Premarket Notice Concerning Bioengineered Foods: A Proposed Regulation Satisfying Some of the Players, Some of the Time

Christine Cochran*

I. INTRODUCTION

The U.S. Food and Drug Administration ("FDA") has proposed a regulation that would require developers of bioengineered foods to submit new products to a review of safety at least 120 days before their commercial distribution.[1] A consulting process currently exists as a voluntary program, but the proposed regulation would make the process mandatory. Many developers of bioengineered foods are voluntary participants in this premarket consultation program, which, upon completion, provides the developer with a credential stating that it has met the "prevailing standard of care" for biotechnology products. In addition to the consulting process, however, the regulation mandates significant public disclosure of information regarding the procedures used to develop the product and any potential risks to consumer safety.

This Note will consider the current regulatory climate for bioengineered food, as well as some of the policy views of groups that are likely to feel the impact of this regulation.[2] Part II.A

* J.D. Candidate, 2003, Washington University School of Law.

1. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pt. 192,592).

2. This Note will not consider the related issue of labeling of bioengineered food. For a discussion of this topic, see Ronald E. Bailey & Linda M. Bolduan, *Genetically Modified Foods: Labeling Issues Are Driving the Regulators and Counsel*, 68 DEF. COUNS. J. 308 (2001); Alicia T. Simpson, Note, *Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods?*, 19 TEMP. ENVTL. L. & TECH. J. 225 (2001); Kelly A. Leggio, Comment, *Limitations on the Consumer's Right to Know: Settling the Debate Over Labeling of Genetically Modified Foods in the United States*, 38 SAN DIEGO L. REV. 893 (2001). A thorough discussion of the international

describes current United States regulatory requirements for bioengineered food. Part II.B describes the proposed regulation in detail, including its costs and benefits.[3] Part II.C describes the perspectives of scholars who believe that more rigorous legislation is imperative. Part II.D describes the perspective of the biotechnology industry, which supports the view that product safety is best advanced when legislation and product stewardship coexist. Part II.E describes the perspective that further regulation is unnecessary and potentially harmful. Further, Part III details the benefits and drawbacks of each perspective, while Part IV submits that, with modification, the proposed regulation will fulfill its described purpose of "ensur[ing] that all market entry decisions by the industry are made consistently and in full compliance with the law."[4]

II. HISTORY

A. Current Regulatory Requirements for Approval of Bioengineered Food Products

The Coordinated Framework for Regulation of Biotechnology ("Coordinated Framework" or "Framework") regulates all

implications of United States policy regarding bioengineered foods is also beyond the reach of this Note. For a synopsis, however, see *infra* note 80 and accompanying text.

3. *See* Mark Geistfeld, *Reconciling Cost-Benefit Analysis with the Principle that Safety Matters More Than Money*, 76 N.Y.U. L. REV. 114 (2001). Many people believe safety is more important than money, though they are reluctant to devote one-hundred percent of their money to eliminating safety risks. *Id.* at 116-17. State and federal governments must make legislative decisions based on cost-benefit analysis where required by statute. *Id.* at 120. A traditional cost-benefit analysis "gives equal weight to economic and safety interests" and "often inequitably favors potential injurers at the expense of potential victims." *Id.* Professor Geistfeld proposes a modified analysis, which accords additional weight to safety interests yet also considers monetary costs. He believes that one variable in determining an appropriate level of safety is whether an individual has voluntarily assumed a risk. *Id.* at 124. If an individual has not voluntarily submitted to a particular risk, the party in control of the risk bears a greater obligation to spend money to minimize the risk than if the individual had chosen to submit. *Id.* Modified cost-benefit analysis is most important in cases where the individual does not voluntarily submit to the risk. *Id.* Professor Geistfeld suggests a rule that "gives the relevant safety interests twice as much weight as ordinary economic interests [to] reduce risk below levels attainable by the conventional cost-benefit negligence standard and strict liability." *Id.* at 185.

4. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pt. 192,592).

bioengineered foods in the United States.[5] The Framework, promulgated in 1986, aligns existing legislation[6] with the administrative procedures of the FDA, the United States Department of Agriculture ("USDA"), and the Environmental Protection Agency ("EPA").[7]

The USDA, the primary regulatory agency for non-bioengineered foods, governs the first step in approving bioengineered foods. A developer of a genetically modified crop that is intended for commercial distribution must first determine whether the crop qualifies as a "plant pest" under the Plant Protection Act.[8] If so, before field-testing the product, the developer must secure a permit from the Animal and Plant Health Inspection Service ("APHIS"), a service that the USDA provides.[9] Next, the developer must declare to

---

5. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

6. *See* 35 U.S.C. § 101 (1952). According to the holding in *Diamond v. Chakrabarty*, an individual may receive a patent on a live, genetically modified organism. 447 U.S. 303 (1980). The Supreme Court held that the Patent Act of 1793 should apply broadly to include such products of "human ingenuity" even though it does not apply to discovery of natural phenomena. *Id.* at 309.

7. The Framework does not promulgate new laws regarding bioengineered food: "Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques[,] . . . for the most part, . . . [the current laws] address regulatory needs adequately." Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303. A key premise of the Framework is that bioengineered foods are merely "an extension of traditional manipulations that can produce similar or identical products [that] enable more precise genetic modifications, and therefore hold the promise for exciting innovation and new areas of commercial opportunity." *Id.* at 23,302. The Framework strives for a full integration of the regulation of bioengineered products, and its two main objectives are to adopt "consistent definitions" and to use "scientific reviews of comparable rigor." *Id.* at 23,303. Additionally, the Framework states that "[a]ny approach to implementing guidelines should not impede future developments in rDNA technology." *Id.* at 23,308.

8. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,304. *See* Plant Protection Act, Pub. L. No. 106-224, 114 Stat. 358, Title IV (2000). The Act defines "plant pests" as:

> [A]ny living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (a) A protozoan; (b) A nonhuman animal; (c) A parasitic plant; (d) A bacterium; (e) A fungus; (f) A virus or viroid; (g) An infectious agent or other pathogen; (h) Any article similar to or allied with (any of the above).

Id. at § 7702(14).

9. Permits for the Introduction of a Regulated Article, 7 C.F.R. § 340.4 (2002). The APHIS permit procedure requires developers to disclose information about potential plant pests 120 days before the proposed release. Developers must also conduct a large scale field test of

the FDA[10] of any foods or food additives[11] that are not "generally recognized as safe" ("GRAS").[12] The absence of such a declaration

---

the product. *Id.* The APHIS may grant developers trade secret protection on their permit applications. *Id.* at 340.4 n.6. A permit application requires, *inter alia*, the following information: contact information for the person requesting the permit and the developers of the article; all names or designations of the article ("scientific, common, and trade names"); information regarding the molecular alterations to the article, including the process used to transform the article; geographic location where the article originated; description of the proposed experiment as well as the proposed safeguards against contamination and dissemination; description of the location of the test site; and description of proposed disposal procedures. 7 C.F.R. § 340.4(b). If APHIS refuses to grant a permit, the developer may appeal. If APHIS grants the permit, the developer is subject to several conditions that are intended to limit the dissemination of the plant pest. The developer must: take the appropriate steps to dispose of contaminated material that has contacted the article; keep the article isolated except as the permit allows; allow the APHIS inspectors to inspect the article and its relevant documentation; identify the article with a label; submit a field test report within six months of the experiment's completion, which includes evidence of harmful effects on the environment; and notify APHIS immediately in the event of accidental release or significant unanticipated effects (including "excessive mortality or morbidity, or unanticipated effect on non-target organisms"). 7 C.F.R. § 340.4(b).

10. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992). This policy states that Congress does not wish to relegate every food component to FDA review, due to the overwhelming burden it would create. *Id.* at 22,989. Where, for example, "the ingredient is a man made chemical having no widely recognized history of safe use in food," the developer must submit a petition for FDA approval. *Id.*

11. A "food additive" is any chemical component intended for use in food, unless the substance is generally recognized as safe. *Id.* Further, 21 C.F.R. § 170.3(3)(1) (2002) defines a food additive as a substance, "the intended use of which results may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food." In addition, "A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive." *Id.*

12. A product may reach GRAS status through one of two paths: (1) scientific review; or (2) if the substance was present in food before January 1, 1958, through "common use in food". 21 C.F.R. § 170.30(a) (2002). Developers generally demonstrate safety through "published studies which may be corroborated by unpublished studies and other data and information." *Id.* For substances used in food before January 1, 1958, developers need not supply exhaustive scientific data. Rather, the FDA will rely on "generally available data and information." *Id.* For substances that are similar to or derived from GRAS products (such as extracts or distillates of GRAS substances, or a substance that is synthetic but chemically identical to a GRAS substance), the FDA has a third procedure for reaching approval: "Affirmation." 21 C.F.R. § 170.35(b) (2002). To "Affirm" a product's GRAS status, the FDA's Commissioner places a sixty day notice of the substance on the Federal Register for public comment. The Commissioner considers any comments, and at the end of the sixty days, publishes a final finding in the Federal Register. *Id.* In *Alliance for Bio-Integrity v. Shalala*, the District Court for the District of Columbia held that the FDA's determination of GRAS status for rDNA foods was a statement of policy, and was therefore free from the reporting and assessment requirements of a "major federal action." 116 F. Supp.2d 166, 174 (D.D.C. 2000). *See infra* notes 27-28 and accompanying text for an explanation of "rDNA".

constitutes, by law, a representation that a product is GRAS.[13] If the product is not GRAS, or was produced through techniques that are not GRAS,[14] the FDA must review the product for safety before it may go on the market.[15] If the altered trait provides protection against insects or other pests, the EPA reviews the product for safety.[16] This review is conducted in addition to the FDA's review of non-GRAS substances.[17]

If a bioengineered food product does not contain any non-GRAS substances, and the product does not fit the EPA's definition of a

---

13. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22, 988, *citing* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 402(a)(1) (1938).

14. The FDA explains that the genetic material transferred during genetic modification and the resulting expression products "would not ordinarily affect the GRAS status of the substances and, thus, would not ordinarily require regulation of the substance as a food additive." Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,990. As long as the expression products (substances produced by the transferred genetic material, such as fats, carbohydrates, or proteins) are "already present in generally comparable or greater levels in currently consumed foods," the FDA finds no need for formal review. *Id.* On the other hand, if an expression product is significantly different from any substance currently found in food, such as "a novel protein sweetener," the FDA would subject that substance to food additive review. *Id.*

15. Premarket review for food additives requires a "reasonable certainty" that no harm will result. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,988. *See also* 21 C.F.R. § 170.3(i) (2002):

> *Safe* or *safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance . . . . In determining safety, the following factors shall be considered: (1) The probable consumption of the substance and of any substance formed in or on food because of its use; (2) The cumulative effect of the substance in the diet taking into account any chemically or pharmacologically related substance or substances in such diet; (3) Safety factors which, in the opinion of experts . . . are generally recognized as appropriate.

16. Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 (2000).

17. Some scholars are critical of this regulatory process. *See* Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 DRAKE J. AGRIC. L. 81, 99 (2001):

> There are several results of this three-part regulatory approach. First, it creates the appearance of a detailed and comprehensive regulatory screen, so much so that promoters of biotechnology . . . can argue these are the most heavily regulated foods in history. Second, the reality may be somewhat less thorough . . . because the division of responsibility [means] it is not clear who is responsible for testing . . . the safety of people actually eating foods made from GMO products.

"plant-pesticide," the developer has two options. The developer may place the product on the market immediately, or the developer may voluntarily consult with the FDA. In the latter case, the developer has an opportunity to receive a credential stating that it has met the "prevailing standard of care" for biotechnology products. This optional consulting process is the subject of the proposed regulation.[18]

B. Proposed Regulation: Premarket Notice Concerning Bioengineered Foods.[19]

The proposed regulation would make mandatory the premarket consulting process that is currently voluntarily followed by many biotechnology developers. It would also require that developers publicly disclose information regarding bioengineering methods, nutritional content, and potential for allergenicity. The FDA drafted this proposed regulation in response to public comment on a 1992 policy statement on plant breeding.[20]

The proposed regulation states that the FDA believes that the food industry has generally submitted new bioengineered foods to the FDA for approval through the voluntary consulting process,[21] and that all bioengineered foods currently on the market have gone through this process.[22] As of the proposed regulation's publication, all developers that have placed a bioengineered food product on the market—except for one—have been large corporations or universities.[23] Yet, the rule will also apply to both small companies

---

18. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (proposed January 18, 2001) (to be codified at 21 C.F.R. pt. 192,592). For a more detailed summary of these regulatory processes, see Stanley H. Abramson & J. Thomas Carrato, *Crop Biotechnology: The Case for Product Stewardship*, 20 VA. ENVTL. L.J. 241, 244 (2001).

19. Rule Summary: "The Food and Drug Administration (FDA) is proposing to require the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. FDA is proposing that this submission be made at least 120 days prior to the commercial distribution of such foods." *Id.* at 4706.

20. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,984.

21. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4707-08.

22. *Id.* at 4708.

23. *Id.* at 4729. The FDA's statistics cover "more than 45 biotechnology submissions," submitted by eleven multimillion-dollar corporations, three universities, and one company that the FDA contends would meet the standards for a "small entity." *Id.*

and international food developers who wish to introduce biotechnology foods in United States markets.[24]

Key issues addressed in the proposed regulation include the methods used for modification of the biotechnology plant product,[25] and the methods for evaluating the safety and accuracy of the transformation.[26] The rule is concerned only with plant transformation involving recombinant DNA ("rDNA") techniques, because of the possibility of "unintended effects through mutations."[27] Unlike traditional plant breeding techniques, the FDA believes that rDNA technology may easily cause a disruption of functional genes and sequences in the target food plant. This disruption could result in consequences such as reduced expression of beneficial nutritional traits, or new or increased expression of harmful traits.[28]

Nevertheless, the FDA also recognizes that rDNA techniques are more efficient than traditional breeding techniques because the rDNA techniques reduce the introduction of "extraneous genetic material,"[29] which traditional methods can prevent only through numerous generations of back-crossing.[30] The FDA does not believe that the premarket regulation of products developed through traditional

---

24. *Id.* at 4712. According to the proposed regulation, the FDA "has tentatively concluded that . . . FDA must be notified of the intent to market [a bioengineered] food, including foods intended for import into the United States." *See also id.* at 4729 (providing a description of the implications to small entities, as described in the Regulatory Flexibility Act. 5 U.S.C. §§ 601-612 (1996)).

25. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4709. "[S]ubstances may be introduced into food using [recombinant] DNA techniques that cannot be introduced by traditional breeding." Traditional breeding techniques, as defined by the FDA, include hybridization of closely related plants that may be cross-fertilized ("narrow cross"), or of related plants that may not be cross-fertilized ("wide cross"). *Id.* at 4710.

26. *Id.* at 4708. The rule cites, for example, the creation of the FLAVR SAVER super™ tomato, where the developer employed molecular biology techniques to evaluate the safety of the product, including Northern, Southern, and Western blots. *Id.*

27. *Id.* at 4710.

28. *Id.* "[T]he introduced genetic segment may insert into a genetically active chromosomal location. Such insertion may disrupt or inactivate an important gene or a regulatory sequence that affects the expression of one or several genes, thereby potentially affecting adversely the safety of the food or raising other regulatory issues."

29. *Id.*

30. *Id.* "Back-crossing" is a method for eliminating unfavorable traits that have been unintentionally introduced through hybridization of related plants. Breeders cross the hybridized plants with parent plants that do not exhibit the unfavorable characteristic.

breeding techniques is necessary,[31] however, and further states that it would not subject all foods developed by rDNA techniques to premarket notification procedures.[32] It would exempt three categories of rDNA biotechnology foods from premarket notification: (1) products of previously submitted transformation events;[33] (2) products employing previously submitted uses of bioengineered food;[34] and (3) products for which the FDA has already issued a letter of compliance—either under the mandatory process proposed in the rule, or under the current voluntary consulting process.[35]

The proposed premarket approval process includes an optional pre-submission consultation with the FDA. This consultation is essentially identical to the current voluntary consultation process. The FDA also suggests that developers of bioengineered products that are intended for non-food uses, but could potentially enter the

---

31. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4711, stating:

> The [FDA] has not found it necessary to assess routinely the safety of foods derived from [traditional] breeding methods, because over the last 50 to 60 years that some of these techniques have been used in plant breeding, breeders have used well established practices successfully to identify and eliminate, prior to commercial use, plants that exhibit unexpected adverse traits.

32. *Id.* "[M]any [rDNA] modifications will result in a food that does not contain an unapproved food additive, does not contain an unexpected allergen, and does not differ significantly in its composition compared with its traditional counterpart or otherwise require special labeling."

33. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4713. The proposed regulation defines a "transformation event" as "the introduction into an organism of genetic material that has been manipulated in vitro." *Id.* at 4734.

34. *Id.* at 4713. The FDA illustrates this exemption by stating, "[A] separate notice would be required, for example, if herbicide tolerance introduced into a variety of sweet corn that is used solely for human food is subsequently transferred, using traditional plant-breeding techniques, to a variety of field corn that would also be used in food intended for consumption by animals." *Id.* From this example, it is unclear what is included in this exemption. Perhaps if an rDNA bioengineered characteristic were transferred via "traditional" techniques from one food intended for human consumption to another food intended for human consumption, then an additional submission would not be required.

> [T]he notification requirement would not extend to bioengineered food obtained from a plant line (or series of plant lines) that derives from a particular transformation event, as long as both the applicable transformation and the use or application of the bioengineered food has been addressed satisfactorily in a completed consultation under the voluntary program.

Id.

35. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4713.

food supply,[36] voluntarily submit to consultation to ensure that the products are not harmful.[37]

Information that developers disclose in either the consultation or premarket notice processes will generally become public record under the Freedom of Information Act ("FOIA").[38] If a developer demonstrates that the information is exempt from FOIA, because it is a trade secret or is otherwise privileged or confidential, then the developer may submit a redacted statement for public disclosure.[39] The fact that the developer has either consulted with the FDA or has provided premarket notice, however, will not be kept confidential.[40]

Regardless of whether developers choose to participate in the optional consulting process, the proposed premarket notification process still requires developers to submit highly detailed information to the FDA regarding the bioengineered food.[41] The FDA expects developers who participate in the optional consulting process to

---

36. Non-food but food-related uses include pharmaceuticals, oral vaccines, and plant-derived products used for industrial applications. *Id.* at 4714.

37. *Id.* at 4714-15. The FDA suggests that voluntary compliance with the consulting process for non-food developers would advise the developers of their responsibility and potential liability. *Id.*

38. *Id.* at 4714.

39. *Id.*

40. *Id.* The FDA models this policy decision on public disclosure of APHIS's request for testing permits. In most cases an APHIS request for testing permit would precede this premarket notification process so that developers' new products would already be public. *Id.*

41. The FDA requests seven pieces of information. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4732, § 192.25. First, the developer must draft a letter that includes an assurance of the proposed product's safety, as well as assurances of cooperation with the FDA. *Id.* Second, the developer must include contact information as well as information about the proposed product, including a description of the introduced genetic material, proposed uses for the product, and uses "not suitable" for the product. *Id.* Third, the developer must list the status of the proposed product with respect to other administrative agencies and foreign governments (including whether or not the developer has received a permit from APHIS). *Id.* Fourth, the developer must describe the methods used to develop the proposed product, including relevant information about the parent plant, the design of the vector, and the location of the transferred genetic material. *Id.* at 4733. Fifth, the developer must disclose the use of antibiotic resistance as a tag for insertion. Further, the FDA "recommends that you contact [it] about the agency's current thinking on this topic." *Id.* Sixth, the developer must discuss any additional substances present in the proposed product as a result of genetic modification, including safety concerns and possible allergenic effects, if relevant (the FDA again recommends that developers seek guidance on this subject). *Id.* Finally, the developer must provide a comprehensive comparison between the proposed product and a "comparable food," including nutritional information, historical uses, toxin levels, and general safety information. *Id.*

spend approximately 190 hours preparing the required reports. This is forty hours more than the FDA expects under the current, voluntary program.[42] At the FDA's estimated cost of seventy-eight dollars per hour, premarket disclosure for one product would cost approximately $15,000 in report preparation time alone. The FDA estimates that developers who do not complete the optional consultation process will spend approximately 275 hours preparing the premarket disclosure reports, at a cost of approximately $21,000.[43] The additional costs that are associated with forgoing the consultation process arise because a developer in that position would have to submit documents describing the process of collecting the disclosure information in addition to the disclosure itself. The FDA has determined that the proposed regulation would have "a significant economic impact on a substantial number of small entities."[44] Nevertheless, because the proposed regulation allows developers to request consultation meetings by telephone instead of in person, the FDA has determined that the rule provides sufficient flexibility to protect the interests of small businesses.[45]

C. Bioengineered Food and the Precautionary Principle: Premarket Notification as Insufficient to Ensure Product Safety

One view of the United States' regulation of bioengineered food is that the U.S. should more closely follow the Precautionary Principle, the risk management model espoused by much of the international community, including the European Union.[46] American legal scholars

---

42. 66 Fed. Reg. at 4726.

43. *Id.* at 4729.

44. *Id.* at 4729. Under the Regulatory Flexibility Act, agencies must seek to minimize adverse economic effects of regulations on small entities. *Id.* at 4729 (citing 5 U.S.C. §§ 601-602). A "small entity," for purposes of the Regulatory Flexibility Act, is a business with fewer than 500 employees or less than five million dollars in annual receipts. Although, to date, only one "small entity" has requested premarket consultation with the FDA, the FDA realizes that many potential developers of bioengineered foods may qualify as "small entities." *Id.*

45. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4729. The proposed regulation also requests comments on additional measures to make the rule more flexible for small entities. *Id.*

46. Some industrialized countries, such as China, have taken a positive view of bioengineered food products. Others, like Brazil, have outlawed bioengineered products altogether. *See* Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology*

who subscribe to this view believe that the FDA fails to take appropriate measures to protect consumers from the unintended adverse effects of bioengineering. Roughly stated, the Precautionary Principle is the concept that when there is an unknown level of risk with respect to a given potential hazard, the potential hazard must be subject to regulations that are significantly more restrictive than is apparently necessary. These more restrictive regulations are supposed to protect against unforeseen harm.[47]

One supporter of the Precautionary Principle is Professor Vern R. Walker, of the Hofstra University School of Law.[48] According to Professor Walker, current FDA regulations regarding bioengineered food rely solely on developers for identifying substances that are not GRAS and that may qualify as "food additives" for purposes of the Coordinated Framework.[49] As a result, he says, "[T]he vast majority of genetically modified foods have not triggered any required FDA review or regulation."[50] If developers do not declare that the

---

and Genetically Modified Organisms, 6 DRAKE J. AGRIC. L. 81, 90 (2001).

47. For a contrary viewpoint, see Christopher D. Stone, *Is There a Precautionary Principle?*, 31 ENVTL. L. REP. 10790 (2001). Professor Stone asserts that discussion of "the" Precautionary Principle is an oversimplification of a wide array of risk management strategies. He gives several examples of attempted articulations of the Precautionary Principle, some of which prohibit actions whose outcomes are not "fully understood," one that prohibits "unacceptable harm to the environment," and another that favorably (and perhaps ironically) refers to cost-effectiveness. *Id.* at 10790-91 (citing G. A. Res. 37/7, U.N. GAOR, 37th Sess., Supp. No. 51, at 17, U.N. Doc. A/37/51 (1982), *reprinted in* 22 I.L.M. 458 (1983); Rio Declaration on Environment and Development, June 14, 1992, princ. 15, U.N. Doc. A/CONF.151/5 (1992), *reprinted in* 31 I.L.M. 874, 879 (1992); James Cameron and Julie Abouchar, *The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment*, 14 B.C. INT'L & COMP. L. REV. 1, 3 (1991)). Professor Stone also suggests a connection between invocation of the Precautionary Principle and trade protectionism: "In the trade area, most prominently, there is concern that, as long as the Precautionary Principle remains nebulous, trading nations will mask as 'precautionary health protection measures' border controls actually designed to shield domestic producers from foreign competition." Stone, *supra* at 10791.

48. *See, e.g.*, Vern R. Walker, *Some Dangers of Taking Precautions Without Adopting the Precautionary Principle: A Critique of Food Safety Regulation in the United States*, 31 ENVTL. L. REP. 10040 (2001) (stating that "although precautionary measures for achieving food safety in the United States are some of the oldest and most successful in the world, even such measures fall short when they are evaluated from the unifying perspective of the Precautionary [P]rinciple.").

49. *Id.* at 10043.

50. *Id.* (citing NATIONAL RESEARCH COUNCIL, COMMITTEE ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 29 (2000)).

bioengineered foods they produce contain "food additives," or if they fail to announce that some technique employed during development is not GRAS, then the product will not trigger precautionary review.[51] In response to the proposition that GRAS status should be per se sufficient to avoid regulatory review, Professor Walker points out that the FDA strictly regulates certain categories of food additives, such as color additives, without exception for GRAS status.[52]

Professor Walker proposes an across-the-board risk management model as rigorous as Congress's regulation of carcinogens in the Delaney Clauses.[53] The level of protection for carcinogenic pesticide residues must be "to a reasonable certainty that no harm will result,"[54] which Congress defined as "a lifetime risk no greater than one in one million, calculated using conservative assumptions."[55] Other substances covered under the Delaney Clauses have a "zero tolerance" level of protection.[56] Professor Walker believes a "reasonable certainty" standard would be more appropriate than the current, less rigorous GRAS standards for genetically modified food.[57] Such a model would reflect the Precautionary Principle because it weighs the risks and benefits of a given substance and sets a level of protection accordingly.[58] Professor Walker argues that using multiple standards for different types of harmful substances based on potential economic consequences is a dilution of the

---

51. *Id.* at 10044. Professor Walker is skeptical of GRAS status because of the broad latitude it can provide a bioengineered food product. For instance, as compared with a color additive, "[t]he permissive trigger for genetically modified foods has the potential to leave many such foods unreviewed by the FDA." *Id.* at 10043-44.

52. *Id.* at 10043.

53. *Id.* at 10042 (citing 21 U.S.C.A. §§ 348(c)(3)(A), 360b(d)(1)(I), 379e(b)(5)(B) (2000)).

54. *Id.* at 10042.

55. *Id.* (citing H.R. REP. NO. 104-669, pt. 2, at 41 (1996) ("It is the Committee's understanding that, under current EPA practice . . . EPA interprets a negligible risk to be a one-in-a-million lifetime risk.")).

56. Walker, s*upra* note 48, at 10042. "If a food additive, for example, is found to induce cancer when ingested by animals, then the FDA has no discretion to approve that additive as safe." *Id.*

57. "The Precautionary Principle would itself provide a justification for a conservative trigger. . . . Moreover, the burden should be on the government to justify any departures from this protective trigger in the case of food." *Id.* at 10044.

58. *Id.*

Precautionary Principle, and thwarts the effectiveness of consistent cost-benefit analysis.[59]

D. Product Stewardship and Economic Efficiency: Premarket Notification as Beneficial to the Bioengineered Food Industry in the United States

Stanley H. Abramson and J. Thomas Carrato[60] describe the policy view of the major U.S. developers of bioengineered food. Such developers have voluntarily consulted with the FDA since 1992.[61] Abramson and Carrato take the position that both the government and private industry should share the responsibility for ensuring the safety of bioengineered food.[62] They believe that additional regulation, such as the proposed regulation, should be part of an ongoing discussion process rather than a total policy shift.[63] They state that, while government agencies must rigorously review new products according to "clear, consistent rules," developers must also assess the safety of their own products, both before and after they go to market.[64] The crux of this position involves extensive "product stewardship" by corporations and through industry cooperation. As product stewards,

---

59. *Id.* at 10045:

> Perhaps lawmakers think that it is more reassuring to the public if they pretend that determining acceptable levels of food risk is always a purely scientific matter, instead of a management decision involving costs and benefits. But adopting the Precautionary Principle would mean placing a higher value on acknowledging scientific uncertainty and on transparency, and placing the burden of proof on those who would trade off protection against benefits.

60. Mr. Abramson's biographical note describes him, in part, as "a principal drafter of the Coordinated Framework for Regulation of Biotechnology during his tenure at the U.S. Environmental Protection Agency." Stanley H. Abramson & J. Thomas Carrato, *Crop Biotechnology: The Case for Product Stewardship*, 20 VA. ENVTL. L.J. 241, 241 n.a1 (2001). Mr. Carrato's biographical note describes him as "Assistant General Counsel for Regulatory Affairs with Monsanto Company in St. Louis, Missouri, and co-chair [of] the company's Health and Environmental Stewardship Council." *Id.* at n.a2.

61. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4704 (proposed January 18, 2001).

62. Abramson & Carrato, *supra* note 60.

63. *Id.* at 266.

64. *Id.*

developers take responsibility to provide products and technologies that are "safe as well as socially and environmentally responsible."[65]

According to Abramson and Carrato, private developers of bioengineered foods are not opposed to significant government regulation.[66] They believe that government regulation serves valuable functions, including assuring developers and the public of product safety.[67] Developers also undertake exhaustive risk analysis, however, including a scientific assessment of the possible risks associated with the product. Because private industry bears responsibility[68] if a product causes any public harm, bioengineered food developers have significant incentive to minimize all assessed risks.[69] In addition to safety risks, Abramson and Carrato believe that developers, rather than governments, are best able to manage the environmental and social concerns regarding their products post-market.[70]

Abramson and Carrato claim that the United States has taken a "middle ground" approach in regulating bioengineered food.[71] This

---

65. *Id.* at 259.

66. "Rigorous, science-based safety assessments must be conducted for each new product or product category, first by the product developers and then by agency scientists." *Id.* at 266.

67. *Id.* at 241.

68. In addition to civil liability, bioengineered food developers must also consider factors including "health, safety, environmental, and agricultural impacts; regulatory acceptance; public acceptance . . . [and] market acceptance." *Id.* at 262. The developer must assess and minimize each potential risk before marketing any new bioengineered food. *Id.*

69. *See id.* at 262. *See also* Charles A. Deacon & Emilie K. Paterson, *Emerging Trends in Biotechnology*, 20 REV. LITIG. 589, 597 (2001). Without clear regulation, an increase in litigation and in plaintiffs' damages may complicate the development of bioengineered food. *Id.* The safety standards that courts apply in tort liability may not reflect the FDA's standards for bioengineered foods. *Id.* Deacon and Paterson explain that this disparity could result in diverging statutory and common law duties for developers of bioengineered foods.

> Hypothetically, where a defendant could demonstrate that it has FDA approval or has stayed within FDA guidelines, the plaintiff could possibly try to establish that the FDA's standard is less stringent than the duties owed under common law in order to demonstrate liability. Biotech companies cannot rely on federal regulatory approval to create a shield from liability.

Id. at 598.

70. Abramson & Carrato, s*upra* note 60, at 266.

71. *Id.* at 245. On the other hand, at the international level, some authors believe that the European Union's position on biotechnology constitutes a "middle ground" when compared with the positions of other international groups. *See, e.g.*, David J. Schnier, *Genetically Modified Organisms and the Cartagena Protocol*, 12 FORDHAM ENVTL. L.J. 377, 404 (2001);

"middle ground" involves more regulation than what is called for by those believing that genetic engineering is no more hazardous than traditional plant breeding. But the approach reflects the view that excessive government oversight may inhibit technical advances.[72] Accordingly, the middle ground approach favors regulations that are less restrictive than those that the European Union and other followers of the Precautionary Principle have implemented, which seek to exclude products from the market until they meet a zero risk standard.[73] Abramson and Carrato contend that current regulation, as promulgated in the Coordinated Framework, regulates bioengineered food but still allows many bioengineered products to reach the marketplace.[74] Regarding the purpose of the Coordinated Framework, Abramson and Carrato say that "[t]his cautionary approach was adopted primarily in response to public perception rather than any inherent danger associated with the technology."[75]

E. Industrial Autonomy as Sufficient to Ensure the Safety of the Food Supply

Some observers of the biotechnology industry believe that, optimally, developers would manage the risks of their bioengineered food products voluntarily and independently of regulation.[76] Thomas

---

Gareth W. Schweizer, Note, *The Negotiation of the Cartagena Protocol on Biosafety,* 6 ENVTL. LAW. 577, 588 (2000).

72. Abramson & Carrato, *supra* note 60, at 244-45. More than three thousand scientists, including two Nobel Prize winners (James Watson and Norman Bourlaug), have signed a letter indicating their support of biotechnology and genetically modified food. Schnier, *supra* note 71, at 382 (citing Petition from C.S. Prakash, Prof., Tuskeegee University, to Scientific Comm., AgBio World, Scientists in Support of Agricultural Biotechnology, *available at* http://www.agbioworld.org/PHP/index_all.phtml (last visited, Jan. 11, 2003)).

73. Abramson & Carrato, s*upra* note 60, at 244-245 (citing Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851 (1996)).

74. *Id.* at 245. *See also supra* note 3.

75. Abramson & Carrato, *supra* note 60, at 246.

76. Thomas P. Redick & Christina G. Bernstein, *Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date with Damocles*, 30 ENVTL. L. REP. 10328 (2000). Redick and Bernstein posit that nuisance law could act as an alternative to strict anti-biotechnology legislation in international food markets:

> Commentators have suggested for years that public nuisance law provides an ideal mechanism for regulating the environmental impacts of biotechnology because it provides an existing legal framework that could prevent threats to the environment

P. Redick and Christina G. Bernstein, scholars in biotechnology risk management, believe that comprehensive voluntary stewardship would have both domestic and international benefits for developers and growers.[77] At the domestic level, under a purely voluntary system, developers and growers would be able to contract freely and plant crops of their own choosing. They would thereby maximize the benefits of bioengineered foods.[78]

Redick and Bernstein suggest that, at the international level, product stewardship could support differing objectives depending on the existing legislation of countries that import U.S. products.[79] In the

---

> before they occur. . . . [P]ublic nuisance law provides a model system that could be used to streamline the approval process in developing countries lacking an adequate environmental regulatory system, provided there is a system of adjudication . . . capable of resolving a threat posed by GMOs.

Id. at 10336 (citing *Daniel P. Larsen, Combatting the Exotic Species Invasion: the Role of Tort Liability*, 5 DUKE ENVTL. L. & POL'Y F. 21 (1995)). Such an approach might supplant a Precautionary Principle-type zero-risk standard with a "more cost-effective, immediate solution to threats of GMOs." Redick & Bernstein, *supra* at 10336. These authors suggest that this approach would be appropriate for countries that wish to receive the benefits of bioengineered foods but lack the resources for full-scale regulation as in the European Union. *Id.*

77. Redick and Bernstein propose a six-step "production scheme" for bioengineered food developers who wish to engage in international trade:

> 1. [S]ecure regulatory approval in major overseas markets before marketing new GMO varieties;
>
> 2. [W]here regulatory approval cannot be secured, establish a segregated stream of commerce to prevent the commingling of unapproved varieties with export-approved varieties;
>
> 3. [P]romote the establishment of reasonable "tolerance levels" (e.g., up to 5 percent unapproved GMO content) in foreign markets that are wary of new GMOs;
>
> 4. [S]pecify appropriately conservative distances for avoiding significant outcrossing;
>
> 5. [E]stablish methods for monitoring outcrossing; and
>
> 6. [M]anage grower incentives and conduct so the system works as planned.

Redick & Bernstein, *supra* note 76, at 10341.

78. *Id.* at 10330. "There is still time to maintain a voluntary approach to managing nuisance risks before the cyclones of litigation or state legislation blow away contracts and the freedom of growers to plant the crop of their choice." *Id.* This freedom to contract would allow growers and developers to make agreements "optimized to local conditions and the needs of the parties to the contract." *Id.* at 10341 (citing Thomas P. Redick *et al*., *Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path Within the Biosafety Protocol*, 4 ENVTL. L. 52 (1997)).

79. U.S. exporters would adhere, at minimum, to industry standards. Redick & Bernstein, s*upra* note 76, at 10341.

European Union, for example, rigid legislation governs bioengineered food. American developers thus face significant regulatory obstacles to importing crops for sale, whether bioengineered or otherwise.[80] Developing countries, on the other hand, may wish to import such goods, but may lack even rudimentary regulation to protect themselves from injury.[81] The former situation might require developers of bioengineered food to adapt their practices to standards that are more rigorous than those in the United States.[82] The latter situation would require developers to adhere to appropriate safety standards, so as not to create environmental or health hazards. In both cases, the incentive to self-impose additional regulation arises from the developer's interest in safely marketing its products around the world.[83] An important aspect of self-imposed regulation is that developers and producers must rigorously adhere to

---

80. *Id.* at 10332. For an in-depth discussion of these laws, see Terence P. Stewart & David S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243 (1999). Genetically modified food imported to the European Union must satisfy two main laws: "The first such law, Council Directive 90/220/EEC, concerns . . . GMO products that may be described as raw materials. The second law, Regulation No. 258/97, applies to . . . 'novel foods,' including foods containing GMOs." *Id.* at 256. Council Directive 90/220/EEC, Part C, describes requirements for placing bioengineered food products on the European market (including foods imported from the United States). *Id.* at 256-57. First, the importer (who could be a developer, manufacturer, producer, etc.) must provide an application involving extensive disclosure to the state in which the importer proposes selling the goods. *Id.* If the member state reviews and approves the application, it must forward the application to all of the other member states in the European Union, any of whom may object, triggering a vote on the proposal. *Id.* at 258-59. Once a product has received approval in this process, the importer may market it, with identifying labeling, throughout the European Union with no further notification, though any individual state may request a "provisional restriction" barring the product from its own borders. *Id.* at 259-60. Regulation No. 258/97 operates in essentially the same way, though it requires additional submission of safety studies. *Id.* at 279.

81. Redick & Bernstein, s*upra* note 76, at 10335.

82. *Id.* at 10341. Logically, developers must take responsibility for apprising themselves of potential regulatory hurdles: "The loss of substantial investment costs to the seed manufacturer who develops a product line that cannot reach its intended market due to the threat of liability can be avoided by careful planning." *Id.*

83. *See id.*:

> [I]ndustry efforts at coordinated stewardship should be initiated on a global basis to ensure that unreasonable releases of GM crops do not occur. In the final analysis, it is in the agricultural biotechnology industry's best interest to develop and adhere to its own set of reasonable standards for identity-preserved chains of commerce.

procedures, lest "one bad apple" cause environmental contamination.[84]

A voluntary program of industry stewardship, say these authors, would protect the industry against the arbitrary actions of government authorities. Their concern is that such authorities may implement standards hostile to bioengineered foods based on subjective criteria or on misinformation.[85]

Other scholars believe that the failure of corporations to develop and use bioengineered foods would result in significant social, economic, and environmental harm.[86] Professor Drew L. Kershen of the University of Oklahoma College of Law further suggests that nations, as well as corporations, who fail to embrace biotechnology are guilty of scientific ignorance.[87] He poses several admittedly improbable examples of consequences that could occur given certain corporations' current opposition to bioengineered food.[88] Professor

---

84. "The 'One Bad Apple' effect takes the 'tragedy of the commons' that gave birth to environmental law to a new level: the entire chain of commerce in a particular crop . . . can be ruined by . . . a single grower who is oblivious to the risk." *Id.*

85. *Id.* at 10330 (contending that government authorities "may be misinformed, angry, or otherwise unsympathetic to the environmental and economic benefits of present and future GMOs").

86. Drew L. Kershen, *Essay: The Risks of Going Non-GMO*, 53 OKLA. L. REV. 631, 633 (2000).

87. *Id.* at 633.

88. The risks of forgoing bioengineered products in favor of traditional products are threefold, finds Professor Kershen, as "[t]wo risks entail legal accountability[, while] the third risk is a societal risk with legal implications. Those three risks are: the risk of legal liability for damages; the risk of environmental [non]compliance; and the risk of scientific ignorance." *Id*. at 632-33. In one example, Gerber (the baby food producer and subsidiary of Novartis, a major developer of bioengineered products), has ceased to use genetically modified components in its products in response to public pressure. *Id.* at 633. Professor Kershen suggests a circumstance in which a baby develops cancer due to carcinogenic toxins that are present in "organic" foods, but are reduced in certain bioengineered foods. *Id.* at 634. Gerber, he suggests, could incur product liability because it "knew of a baby food designed . . . with less risky ingredients and purposefully chose to use the riskier design—i.e., Gerber chose to use [non-bioengineered] ingredients knowing that these have a higher risk of [toxin] contamination." *Id.* at 635.

In another example, because "anti-biotech" groups successfully pressured several major fast food chains to stop using bioengineered potatoes, farmers who supply the fast food chains with potatoes have ceased, or dramatically reduced, planting such crops. *Id.* at 637-39. The benefit of the modified (NewLeaf™) potato is that it is resistant to certain types of insects, thereby reducing the need for pesticides. *Id.* Professor Kershen suggests that the fast food chains' refusal to buy genetically modified potatoes could lead to an environmental crisis because potato farmers continue to contaminate the environment with pesticides which could have been avoided by use of the pest-resistant, genetically modified potato. *Id.*

Kershen's key proposition is that governments[89] and public opinion[90] ought not dissuade bioengineered food developers from the scientific pursuit of safe, nutritious, and environmentally sound products.[91]

III. ANALYSIS

A. Bioengineered Food and the Precautionary Principle: Premarket Notification as Insufficient to Ensure Product Safety

Proponents of the Precautionary Principle believe that premarket notification, as proposed, is merely a token gesture, and that immediate promulgation of comprehensive regulation is necessary to protect food safety in the United States.[92] According to these critics, the United States prides itself on having a safe food supply but exerts relatively little force over developers of bioengineered foods.[93] For example, in stark contrast to the European Union's strict policies regarding bioengineered foods,[94] the United States relies on

89. In his description of the Italian Agriculture Minister, Professor Kershen discusses a possible consequence of the repression of biotechnology: "Italy is at risk not only of falling behind in the rapidly advancing science of biotechnology but also of abandoning the freedom of scientific inquiry. If twenty-first century societies adopt scientific ignorance as a basis for decisions, then scientific method and scientific research are the early victims." *Id.* at 649.

90. Professor Kershen points out that the most vocal opponents to bioengineered food are "among wealthy classes . . . who very likely will never go hungry." At the same time, he says that "[t]hese same consumers know that they will be ill . . . and wealthy consumers have warmly and openly embraced pharmaceutical biotechnology." *Id.* at 651. *See also* Michael Siegrist, *Poorer European Countries are Less Concerned About Biotechnology than Richer Countries*, 12 RISK: ISSUES HEALTH & SAFETY 29 (2001) (A statistical analysis of public opinion regarding bioengineered food in all fifteen members of the European Union showed a strong inverse proportionality between GNP and public confidence in the safety of bioengineered food).

91. Kershen, *supra* note 86, at 651.

92. In addition to the legal scholars discussed in Part II.C, some consumer groups also hold this position, including the Public Interest Research Group (PIRG). For a summary of PIRG's position on the proposed regulation, see Press Release, New FDA Policy Fails to Require Testing or Labeling of Genetically Engineered Food, Jan. 17, 2001, *at* http://www.pirg.org/ge/GE.asp?id2=4806&id3=ge& (last visited Jan. 11, 2003). For a summary of PIRG's position on bioengineered foods in general, see Richard Caplan, *Chew on This*, CHARLESTON GAZETTE-MAIL, at 1C, Apr. 8, 2001, *available* at http://www.pirg.org/ge/reports/gefoodoped.pdf (last visited Jan. 11, 2003).

93. *See* Walker, *supra* note 48, at 10040.

94. Stewart & Johanson, s*upra* note 80. An important consideration upon review of European policy is whether restrictions on bioengineered products are truly a result of concern about safety, or whether the restrictions might reflect protectionist attitudes and a desire to

developers themselves to notify the government when their products may be unsafe.[95] At its very worst, this disparity could result in the cessation of the global trade in American agricultural products, resulting from an international disapproval and mistrust of the products' safety.[96]

In a similarly dramatic worst-case scenario, proponents of the Precautionary Principle worry that without appropriate government regulation of bioengineered foods, the American marketplace could embrace the benefits of bioengineered foods without adequately assessing the risk associated with them.[97] After an initial rapid expansion of the industry, subsequent adverse safety findings could result in a sudden and disabling exposure of the bioengineered food industry to tort liability. Such a scenario would quash the research and development of bioengineered foods, and deprive the American

---

remove cheaper competition. *See generally* Stone, *supra* note 47. If Europeans opposed to biotechnology developed their viewpoints through information promulgated by traditional food producers, the information might suggest such a link. Furthermore, the relative wealth of European nations might explain some other aversion to bioengineered foods but not to bioengineered pharmaceutical products. *See* Kershen, *supra* note 86, at 651. This apparent double standard might support the proposition that Europeans do not mistrust biotechnology outright, but rather maintain their bias against it out of the belief that it is unnecessary.

95. Walker, s*upra* note 48, at 10043. Disclosure to the government of recombinant DNA products is voluntary under current regulations. The proposed regulation would require disclosure of these bioengineered products. *See supra* note 32. Even with the passage of the proposed regulation, however, some bioengineered products could still fall within exemptions from disclosure. *Id.* These exemptions would include previously certified transformation events, products employing previously submitted applications of bioengineered food, and products for which the FDA has already issued a letter of compliance (either under the mandatory process proposed in the rule, or under the current voluntary consulting process). *Id.* The exemptions that would remain after enactment of the proposed regulation are much smaller than current exemptions from premarket regulation.

96. In an unlikely example, if the rest of the world adopted the Precautionary Principle (which requires strict labeling in addition to regulation of development) and the United States continued its current practices, American producers of traditional and bioengineered foods would be unable to compete in the global market. A more likely scenario involves a significant disadvantage for the United States in trading with wealthy industrialized nations who have adopted the Precautionary Principle, though opportunities in technology-favorable nations such as China would be unharmed. *See* Hamilton, *supra* note 46, at 100-02.

97. Such a possibility is the essence of a Precautionary Principle argument. These scholars argue that where risks could be unknown, simply taking precautions against known risks cannot logically be sufficient. *See* Walker, *supra* note 48, at 10040. As a practical matter, however, individuals, companies, and governments must always submit to unknown risks. A cost-benefit analysis to determine an appropriate safety margin remains the usual measure of protection against known risks as well as an aggregate unknown risk. *Id.* at 10044.

and international communities of their possible benefits.

In order to satisfy proponents of the Precautionary Principle, the FDA would have to adopt far more extensive regulation than what is currently proposed.[98] The government would likely have to oversee each stage involved in bringing a bioengineered product to market. This would include the strict observation of developers, farmer/growers, storage facilities, and purchasers of agricultural products. Regardless of whether a product was genetically modified, it could proceed to processing as food or feed only with an airtight pedigree. Possible effects of this sort of policy would include commensurately higher prices for consumers on all types of domestically produced food, as well as greater costs for exporting the products. If products imported from other countries did not adhere to the same production rules as domestic products, they could afford to charge lower prices. Even if imported products had price protections to make them competitive with domestic products, export of the more costly American products to a nation with lighter restrictions would be unprofitable. Such regulation would, therefore, create a competitive disadvantage for American food producers, especially farmer/growers.[99]

B. Product Stewardship and Economic Efficiency: Premarket Notification as Beneficial to the Bioengineered Food Industry in the United States

Large corporations and the federal government often seem to embrace the view that they should cooperate in order to maximize

---

98. *See Id.* at 10043, arguing that the "conservative trigger" applied by the government to color additives in food is superior to the broad reach of the GRAS standard which removes a wide variety of products from governmental scrutiny. The "conservative trigger" would not exempt products already in use, nor products that contain only very small amounts of the regulated substance.

99. The increased expense to farmer/growers arises due to the administrative costs they would incur in monitoring the pedigree of their products, whether the products were bioengineered or traditional. Whether producing or selling traditional or bioengineered products, each person or company through whom agricultural products flowed would have to maintain documentation in order to ensure that the two types of products never mixed with each other. Furthermore, as producers, farmer/growers would bear many of the costs associated with a more complicated contract system for the sale of agricultural products.

both the economic benefits and safety of bioengineered foods.[100] Under such a scheme, corporations would conduct extensive testing of their own products and would make regular, detailed reports to federal agencies, which would maintain vast databases of relevant information.[101] While the government would strive to encourage new developments in bioengineered food, corporations would exert pressure on legislators to ensure the promulgation of extensive but favorable regulations.[102]

This approach would preclude many of the potential problems of embracing the Precautionary Principle. The industry would be able to continue to develop new, safe products and bring them to market without fear of oppression by zero-risk-tolerant policies. Further, by adopting regulations that would be sufficient to ensure safety, but less radical than those advocated by Europe, the exporters of United States food products would not suffer from the higher production costs of adhering to the Precautionary Principle.[103]

On the other hand, this approach, which centers on cooperation between large developers and the federal government, leaves little room for smaller developers who may be crippled by the costly measures proposed by the FDA.[104] These companies may not even have products on the market yet, and may lack the administrative funds or corporate personnel to pursue certification.[105] To retain the benefits of industry and government cooperation while protecting the American tradition of entrepreneurship and competition, United

100. *See* Abramson & Carrato*, supra* note 60, at 242.

101. *Id.* at 266.

102. *Id.* at 264.

103. Ideally, producers who wished to trade in Europe could adopt European procedures of their own accord, but they would not have to charge higher prices across the board where only a fraction of the market required the more strenuous regulation. These producers might choose to adhere to a "crop production scheme" like that suggested by Redick and Bernstein for use in a regulatory environment of industry autonomy. *See supra* note 77.

104. *See supra* note 44. These "small" companies are not necessarily family businesses lacking in sophistication. For statutory purposes they have revenues of up to five million dollars and have as many as 500 employees. For a company of the maximum size, the $21,000 expected cost of premarket certification would be roughly one-half of one percent of the annual revenue. Where a company is smaller than that, however, particularly considering the tight margins under which start-up type companies are known to operate, the costs of the certification could be prohibitive.

105. *See supra* notes 41-45 and accompanying text.

States policy on bioengineered foods must be flexible and efficient.[106]

The current regulatory climate closely resembles this approach to biotechnology regulation. Therefore, the proposed regulation would likely have only a small effect on present-day farmer/growers, food processors, and consumers. Nearly all developers of bioengineered food in the United States are large corporations that already participate in the voluntary consulting process. Thus, the only substantial additional burden imposed by the rule would be a requirement to file disclosure documents.[107] While these requirements are considerable in themselves, their administrative costs may be distributed across the enormous number of producers and farmer/growers who purchase seed for each product that is considered for certification.

C. Industrial Autonomy as Sufficient to Ensure the Safety of the Food Supply

Some observers of the bioengineered food industry advocate industrial autonomy, especially with respect to international trade.[108] In the same way that the adoption of the Precautionary Principle

---

106. *See* Geistfeld, *supra* note 3, at 187. In pursuit of an efficient regulation mechanism of bioengineered products, a cost-benefit analysis should, of course, include safety concerns. It should also consider costs to consumers as well as costs to developers and producers. Professor Geistfeld would find labeling issues (not examined herein) central to the safety side of the analysis, because they are dispositive of consumer assumption of risk. *See supra* notes 2-3. From the economic side of the analysis, a system that imposes equal costs on each product that potentially enters the market, regardless of the size of its likely market, does not satisfy an equitable cost-benefit analysis. Participants in the industry should share in the costs to the extent that they contribute to the risk. Thus, greater participants in the industry would bear a greater share of the costs of ensuring safety. Small companies with relatively slight market participation should bear a smaller share of the costs. Though both large and small developers of successfully certified products would have an opportunity to pass their costs to consumers, a product with a larger consumer base would pass on a marginally smaller share of the cost. Smaller companies with less market penetration would still bear negative effects in such a case.

Costs, then, of the proposed regulation, as it is currently stated, include the administrative costs of compliance as well as possible anticompetitive effects on small companies. Benefits of the proposed regulation might include greater assurance of food safety for domestic consumers, protection against liability for developers of bioengineered foods, and possibly a slightly more favorable position in the international market for bioengineered foods (depending on whether the rule itself is potent enough to have any effect in the global arena).

107. Regulatory Flexibility Act, 5 U.S.C. §§ 601-602 (2000). *See also supra* note 44 and accompanying text.

108. *See generally* Redick & Bernstein, *supra* note 76.

would make American seed stock or American-grown produce prohibitively expensive for less wealthy nations, voluntary product stewardship would permit developers and producers to do business in such countries.[109] In fact, voluntary product stewardship would allow developers latitude to provide products that would adhere to the standards of any country with which they wished to transact. Instead of adherence to a single, prohibitively costly FDA standard applicable to all bioengineered products produced in the United States, the industry could employ a sliding scale of price and product restrictions depending on the location of intended consumption.[110] Such cooperation would maximize competition in the global marketplace, as the most restrictive countries would no longer be able to establish standards for the rest of the world.

Industrial autonomy in the global marketplace would provide a market efficiency greater than any uniform standard could achieve. Without the proposed regulation, or others like it, consumers would

---

109. *Id.* Through Redick and Bernstein's six-step "production scheme," developers could efficiently transact with both of these groups. *Id.* at 10341. A key benefit of industrial autonomy is the maximal freedom of contract for both developers and consumers. *Id.* at 10330. Without government restrictions on labeling for example, or with use restrictions requested by the developer, buyers can procure the lowest possible price. A drawback of this policy would be a disparity of bargaining power between negotiating parties, which could lead to unfair contracts. Developers of bioengineered products who desired to transact with less sophisticated buyers would have to take great pains to ensure that the deal was fair. With regard to remedies available in case of a developer corporation's misconduct, the premise of Redick and Bernstein's proposal is that nuisance law, both public and private, can apply to corporations expanding into markets without biotechnology regulation. Though nuisance law may provide an enforcement mechanism against developers who transact irresponsibly, thereby causing damage to the local environment, developers may find themselves in the position of dealing with farmer/growers who are unwilling to follow environmental precautions. Under these circumstances, without governmental support of the necessary environmental protections, developers would have to take responsibility for cleanup and remedy where farmer/growers were unable or unwilling to do so.

110. The term "sliding scale" seems to connote that wealthy countries can pay more for their products, and should therefore receive greater protection. While this unpleasant proposition may technically be true, where the real additional benefit associated with the costly protections is small, the marginal detriment to a country without such protections is also small. *See also* Siegrist, *supra* note 90. Michael Siegrist's data, which suggest that poorer countries are less averse to bioengineered food, are limited in scope to European countries. *Id.* at 32. If such a trend were broadly applicable, one might expect that underdeveloped countries (and not just less wealthy European countries) would be willing markets for bioengineered foods. *Id.* at 33. Given these countries' lesser ability to pay for the technology, developers might be willing to provide it at a reduced cost.

generally pay lower prices while producers would benefit from greater sales. This viewpoint, however, requires that all industry participants maintain strict self-controls, and thus remains susceptible to the "one bad apple" problem.[111] Further, it provides no governmental protection to developers against their liability to unsatisfied customers.[112] The benefits of industrial autonomy come at a cost of health, safety, and environmental risk for the general public.

Under the industrial autonomy approach, less regulation is better regulation with respect to the competitive market. Under this analysis, the proposed regulation would be an unnecessary barrier to free trade. Advocates of industrial autonomy would be dissatisfied with any rule that purported to regulate either biotechnology or food products in general.

---

111. *See supra* note 84 and accompanying text. The industrial autonomy model does not provide a reasonable or workable philosophy for the domestic regulation of biotechnology. Only in combination with centralized government regulation can the industrial autonomy model increase efficiency without detriment to the safety of citizens or to protection of the environment. In practice, the model would require product compliance only at the location of consumption or sale, not at the location of development. Where centralized government regulation is not available, as in underdeveloped countries, the industry would have to take responsibility to provide safe, environmentally sound products. From this, however, originates the risk of "one bad apple" spoiling the lot. *Id*. While the risk might be unattractive to a country able to acquire a wide variety of goods, for a developing country the additional risk involved may be small as compared to the benefit of receiving bioengineered products at a low cost.

112. *See* Deacon & Paterson, s*upra* note 69. According to Deacon and Paterson's assessment of tort liability with regard to statutory compliance, developers of bioengineered food cannot, as a rule, assume that FDA approval certifies a tort-resistant standard of due care. *Id.* at 598. One product of the proposed regulation, however, is a letter of compliance from the FDA, which states that the developer has met the applicable standard of care. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4713. *See also supra* note 32 and accompanying text. Given a trial court's discretion to require a higher standard than demanded by the FDA, there could be a possibility of a divergent standard of care.

Without centralized government regulation, there would not be a divergent standard of care for bioengineered products between common law and statutory obligations. Common law obligations would be the only relevant standard, and as a result, developers would have virtually unchecked liability to disgruntled consumers. A possible consequence of such liability could be massive tort damage awards. In turn, these could lead to the industry's collapse. Alternatively, developers might choose to pass the costs of the tort awards to their consumers. A worst-case scenario would be that without centralized regulation, one or more developers might fail to act responsibly, causing significant damage to the population or to the environment. Without a grant of executive authority to act against the developers, however, individuals would have to carry the burden, perhaps through nuisance suits. *See generally* Redick & Bernstein, *supra* note 76.

IV. PROPOSAL

The FDA should adopt the proposed regulation to promote a policy of cooperative product stewardship. Cooperative product stewardship between the government and developers of bioengineered foods will provide domestic and international consumers of American products with the greatest variety of safe, environmentally sound products. The proposed regulation, as currently written, will neither cause serious harm nor provide a great benefit to major food developers. Because all current major developers of bioengineered products have participated in the voluntary process, the rule as enacted would add only the costs of preparing the public disclosure documents. As estimated by the FDA, these costs are relatively small when compared to the revenue of major developers.

While the proposed regulation will generally promote the development of bioengineered foods, as drafted, it may still present serious obstacles to small developers. A key area for improvement is the application process for small developers. The principal modification in the rule, as written, is that small developers should be allowed to conduct some consultation sessions over the telephone instead of in person.[113] While this modification may be a valuable governmental concession, one possible improvement might include some form of government subsidy to defray the cost of the process, pending a preliminary showing of an approvable product. Alternatively, the government could pare down the required filings and collect or maintain additional information at its own expense. Financial or administrative assistance would provide small developers with more opportunities to bring new products to market and compete with large developers for the benefit of consumers.

The proposed regulation, if passed, will not have a significant effect on the competitiveness of bioengineered foods imported to the United States. While the rule may increase production costs domestically due to its extensive disclosure requirements, international developers will have to submit to the same process.

---

113. Regulatory Flexibility Act, 5 U.S.C. §§ 601-602 (2000). *See also supra* note 44 and accompanying text.

Therefore, the proposed regulations will not give international developers any price advantage over their domestic counterparts. More importantly, consumers will be assured of the same level of safety with international products as they can with domestic products.[114]

With regard to the export of American bioengineered foods, the proposed regulation may provide additional assurance of product safety in some international markets. It will not placate advocates of the Precautionary Principle, nor will it satisfy those whose primary concerns involve labeling of bioengineered products. On the other hand, the safety standards that developers must meet for certification will provide a benefit to export destinations where there are no such requirements. Adherence to these standards and certification procedures, however, may make United States products more expensive and therefore less competitive in these markets. Where the United States may wish to trade with an underdeveloped or impoverished nation, some reduction of the statutory requirements might allow the sale of bioengineered products that still meet minimum safety standards.

As part of a cooperative product stewardship model, the United States might consider adopting some elements of an industrial autonomy model, especially with regard to international trade. A workable modification of the industrial autonomy model might consist of certain minimum standards for the development and production of bioengineered foods, whereby developers would choose the final standards to meet for a given product, depending on where they wished to market it. Premarket notification itself might not differ significantly for products that are intended for domestic consumption. Yet, developers might choose to follow different or additional requirements for the labeling or post-sale restrictions on using such products.

The United States government should not adopt the Precautionary Principle as the model for biotechnology regulation. While a Precautionary Principle model might make United States products more attractive for sale in the European Union in the short term, it

---

114. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4712. *See also supra* note 24 and accompanying text.

would likely result in prohibitively higher prices domestically and thus dampen efforts to develop new products. As government agencies and developers of bioengineered foods cooperate to develop new products, the more conservatively regulated nations will realize that they are at a trade disadvantage.

V. CONCLUSION

No matter how much attention one pays to the back-stage details of bringing bioengineered foods to market, developers and producers' money and efforts are wasted if consumers lack confidence in the product. Many Europeans have decided to reject biotechnology and to forego its associated benefits. In general, Americans are not up in arms over bioengineered foods, but the average consumer is probably not fully aware of the bioengineered products that he or she encounters on a daily basis. What seems like academic debate over regulatory procedures today may tomorrow become a matter of general social concern, should Congress pass legislation mandating the labeling of bioengineered foods. The FDA and developers of all types of biotechnology should begin to educate the public about the benefits and risks of biotechnology before extremists have a chance to convince them to fear it.