Forest Biotechnology and its Responsible Use

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Summary. Biotechnology[3] is being used as a tool to grow trees with special characteristics. When used responsibly, society and the environment can benefit from advanced tree breeding technologies. The next few years will be a time of rapid expansion for biotech trees throughout the world in an attempt to meet global demand for forest products and to protect future forests against increasing demand. The world will benefit from a mechanism to determine which uses of this technology will bring benefit and other advantages. The Institute of Biotechnology, along with a broad set of stakeholders from around the world, is developing principles for the Responsible Use of biotech trees. Through a highly transparent and open process we can enhance the benefits of these trees while minimizing criticism.

Keywords. *Biotechnology, Forestry, Biomass, Dedicated Energy Crops*

Forest biotechnology in context

"The term biotechnology came into common usage in the 1980s, and its several definitions continue to change. Broadly defined, it is anything that combines biology and technology. Biotechnology has become more controversial as the level of the technology has increased." An excerpt from Genetically Modified Forests from Stone Age to Modern Biotechnology (Burdon et. al. 2006). This book is the most comprehensive review of forest biotechnology. Within the context of forest biotechnology we can refer to "modern" biotechnology as that which postdates the discovery of the structure of deoxyribonucleic acid, or DNA. This new biotechnology is centered on the analysis and manipulation of DNA and the artificial insertion of DNA fragments into organisms. Thus we must split forest biotechnologies into two general groups; breeding technologies, and genetic engineering technologies.

Breeding Technologies

Breeding technologies are described in this section to differentiate them from the scope of the Responsible Use principles that will be discussed in more detail later in this paper. The technologies are ordered from least to most advanced in terms of their reliance on advanced techniques for success. Be aware that one or more of these breeding technologies are used to produce GE trees.

Conventional Breeding

Purposeful breeding of trees involves producing hybrids, progeny of parents from different genetic populations to produce a desired phenotype. An example of this would be a cross between a tree that has exceptional growth and one that shows resistance to a fungus that attacks that particular species. This is a very imprecise method of producing a tree with a specific characteristic because there is no control over additional genetic material being incorporated along with the desired phenotype.

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[3] "Biotechnology: Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." (Convention on Biological Diversity, 1995)

Asexual Propagation

Also referred to as clonal or vegetative propagation, is in contrast to sexual reproduction that requires fertilization via pollen. Sexual reproduction is how most plants reproduce. Asexual propagation produces genetically identical trees and does occur naturally by some tree species. In fact, you can break off a branch of a willow tree, stick it in the ground, and it will sprout roots to form a new willow that is genetically identical to the original tree and thus asexually propagated. Foresters have used this technology to their advantage as a breeding tool for centuries. Propagating a tree vegetative, traditionally by grafting or rooting cuttings, allows the production of individuals that are genetically identical to the original and are therefore members of a clonal family. Tissue culture has become the preferred method of clonal production for some species of plants, including several species of forest trees. This technology is also useful for moving clones across quarantine barriers, since the cultures are free of insects and diseases.

Organogenesis

A type of asexual propagation that literally means 'organ genesis'. It is accomplished by growing a mass of cells in tissue culture that have the ability to produce shoots and grow into full trees.

Somatic Embryogenesis

Cells in a tree other than the pollen and egg cells are called somatic cells. This technology intensive technique is used to rapidly proliferate plant tissue via asexual propagation that mimics steps of the normal embryo development process. Single cells in tissue cultures from shoots, buds, roots, or leaves are induced to form complete embryos that can form plants identical to the original plant where the cells were taken. Large numbers of a given clone can be produced in a short time.

Genetic Engineering Technologies

The issues at hand are based on the advanced science of genetic engineering[4]. Genetic engineering is a process in which specific DNA sequences encoding for very specific and desired traits are introduced into the plant genome. We must be precise in our language and terms because as discussed above, forest biotechnology includes a wide range of technologies in which laboratory based processes are used to improve trees.

Certain types of forest biotechnology require the most immediate attention for principles to govern their responsible use. Clonal propagation of trees is not necessarily the result of biotechnology. Some types of trees in the forest, such as willows, can asexually propagate through shoots or branches without any human intervention. Conventional breeding techniques that include various crossing and selection methods can produce trees that can be asexually propagated. Both breeding and asexual propagation have been used for over 3,000 years and are generally regarded as familiar and safe. Rather than focus on trees that were originally developed through conventional breeding techniques, society should focus its efforts on developing principles for the truly advanced forest biotechnologies.

The Institute of Forest Biotechnology defines 'biotech trees' as: "Any tree that is a product of targeted genetic engineering, and the progeny of these types of trees propagated through sexual or asexual methods." Given

[4] "Genetic Engineering: The use of recombinant DNA and asexual gene transfer methods to alter the structure or expression of specific genes and traits." (Food and Agriculture Organization of the United Nations, 2004)

this definition, biotech trees encompass a spectrum of advanced technologies that introduce genes, or transgenes,[5] via genetic engineering in the following three ways.

Altered native gene function

This type of insertion can cause an increase or decrease (upregulate or downregulate) the expression of native genes. By altering how a gene is expressed, scientists can adjust phenotypic aspects of the tree. This technique can be used to increase the growth of trees, control flowering, and modify their wood composition. Often these types of trees mimic unique tree types that are already in natural tree populations.

Insertion of one or more novel genes from plants

These transgenes would not typically be found in the normal gene pool for the tree they are inserted into. The inserted genes are from other plant or tree species to produces novel trees that would not normally occur through natural selection on a human timescale. However, since the genes do come from the same kingdom it is within the realm of possibilities that given enough time, those genes could naturally become part of the trees genome. This technique is being used to produce trees that are resistant to disease, drought, pesticides, and cold temperatures.

Insertion of one or more novel genes from non-plants

These transgenes are genes that would not typically be found in the normal gene pool for that tree and come from other organisms. This application produces novel trees that would not normally occur through natural selection because the genes come from organisms other than plants. Trees engineered to absorb pollutants from the environment rely on these types of genes.

Transgene that provide new industrial applications

These introduced genes can use either of the two types of transgenes mentioned above, but the end result is a tree that has a novel use or application. Usually the resulting tree is used as a vector to produce material for industrial applications and would not naturally occur. For example, it may be possible to engineer a tree to produce pharmaceuticals, unique biofuels, or chemical feedstock intermediaries. This technology is on the very cutting edge of forest biotechnology today.

While it is impossible to rank and order every possible benefit and risk associated with a technology, we can reasonably expect society to make a distinction between trees that differ most from their native relatives because there may be more of a risk to humans or the environment. It will be society's concerns, whether based on science or a lack of information, which will set the boundaries in the commercialization and stewardship of biotech trees.

In many ways, the source of society's concern involves speed. It has been argued, and will continue to be in some circles, that what humans are doing with genetic engineering is a faster version of the natural processes that occur all the time. Species evolve naturally over time. We can all be thankful for the mutations that have made us humans from simpler life forms. Together mutations and natural selection have created the myriad of species on earth today including the vast variety of trees in our forests. What we are able to do with biotechnology is two fold. We are able to speed up natural evolutionary processes that we can reasonably expect would happen over many millennia. An example of 'accelerated evolution' could be creating a tree that

[5] "Transgenes: a gene or gene construct that has been transferred into an organism such as a plant, using genetic engineering techniques, including transformation techniques, i.e. the process of inserting transgenes into the genetic material (DNA) of an organism." (Convention on Biological Diversity, 2006)

is resistant to a particular virus. We are also able to extend the natural abilities of trees in ways that we can reasonably expect would never happen naturally. An example of 'novel evolution' could be creating a tree that produces pharmaceutical products. Many of our drugs today are derived from tree products, such as tamoxifen (Geffen et. al. 2001), a drug originating from trees and used to fight breast cancer. In the future there may be trees that are engineered to produce products that are not naturally tree-based.

Other biotechnologies that can be used with trees are not included in the IFB's definition of biotech trees because they do not strictly use genetic engineering to achieve their results. Examples of this include mutagenesis[6] and somatic embryogenesis.

Mutagenesis

New varieties of trees, such as new fruit tree varieties, have been generated from the selection of natural or induced mutations that can alter the color, smoothness, shape, and seed characteristics. Mutated branches can be asexually propagated to preserve and maintain the new characteristic resulting from the mutation. Although these trees do contain genes that are modified, the process of natural or non-targeted human induced mutation are not considered genetic engineering here and do not fall within the IFB's definition of a biotech tree. This distinction is in part because many plant mutations are deleterious to the plant and only a few are able to become desirable new varieties. This is mainly because mutagenesis has multiple large impacts on the plant genome that cause a pleiotrophy, or chain reaction of effects in the genetic structure of the tree, that are usually both positive and negative. Wide ranging and random effects on the genetic structure of any organism are rarely beneficial to its survival. In short, mutagenesis is not a form of targeted genetic engineering. It is a random approach that alters a suite of genes in unknown ways.

Biotech trees will change future forests as they undoubtedly are in Asia right now. There are a number of ways that society can address the appropriate use of this technology: through laws and regulations, certification programs, and industrial pledges. Since society places a high value on the earth's forests and the ecosystem services they provide, we believe that the current set of options to address the use of forest biotechnology are not comprehensive enough to ensure that biotech trees will be used responsibly. To fill this gap in performance the Institute of Forest Biotechnology has launched an initiative that will create a set of principles for stewardship of these trees. The Responsible Use® initiative will be discussed in more detail later in this paper. This initiative focuses only on biotech trees; those depicted by the orange colors in the chart below. In very broad general terms, increasing technical advances in biotechnology can potentially lead to greater deviations from native phenotypes. In other words, the more gene function is modified in a particular tree, the more likely that tree will have different characteristics from its native relatives. As the figure below shows, there is a higher *potential* to produce trees with characteristics that are different or altered from native phenotypes as we increase the amount of technology we apply. However, more technology does not necessarily mean more genes are being modified. Much of the advances in biotechnology are to make gene modification more precise and thereby limit the extent of potential risks.

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[6] Human induced mutagenesis changes a genetic structure through the use of mutagens such as ultraviolet light, radiation, or chemicals. It is fair to say that inducing a mutation, whether favorable for creating a specific phenotype or not, rapidly alters the genetic composition of an organism. However, this is not biotechnology that uses living systems to produce the mutated plant. Today this technology is outdated and highly unlikely to be used instead of genetic engineering especially in trees where generation times severely restrict looking for a needle (the phenotype you want) in the haystack (all the cell lines you would have to generate and test).

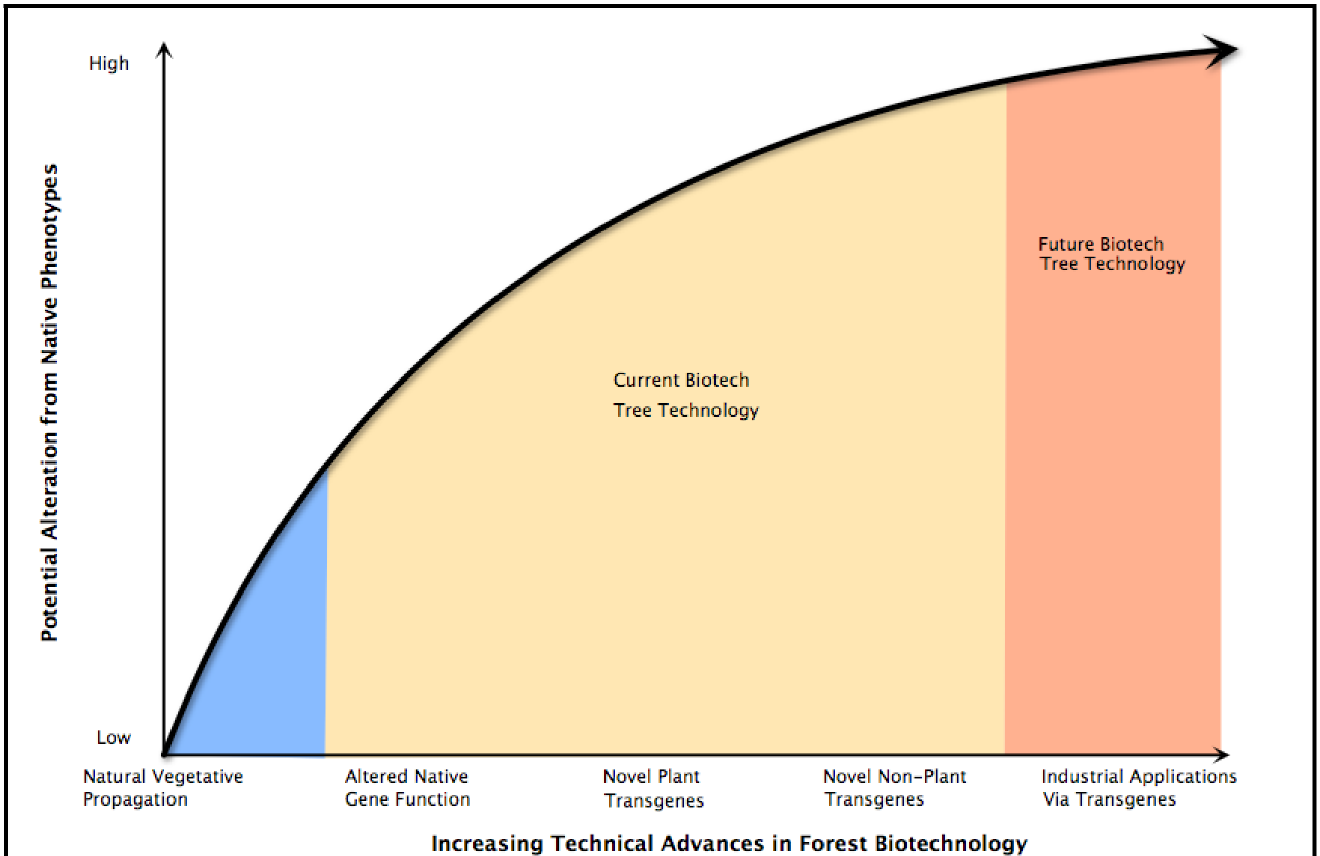

Figure 1

As we will discuss, the Responsible Use initiative will develop a set of principles that all sectors of society can use to be better stewards of biotech trees. There are various types of control imparted on biotech trees by regulatory systems around the world that are described generally in the next section. Rather than duplicate these systems, the Responsible Use initiative will create a higher standard of performance without prescribing a command and control system.

How biotech trees are controlled

There are four main levels of containment for biotech trees we need to consider. Though there are combinations of release control throughout the world, we can think about the relative control of biotech trees starting in the lab under highly controlled environments like greenhouses, then moving to outdoor test plots with a high level of oversight, and ultimately some biotech trees are released to the open environment without the requirement for any controls. The reason these three distinct levels exist is based on both the need to study the phenotypic aspects of growing trees, and the potential for biotech trees to interact with the natural environment. Each level has its own unique aspects that scientists manage in different ways.

Level 1 – Confined to the lab or greenhouse

By confining early results of genetically engineered trees to highly controlled environments, there is almost zero chance that any genetic introgression[7] will occur with trees in the natural environment. This level of control allows scientists to conduct research towards improving and understanding the biology of trees without

[7] Genetic Trensgression: The infiltration of the genes of one species into the gene pool of another.

the risk of affecting living systems outside of the lab or greenhouse. The downside is that labs are much smaller than outdoor plots so space often limits how many trees can be tested, or how long they can be allowed to grow since most trees will grow many meters high.

Level 2 – Field trials with oversight

The outside environment is highly dynamic and can never be perfectly replicated in the lab. For this reason many biotech trees are moved into fields where they are exposed to natural conditions. The spatial and temporal distribution of biotech trees is tightly controlled in field tests in the United States, although other countries may require different levels of specific oversight. This level of control allows researchers to grow more trees, usually to an older age, in real-world conditions to test the performance of the trees and the efficacy of the inserted DNA sequences. In most cases this level requires that each biotech tree planted in the field be managed and tracked according to a specific plan set forth by the regulating authorities.

Level 3 – Released for planting with monitoring requirements

While there are a number of specific details based on regulatory system and the biotech tree itself, this level of control is less restrictive on the spatial and temporal range of the tree. It is possible that a regulatory agency could allow release on the condition that certain aspects of trees and plantings are monitored for potential environmental risks.

Level 4- Released for planting with any regulatory oversight requirements

At this level, a biotech-modified tree is treated no differently than any other planted tree, and there is no requirement for post-launch monitoring or regulatory oversight. To date, there are only three species of biotech-modified trees (virus resistant papaya (United States), plum pox virus resistant plum (United States) and insect tolerant populus (China) at this level in the world today.

There are orders of magnitude in the number of trees among each level. With thousands of highly confined biotech tree specimens and several hundred of field tests around the world there are still only three biotech trees that do not require regulatory oversight and are planted like any other tree. This relatively small number reflects the stringency by which biotech-modified trees are tested and move through some regulatory approval processes, and the increasing difficulty in moving from one level of control to the next either because of regulatory requirements, cost, or simply social demand.

Status of biotech trees in 2008

As of the date of this publication, there were three species of biotech trees in the environment that are either deregulated or not regulated. Meaning that there is no governing body looking specifically at these trees and how they interact with the environment and society.[8] Information regarding the number, type, and governing body of biotech trees is available at the IFB's website.

In 1998 The U.S. gave the papaya a non-regulated status for use in Hawaii to combat a virus. This made the tree available to any farmer interested in planting it. Because papaya is a food crop it had to be reviewed by plant, environmental, and food related agencies; U.S. Department of Agriculture's Animal Plant Health Inspection Service, The Environmental Protection Agency, and the Food and Drug Administration respectively.

[8] APHIS has the authority to repeal an unregulated status on any plant if it subsequently becomes detrimental to society.

In 2002 China commercially released 1.4 million genetically modified Poplar *(Populus)* trees in an area of 300 – 500 hectares (Food and Agriculture Organization of the United Nations, 2004). As opposed to the Papaya, that is considered a food crop, this event marked the first biotech forest tree ever released into the environment. Predominately these trees were modified with the Bt gene that produces a protein toxic to insect pests. This gene is produced by a bacterium in the soil called *Bacillus thuringensis* and is used in a number of biotech crops including corn, cotton, and soybeans. Today there are spurious reports that these trees are now readily available to tree farmers to plant for various purposes.

In 2007 The U.S. deregulated the C5 "HoneySweet" Plum tree engineered to be resistant to the plum pox virus (Animal and Plant Health Inspection Service, 2007). Like the Papaya, this tree is also a food crop and was subjected to similar requirements before it was given a non-regulated status.

Of these three tree species the million plus Poplars released in China is the most interesting test case because these forest trees can cross with native relatives. This can change the genetic make-up of the natural forests; for better, worse, or no significant change at all. Obviously there is no going back – modified genes will be in future forests. This fact has raised the question of whether society should put principles in place so that users of biotech trees know how to be good stewards of them.

Risks and benefits of using biotech trees

Biotechnology is a powerful tool. Humans have had the ability to change living organisms for thousands of years and have had to reckon with unintended consequences ever since they began breeding and translocating plants. Forest biotechnologies that modify genetic operations are no exception. Mankind can now research biological systems at the DNA level, and to even decode entire genomes. This feat was accomplished through years of research in plant and agricultural life sciences. While we can easily decode a human's genome today, it is not as simple for some trees. For example, a representative conifer (pine tree) genome is many times larger than a human's (Keim, 2007). For example, the Loblolly pine's genome is seven times larger. Such a feat has yet to be accomplished in whole, but the Pine Genome initiative is working towards this goal to improve future biofuel production from pine trees, improve forest health, and gain insight into plant evolution (Pine Genome Initiative, 2007).

Unlike the unthoughtful implementation of many new technologies that mankind has embraced with disregard for social and environmental implications, many experts believe that the use of biotech trees can take a radically different course. To date, biotech tree work has focused on either environmental or economic benefits. . This fact is in large part because of the technical difficulties that have to be overcome to genetically modify trees. The difficulties make it very costly and time consuming to make even minor adjustments in trees. The major institutions around the world doing this work are thoughtful in their approaches with many checks and balances along their research chain that ensure resulting biotech trees are useful to society. The bottom line is that there has to be a significant ecological, social, or economic return, or the research is discontinued for more worthwhile work. The rigor of this process doesn't eliminate all risks or unintended consequences associated with biotech trees, but it has created broad categories of risks and benefits that are generally accepted among forest biotechnologists as important to consider during the research and development stage.

Potential benefits of using biotech trees

The following are some beneficial uses for biotech trees identified by the Forest Biotechnology Partnership.

Enhance bio-based products

Trees can be engineered to adjust the characteristics of its wood to suit specific needs. The global demand for biofuels has put an unprecedented amount of resources into developing trees that can readily be converted into liquid fuels. For example, adjusting the ratio of lignin and cellulose can create a cellulose feedstock that is significantly easier to convert into a liquid fuel (United States Department of Agriculture, 2007). Whether it is ethanol, butanol, synthetic gasoline, or even biodiesel, the interest in advanced forest fuels will forever change how society considers purpose grown trees. However, it is not just the race to produce cellulosic biofuels that is putting biotech trees on the fast track to commercial production at unprecedented levels. All conventional forest products can benefit from biotechnology as well. Developing trees that grow faster, denser, and straighter is desirable to lumber companies. Making more cellulose and less lignin means more wood pulp and paper can be produced from a given tree. The list of commercial benefits from biotech trees is long and must include the ancillary benefits of providing renewable products that society uses.

Combat invasive threats

Engineering trees so they are more resilient to a changing climate and are better able to defend against foreign pests is critical to keep our forests healthy. Because of rapid globalization, earth's climate is changing at the same time invasive pests are able to travel from one side of the earth to the other in less than 24 hours in cargo holds. Forests evolved over millennia of relatively stable climates and large spatial separations. Demanding that native trees combat the onslaughts of threats they encounter today without human intervention will result in significant tree deaths and ecosystem change around the globe. This is already being seen in British Columbia, Canada. There the mountain pine bark beetle is estimated to claim 80 per cent of the mature Lodgepole pine by 2013 (Natural Resources Canada Program Description, 2007).

Maximize forest productivity

Making more material on less land that grows more quickly has potential benefits to the pulp and paper industry, the new liquid biofuels industry, and as a method to sequester carbon more quickly. A significant amount of research has gone into making biotech trees to put more fiber on less land to reduce demand on native forests and make it easier to use trees as a fast rotation crop in intensely managed tree plantations (ArborGen Bioenergy Factsheet, 2008). Dense wood crops may also play an important role in international incentive-based programs, such as the United Nation's REDD Programme, to avoid deforestation, slow forest degradation, and reduce the economic incentives that promote illegal logging (UN-REDD Framework Document, 2008).

Replenish indigenous people's forest resources

In many lower income communities in South America, Africa, and Asia, the forests indigenous people historically relied on are decimated. The reasons are multifaceted but the fact remains that people are struggling, forests are declining, and these two situations reinforce one another through complex negative feedbacks. The solution is not as easy as producing biotech trees to reclaim degraded land, but advanced societies interested in improving these situations should not overlook the power of forest biotechnology when novel solutions are needed.

Potential risks of using biotech trees

A recent symposium of international experts on this topic highlighted the following areas of risk that should be addressed when biotech trees are used in the open environment (Institute of Forest Biotechnology, 2008).

Gene flow and introgression

Gene flow refers to escape of a transgene into a native population of the same tree species. Before gene flow can occur there must be seed or pollen dispersal, establishment of the propagule, and survival of the plant to sexual maturity. In some situations gene flow is the desired outcome of releasing biotech trees into the environment. Forest health projects to protect threatened trees species from invasive threats plan on gene flow from genetically modified trees to native ones and thereby confer resistance to the native population. In some instances gene flow to native populations will be less desirable and have to be managed appropriately to protect forests. Introgression is the infiltration of a transgene from one species into the gene pool of another through repeated backcrossing of a hybrid with one of its parents. This situation has similar ramifications to gene flow, but it adds a confounding factor of moving a transgene from one species to another.

Exceptional fitness

While one of the main goals is to produce trees that are better able to thrive in the environment, there are concerns that these more biologically fit trees may out compete native species. This characteristic is commonly referred to as weediness. If a biotech tree is exceptionally fit when compared to its native relatives, there is a chance that it will be so successful in the forest that it keeps other trees from growing as they naturally would. Again, there are instances when exceptional fitness is the desired outcome as well as situations where it can cause ecological problems.

Effects on non-target species

Possible non-target species effects might include harm to beneficial soil organisms, insects, birds, or other plants. For example the Bt gene that is one of the more common genetic modifications in plants produces a protein toxic to insect pests. This gene is produced by a bacterium in the soil called Bacillus thuringensis. Using the Bt Poplars planted in China as an example, there is concern that the Bt gene can inadvertently harm a species of insect. This situation is highly unlikely because of the rigorous research that has gone into the Bt gene, but we use it here as an example only. Other situations where less thorough research has been completed could harm other species that interact with the biotech tree.

Biodiversity effects

These concerns are more broad and can encompass interrelations among forest species that affect the ecosystem as a whole. One such concern focuses on the idea that stands of sterile GE trees would not support a diverse population of species in the larger forest ecosystem. Another concern is that the target function of the biotech tree will have unintended ecosystem consequences. A situation could be envisioned where a biotech tree is exceptionally fit, contains a transgene that inadvertently affects non-target species, and there is gene flow to native trees. This situation could have negative biodiversity effects for the native forest.

These concerns highlight scientific questions that need to be addressed through ecological research. In addition, there are social concerns that are just as valid even if all of the scientific concerns are addressed. The proliferation of sustainable forestry certification schemes shows that the public places a high value on responsible management of natural resources and the well being of forest ecosystems. By recognizing the ecosystem-changing potential that irresponsible biotech tree use can cause, we are in the enviable position today of being able to construct and implement safeguards *before* these trees reach the market en masse. Currently, there are no principles that can ensure the long-term stewardship of biotech trees. That is why the IFB has created the Responsible Use Forest Biotechnology Principles; an initiative to develop these critical principles in a highly transparent and multistakeholder process.

Responsible Use: Forest Biotechnology Principles

The Responsible Use initiative will help protect the future of our forests by creating principles for the use of biotech trees. Principles are concepts of performance, such as 'do not break the law' while an element brings that idea into sharp focus so it can be operationalized on the ground, such as 'follow all national, regional, and applicable international laws.' The IFB will manage the development of these principles by working with Initiative Sponsors, Forest Biotechnology Partners, experts from around the world, and any interested stakeholder. Every draft report, all meeting documents, and all other non-proprietary material relating to these principles is available online at responsibleuse.org. There is also a form on that site where anyone interested in participating in the development of these principles can have their ideas heard. These comments are available to the public for review, but more importantly, they will be used by the Implementation committee when developing the principles.[9]

Society demands sustainability

We need sustainably managed trees for communication, packaging, housing, food, and renewable energy. Currently the world does not have enough sustainably managed forests to fill all these needs. Instead we have illegal logging, land being converted from forests to sprawling housing developments, and an onslaught of invasive threats damaging the health of our forests. Forest biotechnology can be a powerful tool against these threats, but society cannot yet conclude that the use of biotech trees is sustainable.

The IFB is managing the development of principles that:

- Will help determine responsible uses of forest biotechnology
- Are highly transparent, multi-stakeholder driven, and global
- Can not be used in place of sustainable forestry practices because it is not a certification scheme; but that could be used to complement other certification mechanisms
- Will compliment regulations of biotech trees but not supercede them
- Include the entire value chain of biotech trees with performance-based verifiable elements
- Are robust and structured so organizations can verify their adherence to the principles
- Will create teaching material to educate young students – society's future forest stewards
- Are designed to evolve with the science of biotechnology, societal demands on trees, and sustainable resource management techniques

Responsible Use principles scope

The principles will be comprised of verifiable elements that when taken together encompass the entire biotech tree value chain; from idea conception to disposal of products. Through numerous discussions with experts and concerned stakeholders we've developed a conceptual map that includes 10 discrete steps of the value chain. Each of these steps will include one or more verifiable element to help guide biotech tree use. As the diagram shows below, there are three discrete parts of the chain.

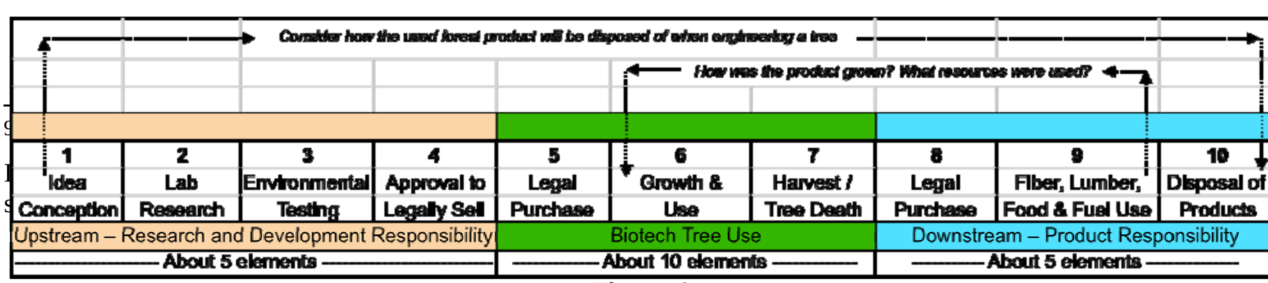

Figure 2

Process steps in the biotech tree value chain:

Upstream Development – Research and Development Responsibility

1. Idea Conception: The beginning of the entire process.
2. Lab Research: Testing ideas in a highly controlled indoor environment. This step covers most lab and bench-scale work up to the point of planting a tree outside. This corresponds with the previously discussed control level one.
3. Environmental Testing: Testing trees outdoors in 'real-world' conditions while under strict control to keep genetic material from leaving the test site. This corresponds with the previously discussed control level two.
4. Approval to Legally Sell: This step is referring to situations where developers of biotech trees are given authority to sell the trees to another party that will plant and grow the trees in the environment without strict control over genetic material.

Biotech Tree Use

5. Legal Purchase: This step begins with the legal purchase of biotech trees. It also corresponds with the previously discussed control level three.
6. Growth and Use: Planting and growing biotech trees in the environment without strict control over genetic material.
7. Harvest or Tree Death: The last step in the use stage is defined by tree death. This step marks the end of issues associated with living genetic material.

Downstream Products – Product Responsibility

8. Legal Purchase: This step begins the product responsibility stage defined by the legal purchase or transfer of material produced by a biotech tree.
9. Fiber, Lumber, Food and Fuel Use: The in-use step of the forest product.
10. Disposal of Products: The last step in the value chain of biotech trees encompasses disposal of forest products.

The total number of elements will be kept as concise as possible while still providing the structure needed to implement each one effectively and to verify that the principle has been followed. Initial stakeholder feedback suggests that approximately 10 verifiable elements for the biotech tree use stage and five elements for both the upstream development and downstream products stages are reasonable targets. However, since the principles and elements are meant to evolve as forest biotechnology does the number and scope may change over time. However, one principle has been unanimously decided upon to date:

Responsible Use Principle Zero: Users must follow all national, regional, and applicable international laws pertaining to biotech trees whether these laws are actively enforced or not.

This principle is important for two reasons. First, it underscores the point that these principles are meant to supplement regulations and not to supersede them. Second, it acknowledges that some countries have regulations that are not enforced. Users need to follow laws of the land regardless of a country's enforcement record.

The IFB will manage development of the principles so they are flexible and do not restrict innovation, yet are straightforward for easy implementation, such as principle zero is. While some aspects of the principles will be prescriptive, our objective is to produce verifiable performance-based criteria.

Developing the principles

It is critical to get a broad stakeholder group to create these principles. It is also necessary to have a smaller group of experts that actually write them. To achieve both of these criteria we have developed a structure modeled after the United Nation's approach. An Implementation Committee will be created from experts in academia, tree growers and users, public interest professionals, environmental scientists, and government representatives. An ideal committee will have representation in each of these categories from every continent. Input from stakeholders will be addressed by the Implementation Committee and the IFB in a strong bottom-up process. Top-down management will include Initiative Sponsors and the IFB's Forest Biotechnology Partnership as depicted below.

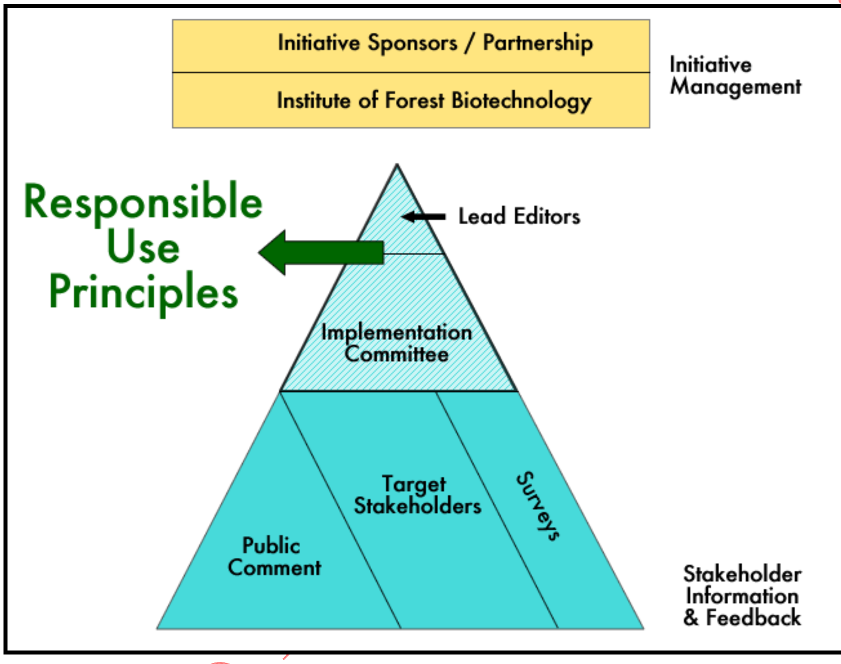

Figure 3

The overall process will be highly collaborative and transparent. As already mentioned, every non-proprietary piece of information pertaining to this initiative is online at responsibleuse.org including the project design document.

Principle development timeline

If we believe that society and the environment will benefit by having thoughtful experts create Responsible Use principles before any biotech trees are released into the natural environment, then we are already too late. As we previously discussed, over a million Bt Populus trees are already at level three in China; as are two fruit bearing trees in the U.S. However, we still have a window of opportunity to do something that will protect the future of forestry. There will be another wave of biotech trees in the next few years that will apply for commercial release; control level three.

At the time of printing our schedule puts release of the first actionable set of principles in November 2009. This timing gives the implementation committee ample time to develop draft guidelines, test them, gather feedback, and revise them. However, the process does not stop in November '09 with an ironclad product. It

is just the end of the beginning, so to speak. An ongoing project will continue to gather input, refine the elements, and add or remove principles as necessary to keep abreast with forest biotechnology. Furthermore, the Responsible Use initiative strives to create a globally applicable set of principles. To do this we will coordinate with additional organizations and experts in the long term. We must act quickly but thoughtfully. Protecting the future of forestry is too important to leave to chance.

The Institute of Forest Biotechnology (IFB)

The IFB is uniquely able to achieve the goals of this initiative. It is the only non-profit organization in the world to address the sustainability of forest biotechnology on a global scale. The IFB has the largest network of experts in this field. With the help of our Partners and Sponsors we bring diverse stakeholders together to address the societal, environmental, and economic aspects of forest biotechnology – and we are expanding to areas where forestry plays a critical role in society and the environment.

The IFB currently has five Initiatives. Some of these have dedicated websites for ease of use and enhanced transparency:

- Responsible Use™: Forest Biotechnology Principles – responsibleuse.org
- Forest Fuels™: Unlocking the potential of fuels made from trees – forestfuels.org
- Pine Genome: Decoding pines for vital forests – pinegenomeinitiative.org
- Heritage Trees™: Species Protection through biotechnology heritagetrees.org
- Addressing Forest Biotechnology Concerns: Dialogue on ecological and social issues

Together we can improve future forests through science, dialogue, and stewardship. Please visit our website, forestbiotech.org, to learn more about protecting the future of forestry.

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