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EFSA



Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)  
Abteilung Gentechnik  
Mauerstr. 39-42

D-10117 Berlin, Germany

30 July 2010

Dear Sirs,

2010/25803

BVL Mauerstraße 39-42 10117 Berlin						
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**Syngenta Crop Protection AG application for authorization of genetically modified Bt11 x MIR162 x 1507 x GA21 maize and derived food and feed products under Regulation (EC) No 1829/2003**

Please find enclosed a submission, made under Regulation (EC) No 1829/2003, for the import of Syngenta Bt11 x MIR162 x 1507 x GA21 maize. The combined maize trait product Bt11 x MIR162 x 1507 x GA21 maize (hereafter referred to as 'Bt11 x MIR162 x 1507 x GA21 maize') is a genetically modified maize (GM) that is produced by conventional breeding crosses using different combinations of the following GM maize events: Bt11, MIR162, 1507<sup>1</sup> and GA21.

The scope of this application covers all food and feed products containing, consisting or produced from Bt11 x MIR162 x 1507 x GA21 maize. The application also covers the import and processing for use as any other maize.

Where cultivated, the intended use of Bt11 x MIR162 x 1507 x GA21 maize is to control important Lepidopteran maize pests and to provide tolerance to herbicides containing glufosinate ammonium or glyphosate. However, the scope of this application does not include cultivation of Bt11 x MIR162 x 1507 x GA21 maize seed in the EU.

Please note that some parts of the technical data provided with this application have already been submitted with earlier applications. In particular, applications for the import and food and feed use of Bt11, 1507 and GA21 maize have been previously assessed by EFSA and approved, while the safety of MIR162 maize for import and food and feed use is currently under review (application EFSA-GMO-DE-2010-82). In order to facilitate the review of this application, the technical dossier contains relevant information that was submitted earlier and it has been completed with an updated bioinformatic analysis and post-market monitoring plan. This will allow a parallel review of this submission with the ongoing assessment of MIR162 maize.

In addition and since 1507 maize is not a Syngenta proprietary event, reference is being made to technical data provided by Dow AgroSciences to support the safety of 1507 maize to human and animal health and the environment. To facilitate the review, please find attached a copy of the Letter of authorization for use of regulatory data from Dow AgroSciences LLC to the National Competent Authorities under Regulation (EC) No 1829/2003 and EFSA granting

<sup>1</sup> Maize line 1507 is normally referred to as Event TC1507 in applications submitted by Dow AgroSciences LLC to most countries other than the European Union.

permission to refer to, use or otherwise rely on data previously submitted by Dow AgroSciences for the authorization of 1507 maize.

The submission consists of one paper copy, contained within lever arch files and two 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. Confidential business information contained within the paper copy is clearly labeled and contained within separate Appendices. Please ensure that the password and the information are protected at all times.

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

Yours faithfully,

Syngenta Crop Protection AG

Encs.

- Letter of authorization for use of regulatory data from Dow AgroSciences LLC to the National Competent Authorities under Regulation (EC) No 1829/2003 and EFSA dated November 6, 2009