

Richard Shank, Ph.D.
Senior Vice President
Regulatory and Governmental Affairs

September 13, 2010

The Honorable Tom Vilsack
Secretary
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250

Re: Confirmation of Regulatory Status

Dear Secretary Vilsack:

The Scotts Miracle-Gro Company (Scotts) has genetically modified Kentucky bluegrass (*Poa pratensis L.*) to be glyphosate tolerant without using plant pest components. Because Kentucky bluegrass itself is not a plant pest, no plant pest components will be involved in the transformation, and the native plant genomes that will be used are fully classified, there is no scientifically valid basis for concluding that transgenic Kentucky bluegrass is or will become a plant pest within the meaning of the Plant Protection Act. Scotts therefore maintains that under current regulations, transgenic Kentucky bluegrass is not a regulated article within the meaning of 7 C.F.R. § 340.1 because it does not satisfy any of the regulatory criteria that would subject it to the Animal Plant Health and Inspection Service's (APHIS) oversight.

Before proceeding further, Scotts requests that APHIS confirm that Kentucky bluegrass modified without plant pest components (as described more fully below) is not a regulated article within the meaning of the current regulations. If the agency does not concur with Scotts' interpretation of the current regulatory scheme, Scotts requests that the Agency provide Scotts with its scientific rationale for concluding that Kentucky bluegrass is or will become a plant pest. Scotts is proceeding with its plans to develop this product beginning with agronomic field trials in the coming months.

I. Glyphosate Tolerant Kentucky bluegrass (*Poa pratensis L.*)

Transformation of Kentucky bluegrass is stably integrated using purified trait DNA transferred by biolistics. DNA transfer does not involve *Agrobacterium* transformation or any other plant pest regulated under the Plant Protection Act. The genetically enhanced material is expressing a more glyphosate tolerant form of 5-enolpyruvylshikimate-3-phosphate synthase from *Arabidopsis thaliana*. The resultant phenotype is a turf grass with glyphosate tolerance.

Donor Genetic Elements:

- 5-enolpyruvylshikimate-3-phosphate synthase from *Arabidopsis thaliana*
- ubiquitin promoter from *Oryza sativa*
- actin intron from *Oryza sativa*
- alcohol dehydrogenase 3' UTR from *Zea mays*

II. Recipient Kentucky bluegrass (*Poa pratensis* L.)

Kentucky bluegrass is not a federal noxious weed. It is listed as an agricultural seed (7 C.F.R. Part 361), and is commonly grown on both home and government lawns. Kentucky bluegrass is native to practically all of Europe, northern Asia, and the mountains of Algeria and Morocco. It is adapted for growth in cool, humid climates, and is most prevalent in the northern half of the United States and the southern half of Canada. It is not common in the Gulf states or in desert regions of the Southwest.

III. APHIS's Interpretation of Its Part 340 Regulations Dictates a Finding that Transgenic Kentucky bluegrass Is Not A Regulated Article

A. APHIS Has Made Clear That Not All Transgenic Plants Are Subject to Regulation

APHIS defines a "regulated article" as:

Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in Sec. 340.2 and meets the definition of plant pest, *or* is an unclassified organism and/or an organism whose classification is unknown, *or* any product which contains such an organism, *or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest.* Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

Id. § 340.1 (emphasis added).¹ Consistent with the PPA's statutory definition of a plant pest, APHIS has elaborated by rule on the definition of a plant pest:

¹ The term "well characterized and contains only non coding regulatory regions" (i.e. operators, promoters, origins of replication, terminators, and ribosome binding regions) means the genetic material added to a microorganism in which the following can be documented: (a) the exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides; (b) The regulatory region and inserted flanking nucleotides do not code for protein or peptide; and (c) the regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis. 52 Fed. Reg. at 22897.

any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

7 C.F.R. § 340.1.

APHIS claims that its regulations are consistent with the Coordinated Framework, because they apply “only [to] genetically engineered organisms or products which are plant pests or for which there is reason to believe are plant pests, and not to . . . an organism or product merely because of the process by which it was produced.”² 51 Fed. Reg. 23352 (proposed rule); 52 Fed. Reg. 22892 (final rule where similar language is used). APHIS has further stated that its concern arises only “when an organism or product is altered or produced by genetic engineering and one or more of its constituents (donor, vector/vector agent or recipient) comes from a family or genus of organisms known to contain plant pests. . . . This is because . . . there is a risk that certain undesirable traits may be transferred to the new organism and may survive when the organism is released into the environment.” 51 Fed. Reg. at 23352.

Moreover, when APHIS amended the regulations in 1993 to establish the notification system for the confined release of transgenic organisms, APHIS reiterated that it believed its policies were consistent with the Coordinated Framework and OSTP policy statements. The preamble to the proposed rule states:

This proposed rule is consistent with the overall Federal policy for the regulation of the products of biotechnology. The proposed rule would reduce regulatory constraints on certain introductions to achieve the Federal policy goal of oversight commensurate with the risk; the President's regulatory review initiative of January 28, 1992; and the Department's request for comments. The proposed rule would also achieve the Federal policy goal of performance-based regulatory principles as outlined in the President's Council on Competitiveness "Report on National Biotechnology Policy" (February 1991).

57 Fed. Reg. 53036 (citations omitted).

² In 1986, the White House Office of Science and Technology (OSTP) published the Coordinated Framework for the Regulation of Biotechnology (the “Coordinated Framework”) to provide guidance for using existing federal statutes and the expertise of existing regulatory agencies to ensure health and environmental safety while maintaining flexibility to allow the growth of the biotechnology industry. *See* 51 Fed. Reg. 23302 (June 26, 1986). The Coordinated Framework is based on the principle that techniques of biotechnology are not inherently risky.

In its October 2008 proposed revision to its regulations, APHIS elaborated on the definition of a plant pest stating, “most plants are not plant pests, with the exception of a few parasitic plant species, such as striga, witchweed, and dodder.” 73 Fed. Reg. 60008, 60010 (Oct. 8, 2008). Rather, plant pests are “organisms” that harm plants. *Id.* Accordingly, APHIS has, on numerous occasions, made clear that not all transgenic plants are to be regulated and, those that are, belong to the limited group of plant pests defined in the regulations.

B. Transgenic Kentucky bluegrass Does Not Fall Within the Regulatory Definition of a Regulated Article

Under APHIS regulations, a transgenic organism is considered a “regulated article” if (1) the donor organism, recipient organism, or vector agent belongs to a genera or taxa designated in 7 C.F.R. § 340.2, *and* (2) the organism meets the definition of a plant pest. The plain language of the regulation requires that both criteria must be satisfied to meet the definition of a regulated article.

Neither the donor organism, nor the recipient organism, nor the vectors Scotts will employ to transform Kentucky bluegrass belong to any taxa identified in § 340.2. Instead, the genetically enhanced material is expressing 5-enolpyruvylshikimate-3-phosphate synthase from *Arabidopsis thaliana*, promoter from *Oryza sativa* and 3’ untranslated region from *Zea mays* with no elements derived from any taxa identified in § 340.2. Therefore, transgenic Kentucky bluegrass does not satisfy the first criterion for a “regulated article.” Since the first criterion is not satisfied, it is not necessary to consider the second criterion. Nevertheless, as shown below, Kentucky bluegrass does not meet the definition of a plant pest set forth in § 340.1. Accordingly, the plain language of the regulation dictates that transgenic Kentucky bluegrass is not a “regulated article.”

The definition of a regulated article also includes transgenic organisms that are unclassified or whose classification is unknown, and any plant product which contains such organisms. There can be no dispute that Kentucky bluegrass, *Arabidopsis*, corn and rice are well classified. Consequently, transgenic Kentucky bluegrass cannot be considered a regulated article because it is unclassified or because its classification is unknown.

APHIS may also regulate organisms or products altered or produced through genetic engineering which APHIS determines are plant pests or has reason to believe are plant pests. There is no scientifically credible argument that transgenic Kentucky bluegrass is or may be a plant pest. The regulatory definition of a plant pest is the same for transgenic organisms as it is for non-transgenic organisms, *i.e.*, insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants. 7 C.F.R. § 340.1. As APHIS recently stated, “most plants are not plant pests, with the exception of a few parasitic plant species, such as striga, witchweed, and dodder.” 73 Fed. Reg. 60008, 60010 (Oct. 8, 2008). Rather, plant pests are “organisms” that harm plants. *Id.* Indeed, APHIS has identified two types of organisms that are of primary concern: (1) pathogens, predators, or parasites (except autoparasitoids) of important natural enemies of plant pests or weeds, or (2) pathogens,

predators, or parasites of important or commercially available pollinators such as honeybees, bumble bees, and alkali bees. *See* 66 Fed. Reg. 51340 (Oct. 9, 2001).

The trait of transgenic Kentucky bluegrass is herbicide resistance to glyphosate, which is not novel. Glyphosate tolerance does not change the plants' basic biological characteristics. The mere presence of the trait does not produce a plant that would directly feed on, infect, parasitize, or contaminate plants, or adversely affect other organisms that are beneficial to plants.

IV. Finding That Transgenic Kentucky bluegrass Is Not A Regulated Article is Consistent With Previous APHIS Determinations

Finding that transgenic Kentucky bluegrass is not a regulated article is consistent with other APHIS regulatory determinations. For example, APHIS recently concluded that genetically engineered petunia that were transformed using genes derived from *Petunia hybrida* and *E. coli*, and transferred by biolistics were not regulated articles. *See* BRS letter to New Zealand Crop and Food Limited dated May 19, 2008 (attached). APHIS determined that the GM petunia was not a regulated article because neither the recipient organism nor the donor organism belongs to any of the genera of plant pests listed in Part 340.2. APHIS also found that no plant pest sequences would be used, even though the *nptII* gene was derived from *E. coli*. On April 20, 2010, APHIS reconfirmed that GM petunia is not a regulated article. *See* E-mail from M. Gregoire to M. Boase (attached).

Transgenic Kentucky bluegrass has been modified in exactly the same manner as the GM petunia, *i.e.*, by using native plant genomes that are not among the genera of plant pests listed in Part 340.2 and transferring DNA by biolistics.

In addition, APHIS found that GE scented geranium was not a regulated article. *See* BRS letter to Dr. John Sanford dated Feb 5, 1993 and related correspondence (attached). The GE scented geranium was modified with wild-type *Agrobacterium rhizogenes* and did not involve the use of recombinant DNA techniques. APHIS concluded that to fall within the definition of a regulated article, the organism must involve a plant pest component *and* be modified by recombinant DNA techniques. Thus, even though the GE geranium involved a plant pest component, because it was not modified using recombinant DNA techniques, it was not a regulated article.

Conclusion

In summary, Kentucky bluegrass is not itself a plant pest, there is no plant pest component involved in the modification of Kentucky bluegrass, and the native plant genomes that will be used have been fully classified. Thus, there is no scientifically valid basis for considering that transgenic Kentucky bluegrass is or will become a plant pest within the meaning of the Plant Protection Act.

Scotts looks forward to receiving the Agency's response

Sincerely,

A handwritten signature in black ink, appearing to read "Rich Shank". The signature is written in a cursive, flowing style.

Richard Shank, Ph.D.
Senior Vice President
Regulatory and Government Affairs

cc: Max Holtzman, Senior Advisor to the Secretary, U.S. Department of Agriculture
Michael Gregoire, BRS Deputy Administrator, U.S. Department of Agriculture



**United States
Department of
Agriculture**

Animal and
Plant Health
Inspection
Service

Marketing &
Regulatory
Programs Business
Services

4700 River Road
Riverdale, MD
20737

Biotechnology Regulatory Services
U.S. Department of Agriculture
4700 River Road, Riverdale, MD 20737

Dr. Murray Boase
Project Leader/Senior Scientist
New Zealand Crop and Food Limited
Plant & Food Biotechnology Group
Crop & Food Research,
Private Bag 11 600,
Palmerston North 4442,
New Zealand

May 19, 2008

Dear Dr. Boase,

This letter is in response to your inquiry of December 12, 2007 for an opinion on the regulatory status of two lines of genetically engineered *Petunia*.

Based on the information you provided about the transformations that Crop and Food Research proposes to use:

1- a petunia chlorophyll A/B binding promoter with a petunia MYB transcription factor that up-regulates the anthocyanin pigment pathway with no selectable marker and no DNA from any other donor. DNA will be transferred using biolistics and will not involve *Agrobacterium* transformation.

2 - All other conditions remain the same, including transformation with biolistics, with the addition of the *nptII* gene from *Escherichia coli* under a native petunia promoter and terminator as a selectable marker.

For the two cases that you outlined in your letter, the genetically engineered *Petunia* plants do not meet the definition of a regulated article and therefore they are not subject to regulation by USDA APHIS under 7 CFR 340. This opinion is based on the following:

- The genus *Petunia* is not among the genera of plant pests listed in Part 340.2. So neither the recipient organism nor the donor organism is considered a plant pest.
- No plant pest sequences are contained in the two examples. Neither *Petunia* nor *E. coli* is considered a plant pest under 7CFR340.2. In the first example, all genes are derived from petunia so no plant pest sequences are used. In the

second example, the *nptII* gene is derived from *E. coli* which is not considered a plant pest sequence.

Therefore, APHIS does not consider the intragenic petunia with and without the *nptII* gene to be a regulated article under current BRS regulations and you will not need a permit from BRS to release, grow or sell these two petunias in the United States. If these are imported from New Zealand they would, however, be subject to nursery stock import regulations under APHIS' Plant Protection and Quarantine (PPQ).

It is important to note that APHIS is currently revising the regulations in 7 CFR 340. We encourage you to monitor the development of these revisions to assess the impact they may have on this determination once they are published.

Michael C. Gregoire

Michael C. Gregoire
Deputy Administrator

Murray Boase

From: Michael.C.Gregoire@aphis.usda.gov
Sent: Tuesday, 20 April 2010 2:37 a.m.
To: Murray Boase
Cc: Nick Ashby
Subject: Re: revision 7CFR340 and petunia opinion

Dear Dr. Boase,

We published proposed changes to our regulations in October, 2008 but we have not as yet published a final version of our new regulations. The letter I sent you is still valid. The following is a link to our web site that provides information about our regulatory revisions. You can check this site from time to time to obtain information about the status of the rule. Thank you.

http://www.aphis.usda.gov/biotechnology/340/340_index.shtml

Michael C. Gregoire
Deputy Administrator, Biotechnology Regulatory Services
Animal and Plant Health Inspection Service, USDA
4700 River Road, Unit 98, Riverdale, Maryland 20737
Phone: 301-734-7324 Fax: 301-734-6352
E-Mail: Michael.C.Gregoire@aphis.usda.gov

"Murray.Boase@plantandfood.co.nz"
<Murray.Boase@plantandfood.co.nz>

To "Michael.C.Gregoire@aphis.usda.gov" <Michael.C.Gregoire@aphis.usda.gov>
cc "Nick.Ashby@plantandfood.co.nz" <Nick.Ashby@plantandfood.co.nz>

Subject revision 7CFR340 and petunia opinion

04/18/2010 10:17 PM

19 April 2010

Dear Dr Michael Gregoire,

During May 2008, you kindly replied to my request of 12 December 2007, for an opinion on the regulatory status of two lines of genetically engineered *Petunia*. In the last paragraph of that letter (copy attached), you mentioned that it was important to note that APHIS was currently revising the regulations in 7CFR 340. Have these revisions been published yet please and if so, how do they impact on the non-regulation status that was determined for the two petunia lines, described in your letter of May 19, 2008? With thanks,

Yours faithfully,

Murray Boase

Murray Boase
Senior Scientist, Plant Biotechnology

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F: +64 6 351 7050

murray.boase@plantandfood.co.nz

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The New Zealand Institute for Plant & Food Research Limited

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Batchelar Road, Palmerston North, 4474, New Zealand

[attachment "image002.jpg" deleted by Michael C Gregoire/MD/APHIS/USDA] [attachment "Petunia opinion letter.5.19.08 copy.doc" deleted by Michael C Gregoire/MD/APHIS/USDA]

Sanford Scientific, Inc.

877 Marshall Rd/Waterloo, NY 13165

Phone: 315-539-1200/Fax: 315-539-0337



December 8, 1992

San 12-8-92

Cathy Joyce

USDA-/Aphis - Biotechnology

FAX: 301-436-8669

Dear Cathy,

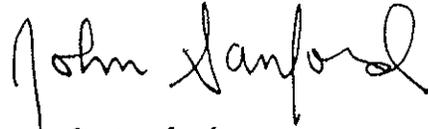
We spoke recently by phone about my small company's desire to release and market a transgenic plant. We have transgenic plants of scented geranium (Pelargonium sp.). Scented geranium is native to South Africa. In North America, scented geranium is grown as a house plant - primarily for its fragrance. Our collaborator, Dr. David Tepfer, INRA, France, has found that the wild-type form of Agrobacterium rhizogenes can infect scented geranium, resulting in classical 'hairy roots'. These transgenic roots bear the natural T-DNA from A. rhizogenes, and this process clearly occurs in nature. Dr. Tepfer has found that some of these roots spontaneously give rise to shoots and intact, transgenic plants. This basic process has been well characterized for many years and occurs naturally (hence plants can be found in nature that still have remnants of T-DNA from natural Agrobacterium transformation events from long ago).

Some of Dr. Tepfer's plants have a distinctly compact habit, due to the natural genes within the T-DNA (this compact habit is a well-known phenotype of such natural A. rhizogenes transformants). In the case of scented geraniums, this habit is horticulturally desirable, in that scented geraniums get very long and etiolated (unattractive) under low light conditions. Therefore, it is these compact plants we wish to release and market.

I would like to emphasize that such plants only contain wild-type T-DNA of Agrobacterium rhizogenes, and no other 'engineered' selectable, or scorable markers, foreign promoters, etc. They clearly are capable of arising naturally.

In this light, we would be very grateful for a letter from your agency, indicating that any plants we produce bearing only wild-type A. rhizogenes DNA are exempt from restrictions from your agency. This is basically what we discussed by phone. Thank you very much for your friendly cooperation.

Sincerely,

A handwritten signature in cursive script that reads "John Sanford". The signature is written in black ink and is positioned above the typed name and title.

John Sanford
President

Sanford Scientific, Inc.

877 Marshall Rd/Waterloo, NY 13165

Phone: 315-539-1200/Fax: 315-539-0337



1/5/93

Cathy Joyce
USDA-/APHIS - Biotechnology
FAX: 301-436-8669

Dear Cathy,

This letter follows your request by phone for clarification on several minor points.

1. *We are only requesting exemption where wild-type T-DNA is introduced from Agrobacterium rhizogenes. We understand that if the T-DNA has been engineered in any way, we will need to re-apply for approval from your agency.*

2. *Our first plants will come from Dr. David Tepfer, INRA, France. We understand that we need an APHIS import permit to bring in such plants, and have already obtained this. Additional plants will be produced by the same method, here in our lab.*

3. *In terms of credentials and scientific competence, Dr. Tepfer is recognized as the world authority on A. rhizogenes and the introduction of its wild-type T-DNA into plants. I am myself a scientist with over 70 publications, over 50 in the area of genetic engineering, and am recognized as an authority in the area of gene delivery into plants.*

I trust this clarifies any uncertainty. Best wishes to you in the new year.

Sincerely,

*John Sanford, Ph.D.
President*



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology,
Biologics, and
Environmental
Protection

FEB 05 1993

Dr. John Sanford
877 Marshall Rd.
Waterloo, NY 13165

Dear Dr. Sanford:

This letter is in response to your letter of December 8, 1992, which requested clarification on whether certain scented geranium plants are regulated by the Animal and Plant Health Inspection Service (APHIS). Your letter stated that the geranium plants were developed by transformation with wild-type *Agrobacterium rhizogenes*, with the result that the presence of wild-type R-DNA in the plant genome confers a horticulturally desirable trait on the modified plants.

Under the Plant Quarantine Act (PQA, 7 USC 151-164a, 166-167) and the Federal Plant Pest Act (FPPA, 7 USC 150aa et seq.) the United States Department of Agriculture is authorized to prevent the introduction, spread, or establishment of plant pests new to or not widely prevalent in the United States. Regulations implementing this authority are codified in Volume 7, Chapter 3 of the Code of Federal Regulations (CFR) and the following paragraphs discuss those regulations that potentially apply to the development, importation, and distribution of the modified scented geranium.

The importation of nursery stock, plants, roots, bulbs, seeds, and other plant products is regulated by the Plant Protection and Quarantine (PPQ) division of APHIS in accordance with 7 CFR Section 319.37. For further information in this regard please contact Permit Unit, PPQ, APHIS, Room 632, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland, 20782. The Permit Unit can be reached by phone at Area Code (301) 436-8645. Additionally, please be advised that a permit from PPQ, APHIS, may be required under 7 CFR Part 330 for the importation or interstate movement of wild-type *Agrobacterium rhizogenes*. For further information in this regard, please contact Dr. Bisham Singh, Room 627, Federal Building, at the address listed above. Dr. Singh can be reached by phone at Area Code (301) 436-8896.

The regulations in 7 CFR Part 340, entitled "Introduction of Organisms and Products Altered for Produced Through Genetic Engineering Which Are Plant Pests Or Which There Is Reason To Believe Are Plant Pests," establish permit requirements for the introduction (importation, interstate movement, environmental release) for certain genetically organisms. In the regulations, a regulated article is defined as "[a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in Section 340.2".



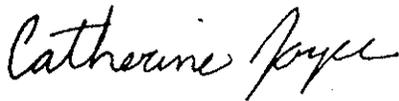
APHIS - Protecting American Agriculture

Section 340.2 is a list of plant pest organisms. Therefore, an organism is a regulated article if: (1) the development of the organism involved a plant pest component; and if (2) the organism has been altered or produced through genetic engineering, with genetic engineering defined in the regulations as "[t]he genetic modification of organisms by recombinant DNA techniques."

Although the development of the geranium plants described in your letter involved *Agrobacterium rhizogenes*, a plant pest component, the geraniums are not regulated articles under 7 CFR Part 340 because they were not modified by recombinant DNA techniques and therefore, they were not altered or produced through genetic engineering as defined in the regulations.

Please feel free to contact our office again if you have any further questions.

Sincerely,

A handwritten signature in cursive script that reads "Catherine Joyce".

Catherine Joyce, Ph.D
Biotechnologist
Biotechnology Permits
Biotechnology, Biologics, and
Environmental Protection

Sanford Scientific, Inc.

877 Marshall Rd/Waterloo, NY 13165

Phone: 315-539-1200/Fax: 315-539-0337



Feb. 25, 1994

Dr. Catherine Joyce
APHIS
FAX: 301-436-8669

Dear Catherine,

One year ago we corresponded about our small company's desire to release and market transgenic plants of scented geranium (Pelargonium sp.). Scented geranium is native to South Africa. In North America, scented geranium is grown as a house plant - primarily for its fragrance. Our collaborator, Dr. David Tepfer, INRA, France, has found that the wild-type form of Agrobacterium rhizogenes can infect scented geranium, resulting in classical 'hairy roots'. These transgenic roots bear the natural T-DNA from A. rhizogenes, and this process clearly occurs in nature. Dr. Tepfer has found that some of these roots spontaneously give rise to shoots and intact, transgenic plants. This basic process has been well characterized for many years in many species, and occurs naturally (hence plants can be found in nature that still have remnants of T-DNA from natural Agrobacterium transformation events from long ago).

We have now used Dr. Tepfer's method to produce transgenic plants of six cultivars of scented geranium. These plants have improved rooting and have a more compact habit. From our correspondence with APHIS these plants are not regulated articles, as they are not defined as recombinant DNA organisms (see your letter of 2/5/93). A letter from EPA from last year also indicated that our product would be exempt under what was then the currently drafted EPA policy. Therefore, unless otherwise notified, we are assuming that there is no restriction preventing us from releasing and marketing these plants. In this light we plan to transfer these plants out of our P1 greenhouse, and to begin plant sales immediately.

I would like to emphasize that such plants only contain wild-type T-DNA of Agrobacterium rhizogenes, and no other 'engineered' selectable, or scorable markers, foreign promoters, etc. They clearly are capable of arising naturally.

For the record, we would be very grateful for a letter from your agency, confirming that any plants we produce bearing only wild-type A. rhizogenes DNA are exempt from restrictions from your agency. Thank you very much for your friendly cooperation.

Sincerely,

A handwritten signature in cursive script that reads "John". The signature is written in black ink and is positioned above the printed name.

John Sanford, Ph.D.
President



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology,
Biologics, and
Environmental
Protection

M/P 30 157

Dr. John Sanford
President
Sanford Scientific, Inc.
877 Marshall Rd.
Waterloo, NY 13165

Dear Dr. Sanford:

This letter is in response to your letter of February 25, addressed to Dr. Catherine Joyce on my staff. In your letter you requested confirmation on the regulatory status under 7 CFR Part 340, of transgenic scented geraniums (*Pelargonium* sp.) developed by your company.

The regulations in 7 CFR Part 340, entitled "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," establish certain permit or notification requirements for the introduction (importation, interstate movement, and environmental release) for certain genetically engineered organisms. In the regulations, a regulated article is defined as "[a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in Section 340.2." Section 340.2 is a list of plant pest organisms. Therefore, an organism is a regulated article if: (1) the development of the organism involved a plant pest component and; (2) the organism has been altered or produced through genetic engineering, with genetic engineering defined in the regulations as "[t]he genetic modification of organisms by recombinant DNA techniques."

Your letter states that the transgenic geraniums for which you are seeking this opinion were developed by transformation with wild-type *Agrobacterium rhizogenes*. Therefore, it is our understanding that the development of transgenic geraniums did not involve the use of recombinant DNA techniques. Although the development of these transgenic geranium plants involved a plant pest component, *Agrobacterium rhizogenes*, the geraniums are not regulated articles under 7 CFR Part 340, because they were not modified by recombinant DNA techniques, and therefore, they were not altered or produced through genetic engineering as defined in the regulations.



Dr. John Sanford

2

However, please be advised that the importation of nursery stock, plants, roots, bulbs, seeds, and other plant products is regulated by the Plant Protection and Quarantine (PPQ) division of the Animal and Plant Health Inspection Service in accordance with 7 CFR Section 319.37. In addition, a permit from PPQ may be required under 7 CFR Part 330, for the importation or interstate movement of wild-type *Agrobacterium rhizogenes*.

Please feel free to contact me or my staff if you have any further questions.

Sincerely,

A handwritten signature in cursive script, appearing to read "John H. Payne".

John H. Payne, PH.D.
Acting Deputy Director