INARI™

Deliberate Release Notification

Part 3 – Environmental Risk Assessment

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"R&D Field trial to evaluate the phenotype and yield of maize lines gene edited for optimised plant architecture."

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OBJECTIVE OF THE ENVIRONMENTAL RISK ASSESSMENT

In the context of performing a field trial in Belgium with gene edited maize lines, this Environmental Risk Assessment (ERA) has been conducted in accordance with Annex IIA of European Directive 2001/18/EC and Commission Decision 2002/623/EC to identify and evaluate potential adverse effects of the gene edited maize lines, either direct or indirect, immediate or delayed, on human health and the environment which the conduct of a field trial with this material may exert. It is conducted with a view of identifying if there is a need for risk management and if so, to ensure that the most appropriate methods are used to mitigate this risk.

This ERA is performed according to the methodology laid out in Annex IIC of Directive 2001/18/EC, supplemented by the guidance notes in Commission Decision 2002/623/EC.

Note
In 2023 INARI Agriculture NV successfully performed a deliberate release in Belgium (ref B/Be/23/V1), as part of its R&D effort to obtain maize lines with an improved plant architecture. The line tested in that field trial was specifically targeting reduction of plant height. The same line (subsequent generation) will be included in the planned trial.

Many aspects of the planned field trial are similar to the summer '23 trial (e.g. location, surface, objectives, techniques, staff). In consequence, the ERA largely builds on the '23 experience. The main differences are:

- *The inclusion of a second edited maize line expected to have an increased biomass (leaf area) and the combination of both lines by conventional crossing;*
- *The intention to collect yield data which requires normal development of the plants and their reproductive parts.*

LIST OF ABBREVIATIONS

EU	European Union
GMHP	Genetically Modified Higher Plant
ILVO	Instituut voor Landbouw-, Visserij- en Voedingsonderzoek
RBD	Randomized block design
RNA	Ribonucleic acid
VIB	Vlaams Instituut voor Biotechnologie

I. CHARACTERISTICS OF THE MODIFIED MATERIAL AND THE RELEASE

Detailed information on the characteristics of the material and the intended release are provided in the technical file of this application. In this section, the main elements relevant for the ERA are summarized.

A. The recipient organism

Maize (*Zea mays*) is a well-known domesticated plant species, with a long history of safe use and which is annually cultivated on global scale. It is a major commodity crop with many applications in food and feed. Furthermore, it has been a primary target for innovative solutions based on genetic engineering and therefore subject of many risk assessments, including by the Belgian and European authorities.

Maize is routinely grown on commercial scale in the region where the trial will be conducted. Furthermore, ILVO, the institute that will take care of the operational aspects of the trial, is equipped for and has a long standing experience in conducting breeding and agronomic trials of maize, conventional as well as genetically modified/ gene edited lines.

Maize is a highly domesticated plant, in many aspects fully relying on the intervention of humans for survival and dispersal:

- Vegetative parts, once severed from the plant, lack the capacity for regrowth or secondary shooting. As an annual plant, individual plants wither at the end of the growing season and die. No survival structures are formed.
- Seeds remain attached to the cobs, preventing seed dispersal before harvest.
- Seeds are not naturally dispersed over long distance. They show no dormancy and are sensitive to low temperatures.
- Maize is not known to cause volunteer issues in farmer's fields or outside (field edges, transportation routes, ..). Maize is not a competitive plant in unmanaged environments.
- There are no compatible wild-relatives in Belgium.
- Although pollen can be carried by wind over long distance, successful pollination remains limited to the immediate vicinity of the plants.

B. The genetic modification(s)

Inari has used a combination of advanced techniques to develop the experimental lines that will be tested in the proposed field trials. For the reduced height line, the starting material was a Cas editor line produced by the research institute VIB. It was subjected to biolistic delivery to introduce a native maize genetic element in particular sites of a native maize transcription factor gene.
For the line with the increased leaf biomass, the starting material was a conventional line and all elements, including the Cas protein, were introduced via biolistic delivery.

While different components were necessary (including a marker carrying plasmid), during subsequent selection steps only those lines were retained that showed the intended insertions of the native maize genetic element and lacked any other inserted sequence.

The insertions of the native maize genetic element have been targeted by gene editing based on specifically designed guide RNAs. Off-target effects has been raised as a possible concern for using gene editing. Assessing potential off-targets with the Geneious Prime tools showed that no matches could be identified. Further confirmation will be planned for lines that are carried forward in product development.

The native genetic element is identified in the maize genome that can alter expression of native genes, this sequence also occurs in the genomes of other crops like soy, rice, and barley. The insertion is not transcribed or expressed as such, and therefore no new proteins are produced.

Insertions of the native genetic element in a native maize transcriptional factor gene and transcriptional coactivator gene are expected to result in altered expressions, which in turn results in suppression of internode elongation or/and increased leaf size and hence increased leaf biomass. Overall, it can be concluded that no new proteins/enzymes are produced, but instead that the levels of existing regulating factors are influenced.

C. The modified organism

As pointed out, the only remaining modification is the gene editing resulting in the precise insertions of a native maize genetic element.

The size of plants is largely determined by growth of the stem. Stem elongation is affected by the expression of the transcription factor gene. Gene editing the native maize genetic element in the specific site results in altered expression of the native transcription factor gene, internode elongation and, hence, plant height is expected to be reduced. Observations in the greenhouse and the results of the summer '23 field trial confirm the phenotype. There were some additional minor differences observed between the control null segregants and edited line: stem cross-sectional areas were significantly reduced in the edited line. Flowering time of both female and male flowers of the edited line seemed delayed with a few days. This shift in flowering time could not be fully assessed due to detasseling and as such the impact on yield could not be determined in the Belgian field trial '23.

The second edit targets the expression of a transcriptional coactivator which is involved in the growth regulatory mechanism of maize leaves. The edit leads to an increased leaf size and hence increased leaf biomass. Initial greenhouse observations confirm a small, yet significant difference in heterozygous lines.

The finally selected modified organism carries no other additional characteristics.

D. The intended release

This confined field trial is a limited scale comparison of two edited lines (each carrying respectively the native maize genetic element in a different targeted insertion site) and their combination.

The trial includes controls (segregating null-lines) and wild type inbreds and hybrids.
The use of null segregants without edit as comparators for studying the phenotype of the edited plants is deemed the best control from a scientific point of view. It is acknowledged that for the comparative analysis between GM and non-GM plants in EU Part C dossiers intended to support an EU market authorization other controls will be required, considering null segregant only as additional information. However, at this early stage of research, the scientific value is prioritized over considering a regulatory finality of the data.
A different maize variety is used for border rows.

Inbred trial

1	Control null segregant (inbred)
2	Homozygous Edit Reduced Height & Homozygous Edit Increased Leaf (inbred)
3	Homozygous Edit Increased Leaf (inbred)
4	Wild type (inbred)

Hybrid trial

1	Control null segregant (Hybrid male 1)
2	Control null segregant (Hybrid male 2)
3	Heterozygous Edit Reduced Height & Heterozygous Edit Increased Leaf (Hybrid)
4	Heterozygous Edit Reduced Height (Hybrid with male 1)
5	Heterozygous Edit Reduced Height (Hybrid with male 2)
6	Heterozygous Edit Increased Leaf (Hybrid)
7	Wild type (Hybrid male 1)

8	Wild type (Hybrid male 2)

The design is a typical randomized block design, with 4 repetitions. In addition to overall development of the plants, the observations will specifically address the intended phenotype (reduced plant and ear height, increased leaf size and biomass) and yield.

The overall surface, including border rows, will be less than 2000 M^2.

E. The potential receiving environment

The field trial site is in a rural area where agricultural crops, meadows and field margins with herbs and bushes are found. The trial itself is surrounded by grass/clover land.

F. Interactions

No particular interactions between the experimental lines and the environment are expected.

G. Information from releases of similar organisms and organisms with similar traits and their interaction with similar environments

There is extensive experience with release of genetically modified as well as gene edited maize, including with the team that will be managing the operational aspects of the field trial.

The gene edited line with reduced height has been tested on the same location in summer ’23. The results have been reported above.

There were no previous releases of the gene edited lines with increase leaf size, neither with the combination of both lines. The intended trial is the first field trial with plants containing this edited transcriptional coactivator gene as well as the combination of both gene edited lines influencing the plant architecture.

II. ENVIRONMENTAL RISK ASSESSMENT

In this section, the characteristics of the GMO linked to the genetic modification that may result in adverse effects on human health or the environment are reviewed. They are based on a generic series of potential adverse effects of GMOs and some that are not applicable for the specific release were discarded at the first step of the risk assessment, i.e. the “identification of characteristics which may cause adverse effects”. For others, the potential impact as well as the likelihood is further analysed, leading to an estimation of the risk for human health or the environment.

A. Persistence and invasiveness of the GMHP, including plant-to-plant gene transfer.

1. Problem formulation including hazard identification

This section addresses the potential for maize with an edited transcription factor gene and an edited transcriptional coactivator gene to become more persistent or invasive compared to wildtype maize either by itself or through outcrossing to sexual compatible species. Maize by itself is not invasive or persistent.

Genetic traits can be vertically transferred in species sexually compatible with the GMHP. As pointed out before, there are no sexually compatible species for maize in Belgium. Any transfer is therefore limited to other maize plants.

The edited maize plants do not differ from conventional maize except for the altered expression of the transcription factor genes. Neither the native genetic element, nor the transcription factor gene and transcriptional coactivator gene produce any new function as such. Therefore, the effect of the reduced stature of the plant and the increased leaf size should be assessed.

2. Hazard characterisation

Maize by itself is not invasive or persistent. It is not expected that the reduced stature and/or the increased leaf size of the edited plant will have an influence on the persistence or invasiveness. On the contrary, in a mixed plant stand with wildtype maize plants the smaller gene edited plants will be experiencing shadow effects reducing their growth capacities. However, maize is only present as human controlled cultivation and such mixed populations do not occur. The realisation of a competitive advantage or disadvantage is therefore not expected.

Outcrossing of the trait will provide a disadvantage to the progeny of the recipient maize plant. The effect in the natural environment will be neutral, if not negative for the same reason. In any case, maize is not a potent competitor in unmanaged areas and this is not expected to change in relation to the reduced height.

3. Exposure characterisation

A normal and complete development cycle is essential for assessing the phenotype throughout the season as well as the yield, which is an essential parameter for an agricultural crop. Interventions such as detasseling, bagging, can be useful when only early stage observations are required and/or when controlled crosses are performed for breeding. Yet, they influence the overall development and yield. It is therefore the intention not to interfere with the normal development of the tassel and ear. In consequence, the spread of pollen is the most important aspect to consider in terms of potential exposure.

Isolation from other maize

Although pollen can be carried over long distance by wind, the potential for a successful cross-pollination with a compatible plant drops quickly over distance. Compared to pollen of other wind-pollinated species, maize pollen grains are relatively large (average of 90 µm) and heavy (0,25 µg) and therefore have a high settling speed and a quick deposition.

The OECD Schemes for the Varietal Certification or the Control of Seed Moving in International Trade[1] include rules and regulations for the varietal certification of seed in order to encourage the use of seed of consistently high quality in participating countries. This includes varietal identity and purity. The OECD Maize Scheme specifies that crops to produce Basic Seed or Certified Seed must be not less than 200 m from any source of contaminating pollen.

Based on extensive experience with GM trials, The Biotechnology Regulatory Services of the US Department of Agriculture has issued minimum separation distances[2] to be used for confined field tests of certain genetically engineered plants. For regulated maize plants that are allowed to open pollinate this minimum separation distance is set at 660 ft (201 m). These two references are seen as the “gold standard” for isolating field trials with GM maize from other maize productions.

A second type of indication comes from the rules on coexistence of different production types, namely conventional, organic and GM crops, within existing agriculture. In 2003, Commission Recommendation 2003/556/EC[3] invited Member States to develop national strategies and best practices for coexistence following the guidelines provided in the Annex to this Recommendation. One of the proposed measures to ensure that GM material would remain

1 OECD Seed Schemes 2022, https://www.oecd.org/agriculture/topics/standards-seeds-tractors-forest-fruit-vegetables/

2 https://www.aphis.usda.gov/biotechnology/downloads/sep_dist_table_0813.pdf

3 Commission Recommendation 2003/556/EC of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming Official Journal L 189 , 29/07/2003 P. 0036 - 0047

separated from non-GM was the use of isolation distances between different types of fields. In the Decree of the Flemish Government[4] establishing general measures for the coexistence of genetically modified crops with conventional and organic crops it is indicated that for the cultivation of GM maize crops, the isolation distance is set at 50 meters from the edges of the plot. ILVO performed a study[5] to investigate the adequacy of the isolation distance and other rules. They conclude that all experiments clearly showed that the proposed isolation distance of 50 meters is more than sufficient to limit cross-pollination of surrounding non-GMO plots such that final GMO levels in the entire harvested batches of silage maize or grain maize remain well below 0.9%.

While the co-existence results confirm the quick reduction of efficient pollination with an increase in isolation distance and 50 meters may be sufficient for not reaching the 0,9% commingling of a market approved line, it would likely not be enough for achieving a no detectable level of an experimental, not approved for market line. We therefore maintain at least 200 m from the closest maize planting, making the likelihood for successful fertilization extremely low.

It is highly unlikely that this isolation distance cannot be met since the entire area is controlled by ILVO. Nevertheless, in such case, an alternative approach will be discussed with the authorities (e.g. securing a border zone of that field to ensure any potentially pollinated material is correctly handled).

Border row with conventional maize
The gene-edited maize will be released in a field trial with limited surface surrounded by border rows of non-modified maize plants. Such border rows have been commonly used as pollen depositories and physical barriers. Due to the lower plant height of the experimental lines compared to the border plants pollen dispersal beyond the trial site will be even more reduced. Furthermore, releasing additional non-GM pollen results in dilution of any pollen released from the experimental material.

Time shift of pollen release
The edits were performed in maize germplasm with a very high maturity index compared to European varieties. It has already been indicated that in consequence the trial period is extended beyond what is usual for European varieties. This also means that the edited plants will be flowering much later then other maize plants planted by local farmers. Although it cannot be guaranteed that the temporal isolation of flowering will be complete, it is an additional factor reducing the likelihood for successful cross pollination beyond the trials site.

Competition at pollinization
Any maize plant at a distance from the trial plot may theoretically receive a mixture of different types of pollen, specifically from:

a. the same plant (selfing),
b. plants in the same field
c. plants in other fields in the neighbourhood
d. plants from the border rows of the field trial
e. plants from the non-edited entries in the trial
f. plants from the edited entries in the trial

Taking into account the number of pollen releasing plants and the isolation distance, it can be safely concluded that in the nearest fields the portion of pollen from the trial, and more specifically the pollen form the edited lines, will be extremely small, if present at all. OECD (2006) specifies that maize pollen landing on a silk, germinates almost immediately after pollination, and within 24 h completes fertilisation. Therefore, the chance that any of the pollen released from the trial and having been exposed to the environmental conditions during the

[4] Besluit van de Vlaamse Regering van 15 oktober 2010 houdende de vaststelling van algemene maatregelen voor de co-existentie van genetisch gemodificeerde gewassen met conventionele gewassen en biologische gewassen, Belgisch Staatsblad 30/11/2010 73420

[5] Van Droogenbroeck B, Taverniers I and De Loose M (2011). De Vlaamse regelgeving omtrent co-existentie: een evaluatie in praktijkomstandigheden, Eindrapport, ILVO

dispersal, will be successful to pollinate a distant plant are negligible. This competition effect has been confirmed in coexistence studies (reviewed by Devos *et al*., 2005[6]). Depending on the size of the field of the pollen donor relative to the size of the recipient field, the levels of cross-fertilization vary. The larger the recipient field in comparison with the donor field, the larger its own pollen mass will be. This pollen cloud, hanging over the recipient field, is a physical barrier and competitor for incoming pollen. The proposed field trial site itself is limited to 0,2 ha (of which only a part is occupied by gene edited plants) and this is much smaller than commercial maize fields.

The border row will be seeded with a local variety and during the trial it will be confirmed that the development is correct, in order to guarantee an adequate guard at the time of flowering.

4. Risk characterisation

Even in the unlikely case of a successful fertilization, the consequence is deemed irrelevant:

- The gene edited traits do not affect the grain production on the remote plant or lead to the expression of unwanted products in the grain on the remote plant;
- Grain on the remote plant that may then carry the gene edited function, will not enter the environment as seeds. Farmers do not use farm saved seed for maize, so no reintroduction will occur.
- Commercially produced maize can be used as grain for fodder, however most of the production is destined for silage. In consequence, the grain is only a fraction of the material that is further used.

In conclusion, although normal developing pants will at some point produce and release pollen, exposure is negligible.

Taken the hazard characterisation together with the exposure characterisation the risk is negligible.

5. Risk management strategies

No risk management strategies are warranted.

6. Overall risk evaluation and conclusions

Results from the assessment support the conclusion that the ability of the gene edited maize to persist in agricultural fields or invade non-agricultural habitats are similar (possibly even lower) to those of conventional maize. Also, the probability of gene transfer through pollen dispersal will be limited and the transferred trait represents rather a disadvantage. The negligible hazard and the very low levels of environmental exposure lead to the conclusion that the edited maize lines do not pose a risk to the environment.

B. Gene transfer from plants to microorganisms.

1. Problem formulation including hazard identification

Gene transfer from the edited maize to microorganisms may bring advantages or disadvantages to the microorganism receiving the genetic information.
The edited maize plants do not differ from conventional maize except for the altered expression of the transcription factor gene and the transcriptional coactivator gene. No new genetic elements, not already present in maize, have been inserted. Care has been taken to select plants for which it can be demonstrated that all markers (including antibiotic tolerance markers) have been eliminated. Therefore, for both the genetic material originating from edited or non-edited maize plants, no difference is expected in the effect of transfer of genetic material to microorganisms.

[6] Devos Y. Reheul D. & De Schrijver A. (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 (2) 71 – 87
https://doi.org/10.1051/ebr:2005013

Therefore, this topic is not applicable and not further elaborated.

C. Interactions of the GMHP with target organisms.

1. Problem formulation including hazard identification

The edited maize lines do not target organisms, such as predators, parasitoids and pathogens. Therefore, this topic is not applicable and not further elaborated.

D. Interactions of the GMHP with non-target organisms.

1. Problem formulation including hazard identification

Introduced traits may have an effect on all kind of organisms interacting with the gene-edited maize plants. Organisms involve beneficial organisms as well as pests and disease-causing organisms.

The gene-edited maize plants do not differ from conventional maize except for the altered expression of the transcription factor gene and the transcriptional coactivator gene. Neither the native genetic element, nor the transcription factor gene and the transcriptional coactivator gene produce any new function as such. Therefore, any non-target organism interacting with the gene edited lines would already have been exposed to the functions.

The resulting phenotype, i.e. the reduced stature of the plants and/or the increase leaf size, is also not expected to have any immediate and/or delayed environmental effects.

Therefore, this topic is not applicable and not further elaborated.

E. Effects of the specific cultivation, management and harvesting techniques.

1. Problem formulation including hazard identification

Changes in the gene-edited maize plants may influence the way the plants are cultivated, managed and harvested.
The reduced stature of the plants may result in a more efficient fertilizer use and disease treatment by allowing more targeted applications later in the season, when really needed.
Such changes are expected to improve the overall agronomic management and contribute to more sustainable agriculture.

In this field trial focussing on confirming the phenotype, plant development and yield, the standard agronomic practices will be used. No change in management will be investigated or implemented yet.

Therefore, this topic is not applicable and not further elaborated.

F. Effects on biogeochemical processes.

1. Problem formulation including hazard identification

Maize is not known to play any specific role in biogeochemical processes.
The edited maize plants do not differ from conventional maize except for the altered expression of the transcription factor gene. Neither the native genetic element, nor the transcription factor gene and the transcriptional coactivator gene produce any new function as such. Also the resulting phenotypes have no correlation with any biogeochemical processes.

Therefore, this topic is not applicable and not further elaborated.

G. Effects on human and animal health.

Human health

1. Problem formulation including hazard identification:
Handling gene-edited maize plant potentially have effects on persons working with, coming into contact with or in the vicinity of these plants.

The edited maize plants do not differ from conventional maize except for the altered expression of the transcription factor gene and the transcriptional coactivator gene. Neither the native genetic element, nor the transcription factor gene and the transcriptional coactivator gene produce any new function as such.

Maize pollen is known to cause allergies in frequently exposed persons. Yet, neither the native genetic element, nor the genes encoding the transcription factor and the transcriptional coactivator are linked with any known allergen.

The resulting phenotype, i.e. the reduced stature of the plants and/or increase leaf size, is also not expected to have any immediate and/or delayed effects on human health.

Therefore, this topic is not applicable and not further elaborated.

Animal health

1 Problem formulation including hazard identification
Introduced traits in gene-edited maize plants may have an effect on animals fed with this maize in case the traits affect the composition of the plant.

The edited maize plants do not differ from conventional maize except for the altered expression of the transcription factor gene and the transcriptional coactivator gene. Neither the native genetic element, nor the transcription factor gene and the transcriptional coactivator gene produce any new function as such. They are not known to code for any toxin or anti-nutritional factor.

2. Hazard characterisation
Only if the composition of nutrients and antinutrients of the gene-edited maize has changed compared to conventional maize varieties, this might have an effect on the nutritional value of the feed. Furthermore, it is highly unlikely that the edited trait, the reduced stature, has any influence on the composition of maize feed.

3. Exposure characterisation
The gene-edited plants in the proposed field trial are not intended to be fed to animals. As all the material, with the exception of samples for further analysis, will be destroyed upon termination of the trial, no materials will enter the feed/food chain.

Any equipment used for the management of the trial, in particular for seeding and harvesting, will be thoroughly cleaned on the site to exclude any carry-over to other fields and dispersal.

Above it was argued that -although unlikely- successful fertilisation of remote maize plants in commercial field may occur via pollen flow. Such harvested material will be oriented to animal feeding. It must be highlighted that although pollen will contribute to the genetic make-up of the seed and hence the next generation, the main quality characteristics of the grain are maternally determined. The genetic sequences relating to the native genetic element, the transcription factor gene and the transcriptional coactivator gene are already present in all maize feed.

Direct consumption (not as feed) can occur in the field e.g. by birds or mammals. It is good practice to avoid damage to the field trials, so whenever needed additional measures will be taken (e.g. netting of the area after seeding to prevent bird damage, fencing in case rabbits damage would be observed). Based on the summer ’23 experience these protective measures will be further improved.

Given the limited area of the field trial and the fact that it is surrounded by border plants, the chance that wild animals will feed on the gene-edited plants is low.

4. Risk characterisation

As the genetic sequences relating to the native genetic element, the transcription factor gene and the transcriptional coactivator gene are already present in all maize feed, no new effects are expected.

Giving the fact that the edited maize in the field trial is not intended for animal feed, the risk is negligible. Also, for wild animals feeding on the maize plants in the trial, the hazard characterisation taken together with the exposure characterisation makes the risk negligible.

Even in the unlikely scenario, that cross-pollination on a maize plant outside of the isolation distance results in grain with the edit(s), no impact is expected as the quality aspects of the grain are maternally determined.

5. Risk management strategies

No risk management strategies are warranted.

6. Overall risk evaluation and conclusions

Results from the assessment support the conclusion that the gene-edited trait will have no effect on feeding animals. The negligible hazard and the very low levels of environmental exposure lead to the conclusion that the edited maize lines do not pose a risk to animal health.

III. CONCLUSIONS ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE

This ERA was performed according to the methodology laid out in Annex IIC of Directive 2001/18/EC, supplemented by the guidance notes in Commission Decision 2002/623/EC. Information on the points listed in Annex IIID of Directive 2001/18/EC, as transposed into the Royal Decree of 21 February 2005 (and amendments) were provided in the previous section and are summarized in this overall conclusion.

Points listed in Annex IIID of Directive 2001/18/EC	Overall risk evaluation
1. Persistence and invasiveness of the GMHP, including plant-to-plant gene transfer.	The ability of the gene edited maize to persist in agricultural fields or invade non-agricultural habitats are lower to those of conventional maize. The probability of gene transfer trough pollen dispersal will be limited and that the transferred trait represents rather a disadvantage. The negligible hazard and the very low levels of environmental exposure lead to the conclusion that the edited maize lines do not pose a risk to the environment.
2. Gene transfer from plants to microorganisms.	The effect of transfer of genetic material form the edited maize to microorganisms is not different from transfer from non-

	modified maize. Therefore, the edited maize lines do not pose a risk to the environment.
3. Interactions of the GMHP with target organisms.	This topic is not applicable.
4. Interactions of the GMHP with non-target organisms.	This topic is not applicable.
5. Effects of the specific cultivation, management and harvesting techniques.	This topic is not applicable.
6. Effects on biogeochemical processes.	This topic is not applicable.
7. Effects on human and animal health	Human health: this topic is not applicable. Animal health: the gene-edited trait will have no effect on feeding animals. The negligible hazard and the very low levels of environmental exposure lead to the conclusion that the edited maize lines do not pose a risk to animal health

The applicant submits that the overall conclusion of the environmental risk assessment is that the intended field trial with the gene edited maize lines will not entail any adverse effects, either direct or indirect, immediate or delayed, on human health and the environment.

The proposed trial includes already several measures (e.g. handling of seeds, use of specialised equipment, cleaning of equipment, provision of an isolation distance to any other maize, planting of border rows with conventional maize) that will contribute to confinement for the material. No need for additional risk management was identified in the ERA.