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”Risky Business”: EPA Decision-Making in the Screening of Biotechnology Products

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NOTES

"RISKY BUSINESS": EPA DECISION-MAKING IN THE SCREENING OF BIOTECHNOLOGICAL PRODUCTS

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I. INTRODUCTION

The practice of using biological organisms to bring out desired agricultural characteristics stretches back for centuries;[1] these traditional agricultural uses underlie the science of modern biotechnology.[2] However, advances in microbiology have only re-

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1. *See* ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, RECOMBINANT DNA SAFETY CONSIDERATIONS 13 (1986) (linking the use of living organisms to modify products for human consumption with the ancient Sumerian practice of using yeast to make alcohol in the form of beer, a ritual that dates back to sometime before 3000 B.C.); *see also* EPA, Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23313, 23314 (1986) (hereinafter "EPA 1986 Statement of Policy"); David J. Earp, Comment, *The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor's Vegetable Patch?* 24 ENVTL. L. 1633, 1635 n.2 (1994) (describing the Office of Technology Assessment's definition of biotechnology as "encompass[ing] traditional practices such as brewing, baking, and animal husbandry.").

However, for an interesting refutation of this analogy, see Michael Pollan, *Playing God in the Garden*, N.Y. TIMES MAG., Oct. 25, 1998, at 48. This author points out that the process of genetically engineering agriculture is different from traditional processes like fermentation: "[G]enetic engineering overthrows the old rules governing the relationship of nature and culture in a plant. For the first time, breeders can bring qualities from anywhere in nature into the genome of a plant . . . ." *Id.*

2. The United States Office of Technology Assessment ("OTA") has defined biotechnology as, "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses." U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHNOLOGY:

cently enabled humans to manipulate the inherited characteristics of microorganisms, plants, and animals.[3] Such technological advances gave birth in the 1980s to the biotechnology industry, a new member of the private sector that aimed at expanding and commercializing the applications of genetic manipulation.[4]

Modern genetically engineered agricultural products have numerous and far-reaching applications.[5] Successful exploitation of these applications may translate into enormous potential profits. For example, in 1992 the biotechnology industry as a whole experienced ten billion dollars in product sales and revenue.[6] Today, a mere six years later, one biotechnology company alone

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AN INTERNATIONAL ANALYSIS, OTA-BA-218, 3 (January 1984).

3. *See* EPA 1986 Statement of Policy, *supra* note 1, at 23314. For an excellent history of the persons & processes behind this scientific explosion, *see* SHELDON KRIMSKY, GENETIC ALCHEMY: THE SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY (1982).

In general, deoxyribonucleic acid ("DNA") contains the genetic information of all living things. *See* Leonard A. Post, Laying the Groundwork: The Techniques and Applications of Recombinant DNA Technology, *in* BIOTECHNOLOGY AND THE ENVIRONMENT: THE REGULATION OF GENETICALLY ENGINEERED ORGANISMS USED IN THE ENVIRONMENT 3, 3-4. Modern techniques of genetic manipulation focus on recombinant DNA ("rDNA") technology, whereby a target piece of genetic information encoded in DNA is identified, isolated and manipulated, resulting in the end product known as rDNA. *See id.*

4. *See, e.g.*, Earp, *supra* note 1, at 1635; Ruth E. Harlow, Note, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553, 553 (1986).

5. *See* Earp, *supra* note 1, at 1635 ("Companies make biotechnological products for a wide range of applications, including healthcare, agriculture, and bioremediation."); *see also* OECD, *supra* note 1, at 16-23 (describing a vast array of potential biotechnological uses).

A sample of agricultural and environmental uses would include: transforming various plant species to attain "resistance to particular herbicides, resistance to viruses and insects, improved fruit ripening characteristics such as delayed spoilage, and improved nutritional value. . . ." Earp, *supra* note 1, at 1636, and using microorganisms "to degrade toxic pollutants . . . produce industrial chemicals, and act as pesticides." EPA 1986 Statement of Policy, *supra* note 1, 51 Fed. Reg. at 4.

6. Earp, *supra* note 1, at 1635 n.3 (citing Ernst & Young's Eighth Annual Report on the Biotechnology Industry).

has reported revenues of seven and a half billion dollars.[7]

However, the risk of introducing genetically manipulated agriculture into the environment remains dangerously uncertain.[8] One major concern is that microorganisms may have the potential to reproduce and spread when released into the environment, as opposed to traditional chemicals, which usually tend to dissipate.[9] As one commentator has noted: "[u]nless the scope and conditions of initial releases of genetically engineered microorganisms are carefully limited, they can upset delicate ecological balances."[10] These risks could present disastrous results, and it is the responsibility of environmental regulators to guard against them.[11]

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7. *See* Bob Van Voris, *In-House Counsel: R. William Ide III, Monsanto Corp.*, NAT'L L.J., Nov. 2, 1998, at B1.

8. *See, e.g.*, Pollan, *supra* note 1, at 49 ("Uncertainty is the theme that unifies much of the criticism leveled against biotech agriculture by scientists and environmentalists.").

9. *See* Thomas O. McGarity, *Federal Regulation of Agricultural Biotechnologies*, 20 U. MICH. J.L. REFORM 1089, 1093-94 (1987); *see also* OCED, *supra* note 1, at 28.

10. McGarity, *Federal Regulation*, *supra* note 9, at 1094. The natural ecological balance can be disrupted in a variety of specific ways: ". . .(i) direct but unanticipated effects of modified organisms on non-target species; (ii) effects on the outcome of direct interactions among species; (iii) alteration of indirect relationships between species; (iv) influences on the biochemical processes that support all ecosystems; and (v) changes in the rate and direction of the evolutionary responses of species to each other and to their physical and chemical environments." OECD, *supra* note 1, at 29.

Furthermore, these risks are not merely speculative. In one of the first genetically engineered microbial pesticide experiments, a bacterium that lived on the roots of crop plants was engineered to secrete a chemical to kill cutworms. However, it soon became apparent that the bacterium applied its pesticide continuously, regardless of whether the target insects are present in the field or not. This experience demonstrates the potential for real harm, not only in terms of the overall ecosystem but also in terms of increasing resistance to the pesticide in the target insect population, which, because of constant exposure, may very well incur a higher threshold of resistance (if not immunity) to the pesticide. *See* McGarity, *Federal Regulation*, *supra* note 9 at 1094.

11. *See* Pollan, *supra* note 1, at 51 (quoting a biotechnology executive as assuring that the government regulatory agencies are responsi-

The EPA has attempted to address these concerns by revising regulations to determine the safety level of a manufacturer's experimental testing of new bioagricultural products.[12] These "screening" regulations administer the EPA's first contact with a genetically engineered microbial product.[13] It is at this initial stage of contact that the EPA determines the safety level of the genetically engineered microbial product, a preliminary decision that will likely influence further regulation of that product.[14] The EPA's decision-making process involves two crucial steps: first, the EPA must gather all relevant information on the particular product to be regulated ("information acquisition"); second, the EPA must assess the information received so as to proceed to a regulatory decision on that product.[15] Information plays a crucial role in the EPA's screening of genetically engineered microbial products.[16]

However, this neat and compact approach obscures a very troubling reality: it is uncertain whether the EPA is able to make quality regulatory decisions in a risk-based industry like biotechnology.[17] Before delving into the EPA's capacity for legitimate decision-making, this Note will provide a brief historical back-

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ble for product safety).

12. *See infra* Section I.C.1 and I.C.2.

13. *See id.*

14. For example, under TSCA, once a specific chemical substance is deemed to satisfy the regulatory safety requirements, it may eventually be exempted from any further regulatory interference by being listed on the TSCA Inventory. *See* Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act; 62 Fed. Reg. 17910, 17911 (1997) (to be codified at 40 C.F.R. Parts 700, 720, 721, 723, and 725) (hereinafter "TSCA Final Rule"); *see also infra* Section I.C.2.

15. *See infra* Section II. It is important to note that information acquisition and information assessment are only two steps in the regulatory maze. *See* John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 U. COLO. L. REV 261 (1991). I have decided to restrict this analysis to these two regulatory steps.

16. *See* Applegate, *Perils*, *supra* note 15, at 261 ("Information remains the sine qua non of the rational development of specific regulatory commands regarding hazardous chemicals.").

17. *See infra* Section III.

ground as context for where we are today. Part I will analyze the historical relationship between federal regulatory agencies and what has become known as the biotechnology industry.[18] Part I will then look at what some early commentators suggested as an ideal regulatory scheme for biotechnology[19] followed by a brief synopsis of the contemporary EPA regulatory scheme.[20] Part II of this Note will critically analyze the capacity of this regulatory scheme to produce legitimate decisions, and maintain that the majority of commentators who have critiqued the EPA's information acquisition strategies have fallen short of laying out in an explicit fashion the very real potential of industry concealment of unfavorable information.[21] Part II will also argue that the lack of any meaningful public participation in the regulation process also hampers the quality of information that the EPA may ultimately acquire.[22] Finally, Part II will question whether the EPA can properly make regulatory decisions based on the information acquired.[23] The general framework used for such decisions is known as "risk assessment"[24] and is itself a highly controversial tool for decision-making.[25] Part III will present a possible alternative to correct this regulatory quagmire. When one examines risk assessment in conjunction with the problems of information acquisition, it becomes apparent that the EPA should make it imperative to publicize the assessment strategies it uses to determine a genetically engineered microbial product's safety at the product's initial screening.[26] By opening the process up to commentary, such a strategy would go a long way toward alleviating these problems.[27]

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18. *See infra* Section I.A.
19. *See infra* Section I.B.
20. *See infra* Section I.C.
21. *See infra* Section II.A.1.
22. *See infra* Section II.A.2.
23. *See infra* Section II.B.
24. *See infra* Section II.B.2.
25. *See id.*
26. *See infra* Section III.
27. *See id.*

I. FEDERAL REGULATION OF BIOTECHNOLOGY

Before analyzing the precise nature of the EPA's decision-making strategies, it is first necessary to step back and review the biotechnology industry's relationship with the federal government. This section will first examine the historical roots of government involvement in the biotechnology industry,[28] as well as one commentator's early suggestion for an ideal regulatory scheme aimed at the then-burgeoning biotechnology industry.[29] Second, it will turn to the actual regulatory regime as currently in force in the EPA and will describe the recent EPA screening regulations.[30] Examining these regulations in light of the history that preceded their development provides a concrete backdrop for the regulatory information demands that will be critiqued later on in this Note.[31]

A. *Historical Background*

Federal regulation of genetic manipulation technologies can be traced back to 1974.[32] At that time, rDNA techniques were first being developed, and some scientists expressed concern that then-existing laboratory research methods would not sufficiently contain the results of laboratory experiments on genetically engineered bacteria.[33] Scientists feared that should such containment strategies fail, the genetically altered bacteria would then colonize in humans or the environment, with possibly catastrophic

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28. *See id.*

29. *See infra* Section I.B.

30. *See infra* Section I.C.

31. *See infra* Section II and III.

32. Various works treat the controversies surrounding the "birth" of biotechnology in some detail. *See, e.g.*, KRIMSKY, *supra* note 3, at 339 (1982); JOSEPH MONROE AND EDWARD J. WOODHOUSE, AVERTING CATASTROPHE: STRATEGIES FOR REGULATING RISKY TECHNOLOGIES (1986); Raymond A. Zilinskas and Burke K. Zimmerman, The Gene-Splicing Wars: Reflections on the Recombinant DNA Controversy (1986); Susan Wright, *Molecular Biology or Molecular Politics? The Production of Scientific Consensus on the Hazards of Recombinant DNA Technology*, 16 SOC. STUD. SCI. 593 (1986).

33. *See* E.J. Woodhouse and Patrick W. Hamlett, Decision Making About Biotechnology: The Costs of Learning From Error, *in* The Social Response to Environmental Risk: Policy Formulation in an Age of Uncertainty 131, 138 (Daniel W. Bromley & Kathleen Segerson eds., 1992).

consequences.[34] While some scientists voluntarily canceled their experiments, agreeing that a closer examination of the risks should precede further experimentation, others continued with their work.[35] In 1974, a National Academy of Sciences committee called for a moratorium on many types of rDNA experiments, and all researchers in the field voluntarily complied.[36] The National Institute of Health later published formal guidelines, banning certain experiments and limiting permissible experiments to those that would conform to specified containment methods.[37]

Such federal involvement in the initial research and development stage of biotechnology led to the expectation of further regulations to govern the biotechnology industry as it moved into the commercialization stage in the early 1980s.[38] However, it was discovered that not only was there an absence of a single statute on point to specifically cover the risks associated with biotechnology, but the various federal agencies were unprepared to apply their enabling statutes to biotechnology.[39] The Reagan administration formed an interagency working group, the Domestic Policy Council Working Group on Biotechnology, and charged it with drafting an overall federal framework for regulating biotechnology.[40]

In 1986, the results were published by the Office of Science and Technology Policy as the "Coordinated Framework for Regulation of Biotechnology"[41] ("Coordinated Framework"). This document emphasized that adequate regulation of biotechnology would be achieved through the existing statutory authorities and that no new legislation would be sought.[42] In light of biotechnology's diverse product developments, the Coordinated Framework

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34. *See id.* at 138; *see also supra* notes 8-11 and accompanying text (discussing the risks of biotechnology).

35. *See* Woodhouse, *supra* note 33, at 138.

36. *See id.* at 138.

37. *See id.*

38. *See* McGarity, *Federal Regulation*, *supra* note 9, at 1100.

39. *See id.*

40. *See id.*

41. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (1986).

42. *See id.* at 23302.

divided regulatory authority among five federal agencies that would regulate biotechnological products that fell under their traditional field of regulation.[43] In anticipation of the problems such a divided regulatory system might produce, the Biotechnology Science Coordinating Committee had already been established to coordinate the policies of the various agencies wielding regulatory authority over biotechnology products.[44]

This brief history of the biotechnology industry describes an enterprise plagued by the perception of risk.[45] The overwhelming response to this perception of risk was careful and steady progress.[46] Unfortunately, this original response has been transformed into the current problematic regime.[47] However, as the current regulations were taking shape, commentators addressed what would ideally be involved in the regulation of an area like biotechnology.[48] This section now turns to analyze those early suggestions, which in the end will hopefully illuminate the present.

B. *The Ideal Regulatory Framework for Biotechnology*

As the biotechnology industry came to prominence in the mid-1980s, commentators had to address not only what an ideal regulatory framework for agricultural biotechnology would look like, but also whether there should be any regulation of agricultural biotechnology at all.[49] Once the latter question had been affirmatively answered, commentators began to speculate on what such

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43. *See* Earp, *supra* note 1, at 1640. These named agencies were the Food and Drug Administration, the United States Department of Agriculture, the Environmental Protection Agency, the National Institutes of Health, and the Occupational Safety and Health Administration. *See id.*

44. *See* Coordinated Framework for Regulation of Biotechnology: Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47174 (1985).

45. *See, e.g.*, McGarity, *Federal Regulation*, *supra* note 9, at 1102.

46. *See id.*

47. *See infra* Section I.C.

48. *See infra* Section I.B.

49. *See, e.g.*, McGarity, *Federal Regulation*, *supra* note 9, at 1102.

a regime would ultimately look like.[50]

These commentators agreed upon certain points, most of which are present in the current regulatory regime in one form or another.[51] Among these points of agreement, commentators stressed the need for some sort of pre-release notification as a favorable method to initiate regulation.[52] Gathering, evaluating, and assessing the risks of relevant data would form a second step.[53] The next logical step presents a risk management procedure, which adequately responds to the risks presented.[54] Finally, in a controversial area like biotechnology, the ideal regulatory regime should provide for broad public participation in the decision-making process.[55]

To varying extents, these ideal elements are all present in the EPA's regulation of genetically engineered microbial products.[56] However, it is important to emphasize that the elements are present to "varying extents" - some more than others.[57] The suggestions of these early commentators have been adopted in ways that may compromise the ultimate effectiveness of the EPA's information acquisition and its subsequent assessment.[58]

The current regulatory framework, as supplemented by recent regulations, lays out the formal decision-making methodology. This following section will briefly analyze the statutes and the relevant regulations. This regulatory framework lays out the statutory basis for the information demands of EPA decision-making.

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50. *See id.*

51. *See infra* Section I.C.

52. *See* McGarity, *Federal Regulation, supra* note 9, at 1102. Advance notification gives an agency an opportunity to decide whether to exercise its regulatory power, and thus allows the agency to play a proactive role in the exercise of that regulatory power. *See id.* at 1102-03.

53. *See id.* at 1103; *see also infra* Section II.A. and II.B.

54. *See id.* at 1106-08. The topic of risk response is beyond the scope of this paper.

55. *See* McGarity, *Federal Regulation, supra* note 9, at 1108.

56. *See id.* at 1109-42; *see also* Mary Jane Angelo, *Genetically Engineered Plant Pesticides: Recent Developments in the EPA's Regulation of Biotechnology*, 7 U. FLA. J.L. & PUB. POL'Y 257 (1996).

57. The lack of any meaningful public participation is one such notable exception. *See infra* Section II.A.2.

58. *See id.*

C. *EPA Statutory Authority*

The EPA reviews genetically engineered microbial products primarily under two statutory authorities.[59] In doing so, the EPA looks to determine whether any health or environmental risks are present.[60]

1. FIFRA

The EPA regulates the use of genetically manipulated pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").[61] FIFRA authorizes the EPA to regulate the testing of new pesticides or new uses of existing pesticides.[62] Traditionally, the EPA was concerned only with regulating large-scale tests.[63] Depending on the degree of risk present, the EPA would then determine whether an Experimental Use Permit ("EUP") was necessary. If an EUP was indeed necessary, the EPA would assume oversight over the proposed testing.[64] The EPA generally presumed that small-scale tests would not require EUP notification.[65]

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59. *See* EPA 1986 Statement of Policy, *supra* note 1, at 23314.

60. *See id.*

61. 7 U.S.C. §§ 136-136(y) (1976). The Act defines "pesticide" as: "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliator or desiccant . . . ." 7 U.S.C. § 136(u) (1976). The broad scope of this definition allows the EPA to regulate the use of both traditional chemical pesticides as well as biological pesticides (whether genetically engineered or not). *See, e.g.*, Angelo, *supra* note 56, at 264.

62. 7 U.S.C. § 136(c) (1976).

63. 40 C.F.R. § 172. Under this regulatory scheme, an individual who intended to test either a new pesticide or a new use of an existing pesticide on a terrestrial application covering a cumulative total of more than ten acres of land or any aquatic application covering more than one surface acre of water was required to notify the EPA prior to initiating such testing. *See id.*

64. *See* Microbial Pesticides; Experimental Use Permits and Notifications, 59 Fed. Reg. 45600, 45600 (1994) (to be codified as amendments to 40 C.F.R. 172) (hereinafter "FIFRA Final Rule").

65. *See id.* Small-scale tests were used to refer to testing on a terrestrial application covering a cumulative total of less than ten acres of land or any aquatic application covering less than one surface acre of

However, as the application of genetically engineered microbial pesticides grew, the EPA realized that small-scale testing of such genetically engineered microbial pesticides would likely pose "sufficiently different risk considerations from conventional chemical pesticides."[66] The agency decided to modify the presumption that small-scale testing would be exempt from the EUP reporting requirement. As per the final rule issued in 1994,[67] the EPA now requires that it be notified prior to small-scale testing in the environment of certain genetically engineered microbial pesticides in order to determine whether such testing should be conducted under an EUP.[68]

In deciding whether to issue an EUP, the EPA considers whether the proposed activity will cause any unreasonable adverse affect on the environment.[69] To determine unreasonable adverse effects on the environment, the EPA must consider both humans and the natural environment, "taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[70] In conducting such an inquiry, the EPA adopts a standard of unreasonable risk,[71] and proceeds by balancing both the risks and benefits presented by use of the pesticide.[72] In order to determine whether the risk is in fact "unreasonable," the EPA undertakes a risk assessment of the product at issue.[73]

The dynamics of the EPA's risk assessment inquiry and its implications will be explored in depth later in this Note. In order to complete the analysis of the formal agency regulatory mechanism in biotechnology, this section now turns to the EPA's other main enabling statute.

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water was required to notify the EPA prior to initiating such testing. 40 C.F.R. § 172.

66. *See* 59 Fed. Reg. 45600, *supra* note 64, at 45600.
67. *See id.*
68. *See id.*
69. *See id.*
70. 7 U.S.C. § 136(bb) (1976).
71. *See* Applegate, *Perils*, *supra* note 15, at 268.
72. *See* Angelo, *supra* note 56, at 265.
73. *See* Applegate, *Perils*, *supra* note 15, at 277.

2. TSCA

Genetically-engineered microbial products may also be regulated under the Toxic Substances Control Act ("TSCA") as chemical substances.[74] Under section 5 of TSCA, all new chemical substances are subject to a screening process known as "premanufacture notification" ("PMN").[75] Once the EPA receives a PMN, the agency has ninety days to determine whether to regulate the product so as to prevent unreasonable risk or substantial exposure.[76] If the agency does not act within those ninety days, the product may be used as intended and will be listed on the TSCA Inventory, which designates those substances that are not "new."[77]

As with the EUP provision of FIFRA, the EPA recently revised the PMN process as it applies to biotechnology.[78] TSCA established certain exemptions from the PMN requirement.[79] In particular, substances manufactured in small quantities for research and development were exempted in what came to be known as the "small quantities" research exemption.[80] This had the effect of exempting nearly all research and development activities from PMN reporting requirements.[81]

Prompted by concerns similar to those under FIFRA, the EPA created a new PMN reporting process for biotechnology known

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74. *See* Angelo, *supra* note 56, at 267. The Act defines chemical substances as "any organic or inorganic substance of a particular molecular identity, including . . . any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature . . . ." 15 U.S.C. § 2602 (1994). The authority to regulate genetically engineered microbial products under TSCA is justified by the EPA under the rationale that "[o]rganisms, both naturally occurring and genetically engineered, are made up of substances of particular identities that occur in nature, or occur in whole or part as a result of a chemical reaction. Thus, organisms are chemical substances under TSCA." Angelo, *supra* note 56, at 267.

75. *See* 15 U.S.C. § 2604 (1994).

76. *See* 15 U.S.C. § 2604(a) (1994).

77. *See* Angelo, *supra* note 56, at 268.

78. *See* TSCA Final Rule, *supra* note 14.

79. *See* 15 U.S.C. § 2604(h) (1994).

80. *See* 15 U.S.C. § 2604(h)(3) (1994).

81. *See* Angelo, *supra* note 56, at 268.

as Microbial Commercial Activity Notices ("MCANs").[82] The EPA reasoned that no amount of microorganisms released into the environment should be considered a "small quantity" because of the unique risks associated with microorganisms — namely, the potential to multiply, spread, and become established in the environment.[83] The EPA will regulate the product development under an MCAN if the agency determines that an "unreasonable risk to human health and the environment" is present.[84] As with the EUP, this inquiry adopts a standard of unreasonable risk[85] that is determined according to the process of risk assessment.[86]

II. THE REALITY OF REGULATION

Having laid out the history of government involvement in bioagriculture and the current regulatory framework for the bioagriculture industry, Part III now critically analyzes how this regulatory framework is acted out in the screening of new products. Both the EPA's information acquisition and information assessment strategies stem from the regulatory framework. However, the deficiencies present in both information acquisition and information assessment become especially glaring in light of the historical government interaction with the industry as well as the EPA rationale for updating the screening regulations.

The screening process serves an important function as the essential initial contact in regulation.[87] The decision of whether or not to regulate is a powerful one and could set the tone for future regulatory efforts of that same product.[88] The legitimacy of the regulatory outcome is in a certain way dependent upon the quality of information available to the agency in making its decision.[89] In analyzing the risk decision-making process of the EPA,

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82. *See* TSCA Final Rule, *supra* note 14.

83. *See* EPA 1986 Statement of Policy, *supra* note 1, at 23326-30.

84. TSCA Final Rule, *supra* note 14, at 17910. This will permit the agency to maintain oversight into the proposed product development. *See id.*

85. *See* Applegate, *Perils*, *supra* note 15, at 268.

86. *See id.* at 277.

87. *See supra* Section II.C.2.

88. *See supra* text accompanying note 14.

89. *See* Applegate, *Perils*, *supra* note 15, at 261-3.

the following section will concentrate on the information acquisition and information assessment.[90]

A. *Information Acquisition*

1. The Regulated Entity

Both TSCA and FIFRA place the burden on the manufacturer to notify the agency in the event of commencing potentially regulated activity.[91] On the one hand, placing the burden of notification on the manufacturer makes sense. Having the regulated entity provide the necessary information to the EPA represents an allocative efficiency of transaction costs — manufacturers may develop this information more cheaply than the EPA since they and their customers may be in a better position to bear the cost of developing the necessary information.[92]

On the other hand, having the regulated party provide the initial information that determines whether regulatory activity will occur carries some very troubling undertones. While it is true that the EPA reviews the data received in conjunction with its own knowledge base,[93] the fact remains that the industry participant is the one providing the initial information. The industry participant has an interest in seeing the product quickly available on the market so a return can be made on the initial invest-

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90. In reality, these two processes are not exclusive but are rather more fluid, open-ended processes. However, for the sake of analysis, this paper draws such a formalistic distinction.

91. Under the 1994 EUP regulations, any party intending to initiate a small-scale test in the environment using certain microbial pesticides must notify the EPA so the agency may then determine whether to oversee the testing under a EUP. *See* 59 Fed. Reg. 45600, 45600 (1994). Similarly, under the 1997 MCAN provisions, a manufacturer must notify the EPA ninety days prior to commencing the manufacture of a genetically engineered microbial, unless that genetically engineered microbe has been specifically exempted from the reporting process. *See* 67 Fed. Reg. 17910, 17911 (1997); *see also* 15 U.S.C. § 2601(b)(1) (1994).

92. Applegate, *Perils*, *supra* note 15, at 310.

93. *See, e.g.*, Applegate, *Perils*, *supra* note 15, at 301-10 (identifying information sources such as compilations of existing data, record-keeping, monitoring, inspection, and the government's own research).

ment.[94] The EPA, however, is looking to such information for possible oversight or even rejection of the proposed activity.[95] These conflicting roles may open the door to a form of agency capture:[96] the regulated entity has great incentive to manipulate the data submitted to the EPA in the hopes of an expedient and favorable resolution to the screening of its product.[97] While some have commented on this dynamic, these commentators tend to downplay the potential for abuse it creates.[98] This paper, however, posits that the potential abuses of this adversarial dynamic should not be glossed over so lightly.

Voluntary disclosure of information encourages the free flow of information that may help the agency to meet its regulatory demands more efficiently.[99] However, the use of this self-disclosed information in a regulatory context to then punish the person who initially disclosed the information can cripple the free flow of such information.[100] This dilemma is well illustrated by the regulatory use of voluntary environmental self-audits.[101] In essence, an environmental audit allows an assessment of the actual and potential environmental problems facing corporations.[102] A

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94. *See infra* text accompanying notes 119-123.

95. *See, e.g.*, FIFRA Final Rule, *supra* note 64, at 45601 (enumerating the possible EPA determinations at the conclusion of an EUP review).

96. *See* Bradford C. Mank, *Superfund Contractors and Agency Capture*, 2 N.Y.U. ENVTL. L.J. 34, 49-52 (1993). The author explains that while capture of the entire EPA is highly unlikely, capture of a discrete unit within the agency may indeed occur. *See id.*

97. *See* Applegate, *Perils*, *supra* note 15, at 311.

98. *See id.* ("The conflict rarely results in outright concealment, falsification, or deliberate misstatement of results (though this unfortunately is not unknown).").

99. *See infra* text accompanying notes 105-108.

100. *See infra* text accompanying notes 110-113.

101. The EPA has defined voluntary environmental self-audits as a "systematic, documented, periodic and objective review by regulated entities of facility operations and practices related to meeting environmental requirements." EPA Environmental Auditing Policy Statement, 51 Fed. Reg. 25004, 25006 (1986).

102. *See* Annette T. Crawley, Note, *Environmental Auditing and the "Good Samaritan" Doctrine: Implications for Parent Corporations*, 28 GA. L. REV. 223, 227 (1993).

company that voluntarily discloses any such environmental problems may attain significant penalty reductions.[103]

The voluntary disclosure of such highly unfavorable information has certain virtues.[104] Voluntarily disclosed violations may be subsequently corrected through the corporation's own initiative, making for a smoother resolution than if the violations were discovered independently by the government.[105] Further, such practice builds favorable public relations as well as good relationships with the regulatory agency and instills a sense of accountability within the corporation.[106] Finally, this practice informs the EPA of compliance trends — knowledge the agency can use in later regulatory development.[107]

In effect, the agency relies on the voluntarily disclosed information to further its goal of ensuring compliance with environmental standards without the need to incur the cost of site inspections and record searches.[108] However, the dynamics of this information exchange present a real problem in that the EPA uses the voluntarily disclosed information to proceed with an enforcement action against the corporation.[109] In the worst case scenario for the corporation, the environmental prosecutor may use the company's own admission of violations in the audit as proof of the requisite knowledge requirement for bringing a criminal violation proceeding.[110] By punishing the good-faith acts of vol-

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103. *See* Krista McIntyre, *Voluntary Disclosure: Gotcha!*, NAT. RESOURCES J. 52, 52 (Spr. 1997) (citing numerous such administrative and judicial settlements in 1996).

104. *See, e.g.*, EPA Final Policy Statement on Incentives for Self-Policing: Discovery, Disclosure, Correction, and Prevention of Violations, 60 Fed. Reg. 66706 (1995).

105. *See* McIntyre, *supra* note 103, at 53.

106. *See id.*

107. *See id.* Another virtue of the environmental self-audit protocol is that the penalties imposed by such an audit present an easy revenue-generating device for an agency that must normally depend on a "fierce budgetary process or congressional approval." Somendu B. Majumdar, *Voluntary Environmental Compliance Auditing: A Primer*, 7 FORDHAM ENVTL L.J. 817, 827 (1996).

108. *See* Majumdar, *supra* note 107, at 827.

109. *See* McIntyre, *supra* note 103, at 53.

110. *See* Mark L. Manewitz et al., *Environmental Audit Policy*, 7 FORD-

untary disclosure with the potential of crushing liability, the EPA may effectively be creating a disincentive to the free flow of information between the regulated community and the EPA.[111] As a result, the industry remains wary of undertaking voluntary environmental audits.[112] Environmental enforcement suffers unless the agency undertakes its own costly enforcement proceedings.

This example illustrates the tension between competing interests present when a regulated entity provides information of its own accord to the regulating agency, information which the agency may then use against the entity. The tension between these competing interests may not only result in the disuse of a valuable and efficient regulatory tool, but also, in the extreme, such reliance on regulated entities for information instrumental in shaping regulatory efforts can lead to outright falsification of data.[113]

Unfortunately, examples of such occurrences are widely present. For example, asbestos industry insiders expressed surprise at the public revelation of the toxic effects of asbestos exposure, when, in fact, serious and widespread harm was suspected as early as the 1930s.[114] The controversy over the current tobacco settlement proposal provides yet another example of regulatory information concealment. As part of the proposed settlement, the industry must disclose internal documents and health files previously asserted to be confidential.[115] Included in these inter-

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HAM ENVTL. L.J. 775, 782 (1996). While the EPA has issued an interim policy statement declaring that the agency will not use audit information in making criminal referrals and will reduce penalties for corporations who voluntarily disclose and correct such violations, regulated entities remain anxious that this is merely a policy statement and as such, non-binding. *See id.* at 786-88.

111. *See* McIntyre, *supra* note 103, at 53.

112. *See* Majumdar, *supra* note 107, at 845.

113. "So many examples of financially motivated bias exist that the motives and work of industrial scientists and consultants are inevitably distrusted." Richard Peto, *Distorting the Epidemiology of Cancer: The Need for a More Balanced Overview*, 284 NATURE 297 (1980).

114. *See* Mary L. Lyndon, *Tort Law & Technology*, 12 YALE J. ON REG. 137, 150 (1995).

115. *See* Tobacco Settlement Document, Appendix VIII, at 64, available at <http://tobaccofreekids.org/html/page_12.html> (visited on

nal documents are discussions of the manipulations of nicotine,[116] which is believed to confirm that the industry fostered cigarette addiction.[117]

These illustrations are directly relevant to bioagricultural industry. Biotechnology as a whole is one of the most highly profitable industries today.[118] Such high profits in the face of rapid technological change have given rise to a highly competitive marketplace. Financial predictions have announced that, "[c]ompanies that are able to accelerate the product development process and reduce time-to-market will realize earlier revenues and a faster return on R[esearch]&D[evelopment] investment."[119] The rapid commercialization of biotechnology is moving ahead with few calls for caution and restraint.[120] While the emphasis on entering the market with the most lead-time drives considerations of profitability of a new product, it also encourages "efficacy research and discourages attention to product

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March 26, 1998). Such disclosure will still be subject to privilege and trade secret protection, to be reviewed by the Attorney General. *See id.* Note: This paper was finalized prior to the recent demise of tobacco legislation. It remains unclear what effect, if any, that demise will have on the settlement.

116. *See* Richard Sloane, "Details of the Tobacco Industry Settlement," N.Y.L.J. August 19, 1997 at 4.

117. *See* American Cancer Society, Official Position on the Tobacco Settlement, available at <http://www.cancer.org/advocacy/tobaccoposition.html> (visited on March 29, 1998).

118. *See, e.g.*, Allen R. Myerson, *Breeding Seeds of Discontent: Cotton Growers Say Strain Cuts Yields*, November 19, 1997, N.Y. TIMES D1, D5 (describing Monsanto, a company involved in bioagriculture as valued at nine billion dollars).

119. Mercer County Chamber of Commerce, *Bio-Imaging Technologies: Re-engineering the Drug Development Process*, 69 MERCER BUSINESS 14, 14 (1993).

120. *See* Woodhouse, *supra* note 33, at 140. In the mid-1980s, while the Coordinated Framework was first to establish its regulatory process, "several flagrant procedural violations occurred, including unauthorized field tests by Monsanto, by Genetic Sciences, and by a Montana State University researcher who declared his deed to be 'an act of civil disobedience.' " *Id.* at 141-42 (quoting Michael D. Lemonick, *Montana's State's Troublesome Elms*, TIME MAGAZINE, Sept. 14, 1987 at 67).

safety and side effects."[121] Research into side effects takes time and may delay a product's market introduction, creating a strong disincentive to study such effects.[122]

These considerations carry important implications. Both the MCAN and EUP regulations apply to the EPA's initial contact with a new genetically engineered microbial product. The adversarial dynamics of this screening process not only encourage the withholding of information (as in the self-audit illustrations), but because of the competitive, profit-driven characteristics of the biotechnology industry, the process also maintains a very real potential for outright concealment of health and safety data that may stall a product's time to market.

2. Public Participation

The degree of public participation is another area of information acquisition that presents problems in the screening of bioagricultural products. Biotechnology regulation as a whole should ideally embrace the broadest possible public participation, considering both the controversial nature of such work[123] and the public's lack of confidence in regulatory agencies.[124] The mistakes encountered by the nuclear power industry illustrate the importance of engaging public confidence in the face of a high-risk technology.[125] Due to a failure to engage the public in

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121. *See* Lyndon, *supra* note 114, at 148.

122. *See id.* at 146.

123. *See, e.g.*, MAE-WAN HO, GENETIC ENGINEERING: DREAM OR NIGHTMARE? (1998); Jeremy Rifkin, *The Biotech Century: Playing Ecological Roulette with Mother Nature's Designs*, EARTH ACTION NETWORK, April 1998, at 36; Melanie Payne, *Genetic Fears*, CHI. TRIB., April 29, 1998, at C7; *Genetic Warfare*, THE ECONOMIST, May 16, 1998, at 87; *Genetic Issues to Heat Up in Congress*, THE BULLETIN'S FRONTRUNNER, August 22, 1997 at 1; *see also* V. Kerry Smith, *Environmental Risk Perception and Valuation: Conventional Versus Prospective Reference Theory in* THE SOCIAL RESPONSE TO RISK: POLICY FORMULATION IN AN AGE OF UNCERTAINTY 23 (Daniel W. Bromley and Kathleen Segerson eds., 1992) (discussing how people formulate perceptions about environmental risks).

124. *See* McGarity, *Federal Regulation*, *supra* note 9, at 1108 (pointing to efforts in the early 1980s to dismantle the EPA and other health and environmental agencies).

125. *See* Woodhouse, *supra* note 33, at 136; *see also* Charles L. El-

early discussions about the nuclear power industry, those advocating for nuclear power as an energy resource faced an overwhelmingly negative public response. The public cried out, fearing potentially catastrophic meltdowns. This backlash destroyed the industry after a hundred billion dollars had already been invested in large-scale nuclear power plants.[126] However, if the public had been engaged at the industry's inception, perhaps alternative, more acceptable modes of operation could have been devised, and the industry would continue to represent a viable energy alternative today.[127] Thus, while public participation can be burdensome to regulatory agencies and possibly even delay regulatory decision-making, it is crucial to engage the relevant public at least during the initial development of a new technology.[128] Should the technology then develop uneventfully, the public will focus its attention on other concerns, and delays should not clog the regulatory process.[129]

Public involvement in agency regulation of new technologies can therefore be described as a central element in creating an "intelligent" regulatory mechanism. Public participation "opens up the process of agency policy innovation to a broad range of criticism, advice, and data;"[130] the decisions ultimately reached tend to be more "intelligent" than those actions decided upon after one-sided contemplation. However, to expect general public comments in a highly technical area like biotechnology is unreasonable; therefore, public interest groups are generally in the best position to serve as proxies for the general public opinion when technical, highly specialized material makes up the subject-matter of agency regulation.[131]

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kins, Current Models of Risk Assessment used in Biotechnology Regulation *in* BIOTECHNOLOGY AND THE ENVIRONMENT: THE REGULATION OF GENETICALLY ENGINEERED ORGANISMS USED IN THE ENVIRONMENT 11, 11-12 (1988).

126. *See* Woodhouse, *supra* note 33, at 136.

127. *See id.* (noting how policy-makers may have pushed more strongly for the development of smaller (thus "safer") reactors).

128. *See* McGarity, *Federal Regulation*, *supra* note 9, at 1108.

129. *See id.*

130. Nat'l Petroleum Refiners Ass'n v. Fed. Trade Comm'n, 482 F.2d 672, 683 (D.C. Cir. 1973).

131. *See* Steven P. Croley, *Theories of Regulation: Incorporating the Ad-*

"Intelligent" decision-making in the context of a risk-enterprise can simply mean the reduction of potential error.[132] Studies of decision-making models have identified four elements that greatly reduce those odds of unacceptably costly errors:

> (1) Early, vigorous review from diverse points of view designed to debate the goals, potential pitfalls, and strategies to be pursued,
> (2) Built-in flexibility to delay accumulation of technological momentum and to make it feasible to alter directions in light of experience,
> (3) Initial precautions to guard against egregious errors during the first several decades when a technological system is likely to have the highest uncertainty, and the greatest potential for inadvertent harm, and
> (4) Active monitoring of feedback and other ways of accelerating learning from experience.[133]

In each of these four elements of intelligent decision-making, there is a continuous emphasis on the value of debate;[134] the more informed the decision-making process is, the more intelligent the ultimate decisions will be.[135]

However, the reality of public participation in the screening process is far from the ideal of contributing to informed and intelligent decision-making.[136] The biotechnology industry developed from cautious and deliberate research and development techniques, emphasizing debate and inquiry before actual testing.[137] Yet, after little more than ten years of experience with bio-

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ministrative Process, 98 COLUM. L. REV. 1, 143 (1998).

132. *See* Woodhouse, *supra* note 33, at 136.

133. *Id.*

134. *See id.* at 136-38 (defining the two principal considerations as the "intelligence of democracy" and flexibility).

135. "Large technological systems affect myriad people [sic] in diverse ways, and no small group of insiders will have sufficient insight (or concern) to protect enough of the competing interests. If lack of early debate allows a technology to evolve in ways that conflict with significant social needs, correcting the imbalance at a later stage can be very costly." *Id.* at 136.

136. This paper focuses only on the EUP and MCAN application process. For a discussion of public participation in the registration process, see McGarity, *Federal Regulation*, *supra* note 9, at 53-57.

137. *See* Woodhouse, *supra* note 33, at 141; *see also supra* Section II.A.

technology, the EPA seems to leave little room for public participation in the regulating and screening of genetically engineered microbial products.[138] The emphasis on debate in the four elements of decision-making seems to have been cast away. According to the four elements of decision-making, this abandonment indicates that the public has shifted its attention to other new industries, as if there were no longer any controversies in biotechnology.[139] As the decision-making model asserts, public involvement is crucial to initial developments in new technologies, but once the industry develops quietly, public attention will most likely be diverted.[140] However, facts to the contrary exist. For example, public interest groups continue to petition the EPA against what these groups find to be dangerous practices;[141] yet, public participation in the screening of genetically engineered microbial products remains practically non-existent.[142]

Perhaps the lack of public involvement may be due to the statutory directive itself.[143] The EUP process of FIFRA presents a degree of public participation that is of somewhat questionable value. In its 1986 policy statement, the EPA noted the possibility of public comment in the EUP process.[144] If the EPA were to determine that an application may have "regional or national significance" it would publish the receipt of such an application in the Federal Register.[145] However, this may actually yield very limited participatory value because manufacturers routinely claim their health and safety data are trade secrets, thus shielding such information from the public until the EPA has completed its decision-making process.[146] As a result, the public normally does not have much substantive information in the Federal Register

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138. *See infra* notes 144-58 and accompanying text.

139. *See supra* note 134 and accompanying text.

140. *See supra* note 130 and accompanying text.

141. *See, e.g.*, Petition for Rulemaking and Collateral Relief Concerning the Registration and Use of Genetically Engineered Plants Expressing *Bacillus Thuringiensis Endotoxins, Greenpeace International v. Browner*, 11-15 (Sept. 16, 1997).

142. *See infra* notes 144-58 and accompanying text.

143. *See* Thomas O. McGarity and Sidney Shapiro, *The Trade Secret Status of Health and Safety Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837 (1980).

144. EPA 1986 Statement of Policy, *supra* note 1, at 23323.

145. *See id.*

146. *See* McGarity, *Trade Secret*, *supra* note 143, at 837-38.

on which to comment. While the applicant may share such information with the public voluntarily, the highly competitive, "rush-to-market" biotechnology industry makes this scenario very unlikely.[147] Thus, public participation in the field-testing of pesticides has been called "inadequate."[148]

Public participation is similarly lacking meaningful attributes under TSCA. Under the traditional PMN reporting process, the EPA not only gives public notice of each PMN it receives, it also publishes a monthly list of all outstanding PMNs for which the ninety-day response time has yet to expire.[149] Under this traditional practice, chemical manufacturers usually claim that virtually all the contents of their PMN are trade secrets.[150] While the EPA regularly attempts to describe allegedly confidential information as generically as possible, it is difficult for the public to know whether or not it should be concerned about a product.[151] Under the new MCAN regulations, the EPA expressed its intention to continue under a similar publishing process.[152] The manufacturer tells the EPA what information should be considered a trade secret[153] upon which the EPA publishes a generic informational narrative as provided by the manufacturer.[154] Depending

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147. *See supra* notes 119-23 and accompanying text.

148. *See* McGarity, *Federal Regulation*, *supra* note 9, at 1139.

149. *See id.* at 1141 (citing 15 USC § 2604(d)(2), (3)).

150. *See id.*

151. *See id.*

152. The EPA has stated:

> All reviews of microorganisms will follow established administrative steps that are the same for all substances subject to PMN review. First, within 5 days of receiving the PMN, EPA will issue an announcement in the Federal Register describing the submission. The announcement will include information on the identity of the new microorganism, the type of use, occupational exposure, production volume, a summary of test data submitted in the notice, and the submitter's identity.

EPA 1986 Statement of Policy, *supra* note 1, at 23327.

153. "[The published document] will have confidential business information deleted according to the manufacturer's instructions, although EPA will strongly encourage manufacturers to release as much information as possible." *Id.*

154. "If the identity and use are claimed as confidential, the Agency will include a generic description provided by the submitter." *Id.*

on the specific type of MCAN application being submitted, the EPA may or may not require the manufacturer to substantiate the claims of confidential business information that will not be made available to the public.[155] While any member of the public may submit comments during that ninety-day period,[156] the degree of public participation here is similarly inadequate. The EPA optimistically points to past voluntary PMN submitters who claimed very little information as confidential,[157] but it is doubtful that such a practice can be expected to continue in the face of the current competitive, "rush-to-market" drive of the biotechnology industry.

The reality of information acquisition presents problems that remain present in the EPA's assessment of that information. The role of the regulated entity and the lack of public participation raise concerns in an industry of risk such as bioagriculture. The following section examines the process of information assessment in EPA screening regulation for genetically engineered microbial products.

B. *Information Assessment*

1. The "Unreasonable Risk" Standard

The regulated entity and the public at large represent only two sources of information that the agency may use in making its decision. The agency must then assess that information. For both the MCAN and the EUP screening process, the EPA will undertake a risk assessment and weigh the risks and benefits of a genetically engineered microbial product's preliminary application.[158] However, problems also exist at this stage of information assessment.

Under TSCA and FIFRA, this inquiry proceeds along the "unreasonable risk" standard.[159] By delineating the threshold of un-

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155. *See* TSCA Final Rule, *supra* note 14, at 17927-78 (no substantiation requirement in TSCA Experimental Release Application, "TERA," an abbreviated reporting notice for individualized tests, *see* 1997 Final Rule at 17912 (6), but substantiation required for most reporting notices).

156. *See* McGarity, *Federal Regulation*, *supra* note 9, at 1141.

157. *See* TSCA Final Rule, *supra* note 14, at 17928.

158. *See supra* Section II.C.

159. *See id.*

acceptable risk as "unreasonable,"[160] the regulatory decision-making assumes four characteristics.[161] In the first place, the regulatory agency is regulating risk, not harm.[162] The regulation of harm attempts to address a definite, identifiable damage that has occurred,[163] but the decision-making process based on risk is, in contrast, a much more open-ended process.[164] Second, the regulatory agency is not looking to determine absolute safety; instead, the agency seeks to determine an acceptable level of "greater-than-zero risk."[165] Third, risk regulation based on a level of unreasonable risk incorporates a "cost" inquiry to determine the acceptable non-zero level of risk.[166] Finally, unreasonable risk deter-

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160. " 'Unreasonable' describes an undefined, nonzero level of risk determined on an ad hoc basis by balancing both health considerations and nonhealth concerns such as technology, feasibility and cost." Applegate, *Perils, supra* note 15, at 268.

161. *See id.* at 270; *see also* Hon. Stephen F. Williams, Keynote Address *in* BIOTECHNOLOGY AND THE ENVIRONMENT: THE REGULATION OF GENETICALLY ENGINEERED ORGANISMS USED IN THE ENVIRONMENT 1 (1988) (exploring the nature of unreasonable risk decision-making in a thought-provoking, yet conversational manner).

162. *See* Applegate, *Perils, supra* note 15, at 271.

163. *See id.* at 272.

164. *See id.* at 273. This characteristic of risk decision-making is one of the main reasons so many commentators have taken issue with risk assessment. *See infra* Section III.B.2.

165. Applegate, *Perils, supra* note 15, at 274. Eliminating all risk from daily activities is virtually impossible. *See* Kathleen Segerson, *The Policy Response to Risk and Risk Perceptions, in* THE SOCIAL RESPONSE TO RISK: POLICY FORMULATION IN AN AGE OF UNCERTAINTY 101, 101 (Daniel W. Bromley and Kathleen Segerson eds., 1992) ("Virtually every human activity involves a certain amount of risk, from walking downstairs and crossing the street and eating and breathing. Thus, the goal of a risk-free environment is meaningless, unless individuals are willing to cease all activity."). The question then becomes, *how much* risk should we allow? *See* Hon. Stephen F. Williams, Keynote Address, *supra* note 161, at 1.

166. Applegate, *Perils, supra* note 15, at 274-6. In determining acceptable levels of risks, the question of costs to be incurred (both on the level of potential hazard to human health and in incurring industry compliance) is an important factor that the agency must address. *See, e.g.*, Hon. Stephen F. Williams, Keynote Address, *supra* note 161; Lester Lave, *Benefits-Costs Analysis: Do Benefits Exceed Costs? in* RISK, COST

mination is invariably an ad hoc decision-making process, allowing flexibility and a wide range of different factors to come into the decision-making process.[167] Ad hoc decision-making can also be seen as increasing the arbitrariness of an already open-ended process.[168]

These four characteristics of determining risk on an unreasonable basis form the background for the information demands of the regulatory regime.[169] Since decision-making about unreasonable risk relies primarily on information,[170] the legitimacy of the agency's decision-making depends in a large part on how the agency chooses to gather, develop, and analyze that information.

2. Agency Decision-Making and Risk: Risk Assessment

In determining whether a product presents unreasonable risk, the EPA will consult its own information knowledge base[171] and conduct a risk assessment inquiry.[172] Quantitative risk assessment is the favored method by the EPA to measure the probable health effects of a toxic substance.[173] This process seeks to calculate risks that cannot be directly observed or measured by analyzing all available toxicity and exposure data. This process, in the-

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AND LIVES SAVED (1996).

167. *See* Applegate, *Perils*, *supra* note 15, at 276-77.

168. *See infra* Section III.B.2.

169. *See* Applegate, *Perils*, *supra* note 15, at 271.

170. "Information remains the *sine qua non* of the rational development of specific regulatory commands regarding hazardous chemicals [under TSCA and FIFRA]." *Id.* at 261.

171. *See id.* at 301-06 (identifying compilations of existing data, record keeping, and government research as some illustration of the agency's own information sources). These other sources of information are outside the scope of this paper, which focuses in on how the agency assesses information through the risk assessment process. For commentary on how the agency develops its own scientific information, see Sidney A. Shapiro, *Resolving Technological Controversies in Regulatory Agencies*, 6 RISK: HEALTH, SAFETY AND ENVIRONMENT 127 (1995).

172. *See* EPA 1986 Statement of Policy, *supra* note 1, at 23323 (stating risk assessment is used under FIFRA's EUP notification); *see also* TSCA Final Rule, *supra* note 14, at 23328 (stating risk assessment is used to evaluate the MCAN process).

173. *See* Applegate, *Perils*, *supra* note 15, at 277.

ory, provides an objective evaluation of the risks posed by a chemical.[174]

It is believed that quantitative risk assessment is an analytical tool that "fits hand in glove" with the four previously mentioned characteristics of unreasonable risk decision-making.[175] Just as the unreasonable risk standard does not aim to measure the degree of harm, quantitative risk assessment measures risk and not actual harm.[176] Moreover, along with the unreasonable risk standard, the use of quantitative risk assessment also implicitly assumes that the mere presence of risk is not a sufficient reason to prohibit the use of a regulated product.[177] Cost is also incorporated as an important factor; quantitative risk assessment provides the framework for the cost-risk-benefit analysis by providing different numerical values as representative of the degree of risk that can later be compared in the decision-making process.[178] Finally, quantitative risk assessment, like the unreasonable risk standard, is a case-by-case analysis of risk determination that takes into account the particular information available about a specific product's characteristics, thus operating in an ad hoc manner.[179]

However, what sounds theoretically plausible does not always translate well into practice. The use of quantitative risk assessment as an analytical tool has been critiqued in a manner that tends to follow one of two possible modes of argument: commentators either strongly disapprove of the use of quantitative risk assessment, or, in contrast, advocate a more moderate, cau-

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174. *See id.* at 277-78. Risk assessment needs to be distinguished from risk management. The former looks to scientifically determine the degree of risk present, while the latter, by considering various political and policy imperatives, looks to characterize and address the determined degree of risk present. *See id.* at 279.

175. *See supra* notes 162-69 and accompanying text.

176. *See* Applegate, *Perils*, *supra* note 15, at 279.

177. *See id.* at 279-80.

178. *See id.* at 280.

179. *Id.* ("Its conclusions are based on toxicity and exposure information about particular chemicals, and it strives to achieve a level of precision about risk greater than that which can be achieved by generalized estimates. It is an *alternative* to generic or qualitative approaches to risk regulation.") (emphasis in original).

tionary implementation of quantitative risk assessment methodologies.[180] While the extreme position maintains that all determinations arrived at through the quantitative risk assessment are fatally flawed, the moderate position recognizes the need for undertaking quantitative risk assessment inquiries and advocates caution in the use of such strategies. Even though the EPA has yet to make public the exact quantitative risk assessment strategies it uses in screening genetically engineered microbial products,[181] it is valuable to analyze the controversy surrounding the use of quantitative risk assessment in the EPA's carcinogenic regulations since this debate highlights the central issue in the use of quantitative risk assessment strategies - namely, the problem of subjectivity.

The process of quantitative risk assessment basically involves four stages.[182] The first involves hazard identification, a qualitative process that places the known risks present into certain categories based on available evidence.[183] The second stage, dose-response assessment, uses animal experiments to achieve certain estimated results that predict likely dose-response at low-levels over long periods of time.[184] The third stage, exposure assessment, looks to estimate the likelihood that people may actually come into contact with the toxic substance.[185] The fourth and final stage, risk characterization, multiplies the dose-response result (the estimate of harm from incremental doses) by the exposure assessment (the estimate of exposure that people are likely to come into contact with); the resulting figure should represent the threat to people present in the concentration of a chemical that might actually reach those people.[186]

In essence, the major criticism directed towards quantitative risk assessment is the uncertainty that predominates the entire

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180. *See infra* notes 203-220 and accompanying text.

181. *See infra* Section III.

182. For an thorough discussion of each stage, *see* Mark E. Shere, *The Myth of Meaningful Risk Assessment*, 19 HARV. ENVTL. L. REV. 409, 430-68 (1995).

183. *See id.* at 430.

184. *See* Applegate, *Perils*, *supra* note 15, at 278.

185. *See* Shere, *supra* note 182, at 430.

186. *See id.* at 430-31.

process; at every stage, the process relies on subjective assumptions that are then stacked upon further assumptions.[187] Each assumption by itself can skew the analysis somewhat, but when the assumptions at each stage are taken together, the numerical result "generates numbers that are meaningless."[188] According to this extreme viewpoint, it is virtually impossible to justify quantitative risk assessment; the typical justifications fail when analyzed against the subjective uncertainty that permeates the entire quantitative risk assessment process.[189] For example, this viewpoint takes issue with those who justify quantitative risk assessment as an overly protective determination of risk. By contending that even though the actual risk present may be much less than the resulting risk assessment value, it is right for the agency to err on the side of public health.[190] The extremist position responds that, first, regulation that does not accurately reflect the actual risks present is inefficient and may in effect decrease available spending for health costs by increasing regulatory costs.[191] Second, the resulting data from animal studies may not accurately reflect human effects.[192] Third, the argument of erring on the side of public health still reflects certain assumptions and does not consider other risks that may be present.[193] Further justifications argue that standardizing the procedures would bring increased consistency and objectivity.[194] This argument also misses the point because, according to the extremist position, "the most that 'consistency' can accomplish is to produce numbers that are con-

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187. *See id.* at 413-14.

188. *See id.* at 414.

189. *See id.* at 468 (the following discussion synthesizes many of this commentator's more elaborate arguments).

190. *See id.* at 469-73.

191. *See id.*; *see also* Williams, *supra* note 161, at 2.

192. *See* Schere, *supra* note 182, at 470.

193. *See id.* at 470-71 (giving various examples such as when the EPA assesses risks in the clean-up of hazardous industrial sites, it assumes a risk present is that "children will eat dirt at the site each day" but does not take into account the risks present for workers and the public "from bringing in heavy machinery to excavate what may be thousands of tons of soil.") (citations omitted).

194. *See id.* at 476-77.

sistently meaningless because of their inherent uncertainty."[195] Finally, those justifications that argue for mere risk prioritizing[196] are criticized in the extremist argument for two reasons. First, risk-prioritizing is an inherently qualitative process that can be accomplished without the need of complicated, elaborate risk assessment models;[197] second, priority-setting is itself a difficult political policy question that involves very subjective moral and ethical questions.[198] According to the extremist viewpoint, quantitative risk assessment is indefensible as a regulatory device.

The problems presented by the EPA's use of quantitative risk assessment in carcinogenic regulation are directly applicable to the problems that quantitative risk assessment could present in the EPA's biotechnology regulation. Carcinogenic toxicity is a process that is not well understood — uncertainty about actual causation as a result of exposure results in uncertainty in determining completely safe threshold levels of carcinogenic exposure.[199] Similarly, the risks presented by a genetically altered product that is released into the environment is just as uncertain.[200] Thus, some have criticized the use of quantitative risk assessment as a methodology in genetically engineered microbial product regulation as continuing to rely on subjective, uncertain policy determinations that are not objectively scientific.[201]

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195. *See id.* at 476 (citation omitted).

196. *See id.* at 477.

197. *See id.* at 478.

198. *See id.* at 478-79. This commentator gives an example that helps to clarify the point:

> Suppose that site A is an abandoned dump that poses relatively serious risks, but is difficult to make substantially cleaner; this situation may occur if chemicals descended through the soil at a site and settled into fractures in the bedrock, where they act as a continuing source of groundwater contamination. Suppose that other sites, B and C, pose relatively lower risks, but these sites are relatively easy to clean because the contamination lies on the soil surface. Which of the sites should receive top priority?

199. *See* Applegate, *supra* note 15, at 264-66.

200. *See supra* notes 8-11 and accompanying text.

201. *See, e.g.*, Harlow, *supra* note 4, at 560-63.

However, other commentators have posed a counter-argument. These commentators maintain that it is possible to assume a moderate stand on the use of quantitative risk assessment as a whole. While one cannot deny the uncertainty presented by the various subjective assumptions made in quantitative risk assessment process, it is useful to return to the advocacy of quantitative risk assessment as a priority-setting device. This moderate position agrees with the view that while it is wrong to base regulatory decisions solely on the basis of quantitative risk assessment, there is a place for quantitative risk assessment as another factor the agency considers in its decision-making as a whole.[202] This viewpoint acknowledges that while quantitative risk assessment is of limited objectively scientific value,[203] it can nonetheless be a powerful tool for prioritizing already-existing risks.[204]

Quantitative risk assessment thus can be placed in perspective as a governmental indicator, which like other common economic indicators, are not presented as absolutely true, but allow for priority-setting to take place and provide the basis for informed debate.[205] Governmental indicators are especially of value for two reasons. First, indicators serve a useful function in planning the best possible course of action to take.[206] In this respect, the prob-

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202. *See* Applegate, *A Beginning and Not an End in Itself: The Role of Risk Assessment in Environmental Decision-Making*, 63 U. CIN. L. REV. 1643 (1995); Carl F. Cranor, *The Normative of Risk Assessment*, 8 RISK: HEALTH, SAFETY, AND ENVIRONMENT 123 (1997); Bernard Goldstein, *Risk Assessment as an Indicator for Decision Making in* RISK, COST, AND LIVES SAVED 67 (Robert W. Hahn ed., 1996).

203. *See* Goldstein, *supra* note 202, at 80.

204. *See id.* at 69.

205. *See id.* at 67 (analogizing quantitative risk assessment as a policy tool similar to "the unemployment level or the gross domestic product").

206. *See id.* at 70:

> For example, money market managers and individual investors pay close attention to any of the indicators that might affect how the Federal Reserve will adjust interest rates, multinational corporations ponder the effect of international trade figures on governmental policy, and businessmen and investors are well aware that figures reflecting unemployment and domestic product are good indicators of whether Congress might be resorting to pump-priming measures.

lem of uncertainty in quantitative risk assessment becomes minimized as indicators are not taken to be expressions of scientific certainty.[207] Second, the question of standardization becomes refocused, since another value of indicators is that they rely on general guidelines to indicate freedom from partisan political bias.[208] One knows, for example, that unemployment indicators should not mysteriously fall just before a presidential reelection.[209] Similarly, by standardizing quantitative risk assessment guidelines, the regulatory process assumes a greater legitimacy.[210] Even though standardization raises the tension between adopting more flexible guidelines that are more easily adaptable to technological change as between more rigid guidelines that afford regulatory certainty,[211] the public debate that results from the proposal to adopt certain guidelines would, in the very least, address this tension. While it may not be fully resolved, debate should allow for the adoption of reasonably informed guidelines that take this tension into account.

However, this analogy should not be taken lightly. Certain important distinctions do exist between the use of quantitative risk assessment as a governmental indicator and other more common indicators already in use. In the first place, quantitative risk assessment attempts to count the uncountable — it extrapolates already-existing, readily observed data to designate a likelihood of some unobserved, as-yet-to-occur determination.[212] Second, hazard identification is an inherently contentious process and represents a qualitative process that cannot easily be quantified.[213] Finally, as opposed to the standard governmental indicators, quantitative risk assessment helps to bridge the gap between

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207. *See id.* at 71-73, 80.

208. *See id.* at 70-71.

209. *See id.* at 69.

210. *See id.* at 71 (mentioning the attempt to standardize carcinogenic quantitative risk assessment guidelines so as to do away with the argument of inefficient regulatory complexity by the various agencies involved in carcinogenic regulation all have different quantitative risk assessment methodologies).

211. *See id.*

212. *See id.* at 74-75.

213. *See id.* at 75-76.

available scientific knowledge and current regulatory needs to provide better decision-making. Quantitative risk assessment provides its own impetus for the research needed to improve the process of risk assessment.[214]

Quantitative risk assessment is a valuable tool if its inherent limitations are recognized. One of the most important of these limitations is that quantitative risk assessment is best suited for setting priorities where the harm has already occurred and the risk is readily observable, rather than the prevention of risks that have yet to occur.[215] The use of risk assessment in screening procedures presents a problem, especially if the data end product of a screening risk assessment is taken as an accurate scientific determination.[216] Furthermore, a question exists about the quality of data available within the agency to assess the product at its screening phase.[217] On one hand, screening relies on possibly outdated scientific information in the agency's own archives.[218] On the other hand, the screening process typically evaluates a product in its pre-market phase, when the least is known about the product's long-term effects.[219]

Nevertheless, screening is a necessary and important step in the regulation of a risk-based industry. The determination of risk necessary before a product is released into the environment and the screening of a product may set the tone for further regulation of that product since the screening stage represents the agency's first contact with the product to be regulated.[220] The tension between the necessity for screening a product's risk and the uncertain determination of that risk can possibly be addressed by returning to risk assessment as an indicator to set pri-

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214. *See id.* at 76-77. This commentator describes how the interplay among scientists and regulators in the risk assessment process allows scientists to know where certain scientific questions are lacking and regulators to address situations where regulatory force is lacking.

215. *See id.* at 69 ("[P]olicy makers do not always recognize that risk assessment is far better as a means to set priorities for situations in which pollution has already occurred that it is for prevention.").

216. *See id.*

217. *See* Applegate, *supra* note 15, at 310.

218. *See id.*

219. *See id.*

220. *See supra* note 14.

orities. If, as the moderate position on the use of risk assessment maintains, risk assessment should not be the sole criterion for decision-making but should be one element in decision-making, one could argue that the EPA may be proceeding on the right track. The agency has stated that both the EUP and MCAN review are not limited to risk assessment, but can also involve review and commentary from other Federal agencies as well as outside expert consultants.[221] Such an extended consultation process would be of especially great importance in screening new genetically engineered microbial products that the agency had not yet confronted. The extended consultation process would assure that the uncertain risk assessment results were but one factor in the review process. Such a review process is already provided for in the regulatory procedure since both the EUP and MCAN screening processes allow for the possibility of extending the limited review period.[222]

Unfortunately, the agency has not set forth any public guidelines on conducting risk assessment of genetically engineered microbial products. This is the most serious critique that can be levied against the current regulatory screening procedure.

III. THE REAL RISK: THE LACK OF PUBLIC RISK ASSESSMENT GUIDELINES

As this Note has set forth, the quality of decision-making is directly related to the quality of information received - the most legitimate and intelligent decision-making process would greatly reduce the possibility of error by incorporating a process of debate within that decision-making.[223] However, in the screening of ge-

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221. *See* EPA 1986 Statement of Policy, *supra* note 1, at 23323 (commenting on the EUP process); *see also id.* at 23328 (commenting on the MCAN process).

222. Both the EUP and MCAN review process allow for an extension of the length of the agency's review where it determines that further information may be needed to come to an accurate determination of unreasonable risk presented by the application. *See* EPA 1986 Statement of Policy, *supra* note 1, at 23323 (commenting on the EUP process); *see id.* at 23328 (commenting on the MCAN process).

223. *See supra* notes 128-36 and accompanying text. It should be emphasized, however, that the thrust of this paper's argument looks to

netically altered products, both the information and the decision-making process present problems serious enough to warrant questioning the legitimacy of risk decision-making.

On first impression, it would seem that the EPA would be extremely sensitive to these concerns, having recently revised its screening regulations to account for greater safety.[224] But problems still abound. The information that the agency receives from biotechnology industry participants may very well conceal adverse health and safety data. The federal statutes provide little relief since published notices available for public comment are of dubious legitimacy when censored by the industry participant. The information available may be of questionable merit.

Moreover, the decision-making process may itself be seriously flawed. The agency acknowledges that it evaluates health and safety data by performing quantitative risk assessment. However, if risk assessment is to provide the most accurate conclusion possible, it must not be the sole determinant in the decision-making process. This Note has shown that risk assessment is most effective when used only as an indicator for decision-making. The agency cannot base its decisions solely on risk assessment results; it must also look to other sources of information, such as outside scientists and other Federal agencies. However, by not publishing any standard statement of how the risks are assessed, the agency does a disservice to the regulated community, and to the public, and to the legitimacy of the regulation itself. The biotechnology community is left with uncertainty as to which factors to take into consideration when designing a new genetically engineered microbial product. The public is left in the dark, in the face of the still-current perception of biotechnology as having the potential for nightmarish consequences. Finally, the agency is hurting the legitimacy of its own regulations. Making its risk assessment

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debate as a valuable tool in creating intelligent decision-making methodologies. This is not to say that the *only* way intelligent decisions can ever be made is through debate. Rather, once an intelligent decision-making methodology is in place, the actual decisions arrived at through the use of such a methodology should be as intelligent as the debate surrounding the creation of such a decision-making methodology.

224. *See supra* Sections I.C.1. and I.C.2.

criteria public opens the screening process up to public debate, opening the door to more intelligent decision-making.[225]

This controversy recently came to light when the EPA responded to criticism that it does not have a formal risk assessment process for genetically engineered microbial products.[226] The agency described that after more than ten years of experience in reviewing genetically engineered microbial products, its risk assessment methods are not only consistent but have also been peer reviewed.[227] Further, a group of outside academics reviewed "major assessments" of genetically engineered products released into the environment.[228] "These intra-agency laurels run directly contrary to the comments of an anonymous EPA risk assessment official who revealed that the agency remains ignorant even of what questions to ask in assessing risks presented by genetically engineered microbial products."[229]

This apparent contradiction is most troubling; while the agency's response and the anonymous source seem entirely contradictory on the surface, a deeper confirmation can be seen. In the first place, the agency's own response implicitly states that in screening genetically engineered microbial products, risk assessment remains the primary tool for decision-making. This is evident in the agency's acknowledgment that the procedure itself has been reviewed, and only those applications the agency calls "major assessments" have themselves been reviewed by outside experts. Second, the agency response does not deny the lack of a standard risk assessment protocol. In fact, the agency is quite upfront about this deficiency: a senior microbiologist in the Office of Prevention, Pesticides, and Toxic Substances ("OPPTS") stated "in terms of a formal document, we don't have one."[230] This official defended the validity of EPA risk assessment on other

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225. *See supra* notes 128-36 and accompanying text.

226. *See* Bert McMeen, *Biotechnology: EPA Program Stirs Controversy Over Adequacy of Risk Assessment Method*, BNA CHEM. REG., D at d8, Sept. 2, 1997, *available in* Westlaw, CHRD d8.

227. *See id.*

228. *See id.*

229. *Id.*

230. *Id.* (statement of Philip G. Sayre, a senior microbiologist in the EPA Office of Prevention, Pesticides, and Toxic Substances).

grounds as well. He mentioned that the risk assessment protocol was indeed publicly informed since the public had access to intermittent workshops on those risk assessment protocols.[231] However, intermittent workshops are no substitute for the focused public commentary received when proposing standardized guidelines. The lack of any formal documented guidelines cheapens the legitimacy of such workshop participation.

Furthermore, the OPPTS official stated that what the EPA examines in conducting risk assessments is published in the screening final rules.[232] However, a review of both the final rules fails to reveal any such description of risk assessment procedure.[233] The official also went on to point to the Proposed Guidelines for Ecological Risk Assessment[234] as a formal document that "mirrors" the overall risk assessment procedure currently in use.[235] The proposed guidelines have since been made final.[236]

Several criticisms can be levied against this attempted defense. In the first place, scientists have criticized the EPA's attempt to address the broad science of ecology in a single set of guidelines.[237] The EPA seemed to respond to this criticism in the final guidelines in its assertion that the guidelines are broad in scope and describe general principles.[238] The EPA intends to follow the broad guidelines "with a series of shorter, more detailed documents that address specific ecological risk assessment topics."[239] The EPA believes this approach to risk assessment will provide

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231. *See id.* (mentioning three workshops held in 1992, 1993, and 1996).

232. *See* McMeen, *supra* note 226 (referring to the TSCA experimental release applications, abbreviated "MCANS").

233. *See* FIFRA Final Rule, *supra* note 64; *see also* TSCA Final Rule, *supra* note 14.

234. *See* 61 Fed. Reg. 47552 (1996).

235. *See* McMeen, *supra* note 226.

236. *See* EPA, Guidelines for Ecological Risk Assessment, 63 Fed. Reg. 26846 (1998), replacing *Framework for Ecological Risk Assessment*, EPA/630/R-92/001 (1992).

237. *See* Pesticide and Toxic Chemical News, *Scientists Critique Ecological Risk Assessment Guidelines*, Dec. 13, 1995 (no page references available) (*available on* Westlaw as 1995 WL 12837058).

238. *See* Guidelines, *supra* note 236, at 26846.

239. *Id.*

the agency with the flexibility needed to address scientific and technological change as it swiftly develops.[240]

While such a flexible approach is indeed laudable in its attempt to keep pace with rampant scientific change, the question remains unanswered: what sort of risk assessment protocol is the EPA using in the screening of genetically engineered products? What the OPPTS official describes as an illustrative document actually offers only vague approximations and ambiguities.[241] The Proposed Guidelines address this:

> [The Proposed Guidelines] are broad in scope, describing general principles and providing numerous examples to show how ecological risk assessment can be applied to a wide range of systems, stressors, and biological/spatial/temporal scales . . . . Because of their broad scope, the Proposed Guidelines do not provide detailed guidance in specific areas nor are they highly prescriptive.[242]

The Guidelines for Ecological Risk Assessment describe only a generalized protocol in the most all-inclusive of terms. The EPA's risk assessment methodology, if there is one, remains a mystery.[243]

This question is of central importance as genetically engineered food products have already widely infiltrated the nation's produce growers.[244] In the above context, the lack of agency can-

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240. *See id.*

241. An argument about how these guidelines could be used as the actual qualitative risk assessment methodology is not within the scope of this paper, as the guidelines are drawn so broadly that countless alternative arguments for a single proposition could be spun. *See* Pesticide and Toxic Chemical News, *Scientists Critique Ecological Risk Assessment Guidelines*, Dec. 13, 1995 (no page references available) (*available on* Westlaw as 1995 WL 12837058) (comments of S.M. Bartell, describing a draft of the regulation as such: "The current draft loses the train of thought as the result of introducing a plethora of issues, considerations, caveats, strengths and limitations.").

242. 61 Fed. Reg. 47552, 47552.

243. The Final Ecological Risk Guidelines retain this broad scope. *See* Guidelines, *supra* note 236, at 26846. It is the EPA's intent to follow these broad guidelines with more detailed regulations aimed at specific areas. *See id.* In the meanwhile however, genetically engineered products continue to be screened.

244. For example, "[as of 1998], some 45 million acres of American farmland [has] been planted with biotech crops, most of it corn,

dor about its risk assessment procedures is quite alarming. And yet, the problems inherent in risk decision-making have been recognized for some time. In 1977, the National Academy of Sciences warned the EPA about relying on regulated industries for data and analysis for its decision-making.[245] In order to combat the danger presented by reliance on such information, certain remedial strategies were suggested, including the use of peer review, review by other agencies, and stringent guidelines and protocols.[246] While the first two recommendations have been wisely followed, the EPA seems to have fallen short on the last piece of advice.

Proposals for designing risk assessment protocols in genetically engineered microbial product regulation existed as early as 1986.[247] The EPA, however, has yet to publish any such document, and instead can only reference a hodge-podge of vague protocols. In the end, everyone suffers: the regulated community, the public, and the legitimacy of the agency's own determinations. The goals of the screening process are highly susceptible to the dangers of subjectivity. This is evidenced by the four characteristics of risk regulation. First, screening looks to regulate the degree of risk, not harm; one must ask what interests are considered in prioritizing these risks. Second, screening acknowledges that the mere presence of risk is not a sufficient reason to prohibit a product's use; one must ask what criteria are used to determine the safety threshold before a product may be prohibited. Third, screening incorporates the question of cost into the risk-benefit analysis; one must ask what costs are considered unacceptable. Finally, screening involves a case-by-case analysis; one must ask to what degree this analysis remains uniform. The question of uncertain subjectivity permeates all these aspects of screening regulation.

If the screening process under TSCA and FIFRA is dangerously susceptible to uncertainty,[248] then the publishing of standardized

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soybeans, cotton and potatoes that have been engineered to either produce their own pesticides or withstand herbicides." Pallon, *supra* note 1, at 45.

245. *See* 2 National Research Council/National Academy of Sciences, Decision-Making in the Environmental Protection Agency 50-58.

246. *See id.*

247. *See, e.g.*, OECD, *supra* note 1, at 24-40.

248. *See supra* Section II.B.

risk assessment protocols may, in this case, provide a simple remedy for the problem. Informed regulation makes for more intelligent decision-making. By publishing a standardized risk assessment protocol, all affected parties benefit in a net gain of information. Industry gains standardized protocols that may be looked to for clear guidance. The public not only achieves greater participatory value, but also has an opportunity to influence the way decisions are made. The agency itself benefits both from more efficient regulation (in the sense that clear guidelines establish the possibility of more streamlined acceptance or prohibition of a substance) and from more intelligent regulation (with the opportunity to receive commentary from affected parties).

Moreover, this recommendation avoids the concern of clogging the regulatory mechanism and creating a disincentive to industry.[249] If, as the EPA maintains, its risk assessment methods are already consistent and peer reviewed, then publishing such a standardized document should not create any greater regulatory hurdles. Rather, such a strategy will likely provide more debate, both on the actual quantitative risk assessment methods used and on whether or not quantitative risk assessment is the sole determinant in its screening decisions. As one commentator has suggested, "even if additional information will never eliminate uncertainty, it can usefully reduce uncertainty and improve agency decision-making."[250]

CONCLUSION

Decision-making about risk is itself a risky enterprise. This problem is highlighted in the screening of products using genetically engineered microbes. The information that the EPA uses may be flawed on two separate levels. On the first level, the regulated community has a very real incentive to conceal health and safety data, due in a large part to the highly competitive nature of biotechnology industry. Second, the screening process itself does not allow for any real significant degree of meaningful public participation. The information that the agency relies upon may thus be seriously flawed and incomplete. Finally, when it comes time for the agency to make its decision about the risk

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249. *See* Elkins, *supra* note 125, at 12 (cautioning against the danger of over-regulation).

250. Applegate, *Perils*, *supra* note 15, at 266.

presented by a genetically engineered microbial product application, it is not clear if the EPA itself even has the capacity to do this properly. The EPA could begin to address these problems of risk decision-making in the regulation of bioagriculture by simply publishing a standard guideline of risk assessment for genetically engineered microbial product screening.