USDA/APHIS Forest and Fruit Tree Biotechnology Workshop
Statement prepared by Richard Meilan[1], 9 July 2003

There is legitimate concern about safety of genetically engineered plants, particularly trees, and it is not just representatives of NGOs expressing these views. More than a decade ago, scientists, both those conducting genetic engineering research as well as ecologists, clearly expressed concerns about how, when, and what kinds of genetically engineered trees should be commercialized. The good news is that the scientific community has clearly been proactive, and continues, via research, to work to meet the challenges presented by genetic engineering. Industry, by funding the study of ecological safety and gene confinement systems, starting in the early 1990's, has also clearly responded to these challenges. Given time constraints, I will cite only two examples to help make my point, although numerous others are available.

First, 14 years ago Ken Raffa[2], a widely regarded entomologist at the University of Wisconsin, published a manuscript in the journal *BioScience* in which he advised that we proceed with caution when adopting biotechnological tools for controlling insect pests. At the conclusion of his article, he made some recommendations. First, he proposed that "…specific guidelines on transgenic release…need to be established." In particular he said that: "Policies must be based on research specifically directed at insect…responses to transgenic plants" and that "development of methods for restricting gene transfer…and limiting expression to specific tissues, times, and herbivore levels is a critical need…." He also suggested that integrated risk management programs be employed.

In a separate article that was published in 1991 but composed at the same time as the Raffa paper, Strauss, Howe and Goldfarb[3] enumerated the limitations of genetic engineering to improve insect resistance of trees. These included:

1) Inefficient systems for insertion of genes in large numbers of tree genotypes;
2) Inability to produce sterile trees, necessary to prevent the release of engineered genes into natural or feral populations;
3) Concerns about insect counter-evolution to overcome the effects of engineered resistance genes; and
4) A lack of public understanding of the true benefits and risks of genetic engineering.

I am happy to report that significant progress has been made in all of these areas during the intervening years. With regard to the need for specific guidelines, I need do no more than remind you of the meeting we are attending today. To its credit, APHIS has recognized that woody perennials have unique characteristics and cannot be treated the same as herbaceous plants. This meeting is meant to serve as a "forum for discussion of genetically engineered trees, and to begin a dialogue with a broad range of stakeholders on the possible criteria used to determine environmental safety and potential benefits and risks of these plants relative to traditional varieties." APHIS has not only included a group of scientists with expertise in fields

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[2] Raffa, K.F. 1989. Genetic engineering of trees to enhance resistance to insects: Evaluating the risks of biotype evolution and secondary pest outbreak. *BioScience* 39(8):524-34.

[3] Strauss, S.H., G. Howe, and B. Goldfarb. 1991. Prospects for genetic engineering of insect resistance in forest trees. *Forest Ecology and Management* 43:181-209.

associated with the environmental release of genetically engineered trees, but they have also invited the public to attend and participate in these discussions.

As many of you already know, APHIS is not the only federal agency that has regulatory oversight for transgenic plants. If an introduced gene imparts a pesticidal property, the U.S. Environmental Protection Agency (EPA) is also involved in non-regulated status determinations. With regard to Dr. Raffa's recommendation for an integrated pest management strategy, the EPA requires that all applications that involve the use of *Bacillus thuringiensis* (BT) toxins include a resistance management plan. This plan must provide an integrated strategy to minimize the risk of the pest developing resistance to the transgene product. This also addresses the issue of insect counter-evolution raised by Strauss *et al.*

Significant progress has also been made on the other shortcomings outlined by Strauss *et al.* Dozens of tree species have been transformed since their article was published. In fact, transformation efficiencies for some (poplar) genotypes are in excess of 30%. In addition, the importance of sterility as a means of transgene confinement is now widely recognized. Laboratories around the world are now actively engaged in flowering control research. Redundant systems are being tested, in an effort to ensure durability. These include everything from tissue-specific expression of cytotoxin genes, to dominant negative mutations and RNA interference. Several promising approaches for sterility are now being field-tested in poplar to determine their reliability under real-world conditions. Gene flow studies and models, needed to understand what levels of gene confinement are required for which genes and conditions, are also being conducted.

Furthermore, several groups are conducting research into the potential for somaclonal variation arising from *in vitro* culture. Others are also investigating the stability of general transgene expression, which is of particular importance for gene confinement systems in perennial crops. To date, transgene expression has been highly stable and somaclonal variation has been very low, at least in poplar. The latter can be dealt with easily during normal screening processes.

Much has also been done with respect to public outreach. In 2001 the biotech community itself convened a two-day symposium in Stevenson, WA. The purpose of the meeting was to discuss the ecological and societal aspects of transgenic forest plantations (http://www.fsl.orst.edu/tgerc/iufro2001/eco-symp-iufro.boku.ac.at/). Of the 28 invited lectures given at the symposium, 14 were from scholars who presented broad environmental, ecological or ethical views. The symposium was held in conjunction with the biennial meeting of the International Union of Forestry Research Organizations Unit on Molecular Biology in Forest Trees. This was the first international symposium that attempted to forge a consensus on how to move forward in research and public debate on genetically engineered trees. Other groups, most notably the Institute of Forest Biotechnology (http://www.forestbiotech.org/), based at Research Triangle Park in North Carolina, are working tirelessly to explain the societal, ecological and economic benefits that may accrue to the public from appropriate uses of biotechnology in forestry worldwide.

I certainly don't mean to imply that we have all the answers, but I am heartened by the response and progress I have seen. The research community has not reacted but taken the lead ahead of the public and NGOs, it continues to listen, and it has the same hopes and concerns as the public at large. As a result, since the emergence of biotechnology, it has been working diligently to identify the risks and exploring ways to ameliorate them. Research with trees takes time, but it is

clearly moving toward the answers we need. The research community is also making its findings available to public so it can make an informed decision about how to proceed with this technology that has the potential both for environmental and economic benefits.

In conclusion, the science of gene confinement is coming along well and is now moving into the field evaluation phase, thanks to APHIS' reasonable field-testing regulations. Such work is virtually impossible in Europe. I would also like to applaud the USDA's biotech risk assessment program; it is critical. The EPA should be doing something similar. I hope that this workshop will not lead to the development of a rigid regulatory framework for trees. I believe there may be circumstances under which fully fertile transgenic plants can be safely deployed commercially, without significant risk to the environment. This will, of course, depend on the transgene being inserted and the species being genetically engineered. For many kinds of transgenes, such as those for domestication traits like reduced lignin, strong confinement systems are unlikely to be biologically warranted, but for others, such as BT, such efforts are critical. Therefore, it is essential for APHIS and other regulatory agencies to have the flexibility needed to evaluate petitions for non-regulated status for trees on a case-by-case basis, in order to take individual characteristics, of both genes and recipient organisms, into consideration.

Thank you for allowing me this opportunity to express my views.