

# **COMMENT**

## **ISSUES IN THE REGULATION OF BIOENGINEERED FOOD**

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### **I. INTRODUCTION**

It has been 17 years since the groundbreaking 1975 meeting at Asilomar where scientists discussed the emerging technology of molecular biology, its vast potential and the possible risks that could result from the ability to transfer DNA from one organism to another.<sup>1</sup> Since then, a number of biotechnology-derived pharmaceutical products have already gone on the market,<sup>2</sup> and the first food and agricultural

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1. Paul Berg et al., *Asilomar Conference on Recombinant DNA Molecules*, 188 SCIENCE 991 (1975).

2. Ann Gibbons, *Biotech Pipeline: Bottleneck Ahead*, 254 SCIENCE 369 (1991).

products have been approved or are close to approval.<sup>3</sup> Many more such products are under development, and there have been no adverse impacts on human health or the environment. Rather, reputable scientific and medical sources stress the potential of biotechnology to improve human health and nutrition, and to ameliorate the adverse impacts of traditional agricultural practices on the environment.<sup>4</sup> Despite the abundance of data indicating the beneficial potential of biotechnology and the absence of harmful incidents, genetic engineering has aroused considerable public suspicion and from some quarters a demand for government oversight out of proportion to the demonstrated risks. The negative perception and resulting regulatory response threatens to adversely affect the development and competitiveness of this fledgling industry, and may also delay or even block the introduction of beneficial products.

This Comment examines issues in the regulatory oversight of the production and consumption of bioengineered food. As an introduction, the Comment first examines the range of products under development and their potential benefits and risks. It next considers the recent controversy over the use of genetically engineered bovine growth hormone, which illustrates many of the issues in this area. The next section presents biotechnology's possible risks and then discusses the advantages of a comparative approach to risk regulation of bioengineered food. Next, the Comment examines the current government regulation of this technology. Since the potential risks involve both the genetically engineered food products and the environmental release of the organisms that produce them, regulation in these areas is analyzed. This regulation has been implemented through the "coordinated framework," an adaptation of existing statutes to the oversight of biotechnology. Although regulation under the coordinated framework has the advantage of not singling out biotechnology for special oversight, the Comment examines some of the criticisms that stem from adapting existing statutes to address biotechnology. The Comment next considers, in light of the benefits of a comparative approach, some recently proposed approaches to regulation. Finally, the Comment contemplates what modifications in government policy and regulation might improve the public perception of biotechnology, strengthen the industry, and foster the generation of products that are not merely profitable, but also truly beneficial to both human health and the environment.

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3. Direct Food Substances Affirmed as Generally Recognized as Safe; Chymosin Enzyme Preparation Derived From *Escherichia coli* K-12, 55 Fed. Reg. 10,932 (FDA 1990) [hereinafter Direct Food Substances Affirmed] (codified at 21 C.F.R. § 184.1685 (1991)); Council on Scientific Affairs, Am. Medical Ass'n, *Biotechnology and the American Agricultural Industry*, 265 JAMA 1429 (1991).

4. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1429-34.

## II. BIOTECHNOLOGY USED IN THE PRODUCTION OF FOOD

Biotechnology as applied to the production of food has the potential to greatly benefit the public, as well as to improve agricultural productivity. The Council on Scientific Affairs of the American Medical Association has stated that agricultural biotechnology has the potential to "meet the needs of a rapidly growing population and minimize the toxic influences of traditional farming practices on the environment."<sup>5</sup> However, due to agricultural economics as well as scientific complexity, the function of many of the first genetically engineered food products is to improve agricultural efficiency and productivity.<sup>6</sup> Since the technology for producing foreign proteins in genetically engineered bacteria is more established than the technology for transforming entire plants or animals, some of the first products are proteins that can be inexpensively produced to replace or augment the same naturally occurring protein. Thus, the first genetically engineered food ingredient approved by the Food and Drug Administration (FDA) is chymosin, an enzyme traditionally obtained from the stomach of calves and used in the production of cheese.<sup>7</sup> Since the genetically engineered chymosin is identical to the enzyme obtained from the traditional preparation and contains no ingredients that are not generally recognized as safe (GRAS), the FDA has concluded that this product, like the traditional product, is GRAS.<sup>8</sup> Bovine somatotropin, a hormone used to increase milk production, has been produced in genetically engineered bacteria and is virtually identical to the naturally occurring protein.<sup>9</sup> It is expected to be approved in 1992.<sup>10</sup>

Genetic engineering techniques have also been applied to commercial food crops. The "antisense" tomato, one of the bioengineered products closest to FDA approval, has been modified to retard the softening and subsequent spoilage that accompanies ripening. This modification improves the farmer's ability to machine-pick ripe tomatoes without bruising them, thus producing a tasty but easily harvested tomato.<sup>11</sup> This type of modification improves the efficiency of the

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5. *Id.*

6. *Id.* at 1431.

7. Direct Food Substances Affirmed, *supra* note 3, at 10,932.

8. 21 C.F.R. § 184.1685 (1991).

9. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-F-470, U.S. DAIRY INDUSTRY AT A CROSSROAD—BIOTECHNOLOGY AND POLICY CHOICES—SPECIAL REPORT 33-34 (1991) [hereinafter OTA, DAIRY INDUSTRY].

10. See Presentation of Milk Inventory Management Program Study Results and Solicitation of Comments, 56 Fed. Reg. 22,514, 22,519 (USDA 1991).

11. This "antisense" tomato was produced by insertion of a gene coding in the antisense orientation for the enzyme, polygalacturonase. Polygalacturonase normally softens the cell walls during ripening. The antisense RNA coded for by that gene binds to the endogenous (sense) polygalacturonase RNA, thereby inhibiting production of the enzyme. International Food Biotechnology Council, *Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification*, 12 REG. TOXICOLOGY AND PHARMACOLOGY I,

agricultural industry and can result in increased supply and lower food prices for consumers. Genetically-engineered herbicide-resistant plants that survive the application of herbicides during weed eradication may also improve the efficiency of farming.<sup>12</sup> Such plants will be used in conjunction with recently-developed herbicides that are rapidly biodegraded and are of low toxicity.<sup>13</sup> Finally, many crops, including tomato, tobacco, potato, alfalfa, cucumber, corn, and soybeans have been genetically engineered to resist plant viruses that might otherwise devastate these plants.<sup>14</sup> This should improve both crop yield and quality, since harvested plants would have far less viral contamination than is present in unmodified plants.<sup>15</sup>

Perhaps the most dramatic improvements in crops will be those that directly improve nutritional quality or reduce environmentally destructive practices.<sup>16</sup> For example, the rapeseed plant has been modified to produce canola oil containing a higher proportion of unsaturated fatty acids.<sup>17</sup> Technical difficulties, however, have hampered the improvement of nutritional quality in the major cereal crops.<sup>18</sup> Research on improvement of nutritional quality, by manipulation of amino acid content or other components, is in progress on these and other

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S110-11 (1990). A second antisense tomato under development accomplishes the production of firm, easily harvested fruit in a different way, by using antisense RNA to inhibit expression of the enzyme that synthesizes the ripening agent, ethylene. Such fruit can be ripened subsequently by exposure to ethylene gas. Paul W. Oeller et al., *Reversible Inhibition of Tomato Fruit Senescence by Antisense RNA*, 254 SCIENCE 437 (1991).

12. Dilip M. Shah et al., *Engineering Herbicide Tolerance in Transgenic Plants*, 233 SCIENCE 478 (1986).

13. Charles S. Gasser & Robert T. Fraley, *Genetically Engineering Plants for Crop Improvement*, 244 SCIENCE 1293, 1295 (1989). Some commentators contend that the genetically-engineered herbicide-resistant plants will lead to the use of more environmentally acceptable herbicides and an overall reduction in herbicide use. *Id.* But others believe that the use of such plants will lead to an increase in the use of herbicides. See Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1431.

14. Patricia P. Abel et al., *Delay of Disease Development in Transgenic Plants that Express the Tobacco Mosaic Virus Coat Protein Gene*, 232 SCIENCE 232 (1986); Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1431; Gasser & Fraley, *supra* note 13, at 1296.

15. Gasser & Fraley, *supra* note 13, at 1296. Virus resistance is accomplished by introducing the gene for viral coat protein into the genetically engineered plants. This results in the production of the coat protein in uninjected plants, but the concentration is typically only 0.01% to 0.5% of that in infected plants. *Id.*

16. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3. Also, genetic engineering of livestock is expected to increase the efficiency of meat production on a given feeding regimen and reduce the fat content of the meat. However, pigs modified to produce excess growth hormone exhibited these traits, but also had substantial side effects—high rates of ulcers, arthritis, cardiomegaly, dermatitis, and renal disease. Thus, improvement of livestock by genetic engineering will require technological advances that eliminate these side effects. Vernon G. Pursel et al., *Genetic Engineering of Livestock*, 244 SCIENCE 1281 (1989).

17. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1431.

18. I. Potrykus, *Gene Transfer to Plants: Assessment of Published Approaches and Results*, 42 ANN. REV. PLANT PHYSIOLOGY & PLANT MOLECULAR BIOLOGY 206 (1991).

crops.<sup>19</sup> Plant geneticists have already produced insect-resistant crops by inserting a gene from the bacterium *Bacillus thuringiensis* (*Bt*) into the plant's DNA. The gene produces a protein that is toxic to certain insect pests, and may lead to a reduction in the use of environmentally destructive pesticides.<sup>20</sup> The *Bt* pesticidal protein, like other proteins, is highly specific in its effects and is inactive against mammals, including humans.<sup>21</sup> Although the *Bt* protein is often referred to as a pesticide incorporated into food, it should be stressed that it is much more species-specific in its action than conventional pesticides, and therefore much safer.<sup>22</sup> Scientists are also investigating other approaches to genetically engineering pest resistant crops.<sup>23</sup> Genetic engineering of pest resistant crops has great potential to reduce the use of synthetic chemical pesticides that may pose problems for human health or the environment.<sup>24</sup>

The state of agricultural biotechnology today is that a variety of items are in development or close to marketing. Those that are farthest along are of the type that will increase agricultural efficiency or productivity, but the current technology has the potential for improving nutritional quality and reducing the use of chemical pesticides. Moreover, there have been no hazardous incidents that should create a fear of this technology and lead to tight regulatory oversight. To the contrary, the Council on Scientific Affairs of the American Medical Association has recommended that physicians play a role in educating the public that "genetic manipulation is not inherently hazardous and that the health and economic benefits of recombinant DNA technology greatly exceed any risk posed to society."<sup>25</sup> Yet public perception of biotechnology is one of suspicion,<sup>26</sup> leading to calls for tighter regulation. The following examination of the recent controversy over bovine somatotropin may illuminate some of these conflicting views on biotechnology.

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19. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1431.

20. Gasser & Fraley, *supra* note 13, at 1295-96. *Bt* is toxic to certain moth and butterfly caterpillars, as well as to certain beetles, flies, and mosquitoes. It has also been reported to be inactive against beneficial insects. *Id.* A potential problem, however, has been discovered recently; some pests have evolved a resistance to *Bt*. Ann Gibbons, *Moths Take the Field Against Biopesticide*, 254 SCIENCE 646 (1991).

21. Gasser & Fraley, *supra* note 13, at 1295-96.

22. Gibbons, *supra* note 20. Farmers have used *Bt* in a spray form since the 1950s; environmentalists have praised it as a safe alternative to chemical pesticides. *Id.* However, not all naturally occurring pesticides produced by plants are benign; many such chemicals (generally not proteins) occurring in commonly eaten foods may be carcinogenic. Such biopesticides are actually present in the diet in far greater amounts than synthetic pesticides. Bruce N. Ames et al., *Dietary Pesticides (99.99% All Natural)*, 87 PROC. NAT'L ACAD. SCI. 7777 (1990). Biopesticides selected for incorporation into food by genetic engineering should be noncarcinogenic and specific in their action; proteins with species-limited activity usually satisfy this test.

23. Gasser & Fraley, *supra* note 13, at 1296.

24. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1429-31.

25. *Id.* at 1434.

26. See *infra* text accompanying notes 43-47.

### III. BOVINE SOMATOTROPIN—A MICROCOSM OF THE ISSUES

Bovine somatotropin (bST), also called bovine growth hormone, was the first major product of recombinant DNA technology available for use in agriculture.<sup>27</sup> bST occurs naturally in cows, but when additional bST produced by genetically engineered bacteria is administered to dairy cows, their milk production is expected to increase an average of 12% without a commensurate increase in feed consumed.<sup>28</sup> The use of bST has been heralded as the technological advance that will have the most dramatic effect on the efficiency of milk production in this decade.<sup>29</sup> Moreover, numerous studies have shown that milk produced by bST-dosed cows is safe for human consumption.<sup>30</sup> The use of bST is also expected to lower environmental pollution, because the decreased intake of feed relative to milk output will decrease the production of manure, urine, and methane—a gas with a strong greenhouse effect.<sup>31</sup> Simply put, fewer cows are required to produce the same amount of milk.

Despite these benefits, bST has elicited considerable public outcry. Consumer groups are threatening to boycott the milk from bST-supplemented cows, grocery chains and food processing companies refused the milk that was approved by the FDA for sale during the investigation period,<sup>32</sup> and states have considered or taken action either banning the use of bST or requiring labeling of products derived from its use.<sup>33</sup>

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27. OTA, DAIRY INDUSTRY, *supra* note 9, at 45.

28. *Id.* at 35. To meet the nutritional needs of extra milk production, voluntary intake of feed increases in cows receiving bST. Although nutritional requirements for each unit of milk produced are the same in bST-supplemented and control cows, bST-supplemented cows have an increased efficiency of conversion of feed into milk because a larger proportion of the cow's total nutrient intake is used to make milk. By requiring less feed to maintain the same level of milk production, there should be substantial savings in dairy cattle feed nationally. *Id.* at 37.

29. *Id.* at 45. Modern breeding techniques such as artificial insemination and embryo transfer would take 10-20 years to produce a similar increase in the efficiency of milk production. *Id.*

30. The evidence for safety is based on the following facts: bST is normally produced by cows; it is normally present at very low levels in both milk and meat and its concentration is not appreciably altered by bST supplementation; it is degraded in the human stomach and therefore has no chance to act on people; bST is species-specific in effect and even if injected into humans, is inactive; and its effects on the composition of milk or meat are extremely minor. Judith C. Juskevich & C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety Evaluation*, 249 SCIENCE 875 (1990); William H. Daughaday & David M. Barbano, *Bovine Somatotropin Supplementation of Dairy Cows—Is the Milk Safe?*, 264 JAMA 1003 (1990); NIH Technology Assessment Conference Statement on *Bovine Somatotropin*, 265 JAMA 1423 (1991).

31. OTA, DAIRY INDUSTRY, *supra* note 9, at 43.

32. Ann Gibbons, *FDA Publishes Bovine Growth Hormone Data*, 249 SCIENCE 852 (1990); Edmund L. Andrews, *Human Threat Ruled Out in Drug for Cows*, N.Y. TIMES, May 8, 1991, at A18.

33. OTA, DAIRY INDUSTRY, *supra* note 9, at 3, 44-45; Robin Eisner, *State Legislators Seek to Broaden Regulation of Biotech Products*, SCIENTIST, Feb. 18, 1991, at 6.

Though ten states introduced bills restricting the use of bST and two states actually enacted such laws,<sup>34</sup> only a few individuals generated the original controversy. Samuel Epstein, a professor at the University of Illinois, joined with genetic engineering critic Jeremy Rifkin to attack the use of bST.<sup>35</sup> In an evaluation of other scientific studies, Epstein questioned the safety of bST-produced milk for human consumption; in addition, he concluded that bST adversely affects the health of cows.<sup>36</sup> Rifkin's group, Foundation on Economic Trends (F.E.T.), demanded the release of environmental assessment records relating to bST.<sup>37</sup> F.E.T. also petitioned the FDA for an environmental impact statement prior to field testing bST. The petition asserted that use of bST would "(1) significantly affect agricultural land use in milk-producing regions of the United States; (2) adversely affect the internal environment of cattle injected with [bST]; and (3) have adverse economic and social impacts on the dairy industry."<sup>38</sup>

The final reason may actually be the most important impediment to acceptance of bST. Concern that small-scale farmers might not be able to compete with large operations using bST resulted in the European Community's 18-month ban of bST.<sup>39</sup> Similar concerns are apparently at the heart of Minnesota's ban on the sale and use of bST.<sup>40</sup> However, bST is merely the latest of many changes in dairy practices that have favored the large, factory-like operation over the small farmer.<sup>41</sup> Moreover, such

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34. MINN. STAT. ANN. §§ 151.01, .15, .25 (West 1992); WIS. STAT. ANN. § 97.235 (West 1991); Eisner, *supra* note 33.

35. Gibbons, *supra* note 32.

36. *Id.* at 852-53. Despite Epstein's conclusions, other studies indicate that bST does not overtly affect bovine health; no detectable increases in diseases such as ketosis, fatty liver, and milk fever have occurred, and reduced resistance to infections has not been detected. OTA, DAIRY INDUSTRY, *supra* note 9, at 41-42. An industry spokesman said that some cows given five times the normal dose developed mastitis. Gibbons, *supra* note 32, at 853. However, reports of increased mastitis and other difficulties were based on small-scale studies that have not been widely accepted. Although the effects of prolonged use of bST are not known, it appears to cause no adverse reactions during the agriculturally useful life of the dairy animal. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1433.

37. Stephen P. Mahinka & Kathleen M. Sanzo, *Biotechnology Litigation and Federal Regulation: Status and Implications*, 42 FOOD DRUG COSM. L.J. 500, 511 (1987) (citing Foundation on Economic Trends v. Department of Health and Human Servs., Civ. No. 87-1009 (D.D.C. filed Apr. 10, 1987)).

38. *Id.* The FDA denied the petition due to the agency's requirement of confidentiality during the approval period of new drug applications. *Id.*

39. Steven J. Rothberg, *From Beer to BST: Circumventing the GATT Standards Code's Prohibition on Unnecessary Obstacles to Trade*, 75 MINN. L. REV. 505, 509-10 (1990).

40. *Biotechnology, Minnesota Governor Vetoes Extension of Ban on Usage of Bovine Somatotropin*, BUREAU OF NAT'L AFFAIRS, DAILY REP. FOR EXECUTIVES, May 31, 1991, at A-10. The governor's vetoes were declared invalid by the Ramsey County District Court in Seventy-Seventh Minn. State Senate v. Carlson, No. C3-91-7547 (Minn. Dist. Ct. 1991), so the Minnesota ban on bST was extended until June 1992. MINN. STAT. ANN. §§ 151.01, .15, .25 (West 1992).

41. OTA, DAIRY INDUSTRY, *supra* note 9, at 10-12. If a national policy in support of traditional farms were adopted, it would require changes in dairy price-support policy

economic and social impacts have never formed a basis for regulation by the FDA, which approves new animal drugs on demonstration that they are effective, safe for the animals as well as the humans who consume the animal products, and safe for the environment.<sup>42</sup>

The bST controversy illustrates some of the difficulties that may be encountered during the introduction of bioengineered food products. Since biotechnology products are already suspect in the public eye, they are easily attacked by a vocal minority. Even if they meet the current regulatory standards, they are especially vulnerable to criticisms that they have adverse environmental, economic, or social impacts that may result from modern dairy or agricultural practices as a whole rather than just from biotechnology. State or local agencies may impose additional regulation that could impede the development of the biotechnology industry and delay advances that might actually be environmentally, economically, or socially beneficial. The question, then, is what regulatory balance should be struck between the potential or perceived risks of biotechnology and its unknown but almost certain benefits.

#### IV. RISKS AND REGULATORY ISSUES CONCERNING BIOENGINEERED FOOD

Although new and unknown technologies are often viewed with suspicion, some features of biotechnology make it particularly susceptible to an exaggerated perception of risk. Public concern may stem from scientists themselves, who initiated a moratorium on some aspects of genetic engineering in 1974.<sup>43</sup> While scientists have since grown comfortable with the technology, the public perception of unreasonable risks lingers on. A recent survey found that 52% of the public "believes that genetically engineered products are at least somewhat likely to represent a serious danger to people or the environment."<sup>44</sup> Biotechnology often suggests the "Frankenstein image." While the current technology generally changes but a single gene, producing a relatively small modification, many people may believe that any interspecies exchange of genetic information results in a dramatic change. Perhaps such views underlie the finding that 24% of a group aware of biotechnology felt that creation of hybrid plants and animals through

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and other areas as well as programs to enhance technology adoption by such small farms. *Id.*

42. Juskevich & Guyer, *supra* note 30.

43. Committee on Recombinant DNA Molecules, Nat'l Research Council, *Potential Biohazards of Recombinant DNA Molecules*, 185 SCIENCE 303 (1974).

44. OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY BACKGROUND PAPER: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY, *excerpted in Federal Oversight of Biotechnology: Hearing Before the Subcomm. on Hazardous Wastes and Toxic Substances of the Senate Comm. on Environment and Public Works*, 100th Cong., 1st Sess. 60, 62 (1987).

genetic engineering is morally wrong.<sup>45</sup> Another aspect of biotechnology that invites public concern is the ability of living things to reproduce; thus any deleterious effects of genetically engineered organisms have the ability to escape human control and self-perpetuate. This leads to a fear that although a deleterious result is unlikely, if it occurs, the outcome could be a problem of substantial magnitude. Such fears of an unlikely but potentially disastrous outcome could greatly hinder the progress of biotechnology. A majority of the public would object to the use of genetically engineered organisms if the risk were unknown.<sup>46</sup>

Food products of biotechnology generate their own specific concerns. Production of bioengineered food usually involves not only a consideration of the safety of the food for human consumption, but also the safety of environmental release of the altered plant. The public's perception of potential danger from food biotechnology is enhanced by its heightened awareness of environmental damage from the introduction of exotic species and of health problems that are manifested only decades after exposure to the causative agent. Yet many similar risks from food stem from traditional agricultural and plant breeding practices that are essential to provide sufficient food to the growing population or to assure the taste, quality, and convenience that consumers and farmers have come to expect. Thus, society accepts environmental risks of pesticide use and dispersal of domesticated plants and animals within certain limits and tolerates low levels of pesticide residues in food. Other risks from food are inherent in the food itself. Food contains many naturally occurring toxicants and carcinogens that are nearly unavoidable in the ordinary diet.<sup>47</sup>

Biotechnology presents few risks beyond those already accepted in traditional foods.<sup>48</sup> As to their environmental risks, "[c]rops modified by molecular and cellular methods should pose risks no different from those modified by classical genetic methods for similar traits."<sup>49</sup> Bioengineered

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45. *Id.* at 63. Note that 26% "of the public who are aware of the classic biological techniques of cross-fertilization and cross breeding also believe that these techniques are morally wrong." *Id.*

46. *Id.*; see also *Review and Outlook: Those Terrifying Cows*, WALL ST. J., Jan. 7, 1991, at A14 ("No modern advance is more vulnerable to damaging public assault today than agricultural biotechnology.").

47. Ames et al., *supra* note 22; International Food Biotechnology Council, *supra* note 11, at S11-78, S20-21.

48. See International Food Biotechnology Council, *supra* note 11, at S104-08.

49. National Research Council, *Executive Summary, Field Testing Genetically Modified Organisms: Framework for Decisions*, 12 RECOMBINANT DNA TECH. BULL. 183, 187 (1989). "At this time, the potential for enhanced weediness is the major environmental risk perceived for introductions of genetically modified plants. The likelihood of enhanced weediness is low for genetically modified, highly domesticated crop plants ...." *Id.* Generally, genetically engineered foods are thought to pose few environmental risks because toxic organisms are not likely to be used in their production. Ecologists, however, voice concerns about possible environmental disruption from the release of genetically engineered organisms, particularly microorganisms. For a discussion of the differing viewpoints of ecologists and molecular biologists, see Sidney A. Shapiro, *Biotechnology and the Design of Regulation*, 17 ECOLOGY L.Q. 1, 6-12 (1990).

organisms' potential for dispersal and environmental disruption is generally similar to their traditional counterparts.<sup>50</sup> Society has long accepted the fact that traditional plant and animal breeding practices may change the nutrient or toxicant levels in the food or alter an organism's potential for environmental dispersal.<sup>51</sup> Although traditional methods usually enhance the safety of the food, they have occasionally increased the level of a deleterious component.<sup>52</sup> The use of antibiotic resistance marker genes in the production of bioengineered food has raised some questions, but most experts agree that the genes should cause no health or safety problem.<sup>53</sup> Bioengineering, as an extension of traditional breeding practices, should pose no greater concern over the safety of the food consumed; it should actually be safer since the recombinant techniques are more specific and thus less likely to produce unwanted side effects such as increased levels of toxicants or weediness.<sup>54</sup> Indeed, as considered above, bioengineering may lower both the environmental and food consumption risks.

New technologies are particularly difficult to regulate when their risks are unknown, but to reap the benefits of such advances it is important that regulation be based on risk and not succumb to exaggerated perceptions of danger. Peter Huber has argued that regulation of new technologies by federal agencies often involves screening that eliminates small risks at the expense of lost opportunity costs of unknown magnitude. By contrast, old technologies are usually

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50. Proposed USDA Guidelines for Research Involving the Planned Introduction into the Environment of Organisms with Deliberately Modified Hereditary Traits, 56 Fed. Reg. 4134, 4135-36 (1991).

51. See International Food Biotechnology Council, *supra* note 11, at S21, S92-93.

52. *Id.* at S21, S27-28.

53. *Id.* at S122-23. Antibiotic resistance genes linked to the gene of interest are used to identify cells carrying the latter gene. Only those cells carrying the resistance gene, and consequently the gene of interest, survive when antibiotics are applied to a field of cells. There has been concern that these genes could be transferred from crop plants to pathogenic organisms, but such transfer is considered highly unlikely. Such transfer would be extremely rare compared to the known increase in resistance genes in bacterial populations due to the use and overuse of antibiotics clinically and in animal feed. *Id.* The FDA is evaluating whether food containing enzymes produced by antibiotic resistance marker genes could inactivate clinical antibiotics taken orally, as well as other issues stemming from the use of antibiotic resistance genes. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,988 (FDA 1992) [hereinafter FDA Statement of Policy]. The biotechnology firm Calgene has asked the FDA to approve the use of its kanamycin resistance gene as a marker. Calgene Inc., Request for Advisory Opinion, 56 Fed. Reg. 20,004 (1991). Recently new techniques for removing the marker genes have become available. Anne S. Moffat, *Excess Genetic Baggage Dumped*, 254 SCIENCE 1457 (1991); Emily C. Dale & David W. Ow, *Gene Transfer with Subsequent Removal of the Selection Gene from the Host Genome*, 88 PROC. NAT'L ACAD. SCI. 10,558 (1991). Special molecular methods plus a year or two of plant breeding are required to remove the unwanted gene. It is possible that the FDA could require biotechnology companies to remove the marker genes, or they could independently opt to do so. Moffat, *supra*, at 1457.

54. International Food Biotechnology Council, *supra* note 11, at xvii-xviii, S84-94. An exception to this may be the possible unintended transfer of allergens from an allergenic to a nonallergic species. See *infra* note 158 and accompanying text.

subject to more lenient standard-setting regulations.<sup>55</sup> Thus, regulations often preserve the present level of safety by tacitly accepting risks posed by old technologies while excluding new technologies with potentially large benefits.<sup>56</sup> The assumption behind screening new risks but setting standards to limit old risks is that barring new risks is economically and socially less costly, because both producers and a market for the new products are not yet established.<sup>57</sup> The benefits of the new products are generally not considered in the screening process because their values are speculative.<sup>58</sup>

Thus, to foster technological advance and its resultant benefits, Huber argues that a comparative system of regulation of old and new risks, one that permits new technologies functionally similar to established technologies and of no greater risk, should be implemented.<sup>59</sup> The comparative approach, allowing a new risk, is justified when the old, risky product is one that society accepts either because it is essential or desirable.<sup>60</sup> "[E]xcessively strict regulation of the safer-than-average product[s] will drive consumption toward the more hazardous ones."<sup>61</sup> Comparative regulation, on the other hand, would favor the safer product, particularly because modern technology usually replaces an old outmoded source of risk rather than adding to it.<sup>62</sup>

Huber suggests a four-step process for implementing comparative regulation:

- 1) The agency must define a risk market comprising products that are functional substitutes for each other.
- 2) It next must identify typically risky products already allowed to compete in that market.
- 3) The agency must then compare the risks of the new substitute with those of products not in fixed supply and already in the market. Only the less safe substitutes must be excluded or otherwise regulated.
- 4) If a new product offers exceptional price or other advantages over existing, more hazardous products, introduction of the safer product could conceivably increase net risk by increasing total consumption. As a final step in comparative regulation, an agency

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55. Peter Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025, 1029-37, 1058, 1065 (1983).

56. *Id.* at 1037-38, 1062-63, 1073.

57. *Id.* at 1051, 1053-54, 1063-66.

58. *Id.* at 1058-59, 1065.

59. *Id.* at 1073-75.

60. *Id.* at 1093-95. Thus, comparative regulation does not justify, for example, allowing a cigarette substitute that is carcinogenic and addictive, though less so than cigarettes, because cigarettes are not accepted as essential or highly desirable (though cigarette smokers might favor a substitute as their only realistic alternative to cigarettes). Food, on the other hand, is obviously necessary, and many of its risks are unavoidable. See International Food Biotechnology Council, *supra* note 11, at S11-78.

61. Huber, *supra* note 55, at 1079.

62. *Id.* at 1073.

must therefore consider whether a candidate for regulation is this type of risk.<sup>63</sup>

The comparative approach is appropriate for the two main regulatory hurdles applicable to biotechnology-derived food products, the oversight of the release of the genetically engineered organism during food development and the evaluation of food safety. In neither case are the risks absolutely quantifiable, but they can be compared to the risks of non-genetically engineered food organisms or products in the same situation. Thus, the risk of release of genetically engineered domesticated plants and animals can be compared to the risk associated with the parental or other comparable strain.<sup>64</sup> Genetically engineered food products can be evaluated by comparison to their unmodified counterparts, and if appropriate, to any food additives that might accomplish the same function as the genetic modification.<sup>65</sup> Food, despite its inherent risks, is of course essential, and society accepts many of the environmental risks from its production because of the desirability of traditional agricultural practices. Bioengineered food is certainly a functional substitute for traditional food, and since people's eating habits are unlikely to change dramatically, introduction of the genetically engineered food should not substantially affect total production and consumption of the product, unless there is an exceptional difference in price.

Another reason for adopting a comparative approach to regulation of biotechnology-derived food products is that biotechnology represents a small man-made risk superimposed on a background of naturally occurring toxins and carcinogens in food.<sup>66</sup> To eliminate small increments of risk above a large natural baseline is inefficient and costly.<sup>67</sup> The comparative approach also has a sound scientific basis because the view that genetic engineering in the production of food is an extension of long-established conventional breeding techniques underlies the concept that when analyzing risk, genetically engineered products should be readily comparable to their traditional counterparts.<sup>68</sup>

The regulatory framework for bioengineered food is in transition from an approach that, by focusing on the process used to produce genetically engineered food, did not always accurately assess the risk of the product. The Bush Administration sought to cure this problem by adopting a policy similar to the comparative regulatory approach

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63. *Id* at 1075-76.

64. Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits, 55 Fed. Reg. 31,118, 31,120 (OSTP 1990); Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753, 6755-56 (OSTP 1992) [hereinafter Exercise of Federal Oversight].

65. International Food Biotechnology Council, *supra* note 11, at S138-43, S165.

66. Ames et al., *supra* note 22; International Food Biotechnology Council, *supra* note 11, at S21.

67. Huber, *supra* note 55, at 1083-85.

68. International Food Biotechnology Council, *supra* note 11, at xvi-xviii.

discussed above.<sup>69</sup> The federal regulatory agencies are currently implementing this policy. This policy approach has the advantage of removing unjustified oversight of biotechnology, but it may have the disadvantage of underregulating the field, especially because it relies on existing statutory authority not directed at biotechnology. Moreover, this policy approach does not address the non-risk based social and economic concerns that contribute to the public's objections to biotechnology. It may, therefore, fuel the demand for state and local regulation of biotechnology.

## V. THE REGULATORY FRAMEWORK

Regulation of bioengineered food falls under the general regulatory scheme that has been established for biotechnology as a whole.<sup>70</sup> The "Coordinated Framework for the Regulation of Biotechnology" (coordinated framework), introduced by the Office of Science and Technology Policy (OSTP) in 1985-86, describes the policies for federal regulation of biotechnology.<sup>71</sup> Under the coordinated framework, regulation of biotechnology relies on existing federal statutes, with each agency maintaining jurisdiction over biotechnology applications within its traditional domain.<sup>72</sup> Oversight of each product is within a single agency, but where more than one agency is involved, one is designated the lead agency.<sup>73</sup> Agencies rely upon existing statutory authority to provide immediate health and safety protection, as well as to eliminate any regulatory delay or uncertainty that might hurt the new biotechnology industry. Underlying this decision was the premise that genetic engineering techniques are basically extensions of the traditional techniques of selective breeding and hybridization, and thus the laws that governed products of those techniques could also apply to biotechnology.<sup>74</sup>

The Biotechnology Science Coordinating Committee (BSCC), established by the OSTP in 1985, had broad authority for promoting cooperation between the agencies and establishing consistent scientific

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69. PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY (1991).

70. Coordinated Framework for Regulation of Biotechnology: Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174 (OSTP 1985) [hereinafter Coordinated Framework—1985]. This regulatory scheme was established during the Reagan Administration, which established a Cabinet Council Working Group on Biotechnology in 1984. Steven H. McNamara, *FDA Regulation of Food Substances Produced by New Techniques of Biotechnology*, 42 FOOD DRUG COSM. L.J. 50, 53-54 (1987).

71. Coordinated Framework—1985, *supra* note 70; Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (OSTP 1986) [hereinafter Coordinated Framework—1986].

72. Coordinated Framework—1986, *supra* note 71. A comprehensive list of the statutes relevant to regulation of biotechnology is found in Coordinated Framework—1985, *supra* note 70, at 47, 181-95.

73. Coordinated Framework—1986, *supra* note 71, at 23,303-05.

74. *Id.* at 23,302-03.

policy and reviews. It was composed of senior policy officials from the United States Department of Agriculture (USDA), the FDA, the National Institutes of Health (NIH), the Environmental Protection Agency (EPA), and the National Science Foundation (NSF).<sup>75</sup> In late 1990, the BSCC was replaced by the Biotechnology Research Subcommittee (BRS) of the interagency Committee on Health and Life Sciences. The BRS is said to have responsibilities similar to the BSCC.<sup>76</sup> Although the BSCC, in its evaluation of the issues, could "develop generic scientific recommendations that could be applied to similar, recurring applications,"<sup>77</sup> it did not re-evaluate agency decisions and thereby delay that agency's response.<sup>78</sup> Two important facets of BSCC's initial mission were to ensure that its constituent agencies regulate biotechnology using scientific reviews of similar stringency, and to establish consistency as to which genetically engineered organisms were subject to regulatory oversight.<sup>79</sup>

The BSCC recognized that many genetically engineered organisms present risks no greater than those developed by traditional techniques. These organisms, like traditionally developed organisms, would require no regulatory approval prior to use.<sup>80</sup> The BSCC established the policy that both intergeneric organisms (organisms with DNA derived from species in more than one genus<sup>81</sup>) and pathogens should come under review. Pathogens include microorganisms bearing DNA from pathogenic organisms.<sup>82</sup> Each agency, using its own statutory authority, then established its own policies or regulations in line with these guidelines.<sup>83</sup>

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75. Coordinated Framework—1985, *supra* note 70, at 48,174, 48,176.

76. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-BA-494, BIOTECHNOLOGY IN A GLOBAL ECONOMY 176 (1991) [hereinafter OTA, BIOTECHNOLOGY IN A GLOBAL ECONOMY]. The Committee on Health and Life Sciences is a committee of the Federal Coordinating Council on Science, Engineering, and Technology, which is headed by the President's Science Advisor. *Id.*

77. Coordinated Framework—1985, *supra* note 70, at 47,176.

78. *Id.*

79. Coordinated Framework—1986, *supra* note 71, at 23,302, 23,303.

80. *Id.* at 23,303.

81. A genus is a group of closely related species; species in different genera are phylogenetically more distantly related than species in a single genus.

82. *Id.* at 23,306-07. Intergeneric or pathogenic organisms that contain only non-coding regulatory regions of DNA (regions not leading to the production of protein) are excluded from this definition. *Id.* at 23,307.

83. Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23,309 (FDA 1986) [hereinafter FDA Statement]; Statement of Policy—Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313 (EPA 1986); Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336 (USDA 1986); Agency Guidelines on Biotechnology, 51 Fed. Reg. 23,347 (OSHA 1986); Statement of Policy, 51 Fed. Reg. 23,349 (NIH 1986); Proposed Rules, 51 Fed. Reg. 23,352 (USDA 1986); Advance Notice of Proposed USDA Guidelines for Biotechnology Research, 51 Fed. Reg. 23,367 (1986).

Under the coordinated framework, several federal agencies, including the EPA, the USDA, and the FDA, could regulate a single bioengineered food product. For example, a plant genetically engineered to contain a biopesticide could come under the authority of the EPA as a pesticide regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).<sup>84</sup> It could also be considered a plant pest regulated under the jurisdiction of the Animal and Plant Health Inspection Service (APHIS), which implements the Federal Plant Pest Act within the USDA.<sup>85</sup> Finally, the safety of the food product could be judged by the FDA through its authority under the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>86</sup> Thus, food products of biotechnology are subject to extensive regulatory authority.<sup>87</sup> Since many food products are subject to both USDA and FDA jurisdiction, this Comment will consider some of their regulations relevant to biotechnology in more detail.

Under the authority granted by the Federal Plant Pest Act and the Plant Quarantine Act, the USDA proposed regulations that have been used to regulate genetically engineered food crops.<sup>88</sup> Specifically, the APHIS requires a permit for the introduction of an organism (regulated article) that "has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent"<sup>89</sup> belongs to one of the genera or taxa listed in the regulations and is a plant pest.<sup>90</sup> A plant pest is "[a]ny living stage . . . which can directly or indirectly injure or cause disease or damage in or to any plants."<sup>91</sup> At first glance, such regulated articles might not appear to include crop plants. Most genetically engineered crop plants, however, have come under this regulation because the most common vector used to introduce the gene of

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84. Coordinated Framework—1985, *supra* note 70, at 47,180. FIFRA is at 7 U.S.C. §§ 136-136y (1988 & Supp. III 1991).

85. Coordinated Framework—1985, *supra* note 70, at 47,188. The Federal Plant Pest Act is at 7 U.S.C. §§ 150aa-150jj (1988).

86. Coordinated Framework—1985, *supra* note 70, at 47,177. The Food, Drug, and Cosmetic Act is at 21 U.S.C.A. §§ 301-392 (West 1972 & Supp. 1992). According to the FDA's new policy, the "EPA will address under its regulatory jurisdiction the food safety issues associated with the pesticide, including marker genes used to confirm the presence of the pesticidal gene. Any food safety questions beyond those associated with the pesticide . . . are under FDA's jurisdiction . . ." FDA Statement of Policy, *supra* note 53, at 23,005.

87. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-BA-360, NEW DEVELOPMENTS IN BIOTECHNOLOGY 4: U.S. INVESTMENT IN BIOTECHNOLOGY—SPECIAL REPORT 100-01 (1988) [hereinafter OTA, INVESTMENT IN BIOTECHNOLOGY].

88. Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336 (USDA 1986); Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests, 52 Fed. Reg. 22,892 (USDA 1987) (codified at 7 C.F.R. §§ 330, 340); 7 U.S.C. §§ 150, 151 (1988).

89. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests, 7 C.F.R. § 340.1 (1991).

90. *Id.* §§ 340.0-3.

91. *Id.* § 340.1.

interest into the genetically engineered crop is the Ti plasmid of *Agrobacterium tumefaciens*, a plant pathogen listed in the regulations.<sup>92</sup>

Before the APHIS can issue a permit for the release of regulated articles, it must comply with the requirements of the National Environmental Policy Act (NEPA) and carry out an environmental assessment.<sup>93</sup> Most genetically engineered crop plants pose no more risk to the environment than the parental strains from which they are derived. If the genetically engineered organisms do pose a risk, they are grown in containment. Thus, these assessments usually indicate no risk to the environment and no environmental impact statement is required.<sup>94</sup> The USDA regulations also have mandatory state notification and review provisions.<sup>95</sup> By mid-1991, more than 150 permits for the release of genetically engineered organisms had been issued by the USDA, with no known adverse environmental effects.<sup>96</sup>

A permit is required during the research phase of the development of a genetically engineered food product, when the environmental effects of the bioengineered crop may be unknown. Permits are not required during the commercial phase, however, because it is impossible to effectively monitor crops grown on a commercial scale. Thus, to enter the commercial phase, data obtained from the field tests must show that the organism is not a plant pest or deleterious to the environment. When that is established, the APHIS can exempt the genetically engineered crop from the regulations requiring a permit, so that commercialization can begin.<sup>97</sup>

The FDA has followed a policy, consistent with that stated in the coordinated framework, that oversight of biotechnology products under its jurisdiction requires no new procedures or requirements.<sup>98</sup> The FDA is responsible for assuring the safety and quality of both plant and animal

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92. *Id.* § 340.2; Gasser & Fraley, *supra* note 13, at 1295; Edward L. Korwek, *Towards Understanding the United States Biotechnology Regulatory Framework*, in BIOTECHNOLOGY: NEW DEVELOPMENTS IN FEDERAL POLICIES AND REGULATIONS 1, 27-28 (Practising Law Inst., 1988). When used as a vector, the pathogenic genes of the Ti plasmid are removed, so the "disarmed" Ti plasmid functions only to insert the gene of interest, and does not produce host disease. Gasser & Fraley, *supra* note 13, at 1294.

93. Coordinated Framework—1986, *supra* note 71, at 23,303-04; International Food Biotechnology Council, *supra* note 11, at S180.

94. See, e.g., Availability of Environmental Assessments and Findings of No Significant Impact Relative to Issuance of Permits to Field Test Genetically Engineered Organisms, 56 Fed. Reg. 24,775, 59,925, 66,616 (USDA 1991).

95. 7 C.F.R. § 340.3 (1991).

96. OTA, BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 76, at 180, 182. As of mid-1990, the USDA had not denied any application for a permit for a small-scale test. *Review of Current and Proposed Agricultural Biotechnology Regulatory Authority and the Omnibus Biotechnology Act of 1990: Hearing on H.R. 5312 Before the Subcomm. on Dep't Operations, Research, and Foreign Agriculture of the House Comm. on Agriculture*, 101st Cong., 2nd Sess. 156 (1990) [hereinafter Hearing on H.R. 5312] (statement of Margaret Mellon, Ph.D., J.D., National Wildlife Federation).

97. Hearing on H.R. 5312, *supra* note 96, at 115 (statement of Dr. James W. Glosser, Administrator, APHIS).

98. FDA Statement, *supra* note 83, at 23,309-10.

bioengineered food products. New animal drugs, including those produced by biotechnology, require premarket approval by the FDA. Moreover, the FDA must approve for human consumption the edible portions of animals that have been administered a new drug.<sup>99</sup> To approve the use, the FDA must confirm the safety of the food product for human consumption; the drug must not accumulate as unsafe residues in the edible portions of the animal.<sup>100</sup> Finally, the efficacy of the drug and its safety for both the animals and the environment must be established.<sup>101</sup> When a new drug produced by genetic engineering is virtually identical to an approved substance produced by conventional technology, the showing for approval is reduced and only a supplemental application to the FDA is necessary.<sup>102</sup>

Regulation of biotechnology-derived foods from plants will depend largely on the use of the food. Generally, regulations differ for "whole foods" such as fruits, vegetables, or grains; for substances unintentionally added to foods; and for food additives.<sup>103</sup> The FDA does not require premarket approval for whole foods, but the burden is on the producer or manufacturer to assure that such foods are safe.<sup>104</sup> However, the FDA can regulate whole foods, including those that are products of biotechnology, under section 402(a)(1) of the FDCA,<sup>105</sup> which sets different safety standards for inherent natural constituents of the food and unintentionally added substances that are poisonous or deleterious.<sup>106</sup> Naturally occurring constituents posing safety problems, such as elevated levels of solanine in a new potato variety or poisons in a toxic mushroom, make the food legally adulterated only "if the quantity of such substance[s] . . . ordinarily render[s] it injurious to health."<sup>107</sup> Unintentionally added substances on the other hand, are contaminants and are subject to a more rigorous standard. The contaminants may be chemicals introduced accidentally by human activities (e.g., polychlorobiphenyls (PCBs), mercury, and lead) or they may be naturally occurring contaminants (e.g., aflatoxin). "Added substance[s]" cause a food to be legally adulterated if they "may render it injurious to

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99. *Id.* at 23,311-12.

100. *Id.* at 23,311. The drug manufacturer must show that methods exist for detection of such residues. *Id.*

101. *Id.* at 23,311-12; OTA, DAIRY INDUSTRY, *supra* note 9, at 5.

102. FDA Statement, *supra* note 83, at 23,311.

103. *Id.* at 23,310, 23,312-13; International Food Biotechnology Council, *supra* note 11, at S160-61.

104. International Food Biotechnology Council, *supra* note 11, at S161.

105. 21 U.S.C. § 342(a)(1) (1988).

106. FDA Statement, *supra* note 83, at 23,312.

107. 21 U.S.C. § 342(a)(1) (1988); *see also* International Food Biotechnology Council, *supra* note 11, at S161.

health."<sup>108</sup> Adulterated food is subject to an enforcement action if it enters into interstate commerce.<sup>109</sup>

Food additives are subject to premarket clearance by the FDA, unless the additive is generally recognized as safe (GRAS).<sup>110</sup> A substance is GRAS either if its safety is known from common use in foods consumed by a significant number of consumers prior to January 1, 1958, or if its safety is determined by well-controlled scientific studies.<sup>111</sup> A company may market a product, believing it to be GRAS, but it runs the risk that the FDA may decide that it is not GRAS and force it off the market. A company wishing to clarify the matter at the outset may obtain the FDA's opinion on the substance by filing a GRAS affirmation petition.<sup>112</sup> If a substance added to food is not GRAS, it is a food additive and under section 409 of the FDCA a company must submit a food additive petition for FDA approval.<sup>113</sup> Thus, if a bioengineered product is a food additive, it requires submission of scientific data showing that it is safe under the conditions for which it will be used.<sup>114</sup> Moreover, under the requirements of NEPA, the manufacturer must prepare an environmental assessment, or an impact statement if the manufacturing process or the use of the food additive will significantly affect the environment.<sup>115</sup>

Since the FDCA does not directly apply to biotechnology, and the first bioengineered food products have only recently or are now undergoing FDA approval, there has been much speculation as to how the FDA will categorize such foods. The FDA has stated that a substance recognized as GRAS may lose that status if production by genetic engineering alters it or produces contaminants such that experts no longer recognize it to be safe.<sup>116</sup> The question of GRAS status is not trivial to the manufacturer, because FDA approval of direct food additives generally takes between five and seven years.<sup>117</sup> So far, the only bioengineered GRAS substance considered by the FDA, chymosin, has retained that status.<sup>118</sup>

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108. 21 U.S.C. § 342(a)(1) (1988); *see also* Jeffrey N. Gibbs & Jonathan S. Kahan, *Federal Regulation of Food and Food Additive Biotechnology*, 38 ADMIN. L. REV. 1, 12 (1988); International Food Biotechnology Council, *supra* note 11, at S161.

109. International Food Biotechnology Council, *supra* note 11, at S161 (citing 21 U.S.C.A. §§ 332 (injunction), 333 (criminal sanctions), 334 (seizure of adulterated articles) (West 1972 & Supp. 1992)).

110. 21 U.S.C. §§ 321(s), 348(a)-(b) (1988); *see also* Gibbs & Kahan, *supra* note 108, at 7, 9.

111. 21 U.S.C. § 321(s) (1988).

112. Affirmation of GRAS Status, 21 C.F.R. § 170.35 (1991). *See generally* Gibbs & Kahan, *supra* note 108, at 11.

113. 21 U.S.C. § 348(a)-(b) (1988); *see also* FDA Statement, *supra* note 83, at 23,313-14.

114. FDA Statement, *supra* note 83, at 23,313.

115. *Id.*

116. *Id.*

117. Coordinated Framework—1985, *supra* note 70, at 47,177.

118. Direct Food Substances Affirmed as Generally Recognized as Safe; Chymosin Enzyme Preparation Derived From *Escherichia coli* K-12, 55 Fed. Reg. 10,932 (1990) (codified at 21 C.F.R. § 184.1685 (1991)).

Another question that arises is whether the FDA will view a food crop with a genetically engineered gene and a resultant change in food composition as a whole food or as containing a food additive.<sup>119</sup> The FDA will soon be setting a precedent on this issue, since Calgene, an agricultural biotechnology company, has recently petitioned the FDA to issue an advisory opinion as to whether its "antisense" tomato is a whole food that contains no food additives.<sup>120</sup> If the FDA views genetically engineered food as whole food, the question arises whether the FDA will regard the altered gene or the resultant change in food composition as inherent constituents of the food subject to the "may render" standard, or as added substances evaluated under the "ordinarily render" standard of section 402(a)(1) of the FDCA.<sup>121</sup> The answer might determine whether the FDA would prevail if it ever attempted an enforcement action where equivocal evidence indicates that a bioengineered food contains a deleterious substance.<sup>122</sup>

## VI. CRITICISM OF REGULATION UNDER THE COORDINATED FRAMEWORK

Not surprisingly, regulation of bioengineered food products, and biotechnology in general, is often viewed as too stringent by biotechnology companies, as too lax by environmentalists, and as lacking a sound scientific basis by academicians. Biotechnology companies often cite regulatory uncertainty as a substantial concern in developing new products.<sup>123</sup> In recent years, the main regulatory hurdle that food biotechnology companies have had to face has involved the release of genetically engineered organisms. The companies acknowledge that APHIS' handling of small field tests has worked well and that many delays have been due to suits or to local restrictions on release.<sup>124</sup> Thus, at

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119. A food additive is defined as:

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized . . . to be safe under the conditions of its intended use.

21 U.S.C. § 321(s) (1988).

120. Calgene, Inc., Request for Advisory Opinion, 57 Fed. Reg. 22,772 (FDA 1992); Donna K.H. Walters, *FDA Asked to Review Biotech Tomato; Genetic Engineering: The California Company's Request is the First for an Altered Food Product*, L.A. TIMES, Aug. 13, 1991, at D2.

121. 21 U.S.C. § 342(a)(1) (1988); see, e.g., David L. Jones, *Food Safety Aspects of Gene Transfer in Plants and Animals: Pigs, Potatoes, and Pharmaceuticals*, 43 FOOD DRUG COSM. L.J. 351, 359 (1988); Gibbs & Kahan, *supra* note 108, at 7.

122. Gibbs & Kahan, *supra* note 108, at 12 n.58.

123. OTA, INVESTMENT IN BIOTECHNOLOGY, *supra* note 87, at 100, 210-11.

124. Hearing on H.R. 5312, *supra* note 96, at 141-42 (statement of Roger H. Salquist, Chairman and Chief Executive Officer, Calgene, Inc.); *Federal Oversight of Biotechnology: Hearing Before the Senate Subcomm. on Hazardous Wastes and Toxic Substances of the Comm. on Environment and Public Works*, 100th Cong., 1st Sess. 34-35 (1987) [hereinafter *Federal*

the federal level, industry concerns for the future stem from uncertainty over regulation of large scale release of genetically engineered crops during commercialization; the adequacy of coordination between the EPA, the USDA, and the FDA when a single product requires oversight by all three agencies; and over how the FDA will handle food products.<sup>125</sup> Industry may actually welcome a case-by-case analysis of the first bioengineered foods, because FDA approval will give an assurance of safety that will boost public confidence in the products.<sup>126</sup> In the long run, however, industry representatives feel that bioengineered foods should require no more screening than traditionally produced foods.<sup>127</sup> Since under current law this would mean that genetically engineered foods classified as whole foods would require no premarket approval, the International Food Biotechnology Council, an industry association, recommends that the FDA establish a voluntary premarket notification system.<sup>128</sup> However, industry's greatest regulatory concern may not be with federal regulations but with the increasing patchwork of state and local regulations. This concern, which will be considered further below, has led industry to lobby for more explicit federal regulation.<sup>129</sup>

Environmental groups have faulted the coordinated framework for incompletely regulating biotechnology through existing statutes not directed at genetic engineering and for not keeping environmental considerations paramount. Environmentalists have criticized the use of the Federal Plant Pest Act to regulate environmental release of genetically engineered agricultural plants and animals because it covers only plant pests.<sup>130</sup> Although use of the Ti plasmid as a vector has brought most plant genetic engineering under the authority of the regulations, environmentalists are concerned that increased use of other means of introducing foreign DNA will leave many bioengineered plants unregulated.<sup>131</sup> Moreover, environmentalists and university researchers are concerned that USDA's statutory authority is inadequate to cover genetically engineered animals.<sup>132</sup> Finally, environmentalists argue that the EPA, rather than the USDA, should be the lead agency in charge of

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*Oversight of Biotechnology Hearing]* (statement of Dr. Larry W. Moore, Oregon State University).

125. *Hearing on H.R. 5312*, *supra* note 96, at 143 (statement of Roger H. Salquist, Chairman and Chief Executive Officer, Calgene, Inc.); Mark Crawford, *Biotech Companies Lobby for Federal Regulation*, 248 SCIENCE 546 (1990).

126. Crawford, *supra* note 125, at 547.

127. International Food Biotechnology Council, *supra* note 11, at xvi.

128. *Id.* at S164.

129. Crawford, *supra* note 125, at 546.

130. *Hearing on H.R. 5312*, *supra* note 96, at 151-56 (statement of Margaret Mellon, Ph.D., J.D., National Wildlife Federation).

131. *Id.* at 155.

132. *Id.* at 153-54; *see also id.* at 131-36 (statement of Dr. Eric M. Hallerman, Virginia Polytechnic Institute) (current regulation of transgenic fishes is incomplete, fraught with procedural uncertainty and legal loopholes).

environmental release of genetically engineered organisms, since EPA's mandate is to protect the environment as a whole, whereas USDA's interest is to promote agriculture.<sup>133</sup>

University researchers cite the nonuniform, overlapping jurisdiction of the many agencies regulating biotechnology as a particularly onerous burden, perhaps because of the smaller scale and budgets of their operations. They are concerned that regulatory agencies will block commercialization of some of their best scientific advances, such as virus-resistant plants containing a gene for viral protein, because the agencies will be unable to decide whether to regulate the plant as a plant pathogen, chemical pesticide, or food additive.<sup>134</sup> This regulatory confusion results in part from the adaptation of existing laws to cover biotechnology.<sup>135</sup> The same types of criticisms of USDA regulation of biotechnology via the Plant Pest Act can be made of FDA's regulation of bioengineered foods through existing regulations and statutes: bioengineered foods do not readily fit into any existing regulatory category. Moreover, university researchers have criticized the scientific basis for the scope of regulation of genetically engineered organisms under the coordinated framework, because they view the emphasis on intergeneric combinations of genetic material as bearing little relationship to the level of risk.<sup>136</sup>

## VII. NEW DIRECTIONS

The President's Council on Competitiveness has responded to some of the criticisms of biotechnology regulation under the coordinated framework in its *Report on National Biotechnology Policy (Report)*.<sup>137</sup> The watchword of this document is that biotechnology regulation should be risk-based; genetically engineered organisms or products should not be subject to unnecessary oversight solely because of the method of their production.<sup>138</sup> The *Report* stresses that products of genetic engineering are not necessarily riskier than conventionally produced products, and thus should not be subject to additional oversight.<sup>139</sup> However, the *Report* retains the position that regulation of biotechnology does not require new statutes or regulatory structures.<sup>140</sup> It recognizes the need for "improving agency coordination, streamlining the regulatory agencies' evaluation processes, periodically reevaluating regulations, [and] addressing

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133. *Federal Oversight of Biotechnology Hearing*, *supra* note 124, at 149 (statement of Rebecca J. Goldburg, Environmental Defense Fund).

134. *Hearing on H.R. 5312*, *supra* note 96, at 126 (statement of Dr. Sue Ann Tolin, Virginia Polytechnic Institute).

135. *Id.*

136. *Id.* at 131-32 (statement of Dr. Eric M. Hallerman, Virginia Polytechnic Institute).

137. PRESIDENT'S COUNCIL ON COMPETITIVENESS, *supra* note 69.

138. *Id.* at 12.

139. *Id.*

140. *Id.* at 14.

problems with state and local laws,”<sup>141</sup> but defers these issues for further study. In sum, the Council’s approach is to foster the development of the biotechnology industry by promulgating a policy in which this new technology is subject to no more regulation than “old risks.”

Specific policy changes reflecting this philosophy have been proposed both for the regulation of the release of bioengineered food-producing organisms and the assessment of food safety and quality. The new policy concerning the release of food producing organisms mandates equivalent, risk-based regulation of traditional and genetically engineered organisms, and thus should lower industries’ burden of federal regulation.<sup>142</sup> The new policy no longer specifies that “integeneric organisms” or “pathogenic” species require oversight. The policy broadly covers all types of genetic modifications, including those resulting from traditional methods, by stating that “[a] determination to exercise oversight . . . should not turn on the fact that an organism has been modified by a particular process or technique.”<sup>143</sup> Rather, all organisms should be regulated according to the risk of introducing them into a particular environment. Federal agencies should not exercise oversight of such introductions unless the risk is unreasonable.<sup>144</sup> However, federal agencies need not choose between imposing or not imposing oversight. Agencies have a range of options, such as “[i]ssuance of suggested industry practices, development of guidelines for certain introductions, and requirements for notification, labeling, prior review or approval of certain introductions.”<sup>145</sup> In determining what level of oversight should be applied, the policy adopts a comparative approach similar to Huber’s. Thus, “[a]n introduction should be subject to no greater degree of oversight than was a comparable organism or product previously used in past safe introductions in a comparable target environment.”<sup>146</sup> In short, this policy suggests a comparative approach to regulation by applying comparable oversight to comparable organisms in similar environments. Such an analysis would apply whether the new organism is, for example, a genetically engineered variety or a newly introduced exotic species.<sup>147</sup>

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141. *Id.* at 15.

142. Exercise of Federal Oversight, *supra* note 64, at 6755-56; cf. Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits, 55 Fed. Reg. 31,118 (OSTP 1990) (preliminary statement of a comparative and risk-based policy of oversight of planned introductions, but differing from the current policy in that organisms produced by traditional means were excluded from oversight). The USDA has proposed similar guidelines for adoption. Proposed USDA Guidelines for Research Involving the Planned Introduction into the Environment of Organisms with Deliberately Modified Hereditary Traits, 56 Fed. Reg. 4134 (1991).

143. Exercise of Federal Oversight, *supra* note 64, at 6756.

144. *Id.*

145. *Id.* at 6758.

146. *Id.* at 6757.

147. *Id.* at 6758.

Consistent with the principles set forth in the *Report*, the FDA has stated that bioengineered plant food products require no special regulation simply because they are bioengineered, and reiterated its intention to regulate such products under existing statutory authority.<sup>148</sup> It has also given some guidance as to how existing statutory authority will be applied to bioengineered foods.<sup>149</sup> Since DNA is a component of all living organisms, the FDA does not consider DNA transferred to plants by bioengineering to be a food additive. However, the FDA could classify the intended protein, carbohydrate, or oil expression product of a transferred gene as a food additive if the product is not GRAS. Plant foods containing such intended expression products would require premarket review under section 409 of the FDCA.<sup>150</sup> If bioengineering unintentionally results in a harmful expression product, that harmful product will be regulated as an added substance. Therefore, under section 402(a)(1) of the FDCA, bioengineered plant foods are adulterated if the level of unintentionally introduced harmful substances "may render" the food injurious to health.<sup>151</sup>

To avoid an FDA enforcement action against adulterated food or unapproved food additives, industry must determine whether its products are safe or whether premarket approval is necessary. In its recent policy notice, the FDA outlined the scientific basis for such an assessment by a manufacturer.<sup>152</sup> The assessment scheme focuses primarily on the levels of toxicants, nutrients, and food allergens, and on the type and nutritional value of introduced or modified proteins, carbohydrates, fats, and oils.

One feature of this assessment, in addition to qualitative and analytical evaluation, is a comparative approach. Acceptable and unacceptable levels of certain food constituents are determined by reference to the host plant when that plant has a history of safe use.<sup>153</sup> By following FDA's guidelines, a manufacturer is expected to determine whether the product is safe, requires FDA consultation because of questionable safety, or is unsafe.<sup>154</sup> Thus, the FDA suggests that the level of toxicants in the new variety should be within the range of toxicant

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148. FDA Statement of Policy, *supra* note 53, at 22,984-85. This statement of policy does not apply to plants containing "pesticide chemicals," which are regulated by the EPA. *Id.* at 23,005; see also David A. Kessler et al., *The Safety of Foods Developed by Biotechnology*, 256 SCIENCE 1747 (1992).

149. FDA Statement of Policy, *supra* note 53, at 22,988-91.

150. *Id.* at 22,990.

151. *Id.*

152. *Id.* at 22,986-87, 22,991-3,004.

153. *Id.* at 22,996. The focus on host and donor plants suggests that the assessment scheme applies only to genetically engineered foods. However, in keeping with its policy of regulating bioengineered products within the same framework as food produced by traditional methods, the FDA states that the assessment scheme applies to the evaluation of "food from new plant varieties derived by traditional methods . . . tissue culture methods . . . and recombinant DNA methods." *Id.* at 22,991.

154. *Id.* at 22,992.

levels in the host variety,<sup>155</sup> and that "the concentration and bioavailability of important nutrients in the new variety [should be] within the range ordinarily seen in the host species."<sup>156</sup> If toxicant levels present a safety concern, the food is unacceptable; if nutrient levels are outside of the normal range, the manufacturer must consult the FDA to determine its course of action.<sup>157</sup> The primary concern raised by the donor species is the potential transfer of allergens or toxicants to the host. The manufacturer must consult the FDA if it is possible that allergens have been transferred from the donor to the host plant.<sup>158</sup> The assessment of food safety may entail qualitative, as well as quantitative comparisons. Thus, a manufacturer must consult the FDA if the introduced protein, carbohydrate, fat, or oil is likely to be a major component of the diet and is not derived from an edible source, or differs substantially from that in the edible source.<sup>159</sup>

This comparative approach is based on the recognition that unmodified, unprocessed foods pose a natural risk by not only varying substantially in nutritional content but also containing a wide variety of toxicants.<sup>160</sup> The baseline level of risk posed by traditional foods is the standard against which genetically engineered modifications must be

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155. *Id.* at 22,996.

156. *Id.* at 22,995.

157. *Id.*

158. *Id.* at 22,997-98. The FDA requires labeling of foods containing an introduced protein that may cause an allergic reaction, e.g., if a bioengineered tomato expresses a peanut protein. Labeling may also be required where other "safety or usage issue[s] exist," but not merely to note that a food is genetically engineered. *Id.* at 22,991. In contrast, the Environmental Defense Fund favors labeling of all genetically engineered foods as well as statutory changes addressing genetic engineering, to ensure that the FDA subjects such foods to premarket safety testing. Jeffrey L. Fox, *Food Proposals for FDA to Savor*, 9 BIO/TECHNOLOGY 1039 (1991).

159. FDA Statement of Policy, *supra* note 53, at 22,999-3,004.

160. International Food Biotechnology Council, *supra* note 11, at S11-78. The International Food Biotechnology Council (IFBC) has also proposed evaluating bioengineered foods on an essentially comparative basis:

The IFBC recommends that the initial basis of the safety evaluation of a genetically modified food should begin with consideration of the lineage of all genetic materials present in the final food product. . . . The IFBC recommends that a food product be considered to present no safety concern if analytical studies indicate that the concentration of inherent constituents does not differ significantly from the concentration range typical of the traditional food, and any new constituent(s), if present, is already accepted for use in food under the anticipated conditions of use.

*Id.* at S138-39.

The IFBC fulfills Huber's first three criteria, *see supra* text accompanying note 63, by defining a risk market including the bioengineered food and the traditional foods for which it is a functional substitute, and by specifying that the bioengineered food be compared to the traditional food from which it is derived. The IFBC then concludes, like Huber, that only the less safe bioengineered foods, those that are significantly different or contain an ingredient not accepted for food use, should be regulated. The IFBC also fulfills Huber's fourth criterion, whether increased consumption would increase net risk, since it recommends that a "food product be considered to present no safety concern if use of the food would not be expected to alter significantly present intake of it or its constituents in comparison with the traditional product." *Id.* at S140.

measured. However, the FDA has applied a comparative analytical approach while relying upon the traditional categories of whole foods, food additives, and GRAS substances to govern its regulation of the product.<sup>161</sup> The use of these rigid categories may hinder comparative evaluation.<sup>162</sup>

Comparison to the corresponding unmodified organism essentially regulates products of biotechnology on a par with organisms produced by traditional methods. This type of comparison equilibrates the new and old risks by removing new risks commensurate with old, unregulated risks from the regulatory process. However, because it requires a judgment by the manufacturer involving risks that may be unknown and unquantifiable, environmentalists and others skeptical of the new technology may feel that it leaves too many products of that technology unregulated or underregulated. Critics may also think that manufacturers using the new technology have too much discretion to unilaterally decide whether their products meet the required standards. Moreover, it is difficult to see how agencies can apply a risk-based policy to certain organisms (e.g., transgenic fish) perceived to be immune to oversight due to gaps in statutory authority. Nor does the policy address ideological deficiencies that result from using existing statutory and regulatory authority. Thus, while the policy may ease regulatory burdens at the federal level, it may create a backlash from the public<sup>163</sup> and from state and local bodies that perceive greater risks from biotechnology and wish to regulate it more stringently.

State regulation of biotechnology has grown despite the current level of federal regulation. Nine states have already adopted laws regulating biotechnology.<sup>164</sup> Three of these, North Carolina, Minnesota, and Florida, require a permit to release genetically engineered plants or other organisms.<sup>165</sup> Most states require submission of the same forms required by federal authorities, and some states require notification of county or city authorities.<sup>166</sup> North Carolina generally requires submission of the federal forms, and reviews the adequacy of federal

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161. FDA Statement of Policy, *supra* note 53, at 22,988-91.

162. Huber, *supra* note 55, at 1082. If the FDA regulates under its current statutory authority, some bioengineered foods might be classified as whole foods and escape both screening and standard-setting regulations, appropriate for "old risks." Others, classified as food additives, would be subject to premarket screening, which in many cases might be overly strict regulation.

163. See, e.g., Molly O'Neil, *Geneticists' Latest Discovery: Public Fear of "Frankenfood,"* N.Y. TIMES, June 28, 1992, at A1; *Group of Chefs Plans Boycott of Genetically Engineered Food,* S.F. CHRON., July 29, 1992, at A3; Michael Schrage, *Genetically Engineered Foods May Be Safe, but They Still Should Be Labeled,* WASH. POST, June 5, 1992, at B11.

164. Eisner, *supra* note 33, at 6 (listing Florida, Hawaii, Illinois, Maine, Minnesota, New York, North Carolina, Rhode Island, and Wisconsin).

165. FLA. STAT. ANN. § 581.083 (West 1991); MINN. STAT. ANN. § 116C.94 (West 1991); N.C. GEN. STAT. § 106-772 (1990).

166. See, e.g., ILL. ANN. STAT. ch. 111 1/2, paras. 7603-7604 (Smith-Hurd 1991); WIS. STAT. ANN. § 146.60 (West 1990).

decisions, but preempts regulation by counties and municipalities.<sup>167</sup> Minnesota and Wisconsin enacted a one-year moratorium on the use of bovine somatotropin (bST).<sup>168</sup> State regulation of biotechnology adds at minimum another round of paperwork when the state and federal laws are equivalent, but imposes an additional regulatory burden when they conflict. The Minnesota and Wisconsin bans on bST are examples of laws conflicting with federal regulation that also contravene the principles of comparative regulation.<sup>169</sup>

The lack of a unified approach on the federal level and the prospect of a patchwork of state regulations has caused the biotechnology industry to lobby for more comprehensive federal regulations.<sup>170</sup> Moreover, it has been suggested that state law should be preempted in regard to biotechnology.<sup>171</sup> The current statutes from which regulatory authority over biotechnology has been derived generally do not preempt state law, permitting state laws more stringent than federal law so long as they do not burden interstate commerce.<sup>172</sup> Thus, new statutory authority would be necessary to effect state preemption.

The Omnibus Biotechnology Act of 1990 (House Bill 5312, not enacted) was a response to the need to revise federal regulation of biotechnology that also addressed the role of the states in regulating biotechnology.<sup>173</sup> H.R. 5312 sought to unify federal review and authorization of release of genetically engineered organisms.<sup>174</sup> It required a permit for release of all "genetically modified organism[s],"<sup>175</sup> closing any gaps in regulatory oversight, and it established an application management board to coordinate jurisdiction between the agencies.<sup>176</sup> It recognized that release of some categories of organisms would not

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167. N.C. GEN. STAT. §§ 106-772, -775 (1990).

168. MINN. STAT. ANN. §§ 151.01, .15, .25 (West 1992); Wis. STAT. ANN. § 97.235 (West 1991).

169. Banning bST essentially imposes a greater regulatory burden on bST-derived milk than on its traditional counterpart, milk produced without hormone stimulation. Since the risk of the bST-derived milk apparently is no greater than that of traditionally produced milk, the ban contravenes the principles of comparative regulation.

170. Crawford, *supra* note 125; cf. Eisner, *supra* note 33, at 6 (the biotech industry is split over whether a national biotechnology policy is necessary).

171. See, e.g., OTA, INVESTMENT IN BIOTECHNOLOGY, *supra* note 87, at 214. Shortly after the initial controversy over recombinant DNA, proposed legislation preempting state laws on biotechnology was suggested, but none has been enacted. See Judith P. Swazey et al., *Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy*, 51 S. CAL. L. REV. 1019, 1069 (1978).

172. Hearing on H.R. 5312, *supra* note 96, at 163-64 (statement of Margaret Mellon, Ph.D., J.D., National Wildlife Federation).

173. H.R. 5312, 101st Cong., 2d Sess. (1990); Hearing on H.R. 5312, *supra* note 96, at 3-41 (text of H.R. 5312). H.R. 5312 was introduced on July 19, 1990. 136 CONG. REC. H5120 (daily ed. July 19, 1990). The bill was not enacted, and the last date of action on it was July 19, 1990. *Bill Tracking Report*, 1990 H.R. 5312, available in LEXIS, Legis Library, BLT101 File.

174. Hearing on H.R. 5312, *supra* note 96, at 3 (text of H.R. 5312).

175. *Id.* at 9.

176. *Id.* at 34.

require full review, but only notification of the agency.<sup>177</sup> Generally, agencies would issue permits unless the proposed activities constitute an "unreasonable risk to human health or the environment."<sup>178</sup> H.R. 5312 also required that the person or company applying for a permit provide the information regarding the release to the appropriate state agency. Further, H.R. 5312 gave the state the opportunity to submit its comments to the overseeing federal agency.<sup>179</sup> In return for this state involvement, H.R. 5312 provided for federal preemption of state authority to regulate or prohibit releases permitted under research and development permits, and allowed state regulation but not prohibition of releases of organisms which have been approved for either a general permit or for commercial purposes.<sup>180</sup> It also required extensive notification of local authorities.<sup>181</sup>

Environmentalists generally approved of the bill for its broad coverage of genetically engineered organisms and its state and local notification procedures, but faulted it for its federal preemption provisions.<sup>182</sup> Industry representatives were pleased with the latter but were concerned that permits might be required in situations where previous experience had shown no adverse effects, suggesting that notification would suffice.<sup>183</sup> Thus, industry may prefer to rely on the administration's policy, which has the potential to remove many organisms from supervision. In the absence of a comprehensive federal biotechnology regulatory scheme, however, both camps are subject to the vicissitudes of the states. Biotechnologists may find more local regulations passed that block their progress to commercialization. Conversely, should a bioengineered organism immune to federal regulation under the current scheme pose a genuine threat to the environment, state regulation could not provide adequate protection to the nation as a whole.

## VIII. PROPOSAL FOR FEDERAL REGULATION OF BIOENGINEERED FOOD

Regulation of the release and consumption of bioengineered food products requires a credible, straightforward regulatory framework that addresses all genetically engineered organisms and products and gives the states and the public confidence that the products of biotechnology

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177. *Id.* at 10, 20.

178. *Id.* at 15-16.

179. *Id.* at 35-38.

180. *Id.* at 38-39.

181. *Id.* at 10-11.

182. *Id.* at 161 (statement of Margaret Mellon, Ph.D., J.D., National Wildlife Federation).

183. *Id.* at 181, 187 (comments of David J. Glass, Vice President, Government and Regulatory Affairs, Biotechnics International, Inc.); *id.* at 190-91 (comments of Warren Springer, Manager, Regulatory Affairs, Northrup King Co.); *id.* at 198 (comments of Rod Townsend, Manager, Regulatory Affairs, Plant Breeding Division, Pioneer Hi-Bred International, Inc.).

are appropriately regulated.<sup>184</sup> That new statutory authority could be similar to H.R. 5312 in extending coverage to all genetically engineered organisms, and it could ease regulatory burdens by coordinating the review process through an applications management board. New statutory authority should be based on the premise that not all products of genetic engineering require oversight. The new statutory scheme should not impose additional regulatory burdens based solely on the process of manufacture or on possible unknown risks; rather, regulation should be commensurate with the risks of the product.<sup>185</sup> Thus, new statutory authority governing the release of genetically engineered organisms could mandate that agencies implement a comparative approach to regulation similar to that proposed by the Council on Competitiveness, rather than an undefined standard where permits would be denied only when there is a risk to health or environment.<sup>186</sup> Based on present and future experience, the agencies could develop categories of genetic changes in particular types of organisms that would require only notification, but no review. This would help avoid unnecessary oversight but provide the authority to regulate when needed.

Recognizing the complexity of the biotechnology industry and its regulation, the extensive technical resources available to the federal review process, and the strong national stake in biotechnology, new statutory authority should also preempt state prohibition of release of genetically engineered organisms allowed by the federal government. It should, however, permit state and local regulation of biotechnology. For example, it should allow states to designate certain areas such as nature preserves as inappropriate for such activities. By giving such regulatory authority, these is the risk that a state could effectively prohibit genetically engineered organisms, perhaps by requiring excessive containment of biotechnology activities. This, however, is somewhat consonant with other federal regulatory statutes that allow states to regulate more stringently than federal statutes require.<sup>187</sup> Because

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184. See generally OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-F-474, A NEW TECHNOLOGICAL ERA FOR AMERICAN AGRICULTURE (1992).

185. A discussion of the benefits and costs of biotechnology regulations, given that no problems have actually occurred, is found in OTA, BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 76, at 195-96.

186. Such an approach to comparative regulation should provide that the new and reference organism be compared in the same environment; e.g., a faster growing transgenic fish would probably pose no more threat than a parental strain in a fish hatchery, but if the intent is to transfer the transgenic fish to the wild, it should be compared to indigenous wild fish.

187. See, e.g., Wisconsin Pub. Intervenor v. Mortier, 111 S. Ct. 2476 (1991) (state or local regulation of pesticide use is permitted so long as it does not authorize a sale or use prohibited by FIFRA); Processed Apples Inst., Inc. v. Department of Pub. Health, 522 N.E.2d 965 (Mass. 1988) (state could establish tolerances for pesticides more stringent than federal levels under the FDCA). State or local authorities who are most familiar with the local terrain would probably be best suited to enact laws that, for example, permit oversized transgenic fish in a sport fishing lake but prohibit them in nature preserves.

biotechnology is a rapidly changing area, any new statutory authority should contain a sunset provision to allow change that will accommodate new advances and understanding of risks.<sup>188</sup>

Since the food products of biotechnology are comparable to traditional foods, they could be regulated under existing statutes, but new regulations addressing generic concerns related to biotechnology would be helpful to developers and regulators.<sup>189</sup> This proposal is consistent with the recommendation of the Administrative Conference of the United States that agencies adopt rules that address recurring regulatory issues concerning biotechnology.<sup>190</sup> Although the food additive and GRAS categories may be appropriate for evaluating bioengineered chemicals and enzymes, transgenic food crops should be evaluated on a comparative basis without reference to whether the gene/product might be considered an added substance or food additive. The provisions could still be self-actuating in the event that manufacturers are confident that their foods meet the specifications, but notification should be mandatory during this period when bioengineered foods are still being introduced.<sup>191</sup> The agencies should continue the practice of giving advisory opinions when manufacturers request advice on the status of their product.<sup>192</sup> Federal regulation of biotechnology-derived food products would not preempt state law, since state law protecting health and safety is generally given considerable deference where there are no explicit preemption provisions, as in the FDCA.<sup>193</sup>

In conclusion, a more comprehensive and straightforward federal statutory and regulatory scheme, addressing both the environmental release of bioengineered food organisms and the safety of the products, could foster both the development of biotechnology and protection of

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188. H.R. 5312 had a sunset provision of seven years. *Hearing on H.R. 5312, supra* note 96, at 40-41 (text of H.R. 5312).

189. Generic concerns might include decisions on the safety of commonly used antibiotic resistance genes used as markers, commonly used vectors, allergens and biopesticides. This would be no different in principle than the regulations listing GRAS substances. For a discussion of antibiotic resistance genes and vectors, see International Food Biotechnology Council, *supra* note 11, at S122-25.

190. General Provisions, Administrative Conference of the United States, 1 C.F.R. § 305.89-7 (1991).

191. Such a notification procedure could include safety data which could be made public and could give the FDA a basis for minimal oversight. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-F-475, A NEW TECHNOLOGICAL ERA FOR AMERICAN AGRICULTURE—SUMMARY 21 (1992).

192. The FDA has indicated that industry should no longer submit requests for advisory opinions. FDA Statement of Policy, *supra* note 53, at 22,985. Moreover, the FDA has no obligation to issue advisory opinions, nor does it routinely publish notices of requests for advisory opinions. Calgene, *supra* note 120, at 22,772.

193. See, e.g., Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963). However, federal regulation of animal drugs may preempt state regulations in that area, since a comprehensive scheme of drug regulation under the FDCA is linked to meat regulation under the Federal Meat Inspection Act, which has explicit preemption provisions. Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp., 626 F. Supp. 278, 282-86 (D. Mass. 1986); 21 U.S.C. § 301 (1988) (ch. 9).

human health and the environment. It should not, however, thwart state or local laws that have long been accepted in the area of food regulation.<sup>194</sup> The only remedies, then, to unduly restrictive regulation at the state level lie in the credibility of the federal scheme and, more importantly, in the public perception of the technology itself. That perception will be greatly improved when biotechnology advances to the point that products are available to fulfill its promise of improvement of human health and the environment.

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194. Many aspects of the FDCA, such as the manufacture and safety of drugs, involve issues so complex and critical that national standards, preempting state law, might best protect the public safety and welfare. Food products have not reached a similar level of complexity and present more situations in which local safety concerns might genuinely exist. In any case, the application of biotechnology to foods or drugs does not seem to present a situation so special that it merits federal preemption even when the FDCA does not preempt state law regarding most food and drug products.