An Agricultural Law Research Article

Developing Countries at Crossroads: Aid, Public Participation, and the Regulation of Trade in Genetically Modified Foods

by

J.M. Migai Akech

Originally published in FORDHAM INTERNATIONAL LAW JOURNAL
29 FORDHAM INT'L L.J. 265 (2006)

ARTICLES

DEVELOPING COUNTRIES AT CROSSROADS: AID, PUBLIC PARTICIPATION, AND THE REGULATION OF TRADE IN GENETICALLY MODIFIED FOODS

*J.M. Migai Akech**

INTRODUCTION

The World Trade Organization ("WTO") faces a crisis of legitimacy that has grown since the aborted Seattle Ministerial.[1] This crisis has largely revolved around the concern that its decision-making processes are undemocratic and have led to the adoption of trade agreements that frustrate the efforts of developing countries to gain a foothold in international trade and promote the development of their citizens.[2] Developing countries feel that the international trade regime only serves to reinforce and exacerbate the vast inequities between rich and poor countries.[3]

There have therefore been efforts, both within and outside the WTO, to reform the governance framework of the organization so that it can better respond to the needs of developing countries.[4] In particular, these reform efforts seem to proceed on the premise that the foremost measure that is required to ensure that the WTO enhances the trade and development of developing countries is to facilitate their active participation in

* Lecturer in Law, University of Nairobi; J.S.D, LL.M. (Trade Regulation), New York University; LL.M., University of Cambridge; LL.B., University of Nairobi. I am grateful to Patricia Kameri-Mbote, who introduced me to the fascinating world of biotechnology, for comments on a previous draft.

1. *See, e.g.*, John H. Jackson, *The WTO "Constitution" and Proposed Reforms: Seven "Mantras" Revisited*, 4 J. INT'L ECON. L. 67 (2001).

2. *See, e.g.*, Ernst-Ulrich Petersmann, *Challenges to the Legitimacy and Efficiency of the World Trading System: Democratic Governance and Competition Culture in the WTO*, 7 J. INT'L ECON. L. 585 (2004).

3. *See* MICHAEL J. TREBILCOCK & ROBERT HOWSE, THE REGULATION OF INTERNATIONAL TRADE 367-76 (2d ed. 1999).

4. *See, e.g.*, Debra P. Steger, Book Review, 5 J. INT'L ECON. L. 565 (2002) (reviewing CLAUDE BARFIELD, FREE TRADE, SOVEREIGNTY, DEMOCRACY: THE FUTURE OF THE WORLD TRADE ORGANIZATION (2001)).

the rule-making and rule-enforcement processes of the WTO.[5]

While these efforts are no doubt important, international trade governance reform initiatives have not sufficiently acknowledged that there are equally important institutional constraints operating within developing countries, which also serve to impede their international trade and development. Foremost among these impediments are bilateral political and economic pressures, which serve to erode the policy autonomy of developing countries to regulate international trade in the interests of their citizens. In particular, these bilateral pressures take advantage of regulatory uncertainty at the international level to facilitate the exploitation of developing countries.

The prevailing regulatory uncertainty over the regulation of trade in genetically modified ("GM") food products provides an excellent illustration of this phenomenon. The United States and the Member States of the European Union ("EU") have taken almost diametric approaches to the regulation of such products.[6] While the United States has taken the approach that GM food products are substantially equivalent to their organic counterparts and should therefore be traded freely, the EU has adopted a precautionary approach to trade in these products on the rationale that they may have adverse impacts on human health and the environment.[7] These divergent approaches reflect deeply-felt views among the citizens of the United States and the EU about how their societies should respond to scientific uncertainty.

Because the international regulatory framework does not effectively govern trade in GM foods, the United States and the EU have utilized bilateral political and economic pressures to prevail

---

5. *See, e.g.*, Amrita Narlikar, *WTO Decision-Making and Developing Countries* ix (Trade-Related Agenda, Dev. and Equity ("T.R.A.D.E.") Working Paper No. 11, 2001) (arguing that "the only hope that developing countries have of working this elaborate and powerful system of rules is through active participation in the rule-making and rule-enforcement processes of the WTO."); Gregory Shaffer, *Parliamentary Oversight of WTO Rule-Making: The Political, Normative, and Practical Contexts*, 7 J. INT'L ECON. L. 629, 630 (2004) ("Most academic commentary has focused on enhancing WTO transparency and the role of organized civil society.").

6. *See, e.g.*, Ian M. Sheldon, *Regulation of Biotechnology: Will We Ever "Freely" Trade GMOs?*, 29 EUR. REV. AGRICULTURAL ECON. 155 (2002); Tim Josling, *Who's Afraid of the GMOs? EU-US Trade Disputes over Food Safety and Biotechnology*, Seminar paper presented at the Ctr. for Int'l Stud. & the Eur. Ctr. of Cal., Univ. of S. Cal., Mar. 11, 1999, *available at* http://www.netamericas.net/Researchpapers/Documents/Joslin/joslin2.pdf.

7. *See* Josling, *supra* note 6, at 6-7.

upon developing countries to adopt favorable regulatory approaches. In particular, these pressures are applied through the instruments of technical assistance—often in the context of the WTO's special and differential treatment ("SDT") regime—and food aid.[8] On the one hand, technical assistance is provided on the condition that the recipients adopt regulatory policies that are favorable to the benefactors.[9] On the other hand, food aid serves as an instrument to capture new markets for GM food products.[10] These bilateral pressures therefore serve to undermine the policy autonomy of developing countries to regulate trade in GM food products in the interests of their citizens. Further, they serve to narrow regulatory conversations by advocating for an approach that largely excludes the citizens of developing countries from participation in the administrative frameworks for regulation.

This Article reviews the experience of developing countries with the regulation of trade in GM food products in light of such bilateral pressures and argues that there is a need for broader public participation in the regulation of biotechnology as this will facilitate national governance in an era in which the international trade regime is rapidly eroding national regulatory decision-making autonomy.[11] Furthermore, broadening public participation promises to rescue governments of developing countries from the aforementioned bilateral pressures by helping to strengthen their hands in negotiations for technical assistance and food aid.[12] That is, developing country governments can use participatory regulatory frameworks as a negotiation tool by showing either that their policies are "rooted in . . . public support" or that there would be a lack of support for—or even op-

8. *See* Ruth Mackenzie, *Globalisation and the International Governance of Biotechnology: The International Regulation of Modern Biotechnology*, at 18-19 (2004), Paper presented at the Globalisation and Poverty Res. Programme of the U. of Sussex Inst. of Dev. Studies, *available at* http://www.gapresearch.org/governance/RMregulationfinal.pdf.

9. Jane Bloom Stewart & Ernestine Meijer, *Regulation of GMO Crops and Foods: A Final Synthesis of Country Studies* 40 (Oct. 31, 2004) (unpublished manuscript, on file with New York University Law Sch. Ctr. on Envtl & Land Use Law).

10. Oxfam, *Food Aid or Hidden Dumping? Separating Wheat from Chaff* 22 (Oxfam Briefing Paper No. 71, 2005) [hereinafter *Food Aid or Hidden Dumping?*], *available at* http://www.oxfam.org.uk/what_we_do/issues/trade/downloads/bp71_food_aid.pdf.

11. *See generally* ALFRED C. AMAN, JR., THE DEMOCRACY DEFICIT: TAMING GLOBALIZATION THROUGH LAW REFORM (2004).

12. *See* Dominic Glover, *Public Participation in National Biotechnology Policy and Biosafety Regulation* (Univ. of Sussex Inst. of Dev. Studies, Working Paper No. 198, 2003).

position to—any unsuitable regulatory reforms they are being urged to implement.[13]

Part I provides the Article's conceptual framework and examines the impact of the WTO's special and differential regime on developing countries' regulatory policy autonomy. Part I also argues that as far as the regulation of trade in GM foods is concerned, the SDT regime undermines these countries' policy autonomy because it facilitates the application of bilateral pressures, and thereby compromises the establishment of democratic regulatory policies supportive of local priorities. Part II examines how international regulatory uncertainty has led to the application of bilateral pressures on developing countries to adopt narrow frameworks for the regulation of trade in GM food products. Part III examines the role of science in biotechnology regulation and argues that broadening public participation will facilitate the adoption of regulatory measures that are responsive to local needs and concerns.

I. *THE IMPACT OF SPECIAL AND DIFFERENTIAL TREATMENT ON POLICY AUTONOMY*

A. *The Idea of Special and Differential Treatment*

"SDT" refers to "a category of measures through which developed countries respond to the particular risks and vulnerabilities that developing countries face in international trade."[14] It denotes the idea that international trade should not only be fair but also take into account the developmental needs of developing countries. The WTO's SDT regime institutionalizes the provision of aid, or development assistance, to developing countries in the international trade arena.[15]

In programmatic terms, this aid regime has three basic elements: preferential market access, market protection, and technical assistance.[16] Preferential market access programs are based

13. *Id.*

14. Frank J. Garcia, *Beyond Special and Differential Treatment*, 27 B.C. INT'L & COMP. L. REV. 291, 291-92 (2004). There are about one hundred and forty provisions that apply special and differential treatment ("SDT") within the current General Agreement on Tariffs and Trade ("GATT") and World Trade Organization ("WTO") system. *See* Peter Lichtenbaum, *"Special Treatment" vs. "Equal Participation:" Striking a Balance in the Doha Negotiations*, 17 AM. U. INT'L L. REV. 1003, 1010 (2002).

15. *See* Garcia, *supra* note 14, at 292.

16. *See id.*

on the idea that developed countries can support the economic development of developing countries, and allows the latter to export their products into the markets of the former at preferential rates. They are essentially handled through the generalized system of preferences ("GSP").[17] Market protection programs are based on the idea of nonreciprocity and encompass measures by developing countries to protect their economies from the adverse impact of competition from the technologically advanced developed countries.[18] Market protection programs include domestic measures to protect "infant industries" in developing countries.[19] For its part, technical assistance entails the provision of aid in various forms to developing countries, and is premised on the idea that "states rich in [trade-related] knowledge, and the resources to pay for it, should share that knowledge and financially support its implementation."[20]

B. *Special and Differential Treatment in Practice*

In practice, the promise of SDT has not been realized sufficiently.[21] Developed countries have either failed to live up to their commitments or attached conditionalities to their SDT programs, thereby negating any potential benefits thereof.[22] Further, the General Agreement on Tariffs and Trade ("GATT") and WTO's SDT provisions have no force of law, and there are, therefore, no sanctions where they are breached by developed

17. *See* GATT Contracting Parties, *Decision on Differential and More Favorable Treatment, Reciprocity and Fuller Participation of Developing Countries*, Nov. 28, 1979, GATT B.I.S.D. (26th Supp.) at 203-05 (1980) (authorizing the generalized system of preferences ("GSP"), which permits developed countries to accord preferential treatment to products from developing countries.).

18. *See* Garcia, *supra* note 14, at 292 (observing that the principle of nonreciprocity recognizes that developed countries should not expect equivalent access or concessions in return).

19. *See id.* at 294.

20. *Id.*

21. It should be noted that some of the causes of the relative failure of SDT programs are to be found within the developing countries themselves. For instance, it is argued that market protection programs in these countries "distort domestic resource allocation and encourage rent seeking and waste." Lichtenbaum, *supra* note 14, at 1016.

22. *See* Frank J. Garcia, *Trade and Inequality: Economic Justice and the Developing World*, 21 MICH. J. INT'L L. 975, 1036-39 (2000) (discussing the effect of conditionalities on U.S. market access measures); *see also* Garcia, *supra* note 14, at 298 (discussing the failure of developed nations to remove domestic barriers to trade in industries critical to developing nations); Lichtenbaum, *supra* note 14, at 1014-16 (discussing the effect of U.S. conditionalities on market access measures.).

countries.[23] In particular, SDT programs have adversely affected the policy autonomy of developing countries in two significant respects, given that the admission of developing countries into the World Food Program ("PMA") is typically conditioned upon compliance "with a host of non-trade-related requirements,"[24] while technical assistance programs primarily seek to promote the interests of the donor countries. For example, the United States' African Growth and Opportunity Act ("AGOA") provides a good illustration of the use of conditionalities in PMA programs. It provides that import tariff concessions will only be granted under the United States' GSP scheme to Sub-Saharan African countries that meet certain eligibility criteria, including the establishment of a market-based economy, the rule of law, and political pluralism.[25] On the other hand, export market development is at least an implicit goal of many technical assistance programs.[26] As we will see, program conditionalities and the export market development goal have both undermined the policy autonomy of developing countries in the context of the regulation of GM food products.

While the WTO's SDT regime clearly needs rethinking, the proposals mooted so far largely remain within the conceptual confines of the existing paradigm. Thus, the WTO's 2001 Doha Ministerial Declaration calls for a review of SDT provisions "with a view to strengthening them and making them more precise, effective, and operational."[27] The hope is that developed countries will be more committed to the realization of SDT. But such hope may be misplaced, considering that the developed coun-

---

23. *See* Gustavo Olivares, *The Case for Giving Effectiveness to GATT/WTO Rules on Developing Countries and LDCs*, 35 J. OF WORLD TRADE 545, 547-48 (2001).

24. Garcia, *supra* note 14, at 303.

25. *See* African Growth and Opportunity Act [AGOA], Pub. L. No. 106-200, Title I, § 104(a)(1)(B), 114 Stat. 251, 254 (2000); *see also* J.M. Migai Akech, *The African Growth and Opportunity Act: Implications for Kenya's Trade and Development*, 33 N.Y.U. J. INT'L L. & POL. 651 (2001) (analyzing the limitations of the African Growth and Opportunity Act [AGOA]).

26. *See, e.g.*, Christopher B. Barrett, *Food Aid and Commercial International Food Trade* 6 (Org. for Econ. Cooperation and Dev. [OECD], Trade and Markets Div. Background Paper, Mar. 2002), *available at* http://aem.cornell.edu/faculty_sites/cbb2/Papers/BarrettOECDReportMar2002.pdf ("It is plain that the trade promotion objective of food aid persists.").

27. World Trade Organization [WTO], Ministerial Declaration of 14 November 2001, ¶ 44, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Ministerial Declaration].

tries' lack of political commitment to SDT has been the major problem in the first place. Indeed, the non-binding character of the SDT regime gives the developed countries discretion, which facilitates their deployment of bilateral pressures to realize their national interests.[28] Because SDT programs are unilateral, the developed countries offering them are free to attach conditionalities and ensure that such programs further their national goals. This explains why developed countries have greatly resisted attempts to transform the existing moral SDT obligations into legal ones. In view of the prevailing international power dynamics, it is thus unlikely that a "more precise, effective and operational"[29] SDT regime will be realized. It is for this reason that developing countries should involve their citizens in the regulatory process if they are to realize their interests, especially in contexts—such as GM food regulation—where there is international regulatory uncertainty.

Efforts to enhance the effectiveness of the SDT regime should therefore be seen in the broader context of the need for the reform of international aid.[30] By and large, the international aid regime does not serve the interests of the developing country recipients due to a host of domestic and international factors. In particular, the donor countries have "captured" the governments of the recipient developing countries, with the result that aid initiatives largely serve the geopolitical and economic interests of the donors and the narrow interests of these governments.[31] Since this capture is facilitated by the lack of effective democracy (that is, participation in and accountability of govern-

28. *See* Garcia, *supra* note 14, at 298; *see also* Lichtenbaum, *supra* note 14, at 1014-16.

29. Doha Ministerial Declaration, *supra* note 27; *see also* Ernst-Ulrich Petersman, *Introduction to Mini-Symposium on Developing Country in the Doha Round*, 8 J. INT'L ECON. L. 34, 351-52 (2005) (observing that the "Doha Round proposals for rendering S&D [special and differential] provisions 'more precise, effective and operational' are perceived as unlikely to enhance development in [less-developed countries] efficiently.").

30. *See* J. M. Migai Akech, *Development Partners and Governance of Public Procurement in Kenya: Enhancing Democracy in the Administration of Aid*, 38 N.Y.U. J. INT'L L. & POL. (forthcoming 2006).

31. *See* Barrett, *supra* note 26, at 6; *see also* Jongeun Lee, Note, *Study of the International Food Security Regime: Food Aid to North Korea During the Famine of 1995-2000*, 11 CARDOZO J. INT'L & COMP. L. 1037, 1060 (2004) (citing Edward Clay & Olav Stokke, *The Changing Role of Food Aid and Finance For Food*, *in* FOOD AID AND HUMAN SECURITY 13, 15 (Edward Clay & Olav Stokke eds., 2000)) ("To some extent, aid has always been used as an instrument for promoting the national interests of the donor country.").

mental decision-making processes) in these countries, efforts to ensure that international regulation responds to the needs and concerns of the citizens of these developing countries must therefore include the democratization of national governance frameworks.

In the context of trade in GM foods, as we will see, the SDT regime has facilitated the application of bilateral political and economic pressures, resulting in policies that do not take into account the needs and concerns of the citizens of developing countries. While such policies may have significant adverse effects on these citizens, they are made "beyond the reach of domestic political structures" due to the capture of developing country governments by the donor countries.[32] Nevertheless, this democracy deficit can be overcome by establishing meaningful institutional frameworks for public participation in biotechnology regulation.

II. *THE REGULATION OF TRADE IN GM FOOD PRODUCTS: INTERNATIONAL UNCERTAINTY AND DEVELOPING COUNTRIES*

A. *The United States/European Union GM Foods Dispute*

There has been a rapid adoption of GM crops in the world's principal agricultural exporting countries, namely the United States, Argentina, and Canada, over the last decade.[33] It has been estimated that "[i]n 2000, of the 43.1 million hectares [of GM crops] planted world wide, [98%] was planted in these three countries, with [68%] of the global total planted in the USA, [23%] in Argentina, and [7%] in Canada."[34] In the United States, "biotech crops accounted for 80% of soybean, 38% of maize, and 70% of corn production" in 2003.[35] These countries have therefore sought market access for their GM food products as they seek to maximize their comparative advantage.

Unfortunately for them, many other members of the WTO have largely sought to exclude GM food products, as they are

32. AMAN, *supra* note 11 at 3.

33. *See* Sheldon, *supra* note 6, at 155.

34. *Id.*

35. Starla L. Borg, Note, *Waiting for the River: The United States and the European Union, Heads Up and High Stakes in the WTO—Genetically Modified Organisms in International Trade*, 43 WASHBURN L.J. 681, 698 (2004).

concerned about the long-term risks associated with genetically modified organisms ("GMOs").[36] The principal culprits here are the EU, which has adopted regulations prohibiting the release of GMOs into the environment and the commercialization of GM foods "until there is extensive evidence that they will not cause harm to humans, animals and the environment."[37] The EU has further adopted regulations for the mandatory labeling of GM foods in response to consumer concerns.[38] It also imposed a moratorium in 1998 on the approval of new agricultural biotechnology products.[39] As a result of these restrictive policies, the United States, which is the EU's principal trading partner, has suffered huge economic losses as a considerable portion of its agricultural products has been excluded from European markets.[40] In the estimation of the United States, these measures amount to protectionism and thus violate international trade rules.[41] Along with Canada and Argentina, the United States has therefore requested a dispute settlement panel under the WTO to challenge the EU's moratorium.[42]

The crux of the U.S./EU trade dispute is a conflict between

36. *See* Sheldon, *supra* note 6, at 160. The concerns over possible adverse impacts of genetically modified organisms ("GMOs") include: (i) potential impacts on non-target species, such as beneficial insects; (ii) the potential spread of GM crops as weeds; (iii) potential for cross-pollination between genetically modified ("GM") crops and non-GM crops and wild plants (also known as "genetic pollution"); (iv) potential impacts on soil bacteria and the nitrogen cycle; (v) indirect effects on the environment, including changed agricultural practices; and (vi) potential impacts on human health. *See* Barbara Eggers & Ruth Mackenzie, *The Cartagena Protocol on Biosafety*, 3 J. INT'L ECON. L. 525, 526 (2000).

37. Sheldon, *supra* note 6, at 160.

38. *See id.*

39. *See* Borg, *supra* note 35, at 685.

40. *See* Marc Victor, *Precaution or Protectionism? The Precautionary Principle, Genetically Modified Organisms, and Allowing Unfounded Fears to Undermine Free Trade*, 14 TRANSNAT'L L. 295, 296 (2001).

41. *See* President George W. Bush, Commencement Address Before the U.S. Coast Guard Academy (May 21, 2003), *available at* http://www.whitehouse.gov/news/releases/2003/05/20030521-2.html (characterizing European regulation of GM foods as based on "unfounded, unscientific fears"); *see also* Press Release, Office of the U.S. Trade Representative, United States Requests Dispute Panel in WTO Challenge to EU Biotech Moratorium (Aug. 7, 2003), *available at* http://www.ustr.gov/Document_Library/Press_Releases/2003/August/Section_Index.html; David Leonhardt, *Talks Collapse on U.S. Efforts To Open Europe to Biotech Food*, N.Y. TIMES, June 20, 2003, at A1 ("The Bush administration and agricultural businesses view the policy as simple protectionism because U.S. companies, which dominate the biotechnology industry, would benefit most from lifting the ban.").

42. *See* Borg, *supra* note 35, at 683.

the goals of free trade in GM products and the protection of human health and the environment in a context in which there is considerable scientific uncertainty surrounding biotechnology, which "has hindered the ability to accurately predict potential harms."[43] This conflict is magnified by a growing public distrust for governmental regulation, as GM crops harmful to human health have in some cases erroneously found their way into the food chain.[44] Further, it does not help the situation that the WTO agreements do not specifically address agricultural biotechnology, thereby creating international uncertainty with respect to the regulation of trade in GM food products.[45] Indeed, it has been suggested that the members of the WTO will have to develop new agreements to deal with matters such as consumer and ethical concerns.[46]

While the United States adopts a product-oriented approach to the regulation of GM foods that is driven by a desire to facilitate free trade, the EU adopts a process-oriented approach that is largely driven by the need for precaution.[47] The U.S. approach is guided by the principle that there should be minimal oversight of food products that are "generally regarded as safe" ("GRAS").[48] Conventional food products are considered GRAS, and GM foods should therefore be judged by the same standards since "they do not differ in any substantial way from those developed through traditional plant breeding methods."[49] The rationale is that "zero tolerance for potentially hazardous ingredients in food would result in few foods ever being marketed."[50] The objective of regulation—under the U.S. approach—should

43. Michelle K. McDonald, *International Trade Law and the U.S.–EU GMO Debate: Can Africa Weather This Storm?*, 32 GA. J. INT'L & COMP. L. 501, 504 (2004).

44. In the United States, for example, Starlink corn, a GM corn manufactured by Aventis CropScience but not approved for human consumption, was discovered to have mixed with other corn used by Kraft and other large manufacturers in food production. *See* Aaron A. Ostrovsky, *The European Commission's Regulations for Genetically Modified Organisms and the Current WTO Dispute—Human Health or Environmental Measures? Why the Deliberate Release Directive is More Appropriately Adjudicated in the WTO Under the TBT Agreement*, 15 COLO. J. INT'L ENVT'L L. & POL'Y 209, 214-15 (2004).

45. *See* Eggers & Mackenzie, *supra* note 36, at 535.

46. *See* Sheldon, *supra* note 6, at 168.

47. *See* Nathan W. Eckley, Note, *Reaping the Benefits of Agricultural Biotechnology through Uniform Regulation*, 35 J. MARSHALL L. REV. 433, 436-37 (2002).

48. Sheldon, *supra* note 6, at 157.

49. *Id.*

50. *Id.*

therefore "not be to establish absolute safety, but to consider whether a GM food (ingredient) is as safe as its conventional counterpart."[51]

Conversely, the EU's precautionary approach is premised on a belief that science is uncertain about the long-run risks associated with GMOs.[52] Thus, even where scientific risk assessments have been carried out on GMOs, they should not be released into the environment or commercialized "until there is extensive evidence that they will not cause harm to humans, animals and the environment."[53] Accordingly, "pro-active measures must be taken to reduce the risk of uncertain scientific dangers in GMOs."[54] In the EU's view, the precautionary approach is particularly suitable because it enables regulatory authorities to take consumers' concerns into account.[55] To a considerable extent, the EU's approach is a response to consumer backlashes against genetically altered foods in the wake of debacles such as the outbreak of mad-cow disease.[56] Unlike the United States, which encourages self-regulation among GM-producing firms, the EU has adopted a regulatory model, which requires prior governmental approval before GMOs can be released into the environment.[57]

Over the last decade or so, while the United States (together with Japan and Canada, who have also adopted the product approach) has approved some one hundred GMOs for release into the environment, the EU has only approved fourteen GMOs.[58] The EU's arduous approval process is thus being

---

51. *Id.*

52. *See id.* at 160.

53. *Id.*

54. Eckley, *supra* note 47, at 443. The precautionary principle is enshrined in Article 174 of the EC Treaty. *See* Consolidated Version of the Treaty Establishing the European Community art. 174, O.J. C. 325/33 (2002), at 107-08.

55. *See* Victor, *supra* note 40, at 320 ("[W]hat drives consumers' concerns is a distrust of the motives of their regulatory authorities, the honesty of their politicians, and the objectivity of their scientists rather than fear of any genuine danger created by GMOs.").

56. *See, e.g., Cow Crunching: BSE/New Evidence on Mad Cows*, ECONOMIST, Aug. 31, 1996, at 49.

57. *See* Council Directive No. 90/220, O.J. L 117/8/5 (1990); *see also* Commission Regulation No. 258/97, O.J. L 043 (1997) (also known as the "Novel Foods Regulation").

58. *See* Eckley, *supra* note 47, at 443.

blamed for impeding trade in GM foods.[59] By contrast, the U.S. approach is being extolled since its liberal GMO approval process "leads to increased profits for corporations, and, in turn, funds future research and development projects for GMO products."[60] Nevertheless, while a liberal GMO approval process may be conducive to free trade, it may not be suitable for the protection of human health and the environment. It has thus been noted that the problem with the United States' laissez-faire regulatory system is that "even when a company does not meet its food safety responsibilities, the [regulator] only takes action after some harm has resulted."[61]

Since the trade policies of the United States and the EU have a significant impact upon developing countries, the latter now find themselves at a loss as to how to regulate GM food products given these diametric approaches.[62] Agricultural products constitute developing countries' principal exports to Europe and the United States.[63] Depending on the regulatory approach they adopt to GM food products, their trade with European countries and the United States could be affected adversely. At the same time, these countries often have trouble feeding their citizens and from time to time do receive food aid, especially from the United States.[64] Furthermore, developing countries have been the recipients of development assistance from the United States and the EU to enable them to establish policies and laws for the regulation of GMOs.[65] Such assistance, however, invariably comes with strings attached, and the expectation tends to be that the recipients will adopt regulatory poli-

---

59. *See id.* at 443, 447.

60. *Id.* at 444.

61. Victor, *supra* note 40, at 305.

62. *See, e.g.*, Robert L. Paarlberg, *Governing the GM Crop Revolution: Policy Choices for Developing Countries* 2 (Int'l Food Pol'y Res. Inst. ("IFPRI"), Food, Agriculture, and the Environment Discussion Paper 33, 2000) ("[D]ivergent policies toward GM technologies in rich countries have now created a complicated problem of policy choice in the developing world . . . . Should governments in the developing world follow the more permissive U.S. approach toward GM crop technologies or the more precautionary EU approach?").

63. *See, e.g.*, Paul Breton & Takako Ikezuki, *The Impact of Agricultural Trade Preferences, with Particular Attention to the Least-Developed Countries*, *in* GLOBAL AGRICULTURAL TRADE AND DEVELOPING COUNTRIES 68, 69 (M. Ataman Aksoy & John C. Beghin, eds., 2003).

64. *See, e.g.*, Barrett, *supra* note 26, at 7.

65. *See* Paarlberg, *supra* note 62, at 31.

cies and laws favorable to the donors.[66]

Developing countries are therefore at a crossroads: Should they adopt a permissive or restrictive approach to trade in GM foods? Should they accept or decline GM food aid? Should they accept or decline development assistance in their efforts to establish suitable regulatory policies and laws on GMOs? These dilemmas are enhanced by the uncertainty over the regulation of GM foods within the framework of the world trade regime. As we will see, this regulatory uncertainty has led the developed countries, especially the United States and the EU, to apply bilateral pressures on developing countries to adopt their respective approaches.

B. *The International Regulatory Framework for Trade in GM Foods*

As a general rule, the GATT/WTO mandates non-discrimination, that is, equal treatment of like products between all contracting parties.[67] Further, it requires national treatment, that is, equal internal treatment of both imported and domestic products.[68] Nevertheless, Article XX of the GATT permits measures intended to protect human health and the environment, provided that "such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade."[69] Thus, restrictive trade measures enacted to protect human health and the environment will be held to violate the GATT if their effect is the differential application of a measure to domestic and foreign products.[70] Historically, it has been difficult for measures to meet the stringent requirements of Article XX since "GATT panels have narrowly construed the language in Article XX in favor of trade and against non-tariff barriers to trade."[71] Typically, the GATT panels overruled such measures on the ground that they were discriminatory and that less discriminatory mea-

66. *See, e.g.*, Stewart & Meijer, *supra* note 9.

67. *See* General Agreement on Tariffs and Trade, art. I, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT].

68. *See id.* art. III.

69. *Id.* art. XX.

70. *See* McDonald, *supra* note 43, at 515.

71. *Id.* at 514.

sures were available.[72] In addition, Article XX measures are only available against products and cannot be directed at process or production methods.[73]

At the Uruguay Round, it was felt that Article XX had some "gray areas" that needed to be resolved.[74] For example, Article XX did not establish any criteria for determining whether measures were necessary and provided no specific procedure for settling disputes on such matters.[75] The Agreement on Sanitary and Phytosanitary Measures ("SPS Agreement") and the Agreement on Technical Barriers to Trade ("TBT Agreement") were the result of this review process. The SPS Agreement sought to elaborate on the health and safety exception contained in Article XX(b) of GATT.[76] In particular, it elaborates on the general procedural requirements to be followed by contracting parties seeking protection of human, animal, or plant life or health.[77] The TBT Agreement builds upon the Tokyo Round Standards Code and establishes guidelines by which contracting parties could implement legitimate product standards.[78] The TBT Agreement applies mainly to voluntary and mandatory labeling requirements that are not covered by the SPS Agreement.[79] Conversely, the SPS Agreement applies to food safety measures, including labeling requirements, and is accordingly thought to be more relevant to resolving the GM foods conflict.[80] It also should be noted that these agreements apply concurrently with the GATT.[81]

---

72. *See* Kevin C. Kennedy, *The GATT-WTO System at Fifty*, 16 WIS. INT'L L. J. 421, 459 (1998).

73. *See* Report of the Panel, *United States—Restrictions on Imports of Tuna*, ¶ 37, GATT B.I.S.D. DS29/R (June 16, 1994) (not adopted).

74. *See* McDonald, *supra* note 43, at 517.

75. *See* Josling, *supra* note 6, at 3.

76. *See* George E.C. York, Note, *Global Foods, Local Tastes and Biotechnology: The New Legal Architecture of International Agriculture Trade*, 7 COLUM. J. EUR. L. 423, 457 (2001).

77. *See*, Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Multilateral Agreement on Trade in Goods, Annex 1A, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter SPS Agreement].

78. *See* Kennedy, *supra* note 72, at 460.

79. *See* Arthur E. Appleton, *The Labeling of GMO Products Pursuant to International Trade Rules*, 8 N.Y.U. ENVTL. L. J.. 566, 574 (2000).

80. *See* McDonald, *supra* note 43, at 519.

81. *See* Ostrovsky, *supra* note 44, at 241 (observing that "even if a measure is found to be lawful under the TBT Agreement, it may still violate the GATT," because the former agreement imposes obligations that are different from and additional to the

The principal purpose of the SPS Agreement is to prevent restrictions on international trade disguised as health and safety measures.[82] The SPS Agreement does not create specific standards, but simply provides general rules for WTO members to follow when establishing sanitary and phytosanitary ("SPS") measures.[83] In particular, it requires members to base their SPS measures on science and not to use them as disguised barriers to trade.[84] The SPS Agreement presumes that "measures which conform to . . . international standards, guidelines or recommendations [are] necessary to protect human, animal or plant life or health."[85] But where a member proposes to impose measures stricter than those established by international standards, it can only do so if it provides sufficient scientific justification for its proposed measures.[86] In the latter scenario, the member is required to undertake a scientific "risk assessment" to evaluate the likelihood of adverse consequences.[87] The risk assessment must be based on an examination and evaluation of available scientific information, and will only justify the imposition of an SPS measure if a "rational relationship" exists between the risk assessment and the measure.[88] Further, an SPS measure that passes this science test must not be more trade restrictive than necessary, must be consistent with comparable regulations, and must be taken without undue delay.[89] The SPS Agreement also requires members to maintain transparent SPS regulations, and prohibits the use of control, inspection, and approval procedures as unjustified barriers to imports.[90]

While the SPS Agreement makes no specific reference to the precautionary principle, it nevertheless provides that "a Member may provisionally adopt . . . [SPS] measures on the basis of available pertinent information" in cases where relevant scien-

---

GATT); *see also* Eggers & Mackenzie, *supra* note 36, at 536 (observing that a measure prohibiting "the use of GM seed stocks because of socio-economic considerations, would still be covered by Articles III, XI and XX of the GATT 1994.").

82. *See* McDonald, *supra* note 43, at 507.

83. *See generally* SPS Agreement, *supra* note 77.

84. *See id.* arts. 2.2-2.3.

85. *Id.* art. 3.2.

86. *See id.* art. 3.3.

87. *See* Victor, *supra* note 40, at 307.

88. *Id.* at 308.

89. *See* Eggers & Mackenzie, *supra* note 36, at 538.

90. *See* SPS Agreement, *supra* note 77, arts. 7, 8.

tific evidence is insufficient.[91] But in such cases, the member is mandated "to obtain the additional information necessary for a more objective assessment of risk and review the . . . [SPS] measure accordingly within a reasonable period of time."[92] The WTO's Appellate Body has determined that a "reasonable period of time" must be established on a "case-by-case basis."[93]

On the other hand, the TBT Agreement covers standards and "technical regulations that focus on non-safety related attributes of all products, such as the characteristics of how a product was produced."[94] Unlike the SPS Agreement, the TBT Agreement does not require scientific justification for any standards or technical regulations, as its scope "extends beyond measures that could justify risk on scientific assessment (such as professional licensing regimes)."[95] The TBT Agreement provides that standards or technical regulations may only restrict trade to the extent and duration necessary to achieve a "legitimate" regulatory objective.[96] It provides a non-exhaustive list of legitimate objectives, which has been held to include protection of consumers, markets transparency, and fair competition.[97]

Further, the TBT Agreement requires members imposing standards or technical regulations to take into account the risks of not achieving the legitimate regulatory objective.[98] In assessing such risks, a member is required to consider "available scientific and technical information, related processing technology, or intended end-uses of products."[99] This list of risk elements is not exhaustive. The TBT Agreement's risk assessment requirements therefore seem to be broader and "much less rigorous" than those of the SPS Agreement.[100] Thus "regulators would

---

91. *Id.* art. 5.7.

92. *Id.*

93. Appellate Body Report, *Japan—Measures Affecting Agricultural Products*, ¶¶ 14, 84, WT/DS76/AB/R (Feb. 22, 1999).

94. Sheldon, *supra* note 6, at 167.

95. Ostrovsky, *supra* note 44, at 221.

96. *See* Agreement on Technical Barriers to Trade, Apr. 15, 1994, Multilateral Agreement on Trade in Goods, Annex 1A, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter TBT Agreement].

97. *See* Appellate Body Report, *European Communities—Trade Description of Sardines*, ¶ 263, WT/DS231/AB/R (Sept. 26, 2002).

98. *See* TBT Agreement, *supra* note 96, art. 2.2.

99. *Id.*

100. Nick Covelli & Viktor Hohots, *The Health Regulation of Biotech Foods Under the WTO Agreements*, 6 J. INT'L ECON. L. 773, 787 (2003).

find it easier to justify a GM food-related measure under the TBT Agreement than under the SPS Agreement."[101]

Some commentators argue that "disputes regarding GMOs and GMO regulations are better handled by the more general [TBT Agreement]" since the scope of the SPS Agreement "may prove to be too narrow to encompass the concerns that surround GMOs."[102] Further, they argue that the SPS Agreement is not designed to protect against the kind of risks that GMOs present.[103] That is, the SPS Agreement only applies to sanitary and phytosanitary measures, which are "only a subset of the total risks associated with GMOs."[104] Because "GMOs present risks that go beyond risks to the sanitary and phytosanitary, it is not clear that the SPS Agreement is designed to regulate measures which seek to protect against risks associated with GMOs in toto."[105]

At the same time, however, the TBT Agreement provides that it does not apply to SPS measures "as defined in Annex A of the [SPS Agreement]."[106] In view of the jurisdictional questions raised by this provision, a question arises as to how a member is to regulate trade in GM foods if it proposes to address the risks presented by GMOs comprehensively. Should such a member be allowed to justify the non-SPS aspects of its regulations on the basis of the less stringent requirements of the TBT Agreement? Much will depend on whether WTO Panels and the Appellate Body would be agreeable to such an accommodating interpretation of the SPS and TBT Agreements.

Another international instrument that seeks to regulate trade in GMOs is the Cartagena Protocol on Biosafety ("CPB").[107] While the CPB is an international environmental

101. *Id.*

102. Ostrovsky, *supra* note 44, at 210-11 (suggesting that "trade regulations designed to protect the environment, so long as their scope is greater than simply the protection of human health, should be considered under the less restrictive demands of the TBT Agreement. This is significant because the TBT Agreement, in not requiring scientific evidence, presents a lower threshold for compliance than the SPS Agreement."). *See, e.g.*, Kara-Anne Yaren, *Trade and Genetically Modified Foods: Frankenfears—A Call for Consistency*, 1 ASPER REV. INT'L BUS. & TRADE L. 149 (2001).

103. *See* Ostrovsky, *supra* note 44, at 221.

104. *Id.* at 222.

105. *Id.* at 222-23.

106. TBT Agreement, *supra* note 96, art. 1.5.

107. The Cartagena Protocol on Biosafety ("CPB") was adopted in Montreal on January 29, 2000 and entered into force on September 11, 2003. The CPB was adopted

agreement, it addresses the international movement of "living modified organisms" ("LMOs") and therefore impacts trade.[108] The main provision of the CPB is its Advance Informed Agreement ("AIA") mechanism, which requires exporters to obtain the consent of the country of import before shipping LMOs to that country for the first time.[109] A party seeking to export an LMO destined for "intentional introduction into the environment" must notify the potential recipient country of its intention through the AIA procedure.[110] The potential importing country must then decide whether to permit the importation of the LMO. The CPB mandates the potential importing country to base its decision upon risk assessments carried out in a "scientifically sound manner."[111] Alternatively, the potential importing country may require the exporter to conduct the risk assessment.[112]

The AIA procedure does not, however, apply to LMOs intended for direct use for food, feed, or for processing (the so-called LMO-FFPs). In practice, this means, for instance, that while "the export of GM maize seeds for field trials needs to be notified to and approved by the party of import in advance, . . . an exporter who wishes to ship a consignment of GM seeds for use as animal feed in a swine farm would not need to obey the strict notification requirements established by the AIA."[113] Instead, the CPB provides for a different procedure for the regulation of LMO-FFPs, under which a country intending to export

---

under the auspices of the Convention on Biological Diversity and is the first binding international agreement dealing with modern biotechnology. *See* SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY: TEXTS AND ANNEXES (2000), http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf [hereinafter CPB]; *see also* Eggers & Mackenzie, *supra* note 36, at 527.

108. *See* Terence P. Stewart & David S. Johanson, *A Nexus of Trade and the Environment: The Relationship Between the Cartagena Protocol on Biosafety and the SPS Agreement of the World Trade Organization*, 14 COLO. J. INT'L L. & POL'Y 1, 3-4 (2003). The CPB defines a "living modified organism" ("LMO") as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." CPB, *supra* note 107, art. 3(g). In using the term "living organism" the CPB "appears implicitly to exclude non-living products of LMOs, for example, processed tomato puree as opposed to fresh tomatoes." Eggers & Mackenzie, *supra* note 36, at 529.

109. *See* CPB, *supra* note 107, arts. 7-10, 12.

110. *Id.* arts. 7(1), 8.

111. *Id.* art. 15(1).

112. *See id.* art. 15(2).

113. Eggers & Mackenzie, *supra* note 36, at 530.

LMO-FFPs is merely required to inform the potential recipient country of its decision through a "Biosafety Clearing-House."[114] In effect, the CPB leaves the regulation of LMO-FFPs to the discretion of the importing and exporting parties.[115]

While the CPB allows parties to take precautionary measures, it limits this right by requiring the party of import to review its precautionary measures in light of new scientific evidence if an exporting country requests it.[116] But precautionary measures under the CPB need not be provisional: "Parties do not have an ongoing obligation to keep [measures] under review unless explicitly requested to do so by the exporter."[117] Further, the CPB allows parties to take socio-economic considerations "arising from the impact of [LMOs] on the conservation and sustainable use of biological diversity" into account in their decision-making on LMO imports.[118] But in doing so they are required to act consistently with their international obligations.[119]

From these provisions of the CPB, it is unclear whether it applies to disputes involving food safety. The CPB provides that it applies to LMOs that may adversely affect the environment, "taking also into account risks to human health."[120] And as pointed out in the preceding paragraph, it only allows the consideration of socio-economic concerns in the context of biodiversity conservation and not human health. While "a damaged environment could adversely affect humans," the EU and the United States have, for example, taken different views on this matter.[121] The United States contends that the Protocol does not apply to food safety, while the EU maintains that it does.[122] In addition, and as we have seen, the CPB leaves the regulation of LMO-FFPs to the parties, thereby excluding most of the GM products that are currently traded from its purview.[123] It would

114. CPB, *supra* note 107, art. 11(1).

115. *See* Eggers & Mackenzie, *supra* note 36, at 531.

116. *See* CPB, *supra* note 107, arts. 10(6), 11(8), 12(2)-(3).

117. Eggers & Mackenzie, *supra* note 36, at 540.

118. *See* CPB, *supra* note 107, art. 26.

119. *Id.*

120. *Id.* art. 4.

121. *See* Stewart & Johanson, *supra* note 108, at 8.

122. *See id.* at 8-9.

123. LMO-FFPs currently make up ninety percent of trade in GM products. *See* Eggers & Mackenzie, *supra* note 36, at 530.

therefore seem that the CPB, which is a "complex and highly negotiated instrument" reflecting "a delicate balance between the competing interests at stake,"[124] sought to steer clear of the domain of the WTO. In these circumstances, it should come as no surprise that "the final language of how the Protocol will relate to other international agreements . . . was not fully resolved."[125] The CPB does not therefore affect the rights and obligations of the parties under the rules of the WTO.[126]

From the foregoing account, it is evident that the existing international framework for the regulation of trade in GM products does not establish clear rules. The framework reflects great compromises between countries favoring free trade in these products on the one hand, and those favoring precaution on the other hand. That is, countries on the opposite ends of this divide have opposed the promulgation of clear international rules in order to preserve their freedom to determine the levels of regulation that they deem appropriate according to national needs and concerns.

Because the international rules are not clear, much depends on how they are interpreted. The language of the above complex international agreements is ambiguous, and the meaning and scope of concepts such as "risk assessment" and "sufficient scientific evidence" are not clearly established.[127] Thus, whether or not these agreements will facilitate a resolution of the "free trade versus precaution" conflict will depend on how the WTO panels and the Appellate Body interpret the meaning and scope of such concepts. For example, how should governments regulate trade in GM products in cases where scientific evidence is either divided or uncertain? In the *Hormones Case*, the WTO's Appellate Body thought that an SPS measure could still be based on a risk assessment even if scientific opinion were divided or uncertain, reasoning that "responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources."[128] The Appellate Body thus advocates a

124. *Id.* at 527.

125. Stewart & Johanson, *supra* note 108, at 23.

126. *See id.*

127. *See* Eggers & Mackenzie, *supra* note 36, at 537.

128. Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)* ¶ 194, WT/DS26/AB/R, WT/DS/48/AB/R, (Jan. 16, 1998).

case-to-case approach in determining whether a measure is based on risk assessment; this does not, however, provide clear guidance as to how governments are to apply risk assessment in the regulation of trade in GM products. Furthermore, governments in developing countries are often not "responsible and representative,"[129] and it is thus plausible that they may allow free trade in GM products on the basis of suspect risk assessments.

In addition, the requirement of the SPS Agreement that a measure be "scientifically based" has been interpreted differently.[130] According to the United States, for example, this requirement recognizes that "scientific certainty is rare and many scientific determinations require judgments between differing scientific views" and "preserves the ability of governments to make such judgments."[131] This interpretation of the SPS Agreement reflects the United States' desire to preserve its freedom to make judgments on science according to national needs and concerns.

In view of the uncertainty of the above international agreements, it is also unclear whether, for instance, the EU's restrictive regime violates international trade rules. In the context of its dispute with the United States, the EU would for instance argue that its regime aims to implement a scientific-based risk assessment as required by the international agreements. Conversely, the United States would argue that if the GM and conventional food products are essentially equivalent, then the EU regulations would violate GATT Article III, as they would be giving the former products less favorable treatment.[132] Thus, basing the regulation of GM food products on the process of genetic modification would constitute a trade barrier if the GM products can objectively be determined to be as safe as their conventional counterparts.[133] The resolution of the dispute will therefore depend on how the safety determination is to be made. And since there are no agreed objective criteria for the

129. *Id.*

130. *See* Julie Teel, Note, *Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 N.Y.U. ENVTL. L. J. 649, 691 (2000).

131. John H. Barton, *Biotechnology, the Environment, and International Agricultural Trade*, 9 GEO. INT'L ENVT'L L. REV. 95, 102 (1996).

132. *See* Sheldon, *supra* note 6, at 167.

133. *See id.*

determination of safety, it will be difficult to argue that the EU's regime violates the international rules.

For this reason, it has been suggested that perhaps the best solution to the EU/U.S. dispute would be for the EU to allow greater market access to U.S. exports that meet its stringent regulations and standards.[134] This suggestion is based on the idea that while the WTO primarily seeks to achieve and maintain negotiated levels of market access, it should equally ensure flexibility in terms of domestic regulation.[135] In other words, the WTO should allow its member countries to establish their own regulations and standards that reflect domestic risk valuations and then only mandate the maintenance of negotiated levels of market access.

As far as developing countries are concerned, however, international regulatory uncertainty has led to the application of bilateral political and economic pressures in the context of SDT programs, whose object has been for these countries to adopt regulatory frameworks that promote the interests of the donor countries.[136] This phenomenon can be observed in the provision of technical assistance to assist developing countries establish biotechnology regulatory frameworks and the administration of food aid.

C. *The Impact of Regulatory Uncertainty on Developing Countries*

The impact of regulatory uncertainty on developing countries should be assessed in the context of their unique concerns regarding trade in GM food products. These unique concerns include food security, poverty, the likely adverse impact of GM food imports on the competitiveness and livelihoods of farmers, different food consumption patterns that are dictated by culture, the likelihood that GM foods will displace developing countries' agricultural exports, and the lack of capacity to regulate biotechnology.[137] To what extent do the technical assistance and food aid regimes take such concerns into account? In the case of food security, for instance, it has been noted that GM crops are likely to be more expensive to purchase and maintain, and are

134. *See id.* at 172-73.
135. *See id.* at 172.
136. *See* Eggers & Mackenzie, *supra* note 36, at 1.
137. *See id* at 2.

thus unlikely to solve the problem of food security since "poverty, rather than inadequate agriculture . . . remains the basis for hunger among the people of developing countries."[138] Further, because multinational corporations control biotech seeds, they may completely dominate seed markets and farmers in developing countries.[139]

The provision of technical assistance includes initiatives by the United States,[140] the EU, and international organizations, such as the World Bank, to strengthen the ability of developing countries to establish and implement science-based sanitary and phytosanitary requirements of trading partners and to participate in the work of standard-setting organizations. Within the context of the CPB, there are also initiatives (funded by the United Nations Environment Program's Global Environmental Facility ("UNEP-GEF"), international organizations, and bilateral donors) to assist developing countries establish national biosafety frameworks.[141] In the case of bilateral technical assistance initiatives, developed countries that favor free trade in GM foods fund GMO research and development in developing countries, while GM food skeptics fund activities related to health and safety regulation.[142] Thus, the United States typically funds GMO research and development whereas the EU funds biosafety programs.[143]

The trouble with these initiatives is that they require developing countries to adopt the policy choices of the donors, thereby foreclosing "public consultation and debate on the ap-

138. McDonald, *supra* note 43, at 522.

139. *See* Borg, *supra* note 35, at 705.

140. In the case of the United States, such technical assistance is administered by the United States Agency for International Development ("USAID"), through its Collaborative Biotechnology Initiative ("CABIO"). This initiative has two main components: the Agricultural Biotechnology for Sustainable Productivity Project ("ABSP"), and the Program for Biosafety Systems ("PBS"). The objectives of the initiative are to facilitate the commercialization of GM crops in recipient developing countries and the establishment of regulatory regimes conducive for such commercialization. *See* GRAIN, *USAID: Making the World Hungry for GM Crops* (2005), *available at* http://www.grain.org/go/usaid.

141. *See id.*

142. *See* Stewart & Meijer, *supra* note 9, at 45.

143. *See id.* It should be noted, however, that the United States also funds biosafety programs, for instance, in South Africa. Some commentators hold the view that the purpose of such funding is to open up international markets for US businesses by ensuring the adoption of weak biosafety regimes. *See id.* at 46.

propriate role of biotechnology" in developing countries.[144] The United States, which is on a mission to ensure worldwide acceptance of GM food products,[145] has in particular applied bilateral pressure on developing countries such as Bolivia, China, Croatia, and Sri Lanka to adopt favorable regulations.[146] In particular, the effect of technical assistance is therefore to paralyze decision-making in developing countries, and thereby impede their ability to address their unique concerns regarding trade in GM food products.[147] In other words, because the technical assistance initiatives are fragmented and often reflect different positions with regard to the development, use, and regulation of GMOs, their impact is to impede rather than promote the ability of developing countries to make and effectively implement their own policies.[148]

The donor countries have also used food aid to influence the policies of developing countries, since accepting food aid means that the affected developing countries also adopt permissive regulatory policies on GM food products. The United States is especially suspected of using food aid as leverage to promote free trade in GM products.[149] By offering GM products in their food aid programs, the United States is said to be seeking to promote the acceptance of these products in developing countries, thereby expanding the markets for U.S. exporters.[150] It is instructive that U.S. legislation on food aid programs gives priority to export of agricultural commodities to developing countries that have "demonstrated the potential to become commercial markets."[151]

The United States has also been accused of dumping agri-

144. Mackenzie, *supra* note 8, at 44.

145. *See* Alan P. Larson, Under-Sec'y for Econ., Bus. & Agric. Aff., Agriculture and Biotechnology in U.S. Foreign Policy, Remarks at the Commodity Club of Washington, D.C., Apr. 10, 2002, *available at* http://www.state.gov/e/rls/rm/2002/9307.htm.

146. *See* Mackenzie, *supra* note 8, at 46.

147. *See id.*

148. *See id.* at 45.

149. *See Food Aid or Hidden Dumping?*, *supra* note 10, at 22.

150. *See* Stewart & Meijer, *supra* note 9, at 47.

151. *Food Aid or Hidden Dumping?*, *supra* note 10, at 21-22 (citing a United States Agency for International Development ("USAID") report stating that "of the 50 largest customers for US agricultural goods, 43—including Egypt, Indonesia, Korea, Taiwan, and Thailand—formerly received food assistance. In short, aid leads to trade, from which Americans stand to benefit.").

cultural surplus through its food aid programs.[152] It has been observed, for instance, that "the [U.S.] rice industry has frequently turned to food aid programs as a buyer for surplus rice production."[153] Food aid programs therefore provide a "critical escape route" for U.S. farmers "when prices are low and production is abundant."[154]

Food aid also tends to displace local production since it can flood local markets and depress prices, thereby undermining the livelihoods of poor farmers.[155] The displacement of local production is exacerbated where, as is increasingly the case with the United States, food aid is monetized, that is, sold in the local markets to generate cash.[156] So that while the GM revolution has the potential to help alleviate the problem of hunger in developing countries, the provision of GM food aid in the current international regulatory environment may instead increase the developmental problems of developing countries since food aid undermines local agricultural production systems.[157]

In such circumstances, the application of bilateral pressures on developing countries to accept GM food aid without an adequate consideration of its likely economic and environmental impacts facilitates the adoption of narrow regulatory frameworks. Zimbabwe's food crisis of 2001-2002 provides a good illustration of this phenomenon. The major issue at the heart of the crisis was whether Zimbabwe should accept GM food aid from the United States.[158] While the Zimbabwe Biosafety

152. *See id.* at 2.

153. *Id.* at 19 ("In years when prices are low, food aid represents as much as [twenty percent] of rice exports.").

154. *Id.*

155. *See id.* at 17 (giving the example of Malawi, where in the period from 2002 to 2003, food aid donors overreacted to a projected 600,000-ton food deficit and sent close to 600,000 tons of food in aid. Because commercial and informal importers brought in an additional 350,000-500,000 tons, Malawi was flooded and maize prices dropped from US$250 per ton to US$100 per ton in the course of a year.).

156. *See id.* at 23.

157. *See id.* at 10 (observing that "[i]n non-emergency situations, shipping in-kind food aid across the world to meet development needs is usually not an ideal—or even a good—strategy for promoting development or for fighting hunger. Careful assessment of the root causes of hunger is necessary before resorting to food aid. In most cases, poverty or lack or income generation is the underlying cause of chronic hunger. Providing food aid is not likely to help those affected over the long term, without also providing support for improving livelihoods.").

158. *See* James Keely & Ian Scoones, *Contexts for Regulations: GMOs in Zimbabwe* 13-44 (U. of Sussex Inst. of Dev. Studies, Working Paper No. 190, 2003).

Board ("the Board") was initially reluctant to do so on grounds of biosafety, there was immense pressure from the World Food Program, the United Stated Agency for International Development ("USAID") and the U.S. State Department for Zimbabwe to accept GM food or be accused of "crimes against humanity."[159] The Board eventually caved in and agreed to accept the GM food aid, reasoning that "on the basis of available evidence from studies in the [United States] and 'basic understanding of gut physiology and biochemistry' the risks of consuming [GM] maize were not significant."[160] But because the Board thought that the dangers of introducing GM maize through planting were apparent, it determined that all maize coming into the country should be milled before distribution."[161]

It has been contended that the Board's decision to accept GM food aid was based on an inadequate consideration of the risks posed by the maize in question.[162] In particular, it is argued that the decision was based on a "leap of faith," as it assumed that the U.S. assessment of the safety of the maize was sufficient.[163] It is pointed out that such data could not, however, have been sufficient because it had not assessed "the consequences of eating GM maize in the volumes and at the frequency that Zimbabweans eat it."[164] In the end, the decision to accept GM maize was based on an inadequate consideration of the risks to human health. Indeed, science took a back seat and the decision was largely based on "wider political and diplomatic" considerations.[165]

Ultimately, therefore, the provision of technical assistance for the establishment of regulatory frameworks and food aid both foreclose adequate public consultation and debate on the appropriate role of biotechnology in developing countries. Further, both demonstrate that the regulation of trade in GM food products is a political process that needs to be democratized if

159. *Id.* at 13 n.9.

160. *Id.* at 14.

161. *Id.*

162. *See id.*

163. *Id.*

164. *Id.* at 15. Maize is Zimbabwe's main staple food and is typically eaten three times a day. *See id.* at 14.

165. *Id.* at 15 ("With intensive lobbying behind the scenes, and high profile visits to senior government officials and the President [of Zimbabwe] by the UN Special Envoy Morris, the niceties of technical biosafety regulations took a back seat.").

there is to be a sufficient consideration of their potential impacts on human health and the environment. The need for broader public participation in developing countries arises especially because the scientists entrusted with regulation often have an interest in the commercialization of biotechnology products and may therefore not make decisions that are in the public interest.[166]

III. *SCIENCE AND DEMOCRACY IN BIOTECHNOLOGY REGULATION IN DEVELOPING COUNTRIES*

A. *The Role of Science in Biotechnology Regulation*

In the biotechnology context, science has largely been deployed as the principal component in the regulatory decision-making process. It is "sound science" that frames the scope of biotechnology regulation, with the result that the regulatory process may not sufficiently take social and economic considerations into account.[167] Indeed, the undemocratic character of biotechnology regulation in developing countries has been attributed to the dominance of the "sound science based free trade paradigm."[168]

Because science by itself cannot comprehensively address the potential impacts of biotechnology, it is necessary to question the paradigm that extols science at the expense of the broader precautionary approaches that embrace other disciplines in the regulation of biotechnology. And if the need for a broader participatory approach to regulation is acceptable, it then becomes necessary to examine the role and nature of democracy (that is accountability and participation) in the process of biotechnology regulation. This is because in biotechnology as well as in other contexts, democracy facilitates the making of "better-informed, more appropriate, and ultimately more effective policies."[169]

A number of scholars have analyzed the role science plays in biotechnology regulation in developing countries. Dominic Glover thus observes that in practice the processes of scientific

166. *See infra* notes 200-09 and accompanying text.

167. *See, e.g.*, Ian Scoones, *Science, Policy and Regulation: Challenges for Agricultural Biotechnology in Developing Countries* (U. of Sussex Inst. of Dev. Studies, Working Paper No. 147, 2002) [hereinafter *Science, Policy and Regulation*].

168. *Id.*

169. Glover, *supra* note 12, at 9.

risk assessment and public participation are separated.[170] The scientists carry out the risk assessments, which form the basis for decision-making, and then inform the public.[171] Science is therefore deemed to be dispositive in matters of biotechnology regulation, and public participation is just but a "technical input to [science-based] rational decision making processes."[172] This, he argues, is also the approach adopted in the CPB's concept of "biosafety," for instance, which is concerned with "the management of the risks associated with the contained use and environmental release of GMOs."[173] In his view, "biosafety is based implicitly on . . . the assumption that environmental and human health risks associated with GMOs can be identified, evaluated and controlled by science."[174] Further, Glover argues that because it is science that frames the implications of GMOs by determining what factors are to be deemed "relevant from a regulatory point of view," the resulting decision-making framework is therefore quite narrow.[175]

This approach to regulatory decision-making also assumes that "the public will naturally accept the judgments of science as soon as it can be made to understand them."[176] It is thus quite paternalistic, as "scientists construe the public as ignorant, and attribute [its] failure to embrace science to fear and misunderstanding founded on ignorance or irrationality."[177] Accordingly, "the public will naturally accept the judgments of science as soon

---

170. *See id* at 4; *see also Science, Policy and Regulation*, *supra* note 167, at 9 ("[F]ormal risk assessment is deemed to be a delimited, technical exercise, one where inputs from objective science are seen to be crucial. With the separation of technical from political, moral, or ethical dimensions this, in turn, allows for a demarcated role for technical expertise which is seen to be independent and objective.").

171. *See* Glover, *supra* note 12, at 6 ("[T]here is a strong and pervasive assumption that public consultations are to take place in separate processes [and, in particular, subsequent to] . . . scientific risk assessments of GMOs.").

172. *Id.* at 7.

173. *Id.* at 5.

174. *Id.* at 6.

175. Glover, *supra* note 12, at 6; *see also* Ian Scoones, *Regulatory Manoeuvres: The Bt Cotton Controversy in India* n. 1 (U. of Sussex Inst. of Dev. Studies, Working Paper No. 197, 2003) [hereinafter *Regulatory Manoeuvres*] ("[T]he framing of the regulatory debate is key. If it is kept narrow, science-focused and risk-oriented, then key elements of the debate are not on the table. If it is broadened and made more inclusive, then the remit of regulatory deliberations widens.").

176. Glover, *supra* note 12, at 7.

177. *Id.*

as it can be made to understand them."[178]

The CPB[179] conceptualizes public participation largely in terms of providing information to the public rather than as a "strategic opportunity to make informed, legitimate and effective policies."[180] Thus, the role of the public is to be a passive recipient of information about biotechnology, and their ignorance is to be cured through education and awareness-raising activities. Because the public is invited to "participate" only after science has made the value judgments, the space for public participation is circumscribed.[181] The public does not therefore get an opportunity to help frame the scope of regulation.[182]

Further, the science-based approach to regulatory decision-making is questionable since science is not only "heavily contested," but the risk assessment methodologies typically adopted also have significant limitations.[183] Ian Scoones argues, for example, that in practice "sound science" is not sound because "conventional risk assessment approaches are often ill-equipped to deal with multiple criteria and incommensurability, where scientific uncertainties, indeterminacy and ignorance prevail."[184] In his view, "standard risk assessment procedures are usually based on the assessment of a limited number of criteria where technical assessments are seen to be sufficient" due to "limited

---

178. *Id.*

179. CPB, art. 23 provides, inter alia, that:

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

CPB, *supra* note 107, art. 23.

180. Glover, *supra* note 12, at 2-3.

181. *See id.* at 13.

182. *See* Glover, *supra* note 12, at 13.

183. *Science, Policy and Regulation*, *supra* note 167, at 15.

184. *Id.* at 9.

budgets, staff and skill shortages and short-time frames."[185] As a result, "more complex criteria are left out of the equation, uncertainties are 'black boxed,' and areas of ignorance avoided."[186] Risk assessment procedures are therefore only able "to look at relatively short-term impacts," and the hope is that "longer term and broader scale impacts will be picked up through monitoring later on."[187]

Scoones further argues that risk assessment processes are dominated by molecular biologists, who possess "little interest in and knowledge of complex ecological processes."[188] As a result, the risk assessment procedures employed ignore the consideration of wider ecological impacts of biotechnology products.[189] Consequently, the biotechnology regulation debate is, in practice, framed by particular disciplines of science at the expense of others, with the effect that the scientific debate around risk assessment becomes "highly fragmented."[190] In addition, he notes that scientists disagree on how field trials should be designed: while agronomists favor "simple plot based" experiments, ecosystems ecologists argue for broader experiments to assess the "likelihood of complex responses at an ecosystem level."[191]

Another notable concern relates to the influence of the biotechnology industry over biotechnology regulatory policy.[192] Peter Newell and Dominic Glover argue that "the imperative of facilitating the commercialization of GM products has been allowed to override a fuller [regulatory] consideration of the potential environmental and socio-economic risks associated with GM crops."[193] Because of such influence, "[b]iotechnology regulations have responded more to commercial and trade concerns than to public anxiety about environmental and social

185. *Id.*

186. *Id.*

187. *Regulatory Manoeuvres*, *supra* note 175, at 34.

188. *Id.* at 35.

189. *See id.*

190. *Id.* ("Those with access to the regulatory system frame the issue in one way (largely around genetic, molecular and chemical issues), and in so doing blackbox a whole range of uncertainties.").

191. *See Science, Policy and Regulation*, *supra* note 167, at 21.

192. *See generally* Peter Newell & Dominic Glover, *Business and Biotechnology: Regulation and the Politics of Influence* (U. of Sussex Inst. of Dev. Studies, Working Paper No. 192, 2003).

193. *Id.* at 5.

risks."[194] Newell and Glover base this argument on their observations of international harmonization of biotechnology regulation and capacity-building initiatives.[195]

The idea behind the international harmonization initiatives is to "reduce barriers to trade by creating common standards and rules of conduct."[196] In this case, Newell and Glover observe that the biotechnology industry has been "keen to ensure that decision-making is technical and devoid of political conflict as [much as] possible," and has "expressed concern about widening the regulatory circle too far, both in terms of the actors involved and the range of issues considered."[197] Because the biotechnology industry funds many of these initiatives, it has sought the promulgation of regulatory frameworks that are suitable for its commercialization objectives. For example, the international harmonization initiatives seek the acceptance of the principle of substantial equivalence for the regulation of GM food products.[198]

The biotechnology industry has also played a prominent role, especially in the UNEP-GEF pilot biosafety programs.[199] As Newell and Glover note, however, industry has been "reluctant to meet developing-country requests for financial support unless [it is assured that its] views and concerns will also be taken on board."[200]

In view of these realities of biotechnology regulation, especially in developing countries, some scholars have called for the development of more participatory and comprehensive approaches that address scientific uncertainty in transparent ways.[201] The following section makes a case for the adoption of

194. *Id.* at 4 (concluding that much contemporary regulation thus "provides *regulation for* business rather than *regulation of* business.").

195. *See id.* at 6-8.

196. *Id.* at 9. There is "a set of global pressures" to establish internationally harmonized regulatory frameworks consisting of the OECD, leading biotechnology companies and the "Miami Group" (the leading GM foods exporters, namely Argentina, Australia, Canada, Chile, the United States, and Uruguay). *See id.* at 9-10.

197. *Id.* (noting, for instance, that "during the negotiation of the Biosafety Protocol, industry sought to resist the attempt by countries such as Ethiopia and Malaysia to insert language that would have allowed States to evaluate the socio-economic impacts of GMOs in their risk assessments.").

198. *See id.* at 10.

199. *See id.* at 15.

200. *Id.* at 7.

201. *See Science, Policy and Regulation*, *supra* note 167, at 3.

such participatory frameworks.

B. *Enhancing Public Participation in Biotechnology Regulation*

If the citizens of developing countries are to play a more effective role in the regulation of biotechnology, there is thus a need to explore alternatives to the prevailing expert model. In particular, biotechnology regulation—as in other regulatory contexts—must be recognized for what it is, that is, a political exercise whose object is to reconcile different rationales in the process of conceiving what is good for society. Further, expertise does not take politics out of the decision-making process because experts often have their own biases. In the case of biotechnology regulation in developing countries, for example, the experts entrusted with regulation are often proponents of the commercialization of GM food products and therefore unlikely to make objective decisions.[202] Furthermore, scientists are often influenced by the agencies that fund their research.[203] Accordingly, it must be appreciated that expertise "can only illuminate choices, not decide them."[204] That is, expertise simply helps to forecast the costs and consequences of particular policy choices. Furthermore, given that competing interests will be affected differently by any regulatory decision, expertise is unlikely to legitimate the decision, especially where it calls for value judgments.[205]

In the interests of governmental legitimacy and balanced allocation of values in the regulatory process, all those likely to be affected by any proposed regulation ought to be meaningfully involved in its formulation and implementation. The concept of legitimacy implicates the inclusiveness and public acceptance of governmental decision-making processes. Thus, in a democracy, governmental decisions should result from the deliberation of all if they are to be legitimate.[206] The regulatory challenges presented by biotechnology should accordingly be seen as

202. *See* Stewart & Meijer, *supra* note 9, at 25.

203. *See Science, Policy and Regulation*, *supra* note 167, at 5.

204. MICHAEL REAGAN, REGULATION: THE POLITICS OF POLICY 2 (1987).

205. *See* ROBERT BALDWIN & MARTIN CAVE, UNDERSTANDING REGULATION: THEORY, STRATEGY, AND PRACTICE 80 (1999).

206. *See* Jack Knight & James Johnson, *What Sort of Political Equality Does Deliberative Democracy Require?*, *in* DELIBERATIVE DEMOCRACY: ESSAYS ON REASON AND POLITICS 279, 280 (James Bohman & William Rehg eds., 1997).

problems of social choice that scientific experts alone cannot resolve legitimately. The process of biotechnology regulation should therefore be politicized to ensure that the various competing interests participate in decision-making.

One key means of politicizing biotechnology regulation would be for developing countries to implement a "deliberative democracy" model.[207] "Deliberative democracy" sees democracy "not simply in terms of popular will and decision, but as a form of legitimation of power that depends on a conception of public justification and deliberative reason."[208] Under this approach, the role of science would not be to "trump citizens' intuitive judgments about which risks are acceptable and which not, but rather to help ensure that citizens' judgments result from an appropriately structured deliberative process."[209]

There will, of course, be obstacles to the realization of such a deliberative approach to biotechnology regulation. For instance, many developing countries face considerable resource constraints.[210] Nevertheless, developing countries stand to gain much from investing in biotechnology, and should thus devote more resources to biotechnology processes in their budgetary allocations. But they should do so in a regulatory context that sufficiently considers the needs and concerns of their citizens. Perhaps more importantly, the implementation of a deliberative approach promises to empower the citizens of developing countries, thereby enabling their governments to better manage the bilateral pressures that accompany the provision of technical assistance and food aid in the context of international regulation of GM food products.

CONCLUSION

The international framework for the regulation of trade in GM food products does not establish clear rules, and has led to the utilization of bilateral political and economic pressures by developed countries in their efforts to prevail upon developing

207. Robert Howse, *Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization*, 98 MICH. L. REV. 2329, 2330 (2000).

208. *Id.* at 2334.

209. Howse, *supra* note 207, at 2335; *see also* Cass R. Sunstein & Richard Pildes, *Experts, Economists and Democrats*, *in* FREE MARKETS AND SOCIAL JUSTICE 128 (Cass R. Sunstein ed., 1997).

210. *See* Howse, *supra* note 207, at 2339.

countries to adopt favorable regulatory approaches. The application of these pressures has been facilitated by the WTO's special and differential treatment regime, under which developed countries provide technical assistance and food aid to developing countries. These pressures greatly compromise the establishment of democratic regulatory policies in developing countries. Further, they present conflicting regulatory approaches thereby impeding the ability of developing countries to formulate and implement their own policies.

For these reasons, developing countries need to enhance public participation in biotechnology regulation. As we have seen, however, existing biotechnology regulation frameworks in these countries largely circumscribe the space for public participation, such that the public does not get an opportunity to help frame the scope of regulation. This approach to public participation needs rethinking for three reasons. First, the impact of GM food products is likely to vary across countries and requires country-specific responses that address local concerns and needs. Accordingly, safety assessments for one country may not suffice for others and standardized tool-kit approaches to regulation that preclude public participation are not appropriate. The public should therefore be given a meaningful opportunity to debate the likely impacts of GM food products on their health and environment. Broadening public participation will thus facilitate a comprehensive consideration of the impacts of these products. Second, public participation promises to facilitate national governance and therefore constitutes a key mechanism for the citizens of developing countries to manage the processes of globalization. Finally, and perhaps more significantly, in the context of trade in GM food products, public participation may rescue the governments of developing countries from bilateral pressures to adopt regulatory frameworks that only serve the interests of donor countries.