Agricultural Biotechnology Regulation: The Pew Initiative and Its Stakeholder Forum

by

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AGRICULTURAL BIOTECHNOLOGY REGULATION: THE PEW INITIATIVE AND ITS STAKEHOLDER FORUM

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I. INTRODUCTION

The Pew Initiative on Food and Biotechnology ("PIFB" or "Initiative") was launched in 2001 with the goal of becoming an objective and independent source of information regarding agricultural biotechnology.[1] PIFB was funded

1. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, MISSION STATEMENT (2003), *available at* http://pewagbiotech.org/about/.

by a grant from The Pew Charitable Trusts to the University of Richmond.[2] Attempting to be neither an advocate for nor against agricultural biotechnology, the Initiative has provided information and encouraged debate and dialogue regarding a broad range of legal and policy issues related to agricultural biotechnology.[3]

Much of the work of the Initiative involves creating and disseminating information about scientific, economic, marketing, and regulatory issues relevant to agricultural biotechnology.[4] PIFB has produced reports and sponsored workshops and conferences highlighting the diverse views of recognized experts on topics relevant to agricultural biotechnology.[5] Products from these workshops and other reports are available on the PIFB web site.[6] Contained in Appendix A to this article, the author has compiled a list of papers, issue briefs, and fact sheets issued by the PIFB, along with a brief summary of each listed document.

One particular activity of the Initiative was its work with the "Stakeholder Forum" project, which began in 2001.[7] In this consensus-building project, the PIFB convened a "small group of representatives from industry, public institutions, academia, consumer and environmental groups, and several other interested parties."[8] For two years, this group worked to develop consensus recommendations that would enhance the U.S. regulatory system for agricultural biotechnology.[9] The Stakeholder Forum project is the primary focus of this article.

II. THE STAKEHOLDER FORUM PROJECT: AN OVERVIEW

A. *Project Goals and Members*

The Forum's primary goal was ambitious; it was to develop a consensus among the stakeholders on "a package of regulatory reforms described in sufficient detail to enable an agreement on implementation."[10] The package of "consensus" regulatory proposals was to address the regulatory activities of the United States Department of Agriculture ("USDA"), the United States Food and Drug Administration ("FDA"), and the United States Environmental Protection Agency ("EPA"), related to the applications of biotechnology to animals and

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2. *Id.*
3. *Id.*
4. *Id.*
5. *Id.*
6. *See id.*
7. *Id.*
8. *Id.*
9. *Id.*
10. STAKEHOLDER FORUM, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, THE STAKEHOLDER FORUM ON AGRICULTURAL BIOTECHNOLOGY: AN OVERVIEW OF THE PROCESS 3 (2003), *available at* http://pewagbiotech.org/consensus/FinalReport.pdf.

plants, and especially any public health and environmental concerns regarding these applications.[11]

Generally, Stakeholder Forum participants included representatives of the biotechnology industry, environmental and consumer advocacy organizations, the farming and ranching communities, food processing and marketing companies, and academic institutions.[12] PIFB chose not to include representatives of trade associations, per se, and to limit the group to about twenty. A list of eighteen Stakeholder Forum members appears in Appendix A of *The Stakeholder Forum on Agricultural Biotechnology: An Overview of the Process*, prepared by the Pew Initiative on Food and Biotechnology.[13]

The selection process involved consultations with leaders and experts from a broad range of relevant interests, including agricultural groups, trade as-

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11. *Id.*

12. *Id.*

13. *Id.* at 11-12. The author understands that participants were asked not to view themselves as representatives of a particular interest group, but rather to bring their diverse experiences and insights into a process intended to serve a broader public interest. The following is the author's attempt to illustrate the diverse backgrounds of the participants by grouping them into various categories:

Those from the biotechnology industry: Steve Daugherty, Director, Government and Industry Relations, Pioneer Hi-Bred International, Inc., Des Moines, IA; John Pierce, Director, Biochemical Sciences & Engineering, Central Research and Development, DuPont, Wilmington, DE; Jerry Pommer, Director, Quality Systems, Trans Ova Genetics, Hull, IA; Linda Strachan, Director, Governmental Affairs, Monsanto, Washington, D.C.

From environmental and consumer advocacy organizations: Richard Caplan, Environmental Advocate, U.S. Public Interest Research Group, Washington, D.C.; Carol Tucker Foreman, Distinguished Fellow and Director, Food Policy Institute, Consumer Federation of America, Washington, D.C.; Rebecca J. Goldburg, Senior Scientist, Environmental Defense Fund, New York, NY; Gregory Jaffe, Director, Biotechnology Project, Center for Science in the Public Interest, Washington, D.C.; Margaret G. Mellon, Director, Food & Environment Program, Union of Concerned Scientists, Washington, D.C.

From farming and ranching communities: Duane Grant, Wheat and Potato Farmer and Board of Directors, National Association of Wheat Growers, Rupert, ID; Andrew G. Jordan, Director, Technical Services, National Cotton Council, Memphis, TN; Bill Northey, Corn Grower, Innovative Farms, Spirit Lake, IA; Roger West, Cattle Rancher (and Chairman, Science and Technology Committee, National Cattleman's Beef Association), Gainesville, FL.

From food processing and marketing companies: Robbin Johnson, Sr. Vice President, Corporate Affairs, Cargill Incorporated, Wayzata, MN; Austin P. Sullivan, Jr., Sr. Vice President, Corporate Relations, General Mills, Inc., Minneapolis, MN.

From academia: Harold D. Coble, Past President, Council for Agricultural Science and Technology, Raleigh, NC; Robert M. Goodman, Professor, College of Agricultural & Life Sciences, University of Wisconsin-Madison, WI; Kathleen Merrigan, Assistant Professor and Director, Agriculture, Food & Environment Program , Friedman School of Nutrition Science & Policy, Tufts University, Boston, MA.

sociations and individual companies, consumer and environmental advocacy groups, Congressional staff, and state and federal agencies. It also involved a small focus group meeting consisting of individuals representing the biotechnology industry, food processors, commodity traders, environmental groups, growers, and consumer advocates.[14]

With Forum membership limited to about twenty, not all views about agricultural biotechnology could be directly represented in the Forum, such as those of federal agencies who were not included.[15] Individuals were ultimately chosen by the PIFB because of their experience and their willingness to work in a collaborative, consensus-oriented process.[16] Those selected also represented interests that would be substantially affected by any recommendations that might be developed.[17]

B. *The Consensus-Building Process*

Three groups were involved with the Stakeholder Forum process: (1) the Pew Initiative on Food and Biotechnology; (2) RESOLVE (a nonprofit organization); and (3) Forum members themselves. PIFB convened the Stakeholder Forum and provided financial and staff support. PIFB served as a neutral facilitator and the sole provider of funding for the work group meetings and plenary sessions.[18] The process of building consensus was run by professional mediators from RESOLVE, "a nonprofit organization specializing in environmental dispute resolution, mediation, consensus building, facilitation, and policy dialogue."[19] "Forum members themselves were responsible for the content of the deliberations" and the scope of their discussions.[20] Forum members chose the substantive topics to be addressed at meetings, determined meeting agendas, selected outside experts to provide assistance as needed, and developed various draft approaches and draft recommendations.[21]

At the first meeting, in Washington, D.C., members adopted operating procedures, "which served to safeguard the members' interests and foster open and constructive dialogue."[22] For example, Forum activities were "conducted as a nonpublic, confidential process."[23] The operating procedures also expressly ad-

14. *Id.* at 4-5.
15. *See id.*
16. *Id.*
17. *Id.*
18. *Id.* at 4.
19. *Id.*
20. *Id.*
21. *Id.*
22. *Id.* at 6.
23. *Id.*

dressed the meaning of consensus.[24] During several of the early meetings, Forum members defined the issues of greatest importance to them and targeted their work toward seeking consensus on those concerns.[25] For example, "the group chose to focus on regulatory issues rather than science or marketing issues, and on domestic regulatory issues rather than international regulatory issues."[26] Over a two-year period, a total of eleven facilitated plenary sessions at five United States locations were held.[27] Numerous work group meetings and conference calls were also held.[28]

"In order to hold in-depth discussions on key issues, Stakeholder Forum members organized into three major work groups: the Animals Work Group, the Environmental Protection Work Group, and the Food Safety Work Group."[29] Information, proposed regulatory approaches, and draft recommendations developed by these work groups were shared with all members of the Forum during plenary sessions.[30] Thus, the initial work product of the working groups could be reviewed, discussed, and/or modified by all Forum members.[31]

The Stakeholder Forum also engaged nearly one hundred outside legal, scientific, business, and policy experts in varying ways.[32] In addition, "Forum members held several meetings with federal agency staff, in order to test the feasibility of draft recommendations and clarify technical issues."[33] For example, "[m]embers of the Animals Work Group met with individuals from the FDA's Center for Veterinary Medicine" and "[m]embers of the Environmental Protection Work Group met with individuals at both the EPA and the USDA."[34]

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24. *Id.* at 24.
The Stakeholder Forum will operate by consensus. Recommendations or other documents will be considered to have achieved consensus if there is no dissent by any Member of the Stakeholder Forum. For the final report containing the recommendations of the Stakeholder Forum, consensus will be defined by the following, 'As a package of ideas and recommendations, all Stakeholder Forum Members can live with and support the overall direction of the recommendations.' *Id.*
25. *Id.* at 6.
26. *Id.*
27. *Id.*
28. *Id.*
29. *Id.*
30. *Id.*
31. *Id.*
32. *Id.*
33. *Id.* at 7.
34. *Id.*

C. *Outcomes*

Although never formally adopted, a "working draft" of the broad principles and components for an effective regulatory system for agricultural biotechnology guided the Stakeholder Forum project.[35] To protect public health and the environment without unduly burdening the development of innovative, productive, and sustainable agricultural practices, a regulatory system must have certain components in place.[36] These essential components include adequate legal authority, adequate resources, a safety-driven approach to risk assessment, and appropriate risk management.[37] "[T]o ensure continuous improvement, and to build and maintain public confidence in the regulatory system, members agreed that the system also must be adaptive, efficient, equitable, transparent, and participatory."[38]

However, the step from agreement on broad principles to agreement on specific recommendations proved to be more difficult. The Stakeholder Forum could not reach complete agreement on all the regulatory reform issues in sufficient detail to achieve its ambitious goal.[39] A partial list of issues that, in the author's opinion, undoubtedly were considered by the Forum, is discussed in Section III, *infra*.

The Stakeholder Forum concluded that an incomplete or imprecise set of recommendations would not be useful, but its members decided to keep open the possibility of future collaboration and agreement.[40] In fact, they agreed it would be desirable to reconvene in twelve to eighteen months to review how the regulatory agencies are addressing various agricultural biotechnology issues and consider whether to renew their pursuit of consensus recommendations.[41] The implications of the Stakeholder Forum's inability to reach consensus on the details of a comprehensive set of regulatory proposals, and the possible reasons for the lack of consensus, are discussed in Section IV, *infra*.

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35. *See id.* at 6.
36. *See id.* at 31.
37. *Id.*
38. *Id.*; *see also id.* (containing a more complete discussion of the essential components and characteristics of a regulatory system).
39. *Id.* at 3.
40. *Id.*
41. *Id.* at 4.

III. EXAMPLES OF REGULATORY ISSUES UNDOUBTEDLY CONSIDERED BY THE STAKEHOLDER FORUM

A. *Pre-Market Approval of Genetically Engineered Plants and Animals*

1. *FDA and Pre-Market Approval of Transgenic Crops: Should the FDA "Formally Approve" Biotech Crops Before they are Marketed to Consumers?*

The FDA's pre-market approval authority for food is found in Section 348 of the Federal Food, Drug, and Cosmetic Act ("FFDCA").[42] This section, the only section dealing with pre-market approval, deals with "Food Additives."[43] The addition of an "unsafe" food additive to food is prohibited.[44] Food additives are unsafe unless, for example, the additive and its use are in conformity with a federal regulation prescribing the conditions for safe use.[45] Thus, under current law, pre-market approval of a transgenic crop is only required if the novel protein or other new substance expressed in a crop by the inserted gene meets the FFDCA definition of food additive.[46] Substances that are generally recognized as safe ("GRAS") by scientists are excluded from the definition of food additives and, therefore, cannot be an unsafe food additive.[47] Food additives used prior to 1958 can also be included under the GRAS exception because of their common use in food.[48]

Should a company about to market a transgenic food or feed crop seek pre-market approval from the FDA? Pursuant to its 1992 Policy Statement, the FDA consults with companies intending to market any new food, including a food derived from a genetically engineered crop.[49] The consultations help the company determine whether it should formally submit a petition for approval

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42. *See* 21 U.S.C. § 348 (2000).
43. *Id.*
44. *See id.* § 342(a)(2)(C)(i).
45. *See id.* § 348(a)(2).
46. *See id.* § 321(s) (defining "food additive" under the act).
47. *Id.*
48. *Id.*
49. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992); *see also* FDA, PRESS OFFICE, U.S. DISTRICT COURT DISMISSES GENETICALLY ENGINEERED FOOD LAW SUIT AGAINST FDA (FDA Talk Paper T00-50, 2000), *available at* http://www.fda.gov/bbs/topics/ANSWERS/ANS01043.html (indicating that the court agreed with the FDA that the policy was not a formal rule, was not a "major federal action", and that the class of genetically engineered foods do not require premarket review and approval).

under Section 409 food additive procedures, or go to market without a Section 409 petition because the new food falls under the GRAS exception.

As of August 18, 2004, this consultation process has been used over fifty-five times for transgenic crops.[50] After the extensive consultation process, during which the company provides data regarding its food safety tests, each crop viewed as GRAS, that is, substantially equivalent to its non-genetically engineered counterpart, does not require a Section 409 pre-market approval petition. Thus, while crops have not been "formally" approved as food additives, they have, nevertheless, gone through a procedure that is, in the author's opinion, tantamount to formal approval.[51] However, this process is subject to the criticism that genetically engineered foods are not even approved by the FDA before they are sold. Should the FFDCA be amended to authorize the FDA, perhaps in a new section distinct from Section 409, to formally approve foods derived from transgenic crops after the consultation process of the 1992 Policy Statement has been successfully completed?

2. *FDA and its Voluntary Consultation Process for Transgenic Crops: Should the Consultation Process Described in the 1992 Policy Statement be Mandatory Rather than Voluntary?*

Even if the public accepts the consultation process, where it is applied, as being tantamount to formal approval of a transgenic crop by the FDA, the regulatory process is still subject to the criticism that the FDA's consultation process for transgenic crops is voluntary, not mandatory. Should the FDA make this process mandatory, as a way of creating greater consumer confidence in the United States system of biotechnology regulation?

In early 2001, the FDA proposed rules that would require manufacturers of plant-derived, bioengineered foods and animal feeds to notify the FDA at least 120 days before products are marketed.[52] As part of the notification, the manufacturer would provide information showing that the foods or feeds are as safe as their conventional counterparts.[53] Also, under the proposed rules, the evaluation process would become more "transparent" because information submitted by manufacturers, as well as FDA responses, would be posted on the Internet or otherwise made more accessible.[54] The period for public comment on the pro-

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50. *See* OFFICE OF FOOD ADDITIVE SAFETY, FDA, LIST OF COMPLETED CONSULTATIONS ON BIOENGINEERED FOODS (Aug. 2004), *available at* http://www.cfsan.fda.gov/~lrd/biocon.html.

51. *See, e.g., infra* App. B (providing an example of a consultation).

52. *See* OFFICE FOR FOOD ADDITIVE SAFETY, FDA, *supra* note 50.

53. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4720 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pt. 192 and 592).

54. *See id.* at 4723.

posed rule ended April 3, 2001,[55] but no further action has been taken by the FDA. Perhaps the FDA is concerned that it does not have the necessary legislative authority to impose such a rule.

3. *FDA and its Pre-Market Approval Process for Transgenic Animals: Does the Approval Process for Transgenic Animals, such as Genetically Engineered Salmon, Provide Adequate Transparency and Public Participation?*

The FDA requires pre-market approval of genetically engineered animals, viewing them as a "new animal drug" under the FFDCA. A new drug must be approved by the FDA before it can be brought to market.[56]

The statutory definition of a drug includes "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[57] The FDA has asserted that the DNA sequences used to transform genetically engineered animals fit within this statutory definition and, therefore, within the meaning of new animal drug.[58] The FDA also considers the expression product of the genetic construct, e.g., a growth hormone, to be a new animal drug. Finally, subsequent generations of the transgenic animal are also considered to contain the new animal drug because the construct is integrated into the animal's genome and stably inherited by its progeny.[59]

A PIFB report on transgenic fish describes the strengths and weaknesses of this regulatory approach to transgenic animals.[60] Regulating transgenic animals as new animal drugs provides a mandatory pre-market approval process, but requires that the process be confidential.[61] Under this approach, the FDA has adequate authority to ensure that transgenic fish are safe for human consumption, but may not have the legal tools and scientific expertise to ensure that transgenic fish (and presumably other transgenic animals) will not cause ecological harm.[62]

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55. *See id.* at 4729.
56. 21 U.S.C. § 355(a) (2000).
57. *Id.* § 321(g)(1)(C).
58. *See id.* § 321(v).
59. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, FUTURE FISH: ISSUES IN SCIENCE AND REGULATION OF TRANSGENIC FISH 41 (2003), *available at* http://pewagbiotech.org/research/fish/fish.pdf.
60. *See generally id.*
61. *See id.* at 52.
62. *See id.*

B. *Continuing Post-Market Oversight of Genetically Engineered Plants*

Some argue that the current regulatory oversight system for agricultural biotechnology is focused primarily on pre-market approval, but that post-market oversight of biotech products has limited resources and is given relatively low priority.[63] Two examples where the adequacy of post-market oversight is questioned are described below.

1. *USDA-APHIS and its "Determination of Non-Regulated Status": Does it Provide Adequate Post-Market Oversight?*

The most common method of USDA "approval" for full commercialization of biotech crops is the granting of a petition for a determination of nonregulated status.[64] Accompanying the decision document is typically an environmental assessment.[65] Where such a determination of non-regulated status has been made, USDA-APHIS arguably does not have the authority to impose conditions on the use of biotech crops, or to require biotech developers to monitor the impact of the crop on the environment.

2. *EPA and the Monitoring of Conditions Imposed When a Pesticidal Protein is Registered: Are Farmers Sufficiently Accountable?*

The EPA is responsible for setting standards to manage the environmental impact of pesticides, including plant-incorporated protectants like *Bt*.[66] For example, one such standard is the twenty percent refuge requirements when planting *Bt* corn, typically requiring at least twenty percent of the corn acreage to be planted in non-*Bt* varieties which helps to impede the development of resistance in the target insect.[67] The EPA now only imposes conditions on the biotech companies – the ones seeking to register the plant-incorporated-protectant. The

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63. *See* MICHAEL R. TAYLOR & JODY S. TICK, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, POST MARKET OVERSIGHT OF BIOTECH FOODS: IS THE SYSTEM PREPARED? 41 (2003), *available at* http://pewagbiotech.org/research/postmarket/PostMarket.pdf.

64. *See* 7 C.F.R § 340.6 (2004).

65. *See id.* § 372.5(b)(4) (stating that approvals and issuance of permits involving genetically engineered species is an APHIS action normally requiring an environmental assessment).

66. *See* 7 U.S.C. § 136(b) (2000) (stating the "Administrator" of the Environmental Pesticide Control Act is the Administrator of the Environmental Protection Agency); *see also* D.L. Uchtmann, *StarLink—A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159, 183-93 (2002).

67. *See* GREGORY JAFFE, CTR. FOR SCIENCE IN THE PUB. INTEREST, PLANTING TROUBLE: ARE FARMERS SQUANDERING Bt CORN TECHNOLOGY? 1, 2 (2003), *available at* http://www.cspinet.org/new/pdf/bt_corn_report.pdf.

companies, in turn, are required to monitor how farmers use their products based on what farmers tell them.

In the aftermath of the StarLink™ incident, the EPA strengthened its post-market oversight of *Bt* crops.[68] On October 15, 2001, when the EPA extended the registrations of five *Bt* corn products an additional seven years, the EPA included new requirements for companies marketing *Bt* corn.[69] Such companies are now required to (1) actually secure the grower's signature on grower agreements prior to receipt of any seed, (2) make the grower agreements available to the EPA, and (3) hire an independent third party to actually survey growers and identify the extent to which the refuge requirements are being implemented at the farm level.[70] Nevertheless, it is arguable that these changes did not go far enough, as there are no government audits of how well farmers are complying. A report published by the Center for Science in the Public Interest, based on data obtained from the USDA, is relevant. It concluded that nineteen percent of all farms growing *Bt* corn in Iowa, Minnesota, and Nebraska violated the refuge requirement in 2002, with small farms being the biggest problem.[71]

IV. THE STAKEHOLDER FORUM: THE LACK OF CONSENSUS—POSSIBLE REASONS AND IMPLICATIONS FOR FUTURE CHANGES IN THE U.S. REGULATORY SYSTEM FOR AGRICULTURAL BIOTECHNOLOGY

The Stakeholder Forum did not achieve consensus on a full range of regulatory reforms in sufficient detail to enable an agreement on implementation.[72] Lacking consensus on a full range of recommendations, Forum members opted to not formally report on any subset of issues and proposals about which they may have reached consensus.[73] Forum members believed "that an imprecise or incomplete package of recommendations would not serve a useful purpose."[74]

In the absence of additional information about the Stakeholder Forum, the public is left to speculate about where and how the consensus-building effort

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68. *See* Uchtmann, *supra* note 66, at 202.

69. *See id.*

70. *See* BIOPESTICIDES AND POLLUTION PREVENTION DIV., EPA, BIOPESTICIDES REGISTRATION ACTION DOCUMENT: *BACILLUS THURINGIENSIS* (*BT*) PLANT-INCORPORATED PROTECTANTS I13-14 (2001), *available at* http://www.epa.gov/oppbppd1/biopesticides/pips/bt_brad2/1-overview.pdf.

71. JAFFE, *supra* note 67, at 5.

72. STAKEHOLDER FORUM, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 10, at 3.

73. *See id.*

74. *Id.*

fell short of its stated goal. Perhaps there was a lack of consensus regarding most of the details of a regulatory reform package. Perhaps there was agreement on most, but not all, of the details. Perhaps there was general consensus about virtually all of the details needed to make the United States regulatory system a better system in the future. However, the costs and risks of implementing some of the detailed recommendations might have been too high in the minds of some stakeholders. For example, if new legislation would be needed as part of the comprehensive package of recommendations (e.g., to expand the authority of a regulatory agency like the FDA), it is uncertain how the legislation might change while moving through an inherently unpredictable legislative process.

What are the implications of the Stakeholder Forum's inability to reach consensus for future changes in the United States system of biotechnology regulation? In the near future, the adoption and implementation of a comprehensive set of changes to the United States system of biotechnology regulation is unlikely in the author's view. The Pew Charitable Trust and the individual stakeholders made a significant investment in the Stakeholder Forum process.[75] Furthermore, the consensus-building process was admirable. Nonetheless, in the author's opinion, the only manner in which a set of comprehensive changes to the regulatory system could be adopted and implemented in the near feature, would be if the Stakeholder Forum had been able to develop a consensus.

Although the adoption of a comprehensive set of changes is unlikely, incremental changes in the United States system of biotechnology regulations are likely to continue, aided by the insights and foundations laid by the Stakeholder Forum, and by the more general research and educational contributions of the Pew Initiative on Food and Biotechnology and others.[76] In fact, the United States system of biotechnology regulation has continued to adapt to new circumstances and technological developments, as anticipated by the 1986 Coordinated Framework for Regulation of Biotechnology.[77] For example, consider the incremental changes adopted in the wake of the StarLink™ incident.[78]

Forum members engaged in candid and substantive discussions and had an opportunity to carefully examine and debate the strengths and weaknesses of the current regulatory system.[79] The Forum process thus exposed stakeholders to different ideas and perspectives and provided opportunities to learn and forge new relationships.[80] Forum members are confident that the relationships they

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75. *See id.*

76. *See id.* at 4.

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

78. Uchtmann, *supra* note 66, at 205-08.

79. *See* STAKEHOLDER FORUM, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 10, at 7-8.

80. *See id.* at 3.

built will influence the actions of their individual organizations and enhance the quality of the ongoing debate shaping the future of biotechnology.[81]

In a more general sense, the research and educational campaign of the Pew Initiative has utilized reports, conferences, and public debates to increase awareness of the many complex issues embedded in discussions about agricultural biotechnology. A better informed public will both demand, and contribute to, the continuing adaptations of the United States regulatory system for agricultural biotechnology to new circumstances.

V. SUMMARY

This article has reviewed the work of the Pew Initiative on Food and Biotechnology, particularly its Stakeholder Forum project. The Stakeholder Forum was composed of leaders from across the spectrum of stakeholders in the United States system of agricultural biotechnology regulation. Forum members sought to develop consensus recommendations, over a two-year period ending in May 2003, that would enhance the ability of United States policies, programs, and regulations governing agricultural biotechnology products to protect public health and the environment. In considering various issues in the United States regulatory system, the stakeholders were guided by a "working draft" of the essential components and characteristics of an effective regulatory system for agricultural biotechnology. The project ended without the development of a complete consensus among stakeholder-participants. However, the project will indirectly influence the ongoing, incremental changes in the United States system of biotechnology regulation. Given the lack of consensus about a comprehensive package of proposed changes from the Forum project, the adoption and implementation of a comprehensive package of United States regulatory reforms is unlikely in the near future.

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81. *Id.* at 4.

APPENDIX A: PAPERS, ISSUE BRIEFS, AND FACT SHEETS ISSUED BY THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY[82]

A. *Animals*

1. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, BUGS IN THE SYSTEM? ISSUES IN THE SCIENCE AND REGULATION OF GENETICALLY MODIFIED INSECTS (2004), *available at* http://pewagbiotech.org/research/bugs/bugs.pdf.

This paper outlines the development status of GM insects, such as honeybees genetically modified to resist disease, parasites, and pesticides; mosquitoes incapable of carrying a type of malaria parasite; biological control organisms for noxious weeds and insect pests; and silkworms able to produce pharmaceutical or industrial proteins. The paper notes the enormous potential benefits of these insects as well as the potential public health, environmental, and food safety risk issues associated with them. The report also examines the regulatory system and points out gaps in authority and areas where transparency, clarity, opportunities for public participation, resources and expertise, efficiency and coordination, or adequate risk management tools could be improved, in the author's opinion. By presenting both scientific and regulatory issues regarding GM insects in this report, the Pew Initiative hopes to jump-start important and necessary discussions between scientists and regulators.

2. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, FUTURE FISH: ISSUES IN SCIENCE AND REGULATION OF TRANSGENIC FISH (2003), *available at* http://pewagbiotech.org/research/fish/fish.pdf. This paper describes some of the products that could be created through the application of genetic engineering to aquaculture as well as the potential environmental and food safety issues associated with such products. The report also analyzes the process through which regulators plan to evaluate transgenic fish. By consolidating both the scientific and regulatory issues concerning genetically-modified fish in this report, the Pew Initiative on Food and Biotechnology hopes to facilitate a robust discussion about genetically-modified fish and the adequacy of the regulatory process through which they may be brought to market.

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82. The author developed this list from the topical listings available from the Pew Initiative on Food and Biotechnology *at* http://pewagbiotech.org/agtopics/ as of February 2004. The summaries appearing below are adapted and extracted from summary language appearing in the publications. The publications, themselves, are available from this website. This list summarizes only papers, issue briefs, and fact sheets. It does not include Agbiotech Buzz Newsletters, News Releases, or News Summaries issued by the Pew Initiative, all of which may be of interest to the reader. The reader is encouraged to browse the Pew Initiative Website by subject *at* http://pewagbiotech.org/agtopics/.

3. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, HARVEST ON THE HORIZON: FUTURE USES OF AGRICULTURAL BIOTECHNOLOGY (2001), *available at* http://pewagbiotech.org/research/harvest/harvest.pdf. This paper is intended to enrich both the knowledge and dialogue surrounding agricultural biotechnology by profiling some of the genetically engineered products being developed by industry and university scientists. The report reviews some of the current research on large-scale crops like corn and soybeans, but it also outlines ongoing research on a much broader range of plants, trees, grasses, animals, insects and fish. While not a comprehensive inventory, Harvest on the Horizon reveals the breadth and scope of current research activities and gives a snapshot of how industry and university researchers are thinking about potential future agricultural biotechnology products.

B. *Environmental Protection*

1. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, BUGS IN THE SYSTEM? ISSUES IN THE SCIENCE AND REGULATION OF GENETICALLY MODIFIED INSECTS (2004), *available at* http://www.pewagbiotech.org/research/bugs/bugs.pdf. A summary appears under the Animals topic.

2. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, DISPUTE OVER LABELING OF GM FOODS THREATENS BILLIONS IN TRADE (2002) *sub nom.* PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, U.S. VS. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD 1 (2003) *available at* http://pewagbiotech.org/resources/issuebriefs/europe.pdf. This issue brief, originally published in June 2002, was updated in August 2003 to reflect recent activities relating to the trade dispute between the U.S. and the EU on genetically modified food. The paper summarizes the history of the GM food issue in Europe, the legislation recently passed by the EU Parliament, impacts on U.S.-EU agricultural trade, and other background issues dividing the U.S. and EU on this topic.

3. DAVID DICKSON, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, BUTTERFLIES, GM CROPS AND SOCIAL RESPONSIBILITIES (2002), *available at* http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierReadItem&type=4&itemid=12&language=1&dossier=6. This report reviews the controversy over the potential threat of genetically modified corn to the Monarch butterfly. The report provides some useful pointers to ways in which such controversies could be better handled in future.

4. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, THREE YEARS LATER: GENETICALLY ENGINEERED CORN AND THE MONARCH BUTTERFLY

CONTROVERSY (2002), *available at* http://pewagbiotech.org/resources/issuebriefs/monarch.pdf. This paper reviews the chronology of the Monarch butterfly controversy from the perspective of a number of key players. It also provides a brief review of the current state of scientific knowledge on the issue – what is now known, and what questions remain. The Pew Initiative on Food and Biotechnology believes that this review of the Monarch butterfly controversy will both help promote understanding of the issue and stimulate broader discussion about how this issue unfolded and how innovative methods were used to ultimately resolve some key issues in this debate.

5. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, HARVEST ON THE HORIZON: FUTURE USES OF AGRICULTURAL BIOTECHNOLOGY (2001) *available at* http://pewagbiotech.org/research/harvest/harvest.pdf. A summary appears under the Animals topic.

C. *Food Safety*

1. MICHAEL R. TAYLOR & JODY S. TICK, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, POST-MARKET OVERSIGHT OF BIOTECH FOODS: IS THE SYSTEM PREPARED? (2003), *available at* http://pewagbiotech.org/research/postmarket/PostMarket.pdf. This report considers regulatory issues arising after biotechnology-derived crops and foods enter the environment or the marketplace; is the regulatory system prepared to ensure compliance with use restrictions or other conditions imposed by regulators to protect health or the environment? More broadly, what is the appropriate degree of control over biotech foods and crops after they enter the environment or the marketplace? What role can and should the government play in achieving this control? How do the post-release and post-market oversight issues posed by biotech crops and foods compare with those posed by conventionally produced ones? The report provides factual background and analysis on these issues, rather than offering policy recommendations, because there are no "right" answers or single solutions to the issues presented.

2. LUCA BUCCHINI & LYNN R. GOLDMAN, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, A SNAPSHOT OF FEDERAL RESEARCH ON FOOD ALLERGY: IMPLICATIONS FOR GENETICALLY MODIFIED FOOD (2002), *available at* http://pewagbiotech.org/research/allergy.pdf. The findings of this report, combined with the proceedings of a scientific meeting on food allergy sponsored by the National Institute of Environmental Health Sciences (NIEHS), suggest that an expanded and coordinated research effort could provide significant dividends in developing a more robust method for understanding and predicting potential new food allergens. The report, coupled with the proceedings of the recent NIEHS meeting, is intended to serve as a mechanism for raising these important

concerns with policymakers, industry, and federal agencies and to catalyze further debate and discussion on the issue.

3. MICHAEL R. TAYLOR & JODY S. TICK, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, THE STARLINK CASE: ISSUES FOR THE FUTURE (2001), *available at* http://pewagbiotech.org/resources/issuebriefs/starlink/starlink.pdf. The disclosure in September 2000 that StarLink™ corn had been found in the human food supply put food biotechnology in the public spotlight and caused concern among consumers and food system stakeholders alike that a product approved only for animal use could find its way to grocery shelves. The StarLink experience raised a number of issues concerning the current regulatory system and public policies affecting genetically modified foods, e.g., how to manage allergenicity issues posed by biotech foods. Most of the issues, however, involve post-approval control of staple food crops that have been genetically modified. This paper is an early step in a case study conducted to identify and analyze the regulatory and public policy issues raised by the StarLink episode. The paper poses questions concerning the adequacy of current legal authority, regulatory procedures, and institutional arrangements for post-approval control of biotech foods.

D. *International/Trade*

1. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, DISPUTE OVER LABELING OF GM FOODS THREATENS BILLIONS IN TRADE (2002) *sub nom.* PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, U.S. V. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD (2003) *available at* http://pewagbiotech.org/resources/issuebriefs/europe.pdf. A summary appears under the Environmental Protection topic.

2. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS (2001), *available at* http://pewagbiotech.org/resources/issuebriefs/1-regguide.pdf. This report is intended to provide a general, descriptive guide to the current set of U.S. laws and regulations under which products of biotechnology are reviewed for health, safety, efficacy, or environmental impacts. It focuses primarily on agricultural biotechnology, defined as the use of rDNA techniques to modify plants and animals traditionally used as food or fiber sources. The report describes the legal authority and the agency review "pathways" as published in agency procedures and regulations. The report does not, however, attempt to evaluate the adequacy, efficacy, or efficiency of the current regulatory system, or to evaluate the agen-

cies' performances under these laws and regulations, issues which are the subject of continuing public debate.

E. *Laws and Regulations*

1. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, BUGS IN THE SYSTEM? ISSUES IN THE SCIENCE AND REGULATION OF GENETICALLY MODIFIED INSECTS (2004), *available at* http://pewagbiotech.org/research/bugs/bugs.pdf. A summary appears under the Animals topic.

2. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, FACT SHEET: 2001-2002 LEGISLATIVE ACTIVITY RELATED TO AGRICULTURAL BIOTECHNOLOGY (2003), *available at* http://pewagbiotech.org/resources/factsheets/legislation/factsheet2002.php. In recent years, both Congress and state legislatures have been active regarding agricultural biotechnology. The majority of activity, as measured by the introduction of legislation, has taken place on the state level. During the 2001–2002 legislative sessions, 158 pieces of legislation related to agricultural biotechnology were introduced in 39 states and 31 pieces of legislation were introduced in Congress. This fact sheet provides an overview of the federal and state legislative activity that took place in 2001–2002 related to agricultural biotechnology, the common concerns driving much of that legislation, and a summary of those bills passed into law.

3. MICHAEL R. TAYLOR & JODY S. TICK, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, POST-MARKET OVERSIGHT OF BIOTECH FOODS: IS THE SYSTEM PREPARED? (2003), *available at* http://pewagbiotech.org/research/postmarket/PostMarket.pdf. A summary appears under the Food Safety topic.

4. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, FUTURE FISH: ISSUES IN SCIENCE AND REGULATION OF TRANSGENIC FISH 1 (2003), *available at* http://pewagbiotech.org/research/fish/fish.pdf. A summary appears under the Animals topic.

5. LUCA BUCCHINI & LYNN R. GOLDMAN, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, A SNAPSHOT OF FEDERAL RESEARCH ON FOOD ALLERGY: IMPLICATIONS FOR GENETICALLY MODIFIED FOOD (2002), *available at* http://pewagbiotech.org/research/allergy.pdf. A summary appears under the Food Safety topic.

6. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, DISPUTE OVER LABELING OF GM FOODS THREATENS BILLIONS IN TRADE (2002) *sub nom.* PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, U.S. VS. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD (2003), *available at* http://pewagbiotech.org/resources/issuebriefs/europe.pdf. A summary appears under the Environmental Protection topic.

7. MICHAEL R. TAYLOR & JODY S. TICK, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, THE STARLINK CASE: ISSUES FOR THE FUTURE (2001), *available at* http://pewagbiotech.org/resources/issuebriefs/starlink/starlink.pdf. A summary appears under the Food Safety topic.

8. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS (2001), *available at* http://pewagbiotech.org/resources/issuebriefs/1-regguide.pdf. A summary appears under the International/Trade topic.

F. *Market Choices*

1. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, DISPUTE OVER LABELING OF GM FOODS THREATENS BILLIONS IN TRADE (2002) *sub nom.* PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, U.S. V. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD (2003), *available at* http://pewagbiotech.org/resources/issuebriefs/europe.pdf. A summary appears under the Environmental Protection topic.

2. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, HARVEST ON THE HORIZON: FUTURE USES OF AGRICULTURAL BIOTECHNOLOGY (2001), *available at* http://pewagbiotech.org/research/harvest/harvest.pdf. A summary appears under the Animals topic.

G. *Plant Biotechnology*

1. MICHAEL R. TAYLOR & JUDY S. TICK, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, POST MARKET OVERSIGHT OF BIOTECH FOODS: IS THE SYSTEM PREPARED? (2003), *available at* http://pewagbiotech.org/research/postmarket/PostMarket.pdf. A summary appears under the Food Safety topic.

2. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, THREE YEARS LATER: GENETICALLY ENGINEERED CORN AND THE MONARCH BUTTERFLY CONTROVERSY (2002), *available at* http://pewagbiotech.org/resources/issuebriefs/monarch.pdf. A summary appears under the Environmental Protection topic.

3. MICHAEL R. TAYLOR & JUDY S. TICK, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, THE STARLINK CASE: ISSUES FOR THE FUTURE (2001), *available at* http://pewagbiotech.org/resources/issuebriefs/starlink/starlink.pdf. A summary appears under the Food Safety topic.

4. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, FACT SHEET: GENETICALLY MODIFIED CROPS IN THE UNITED STATES (2004), *available at* http://pewagbiotech.org/resources/factsheets/display.php3?FactsheetID=2. This fact sheet summarizes the extent to which GM crops have been adopted in the United States compared to other countries. It also shows which GM crops are grown by U.S. farmers and which states plant most GM varieties. Crop varieties developed by genetic engineering were first introduced for commercial production in 1996. U.S. farmers are by far the largest producers of genetically modified (GM) crops.

5. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, HARVEST ON THE HORIZON: FUTURE USES OF AGRICULTURAL BIOTECHNOLOGY (2001), *available at* http://pewagbiotech.org/resources/harvest/harvest.pdf. A summary appears under the Animals topic.

APPENDIX B: EXAMPLE OF FDA CONSULTATION—MONSANTO'S CORN ROOTWORM PROTECTED CORN, MON 863[83]

Date: December 31, 2001
Subject: Monsanto's Corn Rootworm Protected Corn, MON 863 transformation event
Keywords: Corn, *Zea mays*, corn rootworm, Diabrotica sp., Cry3Bb1, *Bacillus thuringiensis* (subspecies *kumamotoensis*), Coleopteran-specific insecticidal protein, *nptII* gene, MON 863

A. *Background*

In a submission dated September 25, 2000, as amended on August 20, 2001, Monsanto provided FDA with its summary of the nutritional and safety assessment of a new insect protected corn line containing the transformation event MON 863. The firm initiated the consultation with the agency regarding this product on September 1, 2000.

B. *Intended Effect of the Genetic Modification and Food/Feed Use*

According to Monsanto, the intended technical effect of the genetic modification of the corn, *Zea mays*, is to protect corn plants from damage by corn rootworm (CRW) feeding. CRW larvae feed on the roots of corn plants reducing the ability of the plant to absorb nutrients and water from the soil, and cause har-

83. This memo is reproduced in its entirety from the Center for Food Safety and Applied Nutrition, Office of Food Additive Safety of the U.S. Food and Drug Administration. The memo is also *available at* http://www.cfsan.fda.gov/~rdb/bnfm075.html.

vesting difficulties due to plant lodging. CRW (Coleopteran, *Diabrotica sp.)* is a significant insect pest problem for corn production in the U.S. corn belt. To confer protection against CRW, Monsanto used a modified *cry3Bb1* gene derived from *Bacillus thuringiensis* subspecies *kumamotoensis* (*B.t.k.),*to express a *B.t.k.* Cry3Bb1 protein that is selectively toxic to Coleopteran species. The modified *cry3Bb1* gene that is expressed in the MON 863 corn line differs from the wild-type *cry3Bb1* gene by the addition of an alanine residue at position 2 of the protein, and by seven amino acid changes. There are 653 amino acids in the full length protein.

Corn grain and its processed fractions are consumed as human food and animal feed. Corn is a raw material in the manufacture of starch which is used as starch product or for the production of high fructose corn syrup and ethanol. Corn oil is processed from the germ. Each of these materials is a component of many foods including bakery and dairy goods, beverages, confections, and meat products. Approximately two-thirds of the corn produced in the U.S. is fed to livestock. Grain is fed directly to livestock. Wet and dry milling by-products (primarily corn gluten meal and feed) are also fed directly or used in feeds. Corn forage is extensively consumed as an animal feed by ruminants. The introduction of the *cry3Bb1* gene and the *nptII* marker gene are not intended to alter the food and feed uses of corn.

C. *Molecular Alterations and Characterization*

Monsanto used a particle acceleration method to introduce a purified, linear DNA into the germplasm of the publicly available inbred line of corn, A634. Monsanto reported that line A634 was used because it responds well to particle bombardment transformation and tissue culture regeneration. As well, it is among the most popular public inbreds used in U.S. hybrid corn production.

The linear DNA vector, PV-ZMIR13L, was prepared by restriction endonuclease digestion (*Mlu* I) of the plasmid, PV-ZMIR13. The linear vector contained the modified *cry3Bb1* gene derived from *B.t.k.*, and the selectable marker gene, *nptII*, derived from the *Escherichia coli* transposon, Tn5. The expression cassette consists of the modified *cry3Bb1* coding region under the control of the 4-AS1 plant promoter (four repeats of an activating sequence and a single portion of the 35S promoter) derived from the cauliflower mosaic virus (CaMV), and the 5' untranslated leader sequence of wheat chlorophyll a/b binding protein (wt CAB leader), the rice actin intron, and the 3' transcriptional termination sequence derived from the 3' untranslated sequence of the gene encoding the wheat heat shock protein 17.3 (tahsp17). The *nptII* expression cassette consists of the *nptII* coding region regulated by the 35S promoter derived from CaMV and the un-

translated 3' transcription termination sequence (NOS 3') from the *Agrobacterium tumefaciens* nopaline synthase gene. The DNA fragment containing the *nptII* gene from the bacterial transposon, Tn5, also contains a 153 base pair (bp) portion of the 378 bp bleomycin binding protein gene (*ble*).

Monsanto performed a molecular analysis using Southern blotting and polymerase chain reaction (PCR) to characterize the MON 863 insertion event. Monsanto stated that the results of these analyses demonstrate that a single copy of the linear DNA vector, PV-ZMIR13L, is integrated at a single site in the corn genome; the modified *cry3Bb1* gene, the *nptII* gene, and their associated promoters and terminators were intact; no additional DNA sequences derived from the plasmid, PV-ZMIR13, could be detected.

Monsanto examined the segregation and stability of the MON 863 event by analyzing segregation data for the CRW-protected phenotype over five generations; performing enzyme linked immunosorbant assay (ELISA) for the expression of Cry3Bb1 protein on plants identified as being positive for CRW-protected phenotype; and by doing Southern blot analysis of DNA extracted from plants spanning three generations. Monsanto concluded that the results of these tests demonstrated the stability of the inserted DNA in MON 863 across multiple generations.

D. *Expressed Proteins*

Two new proteins, a modified Cry3Bb1, and the NptII enzyme, are expressed in the transgenic corn line MON 863. Monsanto reported the results of analysis by ELISA, and as expected, the modified Cry3Bb1 protein is expressed in the tissue of young leaf, grain, mature root, forage, silk, and pollen. Mean levels of the modified Cry3Bb1 protein ranged from 10 to 81 micrograms/g fresh weight of plant tissue, depending on the tissue examined and time of harvest. Upon examination of the tissue of young leaf, forage, and grain by ELISA, NptII enzyme was detected in leaf and forage. Mean levels of NptII protein ranged from not detectable (<0.076 micrograms/g) to 1.4 micrograms/g.

Monsanto discussed how differences in the initiation of translation between prokaryotes and eukaryotes make it highly unlikely that the partial *ble* gene, located twenty nucleotides downstream of the stop codon for the *nptII* gene, would be translated into protein. Monsanto stated that if the partial *ble* gene were translated into protein, the truncated peptide would not dimerize because it lacks the necessary amino acids to dimerize, and also lacks approximately 50% of the residues that are involved in bleomycin binding.

E. *Regulatory Considerations*

The safe use of pesticidal substances as well as the use of selectable markers as inert ingredients in the development of pest-resistant plant varieties is under the regulatory purview of the Environmental Protection Agency (EPA). Thus EPA regulates the use of the insecticidal protein, Cry3Bb1, and the selectable marker NptII, as well as the genetic material encoding them. Therefore, although Monsanto presented information regarding these proteins, including expression levels, we have not addressed the safety of the use of these proteins. The main focus of this consultation is on compositional analysis of this transgenic corn as compared to the parental or other commonly consumed varieties.

F. *Compositional Analysis*

Monsanto conducted compositional analyses on tissues collected from the MON 863 event, its nontransgenic parental control line at four replicated sites, and nine different nontransgenic, commercial corn hybrids grown under field conditions at two replicated sites each. Field trials were conducted at four different sites in the United States. Forage and grain samples were collected from all sites.

Grain samples were analyzed for proximate (protein, fat, ash, moisture), acid detergent fiber (ADF), neutral detergent fiber (NDF), amino acids, fatty acids, vitamin E, minerals (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium, and zinc), phytic acid, and trypsin inhibitor. Carbohydrate levels were determined by calculation. Levels of carbohydrates and the non-essential amino acids cystine, aspartic acid, and glycine were higher in the MON 863 than in the control variety, but were within the range of levels for the nine commercial varieties. However, levels of protein, the essential amino acids leucine and phenylalanine, and the non-essential amino acid glutamic acid were lower in MON 863 than in the control variety, yet they were well within the range of values for the nine control varieties. Further, the levels of the minerals phosphorus, magnesium, zinc and manganese, and vitamin E were also lower in MON 863 than in the control variety, but were within the range of values for the nine control varieties and those reported in the literature. The levels of all the other nutrients measured were not different from the control variety, and the levels were within the range of values for the nine control varieties and those reported in the literature. The level of the antinutrient, phytic acid, was also lower in MON 863 than in the control variety and within the range of values for the nine control varieties.

Forage samples were analyzed for proximate, ADF, and NDF. Carbohydrate levels were determined by calculation. There were no significant differences between levels of these nutrients present in MON 863 than in the control variety, and all values fell within the range reported for the nine commercial varieties and for the range of values reported in the literature.

Monsanto stated that these observations support a conclusion that the measured differences represent normal biological and analytical variability.

G. *Conclusions*

Monsanto has concluded that corn from transformed line MON 863 is not materially different in composition, safety or agronomic characteristics from nontransgenic lines of corn other than for its resistance to corn rootworm feeding damage. At this time, based on Monsanto's reporting of its data and analyses, the Agency considers Monsanto's consultation on transgenic corn line MON 863 to be complete.