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Impact of present and future regulations on bioremediation

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SUMMARY

Innovative treatment technologies are in increasing demand to clean up the nation's existing environmental contamination. There also are mounting pressures for industry to minimize the production or generation of hazardous pollutants. Bioremediation is a viable, cost-effective treatment option for both field remediation and treatment in enclosed systems. The use of innovative treatment technologies is largely regulatory driven. Over the last two decades, at least a dozen Federal environmental statutes have been enacted and hundreds of regulations implemented to control releases of pollutants into the air, water and on land. These statutes not only have created markets for the use of treatment technologies, they also may regulate some aspect of the application of that technology. Regarding bioremediation, four statutes should be reviewed to determine if compliance is necessary before employing microorganisms in the field or in enclosed systems. This paper summarizes the Federal statutes (i.e., the Toxic Substances Control Act (TSCA); the Resource Conservation and Recovery Act (RCRA); the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA); and the Federal Plant Pest Act (FPPA)), and regulations that may impact the bioremediation industry; outlines potential markets for bioremediation that are being driven by regulations; and highlights, within the regulatory framework, promising applications for the bioremediation of hazardous wastes.

Since the mid-1970s, at least a dozen Federal environmental statutes have been enacted and hundreds of implementing regulations promulgated to control releases of pollutants into the air, water and on land. These statutes not only have created markets for the use of traditional and innovative treatment technologies, they also may regulate some aspect of the application of that technology. Regarding bioremediation, four statutes should be reviewed to determine if compliance is necessary before employing microorganisms in the field or in enclosed systems. This paper summarizes the Federal statutes and regulations that may impact the bioremediation industry; outlines potential markets for bioremediation that are being driven by regulations; and highlights, within the regulatory framework, promising applications for the bioremediation of hazardous wastes.

SUMMARY OF APPLICABLE U.S. STATUTES

Toxic Substances Control Act (TSCA)

TSCA grants the Environmental Protection Agency (EPA) regulatory authority over new and existing chemical substances [1]. TSCA authorizes EPA to evaluate new chemicals prior to their manufacture and use in commerce by requiring the submission of a Premanufacture Notice (PMN) [2], and regulate new and existing chemicals that are found to present an unreasonable risk to human health and the environment. Additionally, EPA is authorized to require testing of chemical substances and the collection and reporting of a broad range of data.

In 1984, numerous Federal agencies, including EPA's Office of Toxic Substances, published a coordinated framework for the regulation of biotechnology. For TSCA, the key aspect of the coordinated framework was EPA's announcement to define the term chemical substance to include microorganisms. EPA further proposed that it would regulate genetically engineered microorganisms (GEMs) through the premanufacture notification process.

EPA received many negative comments on its proposal to regulate a process, i.e., genetic engineering, rather than particular microorganisms due to their inherent risk. The commentors argued that other processes (e.g., mutations or deletions) can produce new combinations of traits in microorganisms that also may present a risk to human health and the environment.

In 1986, EPA published a Biotechnology Policy Statement which further defined its regulatory approach [3]. Of most importance was EPA's proposal to alter its regulatory oversight from process to product based. EPA modi-

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fied its approach from regulating the process, such as genetic engineering, that created the microorganism, to regulating particular types of microorganisms considered to pose uncertainty as to the associated risks.

Pursuant to the 1986 Policy Statement, EPA defined as new, and therefore subject to PMN reporting requirements, microorganisms that are the product of inter-generic transfer, or the combination of genetic material from microorganisms of different taxonomic genera. EPA stated that it also would regulate other "higher risk" microorganisms, such as pathogens, through its Significant New Use Rule (SNUR) process, prior to an environmental release [4]. EPA also announced its intention to regulate small-scale (less than 10 acre) R & D field tests of inter-generic microorganisms, and to propose reduced reporting requirements for certain microbial applications in enclosed systems.

Under the 1986 Policy Statement, only the review of inter-generic microorganisms employed for commercial non-R & D applications was immediately effective. For all other aspects of the proposal, EPA must promulgate implementing regulations. The Agency, however, requested the voluntary submission of inter-generic microorganisms used at the R & D level. To date, no microorganisms have been submitted to EPA for bioremediation purposes.

In early 1989, EPA released for public comment a draft of its proposed regulation. EPA's 1989 approach would have regulated:

(i) inter-generic microorganisms through the PMN process;
(ii) "Altered microorganisms" – those that are not intergeneric or naturally occurring – and naturally occurring microorganisms, through the SNUR process; and
(iii) small-scale field releases of inter-generic microorganisms for commercial and academic R & D through a simplified reporting process referred to as the TSCA Environmental Release Application (TERA) [5]. EPA also considered having TERAs be pre-reviewed by local Environmental Biosafety Committees (EBCs) [6].

EPA received vigorous objection to most aspects of this approach. Industry, academia and other government agencies opposed EPA's proposal to regulate naturally occurring and altered microorganisms, and the concept of EBCs. The Agency did, however, receive positive feedback on the review of commercial and academic R & D field releases, and the limited TERA review for small-scale field releases.

As of late 1990, 4 years after EPA published its Policy Statement, the Agency has yet to publish a proposed regulation. There has been significant controversy both within EPA, and between EPA, USDA, and FDA as to the proper scope of the biotechnology regulations. Given the Federal Agencies' inability to develop a workable approach, the Executive Branch's Biotechnology Science Coordinating Committee (BSCC) stepped in to determine the scope of microorganisms appropriate for review across Federal regulatory programs.

In Fall of 1989, the BSCC developed a proposed scope definition that would regulate "organisms deliberately modified by the introduction into or the manipulation of genetic material in their genomes" [7]. This definition also included five broad exemptions. The Committee, however, was unable to reach consensus on a final scope definition. The BSCC then took its proposed "set of principles" to the Vice President's Council on Competitiveness, Subcommittee on Biotechnology. The Biotechnology Subcommittee modified the principles to cover "organisms with deliberately modified hereditary traits, where the planned introduction poses a level of risk requiring oversight." On July 31, 1990, the Office of Science and Technology Policy (OSTP) proposed this definition in the Federal Register for public comment [8].

The notice states that, in evaluating whether an organism presents a risk, an Agency can compare the risk of the organism against previous introductions of similar organisms in similar target/test environments. The notice includes criteria for Agencies to use in evaluating the risk or safety of an organism. These criteria include: fitness; infectivity; virulence; toxicity; pathogenicity; host range; and a number of environmental parameters [9]. The notice also includes a number of exemptions from the scope definition, which have been left to EPA, FDA and USDA to determine their applicability for regulatory purposes. Examples of the exclusions are:

(i) Microorganisms modified solely: (a) through chemical or physical mutagenesis; (b) by the movement of nucleic acids using physiological processes including, but not limited to, transduction, transformation, or conjugation; or (c) by plasmid loss or spontaneous deletion;
(ii) Vascular plants regenerated from tissue culture, including those produced through selection of somaclonal variants, embryo rescue, protoplast fusion, or treatments that cause changes in chromosome number;
(iii) Organisms that have been modified by the introduction of non-coding regulatory sequences that cause no phenotypic or physiological changes in the parental organism;

(iv) Organisms resulting from deletions, rearrangements and amplifications, within a single genome, including its extrachromosomal elements; and

(v) Organisms with a new phenotypic trait(s) conferring no greater risk to the target environment than the parental strain, which is considered to be safe [10].

The refinement of the scope principles have come full circle. Specifically, the BSCC began by taking the "scope" definition away from EPA due to the general dissatisfaction with the Agency's approach. The BSCC, however, also was unable to develop a workable approach. The Vice President's Council then developed a new definition, or set of principles – which is not materially different from EPA's original approach – which it then handed back to EPA, and the other regulatory Agencies, for interpretation.

EPA is expected to adopt, virtually intact, the scope principles as defined by the Vice President's Council. The Agency currently is scheduled to publish its proposed regulations by Fall of 1991.

Biotechnology legislation

In response to years of delay by EPA in issuing its proposed biotechnology regulations, Congressman Roe (D-NJ) introduced the "Omnibus Biotechnology Act of 1990". This bill would, among other things, require EPA to promulgate biotechnology regulations within one year of the date the act is enacted. With respect to EPA oversight, the bill would amend TSCA with a permit system for "genetically modified microorganisms intentionally released to the environment for R & D or commercial purposes". Genetic modification is defined as: "the introduction of new genetic material into its genome, or the manipulation, including deletion, of the genetic material in its genome". This definition does not include manipulations achieved through traditional methods such as selection of spontaneous mutants or other methods specified by the Administrator.

If enacted, this legislation could significantly simplify the scope issue as well as the reporting process under TSCA. EPA would be given specific authority to regulate genetically modified microorganisms, and it no longer would have to try and mold TSCA, a statute designed for chemicals, to fit the practical application of microorganisms. The legislation would require that a permit be obtained only for commercial and R & D field releases of genetically modified organisms. Naturally occurring microorganisms would not be subject to EPA review.

This legislation did not pass in 1990. However, it could move in 1991 if EPA continues to delay issuing its proposed regulations and there is broad-based support for the legislation.

The impact of TSCA on bioremediation

Regardless of EPA's proposed approach, or the above-described legislation, bioremediation likely will not be significantly impacted by TSCA unless genetically modified, or engineered, microorganisms are employed. EPA did, however, at one point consider regulating naturally occurring microorganisms through the SNUR process. Based on the practical implications, and the significant negative comment EPA received on that proposal, it is unlikely the Agency will pursue this approach. Once the bioremediation field advances to the point of releasing genetically modified microorganisms to the environment, a PMN or a TERA may need to be obtained.

The Resource Conservation and Recovery Act (RCRA)

Subtitle C of RCRA requires EPA to promulgate regulations to identify hazardous wastes, set treatment standards for wastes prior land disposed, and issue permits for facilities that store, treat, and/or dispose of these wastes. RCRA primarily was enacted to ensure that hazardous wastes are managed in a manner that protects human health and the environment.

Subtitle C of RCRA is a complicated statute with many implementing regulations. The impact of the regulations varies depending on whether a company generates a RCRA waste, is an owner/operator of a RCRA facility performing some sort of waste management activity, or provides a clean-up service. The following discussion outlines briefly the RCRA program and how it impacts these various activities.

Definition of a solid waste

RCRA regulates treatment, such as bioremediation, only if the technology is used to manage a RCRA hazardous waste. Hazardous waste is defined as a subset of solid waste. That is, in order to be hazardous, a material first must meet the definition of a solid waste. Therefore, to determine whether bioremediation is subject to RCRA, one must first determine if the waste to be treated is a RCRA solid waste. If a material is a solid waste, it must then be determined if it is a RCRA hazardous waste.

RCRA broadly defines a solid waste as any "garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations and community activities" [11].

There are two important exclusions from the definition of a solid waste [12]. The first exclusion is for domestic sewage, and any mixture of domestic sewage, that passes through a sewer system to a Publicly Owned Treatment

Works (POTW). Many industrial generators now avoid RCRA regulation by discharging their industrial waste to a POTW pursuant to pretreatment permits issued under the Clean Water Act [13].

The second exclusion is for point source industrial wastewater discharges that are regulated under the National Pollutant Discharge Elimination System (NPDES) pursuant to Section 402 of the Clean Water Act. This exemption applies only to the actual point source discharge. It does not apply to those industrial wastewaters that are collected, stored or treated before being discharged, or to the sludges generated by the wastewater treatment process.

Definition of a hazardous waste

There are two mechanisms for defining the universe of materials deemed hazardous under RCRA. The first method is identifying whether the solid waste exhibits one of four characteristics. These are: ignitability, reactivity, corrosivity, or toxicity [14]. The first three characteristics refer to properties of the waste itself. The fourth, toxicity, gives some consideration to the potential for certain toxic constituents to leach into groundwater.

Historically, the toxicity characteristic, commonly referred to as the EP, or extraction procedure, has been limited to materials containing certain levels of one of 14 inorganic (metals and pesticides) compounds. Generally, if the leachate from a waste contains any one of these constituents in an amount meeting or exceeding a threshold, or regulatory level, the waste is considered hazardous for RCRA purposes.

As a result of a March 29, 1990 final rule, EPA significantly expanded the universe of characteristic hazardous wastes [15]. This rulemaking added 25 organic constituents to the list of 14 inorganic compounds originally covered, and replaced the extraction procedure with the Toxicity Characteristic Leaching Procedure (TCLP). Thus, leachate from waste that contains any one of the 25 organics, or previously listed inorganics, in an amount that meets or exceeds the applicable regulatory level will be considered hazardous [16]. EPA estimates that this rulemaking will regulate as hazardous waste an additional 730 million metric tons of waste per year.

The second method the Agency uses in identifying hazardous wastes is the listing of specific wastes [17]. There are four lists of hazardous waste. These are:

(i) Wastes from non-specific sources, such as spent halogenated solvents, toluene, or methyl ethyl ketone, which are identified with an "F" code;
(ii) Wastes from specific sources, such as wastewater treatment sludges generated in the production of creosote, which are identified with a "K" code;
(iii) Specific commercial chemical products or their off-specification variants, when they are discarded, along with residue and debris from spills of these materials, which are identified with a "U" code; and
(iv) Specific acutely hazardous commercial chemical products and their off-specification species, when they are discarded, residue and spill debris, and containers and inner liners that hold these materials, which are identified with a "P" code.

A significant difference exists between listed and characteristic wastes. Characteristic wastes can be rendered non-hazardous by eliminating the characteristic. A listed waste, however, regardless of how it is treated or mixed, always remains listed unless it is delisted through a RCRA rulemaking process [18].

The hazardous waste listings and characteristics were broadened significantly by the implementation of two additional regulations and one policy. These are the mixture and derived from rules, and the contained-in policy. Specifically,

(i) The 'mixture' rule provides that any mixture of a solid waste with a listed hazardous waste is that listed hazardous waste, unless and until it is delisted;
(ii) The 'derived from' rule provides that any residue generated from the treatment, storage, or disposal of a listed hazardous waste remains listed, unless and until it is delisted; and
(iii) The 'contained-in' policy provides that any soil, groundwater or other similar material containing a hazardous waste must be managed as a hazardous waste until it no longer contains the waste.

RCRA permits

An exhaustive discussion of the RCRA permitting process is beyond the scope of this paper. However, it is important to understand what type of facilities need to be RCRA permitted, and how this applies to bioremediation.

RCRA Sections 3004 and 3005 require owners or operators of all hazardous waste treatment, storage and disposal facilities to obtain a RCRA permit. Bioremediation companies that provide a clean-up service generally do not need to be RCRA permitted. However, if a bioremediation firm itself receives and treats hazardous waste, the facility at which the activity is undertaken must obtain a RCRA permit.

The Land Disposal Restrictions (LDRs)

The 1984 RCRA amendments required EPA to develop a program to restrict all untreated hazardous wastes from land disposal [19]. EPA was further required to develop treatment standards for each RCRA listed and

characteristic waste based on the Best Demonstrated Available Technology (BDAT). The restrictions were promulgated on a phased-in basis between 1986 and 1990.

EPA published, in two separate rulemakings, its LDRs framework, which included standards for solvents and dioxins [20], and standards for the California-list wastes [21]. The remainder of the listed and characteristic wastes were broken into thirds based on their volume and toxicity. Standards for these wastes were promulgated in three regulations, called the first-third [22], second-third [23], and third-third [24].

Pursuant to the LDRs, RCRA wastes are prohibited from land disposal unless the wastes are first pretreated to the applicable treatment standard, or a petitioner proves to EPA that there will be no migration of the waste, or any constituent thereof, for as long as the waste remains hazardous. Additionally, for purposes of the LDRs, Congress also significantly expanded the definition of land disposal. Land disposal was broadened to include, "any placement of hazardous waste in a landfill, surface impoundment, waste pile, injection well, land treatment facility, salt dome or salt bed formation or underground mine or cave" [25].

EPA was required to establish treatment standards for hazardous wastes in one of two ways. The Agency may require a specific method of treatment, such as biodegradation or incineration; or EPA may establish a specific treatment standard, based on the best demonstrated available treatment technology. Where a treatment standard has been specified, any method of treatment may be used to meet that standard [26]. However, when a treatment method has been established for a waste, it must be treated with that method before the waste can be land-disposed.

Regarding biodegradation, this treatment method, either alone or in combination, can be used on any waste for which a treatment standard has been specified. In addition, EPA identified biodegradation, along with various other technologies, as the method of treatment for certain wastestreams. For example, in the third-third final rule, biodegradation, in addition to other technologies, was identified as the method of treatment for a number of wastewaters [27], such as:

D012 – Endrin
D015 – Toxaphene
D016 – 2,4-D
F005 – 2-Ethoxyethanol
P068 – Methylhydrazine
P081 – Nitroglycerin
P105 – Sodium azide
P112 – Tetranitromethane
U086 – *N*,*N*-Diethylhydrazine
U096 – a,a-Dimethylbenzyl hydroperoxide
U098 – 1,1-Dimethylhydrazine
U099 – 1,2-Dimethylhydrazine
U103 – Dimethyl sulfate
U109 – 1,2-Diphenylhydrazine
U133 – Hydrazine
U160 – Methyl ethyl ketone peroxide

EPA estimates that this final rule combined with the four previous LDR rulemakings will require the treatment of 7 million tons of hazardous wastes that are disposed of in land-based units such as surface impoundments and landfills.

Two important aspects of the established LDRs for bioremediation are the standards for contaminated soil and debris, and the regulatory requirements for the treatment of RCRA wastes in enclosed systems, i.e., a tank or container. Each issue is discussed briefly below.

Soil and debris

In the final third-third rule, EPA granted a two-year national capacity variance for soil and debris contaminated by any first-, second-, and/or third-third wastes where the treatment standards for the wastes are based on *incineration*, *vitrification*, *wet-air oxidation*, or *mercury retorting*. Therefore, if soil and debris is contaminated with a first-, second-, or third-third constituent where the treatment standard was based on some other form of treatment, such as biodegradation, the waste became subject to the LDRs on August 8, 1990.

RCRA tanks or containers

Under current Federal RCRA regulation, hazardous waste generators may accumulate their waste on-site in tanks or containers for up to 90 days without having to obtain a permit or interim status (facilities seeking permitted status), provided that generators comply with certain rules governing the tanks and containers [28]. EPA also has stated in previous rulemakings and memoranda that nothing precludes generators from treating their waste on-site in these accumulation units.

In the third-third final rule, EPA for the first time promulgated requirements for restricted wastes which are treated in RCRA tanks and containers. Specifically, EPA requires that generators treating restricted wastes in 90-day accumulation units, who are the sole treaters of the waste, must prepare a waste analysis plan that justifies the frequency of testing adopted to determine whether the materials meet the applicable treatment standards.

The impact of the LDRs on bioremediation

The LDRs could have both positive and negative impacts on the use of bioremediation. Specifically, the

LDRs prohibit untreated wastes from being placed on the land and then treated, either through land farming or in situ degradation. This could, in the short-run, limit the bioremediation market. Second, where a treatment standard is specified, any method of treatment, including biodegradation, can be used to achieve that standard. Even though this system appears flexible, it is possible that the treatment standards, many of which are based on technologies such as incineration and stabilization, may be difficult to achieve through microbial degradation.

The LDRs, however, do not preclude using treatment technologies, such as bioremediation, to clean up existing contamination at, for example, RCRA corrective action [29] and Superfund sites. These sites could prove to be a significant market for bioremediation.

The LDRs also provide a tremendous incentive for companies to begin minimizing the generation of hazardous wastes. When viewed in tandem with the expanded universe of hazardous wastes under the toxicity characteristic, the LDRs undoubtedly will encourage generators to begin modifying their processes so they can either degrade wastes in process or at the end of the pipe. Biodegradation could prove to be extremely successful in these types of applications.

The five LDR rulemakings are an important set of regulations for the hazardous waste treatment industry. The following discusses briefly three programs that rely heavily on treatment technologies, and increasingly on innovative technologies, to clean up existing contamination. Also discussed is how each program likely will be impacted by the LDRs. These programs are RCRA corrective action, leaking underground storage tanks ("USTs") and Superfund.

RCRA corrective action

In 1984 Congress significantly expanded EPA's authority to compel cleanups at RCRA facilities. One specific provision, Section 3004(u), authorized EPA to require the cleanup of releases of hazardous constituents from any Solid Waste Management Unit ("SWMU") existing on the property of RCRA permitted or interim status facilities.

EPA has been working since 1984 on proposing its corrective action regulations. Even though the general framework of the program has been developed for some time, the Agency has faced numerous political obstacles in issuing the proposed rule. EPA, however, has been implementing its corrective action framework on a case-by-case basis through its regional offices. After significant debate, on July 27, 1990, EPA published its long-awaited corrective action proposed rule [30].

EPA estimates that of the 5700 RCRA treatment, storage and disposal facilities, and the several hundred Federal facilities, there likely will be 80000 SWMUs identified. This program is expected to far outweigh the Superfund program in numbers. EPA estimates that the cost of the program will be on the order of $74 billion over the next several decades. The brunt of the impact is expected to fall on chemical companies, petroleum refineries, wood preservers, and auto manufacturers.

Facilities generally are brought into the corrective action process at the time EPA is considering a permit application, or when a release is identified which justifies action by an interim status facility [31]. The corrective action process is similar to the Superfund process in that first a facility assessment must be undertaken, which then is followed by a facility investigation, and subsequently a corrective measure study to identify the treatment remedy. Once the remedy is selected, EPA issues either an order for an interim status facility, or modifies the facility's permit to require the completion of the corrective action. The implementation of the selected remedy constitutes the fourth and final step of the corrective action process.

Compliance with the LDRs is triggered if a RCRA hazardous waste is placed on the land. In this regard, the definition of a SWMU, and the area of contamination at a Superfund site, is key to understanding when the LDRs are applicable. (See discussion on Superfund below.)

A SWMU is defined as "any discernible unit at which solid wastes have been placed at any time, irrespective of whether the unit was intended for the management of solid or hazardous waste". Examples of such units are chemical storage areas, a garbage dumpster, or a stormwater drainage area. SWMUs also include "any area at a facility at which solid wastes have been routinely and systematically placed, such as loading docks" [32]. EPA has proposed that if there are several SWMUs within a single facility, they will be considered one unit for cleanup purposes if there is no uncontaminated soil between the units. EPA refers to this area of contamination (AOC) as a corrective action management unit (CAMU) [33].

The concept of a CAMU was instituted to provide flexibility so as not to repeatedly trigger the LDRs. Specifically, RCRA wastes can be moved around within the CAMU (e.g., picked up and placed back on the ground) without triggering the LDRs.

Underground storage tanks

In 1984, Congress added Subtitle I to RCRA for the regulation of underground storage tanks (USTs). Subtitle I authorized EPA to develop guidelines for the operation of USTs containing petroleum and hazardous substances, as well as the implementation of technical standards, financial assurance, and corrective action [34].

EPA has determined that USTs containing petroleum

and hazardous substances are a major source of groundwater contamination. EPA estimates there are approximately 2 million UST systems where between 200 000 to 600 000 either are leaking or may be leaking in the near future. Releases from hazardous substance and petroleum USTs must be remediated according to stringent EPA or comparable state-delegated guidelines. EPA has identified bioremediation as a technology applicable to the clean-up of contaminated soils from leaking petroleum USTs.

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), or Superfund

An important distinction between the Superfund and RCRA programs is that RCRA regulates the management of hazardous waste, while CERCLA requires the use of treatment technologies to clean up our nations most contaminated hazardous waste sites [35]. Superfund also establishes a preference for on-site treatment methods that permanently reduce the toxicity and mobility of wastes at Superfund sites, and significant research authorities to develop cost-effective, innovative treatment technologies.

CERCLA grants EPA authority to clean up two types of sites, those that require short-term removals to mitigate immediate sources of damage, and long-term remedial actions designed to permanently clean-up sites. Clean-up of these sites are paid for either by EPA through the use of the 'Superfund', or by the responsible parties, if they can be identified. For a remedial action to be eligible for funding through the 'Superfund', the site must be designated as a "national priority list" (NPL) site by EPA. Currently, there are over 1200 NPL sites, with a potential 30 000 sites awaiting further evaluation.

Once a site is identified and listed on the NPL, the selection of remedy process is similar to that outlined for corrective action sites. EPA or the potentially responsible party (PRP) will do a remedial investigation/feasibility study (RI/FS). The RI is a detailed investigation/characterization of the site; and the FS is an evaluation, based on the data generated from the RI, of the alternative treatment options. Once the RI/FS is completed, which can take many years, EPA prepares the record of decision (ROD). After completion of the ROD, EPA generally must notify the PRPs and allow them the opportunity to consider undertaking the clean-up.

The impact of the LDRs on Superfund clean-ups

CERCLA Section 121(d) requires that all Superfund clean-ups comply with legally "applicable or relevant and appropriate requirements" (ARARs) of all Federal, and more stringent state, environmental laws. The RCRA LDRs are a potential ARAR for Superfund actions. Three questions must be asked to determine if the LDRs are applicable to a Superfund clean-up. These are: (i) whether the CERCLA waste also is a RCRA waste; (ii) whether the RCRA waste is restricted; and (iii) whether the CERCLA action constitutes placement [36].

The first two questions are relatively straight-forward. The LDRs are only applicable to RCRA hazardous wastes. Therefore, it must be determined if the waste is either listed or characteristic as defined by RCRA. Once a hazardous waste determination is made, one must determine if the waste is restricted.

All wastes for which EPA has set treatment standards are restricted. In some cases, however, EPA has promulgated treatment standards of no land disposal or total recycle, which would prohibit these wastes, or the treatment residuals, from being land-disposed. In other cases, however, EPA has granted a variance from the BDAT treatment standards, which means the compliance date for that waste stream has been extended.

If a waste is a RCRA-restricted waste, a determination must be made whether the CERCLA action constitutes 'placement'. For Superfund purposes, the LDRs are triggered if a RCRA hazardous waste is placed in or on the land (e.g., in a landfill, surface impoundment, waste pile or land treatment unit) outside of the AOC. An AOC, like a CAMU, is determined by the extent of continuous contamination.

Leaving restricted wastes in place (e.g., in-situ degradation) or moving wastes within an AOC does not constitute placement. However, movement of these wastes outside the AOC does constitute placement. For bioremediation purposes, if in-situ degradation occurs within the AOC, placement is not triggered. However, if the wastes are picked up and either moved to a tank inside or outside the AOC or placed in a land treatment unit outside the AOC, placement would be triggered.

Technology development

Site program

CERCLA also required EPA to establish an innovative treatment technology research and demonstration program. In response to this mandate, EPA developed the Superfund Innovative Technology Evaluation (SITE) program. The SITE program evaluates three types of technologies:

(i) Available alternative technologies (those that are fully proven, such as incineration);
(ii) Innovative alternative technologies (fully developed technologies); and
(iii) Emerging alternative technologies (pilot scale technologies).

Since 1987, 30 technologies have been accepted into the innovative technology program. The technologies selected include biological, thermal, chemical, solidification/stabilization, and physical treatment processes. The SITE program has selected six biodegradation projects for its innovative technologies program, and two for the emerging technologies program. These projects primarily have been designed to degrade hazardous constituents in such media as sludge, soil, groundwater, lagoon water, and wastewater.

Technology transfer

EPA currently, through its innovative technology office, is developing a database of 'accepted' technologies. This information primarily will be used by EPA's regional offices and contractors in determining appropriate remedies for Superfund clean-ups. In this regard, there is an implicit benefit in participating in the SITE program, for it is an avenue by which to obtain EPA's 'seal of approval'.

However, the SITE program is not the only way a technology can be placed in EPA's technology transfer database. Coordinating with EPA's technology innovation staff to determine the type of data it needs to do a comparative assessment also can achieve this goal. EPA ultimately hopes to be able to compare technologies working from a common database in which the Agency has a high level of confidence. For example, the submission of TCLP data, a test developed by the Agency, would provide EPA a baseline from which it could evaluate technologies.

Federal Plant Pest Act (FPPA)

The United States Department of Agriculture (USDA) through the Federal Plant Pest Act regulates the importation and interstate transport of plant pests. The FPPA defines a plant pest as "that which causes damage directly or indirectly to plants or plant parts, or any processed, manufactured, or other products of plants". If a bioremediation company either imports a plant pest or transports a plant pest across state lines, a permit must be obtained from USDA.

In June, 1987, the Animal and Plant Health Inspection Service (APHIS) promulgated regulations requiring that a permit be obtained for genetically engineered microorganisms that also are plant pests, and which either are imported, transported across state lines, or released to the environment. At 7 C.F.R. Section 340.2, USDA provides a list of microorganisms that are or contain plant pests.

If a bioremediation firm wants to release a genetically engineered organism that classifies as both a plant pest by USDA and an inter-generic microorganism by EPA, it is conceivable that approval would have to be obtained from both agencies.

MARKETING OPPORTUNITIES FOR BIOREMEDIATION

Our nation's hazardous waste problems and the ever mounting number of regulations which control the management of both wastes and sites are providing an impetus for the development of innovative treatment technologies. Currently, due only to the RCRA and CERCLA statutes there are:

(i) 21000 RCRA hazardous waste generators;
(ii) 5000 RCRA hazardous waste treatment, storage and disposal facilities;
(iii) An estimated 80000 solid waste management units pursuant to the RCRA corrective action program;
(iv) 1200 Superfund NPL sites, with a potential of close to 30000 sites; and
(v) An estimated 200000 to 600000 underground storage tanks that may be leaking.

To be meaningful, these numbers which must be narrowed significantly to determine the actual market for a particular technology or application. EPA has numerous databases which afford the ability to search by type of waste and/or site, standard industrial classification (SIC) code, waste management practice, enforcement status, and other parameters. These data can be useful in defining markets for treatment technologies.

In addition to cleaning up existing contamination, significant market opportunities also exist in treating wastes in enclosed systems, or in process before a material actually becomes a waste.

Enclosed systems

Treatment in enclosed systems is an attractive market for two reasons. Enclosed systems entail less environmental variables which could enhance the survivability of a microbial treatment process; and they likely will be subject to less regulatory scrutiny because there are no, or minimal, releases to the environment. For example, in the 1986 biotechnology coordinated framework, EPA states that pursuant to Section 5(h)(4) of TSCA, the Agency would, in a future rulemaking, likely reduce the PMN reporting requirements for certain microbial applications in enclosed systems. The Agency still intends to issue such a regulation [37]. In addition, EPA also allows wastes to be treated in RCRA tanks or containers for up to 90 days without having to obtain a permit provided certain requirements are met.

Waste minimization

A number of factors are providing a significant impetus for industry to begin modifying their manufacturing processes, or developing source reduction strategies. As indi-

cated above, regulations such as the land disposal restrictions, the toxicity characteristic, and corrective action are intended to send a strong waste minimization/source reduction message to hazardous waste generators.

One other regulation is very important from a waste minimization perspective. Specifically, in 1986 CERCLA was re-authorized by the Superfund Amendments and Re-authorization Act (SARA). Title III of SARA is a free standing statute entitled the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA was enacted in response to growing concern about the effect of chemical releases into the environment.

EPCRA authorizes, among other mandates, that EPA require facilities in SIC codes 20–39 (e.g., manufacturing facilities) that have 10 or more full-time employees to report annually to state and federal agencies all releases of certain listed toxic chemicals to air, water and land. The reporting requirement applies to owners and operators of manufacturing facilities that manufacture, process, import or otherwise use a listed chemical in excess of specified threshold quantities.

In 1987, the first year for which EPA received data, manufacturing industries reported 18.0 billion pounds of chemicals as being released to air, water or land, and an additional 4.6 billion pounds were transferred off-site to such facilities as public sewer systems, incinerators, and for treatment and ultimate disposal. Thus, total 1987 releases and transfers were 22.6 billion pounds [38].

For 1988 reporting purposes, EPA removed six chemicals from the Section 313 list. These are: sodium sulfate, sodium hydroxide, aluminum oxide, melamine, C.I. acid blue, disodium salt, and C.I. acid blue, diammonium salt. Sodium sulfate [39], sodium hydroxide, and aluminum oxide, which were the first, second, and sixth ranked chemicals, significantly affected the total volume of releases. After removal of the six chemicals, 1987 releases and transfers would have totaled 7.0 billion pounds.

1988 releases totalled 6.2 billion pounds. This represents an 11% decrease from the 7 billion pounds released in 1987. EPA reported that after adjusting for the removal of the six chemicals from the Section 313 list, some of the decreases in the release data were due to actual reductions. However, EPA further stated that "much of the apparent decline between 1987 and 1988 stems from paper changes, that is from changes in how wastes were estimated or reported, rather than changes in waste generation practices" [40].

These data are being used by EPA in a variety of ways. For example, in September, 1990, EPA Administrator Reilly announced that the Agency will initiate a pollution prevention program targeted at reducing certain Title III emissions by one-third by 1992 and by more than one-half by 1995. EPA also is cross-checking industrial releases with permits to determine compliance with existing regulations; and EPA and Capitol Hill are using the data to determine areas for further regulation and legislation.

CONCLUSION

Innovative treatment technologies are in increasing demand to clean up the nation's Superfund sites, leaking underground storage tanks, RCRA facilities, and other hazardous contamination. There is a growing preference for on-site treatment that produces a minimum of toxic residuals. Bioremediation falls within this category.

From a regulatory and public perceptions standpoint, the two most promising applications of bioremediation are for waste minimization and treatment in enclosed systems. Minimizing hazardous wastes and treating them in enclosed systems have become necessary and attractive options for the industrial sector. This stems from the increasing regulatory controls on land disposal and the increased financial liability associated with hazardous waste management and disposal.

Biotechnology can play a significant role in the recovery, recycling or degradation of hazardous materials either during or at the end of industrial processes. These applications can achieve numerous environmental and industrial benefits, specifically, increased on-site treatment; a reduced regulatory role for the government; reduced lability for industry; and ultimately process optimization and reduced costs.

NOTES AND REFERENCES

1 TSCA §3, 15 U.S.C. §2602. A chemical substance is defined as "any organic or inorganic substance of a particular molecular identity, including (1) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature..." TSCA does not regulate chemical substances used in pesticides, foods, food additives, cosmetics, drugs and medical devices.

2 The PMN process allows EPA a 90-day period (extendable to 180 days) to review a chemical substance prior to its introduction into the marketplace.

3 See 51 Fed. Reg. 23302.

4 SNUR requirements are similar to a PMN review, but are based on a regulatory determination that a particular use of a microorganism constitutes a significant new use. A new use is defined as that which is used in different environments or entailing different exposures.

5 EPA's review of a TERA takes 60 days, as compared with the 90-day PMN review period.

6 The purpose of the pre-review would be to expedite the review process, i.e., to 30 days, once a TERA was submitted to EPA.

7 See 55 Fed. Reg. 31119 (column 3).

8 See 55 Fed. Reg. 31118.
9 See 55 Fed. Reg. 31121 (column 1).
10 See 55 Fed. Reg. 31121 (column 2).
11 See RCRA §1004 (27).
12 See 40 C.F.R. §261.4(a).
13 Industrial wastes discharged to privately owned treatment works are not similarly excluded because they are not subject to the same CWA requirements.
14 See 40 C.F.R. Part 261, Subpart C.
15 See 55 Fed. Reg. 11798.
16 This regulation became effective on September 25, 1990, for large quantity generators (those who generate greater than 1000 kg of hazardous waste per calendar month), and by March 29, 1991, for small quantity generators (those who generate between 100 and 1000 kg of hazardous waste per calendar month).
17 See 40 C.F.R. Part 261, Subpart D.
18 See 40 C.F.R. Section 261.22.
19 RCRA 3004 (d), (e), (f), and (g).
20 See 51 Fed. Reg. 40572; 40 C.F.R. §268.30 and §268.31.
21 See 53 Fed. Reg. 25760; 40 C.F.R. §268.32
22 See 53 Fed. Reg. 31138; 40 C.F.R. §268.33.
23 See 54 Fed. Reg. 26594; 40 C.F.R. §268.34.
24 See 55 Fed. Reg. 22520; 40 C.F.R. §268.35.
25 RCRA §3004(k). 40 C.F.R. §268.2(a).
26 The LDRs requires the use of the toxicity characteristic leaching procedure, or in some cases, a total constituent analysis, to determine compliance with the treatment standards.
27 See 55 Fed. Reg. 22520. The effective date of this final rule was August 8, 1990.
28 See 40 C.F.R. §262.34(a).
29 This is a RCRA site that must undertake a clean-up activity due to a release of a hazardous constituent from a solid waste management unit.
30 See 55 Fed. Reg. 30798.
31 RCRA §3008(h).
32 See 55 Fed. Reg. 30808 (column 1).
33 See 55 Fed. Reg. 30843 (column 1).
34 See 53 Fed. Reg. 37082, and 43322.
35 CERCLA is referred to as Superfund because of the multibillion dollar trust fund the law established to finance the clean-up operations.
36 These questions also must be asked to determine the application of the LDRs to UST remediations.
37 However, EPA biotechnology officials reportedly only consider fermentation systems to be 'enclosed' for purposes of this exemption. EPA has little data on alternate enclosed systems such as batch reactors. This will be an important part of EPA's biotechnology proposed rule for the bioremediation industry to provide comment on.
38 The Title III data can be accessed by the public. These data could prove to be a valuable marketing tool for the waste treatment industry.
39 In 1987, reported emissions for sodium sulfate were 11.6 billion pounds.
40 U.S. EPA. Toxics in the Community: A National and Local Perspective, September, 1990 (page 1).