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Issues Surrounding the International Regulation of Adventitious Presence and Biotechnology

by

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ISSUES SURROUNDING THE INTERNATIONAL REGULATION OF ADVENTITIOUS PRESENCE AND BIOTECHNOLOGY

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ABSTRACT: The use of genetically modified (GM) crops has increased more than 30-fold globally in the past six years, with 58.7 million hectares grown in 2002. With the rapid and widespread adoption of biotechnology into agriculture, it has become increasingly difficult to guarantee the genetic purity of agricultural products cultivated in open environments and produced and distributed in traditional ways. At the same time, concerns have been raised in many parts of the world—particularly Europe—about the environmental, social, and economic consequences of biotechnology in general. This has translated into significant controversy about the unavoidable and accidental, or “adventitious,” presence of GM material in seed, grain, and food products.

This Article serves as an overall introduction to the concept of adventitious presence—including how it is defined and measured and how it has historically been handled and regulated for “traditional,” conventionally bred crops. It provides a general overview of domestic and international policies to address the adventitious presence of GM material in agricultural products, and how regulatory disparities can potentially disrupt trade and lead to disputes within the WTO framework. In light of this, the paper also looks at the relevance of establishing a standard international threshold, as well as the potential of a unique market-oriented proposal from the U.S. Grain Inspection Packers and Stockyards Administration (GIPSA) that utilizes quality control standards to meet various customer adventitious presence threshold requirements.

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The past decade has witnessed the rapid proliferation of biotechnology in agriculture.¹ Between 1996 and 2002, the global area acreage of genetically modified (GM)² crops increased from 1.5 million to 58.7 million hectares, with the United States accounting for 66% of the global total acreage, followed by Argentina (23%), Canada (6%) and China (4%).³ Between 5.5 and 6 million farmers planted GM crops in sixteen in 2002, valued at \$4.25 billion.⁴ GM soybean was the most widely planted biotech crop, representing 62% of the total global GM area, followed by GM corn (21%), GM cotton (12%), and GM canola (5%). Supporters of GM technology attribute the rapid and widespread adoption of biotechnology to the significant benefits GM plant varieties offer to producers, the environment, and consumers, including increased crop productivity, reduction of the use of pesticides, herbicides and other chemical sprays, and potentially lower costs passed on to consumers.⁵ Critics, however, raise a number of concerns with GM techniques, ranging from food safety and environmental harm to socioeconomic stratification.⁶ While policymakers, industry, and civil society groups throughout the world debate the potential benefits of biotechnology in agriculture, some nations or regions have, for a variety of reasons, attempted to prevent the technology's diffusion—either directly through bans on GM seeds and food or indirectly through the implementation of stringent regulations for the approval and labeling of products containing GM material.⁷

The open-air nature of agricultural production has, in fact, always made it difficult to guarantee the purity of agricultural crops. During normal cultivation, production, and distribution, trace amounts of one type of seed, grain, or food product may unintention-

1. Under the United Nations Convention on Biological Diversity, biotechnology is defined as “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.” United Nations Conference on Environment and Development: Convention of Biological Diversity, June 5, 1992, art. 2, 31 I.L.M. 818, 823; *see also* ERIC S. GRACE, *BIOTECHNOLOGY UNZIPPED 2* (1997) (“[B]iotechnology is an umbrella term that covers various techniques for using the properties of living things to make products or provide services.”).

2. For the purposes of this paper, the term “genetically modified” (GM) will be used to describe the class of plant products developed through modern biotechnology, specifically by recombinant DNA techniques. It should be noted that modification of genes can occur without the use of modern biotechnology techniques, however the terms’ wide recognition by consumers and policymakers around the world justifies its use, despite its inaccuracies.

3. CLIVE JAMES, *INT’L SERV. FOR THE ACQUISITION OF AGRICULTURAL BIOTECH APPLICATIONS, PREVIEW: GLOBAL STATUS OF COMMERCIALIZED TRANSGENIC CROPS: 2002*, at 6 (2002), *available at* <http://www.grain.org/docs/isaaa-gm-status-2002-en.pdf> (last visited Oct. 24, 2003).

4. *Id.*

5. *TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY* 162–63 (Mark A. Pollack & Gregory C. Shaffer eds., 2001).

6. *Id.*

7. For example, the United States asserts that the European Union imposed a *de facto* moratorium on the importation and sale of biotech products even though the products had completed environmental and food safety evaluation by European regulatory authorities. *See* Council Directive 90/220/EEC 1990 O.J. (L 117) 15. E.U. regulations also call for the labeling of products that may contain biotech material to enable consumers to choose whether to purchase such products. *See* Council Directive 79/112/EEC 1979 O.J. (L 33) 1.

ally be present in another type due to a number of factors, such as pollen drift, mixing during harvesting, transport, storage and processing, and human error.⁸ The accidental presence of trace amounts of foreign material in an agricultural product is referred to as “adventitious presence.” Before the biotechnology era, national and international regulations recognized the fact that 100% purity was impossible and thus permitted certain allowances for unavoidable variability in seed, grain, and food.⁹ There was little government or public concern regarding these small levels of contamination because they were perceived to be “natural” and not harmful. Now, however, because the foreign material may be genetically modified, adventitious presence has become a source of controversy.

Nevertheless, adoption of biotechnology in agriculture continues to expand in major agricultural exporting countries, while international trade in agricultural products continues.¹⁰ This combined force means that it has become increasingly difficult to guarantee the genetic purity of seed, grain, and food products, and, in following, that stringent regulations regarding the presence and labeling of GM material has the potential to significantly affect trade.¹¹ Regulators in the U.S. and the European Union (E.U.), as well as international entities, have been called upon to specifically address the issue of adventitious presence of GM material in agricultural products. So far, American and European government agencies have adopted different regulatory approaches.¹² While each may have its merits, the lack of consistency and standardization may impose additional costs and uncertainty on agricultural markets. Producers and exporters whose products meet the applicable standards in one country may not have assurance that their products will meet the grade overseas. This uncertainty is compounded by the potential for standards to change because of both internal and external political pressures, including potential challenges to allegedly discriminatory standards at the World Trade Organization (WTO).

This Article provides a brief introduction to the regulation by various governments and international bodies of the accidental or unintentional occurrence of GM material in agricultural products. Part I provides background on the concept of adventitious presence, including how it is defined and measured and how it has historically been handled and regulated for traditional crop varieties. Part II provides an overview of domestic and international policies to address adventitious presence and suggests that regulatory disparities can potentially develop into significant trade barriers and may lead to trade disputes within the framework of the WTO multilateral trading system. Part III examines various stakeholder positions on the need for an international

8. Biotechnology Industry Organization, Issue in Brief: Standards Need to Be Developed for Adventitious Presence of Biotech Products, at <http://www.bio.org/foodag/adventitious.asp> (last visited Nov. 22, 2003) [hereinafter *Adventitious Presence*].

9. MARK S. CONDON, AM. SEED TRADE ASS'N, SEED GENETIC PURITY IN THE PRE AND POST BIOTECHNOLOGY ERAS I, at <http://pewagbiotech.org/events/0911/speakers/condon.php3> (last visited Oct. 26, 2003).

10. CLIVE JAMES, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, PREVIEW: GLOBAL STATUS OF COMMERCIALIZED TRANSGENIC CROPS: 2002, at 6 (2002), available at <http://www.grain.org/docs/isaaa-gm-status-2002-en.pdf> (last visited Oct. 24, 2003).

11. OLIVIER CADOT ET AL., TRADE-RELATED ISSUES IN THE REGULATION OF GENETICALLY MODIFIED ORGANISMS (2d ed. 2001), available at <http://www.inra.fr/Internet/Departements/ESR/UR/lea/documents/wp/wp0203.pdf> (last visited Nov. 22, 2003).

12. *Id.*

threshold, as well as the potential of a unique market-oriented U.S. proposal to utilize quality-control mechanisms to ensure various allowances.

I. ADVENTITIOUS PRESENCE

A. Background

The American Seed Trade Association (ASTA) defines “adventitious presence” as “the unintended or unintentional presence of another seed variety or genetic material, and/or trait(s) from another variety as a result of natural, mechanical, or human means.”¹³ Adventitious presence is an unavoidable reality of plant biology, seed production, and the distribution of commodity crops.¹⁴ Even before modern biotechnology techniques were used in agriculture, adventitious presence of foreign material was common in agricultural products because of several factors, both biological and practical—including gene flow, which can occur from volunteers and pollen drift, and commingling, which can occur in the normal production and distribution processes for agricultural products.

Gene flow in crop plants is achieved when pollen from one plant fertilizes another plant, passing their combined DNA to the offspring.¹⁵ Pollen drift, or the exchange of genes between plants of the same species, is natural and is not something peculiar to GM plants. A variety of factors relate to the degree of pollen drift, including whether the plant is cross- or self-pollinating. Soybeans are self-pollinating plants, which means they rarely exchange genes with neighboring plants.¹⁶ On the other hand, corn often exchanges genes—“[u]nder field conditions, 97% or more of the kernels produced by each corn plant are pollinated by other plants in the field.”¹⁷ For cross-pollinating plants, other biological considerations are also important, including whether the plant is insect or wind pollinated, the weather conditions, the proximity of sexually compatible plants, and environmental and geographical factors.¹⁸

Addressing the factors that contribute to its occurrence can minimize adventitious presence. Several practices that are commonplace in contemporary agriculture to reduce adventitious presence include: (1) avoidance of overlapping pollination periods of two cross-pollinating plants; (2) use of natural or artificial barriers to reduce pollen flow; (3) creation of buffer zones to separate fields; and (4) thorough cleaning of equipment, such as combines and grain elevators, between operations. When considering policies on adventitious presence, it is important to remember that specifically defining or codifying a practice to reduce its occurrence specifically can potentially affect the legal interpretation of liability for adventitious presence. The term “adventitious” implies that the presence of GM material is accidental, which could also

13. American Seed Trade Association, *What Is Adventitious Presence in Seed?*, at <http://www.amseed.com/qaDetail.asp?id=52> (last visited Oct. 24, 2003).

14. Adventitious Presence, *supra* note 8.

15. PEW INITIATIVE ON FOOD & BIOTECH., HAVE TRANSGENES, WILL TRAVEL: ISSUES RAISED BY GENE FLOW FROM GENETICALLY ENGINEERED CROPS 3 (2003), available at <http://pewagbiotech.org/resources/issuebriefs/geneflow.pdf> (last visited Nov. 22, 2003).

16. AgJournal, *To GMO or Not to GMO? Adopt New Harvest Habits for Biotech Crops*, ¶ 11, at http://www.agjournal.com/story.cfm?story_id=832 (May 16, 2000) [hereinafter AgJournal].

17. Ohio State University Extension, *Corn Pollination—An Overview*, at <http://ohioline.osu.edu/agf-fact/0128.html> (last visited Nov. 22, 2003).

18. See AgJournal, *supra* note 16.

suggest that it must also be unavoidable. In turn, this could imply a legal requirement to meet these types of agricultural production, handling, and manufacturing practices in order for adventitious presence to be considered accidental.

Containment facilities such as greenhouses are less common in commercial, bulk production agriculture but are usually more effective in reducing pollen drift and gene flow. Development of alternate storage, transportation, and processing facilities is also possible to reduce adventitious commingling in grain and food production, but in many instances this would be prohibitively expensive. In the case of biotechnology, only when the value of the GM product exceeds the cost of the segregation technique(s) would this be commercially feasible. It is important to emphasize that such methods, either alone or in combination, can limit the extent of adventitious presence but cannot eliminate it altogether. An absolute zero threshold standard for adventitious presence, whether of conventional or GM products, is virtually unattainable.¹⁹

For more than a century, plant scientists and breeders have been using their understanding of pollen drift and gene flow to develop new plants with desirable characteristics (that is, through traditional cross-breeding techniques) and to grow seeds of crop plants that can be sold as “varieties” because they possess uniform phenotypic characteristics (that is, uniform size and height).²⁰ Taking into account that 100% purity is impossible, international seed variety standards, such as those established by the Organization for Economic Cooperation and Development (OECD) Scheme for the Movement of Seed in International Trade,²¹ have been harmonized to facilitate trade and to allow for variations and genetic off-types in seeds of cultivated crop varieties. These standards are not structured around determining the specific genetic identity of the seeds, but instead they describe general phenotypic standards that help governments assure quality. Industry standards for adventitious presence of conventional crop varieties are typically set at 1% to 2%, depending upon the species, the value of genetic purity, and the difficulty of minimizing contamination.²²

As acreage of unconfined commercial production of biotech-enhanced crops increases, the rate of occurrence of adventitious GM material should also increase. That is to say, the percentage of seeds that contain adventitious material from GM sources is directly related to the percentage acreage planted in GM crops.²³ While adventitious presence is not a new concern, the controversy over agricultural

19. American Seed Trade Association, *Isn't Each Commercial Seed Variety Genetically Pure?*, at <http://www.amseed.com/qaDetail.asp?id=61> (last visited Oct. 24, 2003).

20. Letter from Dean Urmston, Executive Vice President, American Seed Trade Association, and Jay J. Vroom, President, American Crop Protection Association, to Richard Hardy, Grain Inspection, Packers and Stockyards Administration (Apr. 16, 2001), at <http://www.croplifeamerica.org/public/issues/biotech/testimony/usdarole.html> (regarding the USDA's Role in Facilitating the Marketing of Grains, Oil Seeds, Fruits, Vegetables, and Nuts in Today's Evolving Marketplace).

21. The Organization for Economic Cooperation and Development (OECD) Scheme for the Movement of Seed in International Trade is an inter-governmental organization comprised of over 50 national seed certification authorities that work together to establish international varietal purity certification standards for seeds of cultivated crop varieties. MARK S. CONDON, AM. SEED TRADE ASS'N, *SEED GENETIC PURITY IN THE PRE AND POST BIOTECHNOLOGY ERAS I*, at <http://pewagbiotech.org/events/0911/speakers/condon.php3> (last visited Oct. 26, 2003).

22. BILL LEASK, CANADIAN SEED TRADE ASS'N, *TROUBLES WITH THRESHOLDS* (2000), available at <http://cdnseed.org/press/Troubles%20With%20Thresholds.PDF> (last visited Oct. 26, 2003).

23. *Id.*

biotechnology has made adventitious presence of GM material in agricultural products a higher priority for policymakers, even though qualified experts throughout the world have identified no additional human health risks from GM seed, food, and feed productions.

Uncertainty about the safety and environmental effects of biotechnology in general and the lack of globally harmonized and consistent standards and processes for regulation and approval of GM plants and products have led to increased government and consumer concern about their accidental presence in traditional seed and food. There is greater concern about the presence of, for example, GM corn in consumer products than there ever had been about trace amounts of rapeseed in canola destined for human consumption. This concern is present despite the facts that the latter is known to contain toxins that can potentially contaminate the food supply and the former is believed by qualified experts to pose no added risk.²⁴

Currently, there is no international standard for allowable trace amounts of GM products in non-biotech products.²⁵ Some countries have begun to address the issue of adventitious presence by implementing mandatory labeling schemes for the presence of approved GM material in agricultural products, with the purported aim of informing and increasing choice for consumers. It is important here to distinguish between the general aims of government requirements and allowances for adventitious presence in agricultural products. Marketing standards and labeling criteria, such as those contained in the OECD Seed Schemes, typically involve quality criteria not involving human or environmental safety. They are set up to ensure fair dealing and trade or some other consumer-oriented preference standard.²⁶ Other regulatory goals may be related to human health or environmental safety—and thus should ideally be based upon scientific risk assessment and risk management concepts. For unapproved GM events that have not received a scientific evaluation, most countries have essentially adopted a “0% threshold” policy. In the case of the E.U., new proposals allow a specified threshold of unapproved adventitious GM material, if it has received a favorable scientific assessment by the regulatory authority.²⁷ It should be re-emphasized that the zero tolerance approach is virtually impossible to achieve, not only because of commingling and gene flow considerations, but also because of limitations in analytical testing methods and protocols.

24. Canola farmers, for example, must take steps to reduce cross-pollination from conventional rapeseed and other close relatives because contamination can increase levels of erucic acid in the crop, making it unmarketable. See ALAN GROMBACHER & LEN NELSON, UNIV. OF NEB.-LINCOLN, NEBGUIDE: CANOLA PRODUCTION (1992), available at <http://www.ianr.unl.edu/pubs/fieldcrops/g1076.htm> (last visited Oct. 24, 2003); Tanya Nelson, Small Farm Center, University of California, Davis, Canola, at <http://www.rain.org/greennet/docs/exoticveggies/html/canola.htm> (Nov. 16, 1991).

25. CANADIAN SEED TRADE ASS'N, TRACE LEVEL SAFETY ASSESSMENT PROCESS FOR BIOTECHNOLOGY-DERIVED MATERIAL IN SEED, FOOD AND FEED (2002) [hereinafter SAFETY ASSESSMENT], available at <http://cdnseed.org/press/CSTA%20Position%20on%20Trace%20Level%20Approval%20Process.pdf> (Dec. 4, 2002).

26. LEASK, *supra* note 22, at 1.

27. Response from the European Commission to Comments Submitted by WTO Members Under Either or Both G/TBT/N/EEC/6 and G/SPS/N/EEC/149, WTO Doc. G/SPS/GEN/337, G/TBT/W/179, at 18 (July 26, 2002), available at http://europa.eu.int/comm/food/fs/gmo/resp_ec_com425_en.pdf.

B. Current Analytical Testing Methods and Standards for Detecting GM Material

Current global regulatory requirements for the labeling of agricultural biotechnology products, such as those described in the following section, necessitate the ability to detect the presence of protein and DNA associated with a GM event. Variance among established GM threshold levels in international trade and commerce points to the need for performance-verified, accurate, and precise methods to detect and quantify GM products.²⁸ Development and validation of fair, enforceable, and where possible, harmonized diagnostic test methods and standards is of paramount importance for research, production, and trade of agricultural biotech products. The lack of standardization may result in inaccurate claims and enforcement actions and may lead to negative economic impacts on trade.

Two types of analytical testing technologies are commonly used to detect the presence of GM material in field crops. The first, called the Enzyme Linked Immunosorbant Assay (ELISA), assesses the presence in a sample of a specific protein produced from target genes. ELISA can provide both qualitative and quantitative results. Qualitative detection methods screen a sample for the presence of a protein or gene and require only one GM seed to detect a biotechnology event.²⁹ Quantitative analytical techniques identify the level of contamination in a sample as a percentage of the tested material. While ELISAs are frequently implemented because of ease of use and qualitative results, some point out that the tests are not event-specific, have an inconsistent level of sensitivity, and cannot detect some transgenic events.³⁰

Another testing technology, Polymerase Chain Reaction (PCR), is used to detect sequences of DNA in the sample genome and has the ability to detect specific genetic events. PCR can be a more sensitive and reliable method than ELISA in determining the presence of introduced genetic material.³¹ However, PCR cannot easily generate information regarding the level of contamination in a sample and is prone to false positives (that is, the test results indicate the presence of biotech material when none is actually present). This testing method is more expensive and time-consuming than ELISA. Whereas ELISA costs approximately \$10 per test and can be completed in approximately 20 minutes, PCR can cost as much as \$200–\$450 per test and can take 2–10 days to complete.³²

Regardless of which test is utilized, it is also important to consider sampling methodology. Sampling error contributes significantly to the overall uncertainty of

28. See *Facilitating the Marketing of U.S. Agricultural Products with New Testing and Process Verification Services*, 67 Fed. Reg. 50,853 (Aug. 6, 2002).

29. GeneScan USA, Inc., Overview of Elisa Testing, available at <http://www.gmotesting.com/elisa.shtml> (last visited Dec. 2, 2003).

30. United States Department of Agriculture, Meeting Summary: Fourth Plenary Meeting of the Advisory Committee on Agricultural Biotechnology (comments from Dr. Don Kendall, Biotechnology Program Manager), available at http://www.usda.gov/agencies/biotech/archive/acab/meetings/mtg_4-01/summary_4-01.html (Apr. 17–18, 2001).

31. Biogenetic Services Inc., GMO Testing of Seed, Grain, Feed, and Food, at <http://www.biogeneticservices.com/gmo/index.htm> (last visited Nov. 22, 2003) [hereinafter *GMO Testing*].

32. *Implications of Testing and Segregating Nonbiotech Crops for Grain Grades and Standards*, in ECON. RESEARCH SERV., U.S. DEP'T OF AGRIC., ECONOMIC ISSUES IN AGRICULTURAL BIOTECHNOLOGY 23 (2001), available at <http://www.ers.usda.gov/publications/aib762/aib762f.pdf> (last visited Oct. 26, 2003).

analytical test results. Therefore, to ensure an accurate assessment of genetic purity, the sampling protocol must ensure consistent sampling techniques that adequately represent the product being tested.³³ A representative sample is crucial to ensure accurate and reliable test results. This will affect the confidence with which the verification of compliance with a given threshold can be accomplished.

Several other concerns also arise with respect to the testing technologies employed. The primary ones include the effectiveness and accuracy of the testing technologies themselves, the capabilities of the laboratories conducting the tests, and the sampling procedures and methodologies. Of paramount importance is the need for increased dialogue between the scientific community, producers, and industry. This communication is necessary to foster progress and to increase the understanding of analytical methods available for detecting biotech material and their impact on the world economy. Providing science-based information and encouraging dissemination of information to refine testing technologies are critical to achieving these goals.

Currently, regulations establishing thresholds for the labeling of products containing approved GM material are enforced in several countries, including the European Union, Australia, New Zealand, and Japan.³⁴ These regulations state that if the GM content in a food product is higher than a threshold percentage (currently set at 0.9% for the E.U., 1% for Australia, and 5% for Japan), then the product must contain a label to alert consumers that it may contain GM material.³⁵ On the other hand, no mandatory labeling regime exists within the United States or Canada, largely because consumers are much less concerned or unaware of GM products in the system.³⁶ In addition, the U.S. Food and Drug Administration (FDA) see no public health concern and believe that labeling GM products could potentially mislead consumers.³⁷

The following sections will explore this issue further by providing a brief introduction to recently imposed and proposed regulations within the European Union. In addition, the role of international bodies, such as the Codex Alimentarius Commission (Codex) and the World Trade Organization (WTO), will be explained. Finally, the current and proposed U.S. regulations for addressing adventitious presence will be analyzed in the context of the E.U. regulations and international regulatory efforts.

33. See NOVEL FOOD TASK FORCE, INT'L LIFE SCI. INST. EUROPE ET AL., METHOD DEVELOPMENT IN RELATION TO REGULATORY REQUIREMENTS FOR THE DETECTION OF GMOs IN THE FOOD CHAIN 17 (ILSI Europe Report Series, Dr. Kevin Yates ed., 2001), available at <http://www.ilsio.org/file/ILSIMeth.pdf> (last visited Oct. 26, 2003).

34. Pioneer Hi-Bred Int'l, Inc., Biotechnology-Adventitious Presence Backgrounder, at <http://www.pioneer.com/biotech/irm/adven%5Fpresence.htm#regulation> (May 1, 2001).

35. *Id.*

36. See *This Food Contains GM Ingredients: Useful or Useless Info?*, 2 AGBIOTECH BUZZ (Aug. 28, 2002), at <http://pewagbiotech.org/buzz/display.php3?StoryID=72>.

37. U.S. Department of Health and Human Services, FDA Announces Proposal and Draft Guidance for Food Developed Through Biotechnology, at <http://www.fda.gov/bbs/topics/NEWS/2001/NEW00747.html> (Jan. 17, 2001).

II. POLICIES TO ADDRESS ADVENTITIOUS PRESENCE OF GM MATERIAL

A. Background

The rise of international trade in agricultural products and the rapid adoption of GM techniques in agriculture and food production have focused more attention on food safety and environmental effects. Ideally, these issues should be addressed within a framework that accomplishes the primary goals of minimizing trade disruptions while also ensuring that appropriate standards for food safety and environmental protection are not compromised.

Adventitious presence of GM material does not inherently compromise food safety. Historically, however, national governments have imposed their own safety and environmental standards and regulations on seed and food products. These standards and regulations have been based on various factors, including culture, laws, and consumer pressures. In particular, the United States and Europe have adopted relatively disparate approaches to food regulation—which is at least partly because of fundamental differences in their respective national cultures.³⁸ For various reasons, including several major food scares related to Bovine Spongiform Encephalopathy (BSE) and dioxin, consumers in the European Union are more wary of modern food technologies. Americans, on the other hand, have remained open to the use of new technologies in food and feed production or preservation.³⁹ These cultural differences are reflected in the regulatory regimes of the two nations—the American system is organized around scientific risk assessment methods carried out by independent government authorities, while the European system often takes greater account of social factors as well as science.⁴⁰

B. Regulation of Adventitious Presence by the European Union

Regulations governing the presence of GM material in seed and agricultural products are more restrictive in the E.U. than in the U.S. Driven by a combination of public food safety concerns and pressure from domestic agricultural producers, the E.U. has adopted several regulations aimed at reducing GM material in non-GM food and feed products available in their markets.

Labelling to indicate the presence of all GM material has been mandatory for food products in Europe since 1997.⁴¹ The European Union Novel Foods Legislation adopted in 2000 required that in order to remain unlabelled, less than 1% of a food's protein or DNA may be derived from GM material and that presence must be adventitious.⁴² In July 2001, the European Commission adopted two legislative proposals to reinforce the current traceability and labeling rules for GM products and

38. TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY 155 (Mark A. Pollack & Gregory C. Shaffer eds., 2001).

39. *Id.*

40. *Id.*

41. Regulation 258/97 of the European Parliament and of the Council Concerning Novel Foods and Novel Food Ingredients, 1997 O.J. (L 43) 1.

42. Commission Regulation 49/2000, art. 1, 2000 O.J. (L 6) 13, 14 (amending Council Regulation 1139/98, 1998 O.J. (L 159) 4).

to streamline authorization and regulation of GM food and feed.⁴³ In November 2002, the European Council reached an overall political agreement on the new draft proposals, which included two significant changes: (1) the 1% labeling threshold for GM food and feed was reduced to 0.9%, and (2) the 1% threshold for unapproved, adventitious GM material that has received a favorable risk assessment by the Scientific Committees or the European Food Safety Authority was reduced to 0.5%. The 0.9% and 0.5% standards operate as default rules, since a committee procedure could further lower the thresholds if necessary for certain products. In addition, for a foodstuff to be labeled "biotech-free" under this standard, none of its ingredients taken individually may contain more than 0.9% of biotech-enhanced material.⁴⁴ In accordance with the E.U.'s co-decision procedure, the European Parliament enacted the Council-amended regulations in July 2003.⁴⁵

The E.U. contends that the introduction of a threshold for adventitious presence of unapproved GM material is a considerable improvement to the current global regulatory status, where most countries do not have legislation allowing any unauthorized GM material at any level. The proposed regulation imposes no obligation on any operator to test for the presence of GM material, but if a test is conducted and GM material is discovered in excess of 0.9%, the consignment would be rejected.

With regard to seed, the European Commission also proposed revisions to the E.U.'s seed marketing directives in July 2001, which were originally established before biotech content became a major commercial issue. Acknowledging that absolute segregation of seed types is technically impossible, the Commission suggests a 0.3% threshold for the adventitious presence of GM material for cross-pollinating crops and a 0.5% threshold for self-pollinating crops and vegetatively propagated crops such as the potato. It is important to note that these figures were calculated to meet exactly the 1% (now 0.9%) threshold that was already established for food and food ingredients, in an effort to ensure that final products derived from a harvest would not require labeling.

U.S. officials believe the new European regulations are overly restrictive and have the potential to create chaos, expense, and increased liability that could severely restrict billions of dollars worth of U.S.-E.U. trade.⁴⁶ They point out that such low thresholds may prove to be harmful to industry, particularly to small seed-producing

43. Proposal for a Regulation of the European Parliament and of the Council Concerning Traceability and Labeling of Genetically Modified Organisms and amending Directive 2001/18/EC, COM(01)182 final, available at http://europa.eu.int/comm/food/demo/food/biotechnology/gmfood/biotech09_en.pdf (July 27, 2001); Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed, COM(01)425 final, available at http://europa.eu.int/comm/food/demo/food/biotechnology/gmfood/biotech08_en.pdf (July 25, 2001).

44. Press Release, European Commission, Commissioner David Byrne Welcomes Political Agreement of Council on Further Labeling Requirements for GMOs in Food and Feed (Nov. 28, 2002), available at [http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/02/1770\[0\]RAPID&lg=EN&display=](http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/02/1770[0]RAPID&lg=EN&display=).

45. Press Release, American Farm Bureau, FB Condemns EU Rule on Biotech Labeling (July 2, 2003), available at <http://www.fb.com/news/nr/nr2003/nr0702.html>.

46. Response from the European Commission to Comments Submitted by WTO Members, *supra* note 27, at 17-18 (Comment by Canada: "To determine the adventitious presence of GMOs, particularly at very low levels . . . will require time consuming and costly tests in modern state of the art labs, and may be particularly onerous for developing countries . . . [The threshold] could be a serious impediment to trade, affecting both GMO products and non-GMO products.").

companies in countries where availability of suitable growing conditions to minimize the incidence of adventitious presence is limited.⁴⁷ Moreover, there is further concern that reliable methods for quantifying such low levels are not yet available (see Part I.B). Inconsistent test results will inevitably increase the degree of uncertainty at all levels, thereby also increasing producer liability and discouraging trade. Cost penalties may also rise significantly as operators are forced to scale up production to cover seed that must be discarded if it fails to meet specific threshold levels.⁴⁸

C. Regulation of Adventitious Presence in International Forums

According to the American Seed Trade Association (ASTA) and the International Seed Trade Association (ISTA), the current methods of end-product testing are not sufficient. ASTA's view is that "[s]eed is destroyed in the testing process for genetic purity, therefore, only a small percentage of a seed lot can be tested"⁴⁹ As a result, ASTA and ISTA worked to develop a new quality-assurance regime called the International Seed Network Initiative (Initiative).⁵⁰ Established in 1999, the Initiative establishes several quality-assurance procedures, including measures to positively identify, trace, and control products through each step of the production process. The Initiative also aims to prevent potential disruptions in seed trade through the establishment of an international standard of tolerance for adventitious material, which they recommend should be set at 1%.⁵¹ Currently, the OECD Seed Scheme supports adoption of the Initiative on a voluntary basis for interested countries. However, a December 2000 press release issued by ASTA points out that the OECD has been unable to formally adopt the Initiative "largely due to lack of agreement by the European Commission."⁵²

With regard to food, Codex, a joint Food and Agriculture (FAO) and World Health Organization (WHO) program to establish food standards, is currently developing a variety of international standards on the safety of biotechnology-enhanced products. Codex has several committees considering various issues related to biotechnology, including the Codex Committee on Food Labeling, the Codex Committee on General Principles, and the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, which is charged with the task of developing standards for assessment of the safety of foods derived from biotechnology by the year 2004.⁵³ These groups have identified the urgent need for countries to develop common understanding and approaches to dealing with biotechnology-enhanced crops to avoid unnecessary trade disputes. While acknowledging that biotechnology can be useful for mankind and

47. EUROPEAN ASS'N FOR BIOINDUS., LACK OF RULES LEADS TO DISRUPTION IN THE SEED TRADE IN MEMBER STATES 1-2 (2001), available at http://www.zs-l.de/gmo/downloads/europabio_submission.pdf (May 30, 2001).

48. *Id.* at 2.

49. News Release, American Seed Trade Association, Mark S. Condon, American Seed Trade Association Calls for Global Standards of Tolerance for Adventitious Biotech Material in Traditional Seed (Dec. 1, 2000), at <http://www.seedquest.com/News/releases/usa/Associations/n3167.htm>.

50. *Id.*

51. *Id.*

52. *Id.*

53. Thomas C. O'Connor & Randall C. Gordon, *Agricultural Biotechnology—Who's Deciding the Rules of the Road?*, 20 NGFA FOCUS ON INDUS. ISSUES 1, 4 (2002), available at <http://www.ngfa.org/members/focus2-7-02.pdf> (Feb. 7, 2002).

should be promoted, Codex also recognizes that this technology requires cautious application to ensure food safety and public confidence. They also have asserted that the safety evaluation of food must be based on scientific risk analysis while taking into account other legitimate factors relevant to the health of consumers and the promotion of fair trade practices. Codex standards are not binding. However, they do provide a basis for resolving trade disputes within the WTO under the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers on Trade (TBT Agreement).⁵⁴ The SPS Agreement applies to those national laws designed to protect life and health from risks that arise from, among other things, additives, contaminants, toxins, diseases, and pests. The TBT Agreement applies to all national technical regulations and standards governing product characteristics, labeling, and packaging. These agreements provide the justification for national laws and regulations that may otherwise be considered trade restrictive and in violation of the General Agreement on Tariffs and Trade 1994 (GATT).

WTO member states may impose sanitary and phytosanitary measures or technical regulations to protect the well-being of their populations. While the text of the specific agreements states that these measures may not unduly inhibit trade,⁵⁵ nations are still given the flexibility and discretion to set their own policies without questioning their ultimate objectives, whether they be political, economic, or social. The agreements also call for national measures to be based on international standards, such as those set for food safety by Codex.⁵⁶ In keeping with the overall rationale of the WTO as a treaty of negative integration, under specific circumstances nations are allowed to set standards more stringent than international ones.

1. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

Article 3.1 of the SPS Agreement requires national sanitary and phytosanitary measures to be “based on” international standards, guidelines, or recommendations, where they exist. Furthermore, Article 3.2 states that measures that conform to international standards will automatically be deemed necessary to protect life or health (that is, they are necessarily presumed to be consistent with WTO law). In the context of food safety and biotech-enhanced products, the relevant international standards are those of the International Plant Protection Convention (IPPC), the International Office of Epizootics (IOE), and Codex according to Annex A of the SPS Agreement.⁵⁷ National measures may be more stringent than established international standards only when there is “a scientific justification.” However, in the absence of adequate scientific evidence, the member country may adopt a measure “based on available pertinent information, including that from the relevant international organizations,” while continuing to seek information necessary for “a more objective assessment of risk

54. *Id.*

55. World Trade Organization, Standards and Safety, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm (last visited Nov. 22, 2003).

56. Thomas C. O'Connor & Randall C. Gordon, *Agricultural Biotechnology—Who's Deciding the Rules of the Road?*, 20 NGFA FOCUS ON INDUS. ISSUES 1, 4 (2002), available at <http://www.ngfa.org/members/focus2-7-02.pdf> (Feb. 7, 2002).

57. National Resources Institute, WTO Agreements on SPS Measures, at <http://www.nri.org/NRET/PWB/Inter.html> (last visited Oct. 26, 2003).

... within a reasonable time.”⁵⁸ In other words, a WTO member may lawfully enact a measure even when it does not have scientific evidence from a risk assessment as its basis but must actually pursue a scientific risk assessment. The measure must be abandoned if risk assessment fails to justify the restriction. Further, the member must offer evidence from a risk assessment if the measure is challenged before a WTO adjudicating body. Article 5.1 of this agreement provides that for a permanent SPS measure to be WTO compatible, it must be based on a risk assessment described as being a scientific process, not a policy exercise. It requires that the implemented measure will mitigate the identified risk.

2. *The WTO Agreement on Technical Barriers to Trade (TBT Agreement)*

Under the TBT Agreement, national measures need only be “in accordance” with international standards, which may or may not include Codex standards.⁵⁹ This requirement is less restrictive than the SPS Agreement. In addition, under the TBT Agreement, a national measure may be more stringent than an international standard when the standard would be an “ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, for instance because of fundamental climatic or geographic factors or fundamental technological problems.”⁶⁰ The TBT Agreement is definitely a weaker standard than the requirement of scientific justification under the SPS Agreement.

3. *Possible Trade Dispute?*

In May 2003, the U.S., Argentina, Canada, and Egypt filed a WTO case against the E.U. over the moratorium on approving agricultural biotechnology products that has been in effect since October 1998.⁶¹ When this claim was filed, U.S. Trade Representative Robert Zoellick stated that the U.S. had

waited patiently for five years for the E.U. to follow the WTO rules and the recommendations of the European Commission, so as to respect safety findings based on careful science [and] [t]he E.U.’s persistent resistance to abiding by its WTO obligations has perpetuated a trade barrier unwarranted by the E.C.’s own scientific analysis, which impedes the global use of a technology that could be of great benefit to farmers and consumers around the world.⁶²

This case was filed because, according to the nations who filed the complaint, the E.U. has violated the SPS agreement by not providing sufficient scientific evidence to support the moratorium on approving agricultural biotechnology products and because they have unduly delayed their approval processes. These violations are causing a

58. Judson O. Berkey, *Implications of Codex Standards for the Regulation of Genetically Modified Food*, ASIL INSIGHTS 9 (2000) (quoting the Codex Standards), at <http://www.asil.org/insights/insigh51.htm> (last visited Nov. 22, 2003).

59. *Id.*

60. *Id.*

61. Press Release, United States Trade Representative, U.S. and Cooperating Countries File WTO Case Against EU Moratorium on Biotech Foods and Crops: EU’s Illegal, Non-Science Based Moratorium Harmful to Agriculture and the Developing World (May 13, 2003), at <http://www.ustr.gov/releases/2003/05/03-31.htm>.

62. *Id.*

growing portion of U.S. agricultural exports to be excluded from E.U. markets and unnecessarily raised concerns about biotech products around the world.⁶³

With regard to the E.U.'s newly proposed and implemented regulations, American Farm Bureau President Bob Stallman stated, "this new labeling and traceability requirement . . . has only made a bad situation worse . . . [because [i]t's commercially impossible to comply with the rule, it's not justified by any scientific analysis and it's just as WTO inconsistent as the biotech ban that the EU says it will replace."⁶⁴ It is not yet clear which of the WTO Agreements—the SPS or the TBT—will apply to dispute arbitration related to the adventitious presence of biotech material in traded seed or food products. There is obviously some relationship between the more stringent SPS agreement and the stated intention of E.U. approval and labeling regulations, which aim to protect human, animal, or plant life and health. Furthermore, even though the proposals call for highly technical labeling requirements, Article 1.5 of the TBT agreement calls for a technical barrier that is also a sanitary and phytosanitary measure to be adjudicated through SPS.

D. Regulation of Adventitious Presence by the United States

In the U.S., there is no federal statute that explicitly focuses on the regulation of agricultural biotechnology. As a result, no single federal regulatory agency has sole, or even primary, regulatory jurisdiction over genetically modified crops. Jurisdiction is divided among the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA). While all three agencies regulate biotech crops to some degree, the federal government maintains that biotech crops pose no unique health or environmental risks.⁶⁵ Perhaps as a result, until recently, the federal government has been relatively slow to develop a consistent national policy on adventitious presence. The absence of a federal policy regarding adventitious presence of unapproved GM events effectively creates a zero tolerance level. In other words, from a legal perspective, no threshold indicates there is no tolerance at any level for the presence of unauthorized GM material. In addition, many unapproved biotech varieties, such as the EPA-regulated plant-incorporated protectants, are not permitted in the food supply at any level.⁶⁶ As more innovative crops are engineered, the number of field tests necessary to determine the safety of these products will increase. Opportunities for accidental cross-pollination and seed commingling of unapproved genetic material with crops destined for human consumption will necessarily rise in proportion to the number of field tests.

1. OSTP

In August 2002, the Office of Science and Technology Policy (OSTP) proposed several science-based policies to limit the adventitious presence of unapproved biotech products in commercial seed, commodities, and processed food and feed. The OSTP

63. *Id.*

64. See Press Release, *supra* note 45, ¶ 3.

65. See, e.g., NAT'L INSTS. OF HEALTH, 1992 REPORT OF THE NATIONAL BIOTECHNOLOGY POLICY BOARD 2 (1992).

66. U.S. Environmental Protection Agency, Introduction to Biotechnology Regulation for Pesticides, at <http://www.epa.gov/pesticides/biopesticides/regtools/biotech-reg-prod.htm#1> (last modified June 18, 2003).

published a request for public comment in the *Federal Register* on the proposed federal actions to update field test requirements for biotechnology-derived plants and to establish early food safety assessments for new proteins produced by such plants.⁶⁷ The proposed measures address only biotechnology-derived crops intended for food and feed use. As explained by OSTP, “[these] measures are aimed at preventing low levels of biotechnology-derived genes and gene products from being found in commercial seed, commodities, and processed food and feed until appropriate safety standards can be met.”⁶⁸ There are three science-based principles central to the U.S. government’s policy to reduce the levels of GM material not yet approved for human consumption. First, the level of confinement of a field test should correlate to the level of risk posed by the adventitious presence of the GM material in feed, food crops, or seed. Second, traits or proteins with unacceptable risk should be field tested with security measures that prevent any crossing or commingling of seed. Lastly, even if traits or proteins pose little risk, measures should still be taken to minimize crossing and adventitious presence. The FDA, EPA, and USDA all play a role in the achievement of these policy goals.⁶⁹ Under the proposed actions, the FDA, through the publication of procedures, would address the adventitious presence of nonpesticidal proteins that may cause allergic or toxicity reactions in people. The agency would publish for comment guidance on procedures to address the possible intermittent, low-level presence of new, nonpesticidal proteins from biotech crops in food and feed. Through this guidance, the FDA would encourage domestic and foreign sponsors to submit protein safety information before nonpesticidal proteins from field-tested plants are found in commercial seed, commodities and food or feed. The FDA would also maintain an Internet listing, consistent with confidentiality requirements, of all proteins it has evaluated and whether or not they have been deemed to be acceptable. “The EPA would rely on its existing processes to address residues of pesticidal proteins in food, and would publish for comment guidance for individuals and organizations conducting field-testing on plant-incorporated protectants (PIPs).”⁷⁰ The EPA regulates PIPs and pesticidal substances as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food Drug and Cosmetic Act (FFDCA). Under the FFDCA, the EPA will issue a rule permitting the residue to be present and will require developers to obtain an experimental use permit before conducting field tests if PIP residues in food are anticipated through gene flow or commingling. Lastly, the EPA will describe containment controls to minimize pesticidal residues. The USDA would be required to amend its regulations by providing the criteria for allowing the presence of materials that pose no unacceptable environmental risk in commercial seed and commodities.⁷¹ The Agriculture Department would also be required to strengthen its field-testing controls by instituting additional safeguards, such as overall confinement

67. See Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants and to Establish Early Food Safety Assessments for New Proteins Produced by Such Plants, 67 Fed. Reg. 50,578 (Aug. 2, 2002), at <http://www.ostp.gov/html/redregbio.html>.

68. See *id.*

69. See *id.* at 50,579.

70. *Id.* at 50,578, 50,579.

71. The proposed regulations would update 7 C.F.R. pt. 340, the Animal Plant Health Inspection Service’s biotechnology regulations under its new authorities under the Plant Protection Act of 2000. See *id.* at 50,580.

procedures, performance standards, and monitoring protocols. Additionally, it will make its regulatory processes more transparent.⁷²

2. GIPSA

However, the policies proposed by OSTP last summer are not the only government initiatives to address adventitious presence concerns. The USDA realized that differences inherent in acceptable methodologies and techniques to detect genetic modification in seed have created technical and financial obstacles for producers. Consequently, on August 6, 2002, the Grain Inspection Packers and Stockyards Administration (GIPSA) and the Agricultural Marketing Service (AMS), subdivisions of the USDA, published an Advance Notice of Proposed Rulemaking.⁷³ The goal of both GIPSA and AMS is to refine acceptable testing methodologies and certification processes to reduce ambiguity and provide uniformity in the grain and seed industry as a whole. Both agencies propose new, voluntary, market-based process verification programs that essentially piggyback off of currently established guidelines and protocols, including sampling recommendations.

Providing a verified, high-quality product is necessary and of particular importance to producers intending to market seed that has not been commercialized in particular markets and for products that contain GM material that may be approved in one country, but not another. The complexity of testing methods or lack thereof makes it difficult to determine certain quality attributes through traditional sampling and end-product testing protocols. Use of a process approach would provide the agricultural and food industry a viable means to ensure quality while reducing risk and associated costs. It is less expensive to reduce the occurrence of adventitious presence throughout production and handling rather than simply testing the end product. Evaluating the handling and production processes theoretically should decrease the amount of rejected finished product, thereby reducing waste.

GIPSA considers its process verification proposal an alternative to its traditional standardized test-and-certify services. Under the proposed program, GIPSA would apply internationally recognized quality management standards to verify the quality process used rather than testing the final product itself. The program would provide producers, marketers, suppliers, and processors with independent verification of their quality processes and standards and would provide a way around traditional inspection and testing, which is expensive, prone to inaccuracies, and trade prohibitive. The requirements of the Process Verification Program would focus on standards for processes—not products—and address the criteria a quality system must meet, but they would not dictate how an organization meets those criteria. This approach allows an organization the latitude to implement a variety of processes that meet differing customer expectations. The program would supply models against which an organization's system could be audited. Such an audit would provide assurance that the system is operating effectively and is supplying the necessary information to effectively manage the processes that influence product quality. The program would be funded through user fees with applicants paying an hourly fee for documentation review, audits, and travel costs at the government-approved reimbursement rate.

72. *See id.*

73. Facilitating the Marketing of U.S. Agricultural Products with New Testing and Process Verification Services, 67 Fed. Reg. 50,853 (Aug. 6, 2002).

III. REDUCING FUTURE TRADE DISRUPTIONS

A. Possible International Standard

No explicit standard, process, or threshold tolerance exists for the recognition of adventitious presence of GM material in non-GM seed, grain, or food. However, as mentioned previously, the seed industry was the first sector to address the establishment of internationally recognized standards and test protocols for the detection and verification of adventitious presence in traditional seed. The industry, represented by such organizations as ASTA and the International Seed Trade Federation, works with a variety of international bodies, such as the OECD Seed Schemes and the International Seed Network Initiative to continually improve seed quality and purity and to establish thresholds at both the national and international levels. Once the industry concluded that it is impossible to guarantee traditional seed to be free of minute levels of biotech material, it urged federal agencies to permit a realistic level of adventitious content in seed products. The seed industry supports the U.S. government's position—based on findings of U.S. governmental and global scientific bodies—that: (1) GM seed is as safe as traditionally crossbred seed and (2) traditional and genetically enhanced crops are equivalent in quality and safety. They realize, however, that international trade and consumer issues demand that the industry maintains the highest level of purity standards for seed produced by both traditional and modern biotechnology methods. The industry also recognizes that producers in specialty markets who need to reduce the presence of biotech material must be cautious to purchase seed that meets their given needs.

The National Associations of State Departments of Agriculture claim that in order to reduce arbitrary restrictions on U.S. exports, it is essential that there be: (1) internationally standardized tests and methodology for detecting biotech-enhanced products within the food chain and (2) an internationally established threshold consistent with sound science and commercial reality for the adventitious inclusion of biotech-enhanced material.⁷⁴ ASTA, as previously noted, contends global tolerance levels are necessary to prevent potential disruptions in domestic and international seed distribution. In fact, ASTA and the International Seed Federation desire a tolerance level of 1% to standardize biotech-testing protocols and to enhance quality-assurance systems, such as farming practices that minimize adventitious presence.⁷⁵

In contrast, the Biotechnology Industry Organization (BIO) claims an effective U.S. trade strategy would include: (1) resisting adoption of the E.U. traceability and labeling proposals, (2) building international support for the U.S. position on biotech trade issues through the WTO and the Codex, and (3) adopting rational, science-based domestic policies on adventitious presence that could serve as an international model.⁷⁶ BIO does not seek establishment of an international standard because of the insufficient development of science-based standards, such as testing protocols to determine achievable thresholds. Furthermore, the process of obtaining international consensus on thresholds is problematic given the large number of national regulatory

74. *Biotechnology—A Key to Agriculture's Future*, NASDA Policy Statement § 3.3 (Oct. 8, 2002), at <http://www.nasda.org/Policies/three.htm>.

75. SAFETY ASSESSMENT, *supra* note 25, at 2–3.

76. Biotechnology Industry Organization, *Agricultural Biotechnology International Trade Fact Sheet*, at <http://www.bio.org/foodag/priorities/tradefacts.asp> (last visited Oct. 26, 2003).

agencies and governments involved in determining approval procedures for biotechnology.

Because of possible conflicts in interpretation of the WTO Agreements, it appears inevitable that disparities in national regulations will persist, irrespective of the work of Codex and other global standard-setting initiatives. Many question the usefulness of a globally accepted threshold for the adventitious presence of biotech-enhanced material if nations can easily argue that the measure is inappropriate for their objectives. From the perspective of the industry and producers, the potential cost increase to meet the thresholds renders the benefit of global standards uncertain. First, there is the potential cost for producers to meet thresholds. Second, the benefit of global thresholds is uncertain because not all consumers in every country view thresholds in the same light (that is, consumer resistance to biotechnology in the European Union could indicate their preference for a lower threshold, while consumers in the U.S. might accept a higher threshold in return for lower costs at the marketplace). Third, there are technical constraints to achieving thresholds, and existing testing technologies may be imprecise.

B. Quality Control Mechanisms

However, the absence of global uniformity of thresholds and testing standards means that few existing or proposed regulations for adventitious presence vary by country and may unnecessarily disrupt trade. Some argue that in place of specific tolerance levels, internationally recognized quality-assurance methodologies would be more appropriate. Under Article 4 of the SPS Agreement, every member nation of the WTO is obligated to accept as equivalent the food regulatory system of a fellow WTO member if it provides the same level of protection to its citizens. However, equivalent regulatory systems need not be identical.

Most of the traditional surveillance systems for food imports have consisted of reviewing customs entries, engaging in field examinations, and collecting samples for laboratory analysis.⁷⁷ However, end-product testing, which measures outcome, typically cannot be relied upon exclusively to provide an adequate level of protection since the results depend on factors such as product uniformity, sample size, testing sensitivity, etc. Quality-assurance controls coupled with adequate verification by a regulatory authority provide a better assurance that food will not present unacceptable perceived risks.⁷⁸ These controls will assure that a specific level of protection is met in many circumstances where end-product testing alone cannot.

For this reason, GIPSA's process verification program is worth consideration because it gives farmers and agribusiness enterprises latitude in implementing processes that meet the expectations of differing customers. According to the ANPR, "[t]his program is . . . expected to be of particular benefit to participants who intend to market commodities with specific end-use attributes or that have regulatory restrictions or concerns with transgenic event(s) that have been deregulated and commercialized in the United States but not in certain other markets."⁷⁹

77. Draft Guidance on Equivalence Criteria for Food, 62 Fed. Reg. at 30,593, 30,593 (June 4, 1997), available at <http://vm.cfsan.fda.gov/~lrd/fr97064b.html>.

78. *Id.* at 30,597.

79. Facilitating the Marketing of U.S. Agricultural Products with New Testing and Process Verification Services, 67 Fed. Reg. at 50,854.