Bioveiligheidsraad
Conseil de Biosécurité

20-01-2015

Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC_2015_0052

Title: Advice of the Belgian Biosafety Advisory Council on the notification **B/BE/14/V2** of VIB for deliberate release in the environment of genetically modified maize with altered growth characteristics

Context

The notification B/BE/14/V2 has been submitted by the VIB to the Belgian Competent Authority (CA) in September 2014 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 maize with modified growth characteristics**. The purpose of the trial is to confirm the modified growth characteristics of the genetically modified (GM) maize under normal field conditions and to measure the effect of the modification on the cob formation and cob filling which is difficult to measure in greenhouse conditions.

The notification has been officially acknowledged by the CA on 9 October 2014 and forwarded 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. Four 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 SBB also took part in the evaluation of the dossier.
The experts and the SBB assessed whether the information provided in the notification was sufficient and accurate in order to state that the deliberate release of the GM maize lines would not raise any problems for the environment, animal or human health in the context of the intended use.

On 21 November 2014, based on a list of questions prepared by the Biosafety Advisory Council, the CA requested the notifier to provide additional information. Answers to the questions were provided on 5 January 2015.

The scientific evaluation has been performed considering following legislation:
- Annex II (principles for the risk assessment) and annex III (information required in notifications) of the Royal Decree of 21 February 2005
- Commission Decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC.

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. The CA forwarded the list of questions to the Biosafety Advisory Council. The questions of the public on biosafety issues of the GM maize under consideration are taken in consideration in the opinion of the Biosafety Advisory Council. Answers to the questions of the public have been sent to the CA.

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-fertilization 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 up pollen and distribute it over distances up to kilometers under suitable climatic conditions. In Belgium (and in Europe) there are no sexually cross-compatible wild relatives with which maize can hybridise and form progeny (OECD, 2003). The only recipient plants that can be cross-fertilised by maize are therefore other cultivated maize varieties.

Seed dispersal of individual kernels of domesticated plants are 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 will only occur after a warm winter period (with no temperatures lower than 0°C for more than 6 to 8 hours) and will be characterized by a low probability of cross-pollination (OECD, 2003; Gruber *et al*., 2008[3]; Palaudelmàs *et al*., 2009[4]). Given the Belgium weather conditions, volunteers are not likely to occur.

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

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

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

The field trial will be conducted during three consecutive growing seasons (from April/May 2015 until October 2017). The surface of the area for cultivation will not exceed 1000 m^2. No glufosinate will be applied to control weeds. Harvesting will occur each year in October.

Prior to complete formation, tassels from the GM maize will be removed by hand in order to prevent the dispersal of GM pollen. The GM maize will be pollinated by non-GM maize planted within and at the borders of the field plot. Monitoring of upcoming tassels will take place every two days until the last leaf has been formed and will be maintained until September 15. Removed tassels will be transported in closed bags and inactivated.

During harvest, cobs of the GM maize will be collected by hand and transported in closed bags to the lab. Seeds will be stored for research or will be inactivated if no longer needed for research. Stems and leaves will be shredded on the field. Roots and the lowest part of the stem will be left in the ground.

The year following the 2.5-year field trial, monitoring for volunteers will be done. The field trial will be left fallow and any volunteer maize plants will be removed and inactivated.

3. Information related to the genetic modification

Two GM maize lines with altered growth characteristics resulting from the introduction of a KLUH gene originating from *Zea mays* and under control of a maize GA2oxidase promoter, will be tested in the field experiment: they are identified as GA2ox_KLUH 139-01 and GA2ox_KLUH 140-01. The KLUH gene encodes for a cytochrome P450 monooxygenase, which is involved in cell proliferation.

In addition, the transgenic lines contain the *bar* gene from *Streptomyces hygroscopicus* that served as a marker for selection of transformants after *Agrobacterium tumefaciens*-mediated transformation. The *bar* gene produces the phosphinotricin acetyl transferase (PAT) enzyme, which acetylates phosphinotricin, also known as glufosinate, the active ingredient of the broad spectrum herbicides, thereby rendering it inactive.

The backbone sequence of the vector used for transformation harbours the *aadA* gene conferring resistance to spectinomycin and streptomycin, two antibiotics still relevant in human and animal therapy. Absence of the *aadA* gene has been demonstrated in the two transgenic lines.

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 compared to non-GM maize is expected, as the intended changed characteristic (bigger leaves) is not known to confer a selective advantage to survivability. Other (unintended) changed characteristics observed are extra lateral side-branches in the tassel, later florescence and a shorter anthesis silking interval. These characteristics will however not impact selective advantage as the tassels will be removed.

Vertical gene transfer through seed and pollen can virtually be ruled out due to the measures taken during the release and the biology of maize:

- pollen dispersal will be prevented by removal of the tassels,

- the cobs will be manually collected, preventing the natural dispersal of seeds,
- the low winter tolerance of spilled seed, and
- the low probability of appearance of volunteers.

The possibility of horizontal gene transfer between plants and micro-organisms is considered as a rare event under natural conditions (Keese, 2008[5]). The possibility of horizontal gene transfer between the GM maize plants and bacteria has been given particular attention due to the presence of the recombination sites attB4, attB1 and attB2. However, the occurrence of an active integrase-excisionase complex in an environment where attP4, attP1 and attP2 are present is estimated low. In case gene transfer from the GM maize to micro-organisms would take place, negative effects on environment and humans are not expected, as the resistance gene (i.e. *bar*) occurs naturally in microbes and the KLUH gene will not confer a selective advantage to bacteria.

Further, it is not expected that the GM maize would have significant effects on organisms (invertebrates, vertebrates and soil micro-organisms) and humans, as no gene that affects organisms 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. As the GM maize will not produce pollen, a possible altered allergenicity of the transgenic pollen (allergy from maize pollen is rare and may occur in case of occupational exposure to high amounts of pollen grains, see e.g. Oldenburg *et al*., 2011[6]) does not form a concern for human health.

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. The removal of any appearing tassel in the transformed line will prevent gene flow by pollen spread. Careful manual harvesting of the cobs and storing them in closed bags will prevent seed dispersal. The seeds, after analysis, and the tassels will be destroyed. To prevent the spread of transgenes into the environment after termination of the field trial, monitoring for GM maize volunteers will be done.

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

[6] Oldenburg 2011. Maize pollen is an important allergen in occupationally exposed workers. Journal of Occupational Medicine and Toxicology

Conclusion

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

Prof. M. De Proft
President of the Biosafety Advisory Council

Annex I: Compilation of comments of experts in charge of assessing the dossier B/BE/14/V2 (ref: BAC_2014_0817)

Bioveiligheidsraad
Conseil de Biosécurité

25 November 2014

Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC_2014_0817
Email: BAC@wiv-isp.be

Compilation of comments of experts in charge of assessing the dossier B/BE/14/V2

Coordinator: M. Van Koninckxloo
Experts: Philippe Baret (UCL), Didier Breyer (WIV-ISP), Patrick du Jardin (ULg-Gembloux Agro BioTech) and Jan Van Doorsselaere (KATHO Roeselaere)
SBB coordinator: Adinda De Schrijver

INTRODUCTION

Dossier **B/BE/14/V2** 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 9 October 2014 and concerns a field trial transgenic maize with altered growth characteristics

Depending on their expertise, the experts were invited to evaluate the genetically modified organisms considered in the notification as regards their potential impacts on the environment, including human and animal health, 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 Royal Decree of 21 February 2005
- Annex III (information required in notifications) of the Royal Decree of 21 February 2005
- Commission Decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC.

LIST OF COMMENTS RECEIVED FROM THE EXPERTS

Remark: The comments below have served as basis for a list of questions that the competent authority forwarded on 20-11-2014 to the notifier with a request to provide additional information. The comments highlighted in grey correspond to the questions/comments selected and send to the notifier.

Items left blank have been evaluated by the experts but they had no comments or questions.

1. INFORMATION RELATED TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

(e.g. reproduction, survivability, dissemination, geographic distribution,...)

Comment 1

B7 – Mais kent een lange historie of veilig gebruik. Please provide scientific references (epidemiological) supporting this sentence.

Note coordinator/SBB: Epidemiological references would only be relevant to ask for in case the evaluated use is animal/human consumption. This use is not the purpose of this field trial.
We do acknowledge the fact that statements should be accompanied by scientific proof. A general remark highlighting this will be forwarded to the notifier.

Comment 2

The parental line used for genetic transformation is the American B104 inbred line. It has been chosen because of its ease of transformation. In a similar field trial notified by VIB in 2011 (B/BE/11/V4) the relevance of using this line in field testing was questioned by the Biosafety Council because (i) this maize is poorly adapted to the Belgian climatic conditions and is maturing extremely late in our circumstances, therefore making its agronomic relevance in Belgium questionable, and (ii) the transformed B104 material is an inbred line with no intrinsic agronomic value. The Biosafety Council recommended in 2011 to test hybrids instead of an inbred line.
It is therefore important to note that in the current notification, the field trial will be performed with the hybrid B104(GA2ox::KLUH) x CML91, a line that is better adapted to the Belgian climatic conditions, with an earlier flowering period.

2. INFORMATION RELATED TO THE GENETIC MODIFICATION

(e.g. methods used for the modification, description of the vector,...)

Comment 1

page 6. The *Agrobacterium* strain used for transformation should be indicated.
page 6. The applicant refers to a previous field trial dossier (B/BE/11/V4) for details on the genetic elements of the vector backbone; we consider that each dossier should be stand-alone and provide the external experts with all the information needed for the risk assessment.
page 7. Minor edit : the location of the 35S promoter is apparent on the plasmid map but annotation was omitted.

3. INFORMATION RELATED TO THE GENETICALLY MODIFIED PLANT

3.1. Information related to the traits and characteristics, which have been introduced or modified

Comment 1

When reading the whole dossier, it becomes clear that different phenotypic traits should be affected by the genetic modification, but which are really the primary intended modifications are less clear (larger leaves, reduced anthesis-to-silking interval, etc.). We acknowledge that the proposed field trial aims at analysing the developmental effects of a maize gene under field conditions, considering that greenhouse and laboratory experiments show strong limitations for studying such kinds of genes and traits. The field trial data may be considered as a basis for the agronomic evaluation of the modified traits. No further information on these traits is expected *ex ante*.

3.2. Information on the molecular characteristics of the final GMO

(e.g. number of copies of the transgenes,...)

Comment 1

page 14. The qPCR analysis for determining the insert number follows a comparative approach using reference lines assumed by the applicant to contain 4, 2 and 1 copies / copy of the bar gene. In the absence of the Southern data which allowed to conclude on the copy number in those reference lines, it is not possible to validate the conclusions pertaining to the two GM lines of this dossier. The Southern analysis should be described and the results included in this dossier, in line with the *Belgian Guidelines for molecular characterisation of Part B notifications under Directive 2001/18/EC*, which state that “the quality of the experimental data should be sufficient to verify clearly any statements made by the applicant” ; a fortiori in this case, lack of data prevents any such verification.

page 14. The dossier concludes on a single locus of integration for both field-tested GM lines, based on segregation analysis, but also provides indications for two T-DNA copies in line 139-01, based on qPCR. Although these data are not contradictory – a single locus may comprise more than one T-DNA insert -, the segregation data and the statistical analysis supporting these conclusions should be provided in the dossier.

Note coordinator/SBB: According to the Guidelines for Molecular Characterisation of a Standard Part B notification, experimental data revealing the number of sites is not a requirement. Therefore, data to confirm single site integration are not asked for.

3.3. Information on the expression of the insert

(e.g. parts of plants where the insert is expressed, (expected) expression of the insert during the lifecycle of the plant,...)

Comment 1

The expression profile of the KLUH gene, under the control of the GA2ox promoter and responsible of the intended trait, is extrapolated from the knowledge obtained on other GM lines containing the GUS reporter gene under the control of the same GA2ox promoter. Although this information is relevant, it cannot be regarded as sufficient for concluding on the expression of KLUH gene in the two GM lines

and supplementary data using RT-PCR for instance should have been provided. It is likely that PCR primers specific to the newly formed transcripts (*i.e.* distinguishing them from endogenous KLUH transcripts) could be designed, as unique sequences are created, for example at the 3' end where the transcription terminator is not the endogenous one but the T35S from CaMV. However, considering that the intended modification aims at changing the level of an endogenous maize protein which raises no safety concerns, this information is not critical for the risk assessment but seems more important for the scientific outcomes of the trials.

3.4. Information on how the GM plant differs from the recipient plant

Comment 1

We acknowledge that the proposed field trials aim at analysing the developmental effects of a maize gene under field conditions, considering that greenhouse and laboratory experiments show strong limitations for studying such kinds of genes and traits.

However, we disagree with the conclusion of the applicant regarding the survival capacity of pollen and seeds, which is proposed to be unaffected on the basis of the reported no-effect on flowering and seed set (page 16, D4c). We see no arguments in the literature supporting correlative or causal relationships between these parameters (i.e. between pollen/seed production and pollen/seed survival). The applicant should be requested to develop his arguments or to generate experimental data on seed survival, which is relevant from an environmental risk assessment point of view.

Note coordinator/SBB: Data on seed survival are generally not required for a field trial, given the mitigation measures taken after the trial to avoid the establishment of maize volunteers. Therefore, the notifier will only be asked to develop his arguments.

3.5. Genetic stability of the insert and phenotypic stability of the GMHP

Comment 1

D5. Voor zover ons bekend zijn hierbij nog geen problemen opgedoken in de vorm van genetische instabiliteit van het donormateriaal. → "ons bekend" is insufficient in a risk assessment procedure. A more scientific discussion (with references to published works) or further testing will be welcome.

Note coordinator/SBB: According to the Guidelines for Molecular Characterisation of GM Higher Plants for a Standard Part B Consent, information on stability, especially genetic stability, is not required. To be in line with the guidelines, we will not ask for further testing. The notifier will only be asked to explain what is meant with "ons bekend".

Comment 2

Although no instability of the introduced DNA and associated traits is expected, the data provided are vague and can hardly support the conclusions : what is exactly "*materiaal van de 2e generatie*" ? Presumably from the parental B104 GM lines (no progeny of the F1 hybrid is normally produced) ? How many plants per generation were analysed (as pooled or individual samples ?) ?

3.6. Any change to the ability of the GMHP to transfer genetic material to other organisms

Comment 1
De tekst op p17/18 mbt overdracht van genetisch materiaal van de GGO in kwestie naar bacterien is bij momenten speculatief. De reviewer kan akkoord gaan met de stelling dat het GA2ox::kluh (indien het terecht zou komen in bacterien) niet zal resulteren in een selectief voordeel.

Comment 2
D6 De cruciale vraag is dan of het chimere construct pGA2ox::KLUH voor *E.coli* een selectief voordeel oplevert en of het gen zich in *E.coli* zal handhaven.

The discussion of this issue is only based on assumption with very few scientific references. Is it possible to design a test before the trial to confirm the absence of horizonral transfer ? Are data available from the previous trial with similar constructs ?

Note coordinator/SBB: Confirming the absence of horizontal transfer seems a daunting task. A more pragmatic way to determine the risks, is to determine if the trait – when horizontal transfer occurs – will have a selective advantage. Which is not expected to be the case. See also other comments on 3.6.

Comment 3
The information provided in the dossier with regards the possibility of and potential consequences associated with horizontal gene transfer between the GM maize and bacteria (in particular due to the presence of the recombination sites attB1, attB2 and attB4) is considered sufficient. It can be concluded that, if such a transfer would happen, it is very unlikely that it would lead to any adverse effects on human health and the environment.

3.7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification

Comment 1
D7 p 19 Bijkomstig kan worden vermeld dat de planten niet bedoeld zijn voor consumptive waardoor dit punt niet relevant is.

Comment 2
The paragraph on allergenicity is far from being up to date. See for example : (Panda et al. 2013). A better discussion of allergenicity risk should be provided by the notifier.

Note coordinator/SBB: The article of Panda et al. (2013) deals with food allergy. As this is an evaluation of a field trial and the plants are not meant for consumption, we do not see the need to ask for more data on (food) allergenicity.

Comment 3
The safety for human health of the PAT protein has already been extensively assessed in the context of its expression in GM plants and no concerns were identified.
The enzyme cytochrome P450 mono-oxygenase is naturally expressed in maize. The notifier states (section D7 of the technical dossier) that "*Er zijn geen redenen om te veronderstellen dat de*

additionele expressie van CYP78A1 onder controle van de GA2oxidase promotor, leidend tot een langere periode van celdeling met als gevolg grotere bladeren toxische, allergene of andere schadelijke effecten op de gezondheid van de mens zou hebben." Since no supporting scientific data is provided in the dossier, such a statement is premature. Nevertheless this should not be considered an issue in the context of the risk assessment of the proposed field trial since the GM maize is not intended for consumption and appropriate risk management measures will be implemented to mitigate the risks.

Note coordinator/SBB: We acknowledge the fact that statements should be accompanied by scientific proof. A general remark highlighting this will be forwarded to the notifier.

3.8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects from the genetic modification, where the GMHP is intended to be used in animal feedstuffs

Comment 1
The comments provided for point 3.7 above also apply.

3.9. Mechanism of interaction between the genetically modified plant and target organisms (if applicable)

Comment 1
Not applicable

3.10. Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification

Comment 1
The dossier lacks of information on the potential impact on pollinators.

Note coordinator/SBB: Asking for this information is irrelevant for this particular dossier as the male flowers producing pollen will be removed. Moreover, maize is predominantly wind-pollinated.

Comment 2
The applicant anticipates phenological alterations resulting from the genetic modification, which include delayed flowering and reduced anthesis-to-silking interval (see page 16, item D4a). In such instances, and depending on the magnitude of these effects, changes in interactions with organisms from the environment (including pests, pathogens, symbionts and epiphytic organisms) cannot be ruled out. From a risk assessment point of view, no significant adverse effects may be expected for small-scale field trials but it is suggested that the applicant reports on the magnitude of these effects and performs a risk assessment of such changes, if relevant, after the release.

Note coordinator/SBB: The male flowers will be removed, thus the effects on non-target organism due to delayed flowering and reduced anthesis-to-silking interval cannot be studied.

3.11. Potential interactions with the abiotic environment

3.12. Description of detection and identification techniques for the GM plant

Comment 1

The notifier provided the necessary data for PCR identification

Comment 2

Annex 9 gives the sequences of the oligonucleotide primers proposed for the PCR detection of the GA2ox::KLUH and *bar* target genes, but the exact map locations of these primers are not indicated. In particular, it is unclear whether the amplicons are specific to the T-DNA inserts or could also result from the corresponding target genes in other contexts (*e.g.* from the native *bar* gene in *Streptomyces*). This information should be given in the dossier. It is also worth noting that the proposed PCR tests are not able to discriminate between the two GM lines 139-01 and 140-01, but this seems acceptable for experimental release, in contrast with commercial releases where event-specific tests would be mandatory.

3.13. Information about previous releases of the GM plant, if applicable

Comment 1

Not applicable (notwithstanding the previous related application B/BE/11/V4, but which is not the same GMP

4. INFORMATION RELATING TO THE SITE OF RELEASE

(e.g. description of the site ecosystem, presence sexually compatible species, proximity of protected areas,...)

Comment 1

E3 - De afstand tot andere maïsplanten zal minimal zijn. → A precise exclusion distance for maize cultivation should be provided by the notifer.

5. INFORMATION RELATING TO THE RELEASE

(e.g. purpose of release, dates and duration of the release, methods for preparing and managing the release site, number of plants,...)

Comment 1

The trial is described as scientific. It is assumed that scientific publication will be written up in the follow up of this trial.

6. INFORMATION RELATED TO THE RISKS FOR THE ENVIRONMENT

6.1. Information on the likelihood for the GMHP to become more persistent than the recipient or parental plants or more invasive

Comment 1
Please refer to the comment in section 3.4 above, pointing to a shortcoming in the evaluation of seed survival. Molecular factors involved in the control of hormone action, as alluded for the introduced gene, might impact primary and/or secondary dormancy of seeds, as well as plant responses to drought and freezing stress, and consequences on the survival (e.g. overwintering) capacity of seeds cannot be ruled out at this stage.

6.2. Information on the selective advantage or disadvantage conferred to the GMHP

Comment 1
D4c - Integendeel, in het labo hebben we aangetoond dat de gemodificeerde planten even gevoelig zijn voor koude stress, althans wat bladgroei betreft, als de niet-gemodificeerde planten. -> no scientific evidence is provided to support this critical statement.

Note coordinator/SBB: Evidence that 'bladgroei' is the same for GM and non-GM maize plants under cold stress will not aid in coming to a risk conclusion. See also comment on section 3.1. We do acknowledge the fact that statements should be accompanied by scientific proof. A general remark highlighting this will be forwarded to the notifier.

Aangezien er geen verschillen zijn in bloem- en zaadvorming, veronderstellen we dat er ook geen verschil zal zijn in het vermogen van pollen en zaden om te overleven. -> this is contradictory with D4a as the objective of the transformation is to modify some reproductive dynamics in order to increase seed set.

Note coordinator/SBB: see also 3.4 for similar remark

Comment 2
See previous comment (in section 6.2)

6.3. Information on potential of gene transfer to other sexually compatible plant species under conditions of planting and its consequences

6.4. Information on the environmental impact resulting from direct and indirect interactions of the GMHP with target organisms

Comment 1
Not relevant in the context of this field trial.

Comment 2
Not applicable

6.5. Information on the environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, including herbivores, parasites, symbionts...

Comment 1
The dossier lacks of information on the potential impact on pollinators.

Comment 2
See comment above in section 3.10

6.6. Information on possible effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or living in the vicinity of the GMHP release

6.7. Information on possible effects on animal health and consequences for the food/feed chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed

Comment 1
Bijlage 1 pagina 2: punt 7: de vraag wordt niet beantwoord; er wordt informatie verstrekt over horizontale transfer naar bacteriën; echter, vermits de planten niet bedoeld zijn voor consumptie is dit punt niet relevant.

Comment 2
Not relevant in the context of this field trial.

6.8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s)

6.9. Information on environmental impact of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs

7. INFORMATION RELATED TO CONTROL, MONITORING, POSTRELEASE AND WASTE TREATMENT

7.1. Precautions taken

7.2. Information on methods for postrelease treatment of site

7.3. Information on postrelease treatment methods for the GM plant material, including wastes

Comment 1
1) Is it true that “Stems and leaves are not reproductive, and for that reason no longer GMO.”?
2) How the plant material (waste) will be “inactivated”?

Note coordinator/SBB: According to the EU legislation, a GMO is an organism that is capable of replication or of transferring genetic material. Stems and leaves are not able to do so and are hence no longer a GMO.

7.4 Information related to monitoring plans and the detection techniques

Comment 1
Please refer to the comment above (in section 3.12) about the limitations of the proposed detection techniques.

7.5. Information on the emergency plan(s) proposed by the notifier

7.6. Information on methods and procedures to protect the site

8. OTHER INFORMATION

8.1 Do you have any other questions/comments concerning this notification that are not covered under the previous items?

Comment 1
Is it possible to have access to the reports on veldproef B/BE/11/V4 ?

Note coordinator/SBB: These are available on the extranet of the Biosafety Advisory Council

Comment 2
In line with Directive 2001/18/EC, the introduction of GMOs into the environment should be carried out according to the “step by step” principle. This means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken.

This notification relates to a field trial for experimental purpose with a GM maize at early stage of development. In this context limited information is still available to identify or characterise some of the potential hazards at the time the risk assessment is conducted, in particular with regards to the phenotypic and agronomic properties of the GM plants and its (un)anticipated interactions with the receiving environment.
I consider that the small scale of the field trial and the risk management measures proposed by the notifier are sufficient to mitigate the risk for human health and the environment and to address the uncertainties remaining as a result of the risk assessment.

Comment 3
Any lessons learned from the related maize application B/BE/11/V4 should be taken into account for the set up and monitoring of this new release.

References

Panda, R., H. Ariyarathna, P. Amnuaycheewa, A. Tetteh, S. N. Pramod, S. L. Taylor, B. K. Ballmer-Weber, and R. E. Goodman. 2013. “Challenges in Testing Genetically Modified Crops for Potential Increases in Endogenous Allergen Expression for Safety.” *Allergy* 68 (2): 142–51.