July 30, 2003

Dr. John Cordts
US Department of Agriculture
APHIS, PPG
Unit 147
4700 River Road
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Dear John:

ArborGen is committed to improving trees and forestry through genetic research and biotechnology. We are developing products that will improve the sustainability of the world's most important renewable resource, trees. Because of the many potential benefits that biotechnology can bring, we strongly urge APHIS to employ a regulatory framework that not only ensures safety but also enables society and the environment to benefit from forestry biotechnology.

ArborGen has received APHIS notification for more than 50 field trials and supports the adoption of a framework that encourages the development of transgenic trees that provide environmental, economic and social benefits, including trees that will be used for commercial forest plantation purposes.

The use of transgenic trees in plantation forests will have a positive impact on the world's natural forests due to expected productivity improvements from each plantation acre. In 1999, the Union of Forestry Research Organizations predicted a 42 percent increase in world demand for wood fiber by the year 2010. There is considerable data demonstrating that the world is on target to meet this prediction. Biotechnology will be important in helping to meet the projected demand because it holds promise to increase productivity through improved stress tolerance, more efficient silvicultural practices for weed control, improved disease and pest resistance and faster growing trees. Increasing productivity allows for more wood to be grown on less land, reducing the pressure to harvest in natural forests.

Other important benefits of applying biotechnology to forestry can include:

1. The restoration of key species that are endangered, including American elm and chestnut, flowering dogwood and the California oaks by the addition of disease resistance genes;
2. Bioremediation of soils through mechanisms such as the uptake of heavy metals by trees;
3. Increasing carbon sequestration;

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4. Increasing productivity at the mill level through better wood utilization or more efficient processing;
5. Increasing the efficiency of lignin extraction, thereby reducing energy consumption and chemical inputs;
6. Trees as a renewable source of energy (Biofuels);
7. High value industrial chemical production.

ArborGen offers the following comments in support of APHIS efforts to appropriately regulate transgenic trees.

<u>ArborGen strongly supports the application of the current regulatory framework for transgenic plants for the regulation of transgenic tree products.</u>

The current regulatory framework for agricultural crops, which utilizes the concept of substantial equivalence, has allowed for the successful commercial introduction of food and feed products that meet regulatory safety standards. Since 1992, sixty products have been approved and many of these products have been widely adopted across the U.S., demonstrating that these crops continue to meet product performance and regulatory safety standards. ArborGen believes that the substantial equivalence concept is also appropriate for trees. In many cases the non-transgenic progenitor is an appropriate comparator. In other cases a comparison with the normal variation of a particular characteristic in the species as a whole may be appropriate. Through these comparative evaluations, made at an appropriate age, predictions about future growth can be made well before a trees reaches biological maturity.

<u>More than 50 years of peer-reviewed science obviates the need for APHIS to develop a whole new set of testing standards for biotech trees.</u>

The forestry industry can provide APHIS with extensive data based on 50 years of forest management practices and sustainability research, 30 years of tree improvement practices and 20 years of forest biotechnology research as a baseline for its data requirements. The forestry industry has developed a wealth of information on genetic testing in tree species and well-understood age-to-age correlations. These data demonstrate that evaluating juvenile trees can be an accurate predictor of what traits will be expressed in mature trees. The selection criteria that have been used during the past five decades of intensive plantation management can be used, employing a substantial equivalence approach, to predict gene expression in adult transgenic trees.

Existing data also can be predictors of a number of impacts that could be part of the APHIS evaluation. For example, extensive libraries of peer-reviewed literature include impacts of forest plantations and natural forest on (not an exhaustive list):

- Genetic diversity
- Landscape/ecosystems

- Ecological interactions
- Wildlife diversity
- Water quality
- Plantation establishment, management, harvesting and intervening treatments (e.g. fertilization, fire suppression, etc.)
- Tree physiology

<u>The data that will be needed by APHIS will be much of the same data required by foresters and forestry companies who will be customers for transgenic plantation trees.</u>

Trees being planted for commercial purposes must meet high expectations of customers including impacts related to the management of the forest and forest sustainability. Only those products that meet rigorous customer performance standards would be brought forward for deregulation.

<u>In evaluating transgenic trees, APHIS should consider how these trees will be grown in the overall industrial planting scheme.</u>

The forestry industry, through its Sustainable Forestry Initiative, manages its land to maximize biodiversity and to minimize environmental impact. Transgenic trees will be planted in accordance with those industry objectives. Industrial forest landowners manage their forests at the landscape level. That is, while areas of the forest are highly managed for volume yields, other areas such as streamside management zones are managed at lower intensity and for other non-forest values. Harvested blocks are separated both temporally and geographically often with wildlife corridors separating harvested areas. Similarly, if transgenic trees are added to the matrix, they also would be planted in zones in order to maintain maximum biodiversity within the overall scheme.

<u>APHIS evaluation of transgenic trees should build on the evaluation procedures already in place for traditionally bred trees.</u>

The perennial nature and biology of trees requires that each potential product be subject to several years of field testing on different sites representative of the expected geographic range of its deployment as part of the product development and performance testing. Just as in traditional tree breeding, any trees with undesirable characteristics would be observed and culled out during the normal field performance evaluation of transgenic trees. Lines with undesirable phenotypes would be rejected as not being commercially viable and would not be brought forward for deregulated status.

<u>APHIS should continue to apply sound risk assessment science principles as the agency evaluates the data requirements for the regulation of transgenic trees.</u>

The essential elements of this system should continue to be science based, with assessments based on a specific trait in a particular species. The geography and environment in which the tree will be grown also must be taken into consideration. Data requirements for deregulation status should be based on risk assessment hypotheses that are testable, where results are achievable, and the efforts required to obtain data are practical. The APHIS risk assessment requirements should be based on an *a priori* reason to suspect threat of serious or irreversible harm, rather than a policy that attempts to address all hypothetical possibilities.

<u>Clonal development systems will be used to scale up transgenic trees, reducing the likelihood of variation among the transgenic tree population.</u>

As the forest industry adopts clonal plantations, data on clonal performance is likely to provide even better models to extrapolate results from small-scale field tests to large-scale plantings. Experience from tree improvement programs indicates that differences in basic morphological traits are readily observable (crown shape, forking, branching patterns) in progeny tests of open pollinated or control pollinated families. Such traits are likely to be even more readily observable in clones. The same models used in predicting future performance of trees in a breeding or genetic improvement program can be utilized for predicting the characteristics that will be exhibited by transgenic trees. Therefore, broad observational level data on growth habit, obtained from field trials, should be acceptable.

Summary statement

There are many potential benefits of forest biotechnology. Several of these benefits will be readily appreciated by the general public. Improved plantation productivity will reduce the pressure to harvest from natural stands, and will allow the world's forests to be maintained even though the world population is making greater demands on wood products for fuel, timber and paper. Native tree species, which have ecological and historical importance such as the American chestnut or elm, will be able to come back from functional extinction caused by disease. Paper and lumber mills will be able to more efficiently process wood in a manner which places less demand on the world's energy resources and which allows the mills to meet their environmental objectives. When a consumer buys computer paper that is produced from transgenic plantation species, he or she will be able to understand that this paper did not come from natural stands, but came from a plantation forest managed as carefully as a crop; and that natural forests are better protected by harvesting to meet the paper demands of the public. People will be able to understand the value of forest biotechnology when they can see land that has been contaminated by heavy metals be reclaimed for housing or park use through the phytoremediation made possible by transgenic trees. The general public will be appreciative that trees, as a renewable resource, can be improved to generate fuels that are cleaner and more competitive in price than oil or coal; or which can be used to produce novel high value products, such as enzymes that can be used for industrial processing or proteins which can be used as pharmaceuticals.

Transgenic tree products must be evaluated by APHIS on a specific trait by particular species basis; with the location where they are to be grown also factored. Risk assessment evaluations by APHIS must be based on recognized risk assessment science principles. Data requirements for the assessments must be founded on risk assessment hypotheses that are testable, where results are achievable and the efforts to obtain data are practical.

Transgenic trees under development for commercial purposes must meet both product performance and regulatory safety standards. In order to meet the demand for forest sustainability and long-term perspective of the industries associated with the forest, only those products that meet these high standards will be socially, economically and environmentally acceptable.

We hope these comments provide useful information. We look forward to future opportunities for providing information as APHIS develops and implements a risk assessment framework that fosters the development of transgenic trees that provide economic, ecological and social benefits.

Sincerely,

Dr. Les Pearson
Director, Regulatory Affairs
ArborGen