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**EUROPEAN COMMUNITIES – MEASURES AFFECTING THE APPROVAL
AND MARKETING OF BIOTECH PRODUCTS**

Request for Consultations by the United States

The following communication, dated 13 May 2003, from the Permanent Mission of the United States to the Permanent Delegation of the European Commission and to the Chairman of the Dispute Settlement Body, is circulated in accordance with Article 4.4 of the DSU.

My authorities have instructed me to request consultations with the European Communities ("EC") pursuant to Article 4 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU"), Article 11 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement"), Article 19 of the *Agreement on Agriculture* ("Agriculture Agreement"), Article 14 of the *Agreement on Technical Barriers to Trade* ("TBT Agreement") and Article XXII of the *General Agreement on Tariffs and Trade 1994* ("GATT 1994") with regard to certain measures taken by the EC and its member States affecting products of biotechnology ("biotech products").

Since October 1998, the EC has applied a moratorium on the approval of biotech products. The EC has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system. A number of applications for placing biotech products on the market have been blocked in the approval process under EC legislation¹ and have never been considered for final approval. The approvals moratorium has restricted imports of agricultural and food products from the United States.

Moreover, the member States maintain a number of national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC. The national marketing and import bans have restricted imports of agricultural and food products from the United States.

The measures affecting biotech products in the EC include:

- (1) the suspension by the EC of consideration of applications for, or granting of, approval of biotech products;

¹ Directive 2001/18, O.J. L 106 17.4.2001, p. 1 (and its predecessor, Directive 90/220, O.J. L 117, 8.5.1990, p. 15, as amended by Directive 94/15, O.J. L 103, 22.4.1994, p. 20 and Directive 97/35, O.J. L 169, 27.6.1997, p. 72); and Regulation 258/97, O.J. L 043, 14.2.1997, p. 1.

- (2) the failure by the EC to consider for approval applications for the biotech products mentioned in Annexes IA and IB to this request; and
- (3) national marketing and import bans maintained by member States, as described in Annex II to this request.

These measures appear to be inconsistent with the SPS Agreement, the GATT 1994, the Agriculture Agreement and the TBT Agreement, including but not limited to the following provisions:

- (1) SPS Agreement, Articles 2, 5, 7 and 8, and Annexes B and C;
- (2) GATT 1994, Articles I, III, X and XI;
- (3) Agriculture Agreement, Article 4; and
- (4) TBT Agreement, Articles 2 and 5.

We look forward to receiving your reply to this request and to fixing a mutually convenient date for consultations.

ANNEX IA

NOTIFICATIONS UNDER DIRECTIVE 2001/18 (90/220)

Biotech Product	Date Submitted to Member State	Date Submitted to Commission	Scientific Committee Action	Status in EC under 90/220	Status in EC under 2001/18
Bayer oilseed rape (MS1/RF1)	April 1995 (France)	27 July 1995	N/A	Favorable opinion from Art. 21 Committee 6 June 1997; Commission decision approving product; France (notifying member State) refused to implement.	N/A
Bayer hybrid oilseed rape (MS1/RF2)	April 1995 (France)	27 July 1995	N/A	Favorable opinion from Art. 21 Committee 6 June 1997; Commission decision approving product; France (notifying member State) refused to implement.	N/A
Bejo Zaden red-hearted chicory (RM3-3, RM3-4 and RM3-6) – already approved for seed production. New application for food/feed use	1994 (Netherlands)	20 Sep 1996	Positive assessment 18 Dec 1998	Not submitted to Art 21 Committee.	N/A
Bayer oilseed rape (Falcon GS40/90)	1 Apr. 1996 (Germany)	25 Nov. 1996	Positive assessment 14 July 1998	Not submitted to Art. 21 Committee.	Submitted to Germany Notification # C/DE/96/5 SNIF ¹ published 14 Feb. 2003
Bayer hybrid oilseed rape (MS8/RF3) for production of hybrid seed	30 Sept. 1996 (Belgium)	16 Jan. 1997	Positive assessment 19 May 1998	Not submitted to Art. 21 Committee.	Submitted to Belgium Notification # C/BE/96/01 SNIF published 7 Feb. 2003

¹ Summary Notification Information Format ("SNIF")

Biotech Product	Date Submitted to Member State	Date Submitted to Commission	Scientific Committee Action	Status in EC under 90/220	Status in EC under 2001/18
Trifolium/ Monsanto/ Danisco Roundup Ready fodder beet (A5/15)	19 Feb. 1997 (Denmark)	9 Oct. 1997	Positive assessment 23 June 1998	Not submitted to Art. 21 Committee.	Submitted to Denmark Notification # C/DK/97/01 SNIF published 3 Mar. 2003
Monsanto Bt cotton (531)	3 Dec. 1996 (Spain)	24 Nov. 1997	Positive assessment 14 July 1998	Negative opinion from Art. 21 Committee; 11 Feb. 1999; not submitted to Council.	Submitted to Spain Notification # C/ES/96/02 SNIF published 14 Feb. 2003
Monsanto Roundup Ready cotton (RRC1445)	30 June 1997 (Spain)	24 Nov. 1997	Positive assessment 14 July 1998	Negative opinion from Art. 21 Committee; 11 Feb. 1999; not submitted to Council.	Submitted to Spain Notification # C/ES/97/01 SNIF published 14 Feb. 2003
Amylogene starch potato	1996 (Sweden)	20 May 1998	Positive assessment 18 July 2002	Not submitted to Art. 21 Committee.	Submitted to Sweden Notification # C/SE/96/3501 SNIF Published 3 Feb. 2003
Bayer winter oilseed rape (Liberator pHoe6/Ac)	15 Feb. 1998 (Germany)	29 Oct. 1998	Positive assessment 30 Nov. 2000	Not submitted to Art. 21 Committee.	Submitted to Germany Notification # C/DE/98/6 SNIF Published 17 Feb. 2003
Syngenta glufosinate tolerant and Bt resistant (Bt-11) corn (stack)	1996 (France)	12 Apr. 1999	Positive assessment 30 Nov. 2000	Not submitted to Art. 21 Committee.	N/A
Monsanto RR corn (GA 21)	27 May 1998 (Spain – for cultivation)	20 May 1999	Positive assessment 22 Sept. 2000	Not submitted to Art. 21 Committee; scope of application changed 19 Jan. 2001 to include import.	Submitted to Spain Notification # E/ES/98/01 (import/use only; not cultivation) SNIF published 17 Feb. 2003

Biotech Product	Date Submitted to Member State	Date Submitted to Commission	Scientific Committee Action	Status in EC under 90/220	Status in EC under 2001/18
Monsanto Roundup Ready oilseed rape (GT73)	21 May 1995 (France – for cultivation. Application for import withdrawn 6 July 1998.)				[see GT73 below]
Syngenta Bt hybrid corn (Bt-11)	17 June 1996 (France – for cultivation); resubmitted 5 Nov. 1998 at request of French authorities				N/A
Monsanto oilseed rape (GT73)	7 July 1998 (Netherlands – for import)				Submitted to Netherlands Notification # C/NL/98/11 (import/use only; not cultivation) SNIF published 22 Jan. 2003 Favorable Assessment by Dutch Competent Authority (undated document)
Bayer Liberty Link soybeans (A2704-12 and A5547-127)	13 Oct. 1998 (Belgium – withdrawn) 24 Sept. 1999 (Portugal)				Submitted to Belgium Notification # C/BE/98/01 (import/use only; not cultivation) SNIF published 7 Feb. 2003

Biotech Product	Date Submitted to Member State	Date Submitted to Commission	Scientific Committee Action	Status in EC under 90/220	Status in EC under 2001/18
Monsanto/ Syngenta Roundup Ready sugar beet	22 Dec. 1998 (Belgium) Initially submitted in France in 1996 and withdrawn.				Submitted to Belgium Notification # C/BE/99/01 SNIF published 7 Feb. 2003
Bayer Liberty Link oilseed rape (T45 X Topas 19/2) (stack)	4 Feb. 1999 (UK)				Submitted to UK Notification # C/GB/99/M5/2 (import/use only; not cultivation) SNIF published 10 Feb. 2003 (seeds with the line containing event T45 only; stack with Topas 19/2 has been replaced in the market and no longer commercially relevant)
Stoneville BXN cotton (10215, 10222, 10224) (formerly held by Aventis and Calgene)	29 Apr. 1999 (Spain)				N/A
Monsanto Bt x Roundup Ready (MON 810 & GA21) corn (stack)	3 Sept. 1999 (Spain)				Submitted to Spain Notification # C/ES/99/02 (import/use only; not cultivation) SNIF published 17 Feb. 2003
Bayer Liberty Link sugar beet (T120-7)	15 Dec. 1999 (Denmark)				N/A

Biotech Product	Date Submitted to Member State	Date Submitted to Commission	Scientific Committee Action	Status in EC under 90/220	Status in EC under 2001/18
Pioneer / Dow AgroSciences Bt corn Cry1F (1507)	23 Nov. 2000 (Netherlands – for import)				Submitted to Netherlands Notification # C/NL/00/10 (import/use only; not cultivation) SNIF published 14 Feb. 2003
Pioneer / Dow AgroSciences Bt corn Cry1F (1507)	11 July 2001 (Spain – for cultivation)				Submitted to Spain Notification # C/ES/01/01 SNIF published 17 Feb. 2003
Monsanto Roundup Ready corn (NK603)	21 Dec. 2000 (Spain)				Submitted to Spain Notification # C/ES/00/01 (import/use only; not cultivation) SNIF published 22 Jan. 2003 Favorable assessment by Spanish Competent Authority (undated document)

Applications Withdrawn

Product	Date Submitted to Member State	Date Submitted to Commission	Scientific Committee Action	Status in EC under 90/220	Status in EC under 2001/18
Pioneer Bt corn (MON 809)	1995 (France)	6 Aug. 1996	Positive assessment 19 May 1998	Negative opinion from Art. 21 Committee in Nov. 1998; not submitted to Council.	
Zeneca extended shelf life tomato (TGT7-F)	1996 (Spain)	24 Nov. 1997	Positive assessment 23 June 1998	Negative opinion from Art. 21 Committee in Dec. 1998; not submitted to Council.	

Product	Date Submitted to Member State	Date Submitted to Commission	Scientific Committee Action	Status in EC under 90/220	Status in EC under 2001/18
Monsanto RR corn (GA 21)	6 Nov. 1997 (UK – for import)	28 Oct. 1999	Positive assessment 22 Sept. 2000	Not submitted to Art. 21 Committee; application withdrawn 29 Mar. 2001.	[see GA21 above]
Pioneer Liberty Link and Bt (T25 x MON 810) corn (stack)	26 June 1998 (Netherlands)	29 Apr. 1999	Positive assessment 6 June 2000	Not submitted to Art. 21 Committee; application withdrawn 12 Dec. 2002.	
Pioneer/Dupont high-oleic soybean (260-05)	19 June 1998 (Netherlands – for import)			Application withdrawn 12 Dec. 2002	

ANNEX IB

REQUESTS SUBMITTED UNDER REGULATION 258/97 – NOVEL FOODS

Biotech Product	Date Submitted to Member State	Scientific Committee Action	Status in EC
Bejo-Zaden Transgenic Radicchio rosso	8 Apr. 1998 (Netherlands)	Under assessment	Pending
Bejo-Zaden Transgenic Green hearted chicory	8 Apr. 1998 (Netherlands)	Under assessment	Pending
Monsanto Roundup Ready corn (GA 21)	24 July 1998 (Netherlands)	Positive assessment 27 Feb. 2002	Pending
Syngenta Bt-11 sweet corn	11 Feb. 1999 (Netherlands)	Positive assessment 13 Mar. 2002	Pending
Pioneer/Dupont high-oleic soybean (260-05)	25 July 1998 (Netherlands)		Still with member State competent authority
Bayer LibertyLink soybeans	2 Feb. 1999 (Belgium)		Still with member State competent authority
Monsanto Roundup Ready corn (GA 21)	16 Mar. 2000 (Netherlands)		Still with member State competent authority
Pioneer Liberty Link and Bt (T25 x MON 810) corn (stack)	20 Apr. 2000 (Netherlands)		Still with member State competent authority
Monsanto/Syngenta Roundup Ready sugar beet	(Netherlands)		Still with member State competent authority
Pioneer / Dow AgroSciences Bt corn Cry1F (1507)	26 Feb. 2001 (Netherlands)		Still with member State competent authority
Monsanto Roundup Ready corn (NK603)	June 2001 (Netherlands)		Still with member State competent authority

Applications Withdrawn

Zeneca extended shelf life tomato (TGT7-F)		Positive assessment 4 23 Sept. 1999	Application withdrawn
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ANNEX II

MEMBER STATE MARKETING AND IMPORT BANS ON BIOTECH PRODUCTS

Member State	Biotech Products	National Measures
Austria	Corn: Bt-176, MON 810, T25	See Federal Official Journal of 13 Feb. 1997, 45, Regulation of the Federal Ministry for Health and Consumer Protection (Bt-176) (<i>Bundesgesetzblatt</i> of 13/II/1997, 45. <i>Verordnung der Bundesministerien fuer Gesundheit und Konsumentenschutz</i> (Bt-176)). See Federal Official Journal of 10 June 1999, 145, Regulation of the Federal Minister for Women and Consumer Protection (MON 810) (<i>Bundesgesetzblatt</i> of 10/VI/1999, 175. <i>Verordnung der Bundesministerin fuer Frauenangelegenheiten und Verbraucherschutz</i> (MON 810)) See Federal Official Journal of 28 Apr. 2000, 120, Regulation of the Federal Minister for Social Protection and Generations (T25) (<i>Bundesgesetzblatt</i> of 28/IV/2000, 120. <i>Verordnung der Bundesministerin fuer soziale Sicherheit und Generationen</i> (T25))
France	Rapeseed: C/UK/95/M5/1; and C/UK/94/M1/1	See Official Journal of 18 Nov. 1998, p. 17379
Germany	Corn: B-176	Modified Administrative Ruling, letter from Robert Koch Institute of the Federal Health Office, Center for Gene Technology, to Novartis Seeds AG, Basel, 31 Mar. 2000 (ordering suspension of approval to release corn variety Bt-176)
Greece	Rapeseed: Topas 19/2	Ministerial decisions of Nov. 1998 banning AgrEvo Topas 19/2
Italy	Corn: Bt-11, MON 809, MON 810, T25	Official Gazette, Presidential Decree of 4 Aug. 2000 (suspending commercialization and use)
Luxembourg	Corn: Bt-176	Official Journal of the Grand-Duchy of Luxembourg, Ministerial Order, 28 Feb. 1997, p. 618