transwitch[™] gene suppression technology, introduction of a truncated version (i.e., a partial copy) of the tomato ACC synthase gene into the tomato genome in the "sense" or normal orientation, resulted in tomato plants that exhibit significantly reduced levels of ACC synthase. The truncated ACC synthase gene coding region is fused to the 35S promoter from cauliflower mosaic virus and the termination sequence from the nopaline synthase gene (*nos*) from *Agrobacterium tumefaciens*. Because only part of the ACC synthase gene is present, it does not code for an active enzyme. ACC synthase is the rate limiting enzyme that converts s-adenosylmethionine to 1-aminocyclopropane-1-carboxylic acid, the immediate precursor to ethylene. Ethylene is a plant hormone known to play an important role in fruit ripening in tomato. Inhibition of ACC synthase biosynthesis results in reduced levels of ethylene biosynthesis. Fruit of these plants exhibit delayed ripening, but ripen as usual when ethylene is applied.

Line 1345-4 has also been transformed with the *nptII* gene from *E. coli* that encodes the enzyme neomycin phosphotransferase II and serves as a selectable marker enabling identification of the transformed plant cells. This gene is fused to *nos* promoter sequence and octopine synthase termination sequence from *A. tumefaciens*, a known plant pest.

These two genes were introduced into line 1345-4 via an *Agrobacterium*-mediated transformation. This is a well-characterized procedure that has been used widely for over a decade for introducing various genes of interest directly into plant genomes.

Line 1345-4 has been field tested since 1992 in the major tomato growing regions of the United States under permits and acknowledgements of notifications by APHIS (USDA No. 92-035-05, 92-301-01, 93-056-01, 93-252-07, 93-302-01, 93-351-02, 94-060-04) and is currently being tested in additional locations in California (USDA Permit No. 94-126-01, 94-158-01, 94-172-01). Line 1345-4 has been evaluated extensively in laboratory, greenhouse, and field experiments to confirm that it exhibits the desired agronomic characteristics and does not pose a plant pest risk. Although the field tests of line 1345-4 have been conducted in agricultural settings, the permit conditions for the tests have stipulated physical and reproductive confinement from other plants.

APHIS Regulatory Authority. APHIS regulations at 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.

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. Line 1345-4 described in the DNAP petition has been considered a regulated article because noncoding DNA regulatory sequences and portions of the plasmid vector are derived from plant pathogens.

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, the Agency can grant the petition in whole or in part. As a consequence, APHIS permits would no longer be required for field testing, importation, or interstate movement of that article or its progeny.

III. PURPOSE AND NEED

APHIS has prepared this EA before making a determination on the status of line 1345-4 as a regulated article under APHIS regulations. The developer of line 1345-4, DNA Plant Technology Corporation, submitted a petition to USDA, APHIS requesting that APHIS make a determination that line 1345-4 shall no longer be considered a regulated article under 7 CFR Part 340.

This EA was prepared in compliance with the National Environmental Policy Act (NEPA) of 1969 (40 CFR 1500-1508) and the pursuant implementing regulations published by the Council on Environmental Quality (42 USC 4331 *et seq.*; 40 CFR 1500-1508; 7 CFR Part 1b; 44 FR 50381-50384; and 44 FR 51272-51274).

IV. ALTERNATIVES

A. No Action.

Under the Federal "no action" alternative, APHIS would not come to a determination that line 1345-4 is not a regulated article under the regulations at 7 CFR Part 340. Permits from APHIS would still be required for introductions of line 1345-4. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from uncontained cultivation of line 1345-4.

B. Determination that line 1345-4 is no longer a regulated article.

Under this alternative, line 1345-4 would no longer be a regulated article under the regulations at 7 CFR Part 340. Permits from APHIS would no longer be required for introductions of line 1345-4. A basis for this determination would include a "Finding of No Significant Impact" under the National Environmental Policy Act of 1969 (42 USC 4331 *et seq.*; 40 CFR 1500-1509; 7 CFR Part 1b; 44 FR 50381-50384; and 44 FR 51272-51274).

V. AFFECTED ENVIRONMENT AND POTENTIAL ENVIRONMENTAL IMPACTS

This EA addresses potential environmental impacts from a determination that line 1345-4 should no longer be considered a regulated article under APHIS regulations at 7 CFR Part 340. Previous EAs prepared by APHIS together with the issuance of permits for field tests of line 1345-4 have addressed various attributes of this tomato. This EA discusses the genetic modification, and the potential environmental impacts that might be associated with the unconfined cultivation of line 1345-4.

Additional technical information is included in the determination document appended to this EA, and incorporated by reference. This

includes detailed discussions of the biology of tomato, the genetic components used in the construction of line 1345-4, and the analyses that lead APHIS to conclude that line 1345-4 has no potential to pose plant pest risks.

A. Potential impacts based on increased weediness of line 1345-4 relative to traditionally bred delayed-ripening tomato

Although various definitions of the term "weed" have been proposed in the scientific literature, the salient point is that a plant can be considered a weed when it is growing where humans do not want it (Baker, 1965; de Wet and Harlan, 1975; Muenscher, 1980). Baker (1965) lists 12 common attributes that can be used to assess the likelihood that a plant species will behave as a weed. 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.

The cultivated tomato is not considered a weed pest and is unlikely to become a weed pest. The cultivated tomato is a perennial that is grown almost exclusively as an annual crop in the United States. Tomato is considered a highly inbred, well-characterized crop plant that is not persistent in undisturbed environments without human intervention. Although tomato volunteers are not uncommon, they are easily controlled using herbicides or mechanical means. Tomatoes also possess few of the characteristics of plants that are notably successful weeds (e.g., it does not produce abundant, long-lived seed; it does not propagate vegetatively; it does not compete well with other plant species in the environment).

Furthermore, the tomato has been grown for centuries throughout the world without any reports that it is a serious weed pest. In the United States, tomato 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 State of California or the Federal Government (7 CFR Part 360).

The parent plant of the line 1345-4 is an agricultural crop plant that exhibits no appreciable weedy characteristics. The relevant introduced trait, inhibition of ethylene biosynthesis, is unlikely to increase weediness of line 1345-4. There is no indication that the presence of a truncated ACC synthase gene in resulting line 1345-4 will convert it into a weed. No other attributes of line 1345-4 tomato suggest that it be any more "weedy" than the present tomato cultivars that are the result of traditional breeding. The line 1345-4 has retained the agronomic characteristics of the parental tomato. DNAP has provided data regarding seed germination rates, yield characteristics, disease and pest susceptibilities, and fruit compositional analyses that support APHIS' conclusion that line 1345-4 is just as safe to grow as any other delayed-ripening tomato.

B. Potential impacts on the sexually-compatible relatives of tomato arising from pollination by line 1345-4

Tomato does not cross-pollinate with other plants in the United States without the intervention of man. Cultivated tomato is self-fertile and is almost exclusively self-pollinating, due, in part, to the presence of an inserted stigma developed through over 50 years of breeding (Rick, 1976). Cultivated tomato is not wind-pollinated and insect pollination is limited (Rick, 1976).

Many other members of the nightshade family are found as weeds in tomato fields. *L. esculentum* is sexually incompatible with all these weedy relatives (Rick, 1979). Two *Solanum* species, *S. lycopersicoides* and *S. rickii* can be crossed with commercial tomato under specific, controlled conditions, but they do not naturally cross with *L. esculentum* (Stevens and Rick, 1986; DeVerna et al., 1990). Neither of these *Solanum* species is a weed pest in the United States.

The cherry tomato, *L. esculentum* var. *cerasiforme*, was most likely the wild progenitor of the cultivated tomato (Rick, 1983). Some biotypes of *L. esculentum* var. *cerasiforme* are successful weeds that have spread throughout tropical America and into southern Texas and Florida (Rick, 1973). Cherry tomato, however, is not considered a weed pest. Although *L. esculentum* var. *esculentum* and var. *cerasiforme* can cross with either plant as male or female parent (Rick, 1979), the probability of line 1345-4 tomato naturally introgressing into var. *cerasiforme* in the United States is almost nil since the rate of outcrossing in var. *esculentum* is low (Rick, 1949; C. M. Rick, personal communication), and var. *cerasiforme* is not present in areas of the U.S. that are devoted to large scale cultivation of tomatoes (J. W. Scott, personal communication to M. Schechtman). There are no published reports that visible traits of cultivated tomato have introgressed into var. *cerasiforme* from cultivated tomatoes in areas where the wild cherry tomato commonly grows.

Because tomato has no relatives other than itself with which it can naturally cross in the United States, and because commercial tomatoes are virtually exclusively self-pollinating, there is little possibility of a cross unaided by man between the line 1345-4 tomato and another plant. Therefore, there is no likelihood that the line 1345-4 tomato will increase the weedy potential of another plant. Cultivation of *L. esculentum* requires maintenance of genetic purity as a standard breeding practice. Regulations specifying procedures for the maintenance of genetic purity have been codified (See 7 CFR Part 201). Even if an outcrossing event involving pollen from a line 1345-4 tomato did occur, there is no reason to believe that the delay in fruit softening brought about by the delayed ripening phenotype could affect seed persistence or weediness potential in progeny. Expression of the truncated ACC synthase gene in any of the lines thus far tested has not changed any morphological or physiological characteristics

that might affect pollination, and there is also no reason to believe that this characteristic could be affected by the introduced genes.

Our analysis of the biology of cultivated delayed-ripening tomato and its relatives leads us to predict that the environmental impacts of cultivation of line 1345-4 anywhere in the world would be no different from such impacts attributable to similar varieties produced with traditional breeding techniques. The species *L. esculentum* is native to the Andes with a center of biological diversity in Peru. Non-cultivated varieties of *Lycopersicon* sp. have not coexisted and co-evolved in the Americas over millennia. Even if line 1345-4 were to be cultivated in agricultural regions around centers of *Lycopersicon esculentum* diversity, there is no reason to expect impacts from line 1345-4 to be significantly different from those arising from the cultivation of any other variety of delayed-ripening tomato (e.g., *rin* phenotype tomato).

Our decision in no way prejudices regulatory action in Mexico or any other country. We note also that any international traffic in line 1345-4 would be fully subject to national and regional phytosanitary standards promulgated under the International Plant Protection Convention (IPPC). The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (98 countries as of December 1992). The treaty, now administered by a Secretariat housed with the United Nations Food and Agriculture Organization in Rome, came into force on April 3, 1952. It establishes standards to facilitate the safe movement of plant materials across international boundaries. Plant biotechnology products are fully subject to national legislation and regulations, or regional standards and guidelines promulgated under the IPPC. The vast majority of IPPC signatories have promulgated, and are now administering, such legislation or guidelines. This includes Mexico, which has in place a regulatory process requiring a full evaluation of line 1345-4 before it can be introduced into their environment. The IPPC has also led to the creation of Regional Plant Protection Organizations (RPPOs) such as the North American Plant Protection Organization (NAPPO). Our trading partners will be kept informed of our regulatory decisions through NAPPO and other fora. In addition to the assurance provided by the analysis leading APHIS to a finding of no significant impact for the introduction of this delayed-ripening tomato variety, it should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary protocols that currently apply to introductions of new delayed-ripening tomato varieties internationally apply equally to those covered by this analysis.

C. Potential impacts on nontarget organisms, including beneficial organisms such as bees and earthworms

Consistent with its statutory authority, APHIS evaluated whether line 1345-4 might indirectly harm plants or plant products (such as some

agricultural commodities). APHIS considered the potential impacts that line 1345-4 might exert indirectly on organisms that are recognized as beneficial to agriculture. APHIS concludes that there is no reason to believe that the unconfined growth of line 1345-4 will pose any deleterious effects or significant impacts on nontarget organisms, including beneficial organisms. The truncated ACC synthase gene is not expressed in line 1345-4 and should not have any toxic properties.

APHIS believes that line 1345-4 will have no deleterious effects on organisms recognized as beneficial to agriculture (e.g., earthworms, honey bees). In addition, there is no reason to believe that the presence of line 1345-4 would have any adverse effect on other organisms, including any species recognized as threatened or endangered in the United States. The release of line 1345-4 from regulation should have no adverse impact on agricultural commodities.

D. Potential impacts on agricultural and cultivation practices.

Delayed-ripening tomatoes may alter agricultural practices by reducing the number of harvests required in a production field, thereby reducing labor and other cost factors in fruit harvesting and losses in shipping. These potential changes will be minor.

E. Line 1345-4 will not cause damage to processed agricultural commodities.

In APHIS' opinion, the components and processing characteristics of line 1345-4 reveal no differences in any component that could have an indirect plant pest effect on any processed plant commodity.

VI. CONCLUSION

APHIS has evaluated information from the scientific literature as well as data submitted by DNA Plant Technology Corporation that characterized line 1345-4. After careful analysis, APHIS has identified no significant impact to the environment from issuance of a determination that line 1345-4 should no longer be a regulated article under APHIS regulations at 7 CFR Part 340.

APHIS has considered the foreseeable consequences of removing line 1345-4 from its regulation, and has reached the following conclusions:

1. Tomato line 1345-4 exhibits no plant pathogenic properties. Although pathogenic organisms were used in the development of line 1345-4, these tomato plants are not infected nor can they incite disease in other plants.
2. Tomato line 1345-4 is no more likely to become a weed than a delayed-ripening tomato developed by traditional breeding techniques. Tomato is not a weed pest, and there is no reason to believe that a

tomato plant with delayed ripening fruit will lead to this tomato becoming a weed pest.

3. Tomato line 1345-4 is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed.

4. Tomato line 1345-4 is unlikely to harm other organisms, such as bees that are beneficial to agriculture.

5. Tomato line 1345-4 should not cause damage to processed agricultural commodities.

Therefore, after review of the available evidence, APHIS concludes that line 1345-4 will be just as safe to grow as traditionally-bred, delayed-ripening tomato varieties that are not subject to regulation under 7 CFR Part 340. APHIS concludes that there should be no significant impact on the human environment if line 1345-4 were no longer considered a regulated article under its regulations (7 CFR Part 340).

VII. LITERATURE CITED

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