



**HAVE YOU GOT A LICENSE FOR THAT TREE?
(and can you afford to use it?)**

by
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I. INTRODUCTION AND OVERVIEW

Multiple natural resource and environmental laws potentially apply to the commercial production of transgenic trees in the U.S. Some of these require premarket licensing by one or more federal agencies, including a comprehensive assessment of environmental impacts. Others provide the federal government and sometimes citizens, with independent authority to take legal action to avert unreasonable risk to man or the environment. Still others focus on special needs – such as those of endangered species or migratory birds.

In the post-StarLink era, greater attention is being paid to the way these laws relate to each other, and to the range of legal requirements that can appropriately be used to address potential impacts on the environment and natural resources. Technology owners have also become painfully familiar with the liability inherent in license conditions that rely on user behavior. The licensing process needs to be transparent and protective. It also needs to work without becoming a barrier to technology innovation.

This paper will examine the legal issues presented by the Office of Science and Technology Policy's January 2001 case study of the bioremediation poplar and its intersecting statutes of jurisdiction – the Plant Protection Act, the Toxic Substances Control Act, and the Superfund/RCRA hazardous waste laws.

The paper will analyze the licensing conditions under consideration for commercialization of the bioremediation poplars, and the liability issues which these raise. The paper will also analyze the potential for legal application of similar conditions to other types of transgenic trees on the drawing board or in filed testing – for insect resistance, enhanced fruit production, improved pulp and paper raw materials, and global warming credit programs.

Finally, the paper will identify some legal options for smoothing the legal path to market and identify opportunities in the law for safe harbor measures, which can enhance the certainty of commercial viability for these trees.

II. APPLICABLE LAW

A consistent principle of health and environmental law in the United States is that products introduced into commerce should either be safe or, if not safe, present no unreasonable risk to man or the environment. How this principle is applied varies quite a bit depending on

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*Presented at July 22-27, 2001 Tree Biotechnology in the New Millennium Symposium, Skamania, Washington
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what law applies, which agency has jurisdiction, and the social perception of risk. For example, some products can only be introduced after government pre-market review -- drugs, food additives, pesticides and new chemicals. Sometimes express approval is a condition of marketing; sometimes just “not saying no” is sufficient. Other products, like consumer products containing hazardous substances, electrical equipment, appliances, etc., are required to meet performance standards but do not require pre-approval. Generally the intended use of the product determines its classification.

Products of biotechnology do not always fit comfortably within the lines the law has drawn based on the historic function and intended use of products. A poplar tree that has been genetically modified to efficiently remove hazardous wastes from the environment presents several different types of risk, subject to different laws. The U.S. Department of Agriculture (“USDA”) has the job of assuring that the genetically modified tree is not a plant pest under the Plant Protection Act (“PPA”).¹ To the extent that job involves a major Federal action significantly affecting the environment, application of the National Environmental Policy Act (“NEPA”)² is triggered. This requires consideration of impacts, effects and alternatives to the proposed action.

The Environmental Protection Agency (“EPA”) has also asserted general authority under the Toxic Substances Control Act (“TSCA”)³ over the genetically modified tree to control any unreasonable risk which may be presented. Finally, all aspects of a hazardous waste site remediation, including selection of the appropriate remedy, are closely regulated. In addition to assuring appropriate control of all risks, public acceptance of the remedy to be selected is a critical factor. In order to get to market, each of these legal standards must be met. The reviewing agencies look to science, data gaps and default assumptions as the basis for risk assessment evaluations and risk management decisions about commercialization.

The relationship and coordination of these multiple authorities is governed by the policy statements contained in the 1986 Coordinated Framework for the Regulation of Biotechnology (“the Framework”)⁴ and the 1992 Policy on Planned Introductions of Biotechnology Products into the Environment.⁵ Both of these policy statements were developed by an interagency task group working under the direction of the White House Office of Science and Technology Policy (“OSTP”). Neither of these policy statements is a rule or creates any enforceable obligation.⁶

¹ 7 U.S.C. § § 7701 *et seq.*

² 42 U.S.C. § § 4321 *et seq.*

³ 15 U.S.C. § § 2601 *et seq.*

⁴ 51 Fed. Reg. 23,302 (June 26, 1986).

⁵ 57 Fed. Reg. 6753 (Feb. 27, 1992).

⁶ *Foundation on Economic Trends, v. Johnson*, 661 F. Supp. 107, 109 (D.D.C. 1986) (Framework is “a first effort to aid in formulation of agency policy with respect to control of microorganisms developed by genetic engineering techniques”).

They simply describe how the different regulatory authorities are intended to fit together. The individual and collective experience of the primary agencies of jurisdiction has also been translated into a substantial body of regulation and guidance for particular types of organisms.⁷

In January 2001, the OSTP issued a series of case studies for public comment describing the path to market for six types of products of biotechnology based on the system of review which has matured under the Framework. These case studies included genetically modified salmon, Bt-maize, herbicide-tolerant soybean, animals producing human drugs, bioremediation using poplar trees, and bioremediation and biosensing bacteria. These case studies highlight the increasing complexity of federal reviews and the implication of ever increasing numbers of the primary environmental and natural resource laws for products designed for use in the outdoor environment. The bioremediation poplar case study discusses the application and coordination of The Plant Protection Act, the Toxic Substances Act, and the Comprehensive Environmental Response, Compensation and Liability Act.⁸

A. The Plant Protection Act

USDA is authorized under the PPA to

[P]rohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.⁹

A “plant pest” is defined as any living stage of a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus, infectious agent or pathogen, or similar or allied article that can injure or cause disease or damage plants or plant products.¹⁰ USDA views this concept broadly. The definition of “plant pest” covers “direct or indirect injury, disease, or damage not just to

⁷ Each of the primary federal agencies has a website providing historic and current information on its activities with relation to the regulation of biotechnology. These include: <http://www.aphis.usda.gov/bbep> (USDA); <http://www.fda.gov/cber/reading.htm> (FDA); and <http://www.epa.gov/pesticides/biopesticides> and <http://www.epa.gov/opptinty/biotech/index.html> (EPA).

⁸ <http://www.ostp.gov/html/012201.html>.

⁹ 7 U.S.C. § 7712(a). The PPA consolidates USDA’s authority under the Federal Plant Pest Act of 1957, formerly 7 U.S.C. § § 150aa-150j, and the Plant Quarantine Act of 1912, formerly 7 U.S.C. § § 151-167. Effective June 22, 2000, those statutes were repealed and replaced by the PPA.

¹⁰ 7 U.S.C. § 7702(14); 7 CFR § 340.1.

agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees.”¹¹

This law is administered by the Animal and Plant Health Inspection Service (“APHIS”). APHIS has established regulations for the introduction of genetically modified plants, including trees, as “regulated articles.”¹² “Introduction” includes the importation, interstate movement, of “release into the environment” of a regulated article. Regulated articles are “released into the environment” when they are used outside the confinement of a laboratory, greenhouse, or other contained structure. *Id.*

The APHIS regulations allow for introduction by notification for all genetically modified plants not listed as noxious weeds under 7 C.F.R. Part 360 which also meet certain eligibility criteria and performance standards. The eligibility criteria require, among other things, that the genetic material be “stably integrated” in the plant genome, that the function of the genetic material is known and its expression does not result in plant disease, that it will not produce an infectious entity or be toxic to nontarget organisms, and that it has not been modified to contain certain genetic material from animal or human pathogens.¹³ The performance standards are essentially designed to ensure containment. Controls on shipment, storage, planting, identification and the conduct and termination of the field trial are specified for this purpose.¹⁴

If APHIS responds to the notification with a denial or if the organism does not meet all of the regulatory provisions, a permit application may be submitted. Comments submitted during the APHIS rulemaking on these provisions highlighted certain concerns regarding the introduction of genetically modified trees under the notification process, citing lifespan in the field and the need to ensure reproductive confinement. APHIS acknowledged the existence of special issues for trees and included a requirement for annual renewal of notifications for all field tests exceeding one year from the date of introduction.¹⁵

¹¹ 62 Fed. Reg. 63312 (Nov. 28, 1997).

¹² A regulated article is defined as “any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 [of the regulation]” and meets the definition of a plant pest, or any organism or product which APHIS determines or has reason to believe is a plant pest. 7 CFR § 340.1. Organisms that are not classified may become regulated articles if there is reason to believe that they are plant pests.

¹³ 7 CFR § 340.3 (b).

¹⁴ *Id.* § 340.3(c).

¹⁵ *Id.* § 340.3(e)(4).

B. The National Environmental Policy Act

The National Environmental Policy Act (“NEPA”)¹⁶ requires that federal agencies publicly address the environmental impact of “every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment.”¹⁷ NEPA compels agencies to develop methods and procedures that will ensure that unquantified environmental amenities and values be given appropriate consideration in decisionmaking. The responsible federal official must prepare “a detailed statement” covering five specific issues, including impacts, effects and alternatives.¹⁸ This detailed statement is commonly referred to as an Environmental Impact Statement (“EIS”). It is typically preceded by a “rough-cut” assessment, or Environmental Assessment (EA) to determine whether a full-fledged EIS is necessary.

The EIS serves as both an aid in decisionmaking for the agency and as a source of information for other interested parties. It provides environmental source material for evaluating the benefit of the proposed project in light of its environmental risks and for comparing these to the environmental risks presented by alternative courses of action.¹⁹ As the Supreme Court has stated:

NEPA has twin aims. First, it places upon an agency the obligation to consider every significant aspect of the environmental impact of a proposed action. Second, it ensures that the agency will inform the public that it has indeed considered environmental concerns in the decisionmaking process.²⁰

The sufficiency of NEPA analysis has been the subject of many lawsuits. Judicial decisions emphasizing the responsibility of the federal agency to take a “hard look” at the environmental impacts of its decisions are legion.²¹ It has been held that “any action that substantially affects, beneficially or detrimentally, the depth or course of streams, plant life, wildlife habitats, fish and wildlife, and the soil and air ‘significantly affecting the quality of the

¹⁶ 42 U.S.C. §§ 4321 *et seq.*

¹⁷ 42 U.S.C. § 4332(C).

¹⁸ 42 U.S.C. 4332(C)(2).

¹⁹ *See Massachusetts v. Andrus*, 594 F.2d 872, 883 (1st Cir. 1979).

²⁰ *Baltimore Gas & Electric Co. v. Natural Res. Def. Council*, 462 U.S. 87, 97 (1983).

²¹ *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21 (1976).

human environment’.²² However, NEPA imposes no substantive obligation to take the least environmentally damaging alternative.²³

C. The Toxic Substances Control Act

The Toxic Substances Control Act (“TSCA”)²⁴ provides EPA with authority to regulate chemical substances which may present an unreasonable risk of injury to health or the environment during manufacture, processing, distribution in commerce, use, or disposal. A “chemical substance” is defined in the law to include “any organic or inorganic substance of a particular molecular identity, including

- Any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and
- Any element or uncombined radical.”²⁵

EPA has, by rule, interpreted this authority to extend to intergeneric microorganisms.²⁶ Specific requirements contained in the Microbial Products of Biotechnology final rule apply to pre-market review of such organisms, including research and development and test market exemptions. EPA has also asserted TSCA jurisdiction over multi-celled intergeneric plants and animals. While there is currently no pre-market review requirement, EPA has taken the position since 1994 that it will use its TSCA authorities as needed to address unreasonable risk issues which may be presented by such plants and animals.²⁷

EPA’s authority under TSCA includes

- premarket review of new chemical substances or significant new uses of existing chemical substances;
- regulation of existing chemical substances to avoid unreasonable risk
- recordkeeping/reporting requirements for health and environmental effects information.²⁸

²² *Natural Res. Def. Council, Inc. v. Grant*, 341 F. Supp. 356, 367 (E.D.N.C. 1972).

²³ *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332 (1989).

²⁴ 15 U.S.C. § § 2601 *et seq.*

²⁵ 15 U.S.C. § 2602(2)(A).

²⁶ 40 C.F.R. Part 725.

²⁷ 59 Fed. Reg. 45,527 (Sept. 1, 1994).

²⁸ *See e.g.*, TSCA Sections 4, 6, 7 and 8, 42 U.S.C. § § 2603, 2605, 2606, 2607.

D. The Comprehensive Environmental Response, Compensation and Liability Act

The Comprehensive Environmental Response, Compensation and Liability Act (“CERCLA” or “Superfund”)²⁹ established a multi-faceted program designed to respond to the harm, or potential harm, to human health and the environment that may be caused by hazardous substances. Each CERCLA site and related response action is unique. EPA has developed a formal process to evaluate each release of a hazardous substance and each site where hazardous substances are located. The process includes a series of assessments that allows the primary threats to human health and the environment to be identified, evaluated, and remedied. After carefully evaluating available remedial alternatives, EPA selects the best remedial alternative.

The statutory goal of this process is to select the cleanup method that best protects human health and the environment, while complying with all applicable environmental laws, and provides a long-term, cost-effective solution. During the process of selecting the cleanup method, EPA indirectly regulates bioremediation by identifying and evaluating bioremediation techniques that can be used to cleanse the site. The blue print for all CERCLA response actions is set forth in the National Contingency Plan (“NCP”) which is codified in 40 CFR Part 300. The NCP describes the procedures that EPA must follow when implementing the CERCLA program in situations where hazardous substances, pollutants, or contaminants have been released into the environment. Criteria for selection of the cleanup technique to be used at any particular site includes community acceptance determined by the result of obtaining public notice and comment.³⁰

A companion statute often used to require cleanup at sites where hazardous wastes are currently managed is the Resource Conservation and Recovery Act (“RCRA”).³¹ The RCRA corrective action program functions in much the same way as CERCLA. One significant difference, however, is that RCRA requires that the corrective action plan be embodied in a permit issued by the appropriate federal or state agency. The RCRA permit requirements apply to the entire facility rather than the area of the corrective action.

III. OSTP/CEQ CASE STUDY NUMBER 5: THE BIOREMEDIATION POPLAR

As noted above, one of the case studies issued for comment by OSTP examines the commercialization process for a hybrid poplar genetically engineered to detoxify trichloroethylene (“TCE”). TCE is an industrial chemical that was commonly used as a metal degreasing agent and a dry cleaning solvent. It is an environmental contaminant found

²⁹ 42 U.S.C. § § 9601 *et seq.*

³⁰ 40 CFR § 300.430(e)(9)(iii).

³¹ 42 U.S.C. § § 6901 *et seq.*

throughout the industrialized world and a remediation focus at many Superfund and RCRA correction action sites.

This bioremediation poplar is described in the case study as one which is still in the research and development state, and not yet in field release trials, although APHIS notifications have been filed and accepted. The federal agencies of primary jurisdiction are the USDA (the PPA) and EPA (TSCA). APHIS has expressed the opinion that permits will be required for the commercial use of such trees. In addition, it is noted that trees grown for this purpose at Superfund and RCRA corrective action sites are expected to be subject to rigorous controls under those programs.

A. The Tree and Its Function

The organism under the federal microscope in this case study is a hybrid between two cottonwood species. One of these is black cottonwood (*Populus trichocarpa*). The other is eastern cottonwood (*Populus deltoides*). Key characteristics of the hybrid include:

- Ability to grow in soil with low levels of TCE;
- Ability to grow rapidly; and
- Ability to be vegetatively propagated.

The poplar was originally modified using a human cytochrome gene known for rapidly detoxifying TCE. A search is underway for other animal and plant genes which might perform the same function with greater public acceptability – a key issue in the success of ultimate commercialization. The tree is designed to absorb TCE from the soil or water in which it grows and express an enzyme which modifies the chemicals into less toxic or nontoxic substances that are translocated to the stems and leaves. The chemical transformation processes occur in the roots, stems and leaves. There is no functional requirement for flowering. Application of techniques to assure sterility limit the potential for outcrossing with wild relatives, an important safety feature as poplars are one of the species which outcross fairly easily.

The potential field of use of the trees is vast. There are thousands of TCE-contaminated sites where these trees could be used for remedial purposes. On a typical site, stems would probably be harvested on short rotations (5-7 years) and trees would be cut down and allowed to resprout until the TCE had been reduced to target levels.

Depending on the metabolites remaining in the stem tissue, the trees might be used in paper production. The hypothesis is that any organochlorine compounds remaining in stem tissue would be broken down by the chemical reactions in pulping. It is anticipated at the current time that the trees would be required to be removed and destroyed at the end of TCE remediation period.

B. Adverse Effects of Potential Concern

The case study identifies four primary categories of risk associated with the bioremediation poplar. These are:

- Health and ecological risks from the products of the TCE breakdown process on the sites being remediated (these include the potential for transpiration of TCE to air and presence and effects on insects and other organisms of metabolites);
- Risk of escape of transgenes into the native eastern or black cottonwood populations, or other reproductively compatible *Populus* species (both eastern and black cottonwoods are perennial, undomesticated plants expected to have wild relatives within pollination distance and precautions to prevent escape of seeds or pollen are important);
- Risk of transgenic trees themselves becoming weeds or otherwise invasive (could these trees effectively compete with their wild relatives in the environment?); and
- Health and ecological risks from materials and products derived from the trees.

C. Potential Benefits

TCE contamination is a wide-spread problem, and a contaminant that is very difficult, expensive, time-consuming and cumbersome to clean up using existing techniques. Today, these techniques include pumping water from the aquifer and stripping the TCE by aeration or charcoal absorption. Other techniques use bacteria to degrade TCE but may need inducers such as toluene and phenol which present their own environmental and health risks.

Poplars, on the other hand could remove TCE while simultaneously helping to restore the ecological structure and function of the contaminated site. Existing poplars can remove TCE from their environment – but not very quickly. The purpose of the modification is to enhance the speed with which this can be done and produce a temporally effective form of remediation. Tree roots would prevent erosion. The trees themselves would provide humus and microclimatic changes producing a more hospitable environment to many organisms. Poplars have a wide geographical distribution and could be successfully used in many areas. Propagation by cuttings is relatively easy and inexpensive. Poplars have an enormous water absorption capacity and could be used to clean shallow aquifers directly and deep aquifers indirectly through the irrigation use of pumped water.

IV. LEGAL ANALYSIS

While the case study does an excellent job of generally describing what the issues are for bioremediation poplars, and the review process employed to date, it is quite vague in its description of what comes next. Two phases of the current research and development process are described – proof of concept and successful bioremediation of contaminated soil. The first is

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underway. When a clone has been identified that detoxifies TCE and has acceptable growth characteristics, the proof of concept phase will end. Successful demonstration of bioremediation will require a large number of trees. During the vegetative propagation stage, the case study suggests that there will be appropriate coordination among the various government agencies (identified as EPA, the Department of the Interior, the National Institutes of Health, the Forest Service and others as appropriate), States and Tribal governments. Environmental impact requirements will be evaluated in that stage.

The case study includes a section on additional information and data to be generated, but this simply recites APHIS and EPA authority to require information. A section on mitigation, management, marketing, use and disposal focuses on controlling reproduction and the need to completely destroy all vegetative parts at the end of the bioremediation project.

Reading between the lines, the case study suggests at least outstanding five legal issues in the commercialization of the bioremediation poplar which remain to be sorted out. These include

- the degree and size of EPA's role under TSCA;
- what conditions might reasonably be expected to be imposed through either an APHIS permit or a TSCA rule;
- whether a USDA permit for commercial release of the trees at a remediation site would trigger EIS requirements under NEPA;
- what if any Endangered Species Act issues might be presented by such a permit; and
- how such a release would fare under the CERCLA remedy selection criteria.

Each of these is briefly evaluated below.

A. EPA's Role Under TSCA

The role of EPA under TSCA in this case study is quite unclear. What EPA has said so far is that it views its TSCA authority essentially as a legal gap-filling authority to address any unreasonable risk associated with the commercial release of genetically modified trees. Unlike the situation with intergeneric microorganisms, where EPA has issued explicit rules requiring pre-market notification and review, there is no explicit pre-market review requirement yet for multi-celled organisms which has been established by regulation. The case for jurisdiction under TSCA over transgenic plants and animals is also less than clear. The logic of the interpretation would also vest EPA with jurisdiction over human beings, a result clearly not intended by Congress when it enacted TSCA.

The potential authorities that EPA could exercise under TSCA in the absence of a pre-market notification rule include a wide-ranging ability to

- issue regulations to control unreasonable risks (including product bans);
- require manufacturers and processors to develop additional scientific data;
- secure imminent hazard injunctive relief in the federal courts; and
- and require recordkeeping and reporting.

TSCA also contains a citizen suit provision allowing “any person” to bring litigation to secure compliance with the provisions of the law and its implementing rules.³²

These authorities are quite general and the courts have strictly construed EPA’s rulemaking authority under TSCA to require the agency to choose the least burdensome and intrusive form of regulation.³³ However, the case study clearly contemplates a role for EPA in tree commercialization, and perhaps even in environmental release research experiments. There are multiple references to EPA’s activity for microorganisms, described at some length in the companion case study on bioremediation and biosensing bacteria.

That case study, which describes a field release experiment for biosensing bacteria conducted at the Oak Ridge National Laboratory in 1996 under a TSCA consent order, describes a closely regulated experimental release, and identifies a number of issues to be addressed prior to commercialization. As a matter of substance, these issues appear to be similar to those considered by APHIS, such as the stability of the new genetic construct. Issues of greater concern to EPA may include use of antibiotic resistance marker genes, the production of metabolites of potential concern and effects on non-target species. While the case study notes opportunities for coordination between the agencies, the mechanism for quick resolution of issues of competing jurisdiction is not apparent.

B. Permit Conditions

The benefits description of the use of genetically modified trees to remediate hazardous waste sites is powerful. It is clear that the concept of this use is highly regarded and environmentally desirable. It is equally clear that there is significant discomfort with uncertainties about the degree of risk which may be presented, and the opportunities for control.

The case study emphasizes the fact that APHIS intends to always require a permit for the commercial release of any trees genetically designed for remediation. It emphasizes that such

³² 15 U.S.C. § 2619(a).

³³ See, e.g., *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

trees will never be consumer products and that the potential for gene flow can be controlled by techniques designed to ensure that these poplars do not flower. The commercialization of this tree will occur under the lens of the national experience with StarLink corn. StarLink, a particular strain of Bt corn, was registered by EPA for use under the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”)³⁴ for animal feed only. It was not registered for human food because of a regulatory concern regarding potential allergenicity to humans. The registration was conditioned, among other things, on grower agreements to assure that StarLink corn was marketed solely for animal feed.

These agreements were ineffective to maintain separation of the two commodity products. StarLink was found in taco shells. Numerous lawsuits have been filed, the product registration has been cancelled, and the producer has since sold its agricultural chemicals division. As it turned out, that condition was a bad idea - and a commercial death sentence for the product.

Similar registration conditions used by EPA under FIFRA which rely on user behavior include requirements for buffer zones around genetically engineered crop plantings to reduce the potential for development of resistant insects and gene drift. The effectiveness of these conditions depends primarily on user compliance and self-policing, given the limited enforcement resources of the agencies. It is expected that, even where full compliance with these conditions occurs, resistant insect pests will develop. That is a political sore spot for organic farmers who rely on traditional Bt pesticides to a substantial degree.

It should, therefore, be expected that conditions which depend on human compliance for effectiveness will not be favored by either regulators or manufacturer/producers. The case of the TCE remediating poplar may present a unique situation in which pruning and other techniques can provide acceptable containment insurance against out-crossing because of the degree of regulation of remediation activities. On the other hand, 30-year remedial actions are not uncommon and 30 years is a long time to rely on the perfection of human control. Other alternatives of greater certainty are likely to be preferred, particularly in the eyes of the relevant community which lives next to the site.

It is to the producer’s benefit and ability to realize value from commercialization of these trees to think creatively about the types of permit conditions that can work for these applications. The law is open to creative suggestion and interpretation so long as the general performance standard of no unreasonable risk can be met.

C. NEPA Compliance

The same reasons which cause APHIS to take the position that a permit will always be required for genetically modified trees and EPA to assert jurisdiction suggest a significant NEPA

³⁴ 7 U.S.C. § § 136 *et seq.*

compliance requirement will apply to the commercialization of these trees. While NEPA is a procedural statute and does not establish substantive criteria by which the agencies judge which alternative action is selected, the case law does require a “hard look” by the agency at the environmental consequences of its action.³⁵

There has been a good deal of NEPA litigation in the biotechnology area. The trend in the case law is that “new” applications trigger full-scale NEPA review. *Foundation on Economic Trends v. Heckler*, 756 F.2d 143 (D.C. Cir. 1985) (the National Institutes of Health could not approve a field release experiment involving frost-resistance enhancing modified bacteria without conducting an EIS); *Edmonds Institute v. Babbitt*, 42 F. Supp. 2d 1, 17-20 (D.D.C. 1999) (the Department of the Interior was required to evaluate a new “bioprospecting” agreement involving Yellowstone National Park under NEPA procedures).

These cases suggest a significant NEPA review will be required for any APHIS permit issued for the commercial release of such poplars. If EPA were to assume the dominant risk assessment function under TSCA, the NEPA requirement would not apply to its activities. It is well established that EPA’s exercise of its substantive regulatory authorities is the functional equivalent of NEPA review.³⁶

D. ESA Issues

The case study does not explicitly address the Endangered Species Act (“ESA”),³⁷ probably because hazardous waste sites are not usually considered to be habitats for endangered species or much else. The ESA prohibits the taking of any endangered species.³⁸ The term “take” means “to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.”³⁹ To the extent that endangered species could be harmed by, for example, making a nest of materials from the TCE remediating trees, a violation of this provision could occur. These provisions can be directly enforced by citizens through the citizen’s suit provisions of the ESA.⁴⁰

The ESA also provides two types of safe harbor provisions in the form of “incidental take” authorizations.⁴¹ Under Section 7, federal agencies are required to consult with the Fish and Wildlife Service (“FWS”) or the National Marine Fisheries Service (“NMFS”) to insure that

³⁵ *Kleppe v. Sierra Club*; see footnote 21 above.

³⁶ *Limerick Ecology Action v. Nuclear Regulatory Commission*, 869 F.2d 719, 729 n.7 (3d Cir. 1989).

³⁷ 16 U.S.C. §§ 1531 *et seq.*

³⁸ *Id.* at § 1538(a)(1)-(2).

³⁹ *Id.* at § 1532(19).

⁴⁰ 16 U.S.C. § 1540(g).

⁴¹ *Id.* at 1539(a).

“any action authorized, funded, or carried out” by the agency will not jeopardize endangered or threatened species or adversely modify its designated or proposed critical habitat.⁴² For example, EPA would be required to consult on decisions regarding the registration of pesticides. APHIS would similarly have to consult on permit decisions and other actions.

If it is determined that an action is likely to adversely affect a listed species, the FWS or NMFS, as the case may be, issues a Biological Opinion. If the Opinion finds that the action is not likely to jeopardize the species’ continued existence or adversely modify its designated critical habitat, the document may, among other things, make an incidental take statement. That statement provides immunity from the take provisions to both the agency and the regulated party. If jeopardy or adverse modification is found, the Opinion offers reasonable and prudent alternatives to the action.

If consultation has not occurred because there was no triggering agency action or if FWS/NMFS refrain from issuing an incidental take statement, the federal agency is liable. That unfortunate result, however, usually has a direct effect on the person whose activities have been authorized by that agency. That effect can be avoided if the person has secured an incidental take permit. Section 10 of the Act provides for the issuance of an incidental take permit based on development, approval and implementation of a habitat conservation plan (“HCP”). An HCP, which is intended to offset the harmful effects the proposed activity might have on a listed species, must set forth “the impact which will likely result from such taking;” the “steps the applicant will take to minimize and mitigate such impacts;” the “alternative actions to such taking” considered by the applicant “and the reasons why such alternatives are not being utilized;” and “such other measures” that may be required “as being necessary or appropriate for purposes of the plan.”⁴³

Under Section 10, therefore, and in concert with an approved HCP, parties may seek to use and develop land inhabited or used by an endangered species, and any resulting “take” of that species, to the extent it “will not appreciably reduce the likelihood of the survival and recovery of the species in the wild,”⁴⁴ is allowed as “incidental to, and not the purpose of, the carrying out of an otherwise lawful activity.”⁴⁵

E. CERCLA Remedy Selection

EPA regulations set nine criteria for the evaluation of the alternatives identified for remedy selection for a Superfund site. 40 CFR § 300.430(e)(9)(iii). These include:

⁴² 16 U.S.C. § 1536(a).

⁴³ *Id.* at § 1539(a)(2)(A)(iv).

⁴⁴ *Id.* at § 1539(a)(2)(B)(iv).

⁴⁵ *Id.* at § 1539(a)(1)(B).

- Overall protection of human health and the environment;
- Compliance with applicable or relevant and appropriate requirements under federal and state environmental law;
- Long-term effectiveness and permanence;
- Reduction of toxicity, mobility or volume through treatment;
- Short-term effectiveness;
- Implementability;
- Cost;
- State acceptance; and
- Community acceptance.

In this list, the last is likely to be the most significant hurdle to realizing the value of the commercialization of the TCE-remediating trees. The education effort will be substantial. It cannot begin too soon.

V. CONCLUSION

There are a number of legal uncertainties on the road to market for genetically modified trees. Other genetically modified trees will face different issues, depending on their intended use. Fruit trees will be subject to FDA jurisdiction to review the safety of the modified fruit as a food. Trees engineered to absorb extra carbon as they grow will likely need to be qualified for measurable and enforceable reductions in carbon dioxide if they are to be used for greenhouse gas control – consistent with requirements for ozone control reduction measures in the current Clean Air Act.⁴⁶ Trees designed with different lignin structures to enhance the ease of paper production will almost certainly face ESA issues.

Understanding the federal legal system and charting a path to the market through that system is crucial to commercial success.

⁴⁶ 42 U.S.C. § 7401 *et seq.*