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EFSA - FARMA

**Syngenta Crop Protection application for authorization of genetically modified stacked maize ( Bt11 x MIR162 x GA21) and derived food and feed products according to Articles 5 and 17 of Regulation (EC) No 1829/2003**

Dear Sirs,

Please find enclosed a submission, made under Regulation (EC) No 1829/2003, for the import of Syngenta Bt11 x MIR162 x GA21 maize. In parallel, Syngenta is asking for the import of Bt11 x MIR162 x MIR604 x GA21 maize in a separate application.

On 17 December 2008, Syngenta has submitted a comprehensive data package to support the authorization of two stacked maize products, Bt11 x MIR162 x MIR604 x GA21 maize and Bt11 x MIR162 x GA21 maize. For formal reasons, EFSA has requested (letter ref PB/KL/shv (2009) 3520020 and verbal communication on 3. February 2009) to submit two separate applications, supported by a common technical dossier which contains a compilation of all data and studies for both maize products Bt11 x MIR162 x MIR604 x GA21 and Bt11 x MIR162 x GA21.

The genetically modified Bt11 x MIR162 x GA21 maize product was produced from the combination of maize events Bt11, MIR162 and GA21, using conventional breeding techniques. The single events are as follows:

- Event Bt11 maize (herein after referred to as 'Bt11 maize') which expresses a truncated Cry1Ab protein for control of certain lepidopteran pests and a phosphinothricin acetyltransferase (PAT) protein that confers tolerance to herbicide products containing glufosinate ammonium.
- Event MIR162 maize (herein after referred to as 'MIR162 maize') which expresses a Vip3Aa20 protein for control of certain lepidopteran pests and a phosphomannose isomerase (PMI) protein, that acts as a selectable marker trait enabling transformed plant cells to utilize mannose as the only primary carbon source.
- Event GA21 maize (herein after referred to as 'GA21 maize') which expresses a modified maize 5-enolpyruvylshikimate-3-phosphate synthase enzyme (mEPSPS) that confers tolerance to herbicide products containing glyphosate.

Both, Bt11 maize and GA21 maize have previously been assessed by the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) and the adopted opinions can be found on the EFSA website<sup>1</sup>.

<sup>1</sup> Please see [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620771029.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620771029.htm)

Bt11 maize and GA21 maize are approved for import, food and feed use in the EU under formerly Directive 90/220/EEC or Directive 2001/18/EC.

The import and use of MIR162 maize has not been previously evaluated in the EU. The data to evaluate the safety of MIR162 maize is included in this application.

Furthermore, an application for cultivation of Bt11 maize is in the registration process and has been assessed by EFSA, scientific opinion was adopted on 20 April 2005, in 2006 and 2008. An application for authorization of all uses of GA21 maize, including cultivation has also been submitted, by Syngenta, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 on 30 June 2008.

Applications for import and use of Syngenta products Bt11 x GA21 maize, Bt11 x MIR604 maize, MIR604 x GA21 maize and Bt11 x MIR604 x GA21 maize have also been submitted under Regulation (EC) No. 1829/2003 and are currently being reviewed by EFSA.

The scope of this application covers all food and feed products containing, consisting or produced from Bt11 x MIR162 x GA21 maize, including products from inbreds and hybrids obtained by conventional breeding. The application also covers the import and processing for use as any other maize. In parallel Syngenta applies for Bt11 x MIR162 x MIR604 x GA21 maize in a separate application.

The submission consists of three electronic copies (two CD-ROM each), one of which is meant for use by the German Competent Authority. The submission contains confidential business information, the disclosure of which could harm individuals or the competitive position of Syngenta and its affiliates. In this regard, the confidential business information has been supplied as a separate electronic copy, which is password protected. The password will be sent to you in a separate letter. Please ensure that the password and the information are protected at all times.

If you require further information, please do not hesitate to contact  
using the contact details below:

Yours faithfully,

Syngenta Crop Protection AG

Encs.