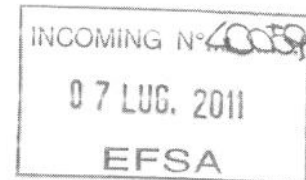


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Sicherheit (BVL)



30 June 2011

Syngenta Crop Protection AG application for authorisation of stacked Bt11 x 59122 x MIR604 x 1507 x GA21 maize in the European Union under Regulation (EC) No 1829/2003

Dear Sirs,

The combined maize trait product Bt11 x DAS-59122-7 x MIR604 x TC1507 x GA21 maize (hereafter referred to as 'Bt11 x 59122 x MIR604 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, 59122, MIR604, 1507 and GA21.

Please find enclosed an application under Regulation (EC) No 1829/2003, requesting the authorisation for import, food and feed use and processing for all potential uses as any other maize of Bt11 x 59122 x MIR604 x 1507 x GA21 maize in the European Union. The scope of the application also includes the sub-combinations of Bt11 x 59122 x MIR604 x 1507 x GA21 maize.

For the purpose of the risk assessment all of the sub-combinations of Bt11 x 59122 x MIR604 x 1507 x GA21 maize have been considered in the evaluation carried out in Sections D.9 and D.10 of Part I and in the detailed and stand alone Environmental Risk Assessment included as Appendix 34 of this application.

Where cultivated, the intended use of Bt11 x 59122 x MIR604 x 1507 x GA21 maize is to control important Lepidopteran and Coleopteran 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 59122 x MIR604 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. All applications for the import and food and feed use of Bt11, 59122, MIR604, 1507 and GA21 maize have been previously assessed by EFSA and approved. 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 updated bioinformatic analysis.

In addition and since 59122 and 1507 maize are not Syngenta proprietary events, reference is being made to technical data provided by Dow AgroSciences LLC to support the safety of 59122 and 1507 maize to human and animal health and the environment. To facilitate the review, Appendix 2 of the application contains 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 permission to refer to, use or otherwise rely on data previously submitted by Dow AgroSciences LLC for the authorization of 59122 and 1507 maize. Updated bioinformatic analysis for 59122 and 1507 maize will be provided to EFSA directly by Dow AgroSciences LLC.

The submission consists of one paper copy, contained within lever arch files and two sets of 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 me.

Yours faithfully,

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