Regulation, Certification, and Use of Biotech Trees

A Responsible Use Initiative Report
Researched and published by the Institute of Forest Biosciences – July 2015

How and where will biotech trees[1] be used in coming years?
Answering this question has been a focus of the Institute of Forest Biosciences (IFB) and its Responsible Use initiative. It is widely assumed that Biotech trees are some of the most heavily regulated plants in the world. This paper begins to quantify the differences between regulatory systems in countries likely to first use biotech trees. Sustainable Forest Management Systems (SFMs) are voluntary programs that act as an additional layer of regulation on biotech tree use. In quantifying these systems the IFB has determined that no forest management system can certify biotech trees as sustainable. This paper takes a holistic look at policies and requirements in countries that are most likely to use biotech trees, and under which circumstances they might first be made commercially available for tree farmers and citizens to plant and grow.

Scope
This paper reviews the regulatory frameworks of biotech trees in Brazil, Chile, Uruguay, U.S., Canada, South Africa, China, and New Zealand. The approach that top SFMs in these countries take toward biotech trees will also be reviewed. These comparative reviews will show where regulations and certification systems overlap and diverge. Finally, an estimate of where, when, and for what purpose biotech trees are likely to be used commercially is discussed.

This work is part of the IFB's Responsible Use initiative. This paper is available in hard copy and online. The online version is open for comments and discussion. We encourage anyone having updated information or constructive questions to participate in the discussion forum. We will strive to keep this information well referenced and updated with help from the broader forest biotech community. Please visit forestbio.org/contact to comment on this document.

The Responsible Use: Biotech Tree Principles
As forest biotechnology takes root with biotech trees being field-tested for biofuels, growth characteristics, and disease resistance, the need for a set of global guiding principles for using these trees became apparent. The IFB developed the Responsible Use: Biotech Tree Principles in a transparent, international, stakeholder driven process to guide long-term stewardship of biotech trees. These principles are the first, and only, practices designed specifically for the long-term stewardship of biotech trees.

A broad set of stakeholders has set aside issues of *whether* biotech trees should be used to create these stewardship principles. Central to the Principles are core beliefs that:

- Biotech trees should benefit people, the environment, or both
- Risks and benefits of biotech trees must be assessed
- Transparency is vital and stakeholders must be engaged
- Social equity and indigenous rights are important and must be respected
- Biotech tree use must follow regulations of the appropriate country

The Responsible Use: Biotech Tree Principles provide a unique opportunity for governments and SFMs to incorporate stewardship oversight of biotech trees into their systems. Visit www.responsibleuse.org to learn more about this effort.

[1] Also called GM trees, the Institute of Forest Biosciences defines Biotech Trees as a tree developed through genetic engineering or which contains discretely engineered DNA. This definition is intentionally inclusive of both the process and the resulting tree. The IFB considers biotech tree offspring to also be biotech trees unless it can be rigorously proven that such offspring does not contain genetically engineered DNA.

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Regulatory Matrix Components

The table on the next page shows a comparison of the regulatory approaches taken towards biotech products in eight countries. Unless otherwise noted, the information sources were U.S. Department of Agriculture's Foreign Agriculture Service GAIN reports. Below are the column labels for table 1.

- **Country** – The country that subsequent column data is in reference to.
- **Biotech Framework** – Whether the country has a coordinated regulatory framework that has the force of law.
- **Oversight Role** – Regulatory authority of transgenic biotechnologies is often divided into various agencies that have specific roles. This column distills these roles into common nomenclature for comparison.
- **Regulatory Agency** – The agency that is responsible for regulating specific aspects of biotechnology.
- **Specific Biotech Tree Regulations** – Whether or not there are specific regulations for biotech trees.
- **Cartagena Protocol Signatory** – Whether or not the country has ratified, approved, or otherwise signed the Cartagena Protocol on Biosafety (Convention on Biological Diversity, 2015).
- **Biotech Stringency** – A relative score based on regulatory stringency criteria used to estimate the overall difficulty of commercializing biotech products in that country. Possible scores range from 0 to 100. A score of 0 indicates that there are no regulatory barriers to commercializing a biotech product while a score of 100 indicates that the regulations make it effectively impossible to commercialize a biotech product. This work is based on research done by Vigani et.al at the University of Milan (Vigani, 2009). Note that Uruguay was not assessed in the original paper. The IFB worked with the researchers at the University of Milan to develop a score for Uruguay using the same methodology and data sources.

Regulatory Matrix - Table 1:

Country	Biotech Framework	Oversight Role	Regulatory Agency	Specific Biotech Tree Regulations	Cartagena Protocol Signatory	Biotech Stringency
Brazil	Yes	Primary agency:	National Biosafety Technical Commission (CTNBio)	No	Yes	50
		Appeals:	National Biosafety Council (CNBS)			
Chile	No	Primary:	None	No	No	35
Uruguay	Yes	Primary agency:	National Biosafety Commission (GNBio)	No	Yes	35*
		Biosecurity policy:	Commission for Risk Management (CGR)			
		Risk coordination:	Evaluation of Risk in Biosecurity (ERB)			
		Risk assessment:	Institutional Articulation Committee (CAI)			
U.S.A.	Yes	Primary agency:	None: Coordinated Framework for Regulation of Biotechnology	No	No	35
		Environmental risk 1:	Planting: Department of Agriculture' s Animal and Plant Health Inspection Service (APHIS)			
		Environmental risk 2:	Plant Incorporated Protectants (PIPs): Environmental Protection Agency (EPA)			
		Food safety:	Department of Health and Human Services' Food and Drug Administration (FDA)			
		Compliance/ Enforcement:	USDA APHIS's Biotechnology Regulatory Services (BRS)			
Canada	Yes	Primary agency:	Canadian Food Inspection Agency (CFIA)	No	No	30
		Human health:	Health Canada (HC)			
		Environmental risk:	Environment Canada (EC)			
South Africa	Yes	Primary agency:	Department of Agriculture, Forestry, and Fisheries (DAFF), with three councils: Executive, Advisory, Registrar	No	Yes	30
China	Yes	Primary agency:	Ministry of Agriculture (MOA)	Yes	Yes	50
		Biotech tree agency:	State Forestry Administration (SFA) - regulates research, production, and import/export of biotech forest trees			
		Biosafety policy:	Ministry of Environmental Protection (MEP)			
		Compliance:	Administration of Quality, Inspection, and Quarantine (AQSIQ)			
New Zealand	Yes	Primary agency:	Environmental Protection Agency (NZ-EPA)	No	Yes	65
		Environmental risk:	Ministry for the Environment (MFE)			
		Compliance/ Enforcement:	Ministry of Primary Industry (MPI)			

*Derived by the IFB using methodologies from Vigani et.al and USDA GAIN report

Government Regulatory Systems Review

The biotech regulatory systems of the eight countries highlighted in this report are briefly summarized below.

Brazil
There are two governing bodies that regulate biotech products in Brazil; The National Technical Commission of Biosafety (CTNBio), and The National Biosafety Council (CNBS). CTNBio has oversight authority over all GMO plants in Brazil (Borem 2011). CNBS only reviews administrative appeals of significant national interest, and only before approval of a product by CTNBio. Once CTNBio approves a product as safe for commerce, it is considered a final decision (Hoff & Silva, 2014). Brazil does not have regulations or systems tailored specifically for biotech trees. Each biotech product is treated on a case-by-case basis. However, CTNBio does have a mechanism for developing normative guides that deal with specific products and procedures.

Chile
Chile does not have a regulatory framework in place to provide oversight for producing biotech products. As a result, no biotech material is allowed to be commercially grown and produced in Chile. The Ministry of Agriculture's Agricultural and Livestock Service (SAG) regulates all biotech material in Chile, which is only allowed for research or export, under Resolution 1523 established in 2001. (Butterworth & Ramirez, 2014).

Uruguay
Decree 353/08 established the current biotech product regulatory framework in Uruguay in 2008. The National Biosafety Commission (GNBio) is primarily responsible for managing biotech products. Various committees operate to inform GNBio decisions. The Commission for Risk Management (CGR) advises on biosecurity issues, manages overall risk assessments, and monitors biotech products in use. The Evaluation of Risk in Biosecurity (ERB) committee coordinates case-by-case risk assessments and identifies experts to populate the Institutional Articulation Committee (CAI) that performs the scientific testing necessary to inform CGR (Markley & Yankelevich, 2012).

United States of America (U.S.A.)
The U.S.A. relies on the Coordinated Framework for Regulation of Biotechnology (CFRB) of 1986 to regulate biotech products. The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) and its Biotechnology Regulatory Services (BRS) oversee safe cultivation and environmental introductions of commercially used biotech products that are determined to be plant pests as defined by Plant Protection Act (7 CFR part 340). By this definition, not all biotechnology tools are considered to use plant pests and therefore are not regulated by the USDA. For example, a biotech plant produced using biolistics my not be regulated by the USDA if no part of a plant pest is introduced into the tree's genome.

Statutory language limits the type of biotech plants and trees that are subject to regulation by APHIS. Older technologies like biolistics, and new technologies such as zinc finger nucleases (ZFN), transcription activator-like effector nucleases (TALENS), CRISPR/Cas9, or other gene editing techniques can develop biotech trees, plants, and animals that are not subject to regulation in the U.S. However, the USDA recognizes that when statutory authority does not require the regulation of a biotech tree, it should still be developed and used according to the IFB's Responsible Use Principles (Firko, 2014).

The Environmental Protection Agency (EPA) has jurisdiction over all biotech products that have Plant-Incorporated Protectants (PIPs) regardless of how the biotech product is developed because it is considered a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The U.S. Food and Drug Administration (FDA) oversees food safety and has jurisdiction over all biotech products intended to serve as food or animal feed. The National Environmental Policy Act (NEPA) requires that all U.S. federal agencies prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) that detail the environmental effects of federal actions unless categorically excluded. An EA or EIS is typically prepared before any biotech product is given regulatory approval to be produced commercially.

Canada

The Food and Drugs Act, through the Novel Foods Regulation, is Canada's framework for regulating biotech products. Established in 1996, this framework provides a robust regulatory system for Plants with Novel Traits (PNTs). PNTs include biotech products in addition to trees developed through a specific genetic change including recombinant DNA techniques, chemical mutagenesis and cell fusion. Conventional cross breed material can also be a PNT if the plant possesses characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a stable population of that plant in Canada. For example, if a plant is bred to have novel herbicide tolerance, but was not developed through transgenic techniques, it would still be considered a PNT and regulated as such. The Canadian Food Inspection Agency (CFIA) oversees the use of biotech plants and performs safety assessments before awarding permits to grow material outside of confined field trials. Health Canada (HC) assesses the human health safety of biotech foods and is responsible for approving their use in commerce. Environment Canada (EC) performs environmental risk assessments for CFIA, and is responsible for other various environmental notifications in Canada (Zimmerman & Lupescu Lupescu, 2014).

South Africa

The GMO Act of 1997 gives the Department of Agriculture, Forestry and Fisheries (DAFF) regulatory oversight for all biotech material in South Africa. This act was amended in 2010 to require scientifically based risk assessment as a prerequisite for decision making related to biotech material. The amendments require that the Minister of Agriculture make a case-by-case determination whether an environmental impact assessment is required under the National Environmental Management Act. The amendments also add specific legislation that allows socio-economic considerations to be an important factor in the decision making process. Eight new provisions were added that deal with unintended release to help slow contamination of non-biotech crops in the country. Three agencies carry out various tasks to achieve these goals; the Executive Council advises the Minister of Agriculture and forms the decision-making body for biotech product approvals, the Advisory Council is made up of 10 scientists to provide expert advice, and the Registrar administers daily activities of the GMO Act (Esterhuizen, 2014).

China

Reports show that the approval process for biotech products in China is unpredictable. The process to use a biotech product in China involves multiple agencies and oversight committees. With biotech trees being the exception, the Chinese Agricultural Genetically Modified Organisms Safety Administration Regulations of 2001 give the Ministry of Agriculture (MOA) oversight for all biotech material in China under Ministerial Decrees 8, 9 and 10. Biotech trees are governed by the State Forestry Administration (SFA), which regulates research, production, and trade of biotech trees that are intended for forestation and wood processing.

In general, Decree 8, "Measures on the Safety Evaluation Administration of Agricultural GMOs" governs the domestic approval and use of biotech material. Biosafety Policy is negotiated and

administered by the Ministry of Environmental Protection (MEP). Administration of Quality, Inspection, and Quarantine (AQSIQ) is responsible for national inspections and quarantine of all biotech material.

The deregulation of biotech trees by the SFA follows a similar process to MOA's. First, lab research is approved. Next are intermediary trials, environmental releases, and finally product testing. Once each stage is completed, test results are submitted to the SFA for a determination. After all the stages are successfully completed, and the SFA has acquired sufficient data, a biosafety certificate is issued, which is valid for 2 years. However, before a biotech tree product can be commercialized, a seed variety registration process must also be completed that could take multiple years and additional field trials (Anderson-Sprecher & Jie 2014).

New Zealand

The Hazardous Substances and New Organisms Act (HSNO) of 1996 gave the Environmental Risk Management Authority (ERMA) oversight for all living biotech material in New Zealand. In June 2010 the Environmental Protection Authority (NZ-EPA) was established as a Crown Agent that creates a third-party distance between the Minister for the Environment (MfE) and the NZ-EPA. ERMA was subsumed in the structure and the NZ-EPA is now responsible for administering biotech regulations (Maginnis & Lee-jones, 2014), while MfE is responsible for any changes to regulation that might be made. The NZ-EPA uses a structured, scientific framework to assess risks and benefits of biotech and other material considered potentially hazardous. There are no regulations specific to biotech trees, or any biotech material in particular (Strabala, 2015). The Ministry of Primary Industries (MPI) Biosecurity New Zealand is charged with enforcing the regulations and controls put in place by the NZ-EPA.

Sustainable Forest Management System Matrix Components

The table on the next page shows a comparison of the approaches taken towards biotech trees for the major forest management systems in eight countries. Below are the column labels for table 2.

- **Sustainable Forest Management System** – The name of the sustainable forest management system (SFM) and the acronym typically used to describe it.
- **Region / Scope** – The countries that the SFM is valid for. Some systems are international, others are regional, and many are specific to a single country.
- **Certified area** – The forested area measured on the ground in hectares (ha). These figures represent 1,000 ha and are rounded to the nearest 100,000 ha. Therefore a forested area that is 16,789,398 ha would be listed as 16,800 ha. Areas smaller than 100,000 ha are rounded to the largest significant digit.
- **Biotech Tree Approach & Decision Basis** – Two pieces of information are listed in this column. The biotech tree approach is the bottom-line decision that the SFM takes on certifying lands that grow biotech trees for production. The decision basis is the reasoning for the approach taken by the SFM.
- **Management Language** – Quoted text from SFM documents that explain in more detail the biotech tree approach and decision basis.

Below are the column labels for table 3.

- **Country** – The country that column data is in reference to.
- **Total Forest Area** – The amount of land in a country that is considered forest. This figure includes all forest types from unmanaged to intensively managed and all forest types in between.
- **FSC, SFI, ATFS, CERFLOR, CertFor, CSA, CFCC** – Acronyms for the various SFMs that are defined in the first column of table 2.

Sustainable Forest Management System Matrix

Table 2 – By Certification System:

Sustainable Forest Management System	Region / Scope	Certified Area (x 1,000 ha)	Biotech Tree Approach & Decision Basis	Management Language
PEFC Programme for Endorsement of Forest Certification	Global and Regional	263,200 [a]	Banned / Precautionary / Lack of data	Genetically-modified trees shall not be used
FSC Forest Stewardship Council	Global and Regional	183,100 [b]	Banned / Precautionary / Lack of data	Use of genetically modified organisms shall be prohibited
SFI Sustainable Forestry Initiative	North America	105,000 [c]	Research allowed / Banned via PEFC registration	Research on genetically engineered trees via *forest tree biotechnology* shall adhere to all applicable federal, state, and provincial regulations and international protocols
ATFS American Tree Farm System	U.S.A.	8,900 [d]	Not addressed / Banned via PEFC registration	None – no language directly addresses the us of biotech trees
CERFLOR Certificação Florestal	Brazil	2,500 [a]	Not addressed / Banned via PEFC registration	
CertFor Certficación Forestal	Chile	1,900 [a]	Banned / Banned via PEFC registration	Until the next Standard streamlining, no new species or variety shall be used in plantations, that come from Genetically Modified Organisms (GMO)
CSA Canadian Standards Association	Canada	36,800 [a]	Banned in reforestation that includes a public discussion component / Banned via PEFC registration	1: The public participation process shall include discussion of… The gene pool of native seed stock, and genetically modified organisms (GMOs) and the associated regulatory/policy requirements 2: "Conserve genetic diversity by maintaining the variation of genes within species and ensuring that reforestation programs are free of genetically modified organisms."
CFCC China Forest Certification Council	China	3,400 [e]	Banned via planned PEFC registration	Specific language is unknown - CFCC is designed to comply with and be endorsed by PEFC

Table 3 – By Country:

Country	Total Forest Area (x 1,000 ha)	PEFC [a]	FSC [b]	SFI [a]	ATFS [d]	CERFLOR [a]	CertFor [a]	CSA [a]	CFCC [e]
Brazil	519,500	2,500	6,400	xxxx	xxxx	2,500	xxxx	xxxx	xxxx
Chile	16,200	1,900	2,300	xxxx	xxxx	xxxx	1,900	xxxx	xxxx
Uruguay	1,700	11	900	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
U.S.A.	304,000	27,000	14,300	24,500	8,900	xxxx	xxxx	xxxx	xxxx
Canada	310,100	100,400	55,000	80,400	xxxx	xxxx	xxxx	36,800	xxxx
South Africa	9,200	xxxx	1,500	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
China	206,900	xxxx	3,400	xxxx	xxxx	xxxx	xxxx	xxxx	3,400
New Zealand	8,300	xxxx	1,300	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx

Data Sources: a (PEFC, 2015) ; b (FSC, 2014) ; c (SFI, 2015a) ; d (American Forest Foundation, 2013) ; e (Cheng, 2012)

Sustainable Forest Management Schemes

PEFC – Programme for Endorsement of Forest Certification

PEFC is an umbrella organization that endorses national forest certification systems around the world. Through its system of mutual recognition and endorsement, PEFC is the largest forest certification system in the world with approximately 230 million hectares certified. PEFC bases their decision to ban biotech trees on two criteria. The first is the Precautionary Principle, and the second is stated as a lack of scientific data that shows the benefits from biotech trees outweigh the risks.

"Criterion 4: Maintenance, conservation and appropriate enhancement of biological diversity in forest ecosystems

5.4.7 - Genetically-modified trees shall not be used.
Note: The restriction on the usage of genetically-modified trees has been adopted based on the Precautionary Principle. Until enough scientific data on genetically-modified trees indicates that impacts on human and animal health and the environment are equivalent to, or more positive than, those presented by trees genetically improved by traditional methods, no genetically-modified trees will be used." (PEFC, 2010)

FSC – Forest Stewardship Council

FSC is the largest single certification system that does not function as an umbrella organization. Approximately 183 million hectares are FSC certified from 79 countries. FSC currently has a 'no GMO' policy as stated in the latest revision (version 5-1) of the FSC International Standard under Principle 10.4, which states, "*The Organization shall not use genetically modified organisms in the Management Unit"* (FSC, 2014). This ban is ostensibly based on precautionary principles, as described in FSC's GMO Policy and mandated by its General Assembly. This policy describes biotech trees as having potential benefits and numerous, *"potential undesirable effects... In most cases, the potential effects and the probability of their occurring are uncertain. These hazards, and the uncertainties about them, are the reason for the prohibition of the use of GMOs in certified forests"* (FSC, 2000). While this policy paper does not have the status of an FSC position, auditors can use it as guidance for making FSC certification decisions. Additional policy language relating to biotech trees appears in the FSC Standard for Chain of Custody (COC) Certification (FSC, 2011a) and their policy on association with FSC that disallows association with organizations directly or indirectly involved in *"Introduction of genetically modified organisms in forestry operations"* (FSC, 2011b).

SFI – Sustainable Forestry Initiative

SFI is a North American standard that allows research on biotech trees to occur within certified forests. Objective 10 of the SFI Forest Management Standard is to invest in forestry research, science, and technology. The language specific to biotech trees states that any research has to *"adhere to all applicable federal, state, and provincial regulations and international protocols."* (SFI, 2015b) Only by registration through PEFC does SFI ban biotech trees by proxy.

ATFS – American Tree Farm System

ATFS applies in the United States and does not address the use of biotech trees in their current certification standard. Only by registration through PEFC does ATFS ban biotech trees by proxy (ATFS, 2015).

CERFLOR – Brazilian National Forest Certification Program

CERFLOR, the Brazilian forest management certification program is administered by the national Institute of Metrology, Standardization and Industrial Quality (INMETRO), a government agency connected to the Ministry of Development, Industry and Foreign Trade. The Brazilian Association of Technical Standards (ABNT) is the body responsible for the process of development and revision of CERFLOR standards. The latest planted forest standard is the 2007 revision. Since the IFB could find no comprehensive translation of the 2007 version, an official copy of the document in Portuguese (ABNT, 2007) was purchased and interpreted for review[2].

Criteria 3.1 addresses biotech tree use. The CERFLOR standard does not, by itself, prohibit the use of biotech trees in a planted forest. The interpreted language of criteria 3.1 is, *"The introduction and use of genetic material must be conducted in a controlled manner and in accordance with biosafety standards. Prior experience with the material must be provided to allow assessment of potential environmental impacts, in addition to assessing the potential forestry benefits to the region."*

CERFLOR is a PEFC recognized SFM. However, the 2011 PEFC evaluation and assessment report does not highlight an inconsistency between CERFLOR criteria 3.1 and PEFC condition 5.4.7 which bans the use of biotech trees (Indufor, 2011). Our assessment shows that only by registration through PEFC does CERFLOR ban biotech trees by proxy.

CertFor – Certficación Forestal

CertFor is the Chilean SFM endorsed by PEFC. CertFor consists of Indicators and Verifiers that are effectively criteria and proof, respectively. Indicator 1.6.3 prohibits the use of biotech trees, *"Until the next Standard streamlining, no new species or variety shall be used in plantations, that come from Genetically Modified Organisms (GMO)"* (CertFor, 2007). In addition, CertFor is recognized as a PEFC national standard and would also ban biotech trees by proxy.

CSA – Canadian Standards Association

CSA applies to Canada. Criteria 6.3.1, "Biological Diversity", requires discussion with stakeholders on a number of topics and practices that can affect biodiversity. Discussion item 1 in this criteria states that the public participation process must include, *"The gene pool of native seed stock, and genetically modified organisms (GMOs) and the associated regulatory/policy requirements."* However, the element that pertains to biotech trees is number 1.3 which states, *"Conserve genetic diversity by maintaining the variation of genes within species and ensuring that reforestation programs are free of genetically modified organisms"* (CSA, 2010). This element does not have an indicator. While the CSA structure is more intricate than many certification schemes, we are certain that CSA does not allow the use of biotech trees. In addition, CSA is a PEFC recognized SFM and thereby bans biotech trees by proxy.

[2] A copy of the CERFLOR interpretation is available to members of the Institute of Forest Bioscience's Forest Biotechnology Partnership.

Potential Biotech Tree Use in Coming Years Components

The table on the next page shows a summary and implications of the regulatory and SFM assessments for each country. Below are the column labels for table 4.

- **Years –** The range in years, from today, that the IFB calculates that a country could potentially use biotech trees commercially.
- **Country** – The country that subsequent column data is in reference to.
- **Regulatory Summary** – A distilled review of the country's stringency score, regulatory system in place, and history of growing biotech products commercially.
- **SFM Summary** – A distilled review of country-specific, and international SFMs that predominate certified forestlands in the country.
- **Use for: Food, Fiber / Fuel, Forest Health** – An assessment of 'probable', 'unlikely', or 'feasible' for whether biotech trees could potentially be used in that country for food production, fiber or fuel production, or for forest health purposes in the given time period. For an assessment of 'probable' or 'feasible', a narrative explaining the rational is given below it. Note that these categories are judgments by the IFB to help foster science, dialogue, and stewardship in these countries, among stakeholders, for these potential uses of biotech trees.

Assessment of Potential Biotech Tree Use in Coming Years Matrix - Table 4:

Years	Country	Regulatory Summary	SFM Summary	Use for Food	Use for Fiber / Fuel	Use for Forest Health
0-3 years	Brazil	• Stringency score = 50 • Robust system in place • Biotech product use history	• CERFLOR does not prohibit biotech trees itself – only prohibition is via PEFC linkage	Feasible	Yes • Deregulated: - biotech Eucalyptus	Unlikely
	Canada	• Stringency score < 50 • Robust system in place • Biotech product use history	• CSA does not prohibit use of biotech trees –prohibition is via PEFC linkage • Largest area of FSC certified forests	Yes • Deregulated: - Biotech apple trees	Feasible • In-country research capacity	Feasible • Forest health problems negatively affect society, economics, and the environment in Canada
	China	• Stringency score = 50 • Specific system in place for biotech tree use • Biotech tree use history	• CFCC language pertaining to biotech trees is unknown - prohibition is via PEFC linkage	Unlikely	Probable • China imports ~50% of its wood used in making pulp, paper, and wood products	Yes • Deregulated: - Bt[3] Poplars - developed for erosion control
	U.S.A.	• Stringency score < 50 • Robust system in place • Biotech tree use history	• SFI does not prohibit biotech trees itself – only prohibition is via PEFC linkage • Second largest area of FSC certified forests	Yes • Deregulated: - Biotech Papaya trees - Biotech Plum trees • Investigating biotech citrus trees	Probable ArborGen LLC petitioned APHIS for nonregulated status of biotech Eucalyptus	Probable • Forest Health Initiative is exploring biotech American chestnuts
3+ Years	Chile	• Stringency score < 50 • No regulatory system in place • No biotech product use history	• CertFor prohibits biotech tree use in addition to prohibition via PEFC linkage	Unlikely	Feasible • Multiple research organizations investigating biotech trees	Unlikely
	New Zealand	• Stringency score > 50 • Robust system in place • No biotech product use history	• No national SFM - FSC is the dominant system	Unlikely	Feasible • In-country research capacity • Gene control may have commercial value	Feasible • Island isolation poses unique forest health threats and opportunities
	South Africa	• Stringency score < 50 • Robust system in place • Biotech product use history	• No national SFM - FSC is the dominant system	Feasible • Biotech crops are grown in South Africa • In-country research capacity	Probable • Economically important forest products industry • Cultural willingness to explore technologies	Feasible • Forest health is a priority • In-country research capacity
	Uruguay	• Stringency score < 50 • Robust system in place • Biotech product use history	• No national SFM - FSC is the dominant system	Unlikely	Feasible • Economically important forest products industry • Proximity to Brazil makes biotech tree use plausible	Unlikely

[3] Bt stands for Bacillus thuringiensis – a pesticide that originated from a soil bacteria and can be incorporated into the genome of plants so they are less susceptible to bugs foraging on the plant's leaves.

Forest Biotechnology Review by Country

The following assessments are intended to help facilitate the science, dialogue, and stewardship of biotech trees around the world. The IFB has found that the best way to advance these goals is to work with stakeholders on practical ideas and issues. It is also important to start using the Responsible Use Principles early in the process of developing biotech trees to foster clarity and transparency with others. For these reasons we have made educated guesses based on the information presented in this document, and through our ongoing discussions with the Forest Biotechnology Partnership and other forestry stakeholders. Note that any forward-looking statements will be italicized to clearly denote them as estimations from the IFB that are not intended to predict certainty.

Brazil

Forest products are an economically important product in Brazil. Brazil produces a large percentage of the wood fiber used around the world. It should be noted that the vast majority of this wood fiber does not originate from tropical hardwood trees in the Amazon. While deforestation in the Amazon is an ever-present concern in Brazil and around the world, most of the rainforest is cleared for grazing land and agricultural food production. Planted forests are the primary source of wood fiber in Brazil with eucalyptus and loblolly Pine being the most planted trees. Biotech tree research in Brazil focuses primarily on these species. Today there are multiple forest products companies engaged in biotech tree research. Currently there is one biotech eucalyptus tree deregulated by CTNBio on April 9, 2015. This tree has been modified for growth and yield increases. This tree represents the first GM forest tree deregulated anywhere in the world since the biotech poplar tree in China. That poplar tree was not subject to modern regulation governing the use of GM trees and its deregulation is widely considered anomalous.

The IFB anticipates that multiple companies will receive deregulation status from CTNBio for other biotech forest trees in the next 24 months..

Canada

As of March 2015, there are no commercially available biotech trees in Canada, but they are being researched and commercially developed in Canada. The legal and regulatory landscape for growing biotech material in Canada is complex. While some local jurisdictions have voted to ban biotech material from certain areas in Canada, these moratoriums may not be enforceable. The federal government via the Canadian Food Inspection Agency (CFIA), not local authorities, regulates biotech products. Regional and local bans, unenforceable as they may be, do affect the research and planting of biotech trees in Canada. For example, the British Columbia city of Richmond has voted to ban planting biotech products and has not yet been challenged in court (Robertson, 2013). Nonetheless, Canadian researchers are working on multiple biotech tree projects, and field-testing the trees in regions where it is uncontrovertibly allowed.

Biotech apple trees:

The Canadian biotech company, Okanagan Specialty Fruits, is seeking commercial approval in Canada and the U.S. for an apple tree that produces apples that do not turn brown when they are cut. Okanagan's "Arctic" apples achieve the non-browning effect by silencing the polyphenol oxidase enzyme (Okanagan Specialty Fruits, 2012). The apple tree variety, (Malus x domestica) with transgenic events GD743 and GS784 has undergone a risk assessment as required by CFIA and the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection

Service (APHIS). Nonregulated status was granted by APHIS on February 13, 2015. This is the first nonregulated status the USDA has granted for biotech apple trees. A petition for deregulation was submitted to CFIA on May 2, 2012, and is still being reviewed by the agency.

The IFB anticipates that a biotech fruit tree will be commercially available in Canada in the next 12 months. We base this estimation on the risk analysis performed by the USDA, its granting of nonregulated status, and the history of biotech product use in Canada. In addition, it is feasible that a biotech tree designed solely to improve the health of native forests will be available in three or more years in Canada based on the devastating effect that multiple pests are having on Canadian forests. Forest products are an economically important product in Canada, and forestry is culturally significant throughout the country.

Chile

Like Brazil, forest products are a critical part of the Chilean economy. Chile is one of the top exporting countries in the world of wood pulp. While biotech research is carried out in Chile, large-scale and commercial plantings are not allowed under current regulations. Chilean researchers are working on biotech trees that include radiata pine and eucalyptus in particular. As of March 2015, there are no commercially available biotech trees in Chile.

The IFB anticipates that the Chilean government will develop a regulatory system that addresses the use of biotech products to remain competitive with other South American countries that export food and fiber commodities. There is an opportunity to learn from other systems around the world, and from the Responsible Use Principles from which we believe Chile will capitalize. It is likely that three or more years will be necessary to accomplish the goals of developing a regulatory system and the risk and benefit analysis most biotech trees go through prior to commercialization. However, since Chile is invested heavily in both forestry and biotechnology research, it may become legally feasible and within reason to speculate that commercial biotech trees could be commercialized in Chile in the near future.

China

Biotech forest trees are commercially available in China. The first biotech tree in China was a poplar transformed in 1989 with a gene that produces a protein toxic to insect pests. This gene is produced by a bacterium in the soil called Bacillus thuringensis (Bt) and is used in a number of biotech crops including corn, cotton, and soybeans to be resistant to insects (Zheng, 2010). China subsequently released 1.4 million genetically modified Poplar (Populus) trees in an area of 300 – 500 hectares (FAO, 2004). As opposed to the Papaya, which is considered a food crop, this event marked the first biotech forest tree ever released into the environment. Today there are spurious reports that these trees are now readily available for private tree farmers to plant.

The IFB anticipates that China will continue to commercialize additional varieties of biotech trees in the next one to three years for commercial fiber or fuel production. It is also feasible, but somewhat speculative, that China may develop biotech trees for forest health or ecosystem protection purposes in coming years.

New Zealand

As of March 2015, there are no commercially available biotech trees in New Zealand. However, lab research and confined field trails of biotech trees are conducted in New Zealand by Scion. Scion is a company owned by the New Zealand government that focuses on research, science,

and technology development for the forest products industry. In early April 2012 Scion's biotech tree field trial was attacked by vandals and severely harmed (Scion, 2012). While the research timeline was affected, the work will continue according to researchers at Scion. Being an island with a robust forest products industry, New Zealand is different from the other countries explored in this report. Islands have historically had built-in isolation from many of the pathogens and pests that can travel over land. This natural security is all but gone for most islands because of human travel and shipping. The isolation that used to be an asset has turned into a liability when invasive pests move to an island with tree species that did not co-evolve resistance to the threat.

The IFB anticipates that protecting forest health will continue to be an important factor in New Zealand forest research, and may accelerate in coming years. Biotech trees, if used responsibly, may be a tool that can help New Zealand and other countries save tree species that are environmentally, socially, and economically important. Commercial use of biotech trees for fiber or fuel production is feasible in New Zealand, but difficult to anticipate with much certainty at this time. The likelihood of using biotech trees to increase or protect forest health is also feasible in the future. In either case, biotech trees will likely not be used for three or more years in New Zealand.

South Africa

As of March 2015, there are no biotech trees commercially available in South Africa, but biotech tree research is conducted in-country. With a mature forest products industry, a focus on maintaining healthy forests, a well-defined regulatory process for biotech products, and a low biotech stringency score, South Africa could benefit from responsibly used biotech trees.

The IFB anticipates that South Africa will have biotech forest trees for food, fiber or fuel, or for forest health purposes in three or more years.

Uruguay

No biotech tree research is carried out in Uruguay at this time. However, Uruguay is an important pulp producing country with a low biotech stringency score. The proximity of Uruguay to Brazil is another factor to consider when assessing biotech tree use. As of March 2015, there are no commercially available biotech trees in Uruguay.

The IFB anticipates that biotech trees for wood pulp production will become a commercially attractive option for Uruguay in the future. It is difficult to estimate if, or when biotech trees will be used in Uruguay. However, the current state of biotech product use in Uruguay suggests that biotech tree commercialization is feasible, and likely on a three-year or longer trajectory.

USA

The United States has historically been at the forefront of biotechnology. In terms of forest biotechnology, the U.S. is working on a number of fronts concurrently.

Biotech Fruit Trees:

While there are no biotech forest trees commercially available in the U.S., there are biotech fruit trees available for commercial planting. Biotech papaya trees that are resistant to the ringspot virus have been available since 1997. Another biotech fruit tree developed to resist the plumpox virus is the U.S. Department of Agriculture's (USDA) HoneySweet variety. This plum tree received EPA registration on August 8, 2011. While not made commercially available as of March 2015, the

USDA is poised to make the tree available if it is needed to combat the plumpox virus. There is also interest in developing citrus trees resistant to the citrus greening bacterial disease.

Biotech Trees for Forest Health:
The Forest Health Initiative is a collaborative effort to advance the country's understanding and role of biotechnology to address some of today's most pressing forest health challenges. The initiative is currently focusing on restoring a test species and an icon of eastern U. S. forests, the American chestnut. This tree was extirpated during the past century by a chestnut blight presumably brought to the United States from Asia. While working to restore the American chestnut as the test tree, the program will explore new approaches to enhance the health and vitality of other trees, forests, and forest ecosystems. One target for this initiative is to develop a cisgenic[4] biotech chestnut that incorporates resistant genes from Chinese chestnuts into an American chestnut tree. More information is available at www.foresthealthinitiative.org.

Biotech Trees for Fiber or Fuel:
Selecting trees with traits that improve growth, form, and compositional characteristics has been an ongoing area of work in the United States for decades. Today, government agencies, companies, and universities are studying biotech trees for increased fiber or fuel production. The freeze tolerant biotech eucalyptus tree that the South Carolina based company ArborGen LLC has developed is furthest along the regulatory process in the U.S. A petition for nonregulated status was submitted to the USDA on January 19, 2011.

ArborGen has also developed a biotech Loblolly pine tree using biolistic techniques. This technique does not trigger APHIS regulatory oversight. The transgenic construct used in this GM tree does not have a PIP and therefore does not trigger EPA's FIFRA regulatory oversight. In effect, this tree is not regulated as a biotech tree in the U.S. and could be commercialized as soon as ArborGen sees it fit.

The IFB anticipates that the USA will have a commercially available biotech forest tree in the next 12 months. This estimation is based on the long history of biotech product use in the United States, and the fact that a biotech eucalyptus has already been submitted for a determination for deregulation to the appropriate agency. In addition, it is possible that a biotech tree designed solely to improve the health of native forests will be available in three or more years.

[4] Cisgenesis is a term used to describe the technique of using genetic material from closely related species in the target tree. The goal is to develop a product that has DNA sequences that could have been incorporated through sexual reproduction given enough time and resources.

The Institute of Forest Biosciences

The Institute of Forest Biosciences (IFB) fosters the use of science and technologies that create healthier and more productive forests now and for the future.

We strive to accomplish this mission by establishing dialogues with diverse stakeholders, assessing risks and benefits, providing objective and accurate information, and promoting actions for long-term forest stewardship that meet human needs in environmentally responsible ways. More information is available at www.forestbio.org

The IFB manages the Forest Biotechnology Partnership – the largest research and communications partnership in the field. This Partnership works with the IFB to develop Initiatives that accelerate the responsible use of forest biotechnologies. More information is available at www.forestbio.org/partners

The Responsible Use: Biotech Tree Principles were developed to guide long-term stewardship of biotech trees. These Principles are the first of their kind and were developed through a transparent, multi-stakeholder mechanism, to achieve the following objectives:

- Establish a high level of performance for managing biotech trees that is recognized around the world.
- Create a simple and effective set of practices so users along the biotech tree value chain know how to use the trees responsibly.
- Increase societal benefits when biotech trees are used by promoting interaction and education between foresters, biotechnologists, and other stakeholders.

Embodied throughout is an understanding that biotech trees and their products should create sustainable benefits. Benefits may be derived from the biotech tree, its products, or scientific insight gained through forest biotechnology research. The Practices give users tools to help them enhance the benefits of forest biotechnology, mitigate risks, and maintain the integrity of a biotech tree's history as it moves along the value chain. More information is available at www.responsibleuse.org

Please cite this report as:

Costanza, A., & McCord, S. (2013). *Regulation, Certification, and Use of Biotech Trees*. Institute of Forest Biosciences, Cary, NC. URL: http://www.forestbio.org/biotech_tree_use

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