

Safety Assessment RP1506 Genetically Modified DP4114xMON810xMIR604xNK603 Maize and sub-combinations

Maes o ddiddordeb ymchwil: [Research projects](#)

Statws y prosiect: Wedi'i gwblhau

Cod prosiect: RP1506

Cynhaliwyd gan: Regulated Products Risk Assessment Unit FSA and Risk Assessment Team FSS

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Summary

Following the submission of application RP1506 from Corteva Agrisciences LLC Represented by Corteva Agriscience UK Limited to the Food Standards Agency (FSA) under assimilated Regulation (EC) No. 1829/2003, FSA/FSS (Food Standards Scotland) have undertaken a safety assessment on genetically modified DP4114xMON810xMIR604xNK603 maize. To support the safety assessment by FSA/FSS, the Advisory Committee on Novel Foods and Processes (ACNFP) provided advice to FSA/FSS on the data submitted for the authorisation of genetically modified DP4114xMON810xMIR604xNK603 maize, as outlined in this document. The advice of the ACNFP has been taken into account in this safety assessment which represents the opinion of FSA/FSS on the safety of genetically modified DP4114xMON810xMIR604xNK603 maize.

DP4114xMON810xMIR604xNK603 maize (*Zea mays* L.) has been obtained by traditional crossing of genetically modified DP4114, MON810, MIR604 and NK603 maize. No additional genetic modification was used to produce this maize hybrid. Therefore, these maize plants produce the transgenic proteins inherited from the single GM maize events. Each single event has been previously assessed and authorised in the EU, during which time the UK was a member state (EFSA, 2018b; EFSA, 2009a; EFSA, 2009b; EFSA, 2009c). The individual events that comprise the stack have therefore not been re-assessed.

In providing its scientific advice, the ACNFP considered data on the composition and agronomic characteristics of the stack, the potential for interactions between the individual events, DNA sequencing and updated bioinformatics analyses, and additional toxicological studies provided by the applicant as part of application RP1791. As the single events have been previously safety assessed and authorised, this safety assessment focused on stability of the transformation events, expression of the transformation events, and potential interactions resulting from the combination of the transformation events as required by Implementing Regulation (EU) No 503/2013 (EC, 2013).

The introduced genes in DP4114xMON810xMIR604xNK603 maize are cry1F, cry34Ab1, cry35Ab1, pat, cry1Ab, cry3A, pmi, and CP4 epsps. The correspondent proteins produced are Cry1F, Cry34Ab1, Cry35Ab1, PAT, Cry1Ab, mCry3A, PMI and CP4 EPSPS. These proteins confer the following traits:

- herbicide tolerance to glyphosate and glufosinate-ammonium herbicides due to the presence of the CP4 EPSPS and PAT proteins, respectively.
- protection against lepidopteran target pests based on the presence of the Cry1F and Cry1Ab proteins, conferring independent modes of action for insect protection
- protection against coleopteran target pests based on the presence of the Cry34Ab1, Cry35Ab1 and mCry3A proteins, conferring independent modes of action for insect protection

Maize is one of the most important crops worldwide and it is grown over a wide range of climatic conditions, well-suited for warm, temperate climates. Maize, grown on 15 million hectares in the EU (14% of the EU's arable land, and 8% of worldwide maize acreage), is the leading cereal in terms of global production volumes. Its principal use is animal feed (83%), followed by starch manufacturing (15%) and cornmeal (2%). The methods of production and manufacturing are well known and have a long history of safe use. Silage maize is cultivated for feed and is mainly used on-farm. Grain maize is used for feed (poultry, corn-cob-mix for pigs), food (maize-meal-products, snacks, cornflakes, oil) or for industrial purposes and non-food products (starch, paper, industrial alcohol). The genetic modification in DP4114xMON810xMIR604xNK603 maize does not impact the production or manufacturing processes currently used for maize.

The scope of the application is for the authorisation for import, processing, and food and feed use of DP4114xMON810xMIR604xNK603 maize. The application does not cover cultivation and therefore no DP4114xMON810xMIR604xNK603 maize will be grown in the UK.

Molecular characterisation confirmed that the genetic insertions in DP4114xMON810xMIR604xNK603 maize were equivalent to those present in the single event GM lines, and the conclusions reached for the single events remain valid for DP4114xMON810xMIR604xNK603 maize and its sub-combinations, irrespective of its origin.

Updated bioinformatics analysis on the open reading frames (ORFs) and newly expressed proteins in maize DP4114xMON810xMIR604xNK603 supported the previous conclusions on the safety of the single maize events reached by the EFSA GMO Panel. Bioinformatic analysis of the sequence regions flanking the insertion sites did not reveal unintended changes or interactions that would need further evaluation. No biologically relevant changes in protein expression values were observed between DP4114xMON810xMIR604xNK603 maize and in the single event maize lines and there are no mechanisms known that could specifically impact on expression levels of any of the sub-combinations. The field trials (including locations and management practices) for the production of test materials for the comparative analysis were considered appropriate, and no differences between DP4114xMON810xMIR604xNK603 maize and the conventional counterpart or the non-GM reference varieties that would raise safety concerns were observed.

Toxicological testing of newly expressed proteins were conducted as part of the previous EU applications, showing no adverse effects. In addition, the 90-day feeding study performed on DP4114xMON810xMIR604xNK603 maize as part of this application raised no safety concerns. No relevant similarity between the inserted protein sequences and known protein toxins or allergens was identified through updated bioinformatic studies.

The ACNFP concludes that considering the nature of the introduced traits, the lack of differences in the agronomic and compositional analyses, and the proposed levels of exposure, there is no evidence that the import, processing, and food and feed use of DP4114xMON810xMIR604xNK603 maize would raise any safety concerns. The ACNFP concludes that DP4114xMON810xMIR604xNK603 maize is as safe as its conventional counterpart.

Safety assessment

[Gweld RP1506 Safety assessment of genetically modified DP4114xMON810xMIR604xNK603 maize and sub-combinations as PDF\(Open in a new window\)](#) (436.85 KB)