Advice on the import and processing of GM maize DAS1131×DP910521×DP202216×DAS-40278-9 and its subcombinations

COGEM advice CGM/260205-01

COGEM has been requested to evaluate the environmental risks associated with the authorisation for import, processing and food and feed use of genetically modified (GM) maize DAS1131 × DP910521 × DP202216 × DAS-40278-9 and its subcombinations (GMFF-2025-34337), as submitted by Corteva Agriscience Belgium B.V. on behalf of Corteva Agriscience LLC (MA 250011).

GM maize DAS1131 × DP910521 × DP202216 × DAS-40278-9 was produced by crossing the four GM parental maize lines using conventional breeding methods. The GM maize expresses the *Cry1*Da2 gene derived from DAS1131 and the *Cry1*B.34 gene derived from DP910521 which confer resistance against certain lepidopteran pests. The GM maize also expresses several herbicide tolerance genes: the *dgt-28 epsps* gene derived from DAS1131 conferring tolerance to glyphosate containing herbicides, the *mo-pat* genes derived from both DP910521 and DP202216 conferring resistance to glufosinate-ammonium containing herbicides and the *aad-1* gene derived from DAS-40278-9 which confers tolerance to 2,4 dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) containing herbicides. Furthermore, it expresses the *zmm28* gene derived from DP202216 leading to increased and extended production of the endogenous ZMM28 protein resulting in plants with an enhanced grain yield potential. In addition, GM maize DAS1131 × DP910521 × DP202216 × DAS-40278-9 contains the *pmi* gene derived from DP910521 which was used as a selectable marker during development of DP910521. For an overview and description of the introduced genes and traits, see Table 1.

Table 1. Description of the introduced genes and traits

Introduced genes	Encoded proteins	Regulatory elements	Traits
*Cry1*Da2* (DAS1131)	Encodes the chimeric insecticidal Cry1Da2 protein originating from *Bacillus thuringiensis.*[1]	Contains the promoter region, including the 5'UTR and intron, and terminator from the *Zea mays* ubiquitin gene 1 (*ubi*ZM1).[2,3]	Resistance to certain lepidopteran insects.
dgt-28 epsps (DAS1131)	5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) derived from *Streptomyces sviceus* fused to a chimeric chloroplast transit peptide (TraP8) from *Brassica napus* and *Brassica rapa* in order to direct the protein to the maize chloroplasts.[4,5]	Controlled by the *ubi*ZM1 promoter, including 5'UTR and intron, and the *ubi*ZM1 terminator from *Z. mays*.	Tolerance to glyphosate containing herbicides.

Introduced genes	Encoded proteins	Regulatory elements	Traits
pmi (DP910521)	Phosphomannose isomerase (PMI) enzyme derived from *Escherichia coli* K12.[6]	Expression of the *pmi* gene is regulated by the promotor region of the *Ubi*ZM1 gene from *Z. mays*[7] located upstream of the FRT1 target site. Contains the proteinase inhibitor II (*pin*II) terminator from *Solanum tuberosum*[8,9], and the additional Z19 terminator from *Z. mays* to prevent transcriptional interference.	Selectable marker: enables transformed plant cells to use mannose as a sole carbon source.
mo-pat (DP910521)	Maize codon-optimised version of phosphinothricin acetyl transferase (*pat*) gene from *Streptomyces viridochromogenes.*[10,11,12]	Promoter and intron region of the actin gene of *Oryza sativa*, and 35S terminator region from cauliflower mosaic virus.[13,14] Two additional terminator regions from the *Sorghum bicolor* ubiquitin gene (sb-ubi) and γ-kafarin gene (sb-gkaf) prevent transcriptional interference.	Tolerance to glufosinate-ammonium containing herbicides.
Cry1B.34** (DP910521)	Encodes the chimeric insecticidal Cry1B.34 protein originating from *Bacillus thuringiensis.*	Contains two copies of the enhancer region from mirabilis mosaic virus (MMV)[15] and the promoter region from Lamium leaf distortion-associated virus (LLDAV)[16], the intron region from the *Z. mays* initiation factor 6 (*zm-i6*) gene, the 5'UTR from the *Z. mays* extension (*zm-extensin*) gene, and the terminator region from the *O. sativa* ubiquitin (*os-ubi*) gene.	Resistance to certain lepidopteran insects.
zmm28 (DP202216)	MADS-domain transcription factor gene originating from *Zea mays* encoding for ZMM28 protein.[17,18,19,20]	*Gos2* promoter (*zm-gos2*) and intron from the ubiquitin gene 1 (*ubi*ZM1) from *Z. mays* and proteinase inhibitor II (*pin*II) gene terminator from *Solanum tuberosum.*	Plants with enhanced grain yield potential.
mo-pat (DP202216)	Maize codon-optimised version of phosphinothricin acetyl transferase (*pat*) gene from *Streptomyces viridochromogenes.*[10,11,12]	Promoter, 5'UTR and intron from the *ubi*ZM1 gene from *Z. mays* and *pin*II terminator from *S. tuberosum.*	Tolerance to glufosinate-ammonium containing herbicides.

Introduced genes	Encoded proteins	Regulatory elements	Traits
aad-1 (DAS-40278-9)	Aryloxyalkanoate dioxygenase (AAD-1) enzyme originating from *Sphingobium herbicidovorans.*[21]	Polyubiquitin promoter and intron (Zm*Ubi*Int) and Zmper5 3'UTR terminator from *Zea mays.*	Cleavage of several synthetic auxins and certain 'aryloxyphenoxy-propionate' (AOPP) herbicides, resulting in a tolerance to several synthetic auxin acting herbicides like 2,4 dichlorophenoxyacetic acid' (2,4-D) and to AOPP containing herbicides.

* The *cry*1Da2 gene is a chimeric gene comprised of sequences from the *cry*1Da2 gene and the *cry*1Ab gene, both derived from *B. thuringiensis*.
** *cry*1B.34 is a chimeric gene comprised of sequences from a *cry*1B-class gene, the *cry*1Ca1 gene and the *cry*9Db1 gene, all derived from *B. thuringiensis*.

COGEM has previously advised positively on import and processing of the parental lines DAS1131[22], DP910521[23], DP202216[24] and DAS-40278-9[25]. COGEM also advised positively on the import and processing of many stacked events containing these parental lines.[e.g. 26 27 28, 29, 30 31] The parental lines DAS1131, DP910521, DP202216 and DAS-40278-9 have all been authorised for import and processing for use in food and feed in the European Union.[32, 33, 34, 35]

Maize (*Zea mays*) is a highly domesticated crop that is cultivated globally. Maize is wind pollinated.[36, 37] Insect pollination of maize is highly limited but cannot be excluded.[38] Maize is very sensitive to weed competition.[39] During the long process of domestication, maize has lost the ability to persist in the wild.[37] After ripening, the seeds (the kernels) adhere to the cob and do not scatter naturally.[38, 40] Consequently, seed dispersal is severely hampered.

Maize does not tolerate prolonged cold and frost, and requires warm conditions to grow.[38, 41, 42] In cultivation areas with warm climatic conditions, volunteers – maize not deliberately planted – can be present the year following maize cultivation due to spilled cobs or kernels. However, these volunteers are usually killed by common mechanical pre-planting soil preparation practices.[38] In the Netherlands the appearance of volunteers is rare, although maize plants occasionally have been observed outside agricultural fields.[44, 43] Any volunteers emerging will be killed by frost at the onset of winter.[44] COGEM is not aware of any reports of feral maize populations in the Netherlands.[44] Hybridisation of GM maize with species other than teosinte – the wild relative of maize – cannot occur. However, as teosinte is absent in maize fields and nature in the Netherlands,[44] hybridisation of GM maize with teosinte will not occur in the Netherlands.

The application for market authorisation of GM maize DAS1131 × DP910521 × DP202216 × DAS-40278-9 (and its subcombinations) for import, processing and use in food and feed contains, amongst others, bioinformatic analyses, phenotypic and agronomic analysis and a post-market environmental monitoring (PMEM) plan. The bio-informatic analysis of each of the inserted elements and its 3' and 5' junctions in GM maize DAS1131 × DP910521 × DP202216 × DAS-40278-9 was updated, using up-to-date databases of allergens, toxins, and other biologically active proteins to assess protein sequence similarities. No indications for potential environmental risks were identified.

The applicant analysed the phenotypic and agronomic characteristics of DAS1131 × DP910521 × DP202216 × DAS-40278-9 and reported that the characteristics of the GM maize did not differ from the non-transgenic, near-isoline control maize (conventional counterpart), and is equivalent to the reference varieties, taking natural variation into account.

There are no indications that the introduced traits in maize DAS1131 × DP910521 × DP202216 × DAS-40278-9 will allow the GM maize to survive in the Dutch environment. A post-market environmental monitoring (PMEM) plan is provided in the application. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan[45,46] – which is part of a PMEM plan – but considers the current GS plan adequate for import and processing of GM maize DAS1131 × DP910521 × DP202216 × DAS-40278-9.

COGEM is of the opinion that the market authorisation for import and processing of GM maize DAS1131 × DP910521 × DP202216 × DAS-40278-9 and GM maize consisting of subcombinations of the parental GM maize lines pose a negligible risk to the Dutch environment. COGEM abstains from giving advice on the potential risks of incidental consumption, as a food/feed assessment is carried out by other organisations.

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