Chicago Journal of International Law

Volume 5 | Number 1 Article 26

6-1-2004

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Recommended Citation

Vallely, Patrick J. (2004) "Tension Between the Cartagena Protocol and the WTO: The Significance of Recent WTO Developments in an Ongoing Debate," Chicago Journal of International Law: Vol. 5: No. 1, Article 26.

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Tension between the Cartagena Protocol and the WTO: The Significance of Recent WTO Developments in an Ongoing Debate Patrick J. Vallely*

On September 11, 2003, the Cartagena Protocol on Biosafety ("Protocol") entered into force. The Protocol attempts to protect biodiversity and human health against adverse effects resulting from the handling and transfer of living modified organisms ("LMOs"). The Protocol defines an LMO as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." Continually increasing trade of LMOs, particularly in agriculture, has triggered much debate concerning the scientific advantages and potential dangers of LMOs to humans and the environment. LMO producers highlight the benefits of LMOs, including insect resistance, increased production, resistance to adverse weather, and a reduced need for pesticides. Critics of LMOs, including many developing countries, cite concerns of human allergic reactions to LMO crops, effects of insect-resistant

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¹ Cartagena Protocol on Biosafety (Montreal, 29 January 2000) Status of Ratification and Entry into Force, available online at http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt (visited Mar 28, 2004). Although the United States has not signed the protocol, many key trading partners of the United States have signed and ratified it, including the European Community, most European nations individually, Japan, India, and Mexico, to name a few.

² Cartagena Protocol on Biosafety to the Convention on Biological Diversity art 1, available online at http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf (visited Mar 28, 2004). The term "LMOs" is basically interchangeable with "genetically modified organisms," or "GMOs" for short. See Olivette Rivera-Torres, *The Biosafety Protocol and the WTO*, 26 BC Intl & Comp L Rev 263, 271 (2003).

³ Cartagena Protocol on Biosafety art 3 (cited in note 2).

See Kirsten N. Jabara, *The Biosafety Protocol*, 8 U Balt J Envir L 121, 138–43 (2001) (summarizing the increasing trade of LMOs and the roles of interested parties).

For a fairly thorough summary of the scientific benefits and concerns surrounding LMOs, see Marsha A. Echols, Food Safety and the WTO: The Interplay of Culture, Science and Technology 67–75 (Kluwer 2001).

crops on other plant life, and the general scientific uncertainty that surrounds this new technology.⁶

Commentators have analyzed in depth the extent to which the Protocol conflicts with various WTO provisions, including the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement").⁷ The most significant conflict between the SPS Agreement and the Protocol regards the amount of scientific evidence of negative effects on the environment or human health an importing state must produce to justify a trade restriction on LMOs. The Protocol allows states to impose trade restrictions on LMOs without scientific justification where science concerning the LMOs' safety is uncertain.⁸ The SPS Agreement, in contrast, requires solid scientific evidence to justify such a trade restriction⁹ and shifts the emphasis of the inquiry to trade concerns.¹⁰

Disputes recently decided and pending before the WTO will significantly affect prior analyses of the conflict between treaties. A recent WTO Appellate Body decision against Japan concerning import restrictions on apples ("Apples")¹¹ sheds light on how the SPS Agreement interacts with trade restrictions based on environmental concerns. Also, a pending panel dispute addressing trade restrictions on LMOs ("Biotech Products")¹² will provide significant guidance as to how the WTO will resolve the conflict between the two treaties.

⁶ Id.

See Rivera-Torres, 26 BC Intl & Comp L Rev at 301–15, 319–23 (cited in note 2); Fiona Macmillan, WTO and the Environment 177–83 (Sweet & Maxwell 2001); Aaron Cosbey and Stas Burgiel, The Cartagena Protocol on Biosafety: An Analysis of Results 12–17, available online at http://www.iisd.org/pdf/biosafety.pdf (visited Mar 28, 2004); Steve Charnovitz, The Supervision of Health and Biosafety Regulation by World Trade Rules, 13 Tulane Envir L J 271, 298–302 (2000); Gretchen L. Gaston and Randall S. Abate, The Biosafety Protocol and the World Trade Organization: Can the Two Coexist?, 12 Pace Intl L Rev 107, 117–51 (2000); Sabrina Safrin, Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements, 96 Am J Intl L 606 (2002).

⁸ Cartagena Protocol on Biosafety art 10.6 (cited in note 2).

⁹ Agreement on the Application of Sanitary and Phytosanitary Measures art 2.2, available online at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf (visited Mar 28, 2004) (hereinafter SPS Agreement).

When compared in whole, the terms of the SPS Agreement repeatedly require states to balance trade concerns with environmental concerns, thus placing a greater emphasis on free trade. See, for example, id art 5.3 (requiring states to consider loss of production and sales when assessing risk); id art 5.4 (requiring states to consider objective of "minimizing negative trade effects"); id art 5.6 (ensuring that trade restrictions "are not more trade-restrictive than required").

World Trade Organization, Report of the Appellate Body, Japan—Measures Affecting the Importation of Apples, WTO Doc WT/DS245/AB/R (Nov 26, 2003).

World Trade Organization, Request for the Establishment of a Panel by the United States, European Communities—Measures Affecting the Approval and Marketing of Biotech Products, WTO Doc WT/DS291/23 (Aug 8, 2003).

This Development does not examine all potential conflicts between the treaties, ¹³ but instead focuses on what these two WTO disputes mean for those conflicts. Part I of this Development provides background on the Protocol, the SPS Agreement, and their potential for conflict. Part II analyzes the *Apples* decision and its significance for the conflict between the two treaties. Part III examines the pending dispute before the WTO concerning a European Community ("EC") trade moratorium on LMOs and the implications of the dispute for the Cartagena Protocol. Finally, Part IV considers the significance of these disputes in understanding the relationship between the two treaties.

I. THE EXISTING CONFLICT BETWEEN THE PROTOCOL AND THE SPS AGREEMENT

The Cartagena Protocol is a product of the Convention on Biological Diversity, a broad biodiversity agreement that came about as a result of the 1992 Earth Summit in Rio de Janeiro: 14

[T]he objective of [the] Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.¹⁵

The Protocol attempts to meet its broad objectives by regulating the procedural and substantive requirements under which states may impose trade restrictions on LMOs.

The first step in the regulatory framework of the Protocol is a notification procedure. Under this procedure, an LMO-exporting state must first notify the importing country of its intent to export, ¹⁶ including a fairly lengthy list of details about the LMO, its intended use, and the measures taken to protect biosafety and human health. ¹⁷ The importing state must then acknowledge the notification ¹⁸ and proceed to engage in a risk assessment procedure. ¹⁹ The Protocol requires parties to conduct risk assessment "in a scientifically sound manner . . . taking into account recognized risk assessment techniques." Annex

For a detailed analysis on all potential sources of conflict between the Protocol and various WTO agreements, see Rivera-Torres, 26 BC Intl & Comp L Rev at 301–21 (cited in note 2).

For a thorough description of the history of the Cartagena Protocol, see id at 269-73.

¹⁵ Cartagena Protocol on Biosafety art 1 (cited in note 2).

¹⁶ Id art 8.1.

¹⁷ Id at annex I.

¹⁸ Id art 9.1.

¹⁹ Id arts 10, 15.

²⁰ Id art 15.

III of the Protocol provides a rough outline of the risk assessment procedure, ²¹ but ambiguity provides states with opportunities to establish procedures that meet their own subjective ends. Following a risk assessment, the importing state may decide to allow importation of the LMO, to prohibit import altogether, or to allow the import on certain conditions. ²²

The most controversial language in the Protocol relevant here is Article 10.6, which incorporates what is known as a "precautionary principle." It states:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . , in order to avoid or minimize such potential adverse effects.²³

This provision is controversial because it seemingly allows a country to restrict trade even in the absence of scientific justification. Some commentators even suggest that this clause of the Protocol permits a state to adopt a "zero tolerance policy," restricting import of all LMOs.²⁴

The preambular language of the SPS Agreement demonstrates goals different than the Protocol. While the SPS Agreement recognizes that states should not "be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health," sounding somewhat like the Protocol, the SPS also concerns itself with "negative effects on trade" and "access to markets." In other words, the SPS balances environmental concerns against free trade concerns, while the Protocol's emphasis is purely environmental. Interpretations of the SPS Agreement reject trade restrictions based on purely local perceptions of what is safe, displacing national attitudes with science-based rules. 26

The SPS Agreement's relative emphasis on trade is reflected heavily in its risk assessment provisions. Appellate Body decisions hold that a party must show probability, not just possibility, of risk to the environment or human health.²⁷ In addition to various scientific factors, the SPS Agreement requires

²¹ Id at annex III.

²² Id art 10.3.

²³ Id art 10.6.

See, for example, Macmillan, WTO and the Environment at 180 (cited in note 7).

²⁵ SPS Agreement at preamble (cited in note 9).

²⁶ Echols, Food Safety and the WTO at 3 (cited in note 5).

Joost Pauwelyn, Applying SPS in WTO Disputes, in David Robertson and Aynsley Kellow, eds, Globalization and the Environment: Risk Assessment and the WTO 63, 66 (Edward Elgar 2001) (summarizing WTO case law and concluding that it is not sufficient for a risk assessment to show only possibility of entry of disease—a party must evaluate the probability of such an entry).

countries to consider "potential damage in terms of loss of production or sales in the event of the entry," the "relative cost-effectiveness of alternative approaches to limiting risks," and the avoidance of a "disguised restriction on international trade." Where a risk justifies regulation of trade, states are instructed not to impose a measure "more trade-restrictive than required" to meet the ends of the regulation. ²⁹ Most importantly with respect to conflict with the Protocol, the SPS Agreement requires that states base trade-restricting measures on "scientific principles" and orders states not to maintain measures "without sufficient scientific evidence."

The most obvious conflict between the treaties is between the Protocol's precautionary principle and the SPS Agreement's requirement of "sufficient" evidence. The Protocol appears to set forth a much lower standard, which may allow states to reject importation of LMOs without any scientific evidence whatsoever, where relevant scientific data is lacking. Although the SPS Agreement contains its own precautionary principle,31 WTO decisions have repeatedly weakened its significance, leading commentators to characterize the SPS Agreement's precautionary principle as eviscerated.³² The WTO Appellate Body found that a precautionary principle "has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise found that if any of the four requirements³⁴ for invoking the SPS Agreement's precautionary principle are not met, then the trade restriction is unwarranted.35 Furthermore, while the SPS Agreement requires states enacting temporary measures without scientific evidence to search for additional scientific evidence justifying the restriction "within a reasonable period of time,"36 the Protocol establishes no such ongoing duty to discover evidence.

SPS Agreement arts 5.3, 5.5 (cited in note 9).

²⁹ Id art 5.6.

³⁰ Id art 2.2 (emphasis added).

³¹ Id art 5.7.

James Cameron, The Precautionary Principle, in Gary P. Sampson and W. Bradnee Chambers, eds, Trade, Environment, and the Millennium 287, 311–12 (UN University 2d ed 2002).

World Trade Organization, Report of the Appellate Body, EC—Measures concerning Meat and Meat Products (Hormones) ¶ 124, WTO Doc WT/DS26/AB/R (Jan 16, 1998).

The four requirements are (1) where available scientific information is not sufficient, (2) measures are adopted on the basis of relevant information, (3) the state restricting trade attempts to obtain information necessary for further risk assessment, and (4) the measure is reviewed in a reasonable period of time. Pauwelyn, Applying SPS in WTO Disputes at 69 (cited in note 27).

World Trade Organization, Report of the Appellate Body, Japan—Measures Affecting Agricultural Products ¶ 91, WTO Doc WT/DS76/AB/R (Feb 22, 1999) (finding there was no need to examine the requirements of the first sentence of Article 5.7 because the requirements of the second sentence were not met).

³⁶ SPS Agreement art 5.7 (cited in note 9).

Some commentators find no necessary conflict, asserting that a state restricting trade under the Protocol must also meet the standards of the SPS Agreement or that the two agreements are consistent.³⁷ However, this conclusion relies on the assumption that both agreements function to limit a state's power to restrict trade, which is not necessarily the case. The Protocol, in many respects, appears to be a *grant* of power—asserting that states may take certain measures to protect biodiversity and human health. If this is true, then the Protocol appears to *grant* power to states that the SPS Agreement *denies*. Also, the fact that numerous commentators have extensively analyzed the potential for conflict between the two treaties illustrates that such a conflict is not a moot issue.

II. IMPLICATIONS OF THE APPLES DISPUTE

The dispute in the *Apples* case involves Japanese policies related to the protection of its domestic apple crops from a bacterium known as "fire blight." The "fire blight" bacterium originated in North America and later spread to Europe and parts of the Mediterranean, but has not yet affected Latin America, Africa, or most of Asia.³⁸ Japan imposed burdensome restrictions on the importation of United States apples, prompting the United States' claim that Japan was in violation of the SPS Agreement.³⁹

The WTO Appellate Body made important conclusions relevant to the treaty conflict here at issue. Japan argued that given the lack of current scientific knowledge concerning the bacterium's pathway and method of transmission, the lower Panel (which found against Japan) should have accorded more deference to Japan's risk assessment. The Appellate Body rejected this argument, upholding the Panel's conclusion that the measure was "clearly disproportionate to the risk identified on the basis of the scientific evidence available." According to the Appellate Body, "total deference to the findings of the national authorities would not ensure" the objective assessment required by the SPS Agreement. Consequently, the Appellate Body found Japan in violation of

See, for example, Cosbey and Burgiel, *The Cartagena Protocol on Biosafety* (cited in note 7); Charnovitz, 13 Tulane Envir L J at 300 (cited in note 7); Safrin, 96 Am J Intl L at 628 (cited in note 7).

World Trade Organization, Report of the Panel, Japan—Measures Affecting the Importation of Apples ¶¶ 2.1–2.6, WTO Doc WT/DS245/R (July 15, 2003).

³⁹ Id ¶ 3.1.

World Trade Organization, Report of the Appellate Body, Japan—Measures Affecting the Importation of Apples ¶ 161 (Nov 26, 2003) (cited in note 11).

Id ¶ 163, quoting World Trade Organization, Report of the Panel, Japan—Measures Affecting the Importation of Apples ¶¶ 2.1–2.6 (July 15, 2003) (cited in note 38).

⁴² Id ¶ 165.

Article 2.2 of the SPS Agreement as the measure in question was imposed without sufficient scientific evidence.⁴³ In coming to this conclusion, the Appellate Body determined that Japan's risk assessment procedure failed to establish a causal relationship between the imposition of the trade restriction and the prevention of the bacterium's introduction. Specifically, risk assessment should not merely consider the possible adverse effects, but "must connect the possibility of adverse affects with an antecedent or cause."⁴⁴

Another significant aspect of the *Apples* decision was the Appellate Body's exposition on burdens of proof. Japan argued that the United States, as the exporter of a disease, had more information regarding the bacterium, and that therefore, the burden of scientific proof should be on the United States to prove the safety of their exports. ⁴⁵ Japan further argued that the United States should be required to prove affirmatively the insufficiency of scientific evidence underlying Japan's measures. ⁴⁶ The Panel rejected these suggestions, emphatically asserting that "the burden is on Japan, as the party invoking Article 5.7 to make a prima facie case in support of its position." ⁴⁷ The Appellate Body upheld the Panel's conclusions, holding that although the complaining party has the burden of establishing a prima facie case of conflict with the SPS Agreement, the responding party "must prove the case it seeks to make in response." ⁴⁸

This case is significant to the future of the Cartagena Protocol in a couple of ways. First, the Appellate Body reinforced the WTO's consistent rejection of measures asserted to protect the health of plants and animals under the SPS Agreement and rejected Japan's request for deference to its scientific risk assessment. This trend demonstrates a general hostility by the WTO to environmental claims of ambiguous scientific validity. It also stands in conflict to the Protocol's precautionary principle, which gives much deference to environmental concerns of individual states. The Panel's focus on Japan's "disproportionate" actions, upheld by the Appellate Body, is also significant. The Protocol has no such proportionality requirement, creating further conflict between the treaties. Assuming future WTO decisions follow the logic in the *Apples* case, the deference and latitude the Protocol affords to states restricting trade will be meaningless.

⁴³ Id ¶ 168.

⁴⁴ Id¶ 202, n 372.

World Trade Organization, Report of the Panel, Japan—Measures Affecting the Importation of Apples ¶ 7.2–7.5, 8.44 (July 15, 2003) (cited in note 38).

World Trade Organization, Report of the Appellate Body, Japan—Measures Affecting the Importation of Apples ¶¶ 149–50 (Nov 26, 2003) (cited in note 11).

World Trade Organization, Report of the Panel, Japan—Measures Affecting the Importation of Apples ¶ 8.212 (July 15, 2003) (cited in note 38).

World Trade Organization, Report of the Appellate Body, Japan—Measures Affecting the Importation of Apples ¶ 153–54 (Nov 26, 2003) (cited in note 11).

The burden of proof issue analyzed in the *Apples* case is also important. The precautionary principle contained in Article 10 of the Protocol suggests a great amount of deference to the state imposing restrictions on trade in justifying the restriction. When combined with the detailed notification requirements imposed on exporters, the Protocol appears to impose a burden on the exporting country to demonstrate the safety of a given LMO export. The actual evidentiary burdens imposed on parties in a dispute under the Protocol are not yet known, as the Protocol defers agreement on specific procedural issues to a later date,⁴⁹ but the text implies that the burden lies with the exporter. This directly conflicts with the assertion in *Apples* that the burden lies on the trade-restricting country to prove its side of the argument, further complicating reconciliation of the two treaties. Such an allocation of burdens, as a procedural matter, will significantly weaken the protections afforded trade-restricting states under the Protocol.

III. IMPLICATIONS OF THE PENDING BIOTECH PRODUCTS DISPUTE

Ambiguity exists as to what would happen in a dispute involving both treaties. To which body would the parties turn? Which body would more likely seize the case? What result? Although this conflict may be distant, a pending case before a WTO Panel will shed light on how the WTO's SPS Agreement jurisprudence applies to LMOs.

On August 7, 2003, the United States requested the establishment of a Panel to examine measures taken by the EC concerning LMOs. ⁵⁰ The United States complains of a moratorium imposed by the EC on all such products, under which the EC has suspended consideration for applications to import such products into the EC. The result of this moratorium has been the exclusion of United States LMO products from the EC's market. The United States also complains of national policies imposed by EC member states having similar effects on LMO imports and alleges that such restrictions violate the SPS Agreement. This dispute is the first in the WTO concerning LMOs.

This dispute will help answer a number of preliminary questions about the conflict between the Protocol and the SPS Agreement. One question is how a WTO panel will evaluate scientific evidence concerning LMOs. The WTO, in other disputes under the SPS Agreement, has generally found scientific evidence

See Cartagena Protocol on Biosafety art 27 (cited in note 2).

World Trade Organization, Request for the Establishment of a Panel by the United States, European Communities—Measures Affecting the Approval and Marketing of Biotech Products (cited in note 12). The United States uses the term "products of agricultural biotechnology" in the dispute, which describes products included in the Protocol's definition of "LMOs." See Cartagena Protocol on Biosafety art 3 (cited in note 2).

and risk assessment procedures lacking, thus rejecting importing states' attempts at restricting the inflow of certain goods.⁵¹ However, LMOs present unique issues not addressed in prior SPS disputes, including the recent emergence of bioengineering technology, the tremendous amount of public concern associated with their safety, and the uncertainty of scientific evidence justifying or mitigating such public concern. Regardless of the outcome, this dispute will have significant ramifications for the trade of LMOs generally.

The implications for the Cartagena Protocol are unclear, given the immaturity of this dispute. If the WTO rejects a science-based justification for the moratorium which appears to be permissible under the Protocol's precautionary principle, then the collision between the Protocol and the SPS Agreement will become more imminent. If the WTO accepts the EC's science, focusing on the gravity of the alleged threat of LMOs, room for harmony between the two treaties will expand. Additionally, if the WTO reemphasizes the importing country's burden to demonstrate harm and causation before restricting import, it will foreshadow future conflicts between the burdens of proof of the two agreements, given the Protocol's apparent placement of burden on the exporting state. Given the overlap in issues between the Biotech Products case and the conflict of treaties discussed in this Development, this case will provide us with guidance as to whether the WTO will permit the Protocol's language to survive as international law.⁵²

IV. CONCLUSION

Although the bulk of commentators conclude that conflict between the SPS Agreement and the Protocol is either non-existent or insignificant,⁵³ the *Apples* decision and the *Biotech Products* case (if the panel there follows the same

See, for example, World Trade Organization, Report of the Appellate Body, Japan—Measures Affecting Agricultural Products ¶ 85 (Feb 22, 1999) (cited in note 35) (upholding Panel's finding of violation of Article 2.2 on some products where the importing country lacked sufficient scientific evidence to maintain a trade restriction); World Trade Organization, Report of the Appellate Body, Australia—Measures Affecting Importation of Salmon ¶¶ 135–38, WTO Doc WT/DS18/AB/R (Oct 20, 1998) (upholding Panel's finding that the importing country failed to conduct a proper risk assessment while maintaining trade restrictions, thus violating Articles 5.1 and 2.2 of the SPS Agreement).

Exactly how a conflict between the two treaties would play out in actuality implicates complex issues of international law that are beyond the scope of this paper. Needless to say, interested parties would have clashing views as to which treaty's language should prevail. For an example of a discussion on how a conflict may be resolved, see Safrin, 96 Am J Intl L at 622–27 (cited in note 7).

⁵³ See, for example, Cosbey and Burgiel, The Cartagena Protocol on Biosafety (cited in note 7); Charnovitz, 13 Tulane Envir L J at 300 (cited in note 7); Safrin, 96 Am J Intl L at 628 (cited in note 7).

Chicago Journal of International Law

trend as in the *Apples* panel) make such a conflict much more likely. The conflict between the two treaties may be resolved by state practice or by an authoritative decision from the WTO, but states are likely to have differing views on the relationship between the two treaties, given their differing interests and goals. The existing scholarly debate and recent developments in the WTO reveal the existence of, at minimum, a political conflict. If the WTO continues on its current path, the peaceful coexistence of these two treaties will almost surely end.