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Transgenic Agriculture: Biosafety and International Trade
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Transgenic Agriculture: Biosafety and International Trade†

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Michael Baram:[1]

1. We stand at the threshold of a new century that will bring novel methods of producing foods, industrial materials, pharmaceuticals, and other products important to society and industry.[2] Today's session will, therefore, address a subject of great importance: the introduction of genetically modified crops, livestock, microorganisms, and other substances into agriculture and related fields, made possible by American and foreign corporate biotechnology.

2. But these genetic advances and their potential benefits[3] are not without controversy.[4] Over the last few years, genetically-modified crops and microorganisms have moved from contained laboratories into commerce and the open environment.[5] Despite testing and other assurances of their safety,[6] there are persistent concerns and some research findings that such products pose threats to ecosystems and consumer health, and to the sustainable development aspirations of developing nations.[7]

3. Thus, concern about "biosafety" has arisen and poses complex issues in policy debates in the United States[8] and abroad,[9] in forums such as the United Nations ("UN"), the European Community,[10] and various non-governmental organizations.[11]

4. After talking with today's speaker and panelists, I see four central issues for discussion. First, does transgenic agriculture pose foreseeable risks to the environment and human health? In addressing this issue, we need to consider recent developments, such as the release of genetically modified microorganisms to combat pests and the

harvest of genetically modified crops which are entering the food chain and now reach the dinner table.[12]

5. Second, biosafety in transgenic agriculture raises a number of critical risk management questions.[13] If transgenic agriculture does present risks, are the risks manageable? Is risk management convenient and affordable for all nations, or does it require sophisticated technology and expertise available only to wealthy countries such as the United States? What steps need to be taken to shape individual and collaborative efforts to manage risk?

6. Several organizations have enacted guidelines for preventing biosafety problems. These guidelines address the technology itself, the need for public education, public involvement, and agricultural training, which raise the third important issue.[14] Are the guidances sufficient and will they be followed?[15] Regulation is not the easy answer from any standpoint. If regulation would be beneficial, should it be technical and rescriptive,[16] an approach we seem to have abandoned in addressing other risks?[17] Alternatively, should regulation focus on performance, with final outcome criteria, and thereby afford more flexibility to the regulated parties?[18] Which institutions should be authorized to manage the risks?[19] Should farmers and other members of the private sector be encouraged to selfregulate? [20] Should responsibility devolve to nations or to nongovernmental organizations?[21] Overall, what infrastructure is needed to maximize the benefits and minimize the risks of this promising new area of technology?[22]

7. Finally, there is the fourth issue to consider here: in addressing these technological and regulatory issues, can we also achieve results which are consistent with principles of free trade? Countries which support multilateral programs to address the risks of genetically engineered products might reconsider if the programs and strictures impair their ability to trade. And should trade be premised on technology transfer to developing nations, in order to develop their capacities and lessen their dependence on multinational biotech agriculture companies and western expertise - an issue that is likely to influence which nations support or reject any binding international agreements and subsequent regulations.

8. We have a most highly-qualified speaker to discuss these complex issues, Dr. Calestous Juma. Dr. Juma is a distinguished scholar, researcher, and author of many books and articles on biotechnology, agriculture, and biodiversity, and serves as Executive Secretary of the United Nations Convention on Biological Diversity ("CBD" or "Convention").[23] The Convention has been ratified by more than 150 nations, with the United States as one of the few non-ratifying countries.[24] The ratifying nations are now devoting their energies to establishing a biosafety protocol, that would be legally binding at the international level.[25] In directing the CBD, Dr. Juma's responsibilities are to protect global biodiversity and promote sustainable development. He now has the additional task of presiding over the CBD Working Group that is developing the biosafety protocol. We are honored to have him here.

9. Our panelists are also leaders in their respective fields. Professor Sheldon Krimsky is a risk policy analyst and biosafety specialist at Tufts University. He is also the author of illuminating books and reports on the subject of genetics and agriculture.[26] Rufus King is

an attorney for biotechnology companies at the Boston law firm of Testa, Hurwitz & Thibeault. Richard Godown represents BIO, the trade association of biotechnology companies.[27]

Calestous Juma:[28]
10. I am very happy to take this opportunity to share with you some of the developments that are taking place under the Convention. Before I get into the issues relating to the international regulation of biotechnology, I would like to spend a few moments giving you some background about the evolution of the concepts under the Convention. The United Nations has a long history of involvement with environmental issues through internal bodies such as the United Nations Environment Programme ("UNEP").[29] Indeed, the UNEP played a central role in facilitating the initial working papers and other materials that evolved into the text of the Convention.[30] In 1992, the United Nations sponsored the Conference on Environment and Development, known as the Earth Summit, in Rio de Janeiro, Brazil, to discuss a variety of issues that confront the threats to natural habitats and ecosystems. The Convention, a particularly important element of that Conference, is designed to look at ecological issues within a larger context.

11. The objectives of the Convention are both simple to express and difficult to achieve. To quote the Convention itself: The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefit arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.[31] This single sentence embraces a primary concern for three issues which will take significant effort to reconcile in the real world: conserving the wealth of organisms and biological differences that exist on earth and intricately work together to make the planet fruitful and habitable; finding ways to continue to use the earth's resources in a environmentally sensitive and sustainable way; and determining an equitable way to share the benefits and control the risks of the technologies and human activities that exploit these resources.

12. The Earth Summit provided a focused opportunity for gathering nations to sign the Convention, which was signed by more than five times the minimum number required to begin future work on binding international agreements in this area.[32] The parties to the CBD understood its role as an unprecedented initial step to greater international understanding and cooperation on issues that span the line between species and ecosystems. Consequently, the ratifying parties left the development of substantive rules used to guide scientific and economic issues to an *ad hoc* and ongoing Working Group.[33] This Working Group has met several times, and through a process of stating positions and discussion, has begun to develop a more common understanding of the elements that a binding international protocol on biological diversity should contain.[34] This work builds on a preliminary effort made by a group of experts at the first meeting of the conference of parties to the CBD at Nassau, Bahamas, in December 1994.[35]

13. One advantage within the Convention is that by establishing an ongoing

Working Group to grapple with the technological and implementation issues that must be addressed in a protocol, the many diverse interested parties have an opportunity to observe the development of international law in this area.[36] Though openness may elicit disparate views on this subject from party and non-party nations, environmental groups, and members of related industries,[37] it also helps those working on the protocol to identify the most critical issues.[38] One hope is that this debate within the Working Group begins that path to consensus and concludes with a strong protocol that will not only protect current parties to the Convention, but will also attract a voluntary commitment to environmental health, technology security, and cooperation by non-parties.

Sheldon Krimsky:[39]
14. I want to say a few words about the substantive body of issues that the Working Group and others have begun to address. Of particular concern are the genetically modified products that are emerging and the grassroots opposition to them in many countries.[40]

15. Much of the controversy about biotechnology is focused in Europe, where some countries refuse to accept certain products, though they are willing to buy and use others.[41] Considerable European opposition stems from a concern that the United States is merely using the World Trade Organization[42] to pressure nations to accept American products without giving proper credence to European concerns.[43] Aside from the political misgivings these European countries have about allowing American products to enter their markets at all,[44] this contentious situation underscores the need to listen and address the risk management issues that accompany the advancement and increasing use of biotechnology.

16. In 1992, Dr. Calestous Juma was one of the cosigners and authors of a report by the International Service for National Agricultural Research ("ISNAR").[45] The report was a first effort to articulate some of the problems in evaluating the biosafety of this new generation of products.[46] With no viable products on the market at the time the report was published, it was mainly a theoretical exercise.[47] The report contained some of the central ambiguities and contradictions of our discourse on biotechnology.

17. One of the greatest tensions in that report, and in reality, is between power and risk. Some members of the biotechnology debate are caught in this dilemma by saying that the power of new biotechnology is unique but the risks are conventional. For example, the ISNAR report quoted a National Research Council publication that said, "The molecular methods have great power because they enable scientists to isolate genes and to transfer them across biological barriers."[48] That statement emphasizes the uniqueness of gene splicing, but the authors diminish its importance by quoting from the same National Research Council document that says, "Crops modified by molecular and cellular methods should pose risks no different from those modified by classical genetic methods for similar traits."[49] This creates a strange ambiguity. On one hand, it is alleged that we

control this great power because we can cross species barriers, while on the other hand, we treat this power as if it is no different than traditional hybridization.

18. This false inference is often made because of confusion between precision and predictability. Recombinant DNA techniques are more accurate, or precise, than classical techniques for modifying organisms.[50] Simply because scientists have higher levels of skill at creating technological applications for the fields of biology and agriculture does not mean that they necessarily have the insight to foretell, or predict the consequences of the technology, such as the properties of a living modified organism.[51] The result is an unfounded leap from understanding genotypes[52] to thinking we understand phenotypes[53] to believing we can predict ecological impacts.[54] There is no knowledgeable basis for moving from understanding genotypes to predicting ecological effects.[55] Simply predicting which genes are in the new organism does not provide a sound foundation for guessing the likely ecological effects of releasing that organism into the wild.[56] Nor does this intellectual leap identify the particular types of risks about which we should be concerned.[57]

19. There are two types of risks in this area, which I call first- and secondorder effects. Consider the implications of genetically modifying a plant. A firstorder effect could be the creation of an ecological imbalance that adversely impacts humans or human systems, such as reducing the nutritional value of the transgenic plant.[58] Second-order effects are less direct. For example, they might occur when growing a genetically modified plant that is susceptible to pests and requires large amounts of a certain herbicide. Over use of the herbicide might cause weed resistance and eventually diminish the herbicide's utility.[59] Second-order effects often escape regulatory oversight in the United States. In reality, these two types of risks, and their effects, may overlap.

20. A high profile example of a transgenic food issue is the bovine growth hormone used to stimulate milk production in dairy cows.[60] This example demonstrates our reoccupation with first-order effects without a commensurate concern for second-order effects. In the debate over the bovine growth hormone, proponents and opponents alike focused on its health effects for human cow-milk consumers.[61] When the mainstream scientific community could not point to direct human health effects from the hormones,[62] the hormones were permitted for use in American dairies[63] without any significant investigation of secondary effects on humans or animals. The necessary regulatory oversight was absent, failing even to insist that the public be informed about hormones through appropriate labeling.[64] Litigation will be the unfortunate result of this misunderstood and underappreciated risk.

21. The risk assessment protocols that we have in the United States are woefully inadequate. What we have amounts to a voluntary system for assessing the risks of transgenic food. Companies that make new food products regulate themselves by comparing their products against certain guidelines issued by the Food and Drug Administration ("FDA"). If businesses decide that their genetically modified products and foods meet the guidelines, then they are free to produce, market, and sell their products without any significant governmental oversight.[65]

The system relies on the corporations that produce genetically modified foods to identify to the FDA any products that are out of compliance with the most basic and routine safety regulations. The FDA does not conduct an analysis of every food product made by transgenic methods.[66] I think this failure to impose stricter scrutiny comes from the initial false inference I mentioned.[67] I believe that the FDA assumes that when you put foreign genes into food, even if the genes cross species lines, the new variety is substantially equivalent to the old.[68] The FDA accepts, uncritically, the analogy between genetically modified food and hybridization of two crops in the same family.[69] Instead, genetic modification is much more like putting a peanut gene into a tomato than crossing two strains of corn.

22. As important as regulatory oversight of the production phase is, it should also be of concern that we have no systematic tests for evaluating the allergenicity of transgenic food products, a first-order effect that should provoke significant concern.[70] America does not have a single agency committed to testing for human allergic reactions to genetically modified food products.[71] Human beings have an amazingly wide range of tolerance but also a wide range of allergies to plants that are used as foods.[72] My concern is that when we begin mixing proteins across species lines, we could find that people will become allergic to some of the new foods.[73] Without testing, these effects can be unpredictable and deadly.[74]

23. Another concern is that when plants are genetically modified by mixing proteins across species lines, some of the transferred proteins will come from bacterial genes.[75] That, too, may cause allergic responses. In addition, it may cause new types of antibiotic resistance, a second-order effect.[76]

24. I propose that we need to know the full scope of the effects of transgenic agriculture before we encourage it. Simply guessing that a transgenic plant or product will be safe because the unmodified products were genetically safe, perhaps with minimal human allergenicity, is not an appropriate response to the potential risks. Today's trend in biotechnology is to treat our current food sources as the feed stock for a new food industry.[77] If this view is analogous to the evolution of the chemical industry, from the use of naturally occurring chemicals to the modern synthetic chemical production, then there will be an enormous exchange of proteins across all the food types.[78] Whether this is an expansion that people desire is another question altogether.[79]

25. I recently spoke with a woman who is a member of the National Institute for Environmental Health Sciences.[80] She has worked on hormones throughout her scientific career. When I asked her whether she would drink milk that was produced with bovine growth hormones, she emphatically said, "No," that she would choose milk without the hormone every time. Her decision was not based on any hard data, but rather a visceral feeling about the current state of events, which does not give individuals an opportunity to choose whether to accept exposure to unknown risks.[81] The concern stems from private industry's control of research, development, and risk assessment of genetically engineered organisms, all without governmental oversight.[82] I wonder how much confidence we can have in the data, which are not

generally available to the public and are produced by the companies that own transgenic products. The question of trust should prompt us to consider whether we have a sufficient number of disinterested scientists to review these new products independently and to evaluate the industry's tests.[83]

26. If these problems create significant and deep divisions in America, there is little doubt that we have a long way to go in proving the safety of transgenic products before the world community will accept them. American industry and policymakers must be more sensitive to the fact that opposition to American biotechnology from certain countries may not be based upon a well-defined and specific endpoint risk.[84] Rather, international distrust of American biotechnology stems from a logical reaction to a lack of vital information about the risks and benefits of genetically modified organisms and plants. The remedy for this distrust is to provide more information and enough time to understand and evaluate the data independently.

27. Food security is a pressing issue for many nations. When countries that face the brunt of food shortages and malnutrition show hesitance toward adopting the new technologies out of fear that they will jeopardize their fragile indigenous agricultural systems, the world, and especially the biotechnology producers, needs to pay close attention. People need sufficient time to understand what is happening to their food supply.[85] To transform the world's food supply, we will need a much better sense of the timing that it takes to do good risk assessment and the techniques required to evaluate whether these products will pose first or second order risks to the world community.

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* *Editor's note:* Four persons originally participated in this Symposium. Because of unavailability prior to publication, the comments of one person, Mr. Richard Godown of BIO, have not been included.

1 Michael Baram is a professor of law at Boston University School of Law. He is also the Director of the Boston University Center for Law and Technology.

2 *See* Robert J. Frederick & Margaret Egan, *Environmentally Compatible Applications of Biotechnology*, 44 BIOSCIENCE 529, 529 (1994) (discussing uses of biotechnology in bioremediation, bioleaching, natural plastics, clean fuels, and agriculture).

3 *See* Cath Blackledge, *Genetic Science Know-How Will Determine Leadership in 21st Century, Says Sykes*, PHARMACEUTICAL BUS. NEWS, July 16, 1997, *available in* LEXIS, Market Library, PROMT File (discussing statements made by the chairman of Glaxo Wellcome about the future of the pharmaceutical industry); *see also* Steve Sternberg, *Prospecting or Modern Day Colonialism? Ethicists Examine Who Profits from Genetic Research*, BIOWORLD TODAY, May 8, 1996, *available in* 1996 WL 9518319.

4 *See* Maurizio G. Paoletti & David Pimentel, *Genetic Engineering in Agriculture and the Environment: Assessing Risks and Benefits*, 46 BIOSCIENCE 665, 670-71 (1996) (listing the following

"questionable uses of genetic engineering": the use of growth hormones in dairy cattle, the use of microbes for pest control, and the release of genetically engineered organisms).

5 *See id.* at 665, 668 (citing *1993 Group of National Experts on Safety in Biotechnology*, ANALYSIS OF FIELD RELEASE EXPERIMENTS (Organization for European Cooperation and Development, Paris, France) May 14, 1993 & Sept. 1993 update). Paoletti & Pimental also state that since 1992, more than 2000 genetically engineered plants have been released without any problem. *See id.* at 668.

6 *See id.* at 665 (explaining that genetic engineering and the use of transgenic species has reduced the time required to develop new crops and improve farming in developing countries).

7 *See* Michael Freemantle, *U.K. Panel Urges Gene Modification Protocol*, CHEMICAL & ENGINEERING NEWS, Feb. 5, 1996, at 9 (reporting an independent advisory panel's warning that new rules are needed to avoid large scale environmental problems).

8 *See generally* Isaac Rabino, *What U.S. Researchers Think of Regulations and Regulators*, 14 BIO/TECH. 147, 147 (1996) (reporting that most U.S. researchers using recombinant DNA "would prefer a centralized unit to be responsible for regulating biotechnology").

9 *See* Michael Baram, *LMO's: Treasure Chest or Pandora's Box?*, 104 ENVTL. HEALTH PERSP. 704 (1996). LMO's are living modified organisms, a term used interchangably with genetically modified organisms (GMOs).

10 *See* Brian Kirsop, *European Union's Drive Toward a Single Market is Moving a Set of European Biotechnology Standards Nearer Completion*, GENETIC ENGINEERING NEWS, Sept. 15, 1997, *available in* 1997 WL 8970594 (reporting on the European Committee for Standardization's efforts to form common standards for "biosafety, . . . containment of genetically manipulated organisms (GMOs), their release and marketing, and protecting the health and safety of workers using GMOs").

11 *See* Frederick & Egan, *supra* note 2, at 534 (listing international organizations that have established biotechnology regulations).

12 *See* Paoletti & Pimentel, *supra* note 4, at 666 (discussing the introduction of new genes into crops and livestock).

13 *See id.* at 533-34 (discussing the need for regulation to control the risks associated with biotechnology and transgenic research); *see also* Ted Plafker, *First Biotech Safety Rules Don't Deter Chinese Efforts*, 266 SCIENCE 966, 966 (1994) (reporting on Chinese releases of transgenic plants and organisms into the environment).

14 *See generally Environmental Release of Genetically Engineered Organisms: Recasting the Debate*, GENEWATCH (Comm. for Responsible Genetics, Boston, Mass.), Mar.-June 1988, at 1, 2, *reprinted in* COUNCIL FOR RESPONSIBLE GENETICS, GENETIC ENGINEERING: UNRESOLVED ISSUES (1992).

15 *See* Rabino, *supra* note 8, at 147 (reporting researchers' opinions of various U.S. agencies' regulatory efforts).

16 *See id.* at 150 (stating that researchers favor risk assessments of their products instead of regulation of the processes used to develop the products); *see also* Paoletti & Pimentel, *supra* note 4, at 665 (asserting that U.S. deregulation of transgenic agriculture followed by the release of genetically engineered organisms into the wild would be a danger).

17 *See AGBIOTECH: USDA Simplifies Approval Rules*, APPLIED GENETICS NEWS, Sept. 1, 1997, *available in* LEXIS, Market Library, PROMT File (reporting amended regulations pertaining to procedures for obtaining non-regulation status of field tests of genetically engineered plants); *see also* Specification of Requirements and Procedures for Genetically Engineered Organisms, 60 Fed. Reg. 43,567, 43,567 (1995) (proposed Aug. 22, 1995) (proposing "to simplify procedures for the introduction of certain genetically engineered organisms").

18 *See* Rabino, *supra* note 8, at 150 (stating researchers disfavor regulation of process).

19 *See id.* at 147-50 (discussing industry opinions of current institutional regulations).

20 *See* Kathryn S. Brown, *Life on the Molecular Farm: Transgenic Plants Are Extending the Range of Chemical Production Possibilities in Agriculture*, 46 BIOSCIENCE 80, 83 (1996) (discussing the application of the USDA's easing of regulations for genetically engineered organisms and criticism that the move places too much responsibility in private hands).

21 *See id.*

22 *See* Paoletti & Pimentel, *supra* note 4, at 671 (concluding that transgenic agriculture has

potential benefits, but without regulation and control, these benefits will be jeopardized).
[23] Convention on Biological Diversity, *opened for signature* June 5, 1992, 31 I.L.M. 818.
[24] *See* PARTICIPATION IN WORLD TREATIES ON THE PROTECTION OF THE ENVIRONMENT: A COLLECTION OF DATA 268-71 (Maria Clara Maffei et al. eds., 1997) (listing parties to the Convention on Biological Diversity).
[25] *See* Convention on Biological Diversity, *supra* note 23, art. 28, 31 I.L.M. at 834; *U.N Expert's Meeting Recommends Protocol on Genetically Modified Organisms*, [1995] 18 Int'l Env't Rep. (BNA) No. 16, at 599 (Aug. 9, 1995).
[26] *See, e.g.,* SHELDON KRIMSKY, BIOTECHNICS AND SOCIETY: THE RISE OF INDUSTRIAL GENETICS (1991); SHELDON KRIMSKY & ROGER P. WRUBEL, AGRICULTURAL BIOTECHNOLOGY AND THE ENVIRONMENT: SCIENCE, POLICY, AND SOCIAL ISSUES (1996).
[27] *Editor's note:* Mr. Godown was unavailable prior to this publication, and his remarks have, therefore, been
deleted.
[28] Calestous Juma is the Executive Secretary of the Convention on Biological Diversity.
[29] *See Biosafety Under the Biodiversity Convention* (visited Nov. 6, 1997) <http://www.iisd.ca/linkages/vol09/0948003e.html> (UNEP is also attempting to develop technical guidelines for biosafety).
[30] *See* Convention on Biological Diversity, *supra* note 23, 31 I.L.M. at 818 *microformed on* Readex No. [ST/]DPI/1307] (Dept. of Pub. Info.) (providing a brief history of the international efforts preceding the CBD's adoption).
[31] *See* Convention on Biological Diversity, *supra* note 23, art. 1, 31 I.L.M. at 823.
[32] *See* PARTICIPATION IN WORLD TREATIES ON THE PROTECTION OF THE ENVIRONMENT, *supra* note 24, at 268-71.
[33] *See* Convention on Biological Diversity, *supra* note 23, arts. 28-29, 31 I.L.M. at 834-35.
[34] *See Governments Start Talks on Biotechnology Safeguards* (visited Oct. 23, 1997) <http//:www.biodiv.org/press/pr7-96.html> (releasing information about the meeting of the Working Group at Aarhus, Denmark); *see also A Brief Analysis of the Meeting* (visited Oct. 18, 1997) <http://www.mbnet.mb.ca/linkages/vol09/0948014e.html> (describing some of the political alignments and negotiations at the Aarhus meeting, including initial attempts to determine what terms must be defined and agreed upon); *Consideration of the Priority Consensus Elements of the Madrid Meeting* (visited Oct. 18, 1997) <http//:www.iisd.ca/linkages/vol09/0948000e.html> (noting progress on identifying a working structure for a protocol at the Working Group meeting in Madrid, Spain).
[35] *See U.N. Expert's Meeting Recommends Protocol on Genetically Modified Organisms*, *supra* note 25, at 599.
[36] *See id.*
[37] *See generally Structure of a Future Protocol* (visited Oct. 18, 1997) <http://www.mbnet.mb.ca/linkages/vol09/0948009e.html> (outlining the widely varying views on the shape of a biodiversity protocol).
[38] *See Biosafety Working Group Outlines Elements for Future Biodiversity Convention Protocol*, [1996] 19 Int'l Env't Rep. (BNA) No. 16, at 688 (July 23, 1996).
[39] Sheldon Krimsky is a professor in the Department of Urban and Environmental Studies at Tufts University.
[40] *See Consumers Differ On Acceptance of Genetically Modified Foods*, MILLING & BAKING NEWS, Mar. 25, 1997, *available in* LEXIS, News Library, MILBAK File (discussing the results of international consumer surveys about genetically engineered food and noting particularly strong opposition in northern Europe); *Coalition Seeks Labeling of Genetically Engineered Corn, Soybeans; Launches Worldwide Boycott*, FOOD LABELING NEWS, Oct. 10, 1996, *available in* LEXIS, Market Library, IACNWS File (reporting that 300 agricultural, health, and trade groups from 48 countries threatened a boycott to force major companies to label food products that use transgenic components).
[41] *See* Julie Wolf, *Europe Turns Up Nose at Biotech Food*, WALL ST. J., Jan. 2, 1997, at 8 (noting that "only about 5% of foods made with genetically modified raw materials will have to be labeled as such under a new EU law"); Caroline Southey, *EU Agrees Rules For Genetically Engineered Foods*, FIN. TIMES, Dec. 2, 1996, at 20 (noting that the European Union labeling rules provide a

"loophole . . . [for] oil made from genetically modified soybeans to be marketed without a special label . . . [and for] a mix of genetically engineered and conventional products to be imported without extra labels").

[42] The World Trade Organization is the successor to the General Agreement on Tariffs and Trade (GATT). *See FAQ* (visited June 3, 1998) <http://www.wto.org/faqs/faq.html>. The WTO is an "international agency overseeing the rules of international trade." *Id.*

[43] *See U.S. Formally Protests EU Ban on Beef Treated With Hormones*, HOUSTON CHRON., May 9, 1996, at 4 (reporting that the U.S. filed formal charges with the World Trade Organization in hopes of forcing the European Union to repeal its ban on hormone-containing beef).

[44] *See, e.g.*, Neil Buckley, *Brussels Defends Maize Ruling*, FIN. TIMES, Apr. 10, 1997, at 3 (reporting the conflict between the European Commission and the European Parliament over the importation of genetically modfied corn, most of which would come form the United States); *U.S. Trade Report Singles Out Japan, EU, China for Criticism*, L.A. TIMES, Apr. 1, 1997, at D3 (noting U.S. Trade Representative Charlene Barshefsky's concern that the EU has manifested "pervasive discrimination against U.S. agriculture exports").

[45] G.J. PERSLEY ET AL., BIOSAFETY: THE SAFE APPLICATION OF BIOTECHNOLOGY IN AGRICULTURE AND THE ENVIRONMENT (1992).

[46] *See id.* at 1.

[47] *See id.* at 5. *But see Biotechnology and Genetically Altered Foods: The Future is Now—What Will We Make of It?*, ENVTL. NUTRITION, Oct. 1, 1996, at S1, *available in* LEXIS, News Library, ASAPII File [hereinafter *The Future is Now*] (noting that the FDA approved rennet in 1990, the first biotechnology product produced by transgenic bacteria).

[48] PERSLEY ET AL., *supra* note 45, at 7 (quoting the National Research Council Report).

[49] *Id.* at 6.

[50] *See id.* at 3.

[51] *See id.* at 4. Henry I. Miller consistently makes this error in POLICY CONTROVERSY IN BIOTECHNOLOGY: AN INSIDER'S VIEW (1997).

[52] A *genotype* is "all or part of the genetical constitution of an individual or group." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 487 (10th ed. 1994).

[53] A *phenotype* consists of "the visible properties of an organism that are produced by the interaction of the genotype and the environment." *Id.* at 872.

[54] *See EPA Recommended to Adopt a Process-Based Approach*, BIOTECH. BUS. NEWS, Feb. 25, 1994, *available* in LEXIS, Market Library, BIOBUS File (stating that recombinant DNA makes possible "novel genetic combinations [which] 'create uncertainties about how the gene will function and how its products may affect the phenotype and its impact upon the environment and human health.'").

[55] *See id*.

[56] *See id*; *see also* MAE-WAN HO, GENETIC ENGINEERING: DREAM OR NIGHTMARE? (1998).

[57] For example, although some scientists suspected that herbicide-resistant crops might cause environmental problems, the nature of the trouble was not known in 1993. *See Transgenic Plants Pose Minimal Risk*, BIOTECH. BUS. NEWS, July 2, 1993, at 17, *available in* LEXIS, Market Library, BIOBUS File. Thus, initial reports suggested that transgenic plants posed little environmental risk because the herbicide-resistant crops were unlikely to develop the invasive properties of weeds. *See id.* Three years later, researchers found an environmental problem: the genetically engineered herbicide resistance may have spread to nearby weeds through ordinary cross-pollination. *See Herbicide Resistance Spreads to Weeds*, APPLIED GENETICS NEWS, Mar. 1, 1996, *available in* 1996 WL 8541653.

[58] The FDA must grant approval for the sale of a food product if its nutritional value as a transgenic food is outside of the normal range for the non-transgenic version. *See The Future Is Now*, *supra* note 47.

[59] *See Herbicide Resistance Spreads to Weeds*, *supra* note 57 (discussing Danish study about spread of genetically-engineered herbicide tolerance); *see generally* SHELDON KRIMSKY & ROGER P. WRUBEL, AGRICULTURAL BIOTECHNOLOGY AND THE ENVIRONMENT: SCIENCE, POLICY, AND SOCIAL ISSUES (1996).

[60] *See, e.g.,* Steven Pratt, *Growth Hormone for Dairy Cows Draws Concern*, CHI. TRIB., Dec. 16, 1993, at 48.

[61] *See* Rogers Worthington, *To Dairy Industry, Hormone Top Issue*, CHI. TRIB., Jan. 7, 1990, at 21 (reporting that in Wisconsin, the debate had "shifted from health concerns to the consumer's right to know" and that concerns about animal health and the economic survival of the small diary farm had fueled the opposition).

[62] *See* International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 75 (2d Cir. 1996) (Leval, J., dissenting) ("Based on its study, the FDA authorized commercial use of rBST on November 5, 1993, concluding that 'milk and meat from [rBST-treated] cows is safe' for human consumption.") .

[63] *See id.* at 69-70.

[64] *Cf. The Future Is Now*, *supra* note 47 ("The FDA . . . does not require genetically altered foods to be labeled solely because they are genetically engineered.").

[65] *See id.*

[66] *See* Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23,309, 23,309 (1986); *The Future is Now*, *supra* note 47 (stating that the FDA uses a case-by-case approach). The "FDA has determined that plant foods produced through biotechnology present no inherent risk and, therefore, should be regulated like any other food entering the marketplace," meaning that only foods that meet certain criteria based on their characteristics, not how they were made, will be regulated. *See also Position of the American Dietetic Association: Biotechnology and the Future of Food*, 95 J. AM. DIETETIC ASS'N 1429, 1431 (1995) [hereinafter *Position of the American Dietetic Association*].

[67] *See supra* notes 58-59 and accompanying text.

[68] *See* Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. at 23,312-13.

[69] *See id.*

[70] Ignorance of a food's allergic effects is an important first-order concern because, without testing, it is impossible to tell to which foods people are allergic and what allergic reactions may result. *See* Rick Weiss, *Report Cites Risk of Allergic Reaction in Brazil Nut Gene-Engineered Soybean*, WASH. POST, Mar. 14, 1996, at A10; *see also Long March of the Tomato*, WASH. POST, May 21, 1994, at A22 (reporting on allergy concerns about the Flavr Savr tomato).

[71] *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (1992) (citing the FDA as the primary federal agency for regulating genetically altered food and the U.S. Department of Agriculture and the Environmental Protection Agency as secondary agencies).

[72] *See id.* at 22,987 ("[O]nly a small fraction of the thousands of proteins in the diet have been found to be food allergens."). Although approximately 1.5% of U.S. adults and 6% of U.S. infants have food allergies, most people develop a tolerance to the problematic foods. *See Food Allergy: Number of People With Food Allergies on the Rise*, DISEASE WKLY PLUS, Oct. 6, 1997, *available in* 1997 WL 13677901.

[73] *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,987 ("FDA's principal concern regarding allergenicity is that proteins transferred from one food source to another . . . might confer on food from the host plant the allergenic properties of food from the donor plant."); *Long March of the Tomato, supra* note 70 (noting that the introduction of new substances into foods could cause allergic responses in people because the foods need not be specially labeled).

[74] *See* Weiss, *supra* note 70 (noting that allergic reactions can range from "a rash to a lifethreatening lung inflammation"); *see also* Beatrice Trum Hunter, *Put Down that Glass of Milk and Read This: Bovine Growth Hormone May Cause Allergies*, HEALTH NEWS & REV., Jan. 1, 1995, at 8 (discussing the possible adverse consequences for infants and adults from exposure to the bovine growth hormone in milk).

[75] *But cf. id.* (stating that bacteria genes rarely cause allergic reactions when used in genetically altered food).

[76] *See The Future is Now, supra* note 47 (explaining that pests may develop resistance to the toxins that were genetically engineered into plants to keep those insects away).

[77] *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22,965.

[78] *See* KRIMSKY, *supra* note 26, at 98-99; *see also* Jane E. Brody, *A Cool Look at Genetically Altered Foods*, N.Y. TIMES, May 19, 1993, at C13 (discussing various naturally occurring proteins that may be added to food).

[79] *See* Mary Jane Angelo, *Genetically Engineered Plant Pesticides: Recent Developments in the EPA's Regulation of Biotechnology*, 7 U. FLA. J.L. & PUB. POL'Y 257, 288-90 (1996) (discussing

public perceptions of biotechnology in food production); *see also* Karen Goldman Herman, Comment, *Issues in the Regulation of Bioengineereed Food*, 7 HIGH TECH. L.J. 107, 111 (1992) (stating that negative public perception of bioengineered food may lead to tighter regulation).

[80] The National Institute for Environmental Health Sciences is one of the National Institutes for Health. *See NIEHS: Introduction* (visited June 4, 1998) <http://www.niehs.nih.gov/external/intro.htm>. The Institute attempts "to reduce the burden of human illness and dysfunction from environmental causes by understanding the interaction" of environmental factors, individual susceptibility, and age. *Id.*

[81] *See* 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, 6279-80 (1994).

[82] *See* Amy Beth Gooen, *Consumer Education Needed for Biofoods to Get to Market*, FOOD & DRINK DAILY, Jan. 26, 1993, *available in* 1993 WL 2792289 ("'Most companies are honest, but given the current climate of public skepticism, the appearance of impropriety could prevent consumer acceptance of a new technology,' [Michael Phillips of the U.S. Congress Office of Technology Assessment] said.").

[83] *See id.*

[84] *See* Scott Kilman, *Europe Shifts Stance on Demand Over Genetically Altered Crops*, WALL ST. J., July 25, 1997, at A2 (explaining that European consumers are generally more apprehensive about genetically altered crops and labeling than Americans).