

**MINUTE**



COMMISSION EUROPÉENNE

SECRETARIAT GÉNÉRAL

Bruxelles, le 17/III/2006  
SG-Graffe(2006) D/ **201135**

Mrs Consuelo Madere  
Monsanto International Sarl  
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Objet: NOTIFICATION AU SENS DE L'ARTICLE 254 DU TRAITÉ CE

Pour le Secrétaire général

Karl VON KEMPIS

p.j. : C (2006) 803 final



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.3.2006  
C (2006) 803 final

Dear Mrs Madere,

The present letter contains the Commission's decision adopted on the basis of Article 30(2) of Regulation (EC) No 1829/2003 on GM food and feed on your request for confidentiality as regards the following applications for authorisation you have submitted:

- EFSA/GMO/UK/2004/01 : NK603 x MON810 maize
- EFSA/GMO/DE/2004/03 : MON863 x MON810 maize
- EFSA/GMO/UK/2004/06 : MON863 x NK603 maize
- EFSA/GMO/BE/2004/07 : MON863 x MON810 x NK603 maize
- EFSA/GMO/UK/2004/08 : IT7-1 Roundup Ready sugar beet
- EFSA/GMO/UK/2005/09 : MON531 x MON1445 cotton
- EFSA/GMO/UK/2005/10 : MON15985 cotton and MON15985 x MON 1445 cotton

According to Article 30 of Regulation (EC) No 1829/2003 on GM food and feed, the Commission must determine, in consultation with the applicant, which information contained in an application for authorisation of a GM food or feed may be considered as confidential and inform the applicant of its decision. Information may only be considered as confidential based on verifiable justification provided by the applicant demonstrating that disclosure of this information might significantly harm its competitive position. However, paragraph 3 of Article 30 of the Regulation provides that some type of information may never be considered as confidential.

Monsanto Europe S.A./N.V. ("Monsanto") has introduced several applications for authorisation under Regulation (EC) No 1829/2003 on GM food and feed and has claimed confidentiality for the study reports commissioned by the company in support of these applications. This issue has been raised in several meetings between the Commission (Directorate General Health and Consumer Protection) and Monsanto, the latest with date of 26 of July 2005, without an agreement being reached.

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The Commission has requested Monsanto to provide verifiable justification for its confidentiality claim concerning the company's applications for authorisation under Regulation (EC) No 1829/2003.

Following the Commission's request, Monsanto submitted to the Commission its arguments by letter of its legal counsellors dated 14 January 2005. Monsanto claimed in particular the information contained in the scientific studies is of the kind described in Article 39.2 of the WTO agreement on Trade-Related Aspect of Intellectual Property Rights ("TRIPS"), and that the right conferred by the Article is a intellectual property right that must be recognised in all Member States.

In our reply dated 4 of February 2005, we confirmed that we remain of the opinion that we are not in a position to conclude that evidence of a significant harm to Monsanto's competitive position had been provided. We would like to restate our view that the reference to Article 39 paragraph 2 of the TRIPS Agreement is not justified, since this Article does not have a direct effect and individual companies may therefore not invoke its provisions. Moreover, the data concerned constitute "data submitted to governments or governmental agencies" according to Article 39 first paragraph and do therefore not fall under the second paragraph of Article 39, but under the third one. Finally, the Commission considered that the absence of confidentiality is in any case justified by reasons of general interest and it is to the applicant to take the appropriate measures to protect the intellectual property of his documents.

Therefore, the Commission reiterated the request to receive from Monsanto verifiable justification, in accordance with paragraph 1 of Article 30 of Regulation (EC) No 1829/2003, of the substantial harm that disclosure of the study reports in question would do to its competitive position.

By letter of 5 August 2005, Monsanto submitted to the Commission a modified request, according to which all study reports submitted in support of the applications for authorisation under Regulation (EC) No 1829/2003 could be made publicly available, with the exception of certain categories of information therein. These categories, for which the request for confidentiality is thus maintained, are:

- (1) Personal data such as the name of an individual involved in the conduct of the studies
- (2) DNA sequence information (excluding primer sequences used for detection) and information on enzyme kinetics
- (3) Study protocols developed by Monsanto
- (4) Individual "raw data" points, i.e. the raw data on individual animals

The Commission has assessed the new request and has reached the following conclusions:

- (1) Personal data

Monsanto request is accepted.

In accordance with Community legislation regarding the protection of personal data, the Commission accepts that such data be withheld from the documents to be made public as disclosure would undermine the privacy and the integrity of the individual concerned.

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- (2) DNA sequence information (excluding primer sequences used for detection) and information on enzyme kinetics

Monsanto request is conditionally accepted.

The Commission considers that confidential treatment cannot be granted for DNA sequence information and information on enzyme kinetics that has already been otherwise made available to the public, for instance by the granting of a patent.

On the other hand, the Commission accepts that this information be kept confidential insofar as it constitutes Monsanto's secret know-how resulting from investments in innovation and research. The Commission can follow Monsanto's argument that the public release of this information would cause substantial harm to the company's competitive position by permitting competitors to create products which are essentially copies of proprietary inventions and thus avoid technical patent infringement.

- (3) Study protocols developed by Monsanto

Monsanto request is conditionally accepted.

The Commission considers that confidential treatment of study protocols cannot be granted for those protocols that reflect standard industrial practices, since their disclosure would not affect Monsanto's competitive position.

On the other hand, confidential treatment can be granted for study protocols that contain details of materials and methods that do not reflect standard practices and have been developed by Monsanto, if the following conditions are fulfilled:

- that these protocols embody secret know-how by the company and
- that the non-disclosure of the study protocols does not prevent the full understanding of the effects of the GMO, food or feed, on human and animal health and the environment or of any of the other information referred to in Article 30(3) of Regulation (EC) No 1829/2003.

- (4) Individual "raw data" points, i.e. the raw data on individual animals

Monsanto request to withhold this information from public disclosure is rejected.

The Commission is of the view that access to the raw data on individual animals is a prerequisite to be able to fully assess the effects of the GMO, food or feed, on human or animal health and on the environment. According to Article 30 paragraph 3 (d) of Regulation (EC) No 1829/2003, information relating to such effects shall not be considered as confidential.

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The present decision will apply as from 17/IV/2006. As from that date the Commission will assess the accessibility of the documents referred to in this decision, including under Regulation (EC) N° 1049/2001 regarding public access to European Parliament, Council and Commission documents<sup>1</sup>, on the basis of the conclusions above.

You are invited to submit before that date to the Commission an overview of the content of the applications listed above in tabular form, in which you indicate for each of the study reports the information that may be treated as confidential according to the present decision.

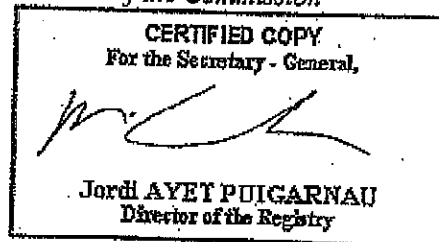
We would also invite you to submit to the European Food Safety Authority before that date an additional version of each one of these applications, in which this information is made illegible.

We would also remind you that, within the same deadline, Monsanto has the possibility of withdrawing its applications for authorisation under Regulation (EC) No 1829/2003. Should this happen, the information on whose confidentiality the Commission and Monsanto do not agree will remain protected according to the terms of Article 30 (7) of the Regulation.

Done at Brussels, 17/III/2006.



*For the Commission*  
*Markos KYPRIANOU*  
*Member of the Commission*



<sup>1</sup> OJ L 145, 31.5.2001, p. 43.