



DG4

General Directorate of Animals, Plants and Food

Division Raw materials and Vegetable sector

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PAR PORTEUR

Your letter dd.  
Your references

Our references 41.173/03/ 48A

Annexe(s) -Statement of the Competent Authority  
-Advice of the Belgian Biosafety Council  
-Expertise report  
-Notification

Date:

02 -02- 2004

**Assessment report in accordance with part C of Directive 2001/18/EC:  
notification C/BE/96/01 (Ms8xRf3 oilseed rape)**

Dear M. Martin,

I'm please to enclose, in accordance with article 14.2 of Directive 2001/18/EC, the notification from Bayer CropScience to place on the market the oilseed rape lines Ms8, Rf3 and Ms8xRf3 (hybrid line) for cultivation and import in the EU for all uses as any other oilseed rape (food, feed and industrial processing). The dossier consists of the following documents:

1. The Statement of the Belgian Competent Authority concerning this notification.
2. The Assessment Report of the notification prepared by the Belgian Biosafety Advisory Council and containing:
  - 2.1. The Advice of the Belgian Biosafety Advisory Council (6 pages)
  - 2.2. As an annex of the advice, the Expertise Report of the group of experts mandated by the Belgian Biosafety Advisory Council (24 pages + annex of 11 pages)
3. The notification (CD-rom) containing additional information and complements according to Article 35 of the Directive 2001/18/EC, and two further letters from the notifier dated 12<sup>th</sup> of January 2004 and 15<sup>th</sup> of January 2004. This application contains confidential information (Part III).

The Belgian Competent Authority hopes that this dossier can be given attention by the other Competent Authorities and that a fruitful exchange of views will take place during the evaluation process.

Rudy Demotte

Minister for Social Affairs and  
Public Health

Freya Van Den Bossche

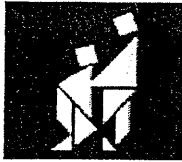
Minister for the Environment, Consumer  
Protection and Sustainable Development

Letter Assessment Report C-BE-96-01

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DG4

Statement of the Belgian Competent Authority

Notification C/BE/96/01 submitted under Directive 90/220/EEC and updated according to Article 35 of Directive 2001/18/EC to place on the market genetically modified oilseed rape (*Brassica napus* L. *oleifera* Metzg.) Ms8, Rf3 and Ms8xRf3 (pollination control system linked to a tolerance to glufosinate-ammonium herbicide)

1. The present Statement is transmitted to the European Commission in accordance with articles 14 and 35 of Directive 2001/18/EC by the Belgian Competent Authority in connection with the notification C/BE/96/01 entitled "A new hybridisation system in oilseed rape (*Brassica napus* L.). Application for consent to market genetically modified organisms (MS8xRF3)" which concerns the placing on the market of the following genetically modified plants (GMOs):
  - The female (male sterile) oilseed rape line Ms8 (ACS-BN005-8) and all progeny derived through traditional breeding crosses with non-genetically modified oilseed rape. Line Ms8 contains a *barnase gene* coding for a ribonuclease and resulting in lack of viable pollen and male sterility, and a *bar gene* conferring tolerance to herbicides containing glufosinate ammonium.
  - the male (fertility restoration) oilseed rape line Rf3 (ACS-BN003-6) and all progeny derived through traditional breeding crosses with non-genetically modified oilseed rape. Line Rf3 contains a *barstar gene* coding for an inhibitor of the Barnase protein leading to restoration of fertility after crossing to the male sterility line, and a *bar gene* conferring tolerance to herbicides containing glufosinate ammonium.
  - the hybrid oilseed rape Ms8xRf3 (ACS-BN005-8 x ACS-BN003-6) obtained through traditional breeding from the parental lines containing events Ms8 and Rf3.
2. The scope of the notification covers:
  - Growing of oilseed rape in the European Union for production and multiplication of parental lines seeds and hybrid seeds, including official testing in the perspective of the listing on national and common catalogues according to the Directives 69/208/EEC, 70/457/EEC and 98/95/EC;
  - Import of seeds from countries outside of the European Union;
  - Processing of the harvested seeds into human food, animal feeding stuffs (meal remaining after oil extraction) and industrial products (bio-fuel, lubricants, cosmetics, paints, etc.).
3. The evaluation of the use as food and feed falls within the scope of the Regulations (EC) No 258/97<sup>1</sup>, of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients and No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. The use of the herbicide is covered by the Council Directive 91/414/EEC of 15 July 1991 concerning the placing on the market of plant protection products.
4. The notification was received by the Belgian Competent Authority in 1996 under Directive 90/220/EEC by Plant Genetic Systems (PGS), presently Bayer CropScience. The notification was forwarded by the Belgian Competent Authority on December 20<sup>th</sup>, 1996 with a positive consent for

<sup>1</sup> Oil derived from MS8xRF3 for human consumption can be placed on the EU market in accordance with Article 5 of the Regulation (EC) 258/97 (October 21<sup>st</sup>, 1999).

placing on the market to the European Commission, which forwarded it further to all competent authorities. In May 1998, the Scientific Committee on Plants (SCP) of the European Commission gave a favourable opinion on the MS8, Rf3 and MS8xRf3 lines. The notification was on the agenda of several meetings of the Regulatory Committee but a vote never took place. On January 16th, 2003 and on basis of Article 35 of the Directive 2001/18/EC, the notifier submitted the update of notification C/BE/96/01 to the Belgian competent authority.

5. The enclosed dossier consists of the Assessment Report prepared by the Belgian Biosafety Advisory Council and containing the Advice of the Belgian Biosafety Advisory Council with as an annex of the advice, the Expertise Report of the group of experts mandated by the Belgian Biosafety Advisory Council, and the notification (CD-rom) containing additional information and complements according to Article 35 of the Directive 2001/18/EC and two further letters from the notifier dated 12th of January 2004 and 15th of January 2004. The application contains confidential information (Part III).
6. The items which the notifier wishes to consider as confidential business information are grouped in part III of the application and have been accepted as confidential by the Competent Authority. The notifier explains the reasons of confidentiality in its document called "Reason for Confidential Business Information (CBI). Nevertheless, and in accordance with Article 31.2 of Directive 2001/18/EC (registers for the purpose of recording the information on genetic modifications in GMOs), some of that confidential business information will not be maintained as confidential after validation of the detection/identification methods.
7. The competent authority, based on the evaluation of the potential risks for human and animal health and for the environment derived from the genetic modification, concludes that the proposed consent to place on the market the product "oilseed rape Ms8, Rf3 and Ms8xRf3 (pollination control system linked to a tolerance to gulfosinate-ammonium herbicide), with notification number **C/BE/96/01**" should be granted:

a) For the following uses:

Import and processing of oilseed rape Ms8, Rf3 and Ms8xRf3 and for its use as other any oilseed rape, **excluding the cultivation** in the European Union of varieties derived from the oilseed rape events Ms8, Rf3 and Ms8xRf3.

b) Under the following conditions:

1. The Ms8, Rf3 and Ms8xRf3 oilseed rape and the products derived from Ms8, Rf3 and Ms8xRf3 oilseed rape shall be specifically labelled during all stages of handling as proposed in the notification.
2. The consent holder is required to supply reference material of Ms8, Rf3 and/or Ms8xRf3 oilseed rape for detection purposes at any time.
3. The consent holder is required to provide a localized case-specific monitoring plan to monitor the presence of feral Ms8, Rf3 and/or Ms8xRf3 oilseed rape at the points of import and processing, and between those locations, as a consequence of seed spillage occurring during import and transport. Furthermore, proposals for action to identify the transgenic character of the feral Ms8, Rf3 and/or Ms8xRf3 oilseed rape and for an adequate reporting system should be included in this monitoring plan.
4. The consent holder is required to provide a more detailed description of the tasks and the kind of data that will be collected by different networks involved in the general surveillance.
5. The consent is granted **only after validation of the methods allowing detection/identification and quantification** of the genetically modified products. As soon as the validation is realized, the information related to the detection/identification methods are not considered anymore as confidential business information.
6. The consent does not include the use of the product for human food and animal feed. For

the consent of this use, the product must comply with the requirements established in of the Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

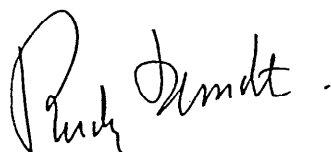
7. The consent is valid for 10 years after approval.

8. The consent for the cultivation is not granted for the following reasons:

- Effective and practicable measures minimizing the environmental risks associated with this GM lines are not yet defined<sup>2</sup>. Effectively, the Belgian Biosafety Council considered that *“presently, a number of the recommendations of the agricultural guidelines proposed by the notifier in order to limit the vertical gene flow and its consequences are impracticable, hardly workable and hard to control in current agricultural practices (...).”*

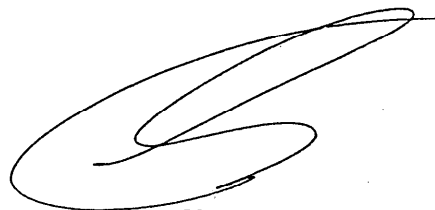
- A loss of biodiversity due to the use of the associated herbicide was demonstrated in the Farm-Scale Evaluation trials realized in UK and no measures compensating this loss of biodiversity were proposed by the notifier<sup>3</sup>. Effectively, the Belgian Biosafety Council observed that *“short term adverse effect on biodiversity of the GM crops and the associated herbicide was demonstrated in the FSE (Field Scale Evaluation) trials.”*

- The long-distance dissemination of pollen, an intrinsic oilseed rape characteristic, will lead to a gene flow to the neighbouring oilseed rape fields (and related wild relatives), at a time where a coexistence regulation is not yet entered into force. Effectively, the Belgian Biosafety Council considered that *“such a gene flow can lead to the long-distance dissemination resulting in the potential fertilization of wild relatives currently present in European wild flora and the adventitious presence of GM material in the neighbouring fields.”*



Rudy Demotte

Minister for Social Affairs and  
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<sup>2</sup> « Adverse effects may occur directly or indirectly through mechanisms which may include : (...) changes in management, including, where appropriate, in agricultural practices.” (Annex II.C2 of Directive 2001/18/EEC ) and “The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined” (Annex II.C5 of Directive 2001/18/EEC ).

<sup>3</sup> “Possible and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.” (Annex II. D.2.9 of Directive 2001/18/EEC )