

Summary Notification Information Format

A. General information

A1. Details of notification

Notification Number

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Member State

Belgium

Date of Acknowledgement

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Title of the Project

Scientific field evaluation of maize with modified growth characteristics

Proposed period of release:

15/04/2020 to 31/10/2022

A2. Notifier

Name of the Institute

VIB

A3. Is the same GMPt release planned elsewhere in the Community?

No.

A4. Has the same GMPt been notified elsewhere by the same notifier?

No

B. Information on the genetically modified plant

B1. Identity of the recipient or parental plant

- | | |
|----------------------------|---------------------------------|
| a) family: | <i>Poaceae</i> |
| b) genus: | <i>Zea</i> , section <i>Zea</i> |
| c) species: | <i>Zea mays</i> |
| d) subspecies: | <i>mays</i> |
| e) cultivar/breeding line: | inbred line B104 |
| f) common name: | maize |

B2. Description of the traits and characteristics which have been introduced or modified, including marker genes and previous modifications

The genetically modified maize plants have modified growth characteristics resulting from the

additional expression of the AN3 gene under the control of the EF1a promoter. This gene is a transcriptional co-activator that is involved in the regulation of cell proliferation. As a result of the modification the duration of growth is elongated which results in the formation of larger plant organs such as larger leaves. It is also results in the formation of more biomass.

The plants also contain the *bar* gene which produces the Phosphinotrycine acetyl transferase (PAT) protein. The gene functions as a selection marker gene during the transformation process. Phosphinotrycine-based herbicides will not be used in the field.

Two of the three lines in the field additionally contain the *aadA*-gene under the control of a bacterial promoter, which provides resistance to the antibiotics streptomycin and spectinomycin when present in the correct bacterial genetic background. The presence of this *aadA*-gene is caused by the presence of vector-backbone sequences in these two lines.

B3. Type of genetic modification

Insertion of genetic material.

B4. In case of insertion of genetic material, give the source and intended function of each constituent fragment of the region to be inserted

The following elements have been inserted into the genome of the recipient maize plants:

All three GM lines contain:

Element	Function	Origin
Left T-DNA-border	T-DNA insert border	<i>Agrobacterium tumefaciens</i>
NOS-BAR (= <i>bar</i> -T _{NOS})	Phosphinotrycine acetyl transferase gevold door de nopaline synthase terminator	<i>Streptomyces hygroscopicus</i> and <i>Agrobacterium tumefaciens</i>
P _{35S}	Transcription promoter	Cauliflower mosaic virus
AttB2	Recombination site*	Lysogenic <i>E.coli</i>
P _{EF1α}	Promoter of the EF1α gene	<i>Brachypodium distachyon</i>
AttB1	Recombination site*	Lysogenic <i>E.coli</i>
AN3	Coding sequence of the ANGUSTIFOLIA3 gene	<i>Zea mays</i>
AttB4	Recombination site*	Lysogenic <i>E.coli</i>
T _{35S}	Transcription terminator of the Cauliflower mosaic virus 35S gene	Cauliflower mosaic virus
Right T-DNA-border	T-DNA insert border	<i>Agrobacterium tumefaciens</i>

Two of the three GM lines contain additionally:

Element	Function	Origin
pVS1sta	Vector stability	<i>Pseudomonas</i>
pVS1rep	Vector replication	<i>Pseudomonas</i>
pBR322bom	'basis of mobility'; involved in conjugation	<i>Escherichia coli</i>
pBR322ori	Origin of replication	<i>Bifidobacterium longum</i>
<i>aadA</i> **	Spectomycine/streptomycine resistance	<i>Escherichia coli</i>

B6. Brief description of the method used for the genetic modification

Immature maize embryos have been co-cultivated with genetically modified *Agrobacterium tumefaciens*. During this co-cultivation the genes of interest (see table above) are transferred to

cells of the immature embryo generating transformed cells. The transformed cells have then been selected using a positive screen (based on herbicide tolerance) and induced to regenerate whole plants.

B7. If the recipient or parental plant is a forest tree species, describe ways and extent of dissemination and specific factors affecting dissemination

Not applicable.

C. Experimental Release

C1. Purpose of the release

The purpose of the release is to confirm the maize's modified growth characteristics under normal field conditions and to measure the effect of the modification on the cob formation and cob filling which is very difficult to measure in greenhouse conditions.

C2. Geographical location of the site

The field trial will take place on grounds belonging to the ILVO research institute in the municipality of Wetteren.

C3. Size of the site (m²)

The trial plot, including non-modified controls, non-modified fertilizer lines and non-modified buffer rows is 1100 m².

C4. 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

The GM lines have not been field tested before.

D. Summary of the potential environmental impact from the release of the GMPTs

The environmental impact from the release is expected to be zero. The modified characteristics are not expected to lead to greater weediness or the ability of the maize to establish in non-agricultural habitats. The modified characteristics are also not expected to change the interaction of the maize with herbivores or other non-target organisms and also not to change the toxicity and allergenicity of the maize. But we have not tested the latter, as this is not necessary and not required for such a small scale field trial of which the produced materials are not going to be consumed by humans or animals. Any concerns about a possible unexpected change in the allergenicity of the maize pollen is also not relevant as the male flowers (the tassels) of the modified maize will be removed before they will be able to shed any pollen. By doing this it is also prevented that any pollen would spread to the environment. The modified seeds that will be formed are well retained in the cobs and these cobs will be very carefully hand harvested, also the tiniest ones, to prevent any spread of seeds.

Also the presence of the aadA gene in two of the three lines does not result in negative impacts. Resistance to the strep/spec antibiotics is widespread in nature and the aadA gene itself is already present in animals for human consumption and in humans. The chances of the aadA gene being picked up by bacteria is low, the field trial is very local, small scale and temporary, and taken together this will not lead to a negative impact. EFSA is of the opinion that the presence of the aadA gene is allowed in plants for field trials.

E. Brief description of any measures taken for the management of risks

The risk of spread of the modified properties to the environment is mitigated by removing the tassel, thus preventing the spread of modified pollen to non-modified maize plants in the surroundings. The formed modified seeds are, as already stated above, well retained in the cobs and these cobs will be very carefully hand harvested, thus preventing any spread of seeds to the environment. Experience with such field trials in the past 8 years has shown that the way the cobs are harvested effectively prevents any volunteers being formed. The field trial plot is surrounded by a 1.80 m high wire fence to prevent accidental trespassing and accidental removal or spread of GM material.

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

There are no specific studies foreseen to gain new data on the environmental and human health impact from the release other than the study of the phenotype and growth characteristics of the maize.

G. Final report

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H. European Commission administrative information

To be filled in by the Commission

I. Consent given by the Competent Authority:

To be filled in by the Commission.