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Dr. John Cordts
US Department of Agriculture
APHIS, PPQ
Unit 147
4700 River Road
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RE: USDA/APHIS Forest and Fruit Tree Biotechnology Meeting/workshop
Docket 03-051-1

Dear John:

These comments are offered by Applied PhytoGenetics, Inc. (APGEN) as a follow-up to the meeting held on July 8-9, 2003 regarding Genetically Engineered Forest and Fruit Trees. The undersigned participated in this meeting, and commends APHIS for holding the meeting and for soliciting input from the public, the regulated community, the scientific community, and other interested parties.

APGEN is a company pursuing phytoremediation – the use of plants, trees and grasses to remove, sequester or degrade hazardous materials from the environment. APGEN is one of the few (perhaps the only) U.S. companies actively pursuing the use of genetically engineered plants for phytoremediation. APGEN is the exclusive licensee of the University of Georgia's patents for phytoremediation of mercury using transgenic plants expressing genes such as merA and merB. At this writing, APGEN has been awarded three release permits from APHIS for field tests of transgenic plants for mercury phytoremediation, with one other application pending, and one such field test was begun in July 2003 under Release Permit 03-044-01r.

APGEN offers the following comments regarding APHIS oversight over genetically modified trees, both at the level of small-scale field testing and at the level of deregulation/delisting for large-scale commercial use.

1. <u>APGEN strongly supports the current regulatory framework for environmental uses of transgenic plants and trees, and APGEN recommends that the current system should be used to regulate transgenic trees, with the adoption of data requirements appropriate for the intended use of the trees.</u>

The undersigned has been involved in the agricultural biotechnology industry and its attendant regulatory and policy debates since the mid 1980s. APGEN believes that the Coordinated Framework first established in 1986, and APHIS regulations first established in 1987 as later amended, have provided a workable and effective balance between the sometimes conflicting needs both for reasonable risk assessments of new products and also for reasonable road maps to allow companies developing such products to get them to market. APHIS in particular should be commended for developing a regulatory framework, and a dedicated, competent staff, that have balanced these needs while retaining the public's confidence. APGEN believes that the current regulations can be used to regulate genetically engineered trees, and that no new regulations are needed for this purpose. However, we support APHIS's efforts to examine and define the need for data requirements that are tailored for uses of transgenic trees under these regulations.

2. <u>APHIS should not institute blanket rules covering the field use of all trees in all circumstances, and APHIS should maintain a case-by-case, species-specific approach to regulation</u>.

As was discussed in detail during the July 8-9 meeting, there are a multitude of different uses for genetically modified trees, which give rise to different potential environmental or plant pest issues. Most obvious is the distinction between fruit or nut trees, whose products are used for food and other purposes, and timber/forestry trees, whose products are not edible and which are grown for the wood. Of course, numerous distinctions exist within each of these broad categories, and in addition there are other broad classes in which trees might be used. For example, transgenic trees might be grown strictly for the use of their biomass (e.g. for energy production), or for use in phytoremediation. This diversity argues strongly for APHIS to maintain a flexible policy of case-by-case reviews for transgenic trees, and to avoid instituting guidelines or regulation meant to apply across the board to all transgenic trees, regardless of application. Our comments below will address the reasons why trees used for phytoremediation pose very different issues than do other uses of trees in food production or forestry, and why across-the-board regulations or guidelines applying to all transgenic trees may harm the development of transgenic trees for use in phytoremediation.

3. <u>Phytoremediation, using transgenic trees and other plants, offers the potential for significant environmental benefits</u>.

Phytoremediation is widely considered to be an innovative technology, that is expected to provide an inexpensive, environmentally-friendly alternative to many more traditional forms of environmental remediation. Although plants of a variety of species are being used in phytoremediation, a number of tree species have found particular utility in specific applications, including hybrid poplars, willows, cottonwood, and Eucalyptus (Glass 1999). To date, commercial phytoremediation has been carried out exclusively using native (naturally-occurring) plants (e.g. see van der Lillie 2001 for a recent overview). However, the techniques of genetic engineering offer some very powerful approaches towards creating improved plants to create phytoremediation solutions for environmental problems that are today difficult to treat in a cost-effective manner (Meagher and Rugh, 1996; Glass, 1997; Meagher, 2000; Pilon-Smits and Pilon, 2000; Kramer and Chardonnens, 2001), and there has been a great deal of research investigating possible use of transgenic plants and trees in phytoremediation. In spite of this research interest, there have been no commercial uses of transgenic plants in phytoremediation. Although there are several reasons why this is so, it is clear that overly-onerous or scientifically-unjustified regulations will only hinder the development of this potentially beneficial technology.

4. <u>There are several ways in which the use of trees in phytoremediation differs from the ways in which trees are grown and used for other applications</u>.

Trees (and other plants) used in phytoremediation are used in ways that differ from traditional practices in agriculture or forestry. In a typical phytoremediation project, one or more plant species, selected or engineered for the specific application, will be planted at a site where soil or groundwater is contaminated with one or more hazardous materials. Planting will usually be by the company that has developed the particular phytoremediation technology, or by entities working closely with that company. Such contaminated sites are usually, but not always, located in urban or industrialized areas, or abandoned properties, rather than typical agricultural or wooded areas, and these sites will often be remote from any areas where the native tree or plant species are grown. Most phytoremediation projects will be relatively small-scale, probably several acres or less even for full-scale remediation projects (although phytoremediation could well be used someday at very large contaminated sites). In most cases, the plants will be maintained on the site for a defined period of time, usually three years or less, and will be removed at the completion of the project (although some projects, such as those using trees to intercept contaminated groundwater, may be left in place for much longer). In some cases, the plants or trees will be expected to sequester high enough concentrations of the contaminants to require disposal as a hazardous waste (probably via incineration). After the project is completed and the site has been cleaned to the desired level, the site will likely be used for industrial, commercial, or residential purposes, rather than continued agricultural use.

To summarize the ways in which uses of transgenic trees in phytoremediation might differ from other uses of transgenics:

- Most phytoremediation projects will have a limited time duration with well-defined endpoints, and in many cases the trees would or could be removed from the site years before they would flower or produce pollen. Some trees could be left onsite indefinitely without flowering, through regularly-scheduled coppicing.
- Most phytoremediation projects will take place in nontraditional settings (urban, industrial, nonagricultural land), often distant from native plant populations or wooded areas.
- Moreover, phytoremediation projects can be viewed as small, managed “plantations” on land that is already environmentally compromised (by the contamination) but in any event is usually neither a “natural” habitat nor one of agricultural importance.
- Many phytoremediation projects will be subject to hazardous waste regulations of various kinds, and so the sites will be heavily monitored, will have limited public access, and will otherwise be subject to considerable government oversight.
- The plants and trees used in phytoremediation will not be used for human or animal food, and in many cases there will be no use of the resulting biomass at the conclusion of the experiment. In fact, in some cases, hazardous waste regulations may require the destruction of the resulting biomass.
- The purpose of the phytoremediation is to alleviate existing environmental damage at the site, and to restore it so it can be used for productive purposes. So, the net result of the activity is always expected to be an environmental benefit.
- Trees used in phytoremediation will generally undergo different commercialization routes than other trees: the trees would not sold to a broad customer base, will likely be

commercially controlled by the technology developer and its partners, and will almost always be used in well-defined, controlled settings.

- Even commercial (i.e., non-research) uses of trees and plants for phytoremediation will be relatively small-scale, and it is hard to imagine any phytoremediation plant being used on the broad commercial scale of a commodity row crop or a tree used in timber production. In view of this and the previous bullet point, it is conceivable that, in some cases, phytoremediation technology developers might prefer to use proprietary transgenic plants and trees for an indefinite period of time under a series of permits, rather than ever submitting a delisting petition for such transgenic lines.

5. <u>Adopt a regulatory framework that will foster the use of transgenic plants in phytoremediation while still addressing risk concerns</u>.

Phytoremediation is widely believed to be an environmentally-friendly and beneficial technology for site remediation. Although it is certainly true that plant pest and other risks need to be assessed and addressed for any use of transgenics in phytoremediation, these are projects that should be encouraged, because their environmental impacts are expected to be positive. APHIS regulations and practice must be flexible enough so that proposed uses of transgenic plants in phytoremediation are reviewed in accordance with the expected uses and their accompanying risks, rather than according to “cookie cutter” guidelines or data requirements adopted across the board for all transgenic trees.

We hope these comments have been helpful. We look forward to continuing opportunities to work with APHIS in developing and implementing an appropriate regulatory structure for the use of transgenic plants in phytoremediation.

Sincerely,

David J. Glass, Ph.D.
President and CEO

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