Pace Environmental Law Review

Volume 3
Issue 1 *1985*

Article 3

September 1985

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I. Introduction

Biotechnology may generally be defined as the use of living organisms, or substances produced or derived from such organisms, to make or modify a product.[1] This definition is very broad, and encompasses both traditional industrial uses of biological processes[2] as well as currently developing advanced biotechnological techniques such as recombinant DNA technology (commonly referred to as genetic engineering).[3]

Biotechnology is rapidly evolving from laboratory scale research and development toward large scale industrial commercialization.[4] The potential areas for industrial application of biotechnology are extremely diverse. Although biotechnology is expected to have its most immediate impact in the

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1. *See* Office of Technology Assessment, U.S. Congress, Commercial Biotechnology: An International Analysis 3, 503 (1984) [hereinafter cited as 1984 OTA Report]; Office of Technology Assessment, U.S. Congress, Impacts of Applied Genetics: Micro-Organisms, Plants and Animals 4, 49 (1981) [hereinafter cited as 1981 OTA Report].

2. Traditional industrial uses of biological processes include processes such as beer brewing, winemaking, and cheesemaking. *See* 1981 OTA Report, *supra* note 1, at 49. Classical plant breeding techniques also fall within the broad definition of biotechnology. *See id.* at 137-40.

3. DNA (deoxyribonucleic acid) is the genetic material found in all living organisms, and contains the genetic code responsible for all inherited characteristics of such organisms. Recombinant DNA technology is used to produce hybrid DNA molecules composed of DNA from different sources. These hybrid or recombinant DNA molecules may be used for purely scientific purposes such as genetic research, or for commercial purposes such as the production of a specific product. *See generally* 1984 OTA Report, *supra* note 1, at 33-43.

4. *See id.* at 65-113. Although biotechnology commercialization was initiated by small entrepreneurial firms organized to apply advanced biotechnological techniques for specific product development, many industrial giants are now heavily involved in biotechnology research and development. Note also that despite the greater amount of attention that has been paid to the smaller biotechnology-based firms, "most of the patents in the field assigned to date are owned by large corporations." Webber, *Biotechnology Firms Gird For Clash over Patent Claims,* Chem. & Eng. News, Dec. 10, 1984, at 18, 19.

pharmaceutical industry,[5] many other areas of potential application also exist. These include plant and animal agriculture, specialty and commodity chemicals, food processing and additives, pesticides, pollution control, toxic waste treatment, metals extraction, and enhanced oil recovery.[6] Some of these applications seek to avoid contact between the microorganisms employed and the outside environment;[7] however, other applications will involve the deliberate release of naturally occurring or genetically engineered microorganisms into the environment.[8]

Although the potential benefits of commercial biotechnology applications are great, there are also legitimate concerns being raised regarding the potential adverse environmental and health effects which may arise with biotechnology commercialization. These concerns have been particularly directed at technologies which are likely to release deliberately either naturally occurring or genetically engineered microorganisms into the environment.[9]

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5. *See* 1984 OTA Report, *supra* note 1, at 119-57; 1981 OTA Report, *supra* note 1, at 59-82.

6. *See generally* 1984 OTA Report, *supra* note 1, at 159-250; 1981 OTA Report, *supra* note 1, at 85-192.

7. The food processing, chemical, and pharmaceutical industries are likely to use fermentation technology in conjunction with naturally occurring or genetically engineered microorganisms to produce specific chemical products. Fermentation technology employs microorganisms as microbial chemical reactors which convert raw materials into end products via biochemical reactions. The microorganisms, raw materials, and end products are all initially contained within a controlled reaction vessel known as a fermenter. Contact between the microorganisms contained within the fermenter and the outside environment is sought to be avoided because contamination can interfere with or destroy the productive microorganism or the desired end product. *See* 1981 OTA Report, *supra* note 1, at 49-56; *see also* McGarity & Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 Vand. L. Rev. 461, 467-73 (1983). However, negligent operation of the fermenter or accident can bring about contact between the microorganism contained within the fermenter and the environment. *See* McGarity & Bayer, *supra*, at 468-70.

8. The use of naturally occurring or genetically engineered microorganisms as microbial pesticides, for pollution control or toxic waste treatment, for *in situ* metal extraction from mining ore, or for enhanced oil recovery will require the deliberate release of such microorganisms into the environment. *See* 1984 OTA Report, *supra* note 1, at 217-30; McGarity & Bayer, *supra* note 7, at 471-73.

9. A congressional report based on 1983 joint House Subcommittee hearings concerning the environmental implications of genetic engineering concluded:

The concomitant issue of the adequacy of the existing federal regulatory framework to prevent any adverse health or environmental effects associated with the commercial use of biotechnology has also been raised.[10] Many federal regulatory statutes have been generally identified as applicable to some aspect of commercial biotechnology. More specifically, the federal government's Office of Science and Technology Policy has issued for public comment a document which identifies various federal statutes which will play a key role in biotechnology regulation,[11] as well as policy statements by the various federal agencies which will be involved in such regulation.[12] A partial list of the more prominent federal statutes already

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> The potential environmental risks associated with the deliberate release of genetically engineered organisms or the translocation of any new organism into an ecosystem are best described as "low probability, high consequence risks;" that is, while there is only a small possibility that damage could occur, the damage that could occur is great.

Staff of House Subcomm. on Investigations and Oversight of House Comm. on Science and Technology, 98th Cong., 2d Sess., Report on the Environmental Implications of Genetic Engineering 9 (Comm. Print 1984) [hereinafter cited as House Subcomm. Report]. The report also noted that "predicting the specific type, magnitude, or probability of environmental effects associated with the deliberate release of genetically engineered organisms will be extremely difficult, if not impossible, at the present time." *Id.* at 10.

10. *See generally id.; see also* Goroski, *Regulation of Designer Genes*, N.Y. St. B.A. Envtl. L. Sec. J., Dec. 1984, at 1-4; Karny, *Regulation of Genetic Engineering: Less Concern About Frankensteins But Time For Action On Commercial Production*, 12 U. Tol. L. Rev. 815 (1981); McChesney & Adler, *Biotechnology Released From the Lab: The Environmental Regulatory Framework*, 13 Envtl. L. Rep. (Envtl. L. Inst.) 10366 (1983); McGarity & Bayer, *supra* note 7. Note that in one study prepared for the federal government concerning current and future federal biotechnology policy issues, many study participants voiced concern over the federal government's "ill-defined regulatory role" in biotechnological research, development, and commercialization. *See* Arthur D. Little, Inc., Study of Federal Biotechnology Policy Issues at I-14 (1984) (prepared for Div. of Policy Research and Analysis, National Science Foundation). The study identified the areas of biotechnology legislation and regulation as a high priority item. *Id.*

11. *See* Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (Dec. 31, 1984). Note that some state statutory authority for biotechnology regulation also exists. For example, New York law provides for state regulation of "recombinant DNA activity." *See* N.Y. Public Health Law §§ 3220-3223 (McKinney 1985); *see also* Goroski, *supra* note 10, at 4.

12. These agencies include the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the United States Dep't of Agriculture (USDA). *See* 49 Fed. Reg. at 50,858.

identified includes:

(1) the National Environmental Policy Act (NEPA);[13]

(2) the Federal Food, Drug and Cosmetic Act (FFDCA);[14]

(3) the Occupational Safety and Health Act (OSHA);[15]

(4) the Resource Conservation and Recovery Act (RCRA);[16]

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13. 42 U.S.C. §§ 4321-4370a (1982 & Supp. I 1983). *See also* McChesney & Adler, *supra* note 10, at 10,371-73. Note that NEPA has been the subject of biotechnology-related litigation, *see* Foundation on Economic Trends v. Heckler, 587 F. Supp. 753 (D.D.C. 1984), *aff'd*, 756 F.2d 143 (D.C. Cir. 1985) (preliminary injunction warranted to prevent deliberate release of genetically altered bacteria into environment in field test sponsored by National Institute of Health (NIH) because NIH, which had approval power over release, failed to compile environmental impact statement required by NEPA); *see also* Comment, *Regulating the Environmental Release of Genetically Engineered Organisms: Foundation on Economic Trends v. Heckler*, 12 Fla. St. U. L. Rev. 891 (1985); Note, *Foundation on Economic Trends v. Heckler: Genetic Engineering and NEPA's EIS Requirement*, 2 Pace Envtl. L. Rev. 138 (1984).

14. 21 U.S.C. §§ 301-392 (1982 & Supp. I 1983). FDA has promulgated its proposed biotechnology regulatory policy pursuant to FFDCA. *See* 49 Fed. Reg. at 50,878-80; *see also* Clausi, *Interfaces of the Food Industry with Biotechnology*, 40 Food Drug Cosm. L.J. 259 (1985); Korwek, *FDA Regulation of Biotechnology as a New Method of Manufacture*, 37 Food Drug Cosm. L.J. 289 (1982); Korwek & Trinker, *Perspectives on the FDA Status of Drug Products Manufactured by the Recombinant DNA Technique*, 36 Food Drug Cosm. L.J. 517 (1981); McGarity & Bayer, *supra* note 7, at 503-05; Comment, *Regulation of Genetically Engineered Foods Under the Federal Food, Drug, and Cosmetic Act*, 33 Am. U. L. Rev. 899 (1984).

15. 29 U.S.C. §§ 651-678 (1982). OSHA has announced its own guidelines pertaining to occupational safety and health as related to biotechnology. *See* 50 Fed. Reg. 14468 (April 12, 1985); *see also* Korwek, *OSHA Regulation of Industrial Applications of Recombinant DNA Technology*, 50 U. Cin. L. Rev. 284 (1981); McGarity & Bayer, *supra* note 7, at 503.

16. 42 U.S.C. §§ 6901-6987 (1982 & Supp. I 1983). RCRA has been identified by EPA as a potential source of authority for federal biotechnology regulation. *See* 49 Fed. Reg. at 50,867-68. RCRA is designed to regulate the generation, transport, treatment and disposal of hazardous waste. *See* 42 U.S.C. at § 6902(4). A RCRA hazardous waste must be a solid waste, *see id.* at § 6903(5), although RCRA defines solid waste very broadly. *See id.* at § 6903(27). Thus "[t]he solid wastes that genetic technology firms and laboratories generate, store, transport, treat, and dispose of could face stringent EPA regulation under . . . RCRA if the agency were to label them hazardous." McGarity & Bayer, *supra* note 7, at 535 (footnote omitted). No biotechnology wastes or living organisms are currently listed as RCRA hazardous wastes. *Cf.* 49 Fed.

(5) the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA);[17] and

(6) the Toxic Substances Control Act (TSCA).[18]

Reg. at 50,866. Nevertheless, it has been advocated that RCRA should be "considered by the food processing industry and the pharmaceutical industry that may produce living waste from the large scale containment methods." McChesney & Adler, *supra* note 10, at 10,369 n.37.

17. 7 U.S.C. §§ 136-136y (1982 & Supp. II 1984). FIFRA regulates pesticides by requiring pesticide manufacturers to register pesticides with EPA prior to sale or distribution. *See id.* at § 136a. Pesticides are defined by FIFRA as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and . . . any substance or mixture of substances intended for use as a plant regulator, defoliant, or dessicant." *Id.* at § 136u. EPA's position is that this statutory language is sufficiently broad on its face to include both naturally occurring and genetically engineered microorganisms which are employed as microbial pesticides. *See* 49 Fed. Reg. at 50,880-86.

EPA has already asserted its FIFRA jurisdiction over microorganisms used as microbial pesticides. Special data requirements necessary for pesticide registration of biochemical and microbial pesticides have been promulgated by EPA. *See* 40 C.F.R. § 158.65 (1985). The data requirements for microbial pesticides apply to both naturally occurring and genetically modified microorganisms. *Id.* at § 158.65(b)(1). EPA has also explicitly stated that "[n]ovel microbial pesticides (i.e., genetically modified or non-indigenous microbial pesticides) will be subject to additional data or information requirements on a case-by-case basis . . . ." *Id.* at § 158.165(b)(2).

Another example of EPA's assertion of FIFRA jurisdiction over potentially commercial biotechnology is in the area of field testing of pesticides. Pursuant to section 5 of FIFRA, a pesticide manufacturer may acquire an experimental use permit (EUP) to test the effectiveness of a pesticide prior to seeking final registration. *See* 7 U.S.C. at § 136c. EPA has not normally required an EUP for a small scale field test of a pesticide conducted prior to final registration. *See* 40 C.F.R. § 172.3 (1985). However, EPA has promulgated an interim policy statement singling out microbial pesticides "which contain naturally occurring microorganisms for use in environments where they are not native (nonindigenous or exotic) or microorganisms which have been genetically altered or manipulated by humans." Interim Policy Statement on Small Scale Field Tests for Microbial Pesticides, 49 Fed. Reg. 40,659, 40,660 (Oct. 17, 1984). EPA now requires notification prior to all small scale field tests involving such microbial pesticides to determine whether an EUP is required. *See id.; see also* 49 Fed. Reg. at 50885-86. Note that EPA has already granted two EUP's for small-scale field testing of two genetically engineered microbial pesticides. *See* Notice of Issuance of Experimental Use Permits, 50 Fed. Reg. 49,760-62 (Dec. 4, 1985). It thus seems clear that EPA intends to exercise its full FIFRA regulatory powers in the regulation of both naturally occurring and genetically engineered microorganisms used as microbial pesticides. This will have a significant impact on the manufacturers of such pesticides, as FIFRA "clearly provides a comprehensive scheme" for pesticide regulation. Karny, *supra* note 10, at 850.

18. 15 U.S.C. §§ 2601-2629 (1982 & Supp. II 1984). EPA has promulgated its proposed TSCA biotechnology regulatory policy. *See* 49 Fed. Reg. at 50,886-95.

All of the above statutes raise interesting issues concerning their applicability and suitability for biotechnology regulation. However, this comment is limited in scope to a discussion of TSCA as statutory authority for the federal regulation of biotechnology. It primarily explores the legal issues and arguments likely to be addressed if litigation is brought challenging TSCA regulation of biotechnology, and also briefly discusses the particular TSCA provisions which EPA has highlighted as being particularly applicable to biotechnology regulation.

II. Statutory Authority For TSCA Biotechnology Regulation

A. *Background*

TSCA was enacted by Congress in 1976 in response to a perceived need for comprehensive, federally imposed regulation of toxic chemicals.[19] TSCA empowers EPA to:

> (1) Acquire data regarding the effects of chemical substances and mixtures on health and the environment.[20]
>
> (2) Regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment.[21]
>
> (3) Take action with respect to chemical substances and mixtures which EPA finds to be imminent hazards.[22]

Only TSCA-defined chemical substances and mixtures are subject to TSCA regulation. A TSCA chemical substance is "any organic or inorganic substance of a particular molecu-

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19. Pub. L. No. 94-469, 90 Stat. 2003 (codified at 15 U.S.C. §§ 2601-2629 (1982 & Supp. II 1984)). Six years of legislative activity preceded TSCA's enactment. *See generally* R. Druley & G. Ordway, The Toxic Substances Control Act 10-27 (1977); *see also* Gaynor, *The Toxic Substances Control Act: A Regulatory Morass*, 30 Vand. L. Rev. 1149, 1149-51 (1977).

20. *See* 15 U.S.C. at § 2601(b)(1).

21. *See id.* at § 2601(b)(2).

22. *See id.*

lar identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature; and (ii) any element or uncombined radical."[23]

Specifically excluded from the definition of chemical substances are pesticides, tobacco, tobacco products, firearms, source materials, special nuclear materials, byproduct materials, foods, food additives, drugs, cosmetics, or devices.[24] Mixtures are also excluded from the statutory definition of chemical substances,[25] and are separately defined as "any combination of two or more chemical substances if the combination does *not* occur in nature and is *not,* in whole or in part, the result of a chemical reaction."[26] However, a combination of chemical substances occurring, in whole or in part, as a result of a chemical reaction *is* a mixture if:

> (1) none of the chemical substances comprising the combination is a new chemical substance;[27] and
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> (2) the combination could have been manufactured for commercial purposes without a chemical reaction at the time of the combination of the chemical substances.[28]

B. *Living Microorganisms as TSCA Chemical Substances*

As a threshold matter, EPA's authority to regulate either

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23. *Id.* at § 2602(2)(A). EPA has identically defined chemical substances in its chemical inventory reporting regulations, *see* Inventory Reporting Regulations, 40 C.F.R. § 710.2(h) (1985).

24. *See* 15 U.S.C. at § 2602(2)(B)(ii)-(vi). Pesticides are regulated by EPA pursuant to FIFRA. Tobacco, tobacco products, and firearms are regulated by the Dep't of Commerce's Bureau of Alcohol, Tobacco, and Firearms. Source materials, special nuclear materials, and byproduct materials are regulated by the Nuclear Regulatory Commission (NRC). Foods, food additives, drugs, cosmetics, and devices are regulated by FDA pursuant to FFDCA.

25. 15 U.S.C. at § 2602(2)(B)(i).

26. *Id.* at § 2602(8) (emphasis added).

27. TSCA section 8(b) required EPA to compile and publish an inventory list of all chemical substances manufactured or processed in the United States within 315 days of TSCA's enactment. *See id.* at § 2607(b). Any chemical substance not on the inventory list is deemed to be a new chemical substance. *Id.* at § 2602(9).

28. *Id.* at § 2602(8).

naturally occurring or genetically engineered microorganisms pursuant to TSCA depends upon whether such microorganisms fall within the TSCA definitions of mixtures or chemical substances. Because EPA's current position is that microorganisms and other life forms are not TSCA mixtures,[29] EPA's regulatory authority hinges entirely upon the position that products of commercial biotechnology, including both naturally occurring and genetically engineered living microorganisms, fall within the TSCA definition of chemical substances.

Although EPA at one time took the position that genetically engineered microorganisms were not within the ambit of TSCA's statutory definition of chemical substances,[30] EPA's

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29. EPA employs two arguments to support this position. First, by definition, no naturally occurring life form can be a TSCA mixture. *See id.* at § 2602(8). Second, although a combination of chemical substances occurring as a result of a chemical reaction may be classified as a mixture if all the chemical substances involved appear on the TSCA section 8(b) chemical inventory list and the combination could have been manufactured for commercial purposes without a chemical reaction, EPA does not believe that life forms fit within this aspect of the TSCA mixture definition because:

> [A]ll the chemical substances in any life form are not likely to be on the [section 8(b)] [i]nventory, and it certainly is *very* unlikely that one could produce a life form by combining the component chemical substances without using chemical reactions. Thus even an artificially produced life form cannot be a mixture.

House Subcomm. Report app. C, *supra* note 9, at 144 n.2 (emphasis in original); *cf.* 49 Fed. Reg. at 50886-96 (EPA makes no mention of regulation of biotechnology products as TSCA mixtures).

30. In December of 1977, then EPA Administrator Douglas M. Costle responded to a Senate inquiry concerning TSCA regulation of genetically engineered microorganisms by stating:

> [A]lthough there is a general consensus that recombinant DNA molecules are "chemical substances" within the meaning of section 3 of TSCA, it is not at all clear whether a host organism containing recombined DNA molecules fits- or was intended to fit that definition . . . . If such organisms are subject to TSCA on the grounds that they are a "combination of . . . substances occurring in whole or in part as a result of chemical reaction," the [a]gency might logically have to include all living things in the definition of "chemical substance" an interpretation which . . . Congress neither contemplated nor intended.

Letter from Douglas M. Costle, EPA Administrator to Adlai E. Stevenson, Chairman, Subcomm. on Science, Technology, and Space, U.S. Senate Comm. on Commerce, Science, and Transportation (Dec. 9, 1977), *reprinted in* House Subcomm. on Science, Technology, and Space, Oversight Report: Recombinant DNA Research and its

current position is that TSCA's definition of chemical substances encompasses both naturally occurring and genetically engineered living microorganisms, as well as the chemical products produced by such organisms.[31] However, the legal validity of this position is uncertain, and "it is not unlikely that EPA's authority may be challenged in court."[32] If EPA is forced to litigate its position that living products of biotechnological advances are subject to TSCA regulation, many statutory construction and policy arguments concerning TSCA will no doubt arise. The discussion below explores these arguments.

C. *Legal Arguments*

EPA's most fundamental argument in favor of its authority to review living organisms as TSCA chemical substances is that, based upon the plain meaning of TSCA's definition of chemical substances, "[a]ny DNA molecule, however created, is an organic substance of a particular molecular identity and is a combination of organic substances of particular molecular identities occurring in whole or in part as a result of a chemical reaction or occurring in nature," and thus is a TSCA-de-

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Applications, 95th Cong., 2d Sess. 88 (1978) (quoted in 1981 OTA Report, *supra* note 1, at 226).

However, only a few weeks after the above statement, EPA altered its position on the possible scope of TSCA's definition of chemical substances. In promulgating its final TSCA chemical inventory reporting regulations, EPA received a comment that "[c]ommercial biological preparations such as yeasts, bacteria and fungi should not be considered 'chemical substances' under TSCA." Inventory Reporting Regulations, 42 Fed. Reg. 64,572, 64,584 (Dec. 23, 1977) (codified at 40 C.F.R. §§ 710.1-.8 (1985)). EPA rebutted this comment by stating that the definition of chemical substance "does not exclude life forms which may be manufactured for commercial purposes and nothing in the legislative history [of TSCA] would suggest otherwise." 42 Fed. Reg. at 64585. EPA has thereafter consistently maintained that it has the authority to regulate living organisms as TSCA chemical substances. *See* 49 Fed. Reg. at 50,886-96.

31. *See id.* at 50,886-87.

32. House Subcomm. Report, *supra* note 9, at 50. Several other commentators have also noted the likelihood of litigation over EPA's expansive view of the TSCA definition of chemical substances. *See, e.g.*, 1984 OTA Report, *supra* note 1, at 372; Karny, *supra* note 10, at 848; McChesney & Adler, *supra* note 10, at 10373; McGarity & Bayer, *supra* note 7, at 505-06.

fined chemical substance.[33] In addition, EPA has asserted that life forms such as microorganisms are themselves TSCA chemical substances because they are combinations of DNA molecules and other TSCA chemical substances.[34]

EPA's position represents a somewhat expansive construction of TSCA's statutory language. As EPA itself has acknowledged:

> TSCA coverage extends to chemical substances and mixtures used in a wide range of general, industrial, commercial, and consumer applications. In the context of biotechnology, products partially subject to review under TSCA include microorganisms in certain physically contained uses (such as the production of pesticides and other commercial chemicals and the conversion of biomass for energy) and in certain uses involving direct release to the environment (e.g., pollutant degradation, enhanced oil recovery, metal extraction and concentration, and certain non-food agricultural applications, such as nitrogen fixation).[35]

A fundamental dilemma presented by either the DNA molecule or life form view of TSCA-defined chemical substances is that, in the extreme, both approaches lead inevitably to the conclusion that plants and animals (including human beings, which are life forms teeming with DNA molecules) fall within TSCA's regulatory scope.[36]

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33. House Subcomm. Report app. C, *supra* note 9, at 143; *see also* 49 Fed. Reg. at 50,886.

34. *See* House Subcomm. Report app. C, *supra* note 9, at 144; *see also* 49 Fed. Reg. at 50,886.

35. 49 Fed. Reg. at 50,887. Note that in implementing TSCA, EPA has chosen in the past to cover pesticide intermediates, but not food, food additive, drug, or cosmetic intermediates under TSCA. EPA explicitly set forth this policy when enunciating its TSCA inventory reporting rules, *see* 42 Fed. Reg. at 64,586, and intends to maintain the same policy for biotechnology products. "Consistent with this policy, microorganisms used to produce pesticides would fall under TSCA jurisdiction, while the pesticide itself would fall under FIFRA." 49 Fed. Reg. at 50,887.

36. As one commentator has warned:

> A court that faces the *reductio ad absurdum* argument that . . . TSCA is a substitute for Title 18 of the United States Code because we are all the slaves of our DNA well might refuse to allow EPA to extend its authority over toxic

However, it seems unlikely that any court would find that plants and animals fall within the ambit of TSCA regulation. First, TSCA's legislative intent and regulatory structure nowhere suggest that TSCA regulation be extended to higher life forms such as plants and animals. Second, EPA has observed that "a DNA molecule *per se* does not have any use aside from the life form of which it is a part."[37] This observation leaves EPA free to "craft an argument that chemical substances which have a use only as part of the life form are not subject to TSCA jurisdiction."[38] The practical result of the above statements is a justification for EPA exclusion of a particular life form and its component DNA from TSCA regulation. Consequently, EPA has explicitly stated that it generally does not intend to regulate plants and animals as TSCA chemical substances.[39] Although this approach does not totally resolve the logical inconsistencies in applying the term chemical substances to some life forms but not others, decisions of this type are probably sufficiently justifiable under the traditional notions of agency policymaking powers, due deference to agency discretion, and the legislative intent underlying TSCA.[40]

EPA may also draw support by analogy for its position that life forms are chemical substances from two recent cases dealing with the patentability of living organisms under U.S. patent law. In *In re Bergy*,[41] the Court of Customs and Patent Appeals held that genetically engineered living microorganisms are patentable subject matter under U.S. patent law.[42] In

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substances to control over organisms that produce toxic substances. McGarity & Bayer, *supra* note 7, at 538 n.341.

37. House Subcomm. Report app. C, *supra* note 9, at 145 n.4.

38. *Id.*

39. *See* 49 Fed. Reg. at 50,887. EPA has set forth a twofold rationale for this approach. First, "[m]ost genetically engineered plants and animals will be used for food or food-related purposes, which are excluded from TSCA." *Id.; see also* 15 U.S.C. at § 2602(2)(B)(vi). Second, although it is likely that plants and animals will in the future be genetically engineered for non-food uses, "major [f]ederal expertise on plants and animals lies in USDA and DOI," not EPA. 49 Fed. Reg. at 50,887.

40. *See infra* notes 49-52 and accompanying text.

41. 596 F.2d 952 (C.C.P.A. 1979).

42. Patentable subject matter is defined by 35 U.S.C. § 101 (1982).

reaching this conclusion, the court observed that the intrinsic nature and potential uses of both naturally occurring and genetically engineered microorganisms "are analogous in practical use to inanimate chemical compositions such as reactants, reagents, and catalysts used in the chemical industry."[43] The court therefore concluded that "no *legally* significant difference [exists] between active chemicals which are classified as 'dead' and organisms used for their *chemical* reactions which take place because they are 'alive.' Life is largely chemistry."[44]

Bergy was affirmed by the landmark United States Supreme Court decision *Diamond v. Chakrabarty*.[45] However, it must be noted that the Court's decision in *Chakrabarty* was limited to the organism at issue in the case: namely, a "human-made, genetically engineered bacterium . . . capable of breaking down multiple components of crude oil" believed useful in the treatment of oil spills.[46] The Court specifically noted that the organism involved was "a new bacterium with markedly different characterisitics from any found in nature . . . ."[47] Thus, if EPA relies on *Chakrabarty* for analogous support of regulation of microorganisms as TSCA chemical substances, it could face the danger of limiting itself to TSCA regulation of only genetically engineered microorganisms. Nevertheless, EPA has stated that it believes its TSCA authority extends over both indigenous and nonindigenous (exotic) naturally occurring microorganisms as well as genetically engineered microorganisms.[48]

EPA also has several persuasive arguments for viewing microorganisms as TSCA chemical substances based upon TSCA's legislative history. First, TSCA was intended to be gap-filling legislation,[49] and "invoking TSCA jurisdiction over

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43. *Bergy*, 596 F.2d at 975.

44. *Id.* (emphasis in original).

45. 447 U.S. 303 (1980).

46. *Id.* at 305 & n.2.

47. *Id.* at 310.

48. 49 Fed. Reg. at 50,881. A nonindigenous or exotic microorganism is one placed in an environment where it is not native. *Id.* at 50,906.

49. *See* S. Rep. No. 698, 94th Cong., 2d Sess. 5, *reprinted in* 1976 U.S. Code Cong. & Ad. News 4491, 4495.

life forms would be consistent with the gap-filling function."[50] Second, TSCA's legislative history shows that Congress recognized that "basically everything in our environment is composed of chemical substances and therefore the definition of 'chemical substances' is necessarily somewhat broad."[51] Finally, a review of the legislative history shows that the Senate version of TSCA did not initially include naturally occurring substances within the definition of chemical substances. The House amended the bill to include naturally occurring substances, and this amended definition was eventually adopted.[52] It can thus be argued that TSCA's express statutory language and Congress's legislative intent both clearly support the view that TSCA's scope is not limited to synthetic or engineered chemical substances, but includes naturally occurring and genetically engineered microorganisms as well.

The above-mentioned arguments favoring EPA's position should not be taken as foreclosing any possible counterarguments. EPA has recognized the major counterarguments to its position, although it feels these counterarguments "require arguing against the plain statutory language."[53] The principal argument against EPA's inclusion of life forms within the TSCA definition of chemical substances goes as follows:

> [T]here is no legislative history that Congress contemplated TSCA regulation of life forms. The legislative history references numerous examples of problems which the statute was intended to address; life forms are not among them. Indeed, at the time Congress considered and passed TSCA, recombinant DNA research was in its infancy, and seemed to have applications only in the pharmaceutical area.[54]

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50. House Subcomm. Report, *supra* note 9, at 144; *see also* 49 Fed. Reg. at 50887.

51. H.R. Rep. No. 1341, 94th Cong., 2d Sess. (1976), *reprinted in* R. Druley & G. Ordway, *supra* note 19, at 174, 182.

52. *See* H.R. Rep. No. 1679, 94th Cong., 2d Sess. 56, *reprinted in* 1976 U.S. Code Cong. & Ad. News 4539, 4541-42.

53. House Subcomm. Report app. C, *supra* note 9, at 144.

54. *Id.* at 144-45.

Several policy arguments can also be made in opposition to EPA's position that life forms are within the TSCA definition of chemical substances. For example, EPA has little expertise or experience in biotechnology.[55] Furthermore, EPA has been slow to implement its toxic substances program due to understaffing and other considerations.[56] Finally, the existing TSCA regulatory structure may not be workable for the regulation of microorganisms and other life forms. EPA has recognized this potential problem:

> Although it appears that living organisms are chemical substances under TSCA, it is somewhat novel to interpret TSCA for such substances, because it has always been interpreted in the context of non-living matter. Terms such as manufacture, process, chemical identity, molecular structure and exposure take on unique meanings when applied to living organisms.[57]

Although the above counterarguments are initially persuasive, they contains several inherent weaknesses. First, TSCA is a remedial statute designed to protect public health and welfare as well as the environment, and thus "should be given a construction consistent with its objectives."[58] Second, the statutory definition of chemical substances appears on its face to include living organisms, and "if Congress has made a choice of language which fairly brings a given situation within a statute, it is unimportant that the particular application may not have been contemplated by the legislators."[59] Third, although "[i]t is likely that in 1976 Congress never considered

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55. House Subcomm. Report app. B, *supra* note 9, at 138.

56. *See* 1984 OTA Report, *supra* note 1, at 372.

57. House Subcomm. Report app. B, *supra* note 9, at 126.

58. School Dist. of Allentown v. Marshall, 657 F.2d 16, 19 (3d Cir. 1981). A remedial statute should be liberally construed to effectuate the remedial purpose for which it was enacted. 3 Sutherland, Statutory Construction § 60.01 at 29 (C. Sands rev. 4th ed. 1974). "What is called a liberal construction is ordinarily one which makes the statutory rule or principle apply to more things or in more situations than would be the case under a strict construction." *Id.*

59. *Bergy*, 596 F.2d at 973 (quoting Barr v. United States, 324 U.S. 83, 90 (1945)) (other citations omitted).

the nascent biotechnology industry,"[60] it seems presumptuous to assume that, at the time of TSCA's enactment, Congress was totally unaware of the potential environmental implications of the emerging area of biotechnology. The scientific, social, and ethical implications of recombinant DNA research were being openly debated during the mid-1970's. In fact, the debates over the potential widespread hazards of such biotechnological research led directly to the promulgation of the original NIH guidelines for recombinant DNA research; these guidelines were published three months before TSCA was enacted into law.[61] Finally, EPA is rapidly acquiring expertise in biotechnology via its FIFRA regulatory programs.[62]

D. *TSCA's Impact on Commercial Biotechnology*

TSCA's regulatory mechanism will clearly have a direct impact on commercial biotechnology. For example, EPA has already set forth in great detail the applicability of TSCA's section 5(a)[63] premanufacturing notification (PMN) provisions to commercial biotechnology.[64] In addition, EPA has specifically noted that the recordkeeping requirements of section 8(c),[65] the notification provisions of section 8(e),[66] and the im-

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60. McChesney & Adler, *supra* note 10, at 10374.

61. *See* Guidelines for Research Involving Recombinant DNA Molecules, 41 Fed. Reg. 27,902, 27,911-922 (July 7, 1976).

62. *See supra* note 17.

63. 15 U.S.C. at § 2604(a).

64. *See* 49 Fed. Reg. at 50,887-93. Note that the PMN provisions apply only to "new chemical substances" (defined as substances not included on the TSCA Chemical Inventory list, *see* 15 U.S.C. at § 2602(9)) and to chemical substances employed for a "significant new use"(to be determined by EPA rulemaking after "a consideration of all relevant factors," *id.* at § 2604(a)(2)). "Naturally occurring substances" are not subject to the PMN requirements, and EPA has proposed "to determine whether a commercial organism is new or naturally occurring on the basis of the techniques used to produce it." 49 Fed. Reg. at 50,888-89.

65. 15 U.S.C. at § 2607(c). Section 8(c) requires that manufacturers, processors, and distributors of chemical substances and mixtures keep records of "significant adverse reactions to health or the environment . . . alleged to have been caused by the substance or mixture." *Id.*

66. *Id.* at § 2607(e). Section 8(e) requires manufacturers, processors, and distributors of chemical substances and mixtures to immediately notify EPA of information "which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment."

portation provisions of section 13(a)[67] are all likely to affect the biotechnology industry.[68]

Other TSCA provisions not specifically highlighted by EPA may also play a role in commercial biotechnology regulation. For example, section 6[69] provides EPA with broad regulatory powers which it may implement upon a finding that the manufacture, processing, distribution, use, or disposal of a chemical substance or mixture "presents or will present" an unreasonable risk of injury to health or the environment."[70] Note that the scope of these regulatory powers is vast: it includes the power to prohibit or limit the manufacture, processing, or distribution of such chemical substances and mixtures, and the power to compel submission or revision of quality control procedures used in the manufacturing or processing of the chemical substance or mixture at issue.[71] However, most of the section 6 provisions are unlikely to be immediately applicable to commercial biotechnology, as "the scientific evidence probably does not support a finding that most genetically engineered molecules or organisms present an unreasonable risk."[72]

Upon a finding by EPA that a chemical substance or mixture is an imminent hazard,[73] EPA may commence a civil action in federal district court pursuant to section 7 to seize the chemical substance or mixture at issue, or for such other relief as may be necessary to protect health or the environment.[74]

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67. *Id.* at § 2612(a). Section 13(a) requires that for any chemical substance or mixture to be allowed entry into the United States, it must comply with all TSCA statutory and regulatory requirements. *Id.* Note that the United States Customs Service has issued a rule requiring importers of chemical substances to certify at the port of entry that either the substances contained in the shipment are subject to TSCA and comply with all applicable TSCA rules and orders, or that the substances at issue are not subject to TSCA. *See* 40 C.F.R. § 707.20 (1985).

68. 49 Fed. Reg. at 50,893.

69. 15 U.S.C. at § 2605.

70. *Id.* at § 2605(a).

71. *Id.* at § 2605(b).

72. Karny, *supra* note 10, at 849.

73. An imminently hazardous chemical substance or mixture is one which "presents an imminent and unreasonable risk of serious or widespread injury to health or the environment." 15 U.S.C. at § 2606(f).

74. *See id.*

This provision would be useful in an emergency situation involving either a naturally occurring or genetically engineered microorganism. However, absent such extraordinary circumstances, it is unlikely to play a major role in biotechnology regulation.

III. Conclusion

It is likely that EPA's stated position that both naturally occurring and genetically engineered microorganisms are subject to regulation as TSCA chemical substances will be upheld if challenged in court. TSCA's broad statutory language defining chemical substances seems clearly inclusive of both naturally occurring and genetically engineered microorganisms. In addition, the legislative history and gap-filling nature of TSCA favor a broad construction of its statutory language. Finally, "the tendency of the courts [is] to construe the environmental statutes broadly in order to achieve their remedial purposes. . . ."[75] Any inherent conflicts resulting from such a broad construction are likely to be left to EPA's discretion and expertise to sort out and align.

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75. McChesney & Adler, *supra* note 7, at 10374.