

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