



Ms. Jitka Götzová
Food Safety Department
Ministry of Agriculture - Food Authority
Tesnov 17,
117 05 Prague 1
Czech Republic

Brussels, 24 October 2008

Subject: *Application for authorisation of MON 89034 × 1507 × MON 88017 × 59122 maize grain in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed*

Dear Ms. Götzová,

We have pleasure in enclosing our joined application for authorisation in the European Union (E.U.) of MON 89034 × 1507 × MON 88017 × 59122 maize grain for all uses as for any other maize grain, excluding cultivation, according to Articles 5 and 17 of Regulation (EC) No 1829/2003 on genetically modified food and feed.

We would like to request the Czech Ministry of Agriculture to act as the national competent authority, as provided for in Articles 5(2) and 17(2) of the Regulation, for this application.

MON 89034 × 1507 × MON 88017 × 59122, developed by Monsanto Company and Dow AgroSciences LLC, combines multiple effective doses in multiple traits and provides season-long yield protection in three areas: above-ground insect control (lepidopteran protection), below-ground insect control (coleopteran -corn rootworm-protection) and weed control (glufosinate-ammonium and glyphosate).

The scope of this new application under Regulation (EC) No 1829/2003 is for all uses of MON 89034 × 1507 × MON 88017 × 59122 maize grain in the E.U. and corresponds to the following category of use, described in Annex II of the *Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed*, final edited version of 28 April 2006¹ :

¹ http://www.efsa.europa.eu/en/science/gmo/gmo_guidance/660.html

1. **Food**
 - 1.1 GM plants for food use
 - 1.2 Food containing or consisting of GM plants
 - 1.3 Food produced from GM plants or containing ingredients produced from GM plants
2. **Feed**
 - 2.1 GM plants for feed use
 - 2.2 Feed containing or consisting of GM plants
 - 2.3 Feed produced from GM plants
3. **GM plants for environmental release**
 - 3.1 Import and processing

This application contains the information required in Articles 5(3) and 5(5) and 17(3) and 17(5) of Regulation (EC) No 1829/2003, and corresponding requirements from Articles 2, 3 and 4 of the Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003.

The requested duration of the authorisation to place on the market MON 89034 × 1507 × MON 88017 × 59122 grain in the E.U. is 10 years.

As required by the European Food Safety Authority (EFSA), we have enclosed one paper copy of the application (5 volumes), as well as two copies in electronic format (two CD-ROMs each), one of which is meant for use by the Czech Competent Authority. A comprehensive table of contents is provided in Attachment 1, which cross-references the contents of the paper and electronic versions.

According to Monsanto's and Dow AgroScience's internal policies 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 Attachment 2 to this letter.

A verifiable justification on confidentiality is provided in Attachment 3.

For this joined application Mycogen Seeds, c/o Dow AgroSciences LLC is the primary contact and therefore we would be grateful if all correspondence could be sent directly to responsible regulatory manager at Mycogen Seeds, c/o Dow AgroSciences LLC (see above for contact details).

We hope that, on the basis of the evidence presented, EFSA will concur with the conclusion of safety of MON 89034 × 1507 × MON 88017 × 59122 grain for all uses as for any other maize grain, excluding cultivation, in the E.U.

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

Yours sincerely,

cc of letter: Mr. Bergman, Ms. Lheureux, Ms. Hernandez Valero, Mr. Dolieslager (EFSA)
Mr. Walsh, Mr. Flüh, Ms. Pelsser, Mr. Goux (E.U. Commission, DG Sanco)
Mr. Van den Eede, Mr. Mazzara (European Commission, DG JRC)
(Monsanto)