

Advice Import GM maize MON87427×MON94804×MON95379×MIR162×MON88017

COGEM advice CGM/260206-01

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 MON87427 × MON94804 × MON95379 × MIR162 × MON88017 and its subcombinations (GMFF-2025-35657, MA 250013_001), as submitted by Bayer Agriculture B.V. on behalf of Bayer CropScience LP.

GM maize MON87427 × MON94804 × MON95379 × MIR162 × MON88017 was produced by crossing the five GM parental maize lines using conventional breeding methods and expresses multiple introduced genes (Table 1). The GM maize expresses two copies of the *cp4 epsps* genes, derived from MON87427 and MON88017, which confer tolerance to glyphosate-containing herbicides. The GM maize expresses a *GA20ox_SUP* suppression cassette, derived from MON94804, which down-regulates the expression of the *ZmGA20ox3* and *ZmGA20ox5* genes and results in reduced levels of the plant hormone gibberellic acid/gibberellin. Consequently, MON87427 × MON94804 × MON95379 × MIR162 × MON88017 has a reduced plant height. Furthermore, the GM maize expresses the transgenes *cry1B.868* and *cry1Da_7* derived from MON95379, and the gene *vip3Aa20* derived from MIR162, which all confer resistance against certain lepidopteran pests. The *cry3Bb1* gene derived from MON88017 confers resistance against coleopteran pests. In addition, GM maize MON87427 × MON94804 × MON95379 × MIR162 × MON88017 contains the *pmi* gene derived from MIR162, which was used as a selectable marker during the development of MIR162.

Table 1. Description of the introduced genes and traits

Introduced genes/cassettes	Encoded proteins	Regulatory elements	Traits
<i>cp4 epsps</i> (MON87427)	The 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme originating from <i>Agrobacterium tumefaciens</i> strain CP4 ^{1,2}	Enhanced 35S (<i>e35S</i>) promoter from cauliflower mosaic virus (CaMV) and nopaline synthase (<i>nos</i>) terminator from <i>A. tumefaciens</i>	Tolerance to glyphosate-containing herbicides
<i>GA20ox_SUP</i> suppression cassette (MON94804)	Two inverted repeats derived from the maize coding sequences of gibberellin 20-oxidase homolog 3 and 5 (<i>GA20ox3</i> and -5), flanked by three <i>Osa-miR1425</i> fragments from <i>Oryza sativa</i>	Promoter and leader from the Rice tungro bacilliform virus (RTBV), ³ intron and flanking exon sequence from the <i>hsp70</i> gene from <i>Zea mays</i> ³ and synthetic 3' untranslated region (UTR) (<i>GST43</i>) based on multiple 3'UTR sequences from <i>Z. mays</i>	Reduced gibberellic acid/ gibberellin levels in the stem and reduced overall plant height ⁴
<i>cry1B.868</i> (MON95379)	A chimeric Cry protein consisting of domains from <i>Cry1Be</i> , <i>Cry1Ca</i> and <i>Cry1Ab</i> , all from <i>Bacillus thuringiensis</i> ⁵	Promoter, 5' UTR and intron from a ubiquitin gene from <i>Zea mays</i> subsp. <i>mexicana</i> ⁶ and the 3' UTR sequence of the <i>lipid transfer protein-like</i> gene from <i>O. sativa</i> ⁷	Resistance against certain lepidopteran insects ^{5,8,9}

Introduced genes/ cassettes	Encoded proteins	Regulatory elements	Traits
<i>cry1Da_7</i> (MON95379)	Maize codon-optimised and adapted version of Cry1Da from <i>B. thuringiensis</i> subsp. <i>aizawai</i> . ⁵	Promoter from the <i>Setaria italica</i> tonoplast membrane integral protein gene, ¹⁰ enhancer from the 35S RNA of figwort mosaic virus (FMV) ¹¹ and the 3' UTR sequence from the <i>GOS2</i> gene of <i>O. sativa</i> ⁷	Resistance against certain lepidopteran insects ^{5,8,9}
<i>vip3Aa20</i> (MIR162)	Variant of a native vegetative insecticidal protein (Vip) class A, subclass a, (<i>Vip3Aa20</i>) originating from <i>B. thuringiensis</i> strain AB887	Polyubiquitin promoter and intron (<i>ZmUbi1nt</i>) from <i>Zea mays</i> and 35S terminator from CaMV	Resistance against certain lepidopteran insects ^{5,8,9}
<i>pmi</i> , also known as <i>manA</i> (MIR162)	Phosphomannose isomerase (PMI) enzyme derived from <i>Escherichia coli</i> K12 ¹²	Polyubiquitin promoter and intron (<i>ZmUbi1nt</i>) from <i>Z. mays</i> and nopaline synthase (<i>nos</i>) terminator from <i>A. tumefaciens</i>	Enables transformed plant cells to use mannose as a sole carbon source
<i>cp4 epsps</i> (MON88017)	The 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme originating from <i>Agrobacterium tumefaciens</i> strain CP4 ^{1,2}	P-ract1 promoter om the gene <i>Receptor for Activated C Kinase 1</i> <i>O. sativa</i> and nopaline synthase (<i>nos</i>) terminator from <i>A. tumefaciens</i>	Tolerance to glyphosate-containing herbicides
<i>cry3Bb1</i> (MON88017)	Variant of the <i>Cry3Bb1</i> protein originating from <i>B. thuringiensis</i> subsp. <i>kumamotoensis</i> ¹³	Enhanced 35S (<i>P-ε35S</i>) promoter from CaMV and wheat heat shock protein (<i>Tahsp 17 '3</i>) derived from <i>Triticum aestivum</i> to stop transcription	Resistance to certain coleopteran insects

COGEM has previously advised positively on the cultivation and import of MON88017,^{14,15} and on import and processing of the parental lines MON87427,^{16,17,18} MON94804,¹⁹ MON95379²⁰, and MIR162^{21,22}. COGEM also advised positively on the import and processing of many stacked events containing these parental lines, e.g. 23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38 as well as the cultivation of a stacked events containing two of the involved parental lines.³⁹ The parental lines MON87427, MON94804, MON95379, MIR162 and MON88017 have all been authorised for import and processing for use in food and feed in the European Union.^{40,41,42,43,44}

Maize (*Zea mays*) is a highly domesticated crop that is cultivated globally. Maize is wind pollinated.^{45,46} Insect pollination of maize is highly limited but cannot be excluded.⁴⁷ Maize is very sensitive to weed competition.⁴⁸ During the long process of domestication, maize has lost the ability to persist in the wild.⁴⁶ After ripening, the seeds (the kernels) adhere to the cob and do not scatter naturally.^{47,49} Consequently, seed dispersal is severely hampered.

Maize does not tolerate prolonged cold and frost, and requires warm conditions to grow.^{47,50,51} 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.⁴⁷ In the Netherlands the appearance of volunteers is rare, although maize plants occasionally have been observed outside agricultural fields.^{50,52} Any volunteers emerging will be killed by frost at the onset of winter.⁵⁰ COGEM is not aware of any reports of feral maize populations in the Netherlands.⁵⁰ 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,⁵⁰ hybridisation of GM maize with teosinte will not occur in the Netherlands.

The application for market authorisation of GM maize MON87427 × MON94804 × MON95379 × MIR162 × MON88017 (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 with the genome of GM maize MON87427 × MON94804 × MON95379 × MIR162 × MON88017 were 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 MON87427 × MON94804 × MON95379 × MIR162 × MON88017 and reported that most characteristics of the GM maize did not differ from the non-GM near-isogenic control line, and is equivalent to the reference varieties, taking natural variation into account.

There are no indications that the introduced traits in MON87427 × MON94804 × MON95379 × MIR162 × MON88017 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^{53,54} – which is part of a PMEM plan – but considers the current GS plan adequate for import and processing of GM maize MON87427 × MON94804 × MON95379 × MIR162 × MON88017.

COGEM is of the opinion that the market authorisation for import and processing of GM maize of MON87427 × MON94804 × MON95379 × MIR162 × MON88017 and its subcombinations poses 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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