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The Regulation and Development of Bioremediation

Susan J. Timian & D. Michael Connolly*

Introduction

The U.S. faces an enormous task in cleaning up hazardous wastes. Thousands of sites have been identified throughout the country, with estimated cleanup costs over \$1.7 trillion using existing technologies.¹

The most widely accepted technologies for waste treatment are incineration and landfill disposal. Yet, these have serious drawbacks. Incineration creates air pollution and ash to be discarded. Disposal in a landfill does not *treat* waste, and space is decreasing as communities are more reluctant to have hazardous wastes in their neighborhoods.

However, bioremediation has the potential of completely degrading waste material with little or no toxic byproducts.² It also has the advantage of lower costs. Bioremediation has been shown to be effective in both the Exxon Valdes oil spill and the Gulf War cleanups.³ In fact, a variety of bioremediation techniques have been successfully employed at over 400 cleanup sites throughout the U.S. at a cost approximately 80–90% lower than other cleanup technologies.⁴ For these reasons, U.S. bioremediation revenues are climbing about 15–20% annually. They are expected to do so thru the year 2000,⁵

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¹ 141 Cong. Rec. S11081 (daily ed. Aug. 1, 1995) (Statement of Sen. Feingold).

² In fact, waste material may be used as a substrate for growing bacteria which could produce useful materials.

³ N. M. Fayad, et al., *Effectiveness of a Bioremediation Product in Degrading the Oil Spilled in the 1991 Arabian Gulf War*, 49 *Bull. Environ. Contam. Toxicol.* 787 (1992); P. H. Pritchard, et al., *Oil Spill Bioremediation: Experiences, Lessons and Results from the Exxon Valdes Oil Spill in Alaska*, 3 *Biodeg.* 15 (1992).

⁴ Kevin Hamilton, *U.S. Bioremediation Revenues Seen Climbing 16% a Year thru 2000*, *Hazardous Waste Business*, Aug. 23, 1995, at 13.

⁵ *Id.*

when the estimated annual spending on bioremediation products is expected to top \$500 million.⁶

The rapid growth of the bioremediation industry has been fueled by regulations that limit the disposal of toxic compounds, driving up the costs of disposal and making bioremediation attractive. Still, the same regulations have hindered growth by favoring older technologies. Furthermore, other regulations effectively prevent the use of genetically altered microorganisms.

Many environmental regulations have driven the development of bioremediation activities. For instance, amendments to the Clean Air Act require that coal burning plants lower sulphur emissions.⁷ In response, a Florida company, Microterra, has developed bacteria that can reduce sulphur concentration in coal.⁸

Even arms control agreements have spurred development of bioremediation technologies. For example, the U.S. and the former Soviet Union have agreed to dismantle most of their chemical weapons. However, the disposal of the hazardous compounds resulting from this dismantling, which are lethal in even minute quantities, has hampered compliance with these agreements. For this reason, the U.S. government has been developing microorganisms to degrade these compounds into non-toxic products.

Although many different regulations on both the state and federal level can affect the future of bioremediation, this report focuses upon the federal statutes and regulations, both existing and under development, which have the greatest impact on bioremediation. These statutes are: the Resource Conservation and Recovery Act (RCRA)⁹ which regulates the treatment and disposal of hazardous materials; the Comprehensive Environmental Response, Compensation and Recovery Act (CERCLA),¹⁰ more commonly known as "Superfund," that funds

⁶ *Id.*

⁷ 42 U.S.C. §§ 7401-7626 (1994). The 1970 version was Pub. L. No. 91-604. The 1977 amendments were Pub. L. No. 95-95.

⁸ Matthew Gallagher, *SO₂ Technologies, Sulphur Dioxide; Environmental Strategies '95*, Chemical Marketing Reporter, June 26, 1995, at SR-10 (Sulphur emissions are the cause of acid rain.)

⁹ 42 U.S.C. § 6901 et seq. (1994).

¹⁰ 42 U.S.C. § 9601 et seq. (1994).

cleanup of contaminated sites throughout the U.S.; and the Toxic Substances Control Act (TSCA)¹¹ that regulates the use of genetically altered organisms.

How RCRA & CERCLA Encourage Bioremediation

RCRA and CERCLA are key factors in the development of bioremediation. Since the passage of RCRA and CERCLA, industry has had an enormous incentive to properly treat and dispose of its hazardous wastes. RCRA provides strict standards for the treatment and disposal of hazardous wastes. These standards are backed up by harsh penalties which include not only fines, but criminal prosecution for corporate executives. CERCLA imposes strict liability for the cleanup costs on those manufacturers which release hazardous wastes into the environment.

RCRA

RCRA was enacted in 1976 to identify and regulate wastes which are hazardous to health and environment. It provides for a complex system which regulates all aspects of hazardous waste storage, treatment and disposal. Under RCRA, the U.S. Environmental Protection Agency (EPA) has the responsibility of identifying hazardous wastes and the authority to develop treatment standards for all hazardous wastes. RCRA also provides for fines and criminal prosecution for violations of RCRA requirements.

Management and disposal of all "hazardous waste" materials must conform to RCRA standards and permitting procedures. The permit spells out the methods for the treatment and handling of the hazardous waste. During the permit process the permittee has the opportunity to present plans to the EPA, which conform to statutory requirements.

Thousands of compounds are subject to RCRA permit requirements. Waste is defined by the statute "as any solid or liquid material which is intended to be discarded." The EPA has two broad categories for hazardous wastes, characteristic waste and listed waste. Characteristic waste displays one of four listed characteristics: ignitability, reactivity, corrosivity or toxicity.¹² The EPA defines

¹¹ 15 U.S.C. § 2601 et seq. (1994)

¹² 40 C.F.R. § 261.20. (1995)

specific tests for determining whether waste has one of these characteristics.¹³ Listed wastes, on the other hand, are specifically identified by the EPA as hazardous.¹⁴ A listed waste may, but does not necessarily, demonstrate one or more of the four characteristics discussed above. Presently, several hundred compounds are listed as hazardous waste.

A key exemption to the Act which benefits bioremediation, is the exclusion of an enclosed treatment facility from RCRA permitting requirements. A totally enclosed facility is a facility directly connected to an industrial process site in a manner which prevents the release of any hazardous waste during treatment. Therefore, bioreactors installed in a plant may qualify as a totally enclosed treatment facility. For the purposes of RCRA, the treatment is part of the process and no hazardous waste material is produced. However, care must be taken to assure that the material released from the plant is not hazardous.

CERCLA

CERCLA provides the EPA with the authority to cleanup sites contaminated with hazardous wastes. The legislation also allows the government to impose the cost of cleanup onto responsible parties.¹⁵ CERCLA is a strict liability statute, requiring no negligence or intent. Furthermore, there is no time limit on potential liability. Those that create, treat or store the hazardous waste can always be held liable for its cleanup. CERCLA therefore provides a tremendous incentive to find and utilize inexpensive means of converting hazardous waste into nonhazardous material.

The Act requires that a potential cleanup site go through an assessment. The first stage identifies any potentially responsible parties. A remedial investigation is then conducted to determine the nature and extent of the contamination. Next, a feasibility study is conducted to evaluate alternative methods of treating the contamination. After the evaluations are complete, the EPA issues a "record of decision," that identifies the treatment procedure to be carried out at the site.

¹³ See 40 C.F.R. § 261.21 (ignitability); 40 C.F.R. § 261.22 (corrosivity); 40 C.F.R. § 261.23 (reactivity); and 40 C.F.R. § 261.24 (toxicity).

¹⁴ 40 C.F.R. § 261.30.

¹⁵ Only if the responsible parties cannot be found or are unable to fund the cleanup, will the government pay for the cleanup out of the "superfund."

In 1986, CERCLA was amended by the Superfund Amendments and Reorganization Act (SARA). At that time Congress sought to encourage the development of new technologies which were not available at the time of the original act. Section 121(b) of SARA requires the EPA to “conduct an assessment of permanent solutions and alternative technologies or resource recovery technologies”. Special emphasis was placed on those technologies which could permanently decrease the level of pollutants. Congress further provided for a “program of research, evaluation, testing, development, and demonstration of alternative or innovative treatment technologies” in section 311(b) of SARA.

How RCRA and CERCLA Inhibit Bioremediation Development

Even though RCRA and CERCLA require treatment of hazardous wastes and the cleanup of contaminated sites, these statutes also have standards which discourage the use of bioremediation. For example, RCRA and CERCLA both require the use of the “best demonstrated available technology” (BDAT), for treatment and cleanup. This creates artificially high standards which cannot be reached with biological technologies. Further, the “derived from” rule requires that any hazardous waste which is treated must still be handled as if it is hazardous waste, even if bioremediation converts the hazardous material to a nonhazardous material.

Best Demonstrated Available Technology Requirements

The EPA requires that treatment standards be set based upon the BDAT. Conventional technologies, such as incineration, may result in lower contamination levels than those obtained using bioremediation, resulting in such conventional technologies being considered the “best” demonstrated available technology. The resulting standards therefore, are not based on the levels necessary to protect health and environment, but are arbitrarily set by the available technology. Furthermore, the ability to achieve lower levels of contamination is not the sole factor in determining the desirability of a cleanup procedure. For example, to cleanup a spill of hazardous material by incineration, the contaminated soil and other material must be removed from the area, which disrupts the environment. The material must then be burned, releasing

pollutants into the air, and requiring the disposal of the resulting ash in a landfill. Alternatively, bioremediation can be accomplished with minimal disruption to the environment and without creating other pollution problems.

The Derived From Rule

Several EPA policies expand the definitions of hazardous waste. To prevent the disposal of hazardous wastes by diluting the wastes with other waste, the EPA adopted a "mixture rule." It provides that any mixture of a solid waste with a hazardous waste is still to be considered a hazardous waste. EPA policies also provide that material such as soil or water which contains hazardous waste is also a hazardous waste.¹⁶ The EPA further has a "derived from" rule which provides that any residue derived from the treatment of listed hazardous waste, such as the waste from a bioreactor, must be treated as hazardous waste.¹⁷

Here the distinction between characteristic waste and listed waste is important. Characteristic waste may be rendered nonhazardous by treatment to the point where the resulting waste no longer demonstrates the hazardous characteristic.¹⁸ However, a listed hazardous waste "will remain a hazardous waste" even after treatment.¹⁹ Therefore, the generator of a listed hazardous waste who effectively treats the waste through bioremediation must still treat the material generated as hazardous waste.²⁰

Bioremediation has potential to convert hazardous material into innocuous compounds. The regulations could encourage the use of bioremediation if standards were set for treatment which would allow the remaining innocuous waste material to be classified as nonhazardous. Generators of waste would have an incentive to treat the waste rather than storing or disposing of the material in approved hazardous waste dumps. They would realize cost savings by avoiding

¹⁶ 40 C.F.R. § 261.3(b)(2).

¹⁷ 40 C.F.R. § 261.3(c)(2)(i).

¹⁸ 40 C.F.R. § 261.3(a)(2)(iii),(d)(1).

¹⁹ 40 C.F.R. § 261.3(c)(1).

²⁰ *But see* 40 C.F.R. § 261.3(c)(2)(i). An exception does exist for material which is reclaimed from the treatment process and retains beneficial uses. For example, if bacteria used to degrade hazardous waste converted the material into a useful product, the product isolated from the bacteria would not be a waste and therefore would not be a hazardous waste.

the need to dispose of the hazardous waste, and would avoid potential future liability for any cleanups of the material required under CERCLA.

Regulating Use of Genetically Engineered Microorganisms

Bioremediation is limited to treating wastes which can be effectively recognized and degraded by microorganisms. Many types of toxic waste are difficult to degrade because of a lack of microorganisms which will recognize and transform the waste. Microorganisms which have evolved over millions of years have not been exposed to the thousands of man-made compounds until relatively recently. Therefore, the bacteria have not had the opportunity to evolve systems to efficiently degrade these waste compounds. Genetically altered organisms could expand the range of compounds and the number of sites at which bioremediation could be used.

Genetic engineering of microorganisms provides a method of creating bacteria which can recognize and degrade these nonnatural compounds. A quick review of the literature finds hundreds of articles concerned with the engineering of bacteria better suited for degrading toxic waste.

However, to date no genetically altered microorganism has been used commercially to cleanup or degrade toxic wastes, primarily due to a lack of government approval. The EPA has the authority to regulate the release of microorganisms under section 5 of the TSCA.²¹ Although the EPA was granted this authority almost twenty years ago, it has approved only a small number of demonstration projects involving closed reactor systems.²²

TSCA

TSCA was enacted in 1976 to enable the EPA to screen new substances prior to their introduction into commerce and to regulate those compounds which present a risk to health or environment.²³ The EPA also has the authority under TSCA to regulate the use of existing and new substances which are unsafe to health or environment.²⁴

²¹ Occasionally, the U.S. Department of Agriculture will be involved if the genetically altered organism falls within the scope of the Federal Plant Pest Act.

²² Hamilton, *supra* note 4.

²³ 15 U.S.C. §§ 2604 and 2605.

However, TSCA does not apply to pesticides, food and food additives, or drugs and cosmetics, which are subject to regulation by other statutes and agencies.²⁵

In 1984, the Office of Science and Technology prepared a proposal for a Coordinated Framework for Regulation of Biotechnology.²⁶ As part of this reworking of biotechnology regulations, the EPA published a proposed policy statement in which it stated that the definition of "new chemical substances" included living organisms and microorganisms.²⁷ This Policy Statement was officially adopted in 1986. The EPA now specifically defines intergeneric microorganisms (microorganisms which have DNA from an organism of a different genera) as "new chemical substances" subject to review under TSCA.

Section 5 of TSCA, which is particularly relevant to bioremediation technologies, requires that the manufacturer of a new chemical substance submit a premanufacture notice (PMN) to the EPA.²⁸ A new chemical substance is any material which is not implicitly or explicitly listed on the TSCA Inventory of Chemical Substances.²⁹ A chemical substance is implicitly listed in the inventory if it is considered to be already in commerce in the U.S. A chemical substance is explicitly listed when a manufacturer files a Notice of Commencement (NOC), indicating the intent to use an approved substance in commerce. Once a chemical substance is listed in the TSCA inventory, other persons may use the substance without notifying the EPA.

The PMN must be submitted at least 90 days prior to introducing the new substance into commerce.³⁰ The manufacturer must identify the chemical, its proposed uses, and the projected amount of use.³¹ In addition, the applicant must submit any known data regarding the environmental and health effects of the substance.³² The EPA then

²⁴ 15 U.S.C. § 2604(e).

²⁵ 15 U.S.C. § 2602(2).

²⁶ 49 Fed. Reg. 50856 (1984).

²⁷ *Proposed Policy Regarding Certain Microbial Products*, 49 Fed. Reg. 50886 (1984).

²⁸ 15 U.S.C. § 2604.

²⁹ 15 U.S.C. § 2607(b).

³⁰ The EPA publishes a document with points to consider when submitting a PMN for a genetically engineered microorganism.

³¹ 15 U.S.C. § 2604(a).

conducts a review to determine whether the material possesses an unreasonable risk to health or environment. If an unreasonable risk is found, the EPA may prohibit or limit its manufacture.

Naturally occurring microorganisms are considered to be implicitly listed in the TSCA inventory. Therefore, the use of natural microorganisms is generally not subject to review under TSCA. Also implicitly included in the inventory, are intrageneric organisms (organisms whose introduced genetic material is derived from microorganisms of the same genera). However, the EPA may designate new uses of chemical substances as "significant new uses," and require the submission of a PMN and review by the agency. Nevertheless, bioremediation with naturally occurring organisms is not significantly impacted by TSCA.³³

No genetically modified microorganism has yet been approved for commercial use. However, the EPA should grant approval for the use of a modified *Rhizobium meliloti* in the next few months.³⁴

Proposed Rules for Use of Genetically Engineered Microorganisms

In September of 1994, the EPA released proposed rules for the regulation of microbial products of biotechnology under TSCA. Most importantly, for the first time the rules are specifically directed to the regulation of genetically engineered microorganisms.

In 1986, when the EPA expanded the scope of TSCA, it realized that new regulations were needed for genetically engineered microorganisms. However, through a lack of initiative on the part of the EPA and activity by large biotechnology firms, these new rules have been delayed. These proposed rules are expected to be finalized in June of 1996 and will become effective 60 days after they are published in final form.³⁵

Even with the expected delays which will occur during an election year, these proposed rules will affect those microorganisms which are

³² 15 U.S.C. § 2604(b).

³³ J. S. Baskt, *Impact of Present and Future Regulations on Bioremediation*, 8 J. Ind. Microbiol. 13 (1991).

³⁴ See, *Science Advisory Panel Split Over Need for Further Testing of Microbe; Member Resigns*, BNA National Environment Daily, Mar. 9, 1995, available in Lexis BNA Library, BNAIED file.

³⁵ 60 Fed. Reg. 23957 (1995).

presently being developed. For this reason, manufacturers should look to the new rules when designing their research projects, in order to facilitate the regulatory process. It should be noted that even prior to the proposed rules becoming effective, these approaches will be useful when seeking approval for release of a genetically engineered microorganism (GEM).

Under the new rules, a manufacturer will submit a Microbial Commercial Activity Notice (MCAN), rather than a PMN. The MCAN must identify the recipient microorganism and describe its phenotypic and ecological characteristics, as well as a detailed description of its genetic modification.³⁶ The proposed rule also requires the manufacturer to provide (i) health effects data, (ii) ecological effects data, (iii) physical and chemical properties data, (iv) environmental fate, and (v) monitoring or test data related to human exposure or environmental release.³⁷ If the information is available in the open scientific literature, the manufacturer need only provide a citation. However, if the information is not available in the literature, the manufacturer must provide a full report of all the necessary studies.

These studies are time consuming and expensive. However, the proposed rules do provide some limited exemptions which include ten well characterized recipient microorganisms.³⁸ In order to qualify for an exemption, the introduced genetic material must be limited in size to include only the structural genes of interest, regulatory sequences, sequences needed to insert the gene into a plasmid, and the sequences needed to transfer and maintain the vector.³⁹ Furthermore, the genetic material must be free of nucleotide sequences which encode identified toxins.⁴⁰

A manufacturer may avoid significant cost and delay by designing a GEM to fit within the exceptions provided by the EPA. First, if it is possible, a manufacturer should choose to use one of the recipient

³⁶ 59 Fed. Reg. 45572 (1994) (Proposed 40 C.F.R. §725.155(d)).

³⁷ 59 Fed. Reg. 45573 (1994) (Proposed 40 C.F.R. §725.160).

³⁸ These microorganisms are: *Acetobacter aceti*, *Aspergillus niger*, *Aspergillus oryzae*, *Bacillus licheniformis*, *Bacillus subtilis*, *Clostridium acetobutylicum*, *Escherichia coli* K-12, *Penicillium roqueforti*, *Saccharomyces cerevisiae*, and *Saccharomyces uvarum*. 59 Fed. Reg. 4579 (1994); EPA officials have indicated that several *Rhizobium* species should be added to this list in the near future.

³⁹ *Id.* (Proposed 40 C.F.R. § 725.421).

⁴⁰ The toxins are listed in the proposed 40 C.F.R. § 725.421(d) (1994).

microorganisms which is eligible for exemption. Second, they should carefully construct all introduced DNA in a manner as not to include uncharacterized DNA. Providing the EPA with a well defined DNA construct can greatly facilitate the review process. According to the EPA, constructs with uncharacterized DNA and poorly constructed genetic maps are responsible for considerable delay in approval.

When the listed microorganisms are not suitable for a manufacturer's needs, a risk assessment must be carried out for the recipient organism. The EPA will add additional organisms to the list as they collect enough data to complete a risk assessment. However, the manufacturer does not need to wait for an organism to be listed as an eligible exemption, as he may submit the needed information.⁴¹ Because of the time required to collect the information, a manufacturer should begin the process as early as possible. Thus, as soon as the new organism is developed, it may be possible to exempt it from the reporting requirements.

Although there is improvement, the new rules are still burdensome and as yet not risk based. The new regulations still regard molecular genetic modification as per se high risk, rather than regulating high risk organisms or uses of organisms. In 1989, the U.S. National Research Council concluded that "no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular methods that modify DNA and transfer genes."⁴² EPA policies regarding the release of genetically modified microorganisms still avoid any type of risk based analysis.

Practical experience with genetically modified microorganisms indicates that they are not per se hazardous to the environment. Over the years, researchers have released thousands of different such organisms into the environment with no reported problems.

⁴¹ Risk assessment documents for the approved organisms are available from the EPA as examples of the information required to complete a risk assessment for the recipient organisms.

⁴² National Academy of Sciences, *Field Testing Genetically Modified Organisms: Framework for Decisions* (1989).

Federal Plant Pest Act

The Federal Plant Pest Act (FPPA) regulates the release of organisms "which can directly or indirectly injure or cause disease or damage in any plants". Therefore, the FPPA would only be applicable in those cases where the microorganism is a plant pest or if it was genetically engineered with DNA from a plant pest and caused damage to plants.⁴³ Like TSCA, the FPPA regulates the use of genetically engineered microorganisms regardless of risk.

Conclusion

The passage of extensive environmental regulations over the past twenty years has resulted in a demand for improved waste disposal and cleanup technologies. Practical experience has shown that bioremediation can be effective and cost efficient in certain cleanup situations. However, wider usage of the technology has been inhibited by federal regulations which were developed before the advent of effective bioremediation and which favor more established technologies. These regulations need to be updated to include risk based criteria in cleanup and treatment requirements.

Genetic engineering provides the tools needed to expand the range of target compounds and increase the effectiveness of bioremediation. However, EPA regulations have prevented the use of GEMs in bioremediation. Recently, the EPA has acted to change these regulations in order to encourage the development of GEM technologies, but as yet the new regulations still regulate all products of genetic engineering irrespective of risk.



⁴³ 7 C.F.R. Part 340. (1996)