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Dr. B. Glandorf
RIVM, Bureau GGO
A. van Leeuwenhoeklaan 9
Postbus 1
NL – 3720 BA Bilthoven
The Netherlands

Brussels, 12 March 2012

Subject: ***Application for authorization to place on the market MON 810 pollen in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed***

Dear Dr. Glandorf

Following the ruling of the European Court of Justice on the presence of MON 810 pollen in honey (Case C-442/09 – Karl Heinz Bablok and Others vs Freistaat Bayern), pollen contained in pollen-based food supplements must be classified as an 'ingredient'. Furthermore, Regulation (EC) No 1829/2003 provides that foodstuffs produced from or containing ingredients produced from GMOs must be authorised before being placed on the market. Therefore, the use of pollen produced by MON 810 would need an authorization under the said Regulation.

We believe that this ruling does not require further regulatory action for the following reasons. Even though the MON 810 authorization according to Regulation (EC) No 258/97 does not specifically include the food use of MON 810 pollen, the authorization according to Directive 90/220/EEC includes a reference to the opinion issued by Scientific Committee of Plants on 10 February 1998. The terms of reference and the opinion of the Scientific Committee of Plants include the food use of MON 810. Moreover, other subsequent approvals are broader in scope and include MON 810 pollen.

MON 88017 × MON 810 is a conventional breeding stack of MON 88017 and MON 810. The scope of the application for MON 88017 × MON 810 (EFSA-GMO-CZ-2006-33) included all uses of MON 88017 × MON 810 as any other maize with the exception of cultivation and was approved by the European Commission on 28 July 2010 (Commission Decision 2010/429/EU of 28 July 2010). It is scientifically well recognized that MON 88017 × MON 810 also produces pollen containing the MON 810 insert alone since the MON 810 and MON 88017 insert are segregating independently, and such pollen cannot be distinguished from pollen produced by MON 810 single plants. The same applies to the following EU authorized products containing MON 810: NK603 × MON 810, MON 863 × MON810, and MON 863 × MON810 ×NK603.

Given the above and EFSA's requirement to reconsider the safety of the singles in light of the scope of the stack before starting the risk assessment of the stack, any product that contains the MON 810 pollen due to the pollen production of the stack (or the single for that matter) is safety assessed and authorized for use in the EU. The application received by EFSA and authorized by the EU Commission for MON 88017 × MON 810 contained a comprehensive safety assessment of MON 810, as well as a safety assessment of pollen containing Cry1Ab (Cry1Ab is the protein expressed in MON 810).

In conclusion, the authorization of the food uses of MON 88017 × MON 810 (and any other MON 810-containing stacks) as any other maize includes the food use of MON 810 pollen as or in food. Our opinion was shared with the EU Commission on 5 September 2011.

Notwithstanding the above, the EU Commission requested Monsanto to submit an application to cover the use of MON 810 pollen as or in food. At several fora, it was communicated by the EU Commission that there is no safety concern with the MON 810 pollen (recently confirmed by EFSA, 2011[1]); however, since no appropriate application covered the use of pollen derived from the MON 810 single event, a new application would be required.

In order not to further extend the legal uncertainty coming with the difference in views on the regulatory status of pollen derived from MON 810, Monsanto presents a new application for MON 810 maize in the European Union (EU) in accordance with Regulation (EC) No 1829/2003. This application is a request for authorization for Monsanto Company to place on the market MON 810 pollen for uses not covered by any previous authorization or application in the EU, according to Article 5 of Regulation (EC) No 1829/2003.

We would like to request the Dutch Institute for Public Health and the Environment (RIVM) to act as the national Competent Authority, as provided for in Articles 5(2) of the Regulation, for this application. The scope of our application includes:

- Food produced from or containing ingredients produced from MON 810, according to Article 3(1)(c) of Regulation (EC) No. 1829/2003: **MON 810 pollen as or in food.**

The requested duration of the authorization to place on the market MON 810 in the EU is 10 years.

The safety of pollen for food use recently has been confirmed by EFSA (2011[1]). Further, a complete data package allowing a conclusion on the safety of MON 810 food and feed uses including import, processing and cultivation has been presented in 2007, leading to an EFSA opinion in 2009[2]. Therefore, the risk assessment presented in this application will only focus on the elements that are necessary to conclude on safety of MON 810 pollen as or in food. This approach was agreed upon by the EU Commission on 16 December 2011. Annex I to this cover letter contains the said risk assessment.

Together with this letter, we included two electronic copies of our application (2 CD-ROMs each; one contains the non-confidential information and the other the confidential information of our application) as well as one paper copy. One electronic copy is

[1] http://www.efsa.europa.eu/en/efsajournal/pub/2434.htm
[2] http://www.efsa.europa.eu/en/efsajournal/pub/1149.htm

intended for use by the Dutch Competent Authority. We request the paper copy and the second electronic copy to be forwarded to EFSA.

According to Monsanto's internal policy for the protection of sensitive information that is submitted in electronic format, the information on these CD-ROMs is password-protected. Passwords have been supplied in Annex II to this letter.

A verifiable justification on confidentiality is provided in Annex III.

We hope that, on the basis of the evidence presented, EFSA will repeat its conclusions on the safety of MON 810 to the scope of this application.

With our advanced thanks for your forwarding of this application to EFSA,

cc of letter: Ms. Waigmann, Ms. Paoletti, Ms. Lheureux, (EFSA)
Ms. D. André, Ms. Pelsser, Ms. Torppa, Mr. Walsh, Ms. Kantorska, (EU Commission, DG Sanco)
Mr. G. Van den Eede, Mr. Mazzara (European Commission, DG JRC)
GMO_secretariat_applications (EFSA)