Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on notification B/BE/26/V1 from VIB for deliberate release in the environment of genetically modified plants for research and development

2 April 2026
Ref. SC/1510/BAC/2026_0374

The notification B/BE/26/V1 has been submitted by the VIB to the Belgian Competent Authority (CA) in January 2026 for a request of deliberate release in the environment of genetically modified higher plants for research and development according to Chapter II of the Royal Decree of 21 February 2005.

The title of the notification is: *Scientific field evaluation of field-specific genes in maize.* The purpose of the release is to decipher the role of the target genes. Plants in which the genes are inactivated and plants in which the genes are constitutively expressed will be tested simultaneously in the field and in a greenhouse. The comparison of the plants in these two different environments is meant to help determine the role and function of these genes.

The CA officially acknowledged the notification on 22 January 2026 and forwarded it to the Biosafety Advisory Council for advice.
Within the framework of the evaluation procedure, the Biosafety Advisory Council, under the supervision of a coordinator and with the assistance of its Secretariat, contacted experts to evaluate the dossier. Three experts from the common list of experts drawn up by the Biosafety Advisory Council and the Biosafety and Biotechnology Unit (SBB), answered positively to this request.
The experts assessed whether the information provided in the notification was sufficient and accurate to state that the deliberate release of the GM maize lines would not pose any problems for the environment, animal or human health in the context of the intended use. See Annex I for an overview of all comments received.

On 10 and 24 March 2026, based on questions prepared by the Biosafety Advisory Council, the CA requested the notifier to provide additional information. Answers to the questions were received by the Secretariat on 17 and 25 March 2026.

For the scientific evaluation, the following legislation was considered: the Royal Decree of 21 February 2005 (Belgian Official Journal of 24.02.2005, p. 7129) modified by the Royal Decree of 19 February 2020 (Belgian Official Journal of 02.03.2020, p. 12666).

In parallel to the scientific evaluation, the CA made the dossier available on its website for a one-month public consultation as required in the abovementioned Royal Decree. No questions of the public tackling biosafety issues of the GM maize were received.

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Summary of the scientific evaluation

1. Information related to the recipient or parental plants

Zea mays is an allogamous plant that propagates through seed produced predominantly by cross-pollination. Maize pollen can be collected by honeybees and other insects. However, these pollinating insects play a minor role in the cross-pollination of maize plants which relies mainly on wind for the dispersal of its pollen (OECD, 2003[1]). Data on pollen dispersal in maize demonstrated that the levels of cross-fertilisation drop rapidly over the initial meters around the pollen source and that most of the released pollen is deposited within about 30 m of the source (Devos *et al*., 2005[2]). At distances farther than 30 - 50 m from the source, pollen dispersal is very low but not zero. However, vertical wind movements can lift pollen and distribute it over distances up to kilometers under suitable climatic conditions. In Belgium (and in Europe) there are no sexually cross-compatible indigenous wild relatives with which maize can hybridise and form progeny (OECD, 2003; EFSA, 2016[3]). Teosinte, regarded as an invasive weed in Europe since its first occurrence in France (1990) and Spain (2009), has so far not been reported in Belgium. The only recipient plants that can be cross-fertilised by maize in Belgium are therefore other cultivated maize varieties.

Seed dispersal of individual kernels of domesticated plants is mainly the result of field operations of harvesting the crop and transporting the grain from the harvested fields to storage facilities. Spilled maize seeds can overwinter, germinate and appear in the field as volunteers. However, maize is incapable of sustained reproduction outside the domestic cultivation area as it has lost its ability to survive in the wild due to its long process of domestication (OECD, 2003). Volunteers can only occur after a warm winter period (with no temperatures lower than 0°C for more than 6 to 8 hours) and are characterised by a low probability of cross-pollination (Grüber *et al*., 2008[4]; Palaudelmàs *et al*., 2009[5]). In the prevailing Belgian climate, volunteers are unlikely to occur.

2. Information on the design and management conditions in the field trial

The field trial will be conducted during one growing seasons (from May 2026 until July 2026). The surface of the area for cultivation will not exceed 90 m^2.

All maize plants will be harvested at the V7 stadium when the seventh leaf appears and thus well before the reproductive stadium commences. Plants will thus neither produce pollen, nor seeds. Some plants (stems and leaves) will be transported to the lab for further analysis. Material will be inactivated if no longer needed for research. Stems and leaves, except for the ones harvested for further analysis in the lab, will be shredded and composted on the field. Roots and the lowest part of the stem will be left on the field for composting.

After the trial, the field will be left fallow and ploughed at the latest during next spring.

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[1] OECD, 2003. Consensus Document on the biology of *Zea mays* subsp. *Mays* (maize). Series on Harmonisation of Regulatory Oversight in Biotechnology (ENV/JM/MONO(2003)11), No. 27:1-49. http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/NT0000426E/$FILE/JT00147699.PDF

[2] Devos *et al*., 2005. The co-existence between transgenic and non-transgenic maize in the European Union: a focus on pollen flow and cross-fertilization. Environmental Biosafety Research 4, 71-87.

[3] EFSA (European Food Safety Authority), 2016. Relevance of new scientific evidence on the occurrence of teosinte in maize fields in Spain and France for previous environmental risk assessment conclusions and risk management recommendations on the cultivation of maize events MON810, Bt11, 1507 and GA21. EFSA supporting publication 2016:EN-1094. 13 pp.

[4] Grüber *et al*., 2008. Post-harvest gene escape and approaches for minimizing it. CAB International 2008 (http://www.cababstractsplus.org/cabreviews)

[5] Palaudelmàs *et al*., 2009. Effect of volunteers on maize gene flow. Transgenic Res. 18, 583-594

3. Information related to the genetic modification

The plants under investigation have been modified in genes that are expressed in the field, but not in the greenhouse.

For some plants, multiplex CRISPR-Cas – using multiple guide RNAs at once – was used to induce frameshift mutations in three target genes. The CRISPR-Cas9 components were introduced into maize embryos via *Agrobacterium tumefaciens*-mediated transformation. A selectable marker (*hygR*), conferring resistance to the antibiotic hygromycin, enabled the identification of the transformed plants. Following selection, transformed plants were backcrossed with the wild-type parent. Progeny lacking the Cas9 T-DNA construct (including *hygR*) were selected through hygromycin testing, and subsequently selfed to produce gene-edited seeds that will be planted in the field.
At the request of the Council, it was demonstrated that the gene-edited plants lack the gentamycin resistance marker gene located on the vector backbone used for transformation. With these additional data, the information related to the genetic modification was considered sufficient.

Other plants were transformed via *Agrobacterium tumefaciens* to overexpress additional copies of the target gene(s). A T-DNA construct, containing the target gene(s) under the control of a constitutive promoter, was introduced into these maize plants. This construct also included a *hygR* gene for selection of transgenic plants, while the vector backbone carried a gentamycin resistance marker. The absence of the latter antibiotic resistance marker gene was demonstrated in the selected plants. Transformed plants overexpressing one or three target genes were subsequently backcrossed with the wild-type parent to produce seeds for field introduction. As a result, 50% of the planted seeds will contain the T-DNA (including *hygR*).

In the field trial, two gene-edited maize lines with three inactivated target genes, two maize lines overexpressing one copy of the target gene and two maize lines overexpressing three copies of the target gene(s) will be introduced.

4. Potential risks for the environment, animal or human health associated with the release of the GM maize

No increased persistence in the field or invasiveness into natural habitats of the modified maize lines compared to non-GM maize is expected, as the harvest of the maize plants at the V7 stadium rules out the development and survival of the modified maize in the year(s) after the field trial.

The maize lines overexpressing the target gene(s) carry the hygromycine resistance marker gene. The likelihood of horizontal gene transfer of this gene to micro-organisms is considered as a rare event under natural conditions (Keese, 2008[6]). Even if such gene transfer were to occur, no negative effects on the environment and human health are expected. Hygromycin resistance genes are widely spread among soil and intestinal bacteria (EFSA, 2004).

Further, it is not expected that the modified maize would have significant effects on organisms (invertebrates, vertebrates and soil micro-organisms) and humans, as no trait that could affect the behaviour or development of organisms via contact or feeding has been integrated. Given the restricted scale of the field trial, any potential effect to organisms and biogeochemical processes - if these would occur - will be of a local and temporal nature.

[6] Keese, P. 2008. Risks from GMOs due to horizontal gene transfer. Environ. Biosafety Res. 7: 123-149.

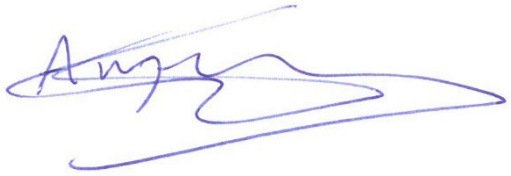
5. Information related to the control, monitoring, post-release and waste treatment

The management measures proposed are considered as sufficient to prevent potential adverse effects to the environment, animal and human health during and after the field trial. After sowing, temporary bird netting will be installed over the trial area to prevent birds from consuming seeds or seedlings. Harvesting of plants before they reach the reproductive phase will prevent seed and pollen dispersal, and all collected plant material will be destroyed after analysis.

Years of experience have shown that no volunteer plants appear in the year following maize field trials. The field will be left fallow and ploughed at the latest during next spring.

Conclusion

Provided that the trial is conducted as described in the dossier, the Biosafety Advisory Council concludes that it is very unlikely that this proposed small scale field trial with modified maize lines will harm human health, animals or the environment.



Prof. Dr. ir. Geert Angenon
President of the Biosafety Advisory Council

Annex I: Compilation of comments of experts in charge of assessing the dossier B/BE/26/V1 (ref: BAC_2026_0260)

Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Compilation of comments of the experts in charge of evaluating notification B/BE/26/V1

Ref. SC/1510/BAC/26_0260

Coordinator: Wouter Vanhove
Experts: Marc De Loose (ILVO); Michel Ghanem (CIRAD); Nina Papazova (Sciensano); Jan Van Doorsselaere (VIVES)
SBB: Adinda De Schrijver

INTRODUCTION

Dossier **B/BE/26/V1** concerns a notification of the VIB, for deliberate release in the environment of genetically modified higher plants (GMHP) according to Chapter II of the Royal Decree of 21 February 2005.

The notification has been officially acknowledged on 22 January 2026 and concerns a scientific field evaluation of field-specific genes in maize.

The comments of the experts will become part (in an anonymous way) of the advice of the Biosafety Advisory Council.

Experts were invited to evaluate the GMHP considered in the notification for their potential impacts on the environment, and information relating to pre- and post-release treatment of the site.

The comments of the experts are roughly structured as in
- Annex II (principles for the risk assessment) of the consolidated version of the Royal Decree of 21 February 2005
- Annex III (information required in notifications) of the Royal Decree of 21 February 2005

EVALUATION FORM

The comments below served as basis for a list of questions that the competent authority forwarded to the notifier with a request to provide additional information. The comments highlighted in grey correspond to the questions/comments selected and sent to the notifier. For the questions/comments that were not selected, a brief explanation is given as to why not.

A. GENERAL INFORMATION

4. INFORMATION RELATING TO THE RELEASE

Have evaluated this section and had no comments/questions: 2 experts

Comment:
Page 1 – The technical dossier mentions a one year trial in 2026, but page 2 mentions that the trial will be repeated for 3 more years. Please clarify.

5. INFORMATION RELATING TO THE SITE OF RELEASE

Have evaluated this section and had no comments/questions: 3 experts

B. SCIENTIFIC INFORMATION

1. INFORMATION RELATING TO THE RECIPIENT PLANT OR, WHERE APPROPRIATE, TO THE PARENTAL PLANTS

Have evaluated this section and had no comments/questions: 3 experts

2. MOLECULAR CHARACTERISATION

(a) Information relating to the genetic modification

Have evaluated this section and had no comments/questions: 1 expert

Comment:
The molecular characterisation of the CRISPR-Cas9 edited lines (Gen123-gRNA1 and Gen123-gRNA2) is adequately documented. Small insertions/deletions (indels) were confirmed in all three target genes via Sanger sequencing and ICE analysis, resulting in out-of-frame mutations. Importantly, the absence of the Cas9 construct in the final plant material was confirmed by a negative hygromycine resistance test on the mother plants, which is appropriate.
For the overexpression lines (Gen1-OE and 3xOE), single-copy T-DNA insertion was confirmed by digital PCR, and the absence of backbone sequences (including the gentamycin resistance gene) was also verified, which is commendable. However, the exact genomic insertion site of the T-DNA has not been determined in this dossier. Although not strictly required at this stage of field evaluation, information on the flanking sequences would strengthen the molecular characterisation of the T-DNA events and allow verification that no endogenous gene disruption has occurred at the insertion locus. According to the Belgian Guidelines for molecular characterisation of Part B notifications, it is recommended to have this information. The applicant is requested to confirm whether flanking sequence data are available or planned.

(b) Information relating to the genetically modified higher plant (GMHP)

Have evaluated this section and had no comments/questions: 1 expert

Comment 1:
Blz 8 van het technisch dossier staat informatie over hoe de planten zijn bekomen die in het veld worden uitgeplant. "*Uit de zo gemaakte planten zijn planten geselecteerd die gewenste mutaties bevatten. Deze planten werden teruggekruist met een wild-type plant waardoor alle mutaties heterozygoot aanwezig zijn in de volgende generatie. Uit deze generatie werden planten geselecteerd die geen actief CAS9 enzym meer bevatten. Deze planten ondergingen zelfbestuiving en zaden hiervan zullen gebruikt worden voor de veldproef."* Hoe is men er zeker van dat de primaire transformanten homozygoot zullen zijn voor de mutatie. Want men stelt dat de zaden die bekomen zijn na terugkruising 100% heterozygoot zullen zijn voor de mutatie.
Een identieke vraag voor de overexpressielijnen. "*Voor de overexpressielijnen werden de genen die onderwerp zijn van het onderzoek na een promotor element geplaatst waardoor deze genen voortdurend zullen worden overgeschreven. Deze werden met behulp van Agrobacterium tumefaciens in de plantencel geïntroduceerd. Na introductie in de cel zullen deze stukken DNA worden geïntegreerd in het DNA van de plantencel op willekeurige plaats. Deze planten werden teruggekruist met een wild-type plant waardoor alle extra genen hemizygoot aanwezig zijn in de volgende generatie."* Zijn de primaire transformanten homozygoot voor de insertie? Want anders kunnen de zaden na terugkruising met het WT niet 100% hemizygoot zijn.

Note coordinator/SBB: Informatie over de zygoticiteit van de planten is naar ons oordeel niet belangrijk om tot een conclusie te komen over de potentiële risico's van deze veldproef.

Blz 13 *Met dezelfde digital PCR is bepaald dat er geen backbone sequenties van de gebruikte constructen in de lijnen aanwezig is, wat dus ook betekent dat de planten geen gentamycine resistentiegen bevatten.* Welk primer paar werd gebruikt om te zoek naar eventuele backbone sequentie? Werd de ganse backbone bekeken? Hoe groot zijn de fragmenten waar naar gezocht werd?

Comment 2:
The Gen1-OE and 3xOE overexpression lines contain a hygromycin resistance gene (Hyg) as a selection marker, derived from Escherichia coli. While this gene is commonly used in plant transformation, its intended presence in field-released plants should be explicitly noted. The notifier confirms (Annex 1 of the environmental risk assessment) that the risk of horizontal gene transfer is negligible and that hygromycin has no clinical application in humans, which is in line with EFSA guidance (EFSA, 2004).
It should also be noted that the overexpression lines will be planted as segregating populations (50% transgenic, 50% wild-type), meaning that individual plant genotyping will be performed post-harvest. The notifier should clarify the method and timeline for this genotyping to ensure proper tracking and documentation of which plants in the trial were indeed genetically modified.

Note coordinator/SBB: Information on the plant genotyping method is not considered as a requirement for risk assessment.

(c) Conclusions of the molecular characterisation

Comment 1:
Page 5 Bijlage 2: the conclusion that Cas9 is absent based on an HygR test is not 100% conclusive. Has it been tested by PCR or other?

Note coordinator/SBB: We agree that on the basis of the HygR test one cannot conclude for 100% that the Cas9 is absent. However, we do not consider the (potential) presence of the

Cas9 gene a hazard that needs further consideration in the risk assessment as the risk of vertical gene transfer will be sufficiently mitigated.

Comment 2:
In conclusie. De vragen hierboven zijn relevant om te begrijpen welke planten uiteindelijk in het veld zullen uitgeplant worden. Het heeft potentieel een impact op de waarnemingen, maar omvat geen risico's voor mens, dier en omgeving.

Comment 3:
The molecular characterisation provides adequate evidence that the intended modifications were successfully introduced. For the CRISPR lines, the out-of-frame nature of the mutations in all three target genes has been confirmed, and the absence of residual T-DNA (including Cas9) has been demonstrated. For the overexpression lines, single-copy events without backbone contamination have been selected.
In my point of view there is still a remaining gap is the lack of flanking sequence data for the T-DNA insertion sites in the overexpression lines. Additionally, the possibility of off-target CRISPR edits, although inherently low with CRISPR-Cas9 and standard guide RNA design, has not been explicitly addressed. Given the small scale of the field trial and the vegetative harvest before flowering, the practical risk is minimal, but the notifier is invited to comment on whether off-target analysis was performed or is planned.

Note coordinator/SBB: Sequencing data, including flanking sequence data for the T-DNA insertion, are not required according to the Biosafety Advisory Council for Part B field trials (see: https://www.biosafety.be/sites/default/files/standard_partb_plants.pdf).
As acknowledged by the expert, information on off-target analysis is not deemed necessary for the risk assessment of a field trial with GM plants.

3. INFORMATION ON SPECIFIC AREAS OF RISK

(a) Any change to persistence or invasiveness of the GMHP, and its ability to transfer genetic material to sexually compatible relatives, and the adverse environmental effects thereof

Have evaluated this section and had no comments/questions: 3 experts

(b) Any change to the ability of the GMHP to transfer genetic material to microorganisms and the adverse environmental effects thereof

Have evaluated this section and had no comments/questions: 3 experts

(c) Mechanism of interaction between the GMHP and target organisms and the adverse environmental effects thereof

Have evaluated this section and had no comments/questions: 3 experts

(d) Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof

Have evaluated this section and had no comments/questions: 3 experts

(e) Potential changes in agricultural practices and management of the GMHP resulting from the genetic modification and the adverse environmental effects thereof

Have evaluated this section and had no comments/questions: 3 experts

(f) Potential interactions with the abiotic environment and the adverse environmental effects thereof

Have evaluated this section and had no comments/questions: 3 experts

(g) Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification

Have evaluated this section and had no comments/questions: 2 experts

Comment:
The documentation correctly notes that maize plants in which the target genes are switched off (as in greenhouse conditions) are considered as safe as field-grown plants in which these genes are active. This reasoning provides a sound basis for concluding that no adverse human or animal health effects are to be expected.
The applicant explicitly states that the plant material from this trial will not be consumed by humans or animals, which further limits any exposure risk. No novel proteins of concern are introduced: the CRISPR lines contain no foreign DNA, and the target proteins expressed in the overexpression lines are endogenous maize proteins. There is no indication that the target gene products would have any toxic or allergenic properties. The overall risk to human and animal health from this trial is considered negligible in my viewpoint.

(h) Conclusions on the specific areas of risk

Have evaluated this section and had no comments/questions: 2 experts

Comment:
The risk assessment provided by the applicant is, in my assessment, appropriate and proportionate to the very limited scale and duration of this field trial. The key risk mitigation measure - harvesting all plant material before the V7 growth stage, well before any reproductive development - effectively eliminates the risk of pollen or seed dispersal. The surrounding buffer rows of wild-type maize, combined with the fenced site and restricted access, provide additional containment.
The main residual uncertainties concern the unknown biological function of the target genes. However, given that these genes are already naturally expressed in field conditions (i.e., their protein products are already present in commercial maize fields), the modification of their expression level in a small, contained, vegetative-stage trial does not present identifiable environmental risks. The overall risk profile of this trial is low.

4. INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE TREATMENT PLANS

(a) Any measures taken

Have evaluated this section and had no comments/questions: 2 experts

Comment:
The applicant describes appropriate containment measures: the trial plot is physically enclosed by a 1.8 m wire fence with a padlocked gate. A 3 m buffer zone of wild-type maize surrounds the trial plot on all sides. Plants will be harvested at the V7 stage, before any possibility of pollen or seed production.
The trial is adjacent to another ongoing VIB field trial (B/BE/25/V1) and will share a border zone. The notifier should clarify how the border between the two trials will be managed to avoid any mixing or contamination of plant material during harvest operations.

Note coordinator/SBB: Once the field trials are completed and samples have been collected, the border plants will be destroyed and remain on the field along with the remains of the GM plants (zie § 4.e.).

(b) Description of methods for post-release treatment of the site

Have evaluated this section and had no comments/questions: 3 experts

(c) Description of post-release treatment methods for GM plant material, including wastes

Have evaluated this section and had no comments/questions: 2 experts

Comment:
The harvest and waste management procedures are clearly described. Plant material destined for further research will be transported in closed, labelled bags to VIB (Zwijnaarde) or ILVO (Merelbeke), while remaining stems and leaves will be shredded on-site. Roots and residual stem bases will be left in the ground to compost.
Since the plants are harvested in the vegetative phase, the shredded material is not reproductively viable. No special inactivation of the shredded material is required. According to the documentation provided, the applicant confirms that plant material not used for research will be inactivated, which is appropriate. It would be useful to clarify the specific inactivation procedure used (e.g., autoclaving, composting under controlled conditions).

(d) Description of monitoring plans and techniques

Have evaluated this section and had no comments/questions: 2 experts

Comment:
The monitoring plan consists of regular visual inspections at least twice per month during the growing period. Since plants are removed before reproductive development, no post-harvest monitoring for volunteer plants is foreseen in the year after the trial, which is justified by the impossibility of seed production.
However, the monitoring plan is limited to visual observation. No protocol is described for what specific phenotypic or agronomic parameters will be recorded during inspections, beyond general control of the trial. A more structured observation protocol (e.g., recording plant health, growth anomalies, or unexpected phenotypic effects of the genetic modifications) would strengthen the scientific value of the monitoring and contribute to the post-release data required under Directive 2001/18/EC.

Note coordinator/SBB: According to Directive 2001/18/EC monitoring of specific parameters is only needed when there are indications of risk. In the absence of such indications, only general observations are recommended. As no potential adverse effects were identified in this case, there is no need to go beyond the general monitoring of the field trial. In line with what has been required for previous Part B notifications, we therefore consider visual observations sufficient.

(e) Description of any emergency plans

Have evaluated this section and had no comments/questions: 1 expert

Comment:
The emergency plan is adequately described. The surrounding buffer rows serve as a physical barrier in case of plant falling, and early harvest would be performed if unexpected circumstances arise. The physical fencing with a locked gate prevents unauthorised access.
The notifier should also describe the emergency protocol in the event of accidental damage to or removal of the buffer zone (e.g., by severe weather or vandalism), and specify the chain of

communication with the Federal Public Service Health in such a scenario, as required by the experimental protocol.

(f) Description of methods and procedures to protect the site

Have evaluated this section and had no comments/questions: 2 experts

5. DESCRIPTION OF DETECTION AND IDENTIFICATION TECHNIQUES FOR THE GMHP

Have evaluated this section and had no comments/questions: 2 experts

Comment 1:
De volgende informatie ontbreekt in het detectieprotocol van mutaties (Bijlage 9.1):

- indien een commercieel genomisch DNA-isolatiekit gebruikt wordt, de naam van het kit;
- een figuur die de positie van de primer-hechtingsplaatsen illustreert;
- aanduiding van welke primer de forward primer is en welke de reverse primer is; en
- de interpretatie van de resultaten, inclusief informatie over de referentiesequentie om de verkregen DNA-sequentie mee te aligneren.

De volgende informatie ontbreekt in het detectieprotocol van de overexpressielijnen (Bijlage 9.2):

- het type PCR (traditionele, digitale of real-time PCR); en
- de parameters die gemeten worden

Richtsnoeren voor welke informatie aangeleverd dient te worden voor Deel B dossiers, zijn te vinden op: https://www.biosafety.be/sites/default/files/partb_protocole_gmo_detection.pdf

Comment 2:
The detection methods described (PCR with target-specific primers followed by Sanger sequencing for CRISPR lines; hygromycin resistance assay and T-DNA-specific PCR for overexpression lines) are appropriate and standard. The notifier correctly notes that the presence of similar indels cannot be definitively attributed to this specific trial, since identical mutations could theoretically arise spontaneously or through conventional breeding.
For the overexpression lines, the presence of the hygromycin resistance gene provides a more specific and robust detection marker. According to the procedure, the applicant should confirm the sensitivity and specificity of these detection assays, and specify the minimum detection limit, particularly in the context of potential low-level cross-contamination scenarios.

Note SBB: For the expression lines a detection protocol based on PCR is provided. The requirements on sensitivity and specificity are considered relevant for GMOs to be placed on the market. For plants to be used in R&D, less strict requirements were set up: see https://www.biosafety.be/sites/default/files/partb_protocole_gmo_detection.pdf.

6. INFORMATION ABOUT PREVIOUS RELEASES OF THE GMHP, IF APPLICABLE

Have evaluated this section and had no comments/questions: 2 experts

ANNEX 1. INFORMATION RELATED TO THE RISKS FOR THE ENVIRONMENT

1. Persistence and invasiveness of the GM plant, including of plant to plant gene transfer

Have evaluated this section and had no comments/questions: 3 experts

2. Plant to micro-organisms gene transfer

Have evaluated this section and had no comments/questions: 3 experts

3. Interactions of the GMHP with target organisms

Have evaluated this section and had no comments/questions: 3 experts

4. Interactions of the GMHP with non-target organisms

Have evaluated this section and had no comments/questions: 3 experts

5. Impacts of the specific cultivation, management and harvest techniques

Have evaluated this section and had no comments/questions: 3 experts

6. Effects on biogeochemical processes

Have evaluated this section and had no comments/questions: 3 experts

7. Effects on human and animal health

Have evaluated this section and had no comments/questions: 3 experts