Notes

The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty

Ruth E. Harlow

At the 1973 Gordon Conference on Nucleic Acids, Herbert Boyer revealed that he and another scientist, Stanley Cohen, had developed a simple technique for splicing genetic material from two different organisms and reinserting the laboratory-made combination of genes into a bacterium.[1] The Boyer-Cohen discovery triggered experiments with the reprogramming of natural organisms in laboratories worldwide.[2] In the decade following this genetic engineering breakthrough, commercial biotechnology emerged as an industry promising economic well-being and other great benefits for the United States.[3] Yet the risks presented by commercial biotechnology initially received little attention.[4]

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1. S. KRIMSKY, GENETIC ALCHEMY 13, 72–73, 339 (1982).

2. The Boyer-Cohen technique transformed genetic engineering, previously accessible to only a few leaders in the field, into a "working tool for molecular biologists." *Id.* at 339. *See* Monmaney, *Yeast At Work*, SCI. 85, July-Aug. 1985, at 30, 33 (after Boyer-Cohen discovery, scientists free to "look for genes in diverse species in the manner of mechanics prowling for spare parts in a junkyard"). "Genetic engineering" describes the deliberate alteration of an organism's basic genetic material, deoxyribonucleic acid (DNA). Joining genes from different organisms results in recombinant DNA or "rDNA;" combining genes, such as with the Boyer-Cohen technique, is one of several basic genetic engineering methods. *See generally* Hopwood, *The Genetic Programming of Industrial Microorganisms*, SCI. AM., Sept. 1981, at 91 (discussing various genetic engineering techniques); OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 4–5, 33–43 (1984) [hereinafter cited as OTA 1984 ANALYSIS] (same).

3. The rapid growth since the mid-1970's of commercial biotechnology—the use of genetic engineering techniques for commercial purposes—has been called a "revolution in applied biology." Abelson, *Biotechnology: An Overview*, 219 SCI. 611, 611 (1983). By 1983, private U.S. investment in the development of commercial biotechnology applications exceeded one billion dollars per year. OTA 1984 ANALYSIS, *supra* note 2, at 3. Exemplifying the great hopes surrounding biotechnology's development, the Office of Technology Assessment predicted in January, 1984, that "[b]iotechnology has the technical breadth and depth to change the industrial community of the 21st century . . . . By virtue of its wide-reaching potential applications, biotechnology lies close to the center of many of the world's major problems—malnutrition, disease, energy availability and cost, and pollution." *Id.* at 65.

4. After the Boyer-Cohen discovery allowed widespread genetic engineering research, the risks associated with *research* became the focus of significant attention by scientists and the public. Concern

Industry researchers may soon release genetically altered microorganisms into the environment to test their ability to perform such tasks as cleaning up an oil spill or protecting crops from frost.[5] Though commercial biotechnology offers benefits like those associated with the computer chip and antibiotics,[6] release biotechnology[7] threatens human health and the natural environment with risks experts now view as comparable to the dangers of nuclear power and toxic chemicals.[8] Individual release risks

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about research risks resulted, for example, in the 1976 publication of "Recombinant DNA Research Guidelines" by the National Institutes of Health (NIH), 41 Fed. Reg. 27,902 (1976). *See generally infra* note 10 (discussing NIH regulation of genetic engineering). The development of commercial applications, however, has until now progressed with little investigation into the risks associated with *commercial use. See* S. KRIMSKY, *supra* note 1, at 285, 287 (after furor over genetic engineering research died down, hazards received little attention; "attention was almost exclusively directed toward commercial breakthroughs, patenting, and sources of capital for research and development").

5. *See* Demain & Solomon, *Industrial Microbiology*, SCI. AM., Sept. 1981, at 67, 74 (genetic engineering has given one microorganism capacity to degrade all components of oil); Kriz, *Growing Biotechnology Industry Sparks Governmental Turf Battle Over Federal Regulation of Potential Health and Environmental Risks*, 8 CHEM. REG. REP. (BNA) 393, 394 (July 6, 1984) (discussing planned release of microorganism designed to lower freezing temperature of plants).

On November 14, 1985, the federal government approved a test release by a California firm of genetically engineered organisms created to protect against frost damage. N.Y. Times, Nov. 15, 1985, at A17, col. 1. The test was scheduled for late December, 1985, or January, 1986. *Id.* Whether the test will actually take place remains uncertain; a suit has been filed to block the experiment because of inadequate risk investigation. *Id.* Government approval came under an interim policy for the regulation of genetically engineered pesticides. *See EPA Grants Permit for Deliberate Release; Rifkin to File Suit to Block Test*, 9 CHEM. REG. REP. (BNA) 955, 955 (Nov. 15, 1985). This interim policy is part of the limited federal regulation taking place pending implementation of a comprehensive biotechnology regulatory plan. *See infra* note 10 (academic research and genetically altered pesticides now regulated; all commercial releases to be scrutinized under Reagan Administration Plan).

6. *See* Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856, 50,856 (1984) (genetic engineering techniques "offer exciting advances, as remarkable as the discovery of antibiotics or the computer chip"); OTA 1984 ANALYSIS, *supra* note 2, at 531 (parallel drawn between semiconductor industry and commercial development of biotechnology); S. KRIMSKY, *supra* note 1, at 287 (vast range of anticipated benefits "limited only by the imagination of the scientists").

7. "Release biotechnology" refers to one aspect of the industry. Commercial biotechnology employs genetic engineering techniques in two ways: (1) the technology may produce familiar substances (e.g., insulin) by means of genetically engineered organisms confined within a laboratory or production facility, or (2) the technology may produce new types of microorganisms, plants, or animals for use in the environment. The first type of biotechnology presents risks of accidental organism release and of injuries to workers' health. If companies follow relatively simple biological and physical containment procedures, however, this type of biotechnology poses little actual risk to health or the environment. *See The Potential Environmental Consequences of Genetic Engineering: Hearings Before the Subcomm. on Toxic Substances and Environmental Oversight of the Senate Comm. on Environment and Public Works*, 98th Cong., 2d Sess. 114 (1984) [hereinafter cited as *Potential Environmental Consequences*] (statement of Thomas McGarity, Professor of Law, Univ. of Texas). Release biotechnology, the second type, poses the larger regulatory problem and is the focus of most current concern about commercial biotechnology. *See* McChesney & Adler, *Biotechnology Released From the Lab: The Environmental Regulatory Framework*, 13 ENVTL. L. REP. (ENVTL. L. INST.) 10,366, 10,367 (Nov. 1983). This Note focuses on the regulatory problem associated with commercial release biotechnology.

8. *See Potential Environmental Consequences*, *supra* note 7, at 116 (statement of Thomas McGarity) (after comparing release biotechnology development to nuclear power development and recalling Three Mile Island accident, warns against late realization of release biotechnology dangers); McChesney & Adler, *supra* note 7, at 10,367 ("current crisis over hazardous byproducts of the postwar chemical revolution counsels a cautious approach" to release biotechnology). Commercial release

still have not been carefully evaluated; commercial biotechnology development continues to outpace risk investigation.[9]

The Office of Science and Technology Policy, piecing together existing federal regulatory powers, has devised an intricate but inadequate plan for screening genetically engineered organisms before their commercial release into the environment.[10] According to the plan, soon to be implemented, the Environmental Protection Agency (EPA) will employ the Toxic Substances Control Act (TSCA)[11] to regulate all commercial release biotechnology not covered by narrower statutes.[12] This Note analyzes the regulatory problem presented by release biotechnology and proposes amendments to TSCA that will enable EPA to function effectively in its central new regulatory role. The Note argues that EPA should now have the obligation under TSCA to engage in intensive, case-by-case scrutiny of release proposals. During these in-depth evaluations, EPA should

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biotechnology, like the nuclear power and chemical industries, creates risks involving a low probability of a high consequence disaster occurring. *See infra* note 29 and accompanying text.

9. *See infra* notes 27–28 and accompanying text.

10. *See* Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984) [hereinafter cited as Reagan Administration Plan]. This plan represents the government's first step toward prerelease screening of all commercial biotechnologies. Since October 17, 1984, federal regulations, using the regulatory power of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136y (1982), have required prior Environmental Protection Agency approval of field tests using genetically engineered pesticides. *See* Microbial Pesticides; Interim Policy on Small Scale Field Testing, 49 Fed. Reg. 40,659 (1984). The NIH Guidelines, while focusing on laboratory research hazards, require prior NIH approval of academic releases to be conducted by researchers receiving government funding. *See* Guidelines for Research Involving Recombinant DNA Molecules, 49 Fed. Reg. 46,266, 46,267–68 (1984). Under the government's 1984 comprehensive regulatory plan, NIH will continue to screen academic release proposals. *See* Reagan Administration Plan, *supra*, at 50,905. No release experiment, academic or commercial, has yet taken place. *See EPA Advisors Cite Lack of Science, Containment Controls in rDNA Regulation*, 8 CHEM. REG. REP. (BNA) 1444, 1444 (Mar. 15, 1985); *see also* N.Y. Times, *supra* note 5 (experiment approved in Nov., 1985, will be first deliberate release if it occurs).

For information about the NIH system, which since 1980 has been available for the screening of commercial release proposals on a voluntary basis, see McChesney & Adler, *supra* note 7; McGarity & Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461 (1983); Karny, *Regulation of Genetic Engineering: Less Concern About Frankensteins But Time For Action on Commercial Production*, 12 U. TOL. L. REV. 815 (1981). For a discussion of the litigation surrounding NIH's approval of an academic release proposal, see Pendorf, *Regulating the Environmental Release of Genetically Engineered Organisms:* Foundation on Economic Trends v. Heckler, 12 FLA. ST. U.L. REV. 891 (1985).

11. 15 U.S.C. §§ 2601–2629 (1982) (originally enacted as Pub. L. No. 94-469, 90 Stat. 2003 (1976)).

12. *See* Reagan Administration Plan, *supra* note 10, at 50,881. Unless congressional action or a lawsuit blocks implementation of the proposed regulatory framework, EPA will begin oversight using TSCA in early 1986. The target date for publication in the Federal Register of the final, binding regulatory statement is January 31, 1986. *See* Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,174 (1985) [hereinafter cited as Plan Update]. Although this Note discusses decisionmaking under TSCA, the general contours of the quasi-adversarial decisionmaking process advocated here are more generally applicable to all government attempts to screen release biotechnology organisms, including EPA's screening of pesticides under FIFRA. For the details of the executive branch plan concerning genetically engineered pesticides, see Reagan Administration Plan, *supra* note 10, at 50,880–86.

use a quasi-adversarial decisionmaking process, a process that accommodates the extreme scientific uncertainty surrounding the regulatory decisions.[13] As knowledge about release biotechnology increases, however, such careful scrutiny may become unnecessary; thus, TSCA amendments should provide for future agency action to allow expedited review of certain genetically engineered products. Modifications in EPA's statutory mandate will enable the agency to cope with its complex regulatory task and will prevent the taking of risks that a well-informed political process finds unacceptable.

I. The Risks of Commercial Biotechnology

A. *Characteristics of the Biotechnology Industry*

Approximately 200 companies are now engaged in biotechnology research and development.[14] The businesses pursuing biotechnology applications most vigorously are involved in the pharmaceuticals industry, animal and plant agriculture, food additives, commodity and specialty chemicals, the energy industry, environmental protection, and electronics.[15] Economic analysts predict that genetic engineering will eventually have an impact on 70 percent of American industry.[16]

Crucial to continuing biotechnology innovation and development are the 150 small firms, many of them new, that are attempting to capitalize on the power of genetic engineering.[17] The small companies have invested heavily in research and feel pressure to recover their investments.[18] Several of these businesses, quickly established following the discovery of simple genetic engineering techniques, have gone bankrupt; others undoubt-

13. For a discussion of what "quasi-adversarial decisionmaking" entails, see *infra* text accompanying notes 89–102.

14. *See* OTA 1984 Analysis, *supra* note 2, at 66.

15. *See id.* at 66–71. Release biotechnology products currently being developed include microorganisms that will degrade environmental pollutants or extract metals from ore, McChesney & Adler, *supra* note 7, at 10,366, as well as organisms that will enhance the supply of nitrogen to plants, Demain & Solomon, *supra* note 5, at 74, or will enable plants to better fight root-eating bugs, Large, *Attempts to Regulate Gene Splicing Proceed in Surprising Harmony Between U.S., Industry*, Wall St. J., Jan. 9, 1985, at 50, col. 1.

16. Kriz, *supra* note 5, at 393.

17. *See* Abelson, *New Biotechnology Companies*, 219 Sci. 609, 609 (1983) (small firms are "[k]ey ingredients in the dynamism of applied biology"). Small companies are crucial because they are the primary source of genetic engineering innovations. *See* Kriz, *supra* note 5, at 399 (according to Office of Management and Budget report, "[i]nnovation, particularly at small firms, is not merely important in this industry—it *is* the industry") (emphasis in original).

18. For example, Genentech, Inc., one of the first U.S. biotechnology firms, spent $35 million in research and development and $20 million for facilities during its first six years of existence without selling a single ounce of product. *Productivity in the American Economy: Hearings Before the Task Force on Economic Policy and Productivity of the House Comm. on the Budget*, 97th Cong., 2d Sess. 85 (1982) (statement of Robert Swanson, President, Genentech, Inc.).

edly will also fail.[19] Such an uncertain, competitive situation may result in the cutting of risk assessment corners, unless the government ensures that adequate risk evaluations occur before the commercial release of genetically engineered organisms.[20]

While new, small biotechnology firms are assuming most of the economic risk during the technology's commercial development, well-established American companies are also making considerable investments in the development effort. The older companies, through equity investments, license agreements, and research contracts, are providing many new genetic engineering firms with the money to remain solvent until sales commence.[21] This combination of established and new firms working together to commercialize genetic engineering has made the United States the world leader in biotechnology.[22] Fear of losing this preeminent position must not blind the industry and the regulators to release biotechnology's risks as commercial development continues.[23]

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19. Abelson, *supra* note 17, at 609. *See also* OTA 1984 ANALYSIS, *supra* note 2, at 97 (within next several years, biotechnology industry will witness "intensified competition that forces some firms out and creates new opportunities for more entrants"); McGarity & Bayer, *supra* note 10, at 465 n.19 (two biotechnology firms shut down and filed for Chapter 11 reorganization in 1982).

20. Don R. Clay, then EPA's Acting Assistant Administrator for Pesticides and Toxic Substances, has told Congress:

> In the long run . . . the intensely competitive nature of the biotechnology industry will presumably create strong incentives for companies to reduce their costs, including those associated with developing strong safety programs. . . . [W]e cannot reasonably expect that economically vulnerable companies will voluntarily place safety as a high priority when their economic success may be at stake.

Environmental Implications of Genetic Engineering: Hearing Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology, 98th Cong., 1st Sess. 252 (1983) [hereinafter cited as *Environmental Implications Hearing*]. *See* Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403, 1411 (1983) (industry's claim that it has too much to lose to take chances in exploiting biotechnology "may have some validity for the giant pharmaceutical companies, but less for the newer firms created to capitalize on the new technology").

21. *See* OTA 1984 ANALYSIS, *supra* note 2, at 11. The established companies also are entering into joint ventures with new biotechnology firms and, to a lesser extent, are investing in their own research and development. *See id.*

22. *See* Reagan Administration Plan, *supra* note 10, at 50,856; *see also* OTA 1984 ANALYSIS, *supra* note 2, at 11 (discussing importance of established and new firms in commercializing biotechnology).

23. The desire to create a stable situation for U.S. biotechnology development, rather than a desire for actual regulation of risks, may explain current moves to erect a regulatory structure. The plan may arise from the belief that U.S. companies can best compete with foreign producers if a lax regulatory scheme allays public fears, but burdens the companies with few restrictions. Presidential science advisor George Keyworth has said that the prospect of losing out to foreign competitors made the industry and the government sit down to agree upon a regulatory plan. Large, *supra* note 15. The plan has received support from industry representatives and criticism from environmentalists. *Regulatory Plan Draws Cautious Support From Industry; Environmentalists Concerned*, 8 CHEM. REG. REP. (BNA) 1228, 1228 (Jan. 11, 1985). Representative James J. Florio (D-NJ) has called the regulatory scheme "window dressing," a "scenario for pretended government regulation." *Florio to Offer Legislation; Conference Marked By Disagreement on Regulatory Scheme*, 8 CHEM. REG. REP. (BNA) 1259, 1260 (Jan. 18, 1985). While acknowledging safety concerns, the plan itself emphasizes that "[t]he tremendous potential of biotechnology to contribute to the nation's economy . . . makes it

B. *The Nature of Release Risks*

Release biotechnology organisms must survive in the environment to perform their work. The genetically altered organisms may be inherently toxic or infective to natural organisms, including humans, with which they come into contact upon release.[24] Because these genetically engineered products can feed, reproduce, mutate, and evolve, they may also produce significant secondary effects in the environment.[25] Experience with transplanting natural species to new environments establishes that releasing genetically engineered organisms into the environment will create ecological and health risks.[26] Risks clearly exist, but because no deliberate release of a genetically altered organism has occurred and scientists have made little progress in estimating release consequences,[27] experts can today describe the risks only in vague and general terms. This scant knowledge concern-

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imperative that progress in biotechnology be encouraged." Reagan Administration Plan, *supra* note 10, at 50,856. *See* Pendorf, *supra* note 10, at 921 (Reagan Administration reluctant to impose regulations that may compromise U.S. lead in field).

24. *See* STAFF OF SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT, HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 98TH CONG., 2D SESS., THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING 16 (Comm. Print 1984) [hereinafter cited as ENVIRONMENTAL IMPLICATIONS REPORT] (three categories of potential release biotechnology dangers are: "(1) ecological disruption due to lack of natural enemies; (2) infectivity, pathogenicity, or toxicity to nontarget organisms . . . ; and (3) exchange of genetic material with other organisms . . . .").

25. For example, after successfully consuming an oil spill, an oil-eating microorganism could persist and feed on naturally occurring hydrocarbons. The flourishing organism could deprive a water ecosystem of oxygen and other nutrients on which naturally occurring species depend, thus establishing a niche for itself to the detriment of insect, plant, or animal life in the area. McChesney & Adler, *supra* note 7, at 10,368. Similarly, a microorganism created to lower the freezing temperature of plants could be carried by the wind from a field into the upper atmosphere and change global weather patterns. *Id.*

26. House sparrows, for example, first came to the United States from England as pets. The species is now one of North America's most damaging agricultural pests. Wines, *Genetic Engineering—Who'll Regulate the Rapidly Growing Private Sector?*, 1983 NAT'L J. 2096, 2098. The catastrophic impact of smallpox virus on the defenseless bloodstreams of 18th-century American Indians also suggests that release biotechnology will present significant risks. *See* Large, *supra* note 15.

27. The lack of progress in accurately assessing biotechnology risks stems from the difficulty of the task and from excitement about biotechnology's benefits, which directs attention away from risks. *See Potential Environmental Consequences*, *supra* note 7, at 20–23 (statement of Dr. Martin Alexander, Dept. of Agronomy, Cornell Univ.) (discussing need for clear distinction between concrete knowledge about benefits, put before society by proponents of release biotechnology, and troublesome lack of information about release risks); *id.* at 148–49 (statement of Jack Doyle, Dir., Agricultural Resources Project, Environmental Policy Inst.) (great pressure for swift federal approval of products, for continued U.S. supremacy in world market, but little debate about technology's possible harmful consequences).

The development of risk assessment procedures is a difficult task because of the complexity of predicting how a new organism will interact with all aspects of a natural environment. The task, however, is not an impossible one. *See* ENVIRONMENTAL IMPLICATIONS REPORT, *supra* note 24, at 10 ("testimony indicated that it would be possible to devise procedures to produce generalized estimates of the probability of environmental damage by, and survival and growth of, a genetically engineered organism"); *Assessment of rDNA Microbe Survivability May Be Possible With Microcosm Ecosystem Test*, 8 CHEM. REG. REP. (BNA) 978, 978 (Nov. 23, 1984) (microcosm test being developed to assess impacts on aquatic settings may provide first reliable method of determining genetically engineered organism's impact before release).

ing risks is a central feature of the regulatory problem; it stands in stark contrast to the quite visible benefits possible from release biotechnology products.[28]

Most experts agree that the probability of harm resulting from the release of a genetically altered organism is low, but they also agree that harm, if it occurs, could be substantial.[29] The harm may be catastrophic because the organisms may infect, poison, or displace natural species; in addition, the genetically engineered organisms can proliferate in a suitable niche, thus producing a large impact on the ecosystem even if only a few organisms are released.[30] Once a problem arises, locating and killing flourishing new organisms may be impossible.[31]

The nature of this risk associated with release biotechnology—low probability of high consequence disaster—points to the need for prerelease screening. The release products that seem likely to bring about catastrophe should be distinguished from safer release biotechnologies, because prevention of their risk, where it can be accomplished at a reasonable cost, is preferable to dealing with a high consequence disaster after it occurs.[32] Because of the structure of the biotechnology industry and the complicated, high magnitude disasters that could result from biotechnology releases, tort liability does not provide adequate prevention of risk through an incentive system.[33] Prerelease screening by the government provides the best means for controlling the potential dangers of release biotechnology.

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28. *See generally* Green, *Genetic Technology: Law and Policy for the Brave New World*, 48 IND. L.J. 559, 574–75 (1973) (genetic engineering development follows usual pattern of progress in technology: "At every stage, the potential or demonstrated benefits are obvious and immediate . . . . Potential adverse consequences . . . tend to be relatively remote and speculative.").

29. *See* ENVIRONMENTAL IMPLICATIONS REPORT, *supra* note 24, at III (release biotechnology risks "are best described as 'low probability of high consequence risks'; that is, while there is only a small possibility of occurrence, the damage that could occur is great").

30. *See id.* at 45–46 (because organisms inexorably expand in favorable environment, size of release is not critical factor; small release could result in "major environmental damage or adverse public health effects").

31. *Potential Environmental Consequences*, *supra* note 7, at 115 (statement of Thomas McGarity) (if unanticipated detrimental impacts occur, "it may not be possible to call [the released organisms] back like we recall defective automobiles"); *see also* Wines, *supra* note 26, at 2100 (little research into recalling organisms has been conducted).

32. The cost of prevention is reasonable so long as it is less than the expected loss through disasters not prevented. The risks of release biotechnology appear to be analogous to toxic chemical and nuclear power dangers, dangers for which elaborate preventive regulatory structures have been created. *See* 42 U.S.C. § 5841 (1982) (Nuclear Regulatory Commission); 15 U.S.C. §§ 2601–2629 (1982) (TSCA). A regulatory mechanism to prevent release biotechnology disasters constitutes a reasonable allocation of resources today. If, in the future, information makes clear that these risks do not deserve careful, preventive attention, resources can be diverted to other problem areas. *See infra* text accompanying notes 105–07; *see also* McGarity & Bayer, *supra* note 10, at 486 ("[w]hen conduct entails a very small probability of a very high consequence accident, the regulatory entity must ensure that the accident never happens"); Diver, *Policymaking Paradigms in Administrative Law*, 95 HARV. L. REV. 393, 431 (1981) (even if data is uncertain, regulator should use comprehensive analysis in attempt to prevent policy error where error could cause irreversible or catastrophic harm).

33. The risks of release biotechnology present an externalities problem. The government must

II. Constraints on Effective Prerelease Screening

The nature of the industry and the nature of the hazards associated with release biotechnology combine to create the need for government regulation through prerelease screening. As it attempts to screen release proposals, the federal government will face difficulties caused by the extreme uncertainty surrounding release risk assessment and by the inadequate structures and powers that have evolved within the government to cope with this regulatory challenge.

A. *Uncertain Science Mixed With Value Judgments*

Scientists can never exactly predict the risk of a release, because no experiment can fully replicate the complex natural environment that a released genetically engineered organism will enter. Yet even if scientists could precisely determine the risks of release biotechnologies, prerelease screening would still present a difficult regulatory problem. The regulator would compare the exact risk measurement for a release proposal, expressed in terms of the probability and magnitude of the expected harm,[34] with the biotechnology's expected benefits. She would then have to decide, based upon a value judgment involving moral, economic, and other considerations, whether the risk was acceptable or unacceptable.[35] Prerelease screening decisions thus necessarily involve both factual determinations and value judgments.

Because scientists cannot precisely predict risk, the factual determination in prerelease screening is itself a tangled one. The factual questions here are "science policy" questions:[36] value judgments enter into pre-

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intervene because industry has insufficient market incentives to take its products' risks adequately into account as it makes production decisions. Government intervention solely through a tort liability structure would create insufficient incentives for several reasons. Many biotechnology companies are judgment proof. Small biotechnology firms are in a precarious financial situation, *see supra* notes 19–20, and larger firms are investing through agreements that could shield them from substantial liability, *see supra* text accompanying note 21. The availability of insurance also blunts the incentive created by the threat of tort liability. Furthermore, proving causation in the biotechnology context may be difficult. *See* Karny, *supra* note 10, at 855. *See generally* Stone, *The Place of Enterprise Liability in the Control of Corporate Conduct*, 90 Yale L.J. 1, 19–28 (1980) (discussing inadequate deterrence of harm-based liability rules).

34. Expressions of risk are typically compound measures that describe the probability of harm and its severity. W. Lowrance, Of Acceptable Risk 70 (1976).

35. "*Risks* are measured. Only when those risks are weighed on the balance of social values can safety be judged: *a thing is safe if its attendant risks are judged to be acceptable.*" *Id.* at 75 (emphasis in original). *See* Doniger, *Federal Regulation of Vinyl Chloride: A Short Course in the Law and Policy of Toxic Substances Control*, 7 Ecology L.Q. 497, 521 (1978) ("regulatory decisions involve moral as well as economic values"). In release biotechnology decisionmaking, one moral issue involves opinions about rapid and widespread use of a powerful, "unnatural" technology. One economic issue concerns the trade-off necessary between profits for the industry through unrestrained sale of beneficial products and costs imposed by a regulatory scheme to protect health and the environment.

36. *See* McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 Geo. L.J. 729, 732 (1979).

release decisionmaking *during the risk assessment stage* because scientists asked to assess risk cannot separate factual determinations from their subjective feelings about the probability of harm and the acceptability of taking risks.[37] As scientists make decisions about what risk possibilities to investigate and what test procedures to employ, they make assumptions that reflect their political and ethical preferences.[38] These preferences are typically not explicitly stated along with the risk determinations; thus unknown biases skew risk measurements.[39] As the government attempts to evaluate release proposals through existing decisionmaking processes, the scientific information available about the possibility of harm will be extraordinarily uncertain because of the lack of risk investigation to date, the uncertainty inherent in predicting interactions with the natural environment, and the unknown biases hidden in the available predictions.

McGarity discusses four reasons for a scientific question being in reality a "science policy" question: (1) sufficient information to answer the question conclusively may not exist, but an experiment could be performed to gather data and answer the question, (2) scientists may interpret gathered data differently, (3) scientists may disagree over inferences from data, or (4) the question may be "trans-scientific" because no experiment can be conducted to gather sufficient data and resolve interpretative disputes. *Id.* at 732–47. Alvin Weinberg explains "trans-scientific" questions as follows:

> Many of the issues which arise in the course of the interaction between science or technology and society . . . hang on the answers to questions which can be asked of science and yet *which cannot be answered by science.* I propose the term *trans-scientific* for these questions since, though they are, epistemologically speaking, questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science.

Weinberg, *Science and Trans-Science*, 10 MINERVA 209, 209 (1972) (emphasis in original). The question of a release biotechnology's risk is a science policy question today both because it is trans-scientific (no experiment short of actual release can conclusively assess the risk associated with release) and because little investigation of release risks has taken place (insufficient data and disagreements in interpreting the data exist although experiments could alleviate this situation).

37. "The belief that science is inherently removed from political consideration and that scientists are, therefore, political celibates is a longstanding one, but in the present social context of science, it is an anachronism." *Curbing Ignorance and Arrogance: The Science Court Proposal and Alternatives*, 19 JURIMETRICS J. 387, 421 (1979) (statement of Professor Dorothy Nelkin). *See* Ashford, Ryan & Caldart, *A Hard Look At Federal Regulation of Formaldehyde: A Departure From Reasoned Decisionmaking*, 7 HARV. ENVTL. L. REV. 297, 311 (1983) (understanding "science policy" nature of question is central step in assessing adequacy of agency's determination of risk; "[s]imply deferring to agency expertise on all determinations that appear to be 'scientific' overlooks the subjective determinations at the heart of the agency's decisions"). A debate concerning the separability of scientific from policy issues surprisingly continues in the legal and scientific literature. Resolution of the separability/non-separability question has important implications for decisionmaking structures. *See* Yellin, *Science, Technology, and Administrative Government: Institutional Designs for Environmental Decisionmaking*, 92 YALE L.J. 1300 (1983). Yellin examines cases which "demonstrate that the distinction between scientific and legal issues is arbitrary and unworkable," *id.* at 1316, and proposes institutional changes that take into account this impossibility.

38. *See* O'Brien, Marbury, *The APA, and Science-Policy Disputes: The Alluring and Elusive Judicial/Administrative Partnership*, 7 HARV. J. L. & PUB. POL'Y 443, 476 n.164 (1984) (scientists' choices of models and tests involve normative, political decisions). Value judgments likewise enter into calculation of a release biotechnology's potential benefits. The primary problem with benefit information, however, is not uncertainty and scarcity, but exaggeration. *See supra* notes 27–28.

39. *See* Hammond & Adelman, *Science, Values, and Human Judgment*, 194 SCI. 389, 392 (1976) (National Academy of Sciences and others involved in technology assessment are "willing . . . to let the process of combining facts and values remain subject to the unexamined vagaries of human judgment").

Although risk estimates will never be precise, scientific knowledge must contribute to decisionmaking regarding release biotechnology if the government is effectively to prevent unacceptable risks and allow acceptable ones.[40] The decisionmaker cannot refrain from action indefinitely, hoping for scientific certainty; either wholesale preclusion or acceptance of release biotechnology products would disserve society.[41] Yet in taking action the decisionmaker must have time meaningfully to consider risk and benefit information before making a policy judgment about a release proposal. Information concerning risk must be obtained and understood, while bias in both benefit and risk estimates must be dealt with. These information generating and processing needs interact with constraints imposed by time and resource concerns to form boundaries for effective biotechnology release evaluation.

Effective decisionmaking must combine available technical information with an *explicit* political determination concerning the acceptability of the risks associated with a genetically altered organism's release.[42] The risk

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40. Though value judgments confuse risk and benefit estimates and a political actor ultimately decides the regulatory question, risk and benefit information is not irrelevant.

> The crucial distinction among Non-Separatists is the degree of belief they profess in the logical progression from the proposition that most environmental issues are Non-Separable [into purely factual and purely political components], to the proposition that in practice all environmental controversies turn on "policy" questions, to the conclusion that science, and by implication, rational analysis itself, have little to contribute to the resolution of environmental problems.

Yellin, *supra* note 37, at 1306 n.27. Yellin correctly rejects complete belief in this logic as "a celebration of ignorance." *Id. See* Handler, *A Rebuttal: The Need for a Sufficient Scientific Base for Government Regulation*, 43 GEO. WASH. L. REV. 808, 809, 813 (1975) (when government contemplates regulation to reduce risk, "an attempt is required to state both the cost and the benefits in quantitative form;" if public officials "choose to flaunt such data, let that then be clear"). *But see* Green, *The Risk-Benefit Calculus in Safety Determinations*, 43 GEO. WASH. L. REV. 791, 805 (1975) (approving of agency decisionmakers determining safety "not only by superimposing value judgments upon authoritative risk-benefit analyses . . . but also by making explicit or implicit adjustments in the evaluation of the risks and benefits themselves"). The approach Green advocates, rejected here, removes decisionmakers from accountability, allowing them to disguise value judgments as "scientific" conclusions. This easy method of obfuscation distinguishes scientific regulatory questions from other uncertain regulatory problems.

41. Because it appears that many release biotechnologies will be both useful and safe, the regulatory challenge is to keep from the market those few products that may cause catastrophic harm while allowing society to reap the benefits of safe genetically engineered organisms. *See Potential Environmental Consequences*, *supra* note 7, at 23 (statement of Dr. Martin Alexander) ("meaningful but not onerous series of tests" essential in evaluating potential dangers).

42. A National Academy of Sciences report on decisionmaking in the toxic chemicals context correctly recommends that "[v]alue judgments about noncommensurate factors in a decision such as life, health, aesthetics, and equity should be explicitly dealt with by the politically responsible decision makers and not hidden in purportedly objective data and analysis . . . ." COMM. ON PRINCIPLES OF DECISION MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT, DECISION MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 7 (1975). *See* Radnitzky, *Science, Technology, and Political Responsibility*, 21 MINERVA 234, 259 (1983) (precondition for rational discussion "is that the evaluative standpoints be made explicit—otherwise they could not be criticised—and that a clear distinction is made between the scientific forecasts and the extra-scientific evaluations"). An "explicit political determination" means that the decisionmaker publicly acknowledges that she has studied evidence for and against regulation (evidence which is made available to the public), and that her

acceptability determination is necessarily a political decision—involving the balancing of economic, aesthetic, moral, environmental, and public health considerations—and thus its legitimacy requires a clear statement of the decision and accountability for it by the decisionmaker.[43] If the decisionmaker refuses openly to acknowledge the political nature of release biotechnology regulation, and instead asserts that regulatory decisions stem only from "scientific facts," public control over acceptability determinations will be more difficult and the decisions will constitute a less legitimate exercise of political power.[44]

To deal effectively with the complex prerelease regulatory problem, therefore, the government should employ a decisionmaking system that accomplishes four goals: (1) the creation and understanding of risk estimates,[45] (2) compensation for biases that enter into expert risk and benefit estimates, (3) accountable decisionmaking that explicitly applies value judgments in determining the acceptability of risk, and (4) decisionmaking accomplished despite time and resource constraints.

B. *The Inadequacy of EPA Regulation Under the Current TSCA*

According to the 1984 "Proposal for a Coordinated Framework for Regulation of Biotechnology,"[46] EPA will use TSCA[47] to regulate those biotechnology products that are not pesticides or other substances covered by more particularized statutes.[48] TSCA's basic structure is well-suited

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decision consists of a judgment as to the proper balance among competing options and values. The alternative is a dishonest decisionmaker who states simply that scientific information *forces* him to make a particular decision, or that science has *proven* a product safe, therefore making regulation unnecessary.

43. Administrative agencies' decisionmaking "must be acceptable—that is, perceived as legitimate—both to those who are directly affected by agency decisions and to the general public as well." Boyer, *Alternatives to Administrative Trial-Type Hearings for Resolving Complex Scientific, Economic, and Social Issues*, 71 MICH. L. REV. 111, 146–47 (1972). Richard Sennett explains that legitimacy in our democracy depends upon "visible" and "legible" use of authority, for this "offers the subjects a chance to negotiate with their rulers and to see more clearly what their rulers can and cannot—should and should not—do." R. SENNETT, AUTHORITY 168 (1980).

44. A problem of legitimacy arises because "use of sophisticated mathematical and biological models . . . distance[s] a modern agency's reasoning from ordinary experience and insulate[s] regulatory decisions from generalist review." Yellin, *supra* note 37, at 1300. Accountability lies at the heart of a democratic system of government. To legitimate the government's use of power in regulatory decisionmaking, "the *electorate* must have an opportunity for the final say about which risks it will bear and which benefits it will seek." Bazelon, *Science and Uncertainty: A Jurist's View*, 22 JURIMETRICS J. 372, 375 (1982) (emphasis in original).

45. The effective decisionmaking system must stress risk creation and understanding because, of the two sides of the issue here, risk considerations are ignored much more than are benefit considerations. Benefit information will exist, because manufacturers have an incentive to produce such information; the challenge for decisionmaking is to cope with bias in benefit estimates.

46. Reagan Administration Plan, *supra* note 10.

47. 15 U.S.C. §§ 2601–2629 (1982).

48. Reagan Administration Plan, *supra* note 10, at 50,887. The plan involves five federal agencies—EPA, NIH, the Department of Agriculture, the Food and Drug Administration, and the National Science Foundation—that will each assert regulatory authority over certain aspects of biotech-

for the release biotechnology oversight task. The statute, however, was designed to regulate the dangers of toxic chemicals, and rests on certain assumptions about the regulatory context that are not valid in the case of release biotechnology.[49] The current TSCA, as it applies to biotechnology, establishes insufficient regulatory power and fails to prescribe adequately the prerelease decisionmaking process. Congress must amend the statute if EPA oversight is to be more than camouflage under which the biotechnology industry develops without restraint.[50]

1. *TSCA's Basic Framework*

As a prerequisite to any control action under the current version of TSCA, EPA must read the act's definition of "chemical substance"[51] to include genetically engineered organisms.[52] Once EPA establishes jurisdiction over release biotechnologies, TSCA provides broad authority to prevent environmental and health hazards.[53]

According to TSCA's premanufacture notice provisions, the manufacturer of a new genetically engineered product will be required to notify EPA ninety days before commercial production commences.[54] The notice must identify the product and must include any health or environmental test data in the manufacturer's possession or control.[55] After receiving premanufacture notification, EPA can act to block release of the organism in two ways. First, if the EPA Administrator finds that the product *may* present an unreasonable risk or that it will be produced in substantial

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nology through existing statutes. Major statutes used in the plan include TSCA, FIFRA, several animal and plant pest control laws, and the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 (1982). *See* Reagan Administration Plan, *supra* note 10; *see also* Plan Update, *supra* note 12, at 47,177-95 (revised matrix listing all regulatory authority applicable to biotechnology). A cumbersome, two-tiered science advisory board system will advise the agencies and coordinate their activities. *See* Reagan Administration Plan, *supra* note 10, at 50,904-05; *see also* Plan Update, *supra* note 12, at 47,174-76.

49. *See, e.g., infra* notes 60-61 and accompanying text.

50. Amending TSCA is preferable to attempting to draft and pass entirely new legislation because the basic TSCA framework is suitable for release biotechnology regulation. *See Potential Environmental Consequences, supra* note 7, at 129 (statement of Thomas McGarity) (discussing disadvantages of attempting to construct new regulatory structure).

51. 15 U.S.C. § 2602(2).

52. The legality of using TSCA's regulatory power to control commercial release biotechnology is questionable. The creative interpretation of "chemical substance" necessary to establish authority over genetically engineered products, *see* Reagan Administration Plan, *supra* note 10, at 50,886-87, may be challenged in court.

53. In addition to the premanufacture regulatory framework that TSCA establishes, the statute gives EPA the power to require testing of and to control use of products already in commerce, and it allows the agency to require certain record-keeping and reporting by manufacturers. *See* 15 U.S.C. §§ 2603, 2605-07.

54. *See* 15 U.S.C. § 2604(a)(1); Reagan Administration Plan, *supra* note 10, at 50,887.

55. *See* 15 U.S.C. § 2604(d)(1). TSCA imposes no routine testing requirements on manufacturers; they only must submit information concerning health and environmental risks that they have voluntarily obtained.

quantities, EPA can by rule require more testing.[56] Pending testing by the manufacturer, EPA can obtain an injunction to block release.[57] Second, if the EPA Administrator finds that the organism *will* present an unreasonable risk to health or to the environment, the agency must by rule ban or regulate use of the genetically engineered product.[58] If the Administrator takes no action within ninety days after premanufacture notification, the company can proceed with production and sale.[59]

2. *Inadequate Screening Power for Biotechnology*

The 1984 plan for biotechnology regulation thus anticipates the EPA Administrator determining, within a very short period of time, whether a release biotechnology product might produce an unreasonable risk. This short screening period may be adequate for regulating chemical dangers, where the volume of new chemicals is great and structural information allows some meaningful but quick assessment of risk.[60] Ninety days, however, is an unrealistic and unnecessarily constricted[61] time frame for the meaningful assessment by EPA of a release biotechnology's potential dangers.

During TSCA's short screening period, EPA cannot know what tests would aid the regulatory decision[62] or meaningfully examine a release

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56. *See* 15 U.S.C. § 2603(a). The move to require testing by the manufacturer must also be based on the existence of insufficient data upon which health and environmental impacts can reasonably be predicted. *See id.* A rule requiring testing must be promulgated pursuant to § 553 of the Administrative Procedure Act, with the added requirement that interested persons have the opportunity to give an oral presentation of data. *See* 15 U.S.C. § 2603(b)(5).

57. *See* 15 U.S.C. § 2604(e)(1)(A). The Administrator must initiate proceedings to block production through an injunction at least 45 days *before* the premanufacture notification period is set to expire, thus within 45 days of the original notice. *See* 15 U.S.C. § 2604(e)(1)(B).

58. *See* 15 U.S.C. § 2605. Rulemaking to limit or ban a product's use must be conducted in accordance with § 553 of the Administrative Procedure Act and the special requirements enumerated in TSCA, which include a required opportunity for an informal hearing. *See id.*

59. *See* Reagan Administration Plan, *supra* note 10, at 50,894. In sum, EPA has 45 days in which to initiate the process of obtaining an injunction pending testing or 90 days to initiate a rulemaking proceeding to ban use of a release biotechnology, if the manufacturer is to be blocked from production when the notice period ends. EPA can extend the notice period to 180 days "for good cause;" the reasons for such an extension must appear in the Federal Register. 15 U.S.C. § 2604(c). An extension constitutes final agency action subject to judicial review. *Id.*

60. EPA reviews approximately 1500 new chemicals under TSCA each year. *See* Lewis, *Reviewing New Chemicals*, E.P.A. J., June 1985, at 6, 6. While quick tests do exist for estimating a chemical's risks, the reliability of these tests has been questioned. *See, e.g.*, Stanfield, *Few Are Satisfied with Statutes Aimed at Controlling the Chemical Revolution*, 1984 NAT'L J. 2200, 2203 (EPA will allow production of chemical without further tests if chemical structure is similar to that of chemicals considered safe, "a practice that some fear could lead to a health disaster").

61. At least for the next few years, the volume of release biotechnology proposals will be much more manageable than the volume of new chemicals; EPA can thus afford to engage in longer, more extensive scrutiny of the release proposals. *See* OTA 1984 ANALYSIS, *supra* note 2, at 386 (500 genetic manipulation patents pending in 1984, with 200 applications received per year [figures include organisms developed for contained use as well as for release]).

62. A testing rule promulgated under TSCA must specify exactly what type of test the manufacturer must perform. *See* 15 U.S.C. § 2603(b).

biotechnology's risks, because information about risks is not easily accessible[63] and EPA lacks staff scientists with expertise in fields related to release biotechnology regulation.[64] Yet, unless the EPA Administrator takes affirmative action to require testing and obtain an injunction, or to control use of the substance through rulemaking, release cannot be delayed long enough for a useful examination of risk. The government has acknowledged that risk assessment methodologies are not yet capable of quick safety determinations.[65] EPA plans, however, to process and approve release biotechnology proposals quickly without such methodologies,[66] thereby providing very little assessment or regulation of biotechnology's hazards.[67] Thus, without routine, significant action by EPA to delay release and thoroughly examine risk—discretionary action which the agency indicates it will not take—the prerelease look at genetically engineered products under TSCA will have little chance of preventing unacceptable

63. "[U]ncertainty about the risks of releasing genetically engineered material into the environment is the salient feature" of the release biotechnology regulatory problem. McChesney & Adler, *supra* note 7, at 10,368. The "key problem" for EPA's Office of Toxic Substances is "to develop reasonable risk assessment methodologies" for release biotechnologies. U.S. Environmental Protection Agency, Regulation of Genetically Engineered Substances Under TSCA (March, 1983), *reprinted in* ENVIRONMENTAL IMPLICATIONS REPORT, *supra* note 24, at 109, 139. Scientists have "bemoaned the lack of a data base for assessing the environmental effects of deliberate release" and warned of the "small but possible chance of environmental disaster." *More Research on rDNA Risk Assessment Called For by Speakers at NAS Conference*, 8 CHEM. REG. REP. (BNA) 1412, 1412 (Mar. 1, 1985).

64. Consideration of release biotechnology's risks requires microbiologists, biochemists, public health specialists, and broad-scale ecologists, among others. EPA's Office of Toxic Substances does not have this type of staff. *See* U.S. Environmental Protection Agency, Regulation of Genetically Engineered Substances Under TSCA (March, 1983), *reprinted in* ENVIRONMENTAL IMPLICATIONS REPORT, *supra* note 24, at 109, 138–39. Government scientists must consider release risks through careful, case-by-case examinations because established, quick risk assessment methodologies do not exist. Reliance on members of a science advisory board for case-by-case evaluations is unsatisfactory in part because members devote little time to the advisory work and thus an advisory board could not handle the caseload. *See* Ashford, *Advisory Committees in OSHA and EPA: Their Use in Regulatory Decisionmaking*, SCI., TECH. & HUMAN VALUES, Winter 1984, at 72, 79 (advisory committees in toxic substances control area meet less often than every six weeks).

65. The 1984 executive branch plan notes "the absence of generally accepted principles of risk assessment," Reagan Administration Plan, *supra* note 10, at 50,894, and states that a major issue is "the need to determine what information is necessary for assessing the risks." *Id.* at 50,882.

66. According to the Reagan Administration Plan, EPA will work to develop a data base and risk assessment methodologies, but EPA will not delay commercial releases until rudimentary information can be developed. The agency intends to determine the level of risk understanding necessary for a "reasoned evaluation" on a case-by-case basis. *See* Reagan Administration Plan, *supra* note 10, at 50,894. Don R. Clay, Director of EPA's Office of Toxic Substances, has said that "[w]e can decide the science is not ready, but the products are coming [for review under TSCA]," indicating that review will proceed despite inadequate scientific knowledge in EPA. *See Risk Assessment Methods Insufficient for Genetically Altered Products, EPA Says*, 8 CHEM. REG. REP. (BNA) 428, 428 (July 20, 1984).

67. Most telling in this regard is a recent action by Dr. Bernadine Healy, Deputy Director of the Office of Science and Technology Policy. In the process of cancelling a National Academy of Sciences study on risk assessment capabilities, Healy said that it would be "absurd" to hold up biotechnology progress while the government explores scientific questions. *Study of Scientific Basis for Regulation of rDNA Products Shelved After Criticism*, 9 CHEM. REG. REP. (BNA) 72, 72 (April 19, 1985).

risk. A statute supposedly invoked for prerelease screening[68] should actually provide that such evaluation will take place, instead of simply making evaluation possible at the Administrator's discretion. The TSCA regulatory scheme fails to meet the fourth goal of an effective decisionmaking system: by imposing an extreme and unnecessary time constraint, the ninety-day provision prevents a meaningful decision about risk.

3. *Politically Muddled Decisionmaking*

Just as the structure of TSCA's regulatory power effectively creates the undesirable presumption of release biotechnology's safety,[69] the decisionmaking process with which EPA implements TSCA will prevent meaningful, accountable prerelease screening. An informed attempt at prerelease evaluation is especially important for prevention of unreasonable risks, because unlike incorrect control actions that EPA may initiate under TSCA, a mistaken staff decision to allow release will most likely be the final action until an unacceptable harm occurs.[70] The current decisionmaking mechanisms in EPA, however, in addition to operating under an unreasonable time limit, fail to satisfy the first three goals of an effective decisionmaking system.

In deciding whether to take action during the TSCA premanufacture notification period, EPA now relies on the limited information submitted by the manufacturer,[71] a possible staff investigation of the product's risk,[72] and possible consultation with an advisory committee composed of scientists.[73] Because TSCA leaves the thoroughness of investigation entirely up

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68. *See* Reagan Administration Plan, *supra* note 10, at 50,886 (TSCA described as means of acting against risks before harm can occur).

69. The presumption of safety exists because meaningful consideration of risk is not routine. As TSCA's powers are now set up, only the extraordinary release proposal would seem to need scrutiny—thus ordinary releases are presumed safe.

70. Incorrect control actions—actions to regulate when risk is acceptable rather than unacceptable—will automatically be further scrutinized during the court or administrative hearing required by TSCA. *See supra* notes 56–58 and accompanying text. Challenge of EPA staff decisions not to take any action and to allow release, however, will be difficult and infrequent. Courts traditionally defer to agency decisions not to act, *see* Ashford, Ryan & Caldart, *supra* note 37, at 304, 310 n.67 (criticizing deference in situations similar to prerelease regulation under TSCA), and concerned citizens will only infrequently bring suit under TSCA's citizen suit provision because of lack of money and the current lack of public information.

71. *See supra* note 55.

72. In reviewing chemicals, EPA completes many premanufacture reviews within three weeks of notice, thus devoting very little time and energy to the majority of premanufacture submissions under TSCA. *See Reauthorization of Toxic Substances Control Act For Fiscal Year 1984: Hearings Before the Subcomm. on Commerce, Transportation and Tourism of the House Comm. on Energy and Commerce*, 98th Cong., 1st Sess. 36 (1983) (statement of Don R. Clay, Acting Assistant Administrator, EPA). EPA must currently review and decide on the safety of a new chemical every 90 minutes. *Debating EPA's New Chemicals Program: A Forum*, E.P.A. J., June 1985, at 12, 12 (statement of Sen. Durenberger).

73. Numerous advisory committees are available to supplement EPA staff work, but the helpfulness of these committees is limited. *See supra* note 64 and *infra* notes 80 & 83. The Reagan Adminis-

to the EPA Administrator, the statute does nothing to guarantee that any risk or benefit investigation will take place.[74] The statute and EPA practice thus fail to provide for any systematic creation and understanding of risk estimates, estimates obviously crucial to prerelease decisionmaking.

EPA attempts to distinguish between "risk assessment"[75] (when it takes place) and "risk management"[76] in its internal operations, but makes no special attempt to assess benefits carefully.[77] The agency has been frustrated by the impossibility of making purely scientific risk assessments.[78] Instead of adopting procedures that compensate for this phenomenon of values mixing with facts, however, EPA has adopted procedures that serve to divert attention from the problem of unknown biases in risk and benefit estimates. EPA attempts to reduce public expectations that high risk assessments mean that risk must be prevented,[79] and the agency sometimes consults an expert panel for additional value-laden advice,[80] rather than

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tration Plan calls for a special science advisory committee to assist EPA in biotechnology regulation. According to the plan, the manufacturer will be able to request the committee to review a premanufacture notice, but other interested parties such as environmentalists will not have this privilege. The committee need not grant any request for consideration of a release proposal, even if the request comes from EPA. *See* Reagan Administration Plan, *supra* note 10, at 50,905. Establishment of the EPA biotechnology advisory committee is expected in early 1986 and will be announced in the Federal Register. *See* Plan Update, *supra* note 12, at 47,174.

74. TSCA nowhere requires either a staff investigation or consultation with an advisory committee. *See* 15 U.S.C. §§ 2601–2629 (1982).

75. "Risk assessment is the use of a base of scientific research to define the probability of some harm coming to an individual or a population as a result of exposure to a substance or situation." Speech by William Ruckelshaus, then EPA Administrator, at Princeton University (Feb. 18, 1984), *reprinted in* E.P.A. J., April 1984, at 12, 12.

76. "Risk management, in contrast, is the public process of deciding what to do where risk has been determined to exist." *Id.*

77. *See* Speech by William Ruckelshaus, then EPA Administrator, before the National Academy of Sciences (June 22, 1983), *reprinted in* E.P.A. J., July 1983, at 3, 4 (National Academy of Sciences has recommended "that these two functions be separated as much as possible within a regulatory agency. This is what we now do at EPA . . . ."). A preferable scheme consists of *three* separate functions—risk assessment, benefit assessment, and risk management. Without benefit assessment as a separate function from ultimate risk management decisionmaking, the decisionmaker can easily alter benefit data to fit whatever decision he is inclined to make.

78. *See* Ruckelshaus, *supra* note 75, at 12 (separation of risk assessment from risk management found "more difficult to accomplish in practice. . . . [V]alues, which are supposed to be safely sequestered in risk management, also appear as important influences on the outcomes of risk assessments.").

79. Recent EPA Administrator William Ruckelshaus has stated that one of EPA's goals in dealing with uncertain risk assessments is to convince the public not to take such assessments too seriously. This tactic gives the agency more flexibility in deciding when to act because of lowered public expectations about the need to act. *See id.* at 14–15 (describing public relations efforts).

80. EPA, for example, in 1984 established a Risk Assessment Forum for consultation on risk assessment questions. *See* Goldstein, *Strengthening the Assessment of Risk*, E.P.A. J., Dec. 1984, at 5, 6. Multiple risk assessments do not ensure increased accuracy, because of the hidden biases in the estimates. After a certain point, attempts to resolve scientific uncertainty are wasted efforts. Necessary for an effective decisionmaking system is a concerted attempt to cope with uncertain information, once available data has been gathered, rather than an attempt immediately to abolish scientific uncertainty. *See infra* note 104 and accompanying text.

moving to a decisionmaking format that compensates for bias and meets the second goal of effective decisionmaking.[81]

Recent occurrences in EPA show how information-gathering is easily distorted within the agency,[82] even when an expert science advisory board is consulted.[83] The decisionmaker can decide to produce only information favorable to his initial view of the premanufacture notice and thus can hide behind "scientific" justification for his decision. This possibility shields the decisionmaker from public accountability and increases the likelihood that prerelease decisions will not reflect society's view of acceptable risk, but merely a high-ranking EPA official's view of acceptability. Because the decisionmaking process does nothing to encourage an explicitly political determination regarding safety, based upon publicly available risk and benefit information, the current process fails to satisfy the third goal of an effective decisionmaking framework, that of accountability.

EPA's present methods of decisionmaking will not guarantee that risk estimates are before the decisionmaker. They will not accomplish compensation for biases in risk and benefit information, nor will they ensure that the ultimate decision about whether to regulate is an explicitly political one. Instead, the current system makes the amount of energy and resources employed in decisionmaking totally discretionary and allows for the political manipulation of data as well as resources. Any prerelease screening that does occur is likely to be politically muddled from the outset because the decisionmaking processes are not carefully defined. At least until the risks of release biotechnology are better understood, a more rig-

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81. Accepting rather than responding to the bias problem, EPA Assistant Administrator John Moore has stated:

> The activities leading to characterization of risk are more fraught with assumptions and subjectivities than one would like. Similarly, the methods available for analyzing the non-risk factors in a quantitative manner are weak. Therefore, risk management decisions are anything but "cut-and-dried." But then, that's the way it is with risk assessment/risk management . . . not predictable perhaps, but always interesting!

Moore, *Making Decisions About Risk*, E.P.A. J., Dec. 1984, at 8, 9.

82. Top EPA officials held secret "science forums," with only industry representatives present, to critique technical documents (prepared by EPA scientists) on the dangers of formaldehyde and DEHP (diethylhexylphthlate). Numerous conclusions in these technical documents were changed, and they then became the basis for the widely criticized decisions not to regulate either of the substances under TSCA. *See* Rushefsky, *The Misuse of Science in Governmental Decisionmaking*, SCI., TECH. & HUMAN VALUES, Summer 1984, at 47, 48–51; Sandler, *EPA's Secret "Science Courts"*, ENV'T, Jan.-Feb. 1982, at 4, 4.

83. The Reagan Administration has attempted to replace many of the scientists on EPA's Science Advisory Board because their views are no longer "acceptable" (though this motivation has not been stated publicly, in an effort to maintain the image that the advisory board gives purely objective scientific advice). *See* Ashford, *supra* note 64, at 72. This highlights the ability to manipulate, without easy public scrutiny, the advice given by advisory committees. EPA officials can either alter committee findings or load the committees with scientists whose views are "acceptable," who will themselves tailor their conclusions according to the politics of the administration.

orous, more open investigation must take place if EPA is to answer adequately the extraordinarily complex prerelease regulatory question.

III. A Proposal for Effective, Flexible EPA Decisionmaking

Congress should step in to modify the executive branch's plan for dealing with the dangers of release biotechnology. An amended TSCA should set up two types of premanufacture review for release biotechnology organisms and should ensure that, at least initially, EPA review is rigorous.

A. *Intensive, Quasi-Adversarial Review*

Congress should specify that in the case of biotechnology products,[84] premanufacture notification under TSCA must come at least one year before production for release.[85] A statutory change in the time allowed for EPA consideration of release proposals will negate the current requirement of significant EPA action merely to give the agency enough time to engage in prerelease screening. This change gives EPA the minimum time necessary for meaningful decisionmaking, allowing the agency to fulfill the fourth goal of an effective decisionmaking system.[86]

Although the ultimate decisionmaker in prerelease screening is the EPA Administrator, a political actor,[87] some decisions will depend on the process through which the Administrator and the agency staff evaluate the product.[88] To replace the present unstructured and politically muddled

84. Amendment of the statute should obviously make EPA's jurisdiction over biotechnology explicit.

85. The year breaks down into six months for EPA to prepare reports, four months for public comment, and two months for decisionmaking about the release proposal. *See infra* notes 92–94 and accompanying text. This structure of one year in which to act according to a required decisionmaking plan is superior to a typical permitting system, one without time constraints on an agency's examination of a permit application. A permitting system would give EPA an infinite amount of time to act and thus open up an easy mechanism for inordinate delay in allowing releases, should EPA be so inclined.

86. In addition to requiring one year for prerelease review, meeting the fourth goal of decisionmaking within time and resource constraints also depends upon Congress appropriating sufficient funds to EPA for TSCA implementation. While funds must be forthcoming, money alone cannot accomplish the complex task of prerelease review; a qualified EPA staff must be given time in which to use the money to good effect.

87. The decisionmaker under TSCA is the EPA Administrator, *see* 15 U.S.C. §§ 2601–2629 (1982), but in practice decisions may be made by the likewise politically appointed Assistant Administrator for Pesticides and Toxic Substances.

88. The emphasis on procedure in these proposed TSCA amendments gains strength not only from the general sense that procedures make a difference and must be specified in administrative and judicial proceedings, but also from recent emphasis in the economics and political science literature on the importance of rational procedures for information-gathering to inform our decisionmaking. Nobel Prize-winning economist Herbert Simon has stressed the importance of "procedural rationality." *See* Simon, *Rationality as Process and as Product of Thought* in 2 Models of Bounded Rationality 444, 452 (1982) ("we must give an account not only of *substantive rationality* . . . but also *procedural rationality*—the effectiveness, in light of human cognitive powers and limitations, of the *procedures* used to choose actions") (emphasis in original). In political science, "policy analysis" is an

decisionmaking procedures used to implement TSCA, Congress should specify a quasi-adversarial decisionmaking process[89] that will put understandable risk and benefit information before the decisionmaker and the public,[90] and that will then require the EPA Administrator to make an explicitly political decision concerning the acceptability of a release proposal's risks.[91]

The quasi-adversarial process would employ two groups within EPA to present evidence to the decisionmaker.[92] A group of staff scientists, with

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expanding sub-discipline aiming towards the "structured use of information to illuminate the consequences of choice." DeLong, *Informal Rulemaking and the Integration of Law and Policy*, 65 VA. L. REV. 257, 330 (1979). "The basic policy analysis criticism of government is that agencies frequently do not structure decisionmaking processes in ways that make explicit the agency's choices and the trade-offs inherent in these choices." *Id.*

The proposal here responds to both the necessity to gather data and the necessity to use that data in a way that addresses this policy analysis criticism. Informed, accountable decisionmaking is an improvement over the current unstructured process: the decisionmaker will feel constrained by the force of the information before him and by the political forces he must contend with after making an accountable decision. Thus, the TSCA amendments will change the substantive outcomes in release biotechnology decisionmaking. More releases—unacceptable releases—will be blocked if an effective decisionmaking system is implemented than would be prevented if TSCA and its use remain unchanged.

89. The adversary system "represents a public forum in which there is a fair opportunity to present opposing views." Yellin, *High Technology and the Courts: Nuclear Power and the Need for Institutional Reform*, 94 HARV. L. REV. 489, 505 (1981). Two important outcomes of employing the adversary model are thus information and a sense of fairness. In the administrative law context, the idea of fairness as a goal extends beyond fairness to the individual parties involved: "the *public* is treated unfairly when a rulemaker hides his crucial decisions, or his reasons for them, or when he fails to give good faith attention to all the information and contending views . . . ." Wright, *The Courts and the Rulemaking Process: The Limits of Judicial Review*, 59 CORNELL L. REV. 375, 379 (1975) (emphasis in original). The analogy of the process advocated here to the adversarial system of decisionmaking used in American courts is intended to be a limited one, focusing on the information presentation process and the fair decisionmaking that such presentation can produce.

A central difference between the adversarial method of decisionmaking and an investigatory or inquisitorial model is the control of the two sides over "what data and arguments should be used in support of the decision." Boyer, *supra* note 43, at 120–21. This method of using adversaries to present information to the decisionmaker serves to assure "the adjudicator the proper informational input *before* he decides the case." This is, as Professor Damaska explains, extremely important to the proper functioning of the American "coordinate" model of adjudication as opposed to the continental "hierarchical" model. Damaska, *Structures of Authority and Comparative Criminal Procedure*, 84 YALE L.J. 480, 527 (1975). The development of all relevant information is crucial in the American trial because factual investigation does not occur at the appellate level. *See id.* at 515. The presentation of all relevant information is likewise crucial to a release biotechnology decisionmaker, because the object of prerelease screening is to *prevent* unacceptable risks and there will be no second inquiry into a product's dangers if the decisionmaker decides to allow release. The premium is on possession of all available information, as it is in the American trial, and thus the adversarial approach to information gathering fits the prerelease screening situation well.

90. The information is "understandable" in the sense that its bias is explicit; the risk and benefit descriptions will not be muddled by unknown preferences because the quasi-adversarial process imposes a clear policy leaning on each side's presentation.

91. As opposed to the judge or jury in a trial, the EPA decisionmaker *must* apply value judgments in addition to the law. The agency decisionmaker should be as explicit and informative to the public concerning his value judgments as a judge is expected to be in stating the law. *See supra* text accompanying notes 42–44.

92. Information is presented by groups that do not directly represent parties in the controversy, because of the need for administrative agencies to take all risks and all benefits into account, rather

members having expertise in all disciplines related to the risks of release biotechnology,[93] would put together a report that makes the strongest possible case for the risks of the release biotechnology product under review. Another staff group, consisting of economists, experts on biotechnology's commercial applications, and others, would draft a report making the best case for the potential benefits of the genetically engineered organism. These reports would be published in the Federal Register within six months of premanufacture notification. After a public comment period,[94] both the reports and a summary of the comments would go to the decisionmaker, who would then determine whether any regulatory action under TSCA was necessary.

In addition to providing the time necessary for careful risk evaluation, this proposed decisionmaking system addresses the three remaining goals of effective prerelease screening. First, it provides for the creation and understanding of risk assessment information. The quasi-adversarial process creates an incentive for the group of scientists to put together the strongest case for risk: the scientists' prestige is tied to performing the job of advocate well.[95] To aid the group in its risk study, the TSCA amendments should include a section that allows the scientists to contract for additional research into release risks and risk assessment methodologies; information

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than merely those related to an individual party. Individual interested parties do have the opportunity to present their cases during the public comment period.

93. EPA will have to hire most members of this group because the Office of Toxic Substances currently lacks experts in many of the relevant areas. *See supra* note 64.

94. The public comment period should be long enough for interested parties carefully to respond. Four months seems appropriate, given that the agency has six months to gather data for the initial, exhaustive reports.

95. The scientists employed by EPA to prepare the case for risk will be more immune to political pressure than scientists on science advisory boards because EPA work is their full-time job. The EPA scientists will derive their professional sense of accomplishment from the agency job, whereas members of advisory boards derive satisfaction and prestige mainly from work in universities or in industry and can approach giving advice to EPA from a more political, rather than professional, standpoint. It is unlikely that a scientist would take the job of risk advocate (or that an economist would join the benefit assessment group) without the intention of performing the job well. Performance of the task of putting together the strongest case for release risks (or benefits) will be monitored publicly through publication of the reports in the Federal Register. The EPA staff is given a good deal of independence by the civil service employment system. *See generally* Rosenbloom, *Accountability in the Administrative State* in ACCOUNTABILITY IN URBAN SOCIETY 87, 92 (1978) (job tenure of career civil servants insulates them somewhat from political pressure by appointed superiors). EPA scientists have repeatedly exhibited this independence in the past. *See, e.g.*, J. LASH, K. GILLMAN & D. SHERIDAN, A SEASON OF SPOILS 141 (1984) (efforts of career scientists at EPA helped prevent loosening of lead-in-gasoline standard desired by Reagan Administration); *supra* note 82 (technical documents prepared by EPA scientists assessed dangers in such a way that regulation seemed necessary; EPA administrators forced to alter documents themselves to support controversial decision not to take action).

Despite the popular conception that scientists are simply objective seekers of truth, the scientific enterprise follows an adversary model; thus, the group of scientists will not be uncomfortable in its adversary role. Levine explains that both within single experiments and within the scientific community, there are claims and counterclaims advanced by each side of a controversy, with each side attempting to advocate the best possible case for its position. *See* Levine, *Scientific Method and the Adversary Model*, 29 AM. PSYCHOLOGIST 661, 669 (1974).

from this research would supplement information given by manufacturers and the information available in the scientific literature.[96]

Second, by setting up two information-gathering groups, each with an obvious bias, the quasi-adversarial model compensates for hidden biases that enter into individual estimates of benefit and risk.[97] Each group argues as best it can for its position, but the argument must be based on evidence, explained and defended in the report; the reports are analogous to lawyers' briefs.[98] Thus, the decisionmaker knows the conclusions of each advocacy group, and the nature and number of studies upon which the conclusions are based. The evidence is further scrutinized through the public comment procedure.[99] In the end, the decisionmaker will have before her the best available case for the product's risks and the best available case for the product's benefits.

Finally, the politically accountable EPA Administrator will be forced to make an explicit value judgment about the situation: the conflicting, publicly presented cases can only thus be resolved.[100] Public input into risk acceptability determinations increases (1) because of the ability to put all relevant information before the EPA decisionmaker, (2) because knowledgeable public pressure relating to value judgments can be brought to

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96. Congress could establish a tax on the sale of biotechnology products to fund such research. In contrast to exclusively requiring prerelease testing by manufacturers, this contract research approach would delay the imposition of some financial burdens on innovative new companies until sales of safe products commence and the companies are better able to survive.

97. The process compensates for the problem of bias in estimates by making the bias explicit and in one direction, therefore allowing the decisionmaker to more knowledgeably weigh the information.

98. Because the reports must contain arguments supported by evidence, the tendency to exaggerate benefits is constrained. Because the adversary process creates an incentive to gather information—EPA scientists' prestige is tied to presentation of the case for risk—the process compensates for the tendency to underestimate low probability risks of a new technology. *See generally* Furrow, *supra* note 20, at 1450-51 (hazards of rare technological disasters often ignored); Green, *Should Technology Assessment Guide Public Policy?*, 69 A.B.A. J. 930, 931-32 (1983) (especially with new technology, risks are underweighed and benefits overweighed).

99. The process of report presentation and public scrutiny, followed by required consideration of the report and public comments in decisionmaking, is analogous to the Environmental Impact Statement (EIS) requirements set up by the National Environmental Policy Act (NEPA). *See* 42 U.S.C. §§ 4321-4335 (1982); 40 C.F.R. §§ 1500-08 (1985); J. BONINE & T. MCGARITY, THE LAW OF ENVIRONMENTAL PROTECTION 119-23 (1984) (explaining procedures for preparing EIS's). The assumption underlying the government's use of the EIS system to put environmental impact information before a vast array of decisionmakers is the same as the assumption behind the quasi-adversarial process here—informing the decisionmaker and the public has desirable consequences relating to the government's ultimate decisions. *See* 115 CONG. REC. 40,416 (1969) (statement of Sen. Jackson) (describing rationale behind and purpose of NEPA). These desirable consequences include error detection by members of the public, public input as to what values to take into account in decisionmaking, and individual suggestions as to how these values should be weighed.

100. The 1983 departure of EPA Administrator Anne Burford because of adverse public reaction to her policies shows that the politically appointed officials at EPA are currently at least somewhat accountable. *See* Note, *Incorporation of Independent Agencies into the Executive Branch*, 94 YALE L.J. 1766, 1775 & n.66 (1985). The Reagan Administration, however, has waged war on government openness and accountability since taking office, *see* Karp, *Liberty Under Siege*, HARPER'S, Nov. 1985, at 53, and thus regulatory programs emphasizing accountability are especially important today to preserve democratic principles.

bear *before* a prerelease screening decision, and (3) because the transparent decisionmaking process allows faster, more effective public pressure even after EPA makes its risk acceptability decision for a particular release biotechnology product.[101] If the government regulates release biotechnology through the quasi-adversarial decisionmaking process, information about risks will be more likely to reach citizens and decisionmakers while harm remains only a possibility. The legitimacy of prerelease decisionmaking will increase because of the enhanced ability of the public to make informed value judgments and to impose these value judgments on accountable agency officials.[102]

Modern regulatory agencies were created in part because courts could not handle complex decisionmaking tasks.[103] The method American courts employ for the presentation of information has a place in regulatory agencies, however, when the agencies must resolve extraordinarily uncertain scientific issues. The "science court" proposals of the 1970's mistakenly attempted to discover scientific truth by pitting two groups of scientists against each other.[104] The adversary model cannot be employed to abolish scientific uncertainty, but it can help regulators respond to an uncertain situation. By bringing out available information on both sides of the issue, the quasi-adversarial process proposed here clarifies the question and the competing values at stake. The process enables effective decisionmaking to take place.

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101. In addition to the informal channels for public pressure that are available outside the quasi-adversarial decisionmaking process, TSCA provides for citizens' suits and petitions. 15 U.S.C. §§ 2619-20 (1982).

102. Public participation in decisionmaking has a utilitarian justification (it may lead to better scientific information), a political justification (it legitimates policies), and a normative justification (it furthers the public's right to know about public risks). *See* Furrow, *supra* note 20, at 1423.

103. *See, e.g.*, J. FREEDMAN, CRISIS AND LEGITIMACY 21-22 (1978) (decisions to use administrative process "in addressing a widening range of social and economic problems constitute a cumulative judgment that the procedural methods of the judicial process are not adequate" to meet regulatory needs); B. ACKERMAN & W. HASSLER, CLEAN COAL/DIRTY AIR 12 (1981) (New Deal ideal states that "it is the expert agency, unencumbered by abstract legalisms, that promises to craft a policy responsive to the complexities of environmental relationships").

104. The science court proposals suggest setting up special institutions or procedures within the government to do away with scientific uncertainty in the same way that legal controversies are resolved in courts. *See* Note, *Procedures for Decisionmaking Under Conditions of Scientific Uncertainty: The Science Court Proposal*, 16 HARV. J. ON LEGIS. 443, 444-47 (1979). These proposals are all based on the separability of factual controversies from policy considerations, *id.* at 447, a premise that this Note rejects. *See* Talbott, *"Science Court": A Possible Way to Obtain Scientific Certainty for Decisions Based on Scientific "Fact"?*, 8 ENVIR. L. 827, 838-39 (1978) (one problem with science court proposal is proponents' assertions that facts and values are separable). In contrast to science court proposals, the quasi-adversarial process copes with uncertainty, explicitly acknowledging that such uncertainty can only slowly decrease and will never completely disappear in the case of release biotechnology risks.

B. *Expedited Review*

The intensive, quasi-adversarial decisionmaking mechanism accomplishes real decisionmaking within time and resource constraints that are reasonable for regulating a new, potentially very harmful technology. Experience under this rigorous regulatory scheme, however, may establish that many release biotechnologies present little risk relative to their benefits, and that these products can easily be identified.[105] Therefore, Congress should add flexibility to biotechnology regulation under TSCA by building an expedited review procedure into the amended statute.[106]

The new TSCA should provide for the possibility of administrative action to exempt groups of genetically engineered organisms from intensive premanufacture review. Under the expedited process, the manufacturers of these organisms could notify EPA only a short time before release might take place. If the notification accurately identified the organism as one eligible for expedited notice because it posed acceptable risk, EPA would be required to allow release. This provision would be especially helpful for aiding the development of release biotechnology products, because once enough information is known for EPA to establish expedited review, producers could submit a notice covering a whole family of safe organisms. Thus, in the product development stage the manufacturer's burden under TSCA regulation would be reduced. Flexibility in the statute allows the all-important balance between business freedom and safety concerns to be restruck as knowledge grows.[107]

Conclusion

TSCA amendments can enable EPA regulation of health and environmental hazards to keep pace with the rapid development of commercial

105. Experience with laboratory research involving genetically engineered organisms has indicated that such research presents less risk than initially anticipated, and the NIH Guidelines regulating research have gradually been made less strict. *See* Karny, *supra* note 10, at 857. A similar change in the regulatory problem could occur as knowledge about release risks increases. Toxic chemical regulation suggests that, while certain release biotechnologies may indeed pose substantial risks, simple compositional tests may be developed to identify quickly at least some of the biotechnologies that pose acceptable risks. *See supra* text accompanying note 60.

106. One important criterion for evaluating procedural systems is efficiency, the capacity to attain decisionmaking objectives "at the least possible cost to avoid waste of scarce social resources." Boyer, *supra* note 43, at 145. The fourth decisionmaking goal discussed here embodies this criterion; the expedited review procedure provides the flexibility needed to achieve efficiency as uncertainty decreases.

107. Nevertheless, Congress must limit EPA's ability to establish expedited review so that this ability cannot be used to circumvent intensive, quasi-adversarial decisionmaking while such decisionmaking remains necessary. Congress could, for example, bar establishment of quick review for several years and then require a public hearing process to establish eligibility for groups of organisms. The Controlled Substances Act provides a possible model process for compiling the list of eligible release biotechnology organisms. *See* 21 U.S.C. § 811(a) (1982) (Attorney General given power to add substances to drug list by means of formal hearings).

biotechnology. To cope adequately with the uncertainty now surrounding release risks, EPA must, at a minimum, have enough time to engage in meaningful prerelease scrutiny. Furthermore, decisionmaking procedures must effectively produce and channel information for an accountable decisionmaker. The revolution set in motion by the perfection of genetic engineering techniques should provoke the government to adopt a new decisionmaking approach to extremely uncertain scientific issues. The combination of agency and judicial virtues in the quasi-adversarial decisionmaking process is especially fitting for the regulation of products made by combining genes from diverse organisms.