

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

Request for the Establishment of a Panel by the United States

The following communication, dated 7 August 2003, from the Permanent Mission of the United States to the Chairman of the Dispute Settlement Body, is circulated pursuant to Article 6.2 of the DSU.

Since October 1998, the European Communities ("EC") has applied a moratorium on the approval of products of agricultural biotechnology ("biotech products"). Pursuant to the moratorium, the EC has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system. In particular, the EC has blocked in the approval process under EC legislation<sup>1</sup> all applications for placing biotech products on the market, and has not considered any application for final approval. The approvals moratorium has restricted imports of agricultural and food products from the United States.

In addition, EC 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 covered in this panel request are:

- (1) as described above, the suspension by the EC of consideration of applications for, or granting of, approval of biotech products;
- (2) as described above, the failure by the EC to consider for approval applications for the biotech products mentioned in Annexes I and II to this request; and
- (3) national marketing and import bans maintained by member States, as described in Annex III to this request.

These measures appear to be inconsistent with the following provisions of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement"), the *General Agreement on Tariffs and Trade 1994* ("GATT 1994"), the *Agreement on Agriculture* ("Agriculture Agreement"), and the *Agreement on Technical Barriers to Trade* ("TBT Agreement"):

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<sup>1</sup> 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.

- (1) SPS Agreement, Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7 and 8, and Annexes B(1), B(2), B(5), C(1)(a), C(1)(b), and C(1)(e);
- (2) GATT 1994, Articles I:1, III:4, X:1, and XI:1;
- (3) Agriculture Agreement, Article 4.2; and
- (4) TBT Agreement, Articles 2.1, 2.2, 2.8, 2.9, 2.11, 2.12, 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.6 and 5.8.

The EC's measures also appear to nullify or impair the benefits accruing to the United States directly or indirectly under the cited agreements.

On 13 May 2003, the United States requested consultations with the EC regarding these measures pursuant to Article 4 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU"), Article 11 of the SPS Agreement, Article 19 of the Agriculture Agreement, Article 14 of the TBT Agreement and Article XXII of the GATT 1994. Consultations were held on 19 June 2003, but have failed to settle the dispute.

Accordingly, the United States respectfully requests the Dispute Settlement Body to establish a panel pursuant to Article 6 of the DSU, with standard terms of reference as set out in Article 7.1 of the DSU.

**Annex I**

**Notifications under Directive 2001/18 (and 90/220) – Deliberate Release**

<b>Biotech Product</b>	<b>Date Submitted to Member State</b>	<b>Date Received by Commission</b>	<b>Scientific Committee Action</b>	<b>Status in EC under 90/220</b>	<b>Status in EC under 2001/18<sup>1</sup></b>
Bayer oilseed rape (MS1/RF1)	Apr. 1995 (France—for import and processing; already approved for seed production)	27 July 1995	N/A	Favorable opinion from Art. 21 Committee, Commission Decision approving product, 6 June 1997. France (notifying member State) refused to implement	N/A
Bayer hybrid oilseed rape (MS1/RF2)	Apr. 1995 (France)	27 July 1995	N/A	Favorable opinion from Art. 21 Committee, Commission Decision approving product, June 6, 1997. France (notifying member State) refused to implement	N/A
Bejo Zaden red-hearted chicory (RM3-3, RM3-4 and RM3-6)	1994 (Netherlands—for food/feed use; already approved for seed production)	20 Sept. 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 <sup>2</sup> published 14 Feb. 2003
Bayer hybrid oilseed rape (MS8/RF3)	30 Sept. 1996 (Belgium)	Jan. 16, 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

<sup>1</sup> Source: "Deliberate releases and placing on the EU market of Genetically Modified Organisms," European Commission, Joint Research Centre, *available at* <[http://gmoinfo.jrc.it/gmc\\_browse.asp](http://gmoinfo.jrc.it/gmc_browse.asp)>.

<sup>2</sup> Summary Notification Information Format ("SNIF")

<b>Biotech Product</b>	<b>Date Submitted to Member State</b>	<b>Date Received by Commission</b>	<b>Scientific Committee Action</b>	<b>Status in EC under 90/220</b>	<b>Status in EC under 2001/18<sup>1</sup></b>
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, Feb. 11, 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 Feb. 11, 1999; not submitted to Council	Submitted to Spain Notification C/ES/97/01  SNIF published 14 Feb. 2003
Amylogene starch potato	6 Aug. 1996 (date notification acknowledged) (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	1996 (France – for cultivation)	12 Apr. 1999	Positive assessment 30 Nov. 2000	Not submitted to Art. 21 Committee	Submitted to France Notification C/F/96/05-10  SNIF Published 30 June 2003  Favorable assessment by French authority published 29 July 2003

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Monsanto Roundup Ready 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 C/ES/98/01 (import/use only; not cultivation)  SNIF published 17 Feb. 2003
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 Roundup Ready 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 authority published 22 Jan. 2003
Bayer Liberty Link soybeans (A2704-12 and A5547-127)	13 Oct. 1998 (Belgium)				Submitted to Belgium Notification C/BE/98/01 (import/use only; not cultivation)  SNIF published 7 Feb. 2003

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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 & 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)				Submitted to Spain Notification C/ES/99/01  SNIF published 21 July 2003
Monsanto MaisGard 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

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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 authority published 22 Jan. 2003

### Applications Withdrawn

<b>Product</b>	<b>Date Submitted to Member State</b>	<b>Date Submitted to Commission</b>	<b>Scientific Committee Action</b>	<b>Status in EC under 90/220</b>	<b>Status in EC under 2001/18</b>
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	
Monsanto Roundup Ready corn (GA 21)	6 Nov. 1997 (U.K. – 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 & 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 II****Requests Under Regulation 258/97 – Novel Foods**

<b>Biotech Product</b>	<b>Date Submitted to Member State</b>	<b>Scientific Committee Action</b>	<b>Status in EC</b>
Bejo-Zaden Transgenic Radicchio rosso	8 Apr. 1998 (Netherlands)  Positive Member State Assessment	Under assessment	Pending
Bejo-Zaden Transgenic Green hearted chicory	8 Apr. 1998 (Netherlands)  Positive Member State Assessment	Under assessment	Pending
Monsanto Roundup Ready corn (GA 21)	24 July 1998 (Netherlands)  Positive Member State Assessment	Positive assessment 27 Feb. 2002	Pending
Syngenta Bt-11 sweet corn	11 Feb. 1999 (Netherlands)  Positive Member State Assessment	Positive assessment 17 Apr. 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 MaisGard Roundup Ready corn (GA 21 & MON 810) (stack)	16 Mar. 2000 (Netherlands)		Still with Member State competent authority
Monsanto/Syngenta Roundup Ready sugar beet (77)	3 Nov. 1999 (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)  Positive Member State Assessment		Pending

**Application Withdrawn**

Zeneca extended shelf life tomato (TGT7-F)	Positive MS Assessment	Positive assessment 23 Sept. 1999	Application withdrawn
Pioneer Liberty Link and Bt (T25 x MON 810) corn (stack)	20 Apr. 2000 (Netherlands)		Application withdrawn

**Annex III****National Marketing and Import Bans**

<b>Member State</b>	<b>Products</b>	<b>National Measures</b>
Austria	Corn: Bt-176, MON 810, T25	<p>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)).</p> <p>Federal Official Journal of 10 June 1999, 175, 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))</p> <p>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))</p>
France	Rapeseed: C/UK/95/M5/1; and C/UK/94/M1/1	Official Journal, No. 200, 18 Nov. 1998, p. 17379; extensions published in Official Journal, No. 267, 30 Aug. 2001, p. 13903
Germany	Corn: Bt-176	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	Government Gazette [Efimeris Tis Kyverniseos] of the Hellenic Republic, Issue No. 1008, 25 Sept. 1998, p. 3.
Italy	Corn: Bt-11, MON 809, MON 810, T25	Official Gazette of the Italian Republic, Decree of the President of the Council of the Ministers, General series – No. 184, 8 Aug. 2000 (suspending commercialization and use)
Luxembourg	Corn: Bt-176	Official Journal of the Grand-Duchy of Luxembourg, A – No. 10, 28 Feb. 1997, p. 618