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The Regulation of Genetically Modified Organisms: Why the *Biotech Products* Case Is a Win-Win Situation for the European Union

by Jonathan G. Dorn

Editors' Summary: The United States and the EU currently stand in discord over the safety and value of GMOs in agricultural products. The disagreement culminated in a 2006 WTO Dispute Resolution Panel ruling in favor of the EU's use of discretionary, protectionist measures when regulating GMOs. In this Article, Jonathan Dorn explores whether international trade can co-exist with environmental protection. He offers background of the differing views on GMOs, explains the U.S. rationale for filing the dispute with the WTO, and argues that the Biotech Products *case is a win-win situation for the EU.*

I. Introduction

The debate over the promise and hazards of genetically modified organisms (GMOs) in agricultural products is spirited and brings into question whether international trade can co-exist with environmental protection.[1] The transatlantic polarization regarding GMO regulation exemplifies the struggle to harmonize free trade and environmental protection. In 2003, this polarization culminated in the United States filing a dispute resolution with the World Trade Organization (WTO) against the European Union (EU) regarding alleged trade bans on products derived from or containing GMOs.[2] Since the dispute over GMOs involves potential risks and human health uncertainties, rather than currently observable health or environmental effects, the WTO ruling in the *Biotech Products* case may prove to be a seminal event in the regulation of international trade. In this Article, I present: (1) an argument that the *Biotech Products*[3] case is a win-win situation for the EU; (2) a background on the differing views on GMOs between the United States and the EU; and (3) the U.S. rationale for filing a dispute resolution and why the EU disagrees with the U.S. allegations.

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1. In this Article, the term "environmental protection" is used broadly to mean preventing ecological harm as well as harm to human health.
2. The U.S. request for the establishment of a dispute panel is entitled: European Communities—Measures Affecting the Approval and Marketing of Biotech Products [hereinafter the *Biotech Products* case]. *See* WT/DS291/23 (Aug. 8 2003).
3. European Communities—Measures Affecting the Approval and Marketing of Biotech Products (Sept. 29, 2006), *available at* http://www.wto.org/english/news_e/news06_e/291r_e.htm.

II. The Ruling in the *Biotech Products* Case: A Win-Win Situation for the EU

A. The WTO Final Ruling

On September 29, 2006, the WTO Dispute Resolution Panel issued a final ruling in the *Biotech Products*[4] case. The Panel dismissed all but two U.S. claims, upholding the U.S. contention that the general de facto moratorium as well as the product-specific de facto moratoria caused "undue delays" in contravention to Annex C(1)(a) and Article 8 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).[5] In light of these findings, the panel recommended that the Dispute Settlement Body request that the EU bring the moratoria on approvals "into conformity with its obligations under the SPS Agreement" and recognizes that the moratoria may already cease to exist per the resumption of GMO approvals.[6]

Arguably, this ruling can be viewed as a win for the EU since the panel did not dispute the right of EU Member States to restrict or ban GMOs as allowed under Article 18 of Council Directive 2001/18/EC and under the SPS Agreement. As noted by Friends of the Earth International, a nongovernmental organization (NGO), the WTO failed to rule on whether GMOs are effectively the same as non-GM foods, i.e., substantially equivalent, or whether GMOs are safe.[7] As discussed in the next section, the concept of sub-

4. *Id.*
5. *Id.* arts. 8.14(a), 8.18(a).
6. *Id.* arts. 8.16, 8.20.
7. Friends of the Earth International, Looking Behind the U.S. Spin: WTO Ruling Does Not Prevent Countries From Restricting or Banning GMOs (2006), *available at* http://www.foei.org/media/2006/WTO_briefing.pdf.

stantial equivalence and the presumption of safety are the main factors segregating U.S. and EU views on GMOs.

U.S. rationale for proceeding with the dispute resolution was to seek a ruling to establish a legal precedent regarding de facto GMO bans under the guise of the precautionary principle. The United States hoped to receive a ruling similar to the *Beef-Hormone*[8] case, where the WTO ruled that the EU ban on the use of growth hormones in beef production was inconsistent with the SPS Agreement.[9] The current ruling fails to meet U.S. expectations and, in fact, may prove to harm the U.S. position on GMOs. Even with a ruling more favorable to the United States, the EU could still claim the victory of elevating its status as a legitimate institution in the international arena. Furthermore, it seems likely that the EU will not comply with an unfavorable WTO ruling, just as it has not complied with the WTO ruling in the *Beef-Hormone*[10] case.

B. The "California Effect"[11]

One consequence of the WTO ruling may be to accelerate a "convergence to the top" where the U.S. perspective on GMOs becomes more aligned with the EU perspective.[12] Since the WTO did not dispute the right of EU Member States to ban GMOs, the social legitimacy of actions against GMOs is likely to intensify. Such actions are expected to follow the "California effect," where the support of stringent regulations in the dominant regional economies (California in the United States and Germany in the EU) leads to a "trading up" of regulatory standards in states with weak regulations.[13]

In the EU, precautionary-based regulation of GMOs will remain strong as Germany continues to tighten regulations on GM crops.[14] Additionally, the leak of a confidential Monsanto Company study indicating that one of its GM corn strains, MON 863, causes abnormalities to the internal organs, and blood of rats fed a diet of MON 863 is leading to further erosion of consumer confidence in GMOs in Europe.[15] A recent illustration of the hostility of the EU market towards GM crops is the Syngenta Corporation's decision to withhold commercialization of Bt-11 sweet corn in the EU, despite receiving approval.[16] Syngenta's decision is based on the lack of demand for GM crops in the EU, as well as on the new regulations for traceability and labeling of GM crops.[17]

The United States approved MON 863 for commercial production in 2003, and the Monsanto study is likely to provide a window of opportunity for U.S. NGOs to push for more stringent regulation of GM crops. In particular, evidence of adverse health effects from the consumption of GM crops is expected to reignite the StarLink® corn controversy. StarLink® corn is a GM crop developed by Aventis Crop Science and is not approved for human consumption. In 2000, laboratory testing indicated that taco shells sold under the Taco Bell Shells label of Kraft Foods Incorporated contained StarLink® corn,[18] illuminating the weak monitoring of GM crop usage in the United States.

A U.S. policy convergence with the EU stemming from the "California effect" is exemplified by the introduction and passage of bills in both the U.S. Congress and state legislatures.[19] Attempts to ban GMOs in California are spilling over into other states. In 2001, state legislators introduced over 100 pieces of legislation, many calling for GMO moratoria, and the number of bills introduced continues to increase.[20] The Maryland Legislature successfully passed House Bill 189 in 2001, barring the introduction of GM crops into the state, and in 2006, Rep. Dennis Kucinich (D-Ohio) introduced H.R. 5271 into the U.S. House of Representatives to assign liability for injury caused by GMOs. That bill is currently being reviewed by the Subcommittee on Health.

III. Scientific Versus Social Rationality: An Evolutionary Divergence Between the U.S. and the EU Regulatory Regimes Regarding GMOs

A. The U.S. Perspective

The U.S. regulatory approach to GMOs is based on a scientific rationality perspective. As discussed by Grant Isaac and William Kerr, this perspective drives the United States to set regulatory policies to maximize technological progress.[21] The premise behind such an approach is that economic development and growth stem from technological advancement and, as a state becomes more developed, the polity will impose more stringent social regulations regard-

8. WT/DS26 (Jan. 16, 1998), *available at* http://www.wto.org/english/tratop_e/dispu_e/repertory_e/index_abreport_ef_e.htm.

9. *Id.* While the EU remains in contravention of the WTO decision in the *Beef-Hormone* case, the ruling has effectively prevented other countries from banning the use of growth hormones in beef production. *See* Yves Tiberghien & Sean Starrs, *The EU as Global Trouble-Maker in Chief: A Political Analysis of EU Regulations and EU Global Leadership in the Field of Genetically Modified Organisms*, Paper Presented at the Conference on Europeanists, in Chicago, Ill. (Mar. 11-13, 2004). *See also* William A. Kerr & Jill E. Hobbs, *The North American-European Union Dispute Over Beef Produced Using Growth Hormones: A Major Test for the New International Trade Regime*, 25 World Econ. 283-96 (2002).

10. Kerr & Hobbs, *supra* note 9, at 33.

11. The "California effect" is a phrase coined to describe the phenomenon whereby market integration creates incentives for states with lax regulations to adopt more stringent regulations from the dominant regional economy. *See* David Vogel, Trading Up (1995).

12. Aseem Prakash & Kelly L. Kollman, *Biopolitics in the EU and the U.S.: A Race to the Bottom or Convergence to the Top?*, 47 Int'l Stud. Q. 617 (2003).

13. *Id.* at 618.

14. A new German law mandates that farmers producing GM foods will compensate neighboring farmers for any genetic contamination of their crops. *See Germany Assembly Adopts Bill on Bioengineered Foods*, Yahoo News, June 18, 2004.

15. Geoffrey Lean, *Revealed: Health Fears Over Secret Study Into GM Foods*, Independent, May 22, 2005.

16. *EU Allows Sale of Genetically Modified Corn*, Wash. Post, May 20, 2004.

17. *Syngenta Decides Not to Market GM Product in the EU After All*, Cordis News, May 26, 2004.

18. Prakash & Kollman, *supra* note 12, at 633.

19. *Id.* at 629.

20. *Id.* at 630.

21. Grant E. Isaac & William A. Kerr, *Genetically Modified Organisms at the World Trade Organization: A Harvest of Trouble*, 37 J. World Trade 1083 (2003). Grant E. Isaac is Associate Professor of Biotechnology Management at the University of Saskatchewan and an Associate of the Estey Centre for Law and Economics in International Trade, Saskatoon, Canada. William A. Kerr is Van Vlict Professor of International Trade at the University of Saskatchewan and a Senior Associate of the Estey Centre for Law and Economics in International Trade, Saskatoon, Canada.

ing environmental protection and food safety.[22] Therefore, in the absence of scientific evidence of human or environmental harm, the United States is willing to accept technologies that pose potential risks to human or environmental health. As discussed in the next section, this is in stark contrast to the EU perspective that embraces a precautionary, zero-risk approach.

The Coordinated Framework for Regulation of Biotechnology (CFRB), published by the White House Office of Science and Technology Policy in 1986, outlines the basic federal guidance for regulating biotechnology products in the United States.[23] The concept of substantial equivalence, embodied by the CFRB, is the idea that existing food sources can serve as the basis for comparison when assessing the safety of human consumption of a GM food or food component.[24] Under this concept, a GMO that is substantially equivalent to its conventional counterpart, with respect to nutritional and allergenic properties, should be regulated no differently. Therefore, the CFRB is based on the principle that techniques of biotechnology are not inherently risky and supports GMO regulation according to physical characteristics, regardless of the method of production.[25]

In 1992, the U.S. Food and Drug Administration (USDA), employing scientific rationality, ruled that GM crops are substantially equivalent to traditional plant breeding.[26] Consequently, the U.S. federal regulatory system views GM foods and agricultural products as posing no unique health or safety risks.[27] This opened the door for the development of GM seeds and crops. In 1996, the first commercial GM crop production initiated the transformation of North American agriculture, and today, only 10 years later, GM varieties comprise 89% of all soybean plantings in the United States, 83% of all cotton plantings, and 61% of all corn plantings.[28] This accounts for 55% of the GM crops planted globally.[29]

B. The EU Perspective

The EU views the role of technology in society from a social rationality perspective. Unlike the United States, the EU perceives technology as a normative activity that disrupts the delicate social balance between citizen preferences and concerns.[30] EU regulatory policies are built on a foundation of technological precaution to ensure that the changes brought about through scientific advancement are socially desirable. Unlike the United States, the EU social rationality perspective tolerates zero risk to human or environmental health posed by technological advancement and focuses regulations on biotechnological processes rather than the physical characteristics of the product.[31] This precautionary approach means that if scientific evidence on potential human or environmental harm is inconclusive, then the GMO should be more stringently regulated or even prohibited to protect citizens against unforeseen future problems. Therefore, the EU views the products of biotechnology, such as GMOs, as inherently different from their conventional counterparts, in contrast to the substantially equivalent edict of the United States.

The difference in U.S. and EU perspectives on GMOs is attributable to two primary factors: (1) a series of food safety crises swept through the EU in the 1990s, effectively eroding EU consumer confidence in food production and food safety regulation[32]; and (2) an EU political response to an institutional legitimacy crisis.[33] In the early 1990s, bovine spongiform encephalopathy (BSE) emerged in the United Kingdom (U.K.), and U.K. health officials insisted that ingestion of meat from BSE-infected animals would not transmit the disease to humans. However, by the mid-1990s, the BSE outbreak had spread to other parts of the EU, and scientific evidence disproved the noninfectious assertion by establishing that consumption of meat from BSE-infected animals could result in human disease.[34] Furthermore, in 1999, an incident at the Flemish fat-melting company, Verkest, led to the contamination of animal feed with polychlorinated biphenyls (PCBs) and dioxins.[35] Chickens fed the contaminated feed incorporated the dioxins into their tissues and eggs and human exposure resulted via consumption of store-bought products. Finally, the persistent recurrence of foot-and-mouth disease outbreaks across the EU further dampens consumer confidence in government regulation of food.[36]

The EU position can also be viewed as a political response to a crisis of international legitimacy.[37] Leading into the GMO debate, civil society groups began placing pressure on the EU to take a stand against globalization, an area where the EU remained silent. Rather than voicing opposition to the civil society movement, the EU rationalized that a strong stance in the GMO debate could create a common EU identity.[38] Therefore, the GMO position articulated by the

22. *Id.* at 1087.

23. *See* 51 Fed. Reg. 23302 (June 26, 1986).

24. *See* Organization for Economic Cooperation & Development et al., Safety Evaluation of Foods Derived by Modern Technology: Concepts and Principles 11 (1992), *available at* http://www.oecd.org/dataoecd/57/3/1946129.pdf.

25. Office of Science & Technology Policy, *Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment*, 57 Fed. Reg. 6753 (Feb. 27, 1992).

26. USDA, *Statement of Policy: Foods Derived From New Plant Varieties*, 57 Fed. Reg. 22984 (May 29, 1992).

27. *See* National Ass'n of State Departments of Agriculture & Pew Initiative on Food and Biotechnology, Peaceful Coexistence Among Growers of Genetically Engineered, Conventional, and Organic Crops 8 (2006), *available at* http://pewagbiotech.org/events/0301/WorkshopReport.pdf.

28. Economic Research Serv., USDA, *Adoption of Genetically Engineered Crops in the United States*, http://www.ers.usda.gov/data/BiotechCrops (last visited Jan. 11, 2007).

29. Charles E. Hanrahan, *Agricultural Biotechnology: The U.S.-E.U. Dispute*, Cong. Research Serv. Rep., RS21556 (Mar. 10, 2006).

30. Isaac & Kerr, *supra* note 21, at 1088.

31. *Id.*

32. Elsa Tsioumani, *Genetically Modified Organisms in the EU: Public Attitudes and Regulatory Developments*, 13 RECIEL 279 (2004).

33. Tiberghien & Starrs, *supra* note 9, at 4.

34. The human form is known as Creutzfeldt-Jakob disease. *See* John Collinge, *Human Prion Diseases and Bovine Spongiform Encephalopathy*, 6 Hum. Molecular Genetics 1699 (1997).

35. Nik van Larebeke et al., *The Belgium PCB and Dioxin Incident of January-June 1999: Exposure Data and Potential Impact on Health*, 109 Envtl. Health Persp. 266 (2001).

36. Wouter Poortinga et al., *The British 2001 Foot and Mouth Crisis: A Comparative Study of Public Risk Perceptions, Trust and Beliefs About Government Policy in Two Communities*, 7 J. Risk Res. 73 (2004).

37. Tiberghien & Starrs, *supra* note 9, at 4.

38. *Id.*

EU serves a far greater purpose than protection of human and environmental health; it helps to establish the EU as a legitimate institution in the international arena.

The EU position on GMOs materialized in 1999 with a de facto moratorium on the approval of new GM products and in 2001 with Council Directive 2001/18/EC. Building off the precautionary principle codified in Article 174(2) of the EU environmental law,[39] Recital 8 in the Preamble of the Council Directive states that "the precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it."[40] The main objectives outlined in the Council Directive are that human health and environmental risks must be assessed before any GMO or GMO-containing product can be marketed or released into the environment. The Council Directive further requires that deliberate releases of GMOs into the environment must conform to the "step-by-step" principle, whereby the scale of GMO release is increased gradually and continues only once risk assessment at each step proves satisfactory.[41] In 2003, the EU continued to strengthen its position on GM products by passing legislation on GM food and feed[42] and on traceability and labeling.[43] This new legislation requires the labeling of food or feed products if GMO material in the product exceeds a 0.9% threshold. Furthermore, to allow traceability, GM products placed on the EU market must be identified and information must be transmitted from operator to operator.

IV. The U.S. and EU Positions in the *Biotech Products* Case

A. The U.S. Rationale

The United States criticized the EU de facto moratorium on the approval of new GM products, but hesitated in taking the EU to the WTO due to concerns over consumer backlash.[44] However, with countries such as Zimbabwe[45] and China[46] beginning to adopt the EU precautionary approach to GM products, the United States became fearful that other countries would begin banning GM products. Consequently, the United States proceeded with filing a dispute with the WTO on May 13, 2003, and is primarily seeking a ruling, rather than a negotiated settlement, to establish a legal precedent regarding de facto GMO bans under the guise of the precautionary principle.

Since the EU had not officially banned the approval of GM products, but classified all applications as pending, the United States concluded that the most successful avenue would be to file the dispute under Annex C(1)(a) and Article 8 of the SPS Agreement.[47] Article 8 of the SPS Agreement mandates Members to comply with Annex C during approval procedures and Annex C(1)(a) requires that "such procedures are undertaken and completed without undue delay." Other relevant U.S. legal arguments against the EU include: (1) violation of Article 5.1 of the SPS Agreement by failing to publish risk assessments on the likelihood of harm resulting from GM products; (2) violation of Article 2.2 by maintaining the de facto moratoria without "sufficient scientific evidence"; and (3) violation of Article 5.5 by regulating GM products more stringently than GM processing agents—this in contravention of the requirement that WTO Members must apply SPS measures indiscriminately to domestic and imported products.[48]

B. The EU Stance

The EU contends that there is no evidence of a moratorium on the approval of GM products, since no official EU communication declared a moratorium.[49] Additionally, the EU discredits the claim that their precautionary approach to the approval of GM products breached the "undue delay" requirements of SPS Article 8 and Annex C(1)(a). The EU argues that precaution is warranted per their obligations under: (1) Articles 10.6 and 11.8 of the Cartagena Protocol on Biosafety,[50] an international agreement to which the United States is not a Member; (2) Council Directive 2001/18/EC; and (3) Article 5.7 of the SPS Agreement. According to the Preamble of the Cartagena Protocol, the protocol stands in parallel to WTO agreements and is not intended to be subordinate. Furthermore, according to Article 30(3) of the 1969 Vienna Convention on the Law of Treaties, the agreement signed later in time prevails when there is a conflict between international agreements signed by the same Party—in this case the Cartagena Protocol.[51]

The EU also argued that there is precedent for thorough review of GM products as exemplified by the three-year delay in Canadian approval of Monsanto's application to commercialize a GM wheat strain.[52] In May 2004, the EU effectively ended the de facto moratorium by approving Syngenta Bt-11, a GM corn variety, for commercial produc-

39. Article 174(2) of the EU treaty specifies: "Community policy on the environment shall . . . be based on the precautionary principle and on the principles that preventive action should be taken."

40. The text of Council Directive 2001/18/EC is available at http://www.biosafety.be/GB/Dir.Eur.GB/Del.Rel./2001_18/2001_18_PR.html.

41. Christopher Hilson & Duncan French, *Regulating GM Products in the EU: Risk, Precaution, and International Trade*, *in* Agriculture and International Trade: Law, Policy, and the WTO 215 (M.N. Cardwell et al. eds., 2003).

42. Commission Regulation 1829/2003, Genetically Modified Food and Feed, 2003 O.J. (L268) 1-23 (EC).

43. Commission Regulation 1830/2003 , Traceability and Labelling of Genetically Modified Organisms, 2003 O.J. (L268) 24 (EC).

44. Tiberghien & Starrs, *supra* note 9, at 33.

45. Ruth Gidley, *African Crisis Fuels Debate Over GM Food*, Reuters, July 19, 2002.

46. *The GM Gamble*, Econ., May 15, 2003.

47. The SPS Agreement deals with safety-related, process, and production method bans and requires a scientific justification for imposed bans. *See* Asif H. Qureshi, *The Cartagena Protocol on Biosafety and the WTO: Co-Existence or Incoherence?*, 49 Int'l & Comp. L.Q. 835 (2000). The text of the SPS Agreement is available at http://www.wto.org/English/tratop_e/sps_e/spsagr_e.htm (last visited Jan. 11, 2007).

48. Steve Suppan, The Institute for Agriculture & Trade Policy, U.S. Versus EC Biotech Products Case: WTO Dispute Backgrounder 8-9 (2005), *available at* http://www.tradeobservatory.org/library.cfm?refid=76644.

49. First Written Submission by the European Communities, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products* ¶¶ 541, 557-563 (May 17, 2004), *available at* http://trade.ec.europa.eu/doclib/docs/2004/june/tradoc_117687.pdf.

50. The text of the Cartagena Protocol on Biosafety is available at http://www.biodiv.org/biosafety/default.aspx.

51. Qureshi, *supra* note 47, at 854.

52. First Written Submission by the European Communities, *supra* note 49, ¶¶ 486-489.

tion. However, as mentioned previously, Syngenta is withholding commercialization due to market concerns.

V. Conclusion

The *Biotech Products* case is effectively a win-win situation for the EU and a U.S. appeal is unlikely to moderate the EU position. The WTO ruling sides with the EU by legitimizing the use of discretionary, protectionist measures when regulating GMOs. Furthermore, the *Biotech Products* case may backfire on the United States by opening a window of opportunity for the weak level of consumer acceptance of GMOs in the EU to spread to the United States. A decrease in U.S. consumer confidence may materialize as a "convergence to the top" where U.S. regulations begin to align with the more precautionary-based regulations in the EU.