

**List of the genetically modified material which has benefited from a  
favourable risk evaluation within the meaning of  
Article 47 of Regulation (EC) No 1829/2003**

(Published by the Commission in accordance with Article 18 of Regulation (EC) No 641/2004)

## **Background**

### **Article 47 of Regulation (EC) No 1829/2003 on genetically modified food and feed provides that:**

1. The presence in food or feed of material which contains, consists of or is produced from GMOs in a proportion no higher than 0,5 % shall not be considered to be in breach of Article 4(2) or Article 16(2), provided that:
  - (a) this presence is adventitious or technically unavoidable;
  - (b) the genetically modified material has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before the date of application of this Regulation;
  - (c) the application for its authorisation has not been rejected in accordance with the relevant Community legislation; and
  - (d) detection methods are publicly available.
2. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of such materials.
3. The thresholds referred to in paragraph 1 may be lowered in accordance with the procedure referred to in Article 35(2), in particular for GMOs sold directly to the final consumer.
4. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).
5. This Article shall remain applicable for a period of three years after the date of application of this Regulation.

### **The detailed rules referred to in Article 47(4) of Regulation (EC) No 1829/2003 have been laid down in Regulation (EC) No 641/2004. Article 18 of this Regulation provides that:**

1. For the purpose of implementing Article 47 of Regulation (EC) No 1829/2003, the Commission shall, on 18 April 2004, publish a list of the genetically modified material that has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before that date and for which an application for authorisation has not been rejected in accordance with the relevant Community legislation.
2. This list shall distinguish between:
  - (a) material in respect of which the Commission has been informed, by any interested party, that a detection method is publicly available; an indication of where the detection method has been made available shall be included;

(b) material in respect of which the Commission has not yet been informed that a detection method is publicly available.

Any interested party may, at any time, inform the Commission that a detection method for material referred to in point (b) of the first subparagraph is publicly available, with an indication of where the detection method is available.

Article 47 of Regulation (EC) No 1829/2003 applies without prejudice to the application of Articles 8 and 20 of the same Regulation regarding the status of existing products (see also Articles 9 to 17 of Regulation (EC) No 641/2004), for which a specific regime applies.

The thresholds referred to in Article 47(1) have not been lowered under the procedure referred to in Article 47(3).

In accordance with Article 4(8) and 5(4) of Regulation (EC) No 1830/2003, the traceability and labelling requirements laid down in Article 4(1) to 4(6) and the traceability requirements laid down in Articles 5(1) and 5(2) respectively shall not apply to traces of the GMOs listed below under paragraph (a) which are present in the products concerned in a proportion no higher than 0,5 % provided that these traces are adventitious or technically unavoidable.

## LIST

**(a) Material in respect of which the Commission has been informed that a detection method is publicly available, as referred to in Article 18(2) (a) of Regulation (EC) No 641/2004**

### FOOD

Event	Crop	Unique identifier	Applicant	Favourable opinion from / date	Detection method
GA 21 <sup>1</sup>	Maize	MON-ØØØ21-9	Monsanto	SCF 22.09.2000	<a href="http://gmo-crl.jrc.it/detectionmethods.htm">http://gmo-crl.jrc.it/detectionmethods.htm</a>

SCF: Scientific Committee on Food  
EFSA: European Food Safety Authority

<sup>1</sup> Foods and food ingredients produced from genetically modified Roundup Ready maize line GA21 have been authorised as novel foods or novel food ingredients under Regulation (EC) No 258/97 on 13.01.2006.

## FEED

Event	Crop	Unique identifier Notification	Applicant	Favourable opinion from / date	Detection method
IPC 531	Cotton	MON-ØØ531-6 C/ES/96/02	Monsanto	SCP 14.07.1998	<a href="http://gmo-crl.jrc.it/detectionmethods.htm">http://gmo-crl.jrc.it/detectionmethods.htm</a>
GA21 <sup>2</sup>	Maize	MON-ØØ21-9 C/ES/98/01	Monsanto	SCP 22.09.2000	<a href="http://gmo-crl.jrc.it/detectionmethods.htm">http://gmo-crl.jrc.it/detectionmethods.htm</a>
GS 40/90	Oilseed rape	ACS-BNØ1Ø-4 C/DE/96/5	Bayer	SCP 14.07.1998	<a href="http://gmo-crl.jrc.it/detectionmethods.htm">http://gmo-crl.jrc.it/detectionmethods.htm</a>
Ms8, Rf3, Ms8xRf3	Oilseed rape	ACS-BNØØ5-8 x ACS-BNØØ3-6 C/BE/96/01	Bayer	SCP 19.05.1998	<a href="http://gmo-crl.jrc.it/detectionmethods.htm">http://gmo-crl.jrc.it/detectionmethods.htm</a>
RRC 1445	Cotton	MON-Ø1445-2 C/ES/97/01	Monsanto	SCP 14.07.1998	<a href="http://gmo-crl.jrc.it/detectionmethods.htm">http://gmo-crl.jrc.it/detectionmethods.htm</a>
T25x MON810	Maize	ACS-ZMØØ3-2 x MON-ØØ81Ø-6 C/NL/98/08	Pioneer	SCP 06.06.2000	<a href="http://gmo-crl.jrc.it/detectionmethods.htm">http://gmo-crl.jrc.it/detectionmethods.htm</a>

SCP: Scientific Committee on Plants

EFSA: European Food Safety Authority

<sup>2</sup> Feed materials produced from GA21 maize have been notified as existing products according to Article 20 of Regulation (EC) No 1829/2003 and subsequently entered in the Community Register of GM Food and Feed.

**(b) Material in respect of which the Commission has not yet been informed that a detection method is publicly available, as referred to in Article 18(2) (b) of Regulation (EC) No 641/2004**

**FEED**

<b>Event</b>	<b>Crop</b>	<b>Unique identifier Notification</b>	<b>Applicant</b>	<b>Favourable opinion from / date</b>
EH92-527-1	Potato	BPS-25271-9 C/SE/96/3501	AMYLO-GENE HB	SCP 18.07.2002
Liberator pHoe6/Ac	Oilseed rape	ACS-BNØØ9-3 C/DE/98/6	Bayer	SCP 30.11.2000
Line A5/15	Fodder beet	DLF-ØA515-7 C/DK/97/01	DLF-Trifolium, Monsanto and Danisco Seed	SCP 23.06.1998

SCP: Scientific Committee on Plants

## Annex

### **Amendments brought to the list since the entry into applicability of Regulation (EC) No 1829/2003 on 18 of April 2004**

The following entries have been deleted from the list (a) section “food”:

- On 19.05.2004, Bt11 Sweet Maize (SYN-BT Ø11-1) following authorisation under Regulation (EC) No 258/97 (Commission decision 2004/657/EC of 19.05.2004, published in the OJ L 300/48 of 25.09.2004).
- On 26.10.2004, NK603 maize (MON-ØØ6Ø3-6) following authorisation under Regulation (EC) No 258/97 (Commission decision 2005/448/EC of 03.03.2005, published in the OJ L 158/20 of 21.6.2005).
- On 13.01.2006, MON863 maize (MON-ØØ863-5) following authorisation under Regulation (EC) No 258/97 on 13.01.2006.

The following entries have been deleted from the list (a) section “feed”:

- On 26.10.2004, NK603 maize (MON-ØØ6Ø3-6) following authorisation under Directive 2001/18/EC (Commission decision 2004/643/EC of 19.07.2004, published in the OJ L 295/35 of 18.09.2004) and entry into application of the Commission decision 2005/448/EC authorising the placing on the market of the product for uses as or in food.
- On 13.01.2006, MON863 maize (MON-ØØ863-5) following authorisation under Directive 2001/18/EC (Commission decision 2005/608/EC of 8.08.2005, published in the OJ L 207/17) and entry into application of the Commission Decision authorising the placing on the market of the product for uses as or in food on 13.1.2006.
- On 8.02.2007, GT 73 oilseed rape (MON-ØØØ73-7) following authorisation under Directive 2001/18/EC (Commission Decision 2005/635/EC of 31.08.2005, published in the OJ L 228/11) and entry into application of this Commission Decision with the validation of a detection method specific to GT73 oilseed rape on 8.02.2007.

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