European Food Safety Authority

EXECUTIVE DIRECTOR

27 SET. 2010

Parma,
Ref. RM/PB/KL/lg (2010) **5055392**

Prof. Dr. D. Bartsch
BVL, Abteilung Gentechnik
Mauerstrs. 39-42
D-10117 Berlin

Subject: **Application for authorisation of genetically modified maize Bt11 x MIR162 x 1507 x GA21 from Syngenta Crop Protection AG submitted under Regulation (EC) No 1829/2003.**
EFSA-GMO-DE-2010-86

Dear Dr Bartsch,

We thank you for your letter dated 04 August 2010 (received 10 August 2010) accompanying a new application submitted by Syngenta Crop Protection AG. The application (1 paper copy consisting of 8 volumes and 1 electronic copy on CD-ROM) is for authorisation of the genetically modified maize Bt11 x MIR162 x 1507 x GA21 in the European Union, under Regulation (EC) No 1829/2003.

The scope of the application covers the placing on the market of maize Bt11 x MIR162 x 1507 x GA21 for food and feed uses, import and processing. The scope of this application does not include the cultivation of maize Bt11 x MIR162 x 1507 x GA21 varieties in the EU.

The application has been named file **No EFSA-GMO-DE-2010-86**. This number should be used each time when referring to this application dossier or to the associated administrative procedure.

The application contains confidential information.

In accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003[1] EFSA in giving its opinion shall endeavour to respect a time limit of six months as from the receipt of valid application. An application can only be regarded as valid if it adequately complies with the requirements of Regulation (EC) No 1829/2003 and its implementing Regulation (EC) No 641/2004[2]. In line with Articles 5(8) and 17(8) of the Regulation, EFSA has developed

[1] Regulation (EC) No 1829/2003 on genetically modified food and feed, OJ L 268, 18.10.2003, p. 1.
[2] Regulation (EC) No 641/2004 on detailed rules on the implementation of Regulation (EC) No 1829/2003, OJ L102, 07.04.2004, p. 14

detailed guidance[3] to assist the applicant in the preparation and presentation of applications. Regulation (EC) No 641/2004 clearly states that the EFSA guidance shall be taken into account when an application is submitted in accordance with Regulation (EC) No 1829/2003.

EFSA presently checks the submitted dossier for accordance with Regulation (EC) No 1829/2003 and the "Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use" (May 2006).

As soon as the application is considered valid it will be made available via EXTRAnet, a secure IT network system to give Member States and the European Commission access to the dossier. Further, the designated contact persons in the Member States and the European Commission will be informed about the start of the evaluation procedure and the three-month consultation period as referred to under Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

Yours sincerely,

Catherine Geslain-Lanéelle

c.c.:

Mr Goux, Ms D. André, Ms Pelsser, Ms Torppa,
Mr Vanhoorde, Mr Walsh – DG SANCO
Mr Van den Eede, Mr Mazzara – DG JRC
Ms Maijala, Ms Lheureux, GMO_secretariat_applications– EFSA
GMO EXTRAnet for applications

[3] Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed, the EFSA Journal (2006) 99, 1-100
http://www.efsa.europa.eu/etc/medialib/efsa/press_room/publications/scientific/1497.Par.0005.File.dat/gmo_guidance%20gm%20plants_en.pdf