

Summary Notification Information Format

GMO Application

Deliberate release of GMO or a combination of GMOs for any other purpose than for placing on the market

APPLICATION TYPE

Summary notification for the release of genetically modified higher plants in line with Decision
2002/813/EC Annex, Part 2.

General Information

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Details of notification

Notification Number

GMOB-2024-24570

Member State

Belgium

Date of Acknowledgement

xx

Title of the Project

Field trial request for three CRISPR-Cas9 maize concepts

Proposed period of release:

15/04/2025 to 30/11/2026

Notifier

Name of institute or company

Corteva Agriscience Belgium B.V.

Is the same GMPT release planned elsewhere in the Community?

Spain in 2025

Has the same GMPT been notified elsewhere by the same notifier?

No

Information on the genetically modified plant

Identity of the recipient or parental plant

- a) family: Poaceae
- b) genus: *Zea*, section *Zea*
- c) species: *Zea mays*
- d) subspecies: *mays*
- e) cultivar/breeding line: CRISPR Cas9 maize
- f) common name: maize

Description of the traits and characteristics which have been introduced or modified, including marker genes and previous modifications *

Three non-transgenic CRISPR-Cas9 maize concepts were developed using CRISPR-Cas9 technology to (1) delete the endogenous Wx1 gene which results in high-amylopectin phenotype of the kernels (referred to as CRISPR-Cas9 waxy), (2) with improved resistance to a Northern Corn Leaf Blight (NCLB) via allele replacement (referred to as CRISPR-Cas9 NLB18), or (3) for improved resistance to two maize fungal diseases: northern corn leaf blight (NCLB) and southern corn rust (SCR) (referred to as CRISPR-Cas9 DL) via incorporation of native maize resistance genes (referred to as cisgenes).

CRISPR-Cas9 waxy maize was generated to delete the endogenous Wx1 gene. The intended phenotype of CRISPR-Cas9 waxy maize is kernels with high amylopectin starch content. Waxy maize starch is a valuable commodity due to physical and chemical properties enabled by its high amylopectin content. Waxy cornstarch has a versatility of uses in the food and paper-making industries. Additionally, waxy cornstarch has applications in the textile, corrugating, and adhesive industries.

CRISPR-Cas9 NLB18 maize with improved resistance to northern corn leaf blight (NCLB) fungal disease which was achieved by targeted replacement of the disease-susceptible allele of the NLB18 gene (NLB18-S) with the disease resistant allele of the same gene (NLB18-R). NCLB is a fungal disease caused by *Exserohilum turcicum*, and is of global economic importance. Resistance to specific races of the pathogen can be improved by certain native disease resistance maize genes.

CRISPR-Cas9 DL Maize was developed using CRISPR-Cas9 technology to incorporate a single sequence locus of cisgenes (NLB18, Ht1 and RppK) for improved resistance to two maize fungal diseases, northern corn leaf blight (NCLB) and southern corn rust (SCR). NCLB and SCR are fungal diseases caused by *Exserohilum turcicum* and *Puccinia polysora*, respectively, both have global economic importance. Resistance to specific races of the pathogen can be improved by certain native disease resistance maize genes.

Genetic modification

Type of genetic modification

Other: CRISPR-Cas9 to delete waxy gene; allele replacement; insertion of cisgenes.
See details in below

Brief description of the method used for the genetic modification *

CRISPR-Cas9 technology was used to create the 3 maize concepts.

CRISPR-Cas9 waxy maize was generated to delete the endogenous *Wx1* gene. CRISPR Cas9 was used to create two double stranded breaks (DSB) which was subsequently repaired by Non-Homologous End Joining (NHEJ), causing inactivation of the *Wx1* gene.

CRISPR-Cas9 NLB18 maize with improved resistance to NCLB was developed with CRISPR-Cas9 technology to replace the disease-susceptible allele of the NLB18 gene (NLB18 S) with the disease resistant allele of the same gene (NLB18-R).

CRISPR-Cas9 DL maize with improved resistance to NCLB and SCR was developed with CRISPR-Cas9 technology to incorporate a single sequence locus of cisgenes (NLB18, Ht1 and RppK).

Is the recipient or parental plant is a forest tree species?

No

Information relating to the experimental release

Purpose of the release (including any relevant information available at this stage) such as agronomic purposes, test of hybridisation, changed survivability or dissemination, test of effects on target or non-target organisms *

The main purpose of the field trial is for educational purposes and to show the potential of gene edited maize.

Geographical location of the release site

The release is planned at an ILVO location in Belgium (Merelbeke-Melle) in 2025/2026

Size of the site (m2)

The trial plot will be captured within the fence includes non-modified controls, and non-modified fertilizer lines, and will be less than 1000 m2.

Relevant data regarding previous releases carried out with the same GM-plant, if any, specifically related to the potential environmental and human health impacts from the release

Not applicable, no prior field releases of CRISPR-Cas9 maize lines occurred in the EU

CRISPR-Cas9 waxy maize non-regulated/non-GMO status has been confirmed in several jurisdictions

Environmental Impact and Risk Management

Summary of the potential environmental impact of the release of the GMPTS in accordance with Annex II, D2 to Directive 2001/18/EC

Various spontaneous and induced mutations in Wx1 gene leading to the waxy phenotype have been reported in maize. The waxy phenotype in current Corteva commercial waxy maize products originate from a maize variety that carries a knockout mutation in the Wx1 gene. The CRISPR-Cas9 waxy maize is not expected to differ from conventional Wx1 maize or non-waxy maize lines in relation to mode(s) and/or rate of reproduction, dissemination and survivability.

The NLB18-R allele from PH26N and similar NLB18 resistance alleles from other conventional sources are present in a number of Corteva maize hybrids developed through traditional breeding and commercialized for over 20 years with a history of safe use. The CRISPR-Cas 9 NLB18 maize is not expected to differ from conventional maize in relation to mode(s) and/or rate of reproduction, dissemination and survivability.

The NLB18, Ht1 and RppK alleles are present in a number of Corteva maize hybrids developed through traditional breeding. The CRISPR-Cas 9 DL maize is not expected to differ from conventional maize in relation to mode(s) and/or rate of reproduction, dissemination and survivability.

Brief description of any measures taken for the management of risks

While no adverse effects to human or animal health, or the environment are anticipated, the following measures will yet be taken to help prevent material from spreading outside the field trial:

- The male flowers will be removed before the plants start producing pollen to avoid spreading via pollen.
- A 1.80m high fence will be placed around the trial to avoid passing through of humans or animals. To avoid bird predation, immediately after sowing a net will be placed over the regulated part of the field until plants have emerged from the soil.
- At the end of the release, all remaining plant matter will be destroyed by chopping and in addition the ears of the CRISPR Cas lines will be composted in a VLACO composting facility. No product from the trial will enter the food or feed chains.

Summary of foreseen field trial studies focused to gain new data on environmental and human health impact from the release

Not applicable