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GENETIC ENGINEERING AND FOOD LABELING: A CONTINUING CONTROVERSY

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INTRODUCTION

Genetic engineering has produced many disconcerting questions. These include questions of an ethical, moral, or religious nature; agricultural, ecological, and environmental concerns; economic and social policy questions; food safety questions; and consumer information concerns. Industry domination over biotechnology has led to secrecy,[1] lack of public input,[2] undue influence over scientists and government,[3]

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[1] Steven Gorelick, *Hiding Damaging Information From the Public*, ECOLOGIST, Sept. 1, 1998, at 301. *See also* Sheldon Rampton & John Stauber, *This Report Brought to You by Monsanto*, PROGRESSIVE, July 1, 1998, at 22.

[2] Gerad Middendorf et al., *New Agricultural Biotechnologies: The Struggle for*

suppression of the press,[4] and control over a technology that can affect all the world.[5]

Proponents of genetic engineering argue that it will help feed a growing population, increase agricultural productivity, help the environment, produce healthier and tastier foods, help developing countries, and help sustainable agriculture.[6] It is difficult to oppose a technology that offers such tremendous promise to the world. In fact, many critics do not dispute the possibilities of extraordinary advancement in health and welfare.[7] These critics see no inherent wrong or harm in this technology, but point out dangers posed by commercial exploitation.[8] They argue that industry domination "is tied to private profit, short-term control over nature, and the neglect of short and long-term social and environmental consequences."[9] They point to similarities between the policies and promises of the green revolution and the policies and promises offered by proponents of biotechnology.[10] The green revolution did increase production.[11] However, it also caused or increased social, political, and economic inequalities in

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Democratic Choice, MONTHLY REV., July 1, 1998, at 85; Ian Slotin, *Biotechnology: Regulation and Social Concerns*, CAN. CHEMICAL NEWS, Apr. 1, 1998, at 22.

[3] David Aboulafia, *Pushing RBST: How the Law and the Political Process Were Used to Sell Recombinant Bovine Somatotropin to America*, 15 PACE ENVTL. L. REV. 603, *passim* (1998); rBST INTERNAL REVIEW TEAM HEALTH PROTECTION BRANCH, HEALTH CANADA, 1998 rBST (NUTRILAC) "GAPS ANALYSIS" REPORT (1998), at 5, 12-13, 30-34 (visited May 10, 1999) <http://www.nfu.ca/Gapsreport.html> [hereinafter GAPS ANALYSIS]; Gorelick, *supra* note 1; Bill Lambrecht, *World Recoils at Monsanto's Brave New Crops*, ST. LOUIS POST DISPATCH, Dec. 27, 1998, at A1; Anne McIlroy, *Parliamentary Bureau: Ottawa Tried to Control Scientists' Testimony*, GLOBE & MAIL, Oct. 27, 1998, at A1; Mark Nichols, *Money and Influence*, MACLEAN'S, Sept. 28, 1998, at 58 (discussing scientists' complaints of industry interference, stifling of research, and control over regulatory agencies); Rampton & Stauber, *supra* note 1; Sheldon Rampton & John Stauber, *The Gag Reflex*, PROGRESSIVE, July 1, 1998, at 25.

[4] Peter Downs, *Monsanto Lying About Effects of Bovine Growth Hormone*, ST. LOUIS JOURNALISM REV., at 13; Donella Meadows, *It's Hard to Get to the Truth Sometimes*, CHARLESTON GAZETTE, Apr. 27, 1998, at 4A; Rampton & Stauber, *supra* note 3; Rampton & Stauber, *supra* note 1.

[5] Middendorf, *supra* note 2.

[6] Travis Brown, *Biotechnology Trends — Grower Promise, Value, & Challenges*, Symposium Presentation, American Agricultural Law Association, Oct. 23, 1998 (paper on file with author).

[7] Middendorf, *supra* note 2; Slotin, *supra* note 2.

[8] Philip McMichael, *Global Food Politics*, MONTHLY REV., July 1, 1998, at 85; Middendorf, *supra* note 2.

[9] Middendorf, *supra* note 2.

[10] *Id.*

[11] *Id.*

many areas of the world.[12]

Most people agree consumers have the right to make informed decisions. Consumers cannot make informed decisions when vital information is kept secret. Informed decision making requires trust, openness, communication, information, and education. Choosing what foods to eat is a very personal decision which affects health. Consumers expect to make informed decisions; however, it is extremely likely that we unknowingly consume genetically engineered foods. We have no way of identifying them.[13] The effects of genetic engineering will be experienced by both consumers and producers. Therefore, this technology should be open to public input and certainly to public knowledge and education.

The first marketed biotechnological agricultural product was a genetically engineered growth hormone injected into cows to stimulate milk production.[14] It was approved by the United States Food and Drug Administration (FDA) in 1993.[15] The United States is still the only developed country to approve this animal drug.[16] Since 1993, many more genetically engineered foods (GMFs) have been approved, and a great many more should be available soon. There are currently thirty-one agricultural GMFs being marketed.[17] These products include tomatoes, corn, potatoes, rice, apples, walnuts, and tobacco.[18] More than thirty-five new GMFs are expected to be marketed within the next few years.[19] Genetically altered plants occupy more than fifty million acres in the United States.[20] Genetic engineering remains controversial despite these successes.

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[12] *Id.*

[13] Marian Burros, *Shoppers Unaware of Genetically Altered Food*, PATRIOT LEDGER, July 20, 1998, at 4.

[14] Aboulafia, *supra* note 3, at 654.

[15] *See* Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension, 21 C.F.R. § 522.2112 (1999).

[16] GAPS ANALYSIS, *supra* note 3, at 9, 12-13.

[17] *Getting Food Output Through Genetically Engineered Crops*, CHEMICAL MARKET REP., June 22, 1998, at FR3.

[18] Niccolo Sarno, *Environment: Genetically Modified Maize on a European Battleground*, INTER PRESS SERV., Sept. 23, 1997. *See also Getting Food Output Through Genetically Engineered Crops*, *supra* note 17; Jim Erickson, *Bt Cotton's A Success, But Super-Pest Could Doom It*, ARIZ. DAILY STAR, May 27, 1998, at 1B.

[19] *Getting Food Output Through Genetically Engineered Crops*, *supra* note 17 (listing agricultural genetically altered products, their attributes, and their manufacturers).

[20] Stan Grossfeld, *Genetic Engineering Debate Shifting to America*, BOSTON GLOBE, Sept. 23, 1998, at A1.

This article focuses on labeling of GMFs and some of the controversies surrounding them. Part I provides background information on genetic engineering and the federal agencies which regulate agricultural biotechnology. Part II provides a brief overview of the laws and regulations governing the food approval process. Part III discusses food labeling requirements. Part IV examines some of the controversies surrounding GMFs. Part V discusses responses to GMFs outside the United States. This article concludes that labeling of GMFs is ethically required and probably inevitable.

I. BACKGROUND

A. Genetic Engineering

What do we have in common with plants, fish, bacteria, fungi, insects, birds, and animals? We all have the same genetic dictionary.[21] We all have deoxyribonucleic acid (DNA) in our chromosomes.[22] DNA is a code, or message, that uses arrangements of four chemical bases to determine the characteristics of all living organisms.[23] DNA determines the characteristics by controlling production of essential chemicals.[24] Genetically modified organisms (GMOs) are created by inserting genetic material from the cells (specifically coded traits) of one organism (the donor) into the cells of another organism (the host).[25] The host will then display the specific trait coded by the donor gene.[26]

In nature, reproduction is between members of the same species. In fact, a species could be defined as a collection of organisms capable

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[21] *See* MICHAEL REISS & ROGER STRAUGHAN, IMPROVING NATURE? THE SCIENCE AND ETHICS OF GENETIC ENGINEERING 13-21 (1996).

[22] *Id.*

[23] *Id.* at 14-15.

[24] *Id.* at 14.

[25] REISS & STRAUGHAN, *supra* note 21, at 1-2, 34-36 (discussing genetic technology for the lay person). *See also* Secondary Direct Food Additives Permitted in Food for Human Consumption; Food Additives Permitted in Feed and Drinking Water of Animals; Aminoglycoside3'-Phosphotansferase II, Final Rule, 59 Fed. Reg. 26,700, 26,702 (1994) (codified at 21 C.F.R. pts. 173 & 573) (1999)) (describing genetic engineering).

[26] Alan Goldhammer, Ph.D., *The Regulation of Agricultural Biotechnology: An Industrial Perspective*, 48 FOOD & DRUG L.J. 501, 505 (1993); Sara M. Dunn, *From Flav'r Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment*, 9 COLO. J. INT'L L. & POL'Y 145, 149 (1998).

of breeding only among themselves.[27] Humans have been selectively breeding plants and animals to tailor traits for optimum yields, pest resistance, or other human desires for more than 10,000 years.[28] This selection is often in ways that would not occur without human intervention.[29] Traditional breeding can result in drastic changes to the organisms involved.[30] Today's domesticated plants bear little resemblance to the wild plants from which they derived.[31] It may seem there is basically little difference between selecting traits through genetic engineering and traditional methods of selecting for traits.[32] Some argue that GMOs are actually safer than organisms produced by traditional breeding due to the precision and specificity of genetic engineering.[33] Others argue that genetic engineering is not a precise technique and gene insertion is actually random; genes are not stable, but are dynamic and ecologically complicated; and transgene instability is common in genetic engineering of plants and animals.[34] There is consensus regarding at least three major differences between traditional breeding methods and genetic engineering:[35] (1) traditional methods utilize closely related species, such is not the case with many GMOs;[36] (2) traditional methods often take years to complete, the time frame for GMOs is much shorter;[37] and (3) genetic engineering allows novel changing of species for novel uses such as "sewage disposal, pollution control, and drug production."[38]

In 1980, the United States Supreme Court held that live, man-made

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[27] *See* REISS & STRAUGHAN, *supra* note 21, at 34.

[28] *Id.* at 3.

[29] *Id.* at 4.

[30] *Id.*

[31] *Id.*; Goldhammer, *supra* note 26, at 504.

[32] *See* SUSAN F. BAREFOOT ET AL., COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY, LABELING OF FOOD-PLANT BIOTECHNOLOGY PRODUCTS 1-3 (July 1994).

[33] Frederick H. Degnan, *The Food Label and The Right-to-Know*, 52 FOOD & DRUG L.J. 49, 49 (1997); Goldhammer, *supra* note 27, at 501. *See also* BAREFOOT, *supra* note 32 (explaining the greater precision of genetic engineering in comparison to traditional selection practices).

[34] Mae-Wan Ho et al., *The Biotechnology Bubble*, ECOLOGIST, May 15, 1998, at 146.

[35] REISS & STRAUGHAN, *supra* note 21, at 5.

[36] *Id.*; Middendorf, *supra* note 2. *See also* Nike L. Ruibal Mendieta et al., *The Potential Allergenicity of Novel Foods*, 75 J. SCI. FOOD & AGRIC. 405 *passim* (1997) (discussing possible allergic reactions due to transferring genes between unrelated organisms).

[37] BAREFOOT, *supra* note 32, at 2-3; REISS & STRAUGHAN, *supra* note 21; Middendorf, *supra* note 2.

[38] REISS & STRAUGHAN, *supra* note 21.

microorganisms are patentable.[39] This gave industry an economic impetus to pursue genetic engineering, a research and capital intensive endeavor.[40] Research and development is concentrated in the private sector where economic survival often depends on rapid commercialization of GMOs.[41] Along with concentration and rapid development, industry has pushed for a reduction in government oversight.[42] These factors greatly reduce public response and participation.[43]

B. Brief Overview of Regulations Affecting Agricultural Biotechnology

Four federal administrative agencies regulate agricultural GMOs in the United States. These are: the United States Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), the National Institutes of Health (NIH) and the United States Environmental Protection Agency (EPA).[44] Statutes governing GMOs include: the Federal Food, Drug, and Cosmetic Act (FDCA),[45] the Federal Plant Pest Act (FPPA),[46] the Toxic Substance Control Act (TSCA),[47] the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[48] the Virus, Serum, Toxin Act (VSTA),[49] and the National Environmental Policy Act (NEPA).[50]

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[39] Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980). The Court stated that Congress intended the Patent Act to cover "anything under the sun that is made by man." *Id.* at 309.

[40] Christine C. Vito, Ph.D., Comment, *State Biotechnology Oversight: The Juncture of Technology, Law, and Public Policy,* 45 ME. L. REV. 329, 330 (1993).

[41] Middendorf, *supra* note 2.

[42] *Id.*

[43] *Id.*

[44] Aboulafia, *supra* note 3, at 608.

[45] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-395 (1999).

[46] Federal Plant Pest Act, 7 U.S.C. §§ 150aa-150jj (1999).

[47] Toxic Substance Control Act, 15 U.S.C. §§ 2601-2622 (1999).

[48] Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1999).

[49] Virus, Serum, Toxin Act, 21 U.S.C. §§ 151-159 (1999).

[50] National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321-4370d (1999).

II. FOOD SAFETY AND GENETIC ENGINEERING

A. Food Safety

The FDA regulates food safety and labeling under authority of the FDCA.[51] Good manufacturing practices and labeling are generally the only regulations affecting food which is of "natural biological origin," has not been modified by a process introduced after 1958, and was commonly consumed in the United States prior to 1958.[52] Foods modified by a process introduced after 1958 may be subject to additional regulation.[53] Because GMOs did not exist until after 1958,[54] they may require such additional regulation.

B. Substantial Equivalence

Consistent with the United Nations Food and Agriculture Organization (FAO), World Health Organization (WHO), and Organization for Economic Co-operation and Development (OECD), the FDA uses the term "substantial equivalence" in safety assessments of foods derived from GMOs.[55] A joint report of the FAO and WHO states that substantial equivalence is a basic assessment tool used in establishing the safety of food products derived from genetically modified organisms:

> The determination of substantial equivalence entails a consideration of the molecular characterization of the genetically modified organism, its phenotypic characteristics, and the key nutrients and toxicants for the food

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[51] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-395 (1999).

[52] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(s) (1999); Eligibility For Classification As Generally Recognized As Safe (GRAS), 21 C.F.R. § 170.30 (1999). *See also* Robert A. Bohrer, *Food Products Affected by Biotechnology*, 55 U. PITT. L. REV. 653, 655 (1994).

[53] Eligibility For Classification As Generally Recognized As Safe (GRAS), 21 C.F.R. § 170.30 (1999).

[54] BAREFOOT, *supra* note 32, at 2-3; REISS & STRAUGHAN, *supra* note 21, at 11-42; Vito, *supra* note 40, at 329.

[55] Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,945 (1997). *See* United Nations Food & Agriculture Organization (visited Nov. 15, 1998) <http://www.fao.org> for background information. The mission of the World Health Organization includes helping the "establishment of international standards for biological, pharmaceutical and similar products." WHO, (visited Nov. 15, 1998) <http://www.who.int/aboutwho/en/mission.htm>. The Organisation for Economic Co-operation and Development [hereinafter OECD] is a group representing 29 major industrialized countries. Representatives of member countries work toward perfecting economic and social policy. *See* Organisation for Economic Co-operation and Development's website at (visited Sept. 8, 1999) <http://www.oecd/about/general/index.htm>.

> source in question. Analyzing a broader spectrum of components is in general unnecessary, but should be considered if there is an indication from other traits that there may be an unintended effect of the genetic modification.[56]

Substantial equivalence is established by showing that the characteristics of the GMO or the food derived from a GMO are equivalent to the same characteristics of conventional plants, animals, and foods.[57] According to the WHO, once substantial equivalence has been established, an organism or food is considered as safe as its conventional counterpart.[58] It is important to remember that substantial equivalence is an assessment tool, not a safety assessment in itself. A food product may be ninety-nine percent equivalent to common food, but contain a new toxicant and thus require extensive testing.[59] Likewise, a product may be only seventy percent equivalent but require little additional testing, "especially if the difference is in nutritional components" and can easily be supplemented by a mixed diet.[60] Novel foods are those in which the donors or the hosts do not have a history of safe food usage. The benefit of substantial equivalence for novel foods ranges from useful to negligible.[61]

The European Union Commission (EUC) does not accept the definition or use of "substantial equivalence" for food labeling of genetically modified foods (GMFs).[62] The EUC wants all references to substantial equivalence eliminated from the Codex Alimentarius (Codex) standards on food labeling.[63] The Codex committee has not reached agreement on mandatory labeling of GMFs. The EUC and most consumer groups want mandatory labeling of GMFs. Some scientists and consumer groups object to the use of the term substantial equivalence

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[56] Conclusions, WHO, (visited Nov. 15, 1998) <http://www.fao/es%2A/esn/biotech/conclude.htm> (describing and detailing WHO conclusions regarding genetically modified organisms and products derived from such organisms).

[57] *Id.*

[58] *Id. See also* Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,944 (1997) (to be codified at 21 C.F.R. pts. 170, 184, 186, & 570) (proposed Apr. 17, 1997).

[59] Norman R. Lazarus, *The Concept of Substantial Equivalence: Toxicological Testing of Novel Foods*, 1996 FOOD SAFETY EVALUATION, OECD DOCUMENTS 98, 98 (1996).

[60] *Id.*

[61] *Id.* at 100.

[62] Peter Menyasz, *Standards: U.S., Europe Make Limited Progress on Labeling Genetically Modified Food*, 15 Int'l Trade Rep. (BNA) No. 22, at 960 (June 3, 1998).

[63] *Id.* Codex Alimentarius was jointly established by the FAO and WHO to set international standards. *Id.*

because it is used as a basis for both eliminating regulatory assessment and failure to require labels on products derived from genetic engineering.[64] The concept of substantial equivalence is subjective and imprecise: "[T]here are no defined tests that products have to go through to establish substantial equivalence."[65]

C. Adulteration

Adulterated food is prohibited from being sold or transported in commerce.[66] Food is adulterated if it carries or contains any "poisonous or deleterious substance."[67] It is not adulterated if the substance is not an added substance and the quantity "does not ordinarily render it injurious to health."[68] All added "poisonous or deleterious" substances are defined as unsafe except to the extent required or unavoidable under good manufacturing practices.[69] The Secretary of Agriculture is mandated to set limits for "poisonous or deleterious substances" which are required or cannot be avoided by "good manufacturing practices."[70] Limits are to be set to the degree the Secretary "finds necessary for the protection of public health."[71] Any quantity exceeding the set limit is "deemed unsafe."[72] Genetic material taken from one organism and "inserted" into the cell of another is an "added substance."[73]

D. Food Additives

Food additives are very broadly defined in the FDCA. A food additive is any substance that might "reasonably" be expected to become a part of food or affect the characteristic of food, if the substance is

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[64] Ho, *supra* note 34 (discussing problems and concerns related to genetic engineering).

[65] *Id.*

[66] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a), 342 (1999).

[67] 21 U.S.C. § 342(a)(2)(A) (1999) (deeming food adulterated if it "bears or contains any poisonous or deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) that is unsafe within the meaning of [U.S.C. section 346].").

[68] 21 U.S.C. § 342(a)(2)(A) (1999).

[69] 21 U.S.C. § 346 (1999).

[70] 21 U.S.C. § 346 (1999).

[71] 21 U.S.C. § 346 (1999).

[72] 21 U.S.C. § 346 (1999).

[73] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992).

not recognized as "safe."[74] By definition, substances "generally recognized as safe" (GRAS) are not food additives.[75] "[I]t is the transferred genetic material and the intended expression product or products that could be subject to food additive regulation, if such material or expression products are not GRAS."[76] Food additive regulation is expensive and time consuming for industry and government.

E. Generally Recognized As Safe (GRAS)

Food may generally be recognized as GRAS "based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food."[77] These views may be based on scientific procedures or on knowledge that a food was commonly consumed in the United States prior to January 1, 1958.[78] Most foods have been in use for hundreds of years. Furthermore, there are well established testing procedures for new plant varieties.[79] Breeders test new varieties for ten to one hundred site-years, the equivalent of five to ten years.[80] New plant varieties derived from widely used plants with a long history of safe use may be GRAS, regardless of selection and breeding methods. For example, corn containing genetic material from soybeans would likely qualify as GRAS. A full review by the FDA would not be needed if experts agreed the soy protein was safe due to its widespread use prior to 1958.[81] In contrast, introduction of a novel protein would likely require formal review and scientific analysis.[82]

F. Self-Determination of GRAS

The manufacturer or developer of a substance or material determines whether the substance or material is GRAS.[83] The sponsor may

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[74] 21 U.S.C. § 321(s) (1999).

[75] 21 U.S.C. § 321(s) (1999).

[76] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992).

[77] Eligibility For Classification As Generally Recognized As Safe (GRAS), 21 C.F.R. § 170.30(a) (1999).

[78] *Id.*

[79] BAREFOOT, *supra* note 32, at 2-4.

[80] *Id.* at 4. *See also* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,986 (May 29, 1992). A site-year is equal to the number of testing sites multiplied by the number of years of testing.

[81] *See* Bohrer, *supra* note 52, at 657-58.

[82] *Id.* at 658.

[83] *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg.

ask the FDA to affirm the GRAS status of the substance, but this is not required.[84] The FDA addressed self-determination of GRAS in a policy statement for new plant varieties specifically addressing GMOs in 1992.[85] The FDA stated that it did not anticipate any serious questions regarding the GRAS status of transferred genetic material.[86] Manufacturers, breeders, and others must determine if their products are food additives requiring premarket approval.[87] This determination may be based on: (1) a long history of safe use; (2) general agreement by experts that there is no safety concern information (unanimous agreement is not required); or (3) exemption by regulation.[88] GRAS recognition may be determined by checking a published list.[89] All GRAS substances are not included in the regulations.[90] Parties are encouraged to consult with the FDA for questions concerning GRAS status of an ingredient or new plant variety.[91] The producer of a new food is responsible for evaluating the safety of the food and assuring FDCA safety requirements are met.[92] The FDA will take enforcement action against any product it concludes is not GRAS, even if the marketing party believed the product was GRAS.[93] The marketing party or manufacturer is held legally responsible for satisfying the FDCA.[94]

The FDA specifically addressed GRAS self-determination in 1997.[95] The FDA has proposed replacement of the current GRAS affirmation process with a notification process.[96] Affirmation of GRAS status involves a time consuming and resource intensive rulemaking process.[97] The new notice requirement was proposed as a way to reduce the government's burden, speed the process, and improve resource allocation.[98] The new process is simpler than the affirmation process.[99] The

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22,984, 22,989 (May 29, 1992).

[84] *Id.*

[85] *Id.*

[86] *Id.*

[87] *Id.* at 22,990.

[88] *Id.* at 22,989-90.

[89] *Id.*

[90] *Id.* at 22,989.

[91] *Id.*

[92] *Id.* at 22,989-90.

[93] *Id.*

[94] *Id.*

[95] Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938 (1997) (to be codified at 21 C.F.R. pts 170, 184, 186, & 570) (proposed Apr. 17, 1997).

[96] *Id.*

[97] *Id.* at 18,941, 18,945.

[98] *Id.*

FDA stated this would increase agency awareness of the composition of the food supply as it encouraged manufacturers to notify the FDA of their self-determinations.[100] The notification procedure is voluntary, as is the affirmation procedure it replaced.[101] Under this process, industry provides the FDA with a detailed summary of the information used for the self-determination, rather than the actual data.[102] The FDA stated that it "does not intend to conduct its own detailed evaluation of the data that the notifier relies on to support a determination that the use of a substance is GRAS or to affirm that a substance is GRAS for its intended use."[103]

III. Food Labeling Requirements

A. Misbranding

Food labeling requirements are covered under the section of the FDCA titled "[m]isbranded food."[104] A food must be labeled using its "common or usual name."[105] Foods containing multiple ingredients must have labels showing the common or usual name of each ingredient.[106] A food having no common or usual name must be labeled with "an appropriate descriptive term."[107] Misbranding occurs when a label is false or misleading.[108] A label is misleading if it fails to reveal all facts that are:

> material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under conditions of use as are customary or usual.[109]

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[99] *Id.*

[100] *Id.*

[101] *Id.*

[102] *Id.* at 18,947.

[103] *Id.* at 18,941.

[104] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343 (1999).

[105] 21 U.S.C. § 343(i) (1999).

[106] *Id.*

[107] Identity Labeling of Food in Packaged Form, 21 C.F.R. 101.3(b) (1999).

[108] 21 U.S.C. § 343(a)(1) (1999).

[109] 21 U.S.C. § 321(n) (1999).

B. Labeling of GMOs

1. Materiality

The FDA addressed labeling of GMOs in a number of statements recorded in the federal register.[110] A key factor in determining whether to include certain facts on a label is whether the facts are material.[111] The FDA considers genetic engineering an "extension at the molecular level of traditional methods [which] will be used to achieve the same goals as pursued with traditional plant breeding."[112] The FDA stated it was unaware of any way in which foods from GMOs "differ in any meaningful or uniform way, . . . or present any different or greater safety concerns than foods developed [by traditional methods]."[113] Thus, the FDA does not consider genetic engineering to be material information and does not require products to be labeled as derived from GMOs.[114]

2. Materiality and Consumer Interest in Labeling

Commentators have questioned whether consumer desires for labeling GMOs are material. They referred to the FDA reasoning behind requiring irradiated foods to be labeled as such.[115] The FDA supported labeling of irradiated foods in part with the statement, "whether information is material . . . depends . . . on whether consumers view such information as important and whether the omission of label information may mislead a consumer."[116] Irradiation can cause changes in organoleptic properties of a finished food.[117] The FDA reasoned that consumers might assume that foods which are not labeled are un-

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[110] Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,838 (Apr. 28, 1993); Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992).

[111] Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,838 (Apr. 28, 1993); Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992).

[112] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992).

[113] *Id.*

[114] *Id.*

[115] Final Rule On Food Irradiation, 51 Fed. Reg. 13,376 (Apr. 18, 1986); *see* 21 C.F.R. 179.26(c)(2) (1999).

[116] Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,838 (Apr. 28, 1993).

[117] *Id.*

processed.[118] Therefore, the FDA concluded, whether a *finished food product* has been irradiated is material and irradiated foods must be so labeled.[119] However, the FDA does not base its decision solely on what consumers view as important; it does not require foods with irradiated *ingredients* to have this information on the label.[120] According to the FDA, there is "no evidence that irradiation of an ingredient would affect the characteristics of a multiple ingredient food in any significant way."[121] Thus, the labeling requirements for this type of food are no different than those for other multiple ingredient foods. The FDA would not likely consider consumer interest as material for labeling of GMFs.

3. Materiality and Labeling Based on Religious or Cultural Needs

A non-safety, non-health reason for labeling is consumer desire for information due to cultural or religious reasons. Eating foods derived from plants in which DNA from animals has been inserted may violate cultural or religious norms of certain groups. The FDA has determined cultural or religious reasons are valid for requiring the labeling of the source of protein hydrosylates.[122] In this circumstance, the source of the protein was a material fact.[123] Another reason the source of the protein hydrolysate is considered material is its effect on compositional and functional properties.[124] Therefore, the source must be included in order to "adequately describe the nature of the ingredi-

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[118] *Id.*

[119] *Id. See also* 21 C.F.R. 179.26(c)(2) (1999).

[120] *See* Irradiation in the Production, Processing, and Handling of Food, 53 Fed. Reg. 53,176 (Dec. 30, 1988); Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,838 (Apr. 28, 1993); *see* 21 C.F.R. 179.26(c)(2) (1999).

[121] Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,838 (Apr. 28, 1993).

[122] Food Labeling; Declaration of Ingredients, 58 Fed. Reg. 2850, 2867 (1993) (to be codified at 21 C.F.R. pts. 101, 102, 130, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, & 169). For example, Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28,592, 28,599 (1991) states:

> [If] if a protein hydrolysate derived from the milk protein casein, were used as an ingredient in a food, the name used to declare this ingredient would have to convey the animal origin of the protein source to adequately inform such an individual of the nonacceptability of the food in his/her diet.

[123] Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,838 (Apr. 28, 1993).

[124] Food Labeling; Declaration of Ingredients, 58 Fed. Reg. 28,592, 28,599 (1991).

ent."[125] However, the FDA takes a different position regarding GMFs. According to the FDA, only a copy and not the original DNA is transferred.[126] The copy then becomes an integral part of the plant.[127] Thus, actual animal DNA is not transferred to plants. In addition, DNA from an animal to a plant does not change the basic nature of the plant.[128] For example, receiving DNA from fish genes does not give a plant "fish-like" qualities. In 1993, the FDA asked for data and information regarding labeling of new plant varieties,[129] however, it has not as yet published a final rule on this issue.

The FDA may arguably be violating the religious freedom of certain groups. The government must not tell people what is or is not a violation of the tenants of their faith. In addition, under the Religious Freedom Restoration Act of 1993, government may not substantially burden a person's free exercise of religion absent a compelling state interest and must use the least restrictive means of meeting its goal.[130] Religious leaders charged the FDA with violating their religious freedom in a complaint filed May 27, 1998, in the United States District Court of the District of Columbia.[131]

4. Materiality and Health Concerns

The FDA requires an allergen transfer assessment when the donor material is from a known allergen.[132] No allergen transfer assessment is required where the donor has no history of food usage.[133] This is because there are currently no assessment protocols for such cases.[134]

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[125] *Id.*

[126] Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,839 (Apr. 28, 1993).

[127] *Id.*

[128] *Id.*

[129] *See* Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,837 (Apr. 28, 1993).

[130] Religious Freedom Restoration Act of 1993, 42 U.S.C. §§ 2000 bb-4 (1999).

[131] *See Justice Department Asks Court to Dismiss Lawsuit Challenging FDA's Policy on Genetically Engineered Foods,* FOOD CHEMICAL NEWS, Aug. 31, 1998 (discussing the basis of the complaint and the FDA and plaintiff's positions).

[132] *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,987, 22,998-23,000 (May 29, 1992).

[133] *Id.* at 22,990.

[134] Mendieta, *supra* note 36, at 405-10. The FDA is unaware of any practical method for prediction or assessment of potential allergenicity of new proteins in food. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992).

Labeling may be required when the donor is a known allergen.[135] A more thorough review of allergens is presented *infra*. Except in rare instances of known allergens or compositional change, the FDA does not require labeling of GMFs.[136]

IV. CONSUMER AND PUBLIC CONCERNS

There are a multitude of consumer concerns regarding genetic engineering and modern agriculture in general. Concerns include: (1) health and food safety issues such as new allergens, toxicity, and antibiotic resistance; (2) adverse environmental consequences such as super-bugs, new viruses, super-weeds, loss of bio-diversity, and upsetting of the natural order; (3) adverse social consequences such as increased industrialization of agriculture, harm to small and moderate sized farms, industry domination of science, harm to the organic industry and home gardeners; (4) concerns of people with religious food restrictions; (5) vegetarian concerns; and (6) animal welfare concerns.[137] It is beyond the scope of this article to address all possible concerns. However, some concerns are discussed in order to show that consumer concerns are not unwarranted. The "consumer right to know" argument must be based on more than idle curiosity, ungrounded fears, speculative harm, or unreasonable safety guarantees (e.g., 100% safe).[138] Consumer desires for labeling of genetically engi-

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[135] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992). *See also* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(a) (1999). The omission of labeling alerting consumers to the presence of foreign genes inducing allergenicity would make the label misleading. For example, if genetic material from peanuts introduced into corn were found to cause allergic reactions in those with peanut allergies, the label would need to alert consumers as they would be unaware otherwise. *Id.*

[136] *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992); Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (1994); Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837 *passim* (Apr. 23, 1993).

[137] *See* REISS & STRAUGHAN, *supra* note 21, *passim. See also* Miguel A. Altieri, *Ecological Impacts of Industrial Agriculture and the Possibilities for Truly Sustainable Farming*, MONTHLY REV., July 1, 1998, at 60; Philip L. Bereano, *The Right To Know What We Eat*, SEATTLE TIMES, Oct. 11, 1998, at B5; Ho, *supra* note 34; Lambrecht, *supra* note 3; Mendieta, *supra* note 36; Middendorf, *supra* note 2.

[138] *See* International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73-74 (2nd Cir. 1996). *See also* Elie Gendloff, Note, *Stauber v. Shalala: Are Environmental Challenges to Biotechnology Too Difficult*, 4 WIS. ENVTL. L.J. 41 *passim* (1997) (discussing the difficulties involved in court challenges to biotechnology and government agency

neered food products have been denied by the FDA[139] and rejected by the courts.[140] Unless there are sufficient health concerns attributed to GMOs, it is unlikely labeling will be required. The FDA interprets its food labeling authority as insufficient to require labeling based on the process used in producing the food, such as the process of genetic engineering.[141] Perhaps the best approach is for consumer, environmental, and animal welfare groups to launch a united campaign to heighten public awareness and public activism. The concerns discussed below are relevant to such a campaign.

A. Allergens

The allergenicity issue is perhaps one of the strongest arguments for labeling of GMFs. Gene transfer often involves transfer of one or more proteins.[142] "All food allergens are proteins."[143] Foods frequently causing allergenicity include: "milk, eggs, fish, crustacea, molluscs, tree nuts, wheat, and legumes."[144] Common health problems related to allergies include asthma, rhinitis, conjunctivitis, and dermatitis.[145] Approximately ten percent of the adult population suffers from allergies, with the number increasing yearly.[146] Severity is also rising; allergic reactions can be life threatening.[147] Food allergies are a very complex health problem because almost any protein can trigger an immune

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actions); Kathleen Lennon, Note, *Government's Udder Disregard for a Consumer's Right to Information on RBST: Mandatory Labeling of Milk Products Should Be Allowed*, 22 VT. L. REV. 433, *passim* (1997).

[139] Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837 (Apr. 28, 1993); Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22, 984 (May 29, 1992).

[140] *See, e.g., International Dairy Foods Ass'n*, 92 F.3d at 73-74. *See also* Gendloff, *supra* note 138; Lennon, *supra* note 138, at 434-38.

[141] *See* Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25837 (Apr. 28, 1993). *See also* Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (1994) *passim* (discussing FDA lack of authority to require special labeling of milk from rBST cows and requirements for voluntary labeling to provide "proper context").

[142] Mendieta, *supra* note 36, at 405-06.

[143] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,987 (May 29, 1992).

[144] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,987 (May 29, 1992).

[145] Mendieta, *supra* note 36, at 406.

[146] *Id.*

[147] *Id.*

response.[148]

There is a major lack of knowledge about the characteristics of food allergens.[149] A primary concern for those with food allergies is that most genetically engineered encoded proteins are of unknown allergenicity.[150] Plant genetic engineering primarily involves gene transfers from organisms lacking a history of food use.[151] There is a distinct possibility that new allergies may arise due to exposure to these proteins. Even a minute amount of an allergen can trigger a severe allergic reaction.[152]

The FDA requires allergen transfer assessments.[153] The procedure is fairly straightforward when the donor is a known allergen.[154] In contrast, currently there are no allergen assessment protocols for genes from non-food donor sources.[155] A product may require labeling to alert susceptible consumers when the introduced protein is one which is known to induce allergic reactions or when it cannot be determined whether it would induce an allergic reaction in a susceptible population.[156] This regulatory stance only pertains to products involving known allergens. Except in rare instances of known allergens or compositional change, the FDA does not require labeling of GMFs. Thus, those susceptible to allergens cannot self-regulate possible exposure to allergens. Note the high incidence of non-food donor sources in this chart of typical gene donor sources for modified traits in new plant varieties.[157]

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[148] *Id.*

[149] *Id.* at 406, 409.

[150] *Id.* at 409.

[151] J.A. Nordlee, *Investigations of the Allergenicity of Brazil Nut 2D Seed Storage Protein in Transgenic Soybean,* FOOD SAFETY EVALUATION 151, 154 (1996), OECD DOCUMENTS (1996).

[152] *See* Mendieta, *supra* note 36, at 409.

[153] *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,987, 22,998-23,000 (May 29, 1992).

[154] *See* Mendieta, *supra* note 36, at 407.

[155] *Id.*; Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992) (stating that the FDA is unaware of any practical method for prediction or assessment of potential allergenicity of new proteins in food).

[156] *See id.* at 22,984. *See also* Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 343(a) (1997). The omission of labeling alerting consumers to the presence of foreign genes inducing allergenicity would make the label misleading. For example genetic material from peanuts introduced into tomatoes and found to cause allergic reactions in those with peanut allergies would need to alert consumers as they would be unaware otherwise.

[157] Mendieta, *supra* note 36, at 407.

Modified Trait in New Plant	**Gene Donor**
Herbicide Resistance	Mutant Petunia, Soil Bacteria, *Streptomyces Hygroscopicus* (bacteria)
Male Sterility	Bacteria
Insect Resistance	*Bacillus thuringlensis* (bacteria)
Virus Resistance	Viral Proteins (coat proteins)
Delayed Ripening	Tomato (antisense gene), Bacteria, Virus
Sulphur-Enriched Soybean	Brazil Nut

Pioneer Hi-Bred International transferred proteins from the Brazil nut *(Bertholletia excelsa)* in an attempt to increase the nutritional value of soybeans used as animal feed.[158] Nuts are a common human allergen;[159] testing established that the transferred gene kept its allergenic properties.[160] Therefore, Pioneer did not market the product due to the possibility it could be diverted to human use.[161]

Requiring products to carry a GMF label would allow highly susceptible individuals to avoid them. This is important because we can not predict the potential allergenicity of novel foods. Labeling provides a way to trace an allergic reaction to its source and to identify possible allergens. Labeling may help develop a list of potential allergens, as well as a list of serum donors for *in vitro* tests. An allergen databank is an important tool in addressing allergenicity.[162]

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[158] *Id.* at 407-10.

[159] *Id.*

[160] *Id.*

[161] *Id.* 2S-albumin was the substance transferred from the Brazil-nut to soybeans in which Pioneer found 2S-albumin kept its allergenicity properties. Animal models are usually not appropriate for testing human allergens. *Id. See also* Nordlee, *supra* note 151, at 151-54.

[162] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 23,000 (May 29, 1992).

B. Toxicity and Nutritional Value

Some of the problems encountered in determining the toxicity or nutritional value of novel foods are similar to those encountered in determining allergenicity. According to the WHO, "classical toxicity tests may have limited application in the safety assessment of whole foods."[163] The Institute of Toxicology National Food Agency of Denmark stated, "it is very difficult to use *in vivo* or *in vitro* models to assess the pathogenicity of GMO's for humans . . . ."[164] Traditional animal feeding tests were developed to assess food additives and similar components of food.[165] These constitute an insubstantial part of the human diet.[166] Animal feeding studies are problematic when dealing with certain foods that may be eaten in considerable quantities by humans.[167] There are confounding differences between species and between individuals within a species.[168] For example, studies show that exposure to certain carcinogens will affect mice and rats differently.[169] Lifestyle, age, gender, pregnancy, lactation, diet, environmental stres-

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[163] WORLD HEALTH ORG., JOINT FAO/WHO EXPERT CONSULTATION ON BIOTECHNOLOGY AND FOOD SAFETY (1996), available at <http://www.fao.org/es%A/esn/biotech/introd.htm#background> (visited Nov. 20, 1998).

[164] Bodil Lund Jacobsen, *The Use of In Vivo and In Vitro Models in the Testing of Microorganisms*, 1996 FOOD SAFETY EVALUATION 130, 132, OCED DOCUMENTS (1996).

[165] A.C. Huggett et al., *The Application of Human-type Diets in Rodent Feeding Studies for the Safety Evaluation of Novel Foods*, 1996 FOOD SAFETY EVALUATION 135, 135, OCED DOCUMENTS (1996).

[166] *Id.*

[167] *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 23,004 (May 29, 1992) (recognizing the limited sensitivity of animal feeding studies on whole food); E.J. Kok & H.A. Kuiper, *Evaluation of Strategies for Food Safety Assessment of Genetically Modified Agricultural Products–Information Needs*, 1996 FOOD SAFETY EVALUATION 80, 82-84, OCED DOCUMENTS (1996); Bruce Hammond et al., *Limitations of Whole Food Feeding Studies in Food Safety Assessment*, 1996 FOOD SAFETY EVALUATION 85 *passim*, OCED DOCUMENTS (1996); David Hattan, *Lessons Learned From the Toxicological Testing of Irradiated Foods*, 1996 FOOD SAFETY EVALUATION 11 *passim*, OCED DOCUMENTS (1996); Huggett, *supra* note 166, at 135-36.

[168] Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 HARV. ENVTL. L. REV. 409, 432-40 (1995). *See also* Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 U. ILL. L. REV. 103, 113, 116-25 (1996).

[169] Shere, *supra* note 168, at 435. For years scientists believed asbestos was not a carcinogen because animal testing did not produce cancer. Betanaphthylamine was not shown dangerous from animal testing. However, it is now known this chemical causes 100% bladder cancer in workers exposed for at least 5 years. *Id.* at 438.

sors, health, and genetic differences are all possible confounding factors that are usually not taken into account.[170] "[T]he dose-response models used to extrapolate from high-dose animal studies to lower-dose human exposures are based on the assumption that the exposed population is of uniform susceptibility."[171] "Risk assessments use a seventy-kilogram male with the general biology of a Caucasian, as a so-called reference man, in developing dose-response predictions and assume that this reference man is an appropriate surrogate for minorities, as well as women and children."[172] Risk assessors often lack necessary information on susceptibility of various population subgroups such as women, fetuses, infants, children, the sick, minorities, and the elderly. Thus, assessments may be inaccurate.[173] It is possible that "more time, effort, and money may have to be invested in carefully characterizing the nutritional influences of [novel foods]."[174] Given problems with animal studies, human studies may be necessary for some novel foods.[175]

The possibility of adverse effects of "inherent natural toxicants" is becoming more apparent.[176] Developing plants with increased natural resistance to pests "often leads to substantial increases of these compounds or even the presence of new compounds."[177] It is widely agreed that such natural toxicants pose a greater health risk than pesticide residues.[178] There is a great need for "improved methods of analysis to determine levels of natural toxicants of crops, foods, and derived products . . . ."[179] This is particularly critical for certain population groups which typically eat large amounts of certain foods, such as fruits and vegetables.[180] This research will require a comprehensive and accessible information system with data covering food plants and their inherent toxicants.[181] As of 1996, no such system was in existence.

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[170] *See* Kuehn, *supra* note 168.

[171] *Id.* at 125.

[172] *Id.*

[173] *Id.*

[174] Hattan, *supra* note 167, at 19.

[175] *Id.* at 20.

[176] J. Gry, *The Role of Databases: The Example of a Food Plant Database*, 1996 FOOD SAFETY EVALUATION 118, 118, OCED DOCUMENTS (1996).

[177] *Id.* at 119.

[178] *Id.*

[179] *Id.*

[180] *Id.* at 118-19.

[181] *Id.*; Kok & Kuiper, *supra* note 167, at 83-84.

Inherent natural toxicants, allergenicity, decreased nutritional value, and problems in risk assessment and evaluation are not unique to GMOs.[182] However, evaluation requirements for GMOs may have stimulated the search for more effective evaluation tools.[183] A recent study reported the efficacy of a modified rodent diet for use in evaluating novel foods, macroconstituents, and macronutrients.[184] Food plant databases are being developed for use in toxicological studies and in establishing substantial equivalence of novel foods to traditional foods.[185]

C. Antibiotic Marker Genes

Antibiotic marker genes are generally not considered a potential health problem.[186] Genetic transfer in the gastrointestinal tract is unlikely but cannot be entirely ruled out.[187] Due to lack of alternative medications, a food safety report from a joint FAO/WHO consultation advised against using certain antibiotic marker genes when the particular antibiotic is critical to treatment of certain diseases.[188]

D. Herbicide Resistant Plants

A weed is a plant that is not wanted where it is currently growing.[189] In developed countries, weeds are typically controlled with herbicides. Up to ninety-five percent of crop land in the United States and Europe is treated with herbicides yearly.[190] Herbicides have combinations of risks and benefits. For example: Paraquat acts on a wide range of weeds and breaks down rapidly, but is toxic to a wide range of animals, while Atrazine has low toxicity, but breaks down very slowly and in some places has polluted ground water.[191] Desirable plants can be genetically altered to be resistant to more environmentally friendly herbicides. Possible benefits include decreased produc-

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[182] *See generally* Shere, *supra* note 168. *See also* Gry, *supra* note 176, at 118-19; Hammond, *supra* note 167, at 87; Huggett, *supra* note 165.

[183] Kok & Kuiper, *supra* note 167, at 83; Gry, *supra* note 176, at 120.

[184] Huggett, *supra* note 165, at 135-41.

[185] Gry, *supra* note 176, at 120.

[186] Biotechnology and Food Safety Report of a Joint FAO/WHO Consultation, *6 Special Issues* (visited Nov. 9, 1998) <http://www.fao.org/es%2A/esn/biotech/six.htm>.

[187] *Id.*

[188] *Id.*

[189] REISS & STRAUGHAN, *supra* note 21, at 139.

[190] *Id.*

[191] *Id.* at 140.

tion costs, decreased herbicide usage, and better weed control. The result would include higher yields, decreased food costs, decreased use of more toxic herbicides, and less risk to ground water.[192]

Arguments against developing herbicide resistant plants are not necessarily centered on the genetic engineering issue. Some of the arguments also hold true for herbicide resistant plants developed using conventional plant breeding methods. However, herbicide resistant plants "are more likely to be developed through genetic engineering than through conventional plant breeding."[193] With conventional breeding, using crosses and selection to cultivate desirable traits, succeeding generations lose vigor because "unwanted recessive genes combine, and their unwanted trait becomes expressive."[194] GMOs will pass their traits to future generations as long as the genetically altered trait is dominant.[195]

One argument against development of herbicide resistant plants is a potential detrimental effect on small to moderate farms.[196] "[B]iotechnology will be a central component of industrialization."[197] It is argued that a few powerful agrochemical companies will dominate the market.[198] Farmers will eventually have less and less choice in the seeds and herbicides they use.[199] These companies will seek to protect their investment and increase profits by using contracts similar to those now used in the poultry industry.[200] This will tie farmers to the agrochemical companies.[201] Profuse contract farming may result in farmers losing their independence and becoming more like piece-work wage earners.[202] Companies may control production in order to maximize profits and recoup research investments.[203] The crop will belong

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[192] *Id.* at 140-41; ECONOMIC RESEARCH SERVICE AGRICULTURAL OUTLOOK-Part II of II, July 22, 1998 [hereinafter AGRICULTURAL OUTLOOK].

[193] REISS & STRAUGHAN, *supra* note 21, at 142.

[194] Dunn, *supra* note 26.

[195] *Id.*

[196] Neil D. Hamilton, *Reaping What We Have Sown: Public Policy Consequences of Agricultural Industrialization and the Legal Implications of a Changing Production System*, 45 DRAKE L. REV. 289, 290-96 (1997); Altieri, *supra* note 137.

[197] Hamilton, *supra* note 196, at 295.

[198] Middendorf, *supra* note 2.

[199] *Id.*

[200] Neil D. Hamilton, *Plowing New Ground: Emerging Policy Issues in a Changing Agriculture*, 2 DRAKE J. AGRIC. L. REV. 181, 189-90 (1997); Hamilton, *supra* note 196, at 293-96.

[201] Hamilton, *supra* note 196, at 293-96.

[202] *Id.* at 293-94.

[203] *Id.* at 295-96.

to the seed company, as will the seeds.[204] Contract farming may encourage the trend toward larger, concentrated farming. It is conceivably more economically efficient to contract with a few large farms rather than many small farms.

Further, it is possible that more, not fewer, herbicides and pesticides will be used.[205] For example, in the past glyphosate (a herbicide with the trade name of Round-up) could only be used before crops emerged from the soil; now glyphosate resistant crops can be sprayed throughout the growing season.[206] As more acreage is devoted to these crops and more glyphosate is used, the chance of weed resistance increases. Resistance increases the amount needed for effectiveness.

Finally, genetic drift may result in weeds becoming resistant to herbicides commonly used to control them. A 1996 research study found that genes inserted into oilseed rape rapidly moved to weedy relatives and the resulting hybrids were viable.[207] In the United States, genetic drift should not be a problem for corn and soybeans, as these do not have compatible relatives in the areas where they are grown. Genetic drift is primarily a concern where the genetically engineered plant has near-by "wild relatives." For example, crop beets easily hybridize with wild beets.[208] Projects are underway to develop a glyphosate resistant beet.[209] Wild weed beets are controlled using glyphosate.[210] Thus, there is a serious risk that resistance to glyphosate will be transferred to wild weed beets. Glyphosate resistance is a big concern for sustainable agriculture as it is "one of the few safe broad-spectrum chemicals."[211]

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[204] *Id.*

[205] REISS & STRAUGHAN, *supra* note 21, at 143; Altieri, *supra* note 137; Joseph Mendelson, *Round-up: The World's Biggest-Selling Herbicide*, ECOLOGIST, Sept. 1, 1998, at 270.

[206] Mendelson, *supra* note 205.

[207] Warren E. Leary, *Genes Inserted in Crop Plants Could Spread to Wild Relatives*, N.Y. TIMES, Mar. 7, 1996, at B14.

[208] REISS & STRAUGHAN, *supra* note 21, at 151.

[209] *See id.*

[210] *See id.* at 151. Monsanto, a large agrochemical company, admits that genetically modified rapeseed will outcross with wild relatives. Yet, Monsanto has developed herbicide resistant canola, also known as rapeseed. In 1998, "more than half of the 13.4 million acres of canola grown in Canada was herbicide-tolerant." David Lees, *Food By Design*, FIN. POST, Oct. 1, 1998, at 24.

[211] Keith Ramsay, *Super-Crop Peril for Seed Growers*, PRESS, June 18, 1998. Genetically modified Canola (rapeseed) can cross with other brassicas. "[W]here two canola (rapeseed) crops with different resistant genes were grown, it would not be possible to grow another GMO crop in the same field for 15 years without risking cross-

A newly introduced plant may "run amok" whether or not it is genetically engineered.[212] A primary concern regarding crops is that they generally have close "wild" relatives that are regarded as weeds.[213] Scientists are divided on the issue of whether adding one or a few genes to a plant will increase the likelihood of its becoming a problem weed.[214] There are scientists with impressive credentials on both sides of this argument.[215] Thus, caution is warranted since we cannot yet determine the long-term consequences, as plants often take a long time to become weeds.[216]

Proponents of genetic engineering argue that herbicide resistance of weeds may not pose a significant problem. A plant is only a weed when it grows where it is not wanted. Plants growing in forests, meadows, or roadsides are not usually sprayed with herbicides and thus should not present a problem. Herbicide resistance does not give wild plants special survival traits that would help them become dominant over non-herbicide resistant wild plants. Traits such as pest, frost, or drought resistance could enhance survival and are more problematic than herbicide resistance. Requiring products to carry a GMO label would allow people with ethical concerns to avoid partaking of products they find objectionable. The marketplace would be more transparent. Biotech companies would be held accountable more easily, giving the industry more incentive to address these and other similar issues.

E. Pest Resistant Plants

The EPA regulates pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[217] Pesticides must be registered with the EPA before they can be sold.[218] Under FIFRA, a pesticide is defined as "any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest, or intended for use as a plant regulator, defoliant or desiccant . . . ."[219] Products must pass safety review by the Office of Pesticide Programs (OPP) before

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pollination." *Id.*

[212] REISS & STRAUGHAN, *supra* note 21, at 148.

[213] *Id.*

[214] *Id.*

[215] *Id.*

[216] *Id.* at 150.

[217] Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1999).

[218] *See* 7 U.S.C. § 136a (1999).

[219] 7 U.S.C. § 136(u) (1999).

FIFRA registration.[220] The OPP defines a plant pesticide as "a substance produced in a plant that is intended to act as a pesticide and the genetic material necessary to produce that pesticidal substance."[221] Thus, a genetically engineered plant that resists a pest by producing a substance that is toxic to the pest is subject to pesticide regulations.

Plant pests cause serious crop losses. For example, the corn borer is responsible for losses in the hundreds of millions of dollars.[222] Yields of cassava, a dietary staple for much of the underdeveloped world, have been reduced thirty to eighty percent due to a virus.[223] Genetic engineering has the potential to increase yields and decrease pesticide use, resulting in decreased production cost. Thus, it may help feed a growing world population at the same time it is helping the environment.

Arguments against using genetic engineering to create pest resistant plants include: (1) introduction of allergens; (2) transferring pest resistance to weedy relatives of domestic crops; (3) evolution of new viruses; (4) evolution of super resistant pests; and (5) harm to animals, fungi, bacteria, and beneficial insects.[224]

The organic community is worried that creating pest resistant plants through gene transfer will hurt organic farming, beneficial insects, and birds.[225] Bacillus thuringiensis (Bt) is a microorganism that produces a natural pesticide (pest toxin).[226] Bt sprays are the single most important natural pesticide used by organic farmers.[227] It is biodegradable, leaves no toxic residues, and does not harm beneficial insects, birds, or mammals.[228] Bt genes have been successfully transferred into a wide variety of crops,[229] including corn, potato, rice, tomato, apple, walnut, and tobacco.[230] The organic industry would be severely injured if pests controlled by Bt spray became resistant.[231] At least one re-

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[220] John L. Kough, *US EPA Considerations for Mammalian Health Effects Presented by Transgenic Plant Pesticides*, 1996 FOOD SAFETY EVALUATION, OECD DOCUMENTS 156, 156 (1996).

[221] *Id.*

[222] REISS & STRAUGHAN, *supra* note 21, at 145.

[223] *Id.* at 146-47.

[224] *Id.* at 145-52.

[225] Sarno, *supra* note 18.

[226] *Id.*; AGRICULTURAL OUTLOOK, supra note 192.

[227] Sarno, *supra* note 18.

[228] *Id.*

[229] *Id.*

[230] *Id. See also* Erickson, *supra* note 18 (reporting on Bt genes being transferred into cotton).

[231] Sarno, *supra* note 18.

search study has found these pesticide resistant plants harm bees.[232] Another study found the Bt toxin harms beneficial insects.[233]

The success of Bt modified crops for increasing yields may be its downfall. The more concentrated the acreage planted, the more quickly pest resistance will develop.[234] University of Arizona entomologist, Timothy Dennehy, reported "[r]esistance is an inevitability with these products . . . I wouldn't be surprised if it starts this year."[235] Seed companies are requiring farmers to sign contracts to follow certain production practices in order to reduce the threat of resistance.[236] The EPA requires farmers planting Bt cotton to use four percent of their land as a pest refuge.[237] The Union of Concerned Scientists says current practices are not sufficient to save this "natural pest control."[238]

F. Growth Hormones

1. Animal Welfare Concerns

Posilac, derived from recombinant bovine somatotropin (rBST), is the first marketed agricultural product developed through genetic engineering.[239]

> rBST use in cows increases the likelihood of cystic ovaries, reproductive disorders, weight loss, fever, twisted stomachs, digestive disorders, lesions, lacerations of knees and feet, spontaneous abortions, . . . decreased immune function, higher rates of stress, internal bleeding, swelling at the injection site, enlargement of internal organs, increased intolerance to heat, higher rates of metabolic disease . . . . [It doubles] the likelihood of hoof rot, uterine infections, retained placentas, and ketosis . . . .[240]

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[232] Ho, *supra* note 34; Sarno, *supra* note 18.

[233] *See* Altieri, *supra* note 137; *Continuing Gulf Between US and EU over Biotech*, AGRA EUROPE, July 3, 1998, at A; Ho, *supra* note 34. Bt only affects these insects after they eat a pest that has ingested a Bt modified plant. Sarno, *supra* note 18.

[234] Erickson, *supra* note 18.

[235] *Id.*

[236] AGRICULTURAL OUTLOOK, *supra* note 192.

[237] International Dairy Foods Ass'n v. Amestoy, 93 F.3d 67, 75 (2d. Cir. 1996); Erickson, *supra* note 18.

[238] Erickson, *supra* note 18.

[239] Aboulafia, *supra* note 3, at 654.

[240] *Id.* at 627. The dissent in *International Dairy Foods Association* rejected the majority interpretation of consumer interest in labeling of milk from rBST injected cows as only curiosity. *International Dairy Foods Ass'n*, 93 F.3d at 78 (Level, J., dissenting). The dissent went on to list some of the possible harmful effects for rBST treated cows contained on the warning label on Posilac, the uncertainties involved in genetic

Results from animal research studies have not been consistent. Some researchers have found few adverse health effects;[241] others have found many.[242] Authorities agree that proper herd management is the key to successful use of rBST.[243]

Injected growth hormones produce leaner pigs, but have also produced adverse health effects in the pigs.[244] Currently, scientists are developing transgene pigs using Insulin-like Growth Factor-1 (IGF-1). "IGF-I helped reduce carcass fat and boost lean body mass, making

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engineering, possible harm to small farmers, and possible negative impact on human health. *See also* Stauber v. Shalala, 895 F.Supp. 1178, 1183-84 (W.D. Wis. 1995) (listing and accepting as undisputed facts, the possible adverse effects on health of cows injected with Posilac).

[241] *See* Junior C. Fontes et al., *Response of Brazilian Crossbred Cows to Varying Doses of Bovine Somatotropin*, 80 J. DAIRY SCI. 3234 (1997) (finding rBST treated cows had tended to have more mastitis than control cows, but finding no other adverse health effects); D.C. Jordan et al., *Effects of Recombinant Methionyl Bovine Somatotropin (Sometribove) in High Producing Cows Milked Three Times Daily*, 74 J. DAIRY SCI. 220 (1991) (finding no negative health effects from rBST); T.C. White et al., *Clinical Mastitis in Cows Treated with Sometribove (Recombinant Bovine Somatotropin) and Its Relationship to Milk Yield*, 77 J. DAIRY SCI. 2249 (1994) (reporting that research by Posilac developer and manufacturer Monsanto found no effect on clinical mastitis).

[242] *See* W.J. Cole et al., *Response of Dairy Cows to High Doses of a Sustained-release Bovine Somatotropin Administered During Two Lactations*, 78 J. DAIRY SCI. 111 (1992) (reporting that research by Posilac developer and manufacturer, Monsanto, found an increase in mastitis, swelling at injection sites, laming, delayed conception and increased incidence of abortion, and decreased reproductivity rates in cows injected with rBST); A.N. Pell et al., *Effects of a Prolonged-release Formulation of Sometribove (N-methionyl Bovine Somatotropin) on Jersey Cows*, 75 J. DAIRY SCI. 3416, at 3426 (1992) (finding more mastitis in cows treated with rBST than in the control cows and swelling at injection sites).

[243] *See Stauber*, 895 F.Supp. at 1191. The FDA approval of Posilac relied on Monsanto's label recommendations of herd management for control of adverse health effects, farmer knowledge of mastitis risk management, and data suggesting increase of mastitis due to Posilac "is not great enough to be significant." *See also* D.E. Bauman, *Bovine Somatotropin: Review of an Emerging Animal Technology*, 75 J. DAIRY SCI. 3432 (1992) (finding proper herd management critical for success): "With BST use, a unit of milk is produced with less feed and protein supplement and with a reduction in animal excreta (manure, urine, and methane)." Thus rBST use is good for the environment. Increased need for proper herd management is a function of increased milk production. Cows producing more milk require better herd management regardless of whether the milk increase is due to rBST, genetic selection, or increased milking frequency. *See* B.A. Crooker & D.E. Otterby, *Management of the Dairy Herd Treated with Bovine Somatotropin*, 7 VETERINARY CLIN. N. AM. FOOD ANIMIAL PRACT. 417-37 (1991).

[244] *Transgenic Pigs Could Lead to Leaner Pork*, EMERGING FOOD R&D REP., Aug. 1, 1998; Ho, *supra* note 34.

the hogs worth 6 dollars more at market than pigs without the transgene."[245] The good news for pigs is that IGF-1 does not appear to have negative consequences on their health.[246] However, there are unanswered human health issues regarding IGF-1.

Regardless of adverse effects for animals, it is unlikely this is a winning argument for banning products or methods. Many current farming practices such as "factory farming" arguably cause adverse effects for animal well-being or inflict unnecessary suffering on animals.[247] American animal welfare laws typically do not cover farm animals.[248] Individuals and organizations challenging farm animal treatment in court face tough, perhaps insurmountable, standing problems.[249] Labeling products based solely on method of production, which includes genetic engineering, is also likely to fail in a court challenge.[250]

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[245] *See Transgenic Pigs Could Lead to Leaner Pork*, *supra* note 244.

[246] *Id. But see Eating Genetically Altered Foods Can Be Hazardous to Health*, BUSINESSWORLD (Philippines), Nov. 6, 1998 (reporting on adverse effects in gene recipient pigs).

[247] *See* Steven J. Havercamp, Note, *Are Moderate Animal Welfare Laws and a Sustainable Agricultural Economy Mutually Exclusive? Laws, Moral Implications, and Recommendations*, 46 DRAKE L. REV. 645, 659-60 (1998); Barbara O'Brien, Comment, *Animal Welfare Reform and the Magic Bullet: The Use and Abuse of Subtherapeutic Doses of Antibiotics in Livestock*, 67 U. COLO. L. REV. 407, 408-21(1996).

[248] *See* Havercamp, *supra* note 247, at 664-67; O'Brien, *supra* note 247, at 407-09. Many state anti-cruelty and animal welfare statutes exempt actions that fall within "acceptable animal husbandry practices," leaving to the industry to set acceptable practices; other state statutes exclude farm animals from the definition of "animal." *Id.* Federal laws only protect livestock during transportation or slaughter. *See, e.g.*, Livestock Transportation Act of 1906, 49 U.S.C. § 80502 (1994) (protecting livestock during transportion); Humane Methods of Livestock Slaughter Act of 1978, 7 U.S.C. §§ 1901-1906 (1999) (covering slaughter of livestock); Animal Welfare Act of 1966, 7 U.S.C. §§ 2131-2159 (1999) (specifically exempting farm animals from the Act).

[249] *See* O'Brien, *supra* note 247, at 428-35. *See also* Animal Legal Defense Fund v. Espy, 23 F.3d 496, 503-504 (D.C. Cir. 1994) (finding plaintiffs were not within the zone of interest of the Animal Welfare Act of 1966, 7 U.S.C. §§ 2131-2159 (1992)).

[250] *See* International Dairy Foods Ass'n v. Amestoy, 93 F.3d 67, 73 (2d Cir. 1996); Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995); Animal Defense Fund of Boston v. Provimi Veal Corp., 626 F. Supp. 278 (D. Mass. 1986). *See also* O'Brien, *supra* note 247, at 435-37.

2. Human Health Concerns

The FDA approved rBST as safe for cows.[251] The FDA also determined its use will not have a negative impact on humans.[252] According to the FDA, there is essentially no difference between milk from cows treated with rBST and milk from untreated cows.[253] The WTO ruled against the European Union's ban on meat produced with growth hormones as a restriction on trade and a violation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS).[254] The WTO found that the European Union ban violated the SPS as it was not based on a risk assessment.[255] The WTO stated there was no evidence of "an identifiable risk to human health" from the use of growth hormones."[256]

Opponents state there are two major areas of human health concerns which have not been satisfactorily addressed. The first concern relates to the reported increase in mastitis in cows injected with rBST.[257] Mastitis is treated with antibiotics.[258] Although milk is tested for antibiotic residue, opponents argue that: (1) not all milk is tested;[259] (2) only

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[251] Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (1994). *See also* Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946 (1993) (approving rBST use and listing a host of possible adverse animal health effects).

[252] Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279, 6280 (1994).

[253] *Id.*

[254] *See* Steve Charnovitz, *The World Trade Organization, Meat Hormones, and Food Safety*, 14 Int'l Trade Rep. (BNA) No. 41, at 1781 (Oct. 15, 1997). *See* Kristin Mueller, Note, *Hormonal Imbalance: An Analysis of the Hormone Treated Beef Trade Dispute Between the United States and the European Union*, 1 DRAKE J. AGRIC. L. 97 (1996) for an analysis of the hormone dispute between the United States and the European Union.

[255] *See* Charnovitz, *supra* note 254.

[256] *Id.*

[257] Aboulafia, *supra* note 3, at 628-29.

[258] *Id.*

[259] *See* GAPS ANALYSIS, *supra* note 3, at 27. "US figures on violative antibiotic residues understate the true incidence of residues. Spot checks likely miss many drugs in use. The existing antibiotic testing program cannot guarantee that illegal residues are not present in the milk supply." *Id* at 4. The Canadian Health Team Review's goal was to determine whether required human safety issues were evaluated. *Id.* After reviewing material from the FDA, NIH, WTO, FAO, EU Commission, Monsanto, and numerous scientific studies, the review found the data failed to "properly address the human safety requirements of this drug under the Food and Drug Act and Regula-

four of the multitude of antibiotics available are tested;[260] (3) "BST use is associated with extensive off label use of antibiotics not approved for treating mastitis because those that are approved are relatively ineffective";[261] (4) mastitis from use of rBST requires longer drug use as it is harder to treat than naturally occurring mastitis "due to higher incidence of infection with S. aureus";[262] (5) overall drug use is increased due to the variety of animal health problems associated with rBST;[263] (6) increased animal antibiotic use is associated with increased pathogen antibiotic resistance;[264] (7) and there are multiple pathways for antibiotic resistant pathogens to infect humans and animals.[265] Thus, drinking milk containing antibiotics is not the only antibiotic danger presented by rBST use.

Antibiotic resistant bacteria are a major world health problem.[266] Scientists believe there is a link between antibiotic use in animals and antibiotic resistance of human pathogens.[267] Antibiotic use for livestock is "anywhere from 100 to 1000 times the amount as used for humans."[268] While scientists are asking for reductions in animal antibiotic use,[269] the FDA recently doubled the tolerance level of tetracy-

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tions." *Id* at 8.

[260] Aboulafia, *supra* note 3.

[261] GAPS ANALYSIS, *supra* note 3, at 27. *See also* Aboulafia, *supra* note 3, at 633 (reporting that "milk products may permissibly contain any one of eighty antibiotics currently used by the industry.").

[262] GAPS ANALYSIS, *supra* note 3, at 27.

[263] *Id.*

[264] *See* Aboulafia, *supra* note 3, at 629-31; O'Brien, *supra* note 247, at 414, 422-26; Chris Bright, *Super-Bugs Arrive*, 12 WORLD WATCH 911 (1999). Dr. George Khachatourians of the University of Saskatchewan reported in the Canadian Medical Association Journal that "abuse of antibiotics by farmers has created mutations of microbes such as salmonella and e. coli that can be passed on to humans in a number of ways." *Use of Antibiotics in Agriculture Creating Superbugs*, DES MOINES REG., Nov. 8, 1998, at 5 [hereinafter *Creating Superbugs*].

[265] O'Brien, *supra* note 247, at 426; Bright, *supra* note 264.

[266] Aboulafia, *supra* note 3, at 629-31; O'Brien, *supra* note 247, at 422-26.

[267] Aboulafia, *supra* note 3, at 629-31; O'Brien, *supra* note 247, at 422-26; Bright, *supra* note 264; Marian Burros, *Eating Well; U.S. Eases Up on Irradiation, Antibiotics*, N.Y. TIMES, Aug. 26 1998, at F5 (stating the National Academy of Sciences has found "humans can contract antibiotic-resistant infections from food animals.").

[268] Bright, *supra* note 264; Joan Murphy, *CSPI Petitions FDA To Ban Subtherapeutic Animal Drug Use; CDC Supports*, FOOD CHEMICAL NEWS, Mar. 15, 1999.

[269] *See* O'Brien, *supra* note 247, at 422-26; *Creating Super-Bugs, supra* note 264. The British, Danish and World Health Organization recommend that animal antibiotic use be restricted to treatment of infection only. *See also Farm Council: Few Conclusions Expected to Be Reached at October 19/20 Meeting*, EUR. REP., Oct. 17, 1998 (reporting that the Danish Minister, H. Dam Kristensen, asked the European Commission

cline in milk and approved the use of antibiotic fluoroquinolone in livestock.[270]

The second major health concern not adequately addressed is increased levels of insulin like IGF-1 in the milk of rBST treated cows.[271] The FDA did not find any difference between IGF-1 levels in milk from treated and untreated cows.[272] The National Institute of Health (NIH) stated "[m]ilk from rbST-treated cows contains higher concentrations of IGF-1."[273] Scientific studies report significantly increased levels IGF-1 in milk from treated cows compared to milk from untreated cows.[274] IGF-1 has been significantly correlated with various types of cancer in humans, including breast, colon, and prostate cancer.[275] "IGF-1 also can survive the GI tract environment to produce lo-

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to "prepare a regulation to control the use of antibiotics" due to the increase in disease resistant pathogens).

[270] Burros, *supra* note 267.

[271] Aboulafia, *supra* note 3, at 632-33; GAPS ANALYSIS, *supra* note 3, at 26.

[272] Aboulafia, *supra* note 3, at 632.

[273] *Id.* at 632-33 & n.199 (citing National Institute of Health, Technology Assessment Conference Statement, Bovine Somatotropin 8 (Dec. 5-7, 1990)).

[274] *Id.* at 632-33; GAPS ANALYSIS *supra* note 3, at 26 (reporting studies show substantial increases in the level of IGF-1 (36 x normal) in milk from treated cows in comparison to milk from non treated cows). *See also* J.A. Newbold et al., *The Effect of Bovine Somatotropin and Diet on Somatotropin Binding Sites in Hepatic Tissue of Lactating Dairy Cows*, 80 J. DAIRY SCI. 1085 (1997) (finding rBST treated cows had significantly increased concentrations of IGF-I compared with IGF-I concentrations in untreated controls); N.W. Tripp et al., *Methionine and Somatotropin Supplementation in Growing Beef Cattle*, 76 J. ANIMAL SCI. 1197 (1998) (finding administering bovine somatotropin to beef cattle significantly increased the levels of IGF-1).

[275] *See* Aboulafia, *supra* note 3, at 634-36; GAPS ANALYSIS, *supra* note 3, at 26. "Epithelial cells in the colon grow more rapidly in response to IGF-I at the levels typically found in milk. Acromegaly, a disease involving high endogenous IGF-I levels, is associated with increased risk of colon cancer and pre-cancerous colon polyps." *Id.* at 27. Adverse effects reported by NIH include an increase in a hormone that causes colon cancer to grow, a strong role in breast cancer, a probable role in a common adolescent bone tumor, implications in lung cancer, and factors which promote retinal neovascularization in mice. *Id. See also* Susan E. Hankinson et al., *Circulating Concentrations of Insulin-like Growth Factor-I and Risk of Breast Cancer*, 351 LANCET 1393 (1998) (finding premenopausal women to have a seven-fold increase in breast-cancer risk if they had increased blood levels of naturally occurring growth hormone IGF-1); R. Torrisi et al., *Effect of Fenretinide on Plasma IGF-I and IGFBP-3 in Early Breast Cancer Patients*, 76 INT'L J. CANCER 787 (1998) (noting "[g]rowing evidence substantiates the role of the insulin-like growth factor I (IGF-1) system in breast tumorigenesis."); A. Wolk et al., *Insulin-like Growth Factor 1 and Prostate Cancer Risk: A Population-based, Case-control Study*, 90 J. NAT'L CANCER INST. 911 (1998) (finding significant correlation between IGF-1 and prostate cancer). This 1998 study found a statistically significant positive association between serum levels of IGF-1 and

cal effects. Under exposure conditions, which would mimic the human scenario (i.e., in milk), IGF-1 appears also to be absorbed intact from the GI tract."[276] "IGF-1 resists pasteurization, stomach enzymes, and is well absorbed across the intestinal wall."[277] It has been postulated that IGF-1 may shorten the incubation period for Bovine Spongiform Encephalopathy (BSE), increasing the risk of infection.[278] In addition, " [i]ncreased IGF-I levels may increase the cows susceptibility to BSE and/or the BST-treated cow's need for increased protein magnifies the odds of exposure to a BSE infective agent."[279] Thus, rBST use may increase the risk of exposure to BSE infection.

One argument in defense of rBST use is that the amounts of IGF-1, antibiotics, or BST contributed to the milk supply from treated cows is diluted due to the pooling of milk.[280] First, it is important to remember that economic advantage is the only value to be derived from the use of rBST.[281] Even this advantage is questionable as the United States and Europe have surpluses of milk[282] and there may be an adverse effect on the economic status of small dairy farmers.[283] The argument that any adverse human health effects will be diluted due to pooling is difficult to justify under these circumstances. In addition, approximately one-third of all dairy cows in the United States are receiving rBST injections.[284] Some milk from untreated cows is diverted to processors who label their products as from cows not treated with rBST.[285] Demand for milk from untreated cows is experiencing rapid

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the risk of prostate cancer. The association was especially strong in men under 70 years old. The subject group consisted of 210 men with newly diagnosed, untreated prostate cancer and 224 matched control subjects. *Id*

[276] GAPS ANALYSIS, *supra* note 3.

[277] CHEMICAL BUS. NEWSBASE, *supra* note 274.

[278] GAPS ANALYSIS, *supra* note 3, at 26.

[279] *Id.*

[280] *See* Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant BST*, 22 COLUM. J. ENVTL. L. 227, 234 (1997). "[rBST] has no therapeutic or social value. It does not cure a disease or solve a health problem. It just makes cows produce more milk-at a time when we already have a surplus of milk." *Why Milk With RBGH Needs to Be Labeled*, 140 Cong. Rec. H2159 (statement of Rep. Bernie Sanders) [hereinafter Statement of Rep. Sanders].

[281] Statement of Rep. Sanders, *supra* note 280; Aboulafia, *supra* note 3, at 636-40, 654; GAP ANALYSIS, *supra* note 3, at 22.

[282] Aboulafia, *supra* note 3, at 637; Statement of Rep. Sanders, *supra* note 280; *Animal Welfare Group Calls for Ban on BST*, AGRA EUR. (London), Aug. 21, 1998.

[283] Aboulafia, *supra* note 3, at 636-40.

[284] *See Biotech Foods Continue to Grow*, EMERGING FOOD R&D REP., Oct. 1, 1998.

[285] *See* Ed Barna, *Dairy Industry Still Formidable in Vermont*, VT. BUS. MAG., Jan.1, 1998, at 59; Christine Blank, *Organic Milk Demand Booms*, AGRIC. FIN., Mar.

growth.[286] The pooled supply will likely contain increasing percentages of milk from treated cows due to likely increases in rBST use plus increased diversion of untreated milk.

Another argument is that IGF-1 is a naturally occurring hormone found in animals, humans, and their milk.[287] However, we do not drink human milk past infancy. Further, this does not counter the argument that increased levels of IGF-1 are correlated with various cancers and other health risks. The issue is whether increased ingestion of IGF-1 is correlated with increased levels of IGF-1.

The human health risk area is very controversial and the heavy hand of industry has served to further confuse the issue.[288] Relating to the IGF-1 controversy is a ninety-day rodent study by Monsanto which was:

> improperly reported, to conclude that rBST (Nutrilac) was not and could not be absorbed into the blood stream . . . The usually required long-term toxicology studies to ascertain human safety were not conducted. Hence, such possibilities and potentials as sterility, infertility, birth defects, cancer and immunological derangement's were not addressed.[289]

V. THE INTERNATIONAL SCENE

The continuing controversy over GMO issues, such as safety, animal welfare, long-term effects, lack of adequate standards, social effects, and threats to biodiversity and the environment have serious international trade implications. Countries can and have used these issues to ban products.[290] The United States is committed to advancing

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1, 1997, at 24; Becky Gillette, *Doin' a Body Good? Studies Link rBGH-Produced Milk and Increased Cancer Risk*, EARTH ACTION NETWORK, Sept. 1, 1998, at 42.

[286] Blank, *supra* note 285; Eric Zorn, *Drink Your Milk With a Healthy Dose of Doubt*, CHI. TRIB., July 7, 1998, at 1.

[287] *See* Burk, *supra* note 280, at 236-38; Gillette, *supra* note 285.

[288] Bereano, *supra* note 137; GAPS ANALYSIS, *supra* note 3; Nichols, *supra* note 3.

[289] GAPS ANALYSIS, *supra* note 3, at 34.

> In November of 1993, the FDA approved rBST zinc suspension to enhance milk production in lactating dairy cows, declaring that the milk from treated cows is safe for human consumption. The United States is the only developed country permitting the use of BST, of which there are four manufacturers. There are reports on file that Monsanto pursued aggressive marketing tactics, compensated farmers whose veterinary bills escalated due to increased side effects associated with the use of rBST, and covered up negative trial results. All four US manufacturers refused to disclose the lists of their research grants to US universities.

Id. at 13.

[290] Mueller, *supra* note 254, at 98, 102-05; Charnovitz, *supra* note 254; *EU Parlia-*

the interests of the biotechnology industry.[291] The United States has applied pressure on foreign governments and continues to treat GMF labeling as an unjustified barrier to trade.[292] The international standard setting committee, Codex Alimentarius Commission Committee on Food Labeling, has been unable to form a consensus on the labeling of GMFs.[293] During discussions, the United States faced stiff opposition from the European Union, India, several Asian nations, Consumers International, the Center for Science in the Public Interest, Greenpeace, organic farmers, and a host of other non-governmental groups.[294] A comprehensive discussion of international implications is beyond the scope of this paper. The goal of this section is to show that the controversy is continuing and some nations have progressed well beyond the United States in protecting the "public's right to know" and giving consumers information they believe will help them make informed decisions.

A. The European Union

The European Union and the United States are each others largest trading partners.[295] The United States and the European Union have been engaged in a protracted battle over the importation, production, and labeling of GMFs.[296] The European Union requires labeling of

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ment Demands Resistance to Lowered Food Quality Standards, 14 INT'L TRADE DAILY (BNA) 1492 (Mar. 12, 1998); Kathleen Hart, *Monsanto Changes Stand on Labeling Genetically Modified Food in EU*, FOOD LABELING NEWS, May 13, 1998; Sarno, *supra* note 18.

[291] *See* David Marchick, Deputy Assistant Secretary for Trade Policy and Programs, Bureau of Economic and Business Affairs, Remarks at the Global Agricultural Attache Conference (Sept. 1, 1998), U.S. Dep't St. Dispatch. Non-acceptance of GMFs is not confined to the European Union, but is a problem in many regions. This problem is expected to increase considerably as the number of GMOs increase and greater percentages of U.S. agricultural products contain GMOs.

[292] *See* Espiner Guyon, *Genetic Food Labels Drew US Threat*, EVENING POST, Sept. 30, 1998, at 3; Daniel Pruzin, *Labeling: United States Reiterates Complaint to WTO on EU Labeling of Genetically Modified Foods*, 15 INT'L TRADE REP. (BNA) 1572 (Sept. 23, 1998).

[293] *See Codex Food Labeling Committee Unable to Agree on GMOs*, FOOD LABELING NEWS, June 10, 1998.

[294] *Id.*

[295] Charles Lister, *A Sad Story Told Sadly: The Prospects for U.S.-EU Food Trade Wars*, 51 FOOD & DRUG L.J. 303, 311 (1996).

[296] *See Agriculture: Glickman Tells Argentines Biotechnology Should Be Top Priority in 1998 WTO Talks*, 14 INT'L TRADE REP. (BNA) No. 49, at 2143 (Dec. 10, 1997); *EU Ministers Establish Labeling Rule for Genetically Modified Organisms*, 15 INT'L TRADE REP. (BNA) No. 21, at 909 (May 27, 1998); Menyasz, *supra* note 62; Kevin

GMFs unless the protein or DNA resulting from genetic engineering "has been destroyed by successive stages of processing."[297] The European Union previously allowed commodities that were co-mingled, and thus may or may not contain genetically modified substances, to use a label stating the product may contain GMOs.[298] A 1998 regulation changed the "may contain" rule. There are now only two alternatives available for labeling GMFs: (1) a mandatory label stating the product contains a genetically modified substance; or (2) a voluntary label stating the product does not contain a genetically modified substance.[299] At least three companies have developed methods to detect the presence or non-presence of genes modified by recombinant DNA methods.[300] The European Union says it does not require segregation of GMF from non-GMF.[301] The biotechnology and food industries insist that mandatory labeling is too costly because it would require the industry to develop "separate transportation, production, and distribution systems."[302] However, Manna International says that segregation of non-GMFs, such as soybeans, has been going on for years.[303] At least sixty percent of all processed foods contain soybeans or soybean derivatives.[304] The United States has voiced a complaint to the WTO's Committee on Technical Barriers to Trade.[305] The United States considers the European Union labeling unjustified for most GMFs such as soybeans and maize because these foods are equivalent to non-GMFs.[306]

O'Sullivan, *US Likely to Force Its Hand on Genetically Modified Food*, IRISH TIMES, Nov. 20, 1998.

[297] Council Regulation 1139/98, 1998 Official J. (L. 159); 1998 O.J. (L. 173). *See also Genetic Engineering: Council Adopts Regulation on GMO Labeling*, EUR. REP. § 2319 (May 30, 1998).

[298] Regulation of the European Parliament and of the Council of the European Union, 258/97, 1997 O.J. (L. 043).

[299] Council Regulation 1139/98, 1998 O.J. (L. 159); 1998 O.J. (L. 173).

[300] Kathleen Hart, *Scientists Consider Testing Techniques to Detect Modified DNA in Foods*, FOOD CHEMICAL NEWS, July 13, 1998.

[301] *EU Ministers Establish Labeling Rule for Genetically Modified Organisms*, *supra* note 296.

[302] Menyasz, *supra* note 62.

[303] Hart *supra* note 300; *See also* Bereano, *supra* note 137 (discussing segregation of foodstuffs).

[304] *EU Weighs Stricter Labeling Rules on Genetically Modified Food Items*, 14 INT'L TRADE REP. (BNA) 2136 (Dec. 10, 1997).

[305] Pruzin, *supra* note 292.

[306] *Id.*

Consumer pressure is continuing in the European Union. The European Union is considering more extensive labeling and inclusion of food additives in the labeling law.[307] The European Union is considering a "moratorium on all new approvals for the marketing of GMOs" and planting of genetically altered crops.[308] A trade war between the United States and the European Union over the issue of genetic engineering is entirely possible.[309] These controversies are making headlines internationally and as such will likely increase awareness worldwide. It will also help GMF opposition groups in the United States. European Union actions influence countries around the world. For example, many South American countries support biotechnology, yet they typically do not approve a GMO until after the European Union has approved it.[310]

B. Japan

Japanese consumers have requested labeling of GMFs.[311] Many Japanese food makers, food retailers, and cooperatives are voluntarily labeling products as GMO free.[312] The Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) is expected to require labeling of GMFs.[313] Two plans are under consideration, both would result in mandatory labeling of most, if not all GMFs.[314] The MAFF will base

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[307] O'Sullivan, *supra* note 296.

[308] *Several Countries Consider Imposing Regulations on GMO Foods*, FOOD & DRINK WKLY., Oct. 19, 1998.

[309] O'Sullivan, *supra* note 296.

[310] Kathleen Hart, *Biosafety Protocol Could Impede Biotech Trade, Analyst Warns*, FOOD CHEMISTRY NEWS, Nov. 16, 1998 (discussing the likelihood of GMO labeling). "The winds are changing, and consumers want to know whether or not they're eating genetically modified (GM) foods." *Id.*

[311] *Labeling: Japan Plans Review of Standards for More Detailed Food Labeling*, 15 Int'l Trade Rep. (BNA) 1417 (Aug. 19, 1998); Sonni Efron, *Japanese Choke on American Biofood Genetically Altered Produce Reaps Opposition. But Moves to Label it Threaten $11 Billion in U.S. Sales*, L.A. TIMES, Mar. 14, 1999, at A1.

[312] *Japan Co-Ops Take Biofood Labeling in Own Hands*, ASIA PULSE, June 18, 1998. Japanese consumers are worried due to growing use of genetically engineered products by U.S. agriculture. Japan depends heavily on imports of U.S. soybeans which are used in the manufacture of important consumer foods such as tofu, soy sauce, and miso. *Id.*

[313] Henry I. Miller, *Japan Shouldn't Fear Thick-Skinned Tomatoes*, ASIAN WALL ST. J., at 10, Nov. 23, 1998.

[314] *Id. See also Agriculture: U.S. Grain Suppliers Express Concern Over Japanese Proposal on GMO Labeling*, 15 INT'L TRADE REP. (BNA) 1496 (Sept. 9, 1998) (discussing likely forms of labeling and consequences).

its decision on the results of a nationwide opinion poll.[315] The Ministry also intends to require labeling for products that have the potential to cause allergies and other health problems.[316]

C. Some Asian and Pacific Island Countries – Plus Islam's Reaction

Singapore's Minister for National Development called upon the Association of Southeast Asian Nations (ASEAN) to develop standards and procedures for regulating GMFs.[317] Singapore is courting the agricultural biotechnology industry and has established an Institute of Molecular Agrobiology.[318] "Several multinational companies have made Singapore their base to serve the Asia-Pacific markets in manufacturing, R&D, and marketing of agrobiotechnology products."[319] Asia is likely going to look favorably on any company that will bring money into their economy, particularly with the current financial crisis. However, even here consumer groups are pushing for moratoriums or labeling.

The Southeast Regional Institute for Community Education, based in the Philippines, has called for a moratorium on importation of GMOs into the Philippines.[320] The Pesticide Action Network (PAN) maintains there is inadequate regulation of GMOs.[321] PAN considers the potential for tragedy staggering and has called for labeling in order for public health organizations to be able to trace problems.[322] Asia-Pacific People's Assembly, an international group of non-governmental organizations, trade unions, activists, academicians, and professionals, is stepping up the fight against GMOs in Asian and Pacific Island countries.[323]

Asia and Pacific Regional Director of Consumers International stressed the need for Hindus, Muslims, and vegetarians to know

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[315] Miller, *supra* note 313.

[316] *Labeling: Japan Plans Review of Standards for More Detailed Food Labeling*, *supra* note 311.

[317] *See Agriculture: ASEAN Urged to Harmonize Regulations on Agricultural Biotechnology Products*, 15 INT'L TRADE REP. (BNA) 606 (Apr. 8, 1998).

[318] *Id.*

[319] *Id.*

[320] Johanna Son, *Philippines: "Mutant" Food Not Just a First-World Concern*, INTER PRESS SERV., Nov. 5, 1998.

[321] *Eating Genetically Altered Foods Can Be Hazardous to Health*, *supra* note 246.

[322] *Id.*

[323] Padmaja Padman, *Forum for Voicing Concern of the People in Asia-Pacific*, NEW STRAITS TIMES, Nov. 15, 1998.

whether certain animal genes have been used in GMFs.[324] The Islamic Jurisprudence Council is calling for GMF labeling so "Muslims can avoid contents prohibited by the Koran."[325]

D. Australia and New Zealand

Australia and New Zealand's Joint Food Regulatory Agency (ANZFA) has proposed a Bill requiring labeling of any GMF that is not "substantially equivalent" to a traditional food.[326] ANZFA's original draft guideline required mandatory labeling for the majority of GMFs.[327] Critics argue that the government has capitulated to pressure from threats by the United States that mandatory labeling would end any chance of a free trade agreement.[328] Eighty-nine groups have formed a grassroots campaign to galvanize citizens into demanding mandatory labeling of GMFs in Australia and New Zealand.[329] A national lobbying group, the Royal New Zealand College of General Practitioner's Working Party on the Environment, has called for a moratorium on all importation and production of GMFs.[330] Surveys show approximately ninety percent of consumers want labeling of all GMFs and a fierce battle is expected over the issue.[331] The Australian food industry has responded to consumer concerns by developing a "voluntary code of practice" which will call for companies to label GMFs.[332] The food industry is taking this stance in hopes of avoiding mandatory labeling.

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[324] *Consumers International Criticizes Labelling Body*, NEW STRAITS TIMES, May 30, 1998, at 5.

[325] *Islam OKs Transgenics*, CHEMISTRY WK., Nov. 18, 1998.

[326] *Labeling Genetically Modified Foods Proposed for Australia, New Zealand*, FOOD LABELING NEWS, Mar. 4, 1998.

[327] Guyon, *supra* note 292.

[328] *Id.*

[329] *Gene-Altered Foods OK for Humans, Says Royal Society*, EVENING POST, Sept. 23, 1998, at 29.

[330] H.D. Lovell-Smith, *Warning on Modified Foods*, EVENING POST, July 8, 1998, at 4.

[331] *Labeling Genetically Modified Foods Proposed for Australia, New Zealand*, *supra* note 326.

[332] Natalie Pargas, *Next Generation Biotech Products Will Face Traditional Labeling Issues in U.S.*, FOOD CHEMISTRY NEWS, July 13, 1998.

E. Canada

New Zealand, Australia, the European Union, and Canada have not approved rBST, despite years of industry attempts to gain approval.[333] The fight against rBST has been a hot item in Canada lately, bringing GMFs back into the public consciousness.[334] Canada is considering changing its current voluntary scheme to one requiring notification and possible pre-market approval.[335]

F. India and Africa

The two countries advocating for the strictest labeling laws for GMFs are India and Norway.[336] Indian consumer groups are seeking mandatory labeling of GMFs and mandatory safety testing.[337]

Twenty-four African countries issued a statement "objecting strongly that the image of the poor and hungry from our countries is being used by giant multinational corporations to push a technology which is neither safe, environmentally friendly, nor economically beneficial to us."[338] A common advertising message from the genetics industry is the desperate need for genetic engineering to feed the growing world population.[339] However, current food production is sufficient to feed the world.[340] World hunger is an access and distribution problem, not a production problem.[341] It is difficult to reconcile "feeding the world" with the newly developed "terminator technology" that will make the seeds sterile after their first use and thus prevent seed saving.[342] Saved seeds account for more than eighty percent of the

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[333] GAPS ANALYSIS, *supra* note 3, at 9.

[334] *Several Countries Consider Imposing Regulations on GMO foods*, *supra* note 308.

[335] *Id.*

[336] Burros, *supra* note 13.

[337] *See Indian Consumer Group Demands Labelling of GMF*, ASIA PULSE, Aug. 17, 1998.

[338] Kenny Bruno, *Monsanto's Failing PR Strategy*, ECOLOGIST, Sept. 1, 1998, at 287 (quoting a statement of the U.N. Food and Agricultural Organization Special Session on Plant Genetic Resources, Aug. 1, 1998).

[339] *See* Grossfeld, *supra* note 20.

[340] *See* Z. BISHAW & M. TURNER, U.N., *A Regional Perspective on Seed Security*, UN FAO INTERNATIONAL WORKSHOP ON SEED SECURITY FOR FOOD SECURITY (Florence, Italy), Nov. 30-Dec. 1, 1997, <http://www.fao.org/WAICENT/FAOINFO/AGRICULT/agp/agps/georgof/Georgo4.htm#Perspective>.

[341] *Id.*

[342] Grossfeld, *supra* note 20.

crop production in developing countries.[343] Farmers also sell or trade excess seed in local markets. These practices would interfere with profits.

CONCLUSION

This article has merely skimmed the surface of a scant few of the controversies surrounding agricultural genetic engineering. This article only peripherally covered some of the projected miracles of this new science, such as helping to prevent starvation by feeding the masses of humanity and helping the environment. However, even these obviously desirable and possibly achievable goals have associated controversies. The industry insists regulations and labeling must be based on sound science. However, scientists and scholars can be found on both sides of the GMO arguments. Opponents and proponents have used exaggerations, inaccurate statements, force, name calling, and "gutter tactics."[344] Some are more guilty or innocent than others, and surely there must be some who have been entirely neutral.

Industry insists GMOs are safe for human and animal consumption, as well as for the environment. This is misleading because of the uncertainties involved. We do not know the long term effects. We have not determined the safety for certain populations. We do not have assessment protocols for some health concerns. Regulatory agencies make determinations based on data supplied by the industry. There is a lot of trust and good faith built into the regulatory process. In some ways the industry is self-regulating, particularly in the area of the GRAS status of foods.

We put food into our bodies daily. What we choose to eat is a highly personal decision, and one we face each day of our lives. Some of us give it little thought. Others consider it one of the most important decisions they make. Consumers lose faith in the industry and in the government when these entities deny them information they believe is "material" to making informed decisions. Force feeding is repugnant. People will likely become suspicious if a fierce and noisy battle between opponent and proponents comes to the United States. People who might have paid little attention to the issue will become more interested as the fighting intensifies.

The battle over labeling of GMFs and inadequate regulation of the

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[343] BISHAW & TURNER, *supra* note 340.

[344] Bruno, *supra* note 338; Grossfeld, *supra* note 20; Lambrecht, *supra* note 3. *See also supra* notes 1-4.

industry is moving to the United States.[345] Consumers in the United States, for the most part, are unaware of the amount of GMFs and so it is difficult to judge their likely reactions to anti-GMO campaigns.[346] Consumer polls show differing results.[347] Organic consumers appear to be both aware of GMFs and adamantly opposed to GMFs.[348]

Labeling will provide a level of transparency that is missing in the United States. Labeling will help health agencies trace problems should they develop. Labeling will give an incentive for industry to develop better testing methods. Industry will try to justify the tremendous increase in GMFs and allay consumer unease with advertising campaigns which will improve consumer awareness and knowledge. As opponents will challenge the industry campaigns, public debate will ensue. This will eliminate secrecy, and industry will be held accountable in a public arena.

The best strategy for industry is to encourage labeling and transparency. This will show they have nothing to hide or fear. Being "upfront" with consumers has paid off for one biotech firm in Britain. It joined with two large retailers to market tomato paste clearly labeled as a GMF.[349] Surprisingly, the GM paste outsells traditional pastes.[350] The biotech giant, Monsanto, is no longer opposing the labeling of GMFs in the European Union.[351] This puts Monsanto in contradictory positions because it opposes labeling in the United States.[352] A Monsanto spokesperson in the European Union said: "People want to see you're being open with them. It's a question of transparency, openness, and trust."[353] This is exactly what critics have been saying for years. Monsanto and the industry will have their words and actions thrown back at them if they continue to talk and act in contradictory ways. It is critical for the industry to coordinate a common, consistent, and believable stance as labeling of GMFs seems to be the wave of

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[345] Grossfeld, *supra* note 20.

[346] Bruno, *supra* note 338; Burros, *supra* note 13.

[347] *Continuing Gulf Between US and EU Over Biotech*, *supra* note 233 (reporting contrary results from two consumer opinion polls on labeling of GMFs).

[348] Burros, *supra* note 13.

[349] Brandon Mitchener, *Tomato Wars: Safeway, Sainsbury's Say Novel Paste Hits Spot in Britain*, WALL ST. J. EUR., Nov. 16, 1998, at 1.

[350] *Id.*

[351] Scott Kilman, *Monsanto Brings 'Genetic' Ads to Europe*, WALL ST. J., June 16, 1998.

[352] *Id.*

[353] Hart, *supra* note 290.

the future.[354]

[354] *See* Hart, *supra* note 310.