



July 29, 2003

John M. Cordts  
Biotechnology Regulatory Services  
Unit 147  
USDA/APHIS  
4700 River Road  
Riverdale, MD 20737  
[John.M.Cordts@aphis.usda.gov](mailto:John.M.Cordts@aphis.usda.gov)

*Re: Genetically Engineered Forest and Fruit Trees: Written Comments*

Dear Mr. Cordts:

Mendel Biotechnology, Inc. is a private functional genomics company founded in 1997 by five internationally acclaimed plant scientists. The company is dedicated to creating value through the discovery, development and commercialization of knowledge about plant gene expression. Mendel's mission is to conduct research to identify the complete set of plant regulatory genes called transcription factors, characterize and patent their functions, and develop in collaboration with strategic partners genetically modified crops with enhanced agronomic traits. Mendel has identified the complete set of transcription factor genes in the genome of *Arabidopsis thaliana*, and systematically analyzed their function. Transcription factors have been discovered that control disease resistance, yield, fertilizer use efficiency, freezing and drought tolerance, and many other complex traits. Plants and plant-derived products based on these discoveries will create significant benefit for agriculture, horticulture, and forestry consumers and producers worldwide.

Effective, transparent, and objective regulatory institutions and requirements are essential for mankind to realize the benefits offered by biotechnology for improving the production of plant-derived food, feed, fiber and chemical products in an environmentally safe and sustainable manner. Rigorous, yet objective, realistic and measurable regulatory requirements benefit consumers, producers and technology providers in at least the following ways:

- Consumers and producers can be confident that products receiving a determination of non-regulated status have been thoroughly evaluated and shown not to pose an unacceptable risk to the environment, wildlife, or mankind.
- Producers can be confident that appropriate agricultural, horticultural or silvicultural practices for non-regulated products have been thoroughly evaluated, and that use of non-regulated products as recommended by the technology providers will provide economic benefits for the producers in an environmentally safe and sustainable manner.

- Technology providers can be confident that clearly defined, objective, realistic, and measurable endpoints and criteria for achieving a determination of non-regulated status exist.

In contrast, poorly defined, non-transparent, and non-objective regulatory institutions and requirements will severely inhibit development of new technologies for improving agriculture, horticulture and silviculture, and I believe, increase the potential for environmental damage and unsustainable production practices. It takes six to twelve years to discover, develop and commercialize a genetically modified plant variety at a cost of 50 to 300 million dollars<sup>1</sup>. If these times and costs are coupled with a “high-risk” regulatory system in which the criteria necessary to achieve a non-regulated status are ill-defined, subject to non-objective interpretation, or simply unreasonable, industry will not invest in the development of these new technologies. The lack of new technologies, at a minimum, will perpetuate current production practices, some of which have known negative environmental impacts, such as deforestation to produce timber products and increase available land for agriculture<sup>2</sup>.

There are no easy answers to the overarching questions posed by the organizers of the USDA/APHIS public meeting regarding Genetically Engineered Forest and Fruit Trees. However, I believe there is a straightforward process to obtain objective answers to these questions, and that is sound science. There are vastly differing opinions about the commercial use of transgenic plants, particularly in the case of long-lived perennials such as trees. However, emotional rhetoric based on non-objective, anecdotal evidence to support or oppose transgenic trees will not resolve the controversy. Instead, I believe resolution of the controversy and answers to the difficult questions posed by the organizers will only come from objective, science based regulatory requirements that allow measurable and reproducible data to be evaluated based on reasonable criteria, thereby enabling rational decisions regarding transgenic trees.

Sincerely,

William F. Goure  
Vice President  
Mendel Biotechnology, Inc.

---

<sup>1</sup> Gregory D. Graff and James Newcomb, “Agricultural Biotechnology at the Crossroads, Part 1: The Changing Structure of the Industry”, Bio Economic Research Associates, Cambridge, MA. [www.bio-era.net](http://www.bio-era.net).

<sup>2</sup> Gerald Urquhart, Walter Chomentowski, David Skole, and Chris Barber, “Tropical Deforestation” in NASA’s Earth Observatory Library. <http://earthobservatory.nasa.gov/Library/Deforestation/>.