EC – APPROVAL AND MARKETING OF BIOTECH PRODUCTS[1]

(DS291, 292, 293)

PARTIES		AGREEMENT	TIMELINE OF THE DISPUTE	
Complainants	*United States* *Canada* *Argentina*	*SPS Arts. 2.2, 2.3, 5.1, 5.5, 5.6, 5.7, 7, 8, 10.1; Annex B(1), C(1)(a), C(1)(b), C(1)(c), C(1)(e)*	Establishment of Panel	*29 August 2003*
			Circulation of Panel Report	*29 September 2006*
Respondent	*European* Communities		Circulation of AB Report	*NA*
			Adoption	*21 November 2006*

1. MEASURES AND PRODUCTS AT ISSUE

- Measures at issue: (i) Alleged general EC moratorium on approvals of biotech products; (ii) EC measures allegedly affecting the approval of specific biotech products; and (iii) EC member State safeguard measures prohibiting the import/marketing of specific biotech products within the territories of these member States.

- Products at issue: Agricultural biotech products from the United States, Canada and Argentina.

2. SUMMARY OF KEY PANEL/AB FINDINGS[2]

General EC moratorium

- Existence of moratorium: The Panel found that a general de facto moratorium on approvals of biotech products was in effect on the date of panel establishment, i.e., August 2003. It was general in that it applied to all applications for approval pending in August 2003 under the relevant EC legislation, and de facto because it had not been formally adopted. Approvals were prevented through actions/omissions by a group of five EC member States and/or the European Commission.

- SPS Arts. 5.1 and 2.2: The Panel found that the EC decision to apply a general moratorium was a decision concerning the application/operation of approval procedures, i.e., a procedural decision to delay final substantive approval decisions. It was not applied for achieving the EC level of sanitary or phytosanitary protection and, hence, was not an "SPS measure" subject to Arts. 5.1 or 2.2.

- SPS Annex C(1)(a) and Art. 8: The Panel found that the general moratorium led to undue delay in the completion of the EC approval procedure conducted in respect of at least one biotech product at issue and thereby to the European Communities acting inconsistently with Annex C(1)(a) and, by implication, Art. 8.

Product-specific measures

- SPS Annex C(1)(a) and Art. 8: The Panel found that in 24 of the 27 product-specific approval procedures it examined, the procedure had not been completed without undue delay. In respect of these procedures, the European Communities had, therefore, acted inconsistently with Annex C(1)(a) and, by implication, Art. 8.

EC member State safeguard measures

- SPS Arts. 5.1, 2.2 and 5.7: According to the Panel, the record did not indicate that there was insufficient evidence to conduct a risk assessment within the meaning of Art. 5.1 and Annex A(4) for the biotech products subject to safeguard measures. As a result, Arts. 5.1 and 2.2 were applicable. In this regard, the Panel found that none of the safeguard measures at issue were based on a risk assessment as required under Art. 5.1 and defined in Annex A(4). By maintaining measures contrary to Art. 5.1, the European Communities had, by implication, also acted inconsistently with Art. 2.2.

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2 Other issues addressed in this case: unauthorized disclosure of confidential interim panel reports; consultation of scientific experts; submission of new evidence at interim review stage; DSU Art. 6.2: specificity required in case of de facto measures; findings on measures no longer in existence on the date of panel establishment and on measures that subsequently cease to exist; DSU 19: qualified recommendation; VCLT Art. 31(3)(c): relevance of other rules of international law to the interpretation of the WTO Agreement; precautionary principle in international law; precautionary approach: (i) in the context of SPS Annex C(1)(a), (ii) in the context of SPS Art. 5.1; SPS Annex A(1): (i) scope of SPS Agreement (e.g., environment, labelling, co-existence), (ii) meaning of "SPS measure"; relationship between the SPS Agreement and the TBT Agreement; SPS Art. 5.1: meaning of "appropriate to the circumstances"; SPS Art. 5.7: (i) relationship with SPS Arts. 2.2 and 5.1, (ii) relevance of appropriate level of sanitary or phytosanitary protection, (iii) time at which insufficiency of scientific evidence is to be assessed; GATT Art. III:4.