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SABP

The South Asia Biosafety Program (SABP) is an international developmental program initiated with support from the United States Agency for International Development (USAID). The program is implemented in India and Bangladesh and aims to work with national governmental agencies to facilitate the implementation of transparent, efficient and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds and environmental protection.

SABP is working with its in-country partners to:

- Identify and respond to technical training needs for food, feed and environmental safety assessment.
- Develop a sustainable network of trained, authoritative local experts to communicate both the benefits and the concerns associated with new agricultural biotechnologies to farmers and other stakeholder groups.
- Raise the profile of biotechnology and biosafety on the policy agenda within India and Bangladesh and address policy issues within the overall context of economic development, international trade, environmental safety and sustainability.

KEY CONSIDERATIONS FOR THE ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY ENGINEERED TREES INTENDED FOR USE IN PLANTATION FORESTS

According to the United Nations Food and Agriculture Organization, the world's forest area is slightly greater than 4 billion hectares, which is 31% of the terrestrial land area on earth.[1] These forests are vital to the world's ecological, social, cultural and economic well-being. Forests play a major role in the global carbon cycle, with 289 gigatons of carbon stored in forest biomass alone (FAO 2010a), and they protect soil and water resources, control avalanches, stabilize sand dunes, control desertification and protect coastal regions. Forests also provide habitats for many of the world's plants and animals, thus contributing to global biodiversity. Wood is an economically important commodity, serving as the raw material for lumber, pulp, paper, packaging, and increasingly as a feedstock for bioenergy, biofuels and biomaterials. Forests continue to provide the majority of fuel used for cooking and heating throughout the world. Forests are also important spaces for recreation and tourism, and are of cultural and spiritual value to many people.

The use of intensively managed, highly productive forest plantations that incorporate the most advanced methods for tree breeding is one solution to meet the growing demand for wood and other forest products. As a consequence, there is a growing interest in applying advanced molecular tools, including genetic engineering, to improve the productivity or marketable traits of trees deployed in commercial plantations.[2] At the same time, concerns have been expressed about the safe use of genetically engineered trees in forests,[3] which are highly valued for the environmental, economic, cultural and social services they provide.

Photo: FAO, Jim Carle (FO-6960)

It has been nearly 20 years since the first approvals for commercial cultivation of genetically engineered plants, and although countries may regulate genetically engineered plants using different procedures, the environmental risk assessment paradigm used is essentially the same for all. This can be attributed to the persistent efforts of multi-lateral organizations such as FAO, the Organization for Economic Cooperation and Development (OECD), and the Secretariat to the Convention on Biological Diversity to promote harmonization in the evaluation of the safety of genetically engineered organisms. This paradigm considers the biology of the crop (host) plant which has been genetically engineered, the characteristics of the introduced trait, the likely receiving environment (including relevant management practices in that environment) and their interactions.[4-10]

In order to examine how the environmental risk assessment paradigm used for genetically engineered crop plants may be applied to genetically engineered trees that are intended for use in plantation forests, a working group of experts in silviculture, forest tree breeding, forest biotechnology and environmental risk assessment was convened by the Center for Environmental Risk Assessment in April 2012. The working group's deliberations, summarized below, emphasized the importance of differentiating between environmental risk assessment for confined field trials of genetically engineered trees, and environmental risk assessment for unconfined or commercial releases. In the case of the latter, particular attention is paid to characteristics of forest tree species that distinguish them from shorter-lived plant species, the temporal and spatial scale of forests, and the biodiversity of the plantation forest as a receiving environment.

WHAT IS A PLANTED FOREST?

The worldwide average growth rate in natural forests is around 2 m^3 per hectare per year.[11-12] At this level of productivity, approximately 1.7 billion ha of forest land must be harvested annually to meet the current total world demand for wood. However, the potential to produce more wood exists through the intensive management of forest plantations. In 2000, planted forests comprised only 5% of the forest land base but contributed approximately 35% of the industrial wood harvested.[13] Since then, the acreage devoted to planted forests has risen to 264 million hectares, representing 7% of the world's forests. From 2005 to 2010, the area of planted forests increased by about 5 million hectares per year, mostly through afforestation of previously non-forested land.[14] Approximately three quarters of planted forests consist of native species and the remaining 25% is introduced species.[14] Improved plantation management that includes site preparation, weed control, forest fertilization, and utilization of improved genotypes has led to substantial increases in productivity and shortening of rotations (growth and harvest cycles) in many parts of the world.[15-17] These silvicultural practices are a key aspect of the receiving environment and should be considered in the environmental risk assessment of genetically engineered forest trees.

To sustainably realize the potential productivity in managed plantations, integrated silviculture regimes are needed where the tree crop, soil, and other vegetation are actively managed to optimize growth.[18] Implementation of these intensive regimes requires knowledge of how a tree's genetic make-up interacts with the environment to affect productivity, stem quality, wood quality, and resistance to insects and diseases.[17] In addition, a site-specific understanding of what resources limit production (temporally and spatially) and how cultural treatments can be used to ameliorate these limitations are required.[19] In many respects, intensive plantation silviculture is similar to agriculture, but is still firmly based on forestry's strong ecological foundations.

ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY ENGINEERED TREES IN CONFINED FIELD TRIALS

Confined field trials are just that: small scale field studies of experimental transgenic plants that are managed according to strict provisions designed to mitigate impacts on the surrounding environment. Such trials provide scientists with an essential experimental platform to further basic and applied scientific research through the evaluation of genetically engineered plants outside of the artificial environments of the laboratory or greenhouse. Confined field trials also provide product developers with an opportunity to evaluate the performance of transgenic events and collect data necessary to address regulatory requirements.

Tree species differ in a number of characteristics from typical crop plants, including the extent of domestication, time to reproductive maturity, length of life cycle, dispersal distances of reproductive material, and trees' physical size. For confined field trials of genetically engineered trees, one of the most important aspects of the environmental risk assessment is determining if the risk mitigation measures used to confine the release will be effective. The impact of the confined release of a genetically engineered tree on the environment will be minimized by the generally small scale of the release.

Additionally, other conditions imposed on the trial such as measures to prevent ready access by wildlife or humans and post-harvest management and monitoring requirements also contribute to minimizing potential environmental impacts. To determine the effectiveness of risk mitigation measures, a number of key aspects need to be considered. These include understanding the reproductive biology of the host species; the biology of any sexually compatible species also present in or proximal to the receiving environment; the long-distance dispersal of propagules; and ecological interactions particularly if the interactions are with species of concern such as protected species or weeds. It also requires information about the expected phenotype conferred by the introduced trait(s), the characteristics of any new expressed proteins, and the receiving environment including silvicultural practices.

Reference biology documents, such as those published by the OECD and a number of individual countries, are available for many plant species including several trees.[20-21] These simplify the exercise of accessing essential information about the host organism as they provide information about the reproductive biology of the species and taxonomic relationships, including the ability to cross with related species in the receiving environment. Additionally, the possibility of dispersal of propagules by humans and animals is addressed. Tree species that are currently used for plantation forest production have been well studied, and extensive information exists that can contribute to proposing and assessing effective strategies for confining field trials of genetically engineered trees.[22-25]

It is additionally important to consider how the introduced trait, both in its intended as well as any observed unintended effects, might alter the biology of the tree with respect to the ability to achieve adequate confinement. Several sources of information can be used to inform the risk assessment. For example, the expected effect of the gene on the tree's phenotype will be available to use in the risk assessment and experience with the same or similar genes introduced into crop plants can enhance a risk assessor's understanding of the potential effects.[10,26] Additionally, the objectives for development of many genetically engineered trees involve the same traits as those sought through traditional breeding. The potential environmental impacts of these traits will be the same, or similar, to those introduced by conventional improvement programs, and so risk assessments should be informed by experience with conventionally derived traits.[27-29]

ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY ENGINEERED TREES FOR COMMERCIAL RELEASE

The paradigm for environmental risk assessment of genetically engineered plants considers the biology of the host plant, the characteristics of the introduced trait(s), the intended receiving environment, and interactions between these. When applied to the environmental risk assessment of genetically engineered plants for an unconfined or commercial release, the context of the assessment is very different than for confined field trials. In the context of commercial release, limits and controls are generally not required (other than those practices that are normally applied when growing the conventional counterpart) unless there are specific concerns identified in the risk assessment that are subject to conditional post-release management practices. Consequently, an environmental risk assessment for an unconfined release of a genetically engineered forest tree will usually require significantly more information than for the environmental risk assessment of a confined field trial unless there is extensive familiarity with the introduced trait or prior review of the same or similar genetically engineered trees has already been completed. Instead of focusing on confinement measures, other aspects require greater consideration such as the phenotype of the genetically engineered tree, potential consequences of introgression of the transgenic trait into sexually compatible populations, and impacts of longer-term exposure on organisms in the receiving environment. Data accrued from laboratory studies and confined field trials are supplemented with information from the literature and past risk assessments (where relevant) to address these topics.

KEY CONSIDERATIONS

Plantation forests are highly managed ecosystems. While they provide important ecosystem services, the primary purpose of such forests is to produce wood and other forest products. Much is known about the biology of the tree species used in plantations, and the site-specific effects of silvicultural practices on productivity, reproduction and growth. The fact that plantation forests are intensively managed means that there is significant familiarity with and knowledge about both the host plant and the receiving environment, and this knowledge is fundamental to a robust environmental risk assessment.

The environmental risk assessment paradigm that has been successfully applied to the pre-commercial evaluation of genetically engineered crops is equally applicable to the risk assessment of genetically engineered trees that will be used in planation forestry. While the biology of forest trees differs from annual row crops, characteristics of trees such as longevity, size and scale are manageable and do not preclude the evaluation of genetically engineered trees for deployment in confined field trials or forest plantations. Regulatory authorities in countries such as Australia, Canada, Japan, and the U.S. have approved the unconfined release of other long-lived perennial species such as transgenic alfalfa, rose, plum and papaya, and most governments have related experience in the risk assessment of non-transgenic, introduced perennial species that is highly relevant to the environmental risk assessment of forest tree species.

Environmental risk assessment for confined field trials of genetically engineered trees must be distinguished from environmental risk assessment for unconfined releases. The emphasis for risk assessment in relation to confined field trials is the expected effectiveness of confinement measures designed to minimize environmental exposure. Biological information relevant to effective confinement primarily consists of knowledge about the characteristics of the tree's reproductive biology, the effect that the transgenic trait is anticipated to have on those characteristics, and the presence of sexually compatible species in proximity to the trial site.

Environmental risk assessment of genetically engineered trees for unconfined release focuses on the behavior and interactions of the genetically engineered tree in the anticipated areas of deployment. Information about host biology and the receiving environment is supplemented with additional data accrued from laboratory tests and studies undertaken during confined field trials. In some cases, such as the transformation of a tree species with a gene that has already undergone significant evaluation in one or more crop species, those data may come from the literature and/or other risk assessments, and does not need to be repeated.

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