PRODUCT VS. PROCESS: TWO LABELING REGIMES FOR GENETICALLY ENGINEERED FOODS AND HOW THEY RELATE TO CONSUMER PREFERENCE

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INTRODUCTION

The labeling of food in the United States serves two important functions. First, labels provide consumers with information necessary for the protection of public health, safety and welfare. Second, labels promote fair trade practices in food marketing.[1] Both functions serve consumers in different ways so agencies that develop labeling regimes use a range of methods to assure their labels are effective. Agencies do not always consider consumer opinion when setting labeling policies that can have a negative effect on consumer confidence. What happens when an agency believes that a labeling policy is looking out for consumer welfare but consumer confidence itself remains low?

This paper will examine two labeling regimes and the methods used to develop accurate labels for foods containing the products of genetic engineering (GE). Under certain circumstances, these policies can satisfy their respective goals, though each handle consumer preference and expectation very differently. While one relies on consumer impressions, the other focuses on scientific risk-based decision-making. The result of applying these two divergent policies is that GE foods are treated very differently depending on which federal agency is applying their methodology.

The United States has one marketing regime enforced by the United States Department of Agriculture (USDA) who, after considering consumer expectation, determined that genetic engineering is a *process* incompatible with the principles of the National Organic Program (NOP). Therefore, no food containing GE products can be labeled organic under the USDA approach. The United States also recognizes the labeling authority of the Federal Drug Administration (FDA), which refuses to label GE *products* because they are not materially different from the food in its natural state. This determination was based on scientific principles meant to protect consumer health without being misleading.

This paper will look behind this process/product dichotomy and discuss the reasons each agency began to look at the process of genetic engineering differently than the product. The paper then examines consumer concerns about GE foods to determine whether people are generally worried about the risks posed by the food itself or the processes utilized to make the food. After showing that consumer concerns do not fit neatly into one or the other of these categories, the paper concludes by asking how we might be able to encourage greater confidence in consumers about foods that now carry the stigma of risk but are deemed safe by scientific standards.

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[1] Kyle W. Lathrop, *Pre-empting Apples with Oranges: Federal Regulation of Organic Food Labeling*, 16 J. CORP. L. 885, 885-86 (1992).

I. ORGANIC FOOD REGULATION

A. Principles Guiding the Organic Movement

Lord Walter Northbourne first coined the term "organic farming" in 1940 as a chapter heading in his book *Look to the Land*.[2] Little did he know how greatly these two words would contrast the current scientific progress occurring in agriculture at the time. The 20th century brought advances such as the regulation of plant growth by specific chemical substances and the use of poisons to control pests.[3] For example, herbicides — chemicals that kill undesired weeds while leaving crops unscathed — were developed, thus eliminating the need to for manual weed control.[4] Discoveries in chemical science also gave farmers more control over the growing cycles of their plants, which provided great economic benefits.[5] Because these technologies were such an advantage to the farmer, chemical use quickly became widespread. A 1947 horticulture book expresses that, "A chemical revolution is sweeping through the agricultural world. It is unrivalled by any of the previous great advances in agriculture and, perhaps, by most advances in the biological field."[6]

In 1962, Rachel Carson published *Silent Spring*, which exposed the dangers of pesticides to human health and the environment.[7] In doing so, she explained the interrelationship of living organisms. She helped people understand that humans are not separate from nature and that what is done to one species will affect all others in the environment, including humans.[8] This realization served as a catalyst for the modern organic agriculture movement by creating broad public awareness of the need to be conscious and careful of our agricultural practices.[9] In this way, organic agriculture has become a philosophical reaction to technology, striving to eliminate all "chemicals" except those that are "natural" or "organic."[10]

This broad concern about on environmental protection permeates the modern organic community. According to one marketing survey, consumers of organic food are 31% more concerned about pollution and the environment than the general population.[11] Studies also show that

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2 RONALD F. KORCAK, HISTORY OF THE ORGANIC MOVEMENT (1991) *available at* http://www.hort.purdue.edu/newcrop/history/lecture31/r_31-2.html (last visited May 1, 2004).

3 Jules Janick, *Purdue University Lecture 31 History of Horticulture* (2002), *available at* http://www.hort.purdue.edu/newcrop/history/lecture31/lec31.html.

4 *Id.*

5 *Id.*

6 *Id.*, *quoting* AVERY AND JOHNSON, HORMONES AND HORTICULTURE (1947).

7 *See generally* RACHEL CARSON, SILENT SPRING (1962).

8 *See* PAUL BROOKS, HOUSE OF LIFE: RACHEL CARSON AT WORK (1972).

9 *Id.*

10 Jules Janick *supra* note 3.

11 *Consumer Profile Facts*, Organic Trade Association, *at* http://www.ota.com/organic/mt/consumer.html (last visited May 20, 2003).

organic consumers are generally as concerned about environmental protection as they are about their own personal safety.[12] Organic agriculture has responded to these concerns by producing food in ways that are consistent with these ideals.

These ideals are nicely articulated by The International Federation of Organic Agriculture Movements (IFOAM), the self-proclaimed "worldwide umbrella organization of the Organic Movement."[13] IFOAM's goal is to provide authoritative information about organic agriculture and to promote its worldwide application.[14] Additionally, it serves its member organizations by providing representation at international policy making forums.[15] IFOAM defines organic agriculture to be "all agricultural systems that promote the environmentally, socially and economically sound production of food . . . By respecting the natural capacity of plants, animals and the landscape, it aims to optimize quality in all aspects of agriculture and the environment."[16]

At the international level, both the public and private sectors have codified these principles to help guide governments and private certification bodies in setting standards for specific organic programs. The Food and Agriculture Organization (FAO) of the United Nations (UN) created the Codex Alimentarius for the public sector and IFOAM established the International Basic Standards for Organic Production and Processing for the private sector.[17] Governments can use these standards to develop national organic agriculture programs, which can be modified to respond to a specific country's needs.[18]

The standards set forth the idea that organic farming systems should rely on ecologically based production methods such as cultural and biological pest management. They virtually exclude the use of synthetic chemicals in crop production and prohibit the use of antibiotics and hormones in livestock production.[19] Under organic farming systems, the fundamental components and natural processes of ecosystems — such as soil

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12 CATHERINE R. GREENE, U.S.DEPT. OF AGRIC., U.S. ORGANIC FARMING EMERGES IN THE 1990s, ERS AIB No. 770 at 3 (2001).

13 *About IFOAM, at* http://www.ifoam.org (last visited April 21, 2004).

14 *Id.*

15 *Id.*

16 *Id.*

17 *See generally* CODEX ALIMENTARIUS COMMISSION GUIDELINES FOR PRODUCTION, FAO/WHO, PROCESSING, LABELING AND MARKETING OF ORGANICALLY PRODUCED FOODS, July 2001, *available at* http://www.fao.org/organicag/doc/glorganicfinal.pdf (last visited Feb. 25, 2004). *See generally* Basic Standards for Organic Production and Processing, IFOAM General Assembly (Sept. 2000), *available at* http://www.ifoam.org/standard/index_neu.html (last visited Feb. 25, 2004).

18 *Frequently Asked Questions- "What is behind an organic label?"* Organic Agriculture at FAO, *at* http://www.fao.org/organicag/fram11-e.htm (last visited Feb. 25, 2004).

19 GREENE, *supra* note 12, at 1.

organism activities, nutrient cycling, and species distribution and competition — are incorporated directly and indirectly as crop management tools.[20] Consumers who buy organic foods do so because foods grown in this way provide them with perceived benefits over foods grown with chemicals.[21]

B. Need for Uniformity – Establishing the Organic Foods Production Act

What began as a grass roots effort by organic farmers and home gardeners has matured into a thriving industry.[22] Organic farming became one of the fastest growing segments of U.S. agriculture during the 1990's. Between 1992 and 1997 certified organic cropland more than doubled[23] and sales of organics increased more than 20% annually from 1990-2000.[24] Industry estimates of U.S. organic sales from 1990 through 1996 show sales growing 20-25% annually and reaching $3.3 billion in 1996.[25] There are estimates that organic food sales were $7.8 billion in 2000, a 20-percent increase over 1999 sales.[26]

The growing popularity of organic food brought with it a need for an effective labeling system to distinguish organic from non-organic foods. Before 1990, private organizations and state agencies had the authority to certify organic practices in their jurisdiction. Not surprisingly, there was no uniformity in standards and therefore no guarantee that "organic" meant the same thing from state to state.[27] By 1990, twenty-two states had adopted organic food statutes that all varied in one way or another.[28]

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[20] *Id.* at 1.

[21] *Consumer Profile Facts,* Organic Trade Association, *at* http://www.ota.com/organic/mt/consumer.html (last visited May 20, 2003). "The 'Organic Lifestyle Shopper Study 2000,' conducted by the Hartman Group market research firm, reports that the top five motivators for organic food and beverage purchases are: health/nutrition, 66% (most organic users consider that organic products contribute to their overall health, rather than associating organic products with any specific health benefit); taste, 38%; food safety, 30% (organic consumers are concerned about food safety); environment, 26%; and availability, 16%.

[22] Cindy Joffe Hyman, *Comment: Food For Thought: Defending the Organic Foods Production Act of 1990 Against Claims of Protectionism*, 14 EMORY INT'L L. REV. 1719 (2000).

[23] GREENE, *supra* note 12, at 6.

[24] *Id.* at 2.

[25] *Organic Farming and Marketing: Questions and Answers,* U.S. DEPT. OF AGRIC./ERS Briefing Room, *at* http://www.ers.usda.gov/briefing/Organic/Questions/orgqa5.htm (last updated June 24, 2003).

[26] *Id.*

[27] Kenneth C. Amaditz, *The Organic Foods Production Act of 1990 and its Impending Regulations: A Big Zero for Organic Food?* 52 FOOD DRUG L.J. 537, 539 (1997); S. REP. NO. 101-357(1990), *reprinted in* U.S.C.C.A.N. 4942, 4944.

[28] S. REP. NO. 101-357(1990), *reprinted in* U.S.C.C.A.N. 4942, 4943.

> Farmers and processors have no choice but to produce and label their products according to conflicting standards. As a result, consumers are left to decipher a confusing array of private and State labels. Even the most sophisticated organic consumer finds it difficult to know, with certainty, what the term "organic" really means. For example, currently processed food may be labeled "organic" regardless of whether it contains 100 or 20 percent organically grown ingredients.[29]

This confusing web of regulations had the potential to hinder the growing market for organic goods. Production methods were very important to organic consumers and because there was no regulatory consensus on the issue producers did not know what methods to use. It became clear that uniform production standards were needed to ensure that the end product was consistent with consumer expectations and labeling representations. Reliability in the form of a national standard for organic foods could encourage the growth of this burgeoning market, so the National Association of State Departments of Agriculture, American Farm Bureau Federation, several major organic industry trade associations, as well as consumer interests rallied Congress for a national organic labeling program.[30]

To address this problem, Congress adopted the Organic Foods Production Act of 1990 (OFPA).[31] The OFPA had three main goals: (1) establish national standards governing the marketing of certain agricultural products as organically produced; (2) assure consumers that organically produced products meet a consistent standard; and (3) facilitate interstate commerce in fresh and processed food that is organically produced.[32] In the OFPA, Congress broadly defined "organically produced" as "an agricultural product that is produced and handled in accordance with this chapter."[33] Congress was reluctant to specifically define "organic food" in the Act but their goal for the "organically produced" label is clear from the legislative history.

> Organic food is food produced using sustainable production methods that rely primarily on natural materials. The "organically produced" label authorized under this bill therefore pertains to the production methods used to produce the food rather than to the content of the food.[34]

The task of defining these production methods became one of the most difficult and controversial endeavors that grew out of the OFPA.

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29 *Id.*
30 S. REP. NO. 101-357(1990), *reprinted in* U.S.C.C.A.N. at 4942, 4944.
31 Organic Foods Production Act, 7 U.S.C. §§ 6501-6522 (2004).
32 7 U.S.C. §6501 (2004).
33 *Id.* at §6502 (14).
34 S. REP. NO. 101-357(1990), *reprinted in* U.S.C.C.A.N. at 4942, 4944.

The Act gave the United States Department of Agriculture the responsibility for achieving this goal by establishing an organic certification program.[35] The OFPA contained three specific guidelines to guide the USDA. First, organic agricultural products had to be produced without the use of synthetic chemicals. Second, products could not be grown on land to which any prohibited substances had been applied during the three years immediately preceding harvest. Third, products had to be produced in compliance with an organic plan agreed to by the producer and the certifying agent.[36]

The remaining details of the USDA organic certification program were to be developed by the agency, based in part on the recommendations of the National Organic Standards Board (NOSB or Board).[37] The Board is appointed by the Secretary of Agriculture[38] from each of the following categories of people: farmer, handler, retailer, consumer, environmentalist, scientist and certifying agent.[39] The Secretary was to carefully select Board members to provide a balance of interests but there was much debate concerning appropriate representation.[40] Some thought industry should play a large role while others argued this would be a conflict of interest.[41] In the end, the Secretary structured the Board so that farmers and handlers represented one half of the seats while consumer and environmental organizations represented the other half.[42] Once the Board was assembled, the USDA would be left to adopt regulations establishing an organic program that would finally define and standardize what it meant to be "organic."

C. Adoption of a National Organic Program

For a variety of reasons, including the 1992 Bush to Clinton administration change, the NOSB members were not appointed until 1992 and they then took two years to issue the first set of recommendations in 1994.[43] From 1994 to 1996, the Board issued a surplus of recommendations covering all topics relevant to the new program.[44] With respect to genetically modified organisms, the NOSB recommended the following:

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35 *See* 7 U.S.C. §6503 (a) (2004).

36 7 U.S.C. §6504 (2004).

37 7 U.S.C. § 6518 (2004).

38 7 U.S.C. §6518 (c) (2004).

39 7 U.S.C. §6518 (b) (2004).

40 S. REP. NO. 101-357(1990), *reprinted in* U.S.C.C.A.N. at 4942, 4950.

41 *Id.*

42 *Id.*

43 Kenneth C. Amaditz, *The Organic Foods Production Act of 1990 and its Impending Regulations: A Big Zero for Organic Food?* 52 FOOD DRUG L.J. 537, 545 (1997).

44 *Id.*

> The National Organic Standards Board recommends that the class of genetically engineered organisms and their derivatives be prohibited in organic production and handling systems. Genetically engineered is defined as: Made with techniques that alter the molecular or cell biology of an organism by means that are not possible under natural conditions or processes. Genetic engineering includes recombinant DNA, cell fusion, micro- and macro-encapsulation, gene deletion and doubling, introducing a foreign gene, and changing the positions of genes. It shall not include breeding, conjugation, fermentation, hybridization, in-vitro fertilization and tissue culture.[45]

In 1997 the USDA published the first proposed rule, establishing the National Organic Program (NOP or Program) under the authority granted by the OFPA.[46] The Program would establish national standards for organic production and handling of agricultural products. Together, these standards would come to define what it means to practice "organic agriculture." For example, the NOP promoted the importance of crop rotation as a means of ensuring soil fertility and pest management[47] and emphasized the need for land used to grow organic produce to be clearly defined by identifiable boundaries.[48] The Program provided for a discussion of prohibited livestock health care practices, such as medicating in the absence of illness[49] and created an accreditation program for those wanting to certify organic operations to comply with the program's requirements. In addition, the Program established labeling requirements and enforcement provisions.[50]

The proposed plan immediately became the center of controversy. It seemed that the USDA had disregarded almost all of the policy proposals made by the NOSB[51] by adopting standards that allowed the use of genetic engineering, nuclear irradiation and toxic sewage sludge in fertilizer applied on organic crops as permitted "organic" practices under the rule.[52] The USDA gave a number of reasons why it included these methods in the proposed rule. The Agency was concerned that foreign trading partners would point to the exclusion of genetic engineering as

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45 NATIONAL ORGANIC STANDARDS BOARD, BIOTECHNOLOGY POLICY, Board Meeting Sept. 19, 1996, *at* http://www.ams.usda.gov/nosb/archives/biotech/policy.html (last visited Feb. 25, 2004).

46 National Organic Program, 62 Fed. Reg. 65850 (proposed Dec. 16, 1997) (to be codified at 7 C.F.R. pt. 205).

47 *Id.* at 65871.

48 *Id.*

49 *Id.* at 65881.

50 *Id.* at 65896.

51 Ben Lilliston & Ronnie Cummins, *"Organic vs. Organic": The Corruption of a Label,* ECOLOGIST, (28) 4 (1998).

52 *Id.*

evidence of a valid concern over the safety of bioengineered commodities.[53] The USDA saw that the United States was the world's leading advocate for genetic engineering and had already expended billions of dollars and millions of acres of agricultural land to genetically altered crops.[54] Because biotechnology was such a large part of the agricultural system, the USDA was concerned about how excluding biotech would impact the industry. In addition to a big push from the Clinton White House, the USDA claimed to have legitimate research purposes for including these methods in the proposal.

> USDA senior marketing specialist Michael Hankin argues that it was appropriate to include bioengineering in the proposed standards because the agency wanted feedback from the public on its inclusion. "The department supports the [organic] industry and is responsive to the wants and needs of the consumers," he says.[55]

For these reasons, the USDA rejected the recommendations made by the NOSB and released a proposed rule under which a product produced by genetic engineering could be labeled and marketed as organic.

If feedback is what they were after, the USDA got exactly what they wanted. The public submitted 275,603 comments to the USDA in response to the proposal, almost all of which opposed the use of genetic engineering in organic production systems.[56] Many of the comments expressed the idea that the inclusion of genetic engineering in organics would be contrary to consumer expectations and would increase consumer confusion regarding the meaning of the organic label.[57] Consumers Union cited a report, "The Evolving Organic Marketplace," by Hartman and New Hope, in which the authors discuss polling they conducted of 1,000 consumers in August 1997.

> When consumers were asked an open-ended question as to what characteristics they felt an organic product has, 36% volunteered that organic meant "natural" rather than artificial and 29% viewed organic products as being natural, close to nature or containing natural ingredients. "Natural" was

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53 Internal Memoranda from Lon S. Hatamiya, Administrator, Agricultural Marketing Service, USDA, to Michael V. Dunn, Assistant Secretary, Marketing and Regulatory Programs, USDA (May 1, 1997) *reviewed in* Leora Broydo, *Organic Engineering*, Mother Jones, May/June 1998, *available at* http://www.motherjones.com/mother_jones/MJ98/broydo.html (last visited May 1, 2004).

54 *Id.*

55 *Id.*

56 *See e.g.,* National Organic Program, 65 Fed. Reg. 13512-01, 13513 (proposed March 13, 2000) (to be codified at 7 C.F.R. pt. 205).

57 *See id.* at 13514. *See also* Consumers Union's comments on Docket No. TMD-94-00-2, National Organic Program, published in the Federal Register, 62 Fed. Reg. 65890 (December 16, 1997), *available at* http://www.consumersunion.org/food/orgny798.htm (last visited February 25, 2004).

> the second most common defining concept expressed, after absence of chemicals, pesticides or artificial ingredients (44%). Since genetically engineered foods are created by altering genetic material in ways that do not occur in nature, their inclusion in organic would be contrary to consumer expectations, and would increase consumer confusion about the meaning of the organic label.[58]

Consumer expectation is key to the National Organic Program because one of the goals of the Organic Foods Production Act is the creation of a marketing regime that is uniform, for the sake of both producers and consumers of organics.[59] After the USDA considered the many comments they undertook to rewrite much of the rule.[60] The agency went through another rulemaking and comment period with a revised proposed rule[61] before the final rule became effective in February of 2001.[62] The final rule essentially adopted the previously quoted definition set forth by the NOSB and supported by the vast majority of public comments. The final rule banned the use of genetic engineering under the NOP[63], defining it as an "excluded method."[64]

The USDA based the decision to exclude genetic engineering on the consumer understanding of "naturalness," gleaned from the thousands of comments to the proposed rule.[65] The USDA made it abundantly clear that though there was no scientific evidence that the use of excluded methods presented risk to human health or the environment, they needed to recognize the fact that including such methods in the production of organically grown food runs counter to consumer expectations.[66]

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58 Consumers Union's comments on Docket No. TMD-94-00-2, National Organic Program, *published in* the Federal Register, 62 Fed. Reg. 65890 (Dec. 16, 1997), *available at* http://www.consumersunion.org/food/orgny798.htm (last visited February 25, 2004).

59 See 7 U.S.C. §6501 (2004).

60 *See* National Organic Program, Proposed Rule, 65 Fed. Reg. 13512-01, 13513 (March 13, 2000) (to be codified at 7 C.F.R. pt. 205). In addition to eliminating GE foods from the organic label, other changes include removing irradiation and sewage sludge as acceptable methods, adjusted the National List to better reflect the NOSB's recommendations and developed standards for livestock production. All these changes were in response to the abundant commentary.

61 *Id.*

62 National Organic Program Final Rule, 65 Fed. Reg. 80548-01 (Dec. 21, 2000) (codified at 7 C.F.R. § 205 et seq).

63 65 Fed. Reg. 80548-01, 80549 (Dec. 21, 2000) (codified at 7 C.F.R. § 205.105).

64 65 Fed. Reg. 80548-01, 80549 (Dec. 21, 2000) (codified at 7 C.F.R. § 205.2).

65 65 Fed. Reg. 80548-01, 80549 (Dec. 21, 2000), explaining that the "variety of methods used to genetically modify organisms . . . by means that are not possible under natural conditions or processes and are not considered compatible with organic production."

66 See National Organic Program, 65 Fed. Reg. 13512-01 13514 (March 13, 2000) (to be codified at 7 C.F.R. pt. 205).

Therefore, to be labeled "organically grown" under the National Organic Program, a food must not be genetically engineered or contain genetically modified products.[67]

II. Regulation of Biotechnology

A. The Coordinated Framework

In 1986, the Office of Science and Technology Policy (OSTP) issued guidelines for regulating the biotechnology industry. To assist in developing these guidelines, the OSTP formed an interagency working group, which "sought to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry."[68] The guidelines are called The Coordinated Framework for Regulation of Biotechnology (Framework) and describe the comprehensive federal plan for ensuring the safety of biotech research and products.[69]

The Framework is based on the momentous decision made by the working group, that no new laws are needed to regulate biotechnology, only select new regulations.[70] It explains that, "existing statutes provide a basic network of agency jurisdiction over both research and products; this network forms the basis of this coordinated framework and helps assure reasonable safeguards for the public."[71] The Framework allocates oversight responsibilities under the several relevant statutes and among the several relevant federal agencies, provides for interagency coordination mechanisms and includes official statements of policy from the relevant regulatory agencies.[72]

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67 7 C.F.R. § 205.105 (2004).

68 The Coordinated Framework, 51 Fed. Reg. 23302 (June 26, 1986).

69 *Id.*

70 Senator Al Gore, *Planning a New Biotechnology Policy*, 5 Harv LJ & Tech 19, 23 (Fall 1991). *See also,* The Coordinated Framework, 51 Fed. Reg. 23302 (June 26, 1986): "Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately." *Id.*

71 The Coordinated Framework, 51 Fed. Reg. 23302 (June 26, 1986).

72 The Federal Plant Pest Act governs the importation and movement of plant pests. The Federal Food, Drug and Cosmetic Act (FFDCA) governs foods, food additives, cosmetics, human and veterinary drugs, and medical devices. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) governs pesticides. The Toxic Substances Control Act (TSCA) governs chemicals. A range of statutes (the Clean Air Act, Clean Water Act, Oil Pollution Act, "Superfund" law and Resource Conservation & Recovery Act) govern the use of pollution control techniques. Each of these laws is administered by a federal agency. The Food & Drug Administration (FDA) administers FFDCA. The Environmental Protection Agency (EPA) administers FIFRA, TSCA and the pollution-control statutes. The Department of Agriculture

The Framework invokes the principle that "techniques of biotechnology are not inherently risky and that biotechnology should not be regulated as a process, but rather that the products of biotechnology should be regulated in the same way as products of other technologies."[73] Under the Framework, new products developed through biotechnology would be regulated, by the appropriate agency applying existing federal statutes and regulations, "in essentially the same manner for safety and efficacy as products obtained by other techniques."[74] In doing so, the Framework is expected to evolve according to the experiences of the industry and the agencies. Just as with all regulatory fields, modifications can be made to existing policies through administrative or legislative actions.[75]

B. Statement of Scope

In 1992, the OSTP published a statement addressing how oversight should be exercised within the scope of discretionary authority afforded by statute.[76] The OSTP recognized that because the statutory bases for regulation among the involved agencies may differ, there needed to be common principles to govern decisions about how to exercise authority over introductions of biotechnology products.[77] This "Statement of Scope" delineated the principle that "to ensure the safety of planned introductions of biotechnology products into the environment while not unduly inhibiting the benefits of such introductions, [agencies must focus] on the characteristics and risk posed by an introduction, rather than on the process by which a product is created."[78]

To justify this risk-based approach the OSTP began by detailing a number of scientific observations that support the conclusion that "genetically modified organisms are not *per se* of inherently greater risk than unmodified organisms."[79] They emphasized that no conceptual dis-

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(USDA) administers the Federal Plant Pest Act while also funding many research projects involving biotechnology.

[73] COMM ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS, NAT'L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST PROTECTED PLANTS: SCIENCE AND REGULATION 22, 26 (2000), *quoted in* Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. LJ REFORM 403, 431 (Spring 2002).

[74] SUBCOMMITTEE ON BASIC RESEARCH, 106TH CONG., SEEDS OF OPPORTUNITY: AN ASSESSMENT OF THE BENEFITS, SAFETY, AND OVERSIGHT OF PLANT GENOMICS AND AGRICULTURAL BIOTECHNOLOGY, Comm. Print 106-B (April 13, 2000). This document was prepared by Chairman Nick Smith.

[75] The Coordinated Framework, 51 Fed. Reg. 23302 (June 26, 1986).

[76] *See generally* Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introduction of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753, 6754 (Feb. 27, 1992) [hereinafter Statement of Scope].

[77] *Id.*

[78] *Id.* at 6755.

[79] *Id.*

tinction exists between genetic modifications of plants by classical methods and techniques that transfer specific genes and so the same biological laws govern the responses of organisms modified by both methods.[80] The OSTP admitted that information about the process used to produce a genetically modified organism is important in understanding the characteristics of the product but insists that this is not a useful criterion for determining whether the product requires more or less oversight.[81]

The Statement of Scope also emphasized the fact that genetic modification is more precise than classical methods thus reducing the uncertainties associated with any intended application.[82] Because genetic engineering allows scientists to directly manipulate desired traits at the genetic level rather than relying on crossing crops with their wild relatives the result is more certain.[83] These considerations led to the conclusion that the process of modification is independent of safety. "It is the characteristic of the organism, the environment, and the application that determines the risk of the introduction, not the technique used to produce the organism."[84]

Based on these findings, the OSTP developed three fundamental principles to guide agency regulation. First, oversight should not turn on the fact that an organism has been modified, because such fact alone is not a sufficient indication of risk.[85] Second, oversight that limits the production of an organism should be based on evidence that the risk presented by introduction of the organism is "unreasonable."[86] Third, organisms modified for a new trait that does not pose an enhanced risk to the environment should not be subject to a higher level of oversight than the unmodified organism.[87]

The government's general policy therefore, emphasizes that genetically engineered organisms and their products should be regulated on the basis of risk rather than the process by which they are created. The OSTP's Statement of Scope promotes this risk-based approach to regulation, noting that it is scientifically sound, properly protects public health and the environment against risk, and avoids hindering safe innovations.[88]

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80 *Id.*
81 *Id.*
82 *Id.* at 6756.
83 *Id.*
84 *Id.*
85 *Id.*
86 *Id.*
87 *Id.*
88 *Id.*

C. *USDA Departs from the Framework*

When the USDA included genetic engineering as a permissible use in its initial proposed rule defining "organic", it was clearly attempting to follow the principles set forth in the Coordinated Framework. However, with respect to the preferences and expectations of organic consumers, the Framework proved unworkable. The organic consumers' expectations as to the process by which food is produced conflicts with the product-based principles expressed in the Framework. The USDA realized that the application of such product-based standards contradicts the explicit goals of the OFPA, to establish an organic certification program that would differentiate agricultural products that were produced using only organic methods.[89]

To justify the decision to exclude genetically engineered food in the final rule, the USDA made it abundantly clear that the National Organic Plan is all about process as opposed to product, the opposite of the policies set forth by the Statement of Scope. In an effort to stay true to this idea, the USDA rejected comments that requested changing the definition of excluded methods to include the products of such methods (i.e. genetically engineered plants).

> The emphasis and basis of these standards is on process, not product. We have specifically structured the provisions relating to excluded methods to refer to the use of methods. Including the products of excluded methods in the definition would not be consistent with this approach to organic standards as a process-based system. For the same reason, we have retained the term "excluded method" to reinforce that process-based approach.[90]

The USDA's process justification for departing from the rule is a clear example of how the product/process dichotomy guides the regulation of GE foods. Because the purpose of the OFPA was to create a marketing scheme, one that should reflect the applicable market, it was permissible under the Framework to exclude GE foods based on consumer opinion. The dichotomy becomes even more apparent after examining the FDA's policy for labeling GE foods.

III. Food Regulation by the Food and Drug Administration

A. *Regulation of Food and Labeling*

The FDA is the primary Federal agency responsible for the safety of the commercial food supply. The Federal Food, Drug and Cosmetic Act (FDCA) gives the FDA authority to initiate legal action against produc-

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89 See 7 U.S.C. §6501 (2004).

90 National Organic Program Final Rule, 65 FR 80548-01 (2000).

ers of food that is "adulterated" or "misbranded" within the meaning of the act.[91] According to the FDCA,[92] an adulterated food can be defined as such because it contains deleterious substances that may render it injurious to health,[93] contain residues of unsafe pesticides,[94] or has been produced under unsanitary conditions whereby it may have been rendered injurious to health.[95]

The FDA is to protect consumers against misbranded foods if they are "false or misleading in any particular."[96] To determine whether a label is misleading, the FDA must consider whether the label "fails to reveal facts . . . material with respect to consequences which may result from the use of the articles to which the labeling . . . relates under the condition of use prescribed . . . or as are customary or usual."[97] In other words, the FDA is responsible for implementing safety and economic protections over the commercial food supply. The FDA interprets the above provisions of the FDCA as granting it limited authority only in situations in which a food is produced in a way that ultimately renders it "injurious to health".[98] To determine whether or not a food is injurious to health necessarily requires examination of the food itself, not the processes by which it was produced.[99] This risk-based, product-based interpretation compliments the view expressed in the Statement of Scope.

B. FDA's Policy on GE

In 1992, the FDA issued its "Statement of Policy" with respect to "Foods Derived From New Plant Varieties."[100] The Policy discussed the safety and regulatory status of these foods and how the FDA was going to apply its regulatory framework to genetically engineered foods. The FDA invoked the "substantial equivalence" doctrine, which holds that if a GE crop shares similar health and nutritional characteristics with its

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91 21 U.S.C. 342(a)(1) (2004).

92 This is an abbreviated list of traits that can define a food as adulterated. It is not meant to encompass all possible definitions, but rather to emphasize the point that the FDA regulates food for safety.

93 21 U.S.C. §342 (a)(1) (2004).

94 21 U.S.C. §342 (a)(2)(b) (2004); *see also,* 21 U.S.C § 346(a) (laying out tolerance and exemptions for pesticide chemical residues and providing procedures to guide FDA in determination that pesticide is safe).

95 21 U.S.C. § 342 (a)(4) (2004).

96 21 U.S.C. § 343 (a)(1) (2004).

97 21 U.S.C. § 321 (n) (2004).

98 *See* McGarity, *supra* note 73 at 433. *See also* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed Reg. 22984 (May 29, 1992) [hereinafter FDA Statement of Policy].

99 The FDA does look to certain production methods, such as sanitary practices, but only because unsanitary practices tend to produce foods that could be injurious to health.

100 *See* FDA Statement of Policy, 57 Fed Reg. 22984, 22991 (May 29, 1992).

conventional counterpart it is deemed substantially equivalent or equally safe and will not require special scrutiny when regulating.[101] The FDA states in its Policy that "the agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding."[102]

With respect to labeling, the FDA interpreted the substantial equivalence doctrine as limiting its ability to require mandatory labeling of genetically engineered foods under FDCA §321(n).[103] Because the "new techniques" are not considered different from traditional methods, the FDA argued that the process itself is not "material" within the meaning of FDCA §321(n).[104]

This FDA interpretation was upheld in *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000). In 1998, Alliance for Bio-Integrity, a nonprofit organization dedicated to the advancement of human and environmental health through sustainable and safe technologies,[105] led a coalition of public interest groups, religious leaders, and scientists in filing a lawsuit aimed at reforming FDA policy on GE foods. Among other claims, the Plaintiffs argued that the FDA should have taken into account widespread consumer interest in having genetically engineered foods labeled.[106] The court's response was to emphasize the FDA's *limited* authority with respect to labeling decisions.[107] The court explained that materiality was a factual predicate to the labeling requirement and that only after such a finding could the agency consider consumer opinion.[108] The Plaintiffs also argued that the process of genetic engineering was a material fact under the statute,[109] but the court upheld the FDA's interpretation holding that it was reasonable and therefore was entitled deference.[110]

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101 *Substantial Equivalence in Food Safety Assessment*, Council for Biotechnology Information, (March 2001), *available at* http://www.whybiotech.com/html/pdf/Substantial_Equivalence.pdf (last visited April 22, 2004).

102 FDA Statement of Policy, 57 Fed Reg. 22984, 22991 (May 29, 1992).

103 *See* McGarity, *supra* note 73 at 459. *See also* FDA Statement of Policy, 57 Fed Reg. 22984, 22991 (May 29, 1992).

104 *See* McGarity, *supra* note 73 at 459. *See also* FDA Statement of Policy, 57 Fed Reg. 22984, 22991 (May 29, 1992).

105 *See generally* Alliance for Bio-Integrity website, *at* http://www.biointegrity.org (last visited May 10, 2003).

106 Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d. 166, 177 (D.D.C. 2000).

107 *Id.* at 178.

108 *Id.* at 179.

109 *Id.*

110 *Id.* at 204. The court applied the test for agency deference laid out in Chevron v. Natural Res. Def. Council, 467 U.S. 837 (1984). The test is as follows: If the court determines that Congress spoke directly to the issue at hand, then the agency must

IV. Comparison of Policy Justifications

The holding in *Alliance* established that the FDA has the authority to require labeling of only those GE foods that pose a "unique risk to consumer health" or result in "uniform changes" to food.[111] In this respect, the FDA has the strictly and narrowly interpreted statutory authority to follow the principles set forth in the Framework. This is in stark contrast to the USDA, which has departed from the Framework in developing the organic label under the OFPA. While the USDA responded to the consumer backlash that occurred following the first proposed rule, the FDA stood its ground. Assuming that the legal analysis in *Alliance* is correct and the FDA lacks the authority to require labeling for reasons other than safety, and assuming that there is no safety issue with respect to most GE foods, is a new authority needed to allow process-based labeling of GE foods in response to consumer desires?

A. Purpose of the Regulations

Difference in purpose is a key distinction between the Organic regulations and the Statement of Policy. The NOP under the USDA is explicitly a marketing regime while the Statement of Policy is a statement of how the FDA is going to protect consumers from the risks GE foods may pose.[112] These two inherently different issues call for different considerations.

The USDA justifies its elimination of GE almost exclusively on the fact that the development of a marketing scheme requires the consideration of consumer expectation.

> Based on this overwhelming public opposition, this proposal prohibits its use [excluded methods] in the production of all organic foods even though there is no current scientific evidence that use of excluded methods presents unacceptable risks to the environment or human health. While these methods have been approved for use in general agricultural production and may offer certain benefits for the environment and human health, consumers have made clear their strong opposition to their use in organically grown food.[113]

The USDA's justification is re-enforced in a comment from a pro-GE organization, "The [American Crop Protection Association] can accept

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give effect to that congressional order; if the statute is ambiguous, and the court determines the agency interpretation is reasonable, then the court must give deference to its decision. *Id.*

111 McGarity, *supra* note 73, at 462.

112 *See* 7 U.S.C. §6501 (2004), FDA Statement of Policy, 57 Fed Reg. 22984, 22991 (May 29, 1992).

113 National Organic Program, 65 Fed. Reg. 13512-01, 13513 (proposed March 13, 2000) (to be codified at 7 C.F.R. pt. 205).

the exclusion of modern biotechnology from organic production as an 'excluded method' *only* with the clear understanding that the organic designation is in no way an indication of safety or quality but is rather a marketing standard."[114]

In contrast, the FDA's mission is to make sure that the foods we eat are safe and wholesome. In developing safety standards to implement this mission, the FDA does not consider public opinion. This position, which has been upheld by the federal courts, is that science-based inquiries are sufficient to answer safety questions.[115] Therefore, as long as the FDA sees no evidence that the bioengineered food poses human health concerns or that it is in any way less safe than food produced through traditional methods, they will not require labeling of GE foods.

Nonetheless, there is still considerable consumer backlash against the FDA's labeling policies with regard to GE products. The handful of nonprofit organizations that lobbied the FDA for increased labeling regulations prior to the 1992 Statement of Policy increased, by 2001, to over fifty-four all working to get GE foods labeled.[116]

> One of the most controversial public policy issues surrounding genetically modified (GM) foods is whether food products containing ingredients from GM crops should be labeled so that consumers can make informed purchasing decisions.[117]

Assuming that the FDA's policies adequately achieve its goals, the following can be deduced. If consumers are interested in labeling GE foods because of concern over the safety of the product, then the current regulatory structure (which bases its conclusions on the risks posed by the product as opposed to the processes involved in developing the product) provides adequate protection. If however, consumers desire labeling of GE foods based on concerns about the processes that their foods undergo prior to coming onto the market, then perhaps a restructuring of the policy is necessary to develop a marketing system that meets consumer needs.

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114 *See* American Crop Protection Association comment on Docket No. TMD-00-02-PR2, RIN 0581-AA40, National Organic Program, published in the Federal Register 62 Fed. Reg. 65890 (December 16, 1997) *available at* http://www.croplifeamerica.org/public/issues/organic/natrule.html (last visited February 26, 2004).

115 With respect to GE foods, see Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d. 166, 177 (D.D.C. 2000).

116 Kurt Eichenwald, *Biotechnology Food: From the Lab to a Debacle,* N.Y. TIMES, Jan. 25, 2001, A1, *available at* http://www.nytimes.com/2001/01/25/business/25FOOD.html?ex=1083211200&en=451ddafcb3e46787&ei=5070 (last visited May 1, 2004).

117 PR Newswire, *How Consumers Process Information at Heart of Debate Over Labeling of Genetically Modified Foods; Pew Initiative Policy Dialogue Explores Consumer Education, International and Economic Issues Around Biotech Crop,* (June 27, 2002), *available at* http://www.organicconsumers.org/gefood/uslabels070302.cfm (last visited February 26, 2004).

B. Consumer Opinions About GE Foods

Polls conducted by industry, consumer and media groups consistently show that U.S. consumers overwhelmingly want GE foods labeled. According to a study conducted by Rutgers University, ninety percent of Americans said foods created through genetic engineering processes should have special labels on them.[118] An ABCNews.com poll found that ninety-three percent of Americans felt the federal government should require labels indicating if food has been genetically modified or bioengineered.[119] A Pew Initiative survey concluded that 75% of Americans say it is important to them to know whether a food product contains genetically modified ingredients.[120] One of the foremost biotech companies in the world, Novartis, conducted a survey and ninety-three percent of respondents agreed that GE foods should be labeled as such, with seventy-three percent agreeing strongly with that position.[121]

Though these polls suggest that consumers are concerned about foods produced using genetic engineering, it also appears that consumers know little about GE foods.[122] As a result, the underlying reasons for consumer views are uncertain. Why do consumers want to know whether the food they are buying has been genetically modified? Are they concerned that the *products* of GE are unsafe to eat or do they have concerns about the *process* of GE for other reasons?

C. The Hazard Model

Conveniently, in spring 2000, the FDA conducted an informative consumer study that shed light on these very questions.[123] The study found that consumers are primarily worried about the unknown conse-

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118 For a summary of the following polls and additional information, see *Compilation and Analysis of Public Opinion Polls on Genetically Engineered Foods*, Center for Food Safety at http://www.centerforfoodsafety.org/facts&issues/polls.html (Feb. 1, 2000).

119 *Id.*

120 *Id.*

121 *Id.*

122 *See Public Sentiments about Genetically Modified Foods*, Pew Initiative on Food and Biotechnology (March 2001), *available at* http://pewagbiotech.org/research/gmfood/1.php3 (last visited May 21, 2003). (Explaining their findings that Americans know relatively little about genetically engineered foods and biotechnology: "Few consumers believe that genetically modified foods are in wide use in the foods supply, and even fewer believe that they have eaten them. Only 14% of consumers believe that more than half of food in grocery stores contains genetically modified ingredients. Only 19% say they have eaten GM foods, 62% say they have not, and 19% say they don't know.")

123 Alan S. Levy and Brenda M. Derby, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, OFFICE OF SCIENTIFIC ANALYSIS AND SUPPORT, REPORT ON CONSUMER FOCUS GROUPS ON BIOTECHNOLOGY (Oct. 20, 2000), *available at* http://www.cfsan.fda.gov/~comm/biorpt.html (last visited February 26, 2004).

quences that might be associated with the technology but which cannot be anticipated based on current science or knowledge.[124] This widely held view seemed to be based on analogies that participants made with other technological innovations of modern agriculture, such as growth hormones, pesticides and animals being given large amounts of antibiotics.[125] Consumers viewed these technological innovations as primarily benefiting food producers, with little benefit to the consumer and potential unanticipated long-term negative impacts.[126] The FDA coined this viewpoint, the hazard model, which is marked by skepticism that consumer interests are not sufficiently considered by those in power.[127]

The hazard model explains that consumers are worried about the *process* used to create GE foods in addition to the *products* themselves. But in the case of GE foods, the hazard model explains that the reason that consumers worry about process and product is different than it is in the case of organic foods and other non-technology-based food safety issues. Though the Organic Program addresses process concerns and the FDA labeling policy addresses product safety concerns, it seems that neither policy considers the unique concerns expressed in the hazard model.

1. The Hazard Model and FDA Policy

The FDA's 1992 policy, discussed in Section III of this paper, focuses on the risks posed by the *products* of genetic engineering.[128] The FDA study explained that most participants accepted that the short-term safety of GE foods can be determined by science and therefore are not in question.[129] It can then be reasoned that the FDA policy, addressing the safety of products, is sufficient to satisfy consumers that they are not at risk in the short-term.

An ongoing argument in support of the FDA policy is that because many consumers lack knowledge about GE foods, mandatory labeling will be misleading to those who are already concerned about the safety of products, tending to exacerbate consumer fears that may not be well founded.[130] The FDA takes safety into account in its labeling policies and has determined that, except in two circumstances, GE foods are safe.[131]

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124 *Id.*

125 *Id.*

126 *Id.*

127 *Id.* For the remainder of the paper, I will use the phrase "hazard model" to describe the unique consumer concerns enumerated in the FDA study with respect to the labeling of GE foods.

128 FDA Statement of Policy, 57 Fed Reg. 22984, 22991 (May 29, 1992).

129 *Id.*

130 PR Newswire, *supra* note 117.

131 There are two exceptions: 1) when the donor organism may be an allergen; and 2) when the vitamin amount has changed.

This being the case, it is reasonable to think that mandatory labels could mislead consumers into believing otherwise.

> The labeling debate raises a number of contentious issues about how consumers perceive information," said Michael Rodemeyer, Executive Director of the [Pew] Initiative. "Although most polls show consumers in favor of these labels, there are questions as to how useful labels might be and whether they may cause unnecessary fears over products that most scientists have found to be as safe as their conventional counterparts.[132]

The FDA basis its assumption, that consumers are concerned about the safety of products, on consumer research conducted in other areas of food policy. In developing regulations for nutrition and use-by-date labeling the FDA found that consumers demand product information about product characteristics that are relevant to their health and safety concerns.[133] But with GE foods, the type of information that consumers want is how the food product was produced, rather than the compositional effect of the process on the food product.[134] Why is this? The FDA made several conclusions in its study.

> [I]nformation about product characteristics does not exhaust what consumers want to know. The concept of long-term effects, which seems to underlie the demand for biotechnology labeling, implies that it is unknown product characteristics that are of concern. *A surrogate for knowing about unknown product characteristics is knowing about the technology by which the product was produced, which may explain why they want to know about the process.*[135]

The FDA's labeling policy is to assure that consumers are informed about product characteristics that could pose risks to their health. Because the agency has determined that GE foods do not pose a risk to consumer health, their policy will not allow for the labeling of GE products. But as the hazard model explains, consumers are concerned that the process of genetic engineering may create unknown product characteristics that could pose risks in the long-term. Hence, informing consumers about the processes their foods have gone through can increase consumer confidence in the product itself. Therefore consumer concerns are not completely addressed in the case of GE foods, by informing them solely of product-based risks.

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132 PR Newswire, *supra* note 117.

133 Levy, *supra* note 123.

134 *Id.*

135 *Id.*

2. The Hazard Model and Organic Policy

Likewise, the issue of labeling GE food cannot be addressed by the regulatory policies followed in implementing the OFPA and the NOP. With respect to GE foods, organic consumers and non-organic consumers both want labels to tell them something about the way that the GE food was produced. Despite this seeming similarity, each group is concerned about process for different reasons.

As discussed in Part I, the USDA organic label was created in accordance with organic principles that promote awareness of the impacts that production of food has on the environment, the animal world and society as a whole. After much consideration, the USDA decided that genetic engineering was not consistent with these ideals and concluded that the organic label should not be used on foods that have gone through GE processes. In this way, the USDA's regulations for the organic label were process-based.

As described above, the average consumer wants GE foods labeled because of a fear of long-term health effects. For most participants in the FDA study, concerns about biotechnology did not include recognition of possible environmental or societal impacts of GE food production.[136] Though a few participants expressed concerns about the negative impacts on small farmers or problems with sterile seeds and contamination across fields, these kinds of concerns were rare.[137]

The organic label is inadequate to satisfy the average consumers' fear of GE foods because it does not give them the information that they are looking for. As mentioned earlier, the focus on process for these consumers is a surrogate for knowing about product characteristics that are unknown and/or poorly understood. Though it is true that a consumer who buys organic products is assured that they contain no GE foods, the label says nothing about the product itself unless you believe in the organic ideals. Therefore, reliance upon the organic label makes it necessary for a consumer to buy into a whole set of ideals without ever having their concerns directly addressed.

CONCLUSION

The labeling debate continues to polarize entrenched interests and confuse consumers. The FDA and its advocates argue that the agency does not have the authority to label GE foods, and that to label them under the current scheme would mislead consumers and stigmatize industry. On the contrary, proponents of labeling argue that consumers

136 *Id.*
137 *Id.*

have a right to know how their food is produced and that this is reason enough to require labeling such foods.

Both sides have valid counter arguments. In response to the FDA's anti-labeling stance, proponents of labeling claim that the labeling authority granted by the FDCA is being interpreted too narrowly by the FDA and that the substantial equivalence doctrine is being abused in order to favor the biotech industry.[138] In response to "right to know" arguments, those who support the FDA's anti-labeling stance claim that there are many processes that our foods go through that are not indicated on labels.[139] The FDA's policy looks out for characteristics in foods that are material with respect to consequences; to label foods that are considered safe would be putting a warning on something unnecessarily. Focusing less on labels and more on other regulatory devices that address public concerns without stifling industry may be one way to resolve this debate.

The director of The Biotechnology Project at the Center for Science in the Public Interest (CSPI), Gregory Jaffe, addressed the issue of alternative regulatory devices at a conference in Egypt called Biotechnology and Sustainable Development: Voices of the South and North.[140] CSPI is a non-profit consumer advocacy organization that focuses on improving

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138 *See Should Genetically Modified Foods be Labeled?,* Craig Holdrege, Say No To GMOs, *at* www.saynotogmos.org/regulatory_2.htm (last visited May 21, 2003). He argues that the FDA is ignoring their responsibilities as a consumer protection agency that is authorized to promote honesty and fair dealing with consumers. He claims its policy narrowly couples labeling of GE foods with safety, leaving out all the other criteria. He discusses the irony that the FDA requires juice to be labeled "concentrate" to distinguish it from fresh-squeezed in the name of consumer protection but claims that genetically engineering food is not considered material information that should be available to the consumer. He also claims that the concept of substantial equivalence, by virtue of its narrowness is misleading. His reasoning is that the term itself suggests that all the substances in the foods are the same, but in reality only a specific subset of substances has been investigated and taken into account in the designation.

139 *See* PBS interview with Martina McGloughlin, *at* http://www.pbs.org/wgbh/harvest/interviews/mcgloughlin.html (last visited April 24, 2004). "[Labeling food that is produced using recombinant DNA technology is] a complete departure . . . from the original intent of regulations on the U.S. . . . where the focus up until now had been on the product, not the process by which it's produced. If you look at a package of sausages, it doesn't say, 'This was produced using extrusion processes.' Most people would never want to see how sausages are produced . . . Agricultural practices or processing practices have never been a requirement of labeling. And now [in Europe] suddenly they are, which is a total departure from the way regulations have been put into place . . ."

140 *See* Gregory Jaffe, *A Consumer Perspective on Regulating Agricultural Biotechnology* (March 18, 2002), *available at* http://cspinet.org/biotech/egyptfnl.pdf (last visited February 26, 2004).

the safety and nutritional quality of our food supply.[141] The Biotechnology Project strives to accurately identify the risks and benefits of biotechnology, ensure that the U.S. regulatory system is up to the task of preventing significant risk, and keep the public informed about the facts surrounding agricultural biotechnology.[142]

In his presentation at the conference, Jaffe discussed how a mandatory pre-market approval system would increase public trust in the governmental review of GE foods and public confidence in their safety.[143] The FDA currently uses a voluntary system that is inadequate considering the significant debate concerning the labeling of GE foods.[144] Jaffe explained that a mandatory process would also increase the likelihood that consumers will accept biotech foods, allowing farmers and the environment to realize the benefits that the biotech crops were designed to provide.[145]

According to Jaffe, the ideal regulatory system for biotechnology needs to include: 1) adequate legal authority to put products through both food safety and environmental review; 2) flexibility to adapt to new technologies; 3) equitable ways of reviewing products in order to be fair to those subject to review; and 4) an easily understandable process that is equally clear to the participant and the outsider.[146]

As Jaffe explained, consumer trust in the regulatory process is key to instilling consumer trust in regulated products.[147] To earn consumer trust, the regulatory system must be mandatory, transparent, contain established safety standards, invite public participation, and be backed up by post-approval monitoring and enforcement.[148]

A mandatory pre-market approval system is but one plausible alternative to mandatory labeling that provides insight into the problems with the current schemes. Notwithstanding the reality that both the National Organic Program labeling system and the FDA's labeling policy reflect potentially successful methods of dealing with certain consumer issues, there is still the issue of low consumer confidence in GE foods. Jaffe's alternative is but one possible way the agencies might address valid consumer concerns that do not fit neatly into the process/product dichotomy.

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141 *See generally* Center For Science in the Public Interest Website, *at* http://www.cspinet.org (last visited February 26, 2004).

142 *See* Gregory Jaffe, *A Consumer Perspective on Regulating Agricultural Biotechnology*, (March 18, 2002) *available at* http://cspinet.org/biotech/egyptfnl.pdf (last visited February 26, 2004).

143 *Id.* at 3.

144 *Id.*

145 *Id.*

146 *Id.* at 4-5.

147 *Id.* at 9-10.

148 *Id.* at 6-9.