Bioveiligheidsraad
Conseil de Biosécurité

10-02-2011

Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC_2011_0117

Title: Advice of the Belgian Biosafety Advisory Council on the notification **B/BE/10/V2** of BASF Plant Science Company for deliberate release in the environment of genetically modified potatoes resistant to *Phytophthora infestans.*

Context

The notification B/BE/10/V2 has been submitted by BASF Plant Science Company to the Belgian Competent Authority (CA) in November 2010 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: **Application for the release into the environment of potato lines with improved resistance to *Phytophthora infestans,* 2011 and 2012**. The specific purpose of the trials is to evaluate the resistance to *Phytophthora infestans* under realistic Belgian climatic and soil conditions. The purpose of the release is to compile data on agronomical performance, as well as to collect plant material for further analyses (e.g. biochemistry, molecular biology).

The notification has been officially acknowledged by the CA on 3 November 2010 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. Five 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 in order to state that the deliberate release of the genetically modified (GM) potato lines would not raise any problems for the environment, animal or human health.

On 17 December 2011, based on a list of questions prepared by the Biosafety Advisory Council, the CA requested the notifier to provide additional information. A new version of the dossier and answers to the questions were provided on 6 Januari 2011 by the Biosafety Advisory Council. On 24 January 2011 the Biosafety Advisory Council did not forward an

advice. Some members of the Council raised additional questions. The CA forwarded the questions to the notifier. Answers were received on 7 February 2011.

For the purpose of the scientific evaluation, the following legislation has been considered:
- 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 tackling biosafety issues of the GMOs 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

Potato (*Solanum tuberosum* ssp. *tuberosum*) is mainly a selfing species, but cross-pollination can also occur (OECD, 1997[1]). The pollen is relatively heavy and is spread by wind and insects, especially bumblebees. Flowering, pollen fertility, berry formation and seed set differ according to the *Solanum tuberosum* ssp. *tuberosum* cultivar considered. The cultivar considered here, P880, flowers abundantly, produces berries frequently and sets viable true seed.

Solanum tuberosum is sexually compatible with other potato varieties cultivated in Belgium, but not with related wild *Solanum* species occurring in Belgium as *Solanum nigrum* ssp. *nigrum*, *Solanum nigrum* ssp. *schultesii*, *Solanum triflorum*, *Solanum dulcamara* and *Solanum nitidibaccatum* (De Vries et al., 1992[2]; OECD, 1997). Field experiments have shown that cross-pollination reduces rapidly (few meters) with the distance, even for highly male-sterile varieties (Conner, 2006[3]; Petti et al., 2007[4]). True potato seeds can survive in the soil and have been reported to retain their viability over a seven-year rotation in the mild climate of Scotland (Lawson, 1983[5]). Further, potato seeds can be dispersed by small mammals, but rarely by birds as they are poisonous. Plants arising from true seeds have a lower fitness

[1] OECD (1997) Consensus Document on the Biology of *Solanum tuberosum* subsp. *tuberosum* (Potato). Series on the Harmonization of Regulatory Oversight in Biotechnology, No. 8
[2] De Vries F.T., van der Meijden R., Brandenburg, W.A. (1992) Gorteria, Botanical Files. A study of the real chances for spontaneous gene flow from cultivated plants to the wild flora of the Netherlands. Supplement 1
[3] Conner A.J. (2006) Biosafety evaluation of transgenic potatoes: Gene flow from transgenic potatoes. International Symposium Ecological and Environmental Biosafety of Transgenic Plants, p.125-137
[4] Petti C., Meade C., Downes M., Mullins E. (2007) Facilitating co-existence by tracking gene dispersal in conventional potato systems with microsatellite markers. Environmental Biosafety Research 6, 223-235.
[5] Lawson, H.M. (1983) True potato seeds as arable weeds. Potato Research 26, 237-246.

compared to potato plants grown from tubers. They usually do not persist for more than one or two growing seasons and have rarely been seen outside the fields (Conner, 2006).

The main reproduction in potatoes is by vegetative propagation through tubers (OECD, 1997). Tubers that are not covered by thick layers of soil usually are killed by winter frost. In contrast to potato seed, tubers do not remain dormant and will sprout the next season. In contrast to true potato seed, tubers do not remain dormant and will sprout the next season.

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

The notifier announces that the trial will take place during two years (2011 and 2012); each year on a different plot not larger than 1500 m^2. The planting will take place earliest in April-May and harvesting in August/mid October of each year. Preparation and management of the trial site will be according to conventional agricultural practice. Tubers will be removed by hand and transported to the laboratory in closed bags, where they will be destroyed after analyses. The notifier announces that the year following the release, the field plot will remain fallow or will be planted with cereals. Emerging volunteers will be destroyed prior to flower setting. The notifier announces that monitoring will be extended until there is a whole season without any potato volunteers.

3. Information related to the genetic modification

The genes introduced for improving resistance to *Phytophthora infestans* are resistance (R)-genes from the wild potato species *Solanum bulbocastanum*: *Rpi-blb1* and *Rpi-blb2* genes with their endogenous promoter and terminator regions. The two genes belong to the NBS-LRR (Nucleotide Binding Site – Leucine Rich Repeat) class of R-genes and code for proteins that recognise specific proteins - termed elicitor proteins - of *Phytophthora infestans*. Recognition of the elicitor proteins will lead to local plant cell death and will thus prevent further development of the pathogen *Phytophthora infestans*.

The GM potato lines were produced via *Agrobacterium*-mediated transformation of potato leaf tissue using the binary vector VCPMA16. An acetohydroxyacid synthase gene conferring tolerance to herbicide imazamox was used for selection of transformed plant tissue. On the vector backbone of VCPMA16 no antibiotic resistant marker genes are present. The information related to the genetic modification is considered as sufficient and in accordance with the guidelines of the SBB (SBB, 2002)[6].

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

A concern associated with the release of GM potato is the potential impact of gene flow between GM and non-GM potatoes. Different paths have to be considered: gene flow by pollen, by true seeds and by tubers. The variety under consideration, P880, flowers abundantly, is fertile and produces berries with viable seeds.

The notifier announces to imply an isolation distance of 150 m to commercially cultivated non-GM potatoes which is in line with the recommended distance for field trials in the literature of

[6] SBB (2002) http://www.biosafety.be/gmcropff/EN/TP/partC/GuideMGC_PartB_C.htm

20 m (Conner and Dale, 1996[7]). The Biosafety Advisory Council is of the opinion that under the presented trial conditions outcrossing to neighbouring non-GM potatoes is very unlikely, but cannot be fully excluded. Taken into account that current agricultural practices (rotation) in Belgium offer good opportunities to eliminate occasional seedlings arising from true seed, the risk for the environment in neighbouring fields is considered as very low.

As both occasional seedlings as well as tubers may survive in the soil of the field trial and may produce volunteers in subsequent years, the Biosafety Advisory Council welcomes the propositions of the notifier to control volunteers (see point 2) in the field trial.

The possibility of horizontal gene transfer between GM plants and bacteria is considered as a rare event under natural conditions.

No effect is expected on non-target organisms. Risks for animals and humans are considered as very low. Indeed, the potatoes used in this trial will not be consumed, as the notifier announces to destroy the tubers after harvest. The notifier also announces to safeguard the field trial as the entrance will be prohibited by a fence.

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

The Biosafety Advisory Council appreciates the proposed management measures to prevent potential adverse effects to the environment, animal and human health. However, to minimise the spread of transgenes into the environment, the Biosafety Advisory Council proposes additional measures.

Conclusion

Based on the scientific assessment of the dossier by Belgian experts, on the answers on the additional questions, on data provided in the COGEM advice[8] in The Netherlands, the majority of the members of the Biosafety Advisory Council proposes a conditional positive advice.

The majority of the members of the Biosafety Advisory Council considers the risks for the environment and human health as negligible on the conditions listed hereunder:

a) Field trials are permitted in 2011 and 2012.
b) The area of the trials is restricted to approximately 2500 m^2.
c) Well before the start of the trial, the notifier provides a correct and accurate field design with a clear identification of individual plots and an accurate number of plants per plot. The precise location of the trial shall be given with references to fixed retrievable points.
d) The entrance of the field trial will be prohibited by a fence.
e) It is the responsibility of the notifier to respect the 150 m distance between the field trial and the closest non-GM potato field.

[7] Conner A.J. and Dale P.J. (1996) Reconsideration of pollen dispersal data from field trials of transgenic potatoes. Theoretical and Applied Genetics 92, 505-508.
[8] COGEM advies van 26 januari 2010, kenmerk CGM/100126-02

f) The outermost potato ridges of the field trial shall be planted with a non-GM potato variety. Ideally a variety that flowers simultaneously with the GM lines, without producing berries shall be planted. If not available, the non-GM isogenic variety is acceptable. At all sides of the trial area, the width of this surrounding area should be at least 3 m.
g) All personnel working in the trials will be trained to work with GMOs.
h) Harvesting of the whole experimental area (both GM potatoes and border ridges) must be done by hand. People who pick up the tubers must do everything they can to pick up all the tubers, including the smallest ones.
i) The trial area, extended with a strip of 5 m at all sides of the field trial, shall remain fallow for a period of at least 12 months after the harvest of the GM potatoes. At all time during this period, seedlings and emerging tubers must be killed with a systemic herbicide every 2 weeks. After the fallow period the land may be re-cropped with cereals and maize to allow a good control of volunteers with herbicides. Growing potatoes is not allowed during the whole monitoring period.
j) No ploughing is allowed during the whole monitoring period.
k) The monitoring period shall be x years. If during the year x-2, no volunteers appear anymore, the monitoring period may be ended at the end of the year x.

In order to allow extending its knowledge on the subject, the Biosafety Advisory Council wishes:

1. The notifier to transfer in detail at the end of 2011 and at the end of 2012 all trial results to the Biosafety Advisory Council. This report includes the detailed field design and well identified photographs demonstrating the reaction of all potato genotypes to *Phytophthora infestans.*
2. The notifier to invite the Biosafety Advisory Council to visit the field trial in order to observe the reactions of the GM and the non-GM potatoes to *Phytophthora infestans.* We propose 2 invitations in 2011 and 2 in 2012 on appropriate dates.
3. The permission for the 2012 trial to depend on a positive evaluation of the 2011 trial by the Biosafety Advisory Council; the evaluation will be based on points b-j and 1-2.

This advice is for a field trial with a restricted area only and only concerns the genetic transformations described in the dossier.

dr. J. BREYER

p.o. Prof. D. Reheul
President of the Biosafety Advisory Council

Annex I: Minority opinions.
Annex II: Summary Notification Information Format submitted by the notifier in November 2010.
Annex III: Compilation of comments of experts in charge of assessing the dossier B/BE/10/V2 (ref: BAC_2010_1051).

Annex I: Minority opinions

1. Minority opinion expressed by Mrs Philippe Baret and Damien Winandy

Par principe, les dossiers devraient être présentés de telle sorte que le contrôle des risques ne doive pas faire l'objet d'une série de conditions imposées par le Conseil.

Outre cette question de principe, nous considérons que la présentation des éléments relatifs à l'évaluation des risques dans ce dossier est d'une qualité insuffisante pour rendre une décision positive. De plus, la distance d'isolation de 10 m déclarée dans le SNIF est en contradiction avec les distances proposées dans la littérature scientifique récente.

2. Minority opinion expressed by Ms Lucette Flandroy

Whereas 2 different files have been considered, my considerations hereunder can apply to files B/BE/10/V1 and B/BE/10/V2.
I do not agree with the positive advice given by the BAC on these files for the following reasons in A) and C) :

A) This type of conditional positive advice, containing a large series of additional requirements from the BAC, raises principles issues:

1. in relation to the legislation that foresees that the notifiers themselves should make risk assessments and should propose measures to avoid or mitigate potential risks.
2. in relation to the confidence that can be given to notifiers that did not make tests or foresee adequate measures or monitoring to detect/avoid several theoretical potential risks.

B) This being said, it is admissible that the correct enforcement of supplementary conditions imposed to give this positive advice could fill up a blank in the risk assessments performed by the notifiers of which I, as well as several other BAC members including the coordinator of this file, have underlined various gaps and contradictions, even if this risk assessment is intended only for a limited field trial and not for putting on the market (N.B: these supplementary conditions should in any case than be very precise: ex.: more precision should be given for the fence around the field).

C) To better fill the gaps in the risk assessment performed by the notifiers, I would in any case require at least the hereunder additional conditions to test the possibility of adverse effects - resulting from unwanted modifications in these GM events through the transgenetic process – and to avoid as much as possible their occurring in case of repetition/extension of field trials:

1. to make quantitative analysis of *solanine* (potentially toxic not only for humans but also for animals for which a fence around the field would not be a sufficient barrier to avoid their entrance on the field) in the GM potato tubers and leaves, compared to the adequate controls, prior to starting the field trials.
2. alternatively, in order to better discourage entrance of humans on the field and in absence of further characterization of the lines under trial, to place a panel signaling "potential danger/toxicity if transgressing the fence" at several places near the fence around the field.

3. to test and compare pollen dispersal of GM plants with that of the adequate controls (for ex. through pollen captors at some distances around the field) (Pertinence of the case by case approach in absence of further characterization of the lines under trial, even if the literature shows poor pollen dispersal in general at middle distance for several other GM and conventional potato lines).

D) It is obvious that, in case of putting on the market, the antibiotic resistance marker genes should be eliminated from the selected lines, with better scientific proves of removal than those furnished in this field trial file (Pertinence of the case by case approach of the horizontal transfer of genes from plants to microorganisms, especially in case of remaining decaying parts of the plants on the fields. The concerned antibiotics are important for human and veterinary use).

PART 2 (COUNCIL DECISION 2002/813/EC)

SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE RELEASE OF GENETICALLY MODIFIED HIGHER PLANTS *(ANGIOSPERMAE AND GYMNOSPERMAE)*

A. GENERAL INFORMATION

1. Details of notification

a) Notification number: B/BE/10/V2

b) Date acknowledgement of notification:

c) Title of the project:

Application for the release into the environment of potato lines with improved resistance to Phytophthora infestans, 2011 and 2012

d) Proposed period of release: from 01/04/2011 until 31/10/2012

2. Notifier

Name of institute or company:

BASF Plant Science Company GmbH
Carl-Bosch-Straße 38
67056 Ludwigshafen
Germany

3. Is the same GMPt release planned elsewhere, inside or outside the Community [in conformity with Article 6 (1)] by the same notifier?

Yes (x) No ( )

If yes, insert the country code(s): SE, NL, DE, CZ, UK

4. Has the same GMPt been notified for release elsewhere, inside or outside the Community, by the same notifier?

Yes (x) No ( )

If yes, notification number(s): B/SE05/03, B/SE/05/8615, B/NL/05/03, B/NL/07/07, B/DE/05/174, B/DE/06/183, B/DE/07/191, B/CZ/07/01, B/GB/06/R42/01

B. INFORMATION ON THE GENETICALLY MODIFIED PLANT

1. Identity of the recipient or parental plant

a)	Family name:	*Solanaceae*
b)	Genus:	*Solanum*
c)	Species:	*tuberosum* L.
d)	Subspecies (if applicable):	*tuberosum*
e)	Cultivar/breeding line (if applicable):	P800
f)	Common name:	Potato

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

- improved resistance to *Phytophthora infestans*
- tolerance to Imidazolinone herbicides, mediated by the *ahas* gene as selectable marker gene to identify transgenic cells in tissue culture

3. Type of the genetic modification

a)	Insertion of genetic material:	(x)
b)	Deletion of genetic material:	( )
c)	Base substitution:	( )
d)	Cell fusion:	( )
e)	Other, specify:	...

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

- T-DNA borders, pTiT37, for incorporation into plant chromosome
- ahas gene, *Arabidopsis thaliana*, imidazolinone tolerance in plant material
- Promoter and terminator from nopaline synthase gene, *Agrobacterium tumefaciens*, gene regulation
- Resistance genes Rpi-blb1 and Rpi-blb2, *Solanum bulbocastanum*, with endogenous promoters and terminators for improved resistance to *Phytophthora infestans*

5. In the case of deletion or other modification of genetic material, give information on the function of the deleted or modified sequences

Not applicable.

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

Plasmid-derived DNA was introduced into the potato lines by *Agrobacterium*-mediated gene transfer technology using a binary vector system. This is standard technology for potato transformation.

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

Not applicable.

C. INFORMATION RELATING TO THE EXPERIMENTAL RELEASE

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

The purpose of the release is to assess the tolerance of the genetically modified potato lines to *Phytophthora infestans* under Belgian climatic and soil conditions.

2. Geographical location of the release site

The release site will be located in the municipality of Wetteren.

3. Size of the site (m^2)

The field size will be less than 1500 m2 per year.

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

Releases of the same potato plants have been conducted in the Netherlands, Sweden, the Czech Republic, United Kingdom and Germany. No adverse impacts on the environment or human health have been recorded in any of the trials.

D. SUMMARY OF THE POTENTIAL ENVIRONMENTAL IMPACT OF THE RELEASE OF THE GMPTS IN ACCORDANCE WITH ANNEX II, D2 OF DIRECTIVE 2001/18/EC

The genetically modified potato lines contain two NBS-LRR-genes, Rpi-blb1 and Rpi-blb2, from *Solanum bulbocastanum* for conferring improved resistance to *Phytophthora infestans*. Many conventional potato varieties also contain NBS-LRR-genes that have been introgressed from wild Solanum species. An intended effect of the introduced trait is an increased survivability in potato fields exposed to *Phytophthora infestans*. This possible selective advantage, however, is of importance only in the agricultural field, and will not improve the survivability in the surrounding environment. The reduced need for fungicides on these lines can easily be identified as an environmental benefit.

The ahas gene expressed in the potato plants imparts tolerance to the herbicidal active substance Imazamox to the shoots during the selection process in cell culture. This confers no selective advantage in the field since Imidazolinone herbicides are not approved for use on crops in the UK and since no field tolerance is expected in the potato plants. No difference with respect to persistence in agriculturally utilised habitats or invasiveness into natural habitats as compared to conventional potato varieties is expected. Through the measures which are taken during the release, distance from or absence of conventionally cultivated potatoes or wild species, the possibility of any gene transfer can be virtually ruled out. Even in the very improbable event that pollen were to be transferred to genetically unmodified potato plants, no consequences are to be expected, since potato propagation conventionally takes place via tubers and not

via seeds. The interactions of the genetically modified potato line with non-target organisms and the effects resulting from this will be comparable to those with conventional potato varieties. Furthermore, no toxic or allergenic effects are expected on the basis of the improved resistance to *Phytophthora infestans* or the expressed AHAS protein. No effects on biogeochemical processes are expected, other than those that apply also to conventional potatoes.

E. BRIEF DESCRIPTION OF ANY MEASURES TAKEN BY THE NOTIFIER FOR THE CONTROL OF RISKS INCLUDING ISOLATION DESIGNED TO LIMIT DISPERSAL, FOR EXAMPLE MONITORING AND POST-HARVEST MONITORING PROPOSALS

An isolation distance of 10 m to other commercial potato cultivations will be observed. Planting and harvesting equipment will be cleaned on site to prevent the dispersal of GM tubers. There will be no potato cultivation on the release area the year following the release. Potential volunteers will be monitored and removed according to conventional agricultural practice. During the release the trial site will be monitored at defined intervals.

Measures in place under current field trial practice will safeguard that all seed and plant material is properly managed, harvested, stored, transported or disposed of. The GM potato lines will be cultivated under conventional agricultural practices.

F. SUMMARY OF PLANNED FIELD TRIALS DESIGNED TO GAIN NEW DATA ON THE ENVIRONMENTAL AND HUMAN HEALTH IMPACT OF THE RELEASE (WHERE APPROPRIATE)

Not applicable.

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17-01-2011

Secretariaat
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O./ref.: WIV-ISP/41/BAC_2011_0059
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Compilation of comments of experts in charge of assessing the dossier B/BE/10/V2

Coordinator: Prof. P. Baret (UCL)
Experts: Kürt Demeulemeester (PCA-Beitem), Adinda De Schrijver (WIV-ISP), Patrick du Jardin (ULg-Gembloux Agro-BioTech), Jean Jacquemin (CRA-W Gembloux), Henri Maraite (UCL) and Michel Van Koninckxloo (HEP Hainaut-Condorcet)

SBB: Didier Breyer, Adinda De Schrijver, Martine Goossens, Philippe Herman, Katia Pauwels

INTRODUCTION

Dossier **B/BE/10/V2** concerns a notification of BASF Plant Science 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 3 November 2010 and concerns a field trial with a potato line genetically modified to be resistant to *Phytophtora* disease.

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 16 December 2010 to the notifier with a request to provide additional information. The comments highlighted in grey correspond to the questions addressed to the notifier.

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

Please note that questions on measures to be taken have not been sent to the notifier, as finally it is not up to the notifier which measures need to be implemented. These questions have been taken into account in the discussions of the Biosafety Advisory Council.

The answers of the notifier were received on 6 January 2011 by the Biosafety Advisory Council and evaluated by the experts.

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

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

Comment 1:

Variety P880 is considered as frequently mature seed producing. This can result in a lot of volunteer plants in the year(s) after the trial. Therefore, detailed assessment of berry formation during the trial should be done, in order to anticipate the risk of volunteers rising from true seed and to justify that only one year without volunteers is long enough for the post-trial monitoring.

Comment 2: see Q1

Recipient line P880: the breeding history should be described and the name of the backround cultivar or related cultivars with know agronomic characteristics should be mentioned. Indeed, self-crossing rates and seed set capacity depend on the cultivar and this information is relevant from a RA point of view. Page 5 of the dossier mentions that “the potato variety P880 is considered as frequently mature seed producing”, but this information is vague in the absence of further information on the genotype.

The parallel B/BE/10/V1 dossier mentions two *Solanum* species, in addition to *S. nigrum* and *S. dulcamara* : *S. trifolium* and *S. nitidibaccatum*, which are not mentioned by this B/BE/10/V2 dossier. This should be clarified (presence of the two species or not and outcrossing ability with cultivated potato).

Comment 2:

Minor information. Natural resistance to Phytophthora of the line P880 is not listed in the table “Properties”

Note coordinator/SBB: Not transmitted as not essential for risk assesment.

Comment 3: see Q1 & Q8

There is a discrepancy between point B.1 (f) mentioning frequent berry formation for variety P880, or B.4 (b) frequent production of mature seed and B.2(a) (i) stating that “berry development is rare”.
There is also a discrepancy between the statement B.4 (a) “Wind dissemination is considered to be marginal (OECD, 1997; Eastham and Sweet, 2002). “ and the precise statement of the later reference

on p. 35 (4.3): “Wind is considered a more important vector than insects in effecting pollination”. Bock et al. 2002 also state on p. 67 (3.3.2.1.) “Wind is considered a more important vector than insects in effecting cross-pollination.“
The statement « Field trials showed minimal dispersal of pollen beyond the immediate vicinity of potato fields (5m to 10m).(Bock et al., 2002) » is outdated by more recent trials of which the notifier should be aware. Petti et al. 2007 reported indeed gene flow in potatoes beyond an isolation distance of 20m.

2. INFORMATION RELATED TO THE GENETIC MODIFICATION

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

Comment: see Q2
For the sake of completeness and in the absence of a detailed description of the vector components in the dossier, the applicant is requested to to indicate whether the *bom* sequence for conjugational transfer is present in plasmid VCPMA16, as it is present in the pZP plasmid family from which it is derived. This conclusion is drawn from the reading of Hajdukiewicz et al 1994 describing the pZP family. If such is the case, the VCPMA16 plasmid map on page 8 of the dossier should be amended accordingly.

3. INFORMATION RELATED TO THE GENETICALLY MODIFIED PLANT

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

3.2. Information on the molecular characteristics of the final GMO

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

Comment:
The presence of the backbone sequence coding for the antibiotic resistance gene *aadA* was checked via PCR analyses and found to be absent in the GM potato lines. Even if the gene *aadA* would have been present, this would not have been a biosafety issue. Following the opinion of EFSA (2004), the *aadA* gene is allowed in field trial experiments.

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,...)

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

Comment: see Q9
References are missing on previous field trials. Are these the same as under D.13?

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

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

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

Comment: see Q10
The NBS-LRR resistance genes are very diverse and their ubiquitous occurrence in plants can not be regarded as an argument that the protein encoded by the transgene is not toxic or allergenic to humans and animals, in the absence of direct testing of the NBS-LRR protein considered. I thus disagree with the argumentation of the applicant, and the management and monitoring of the trial should be conducted in a way that the risk of any unintended consumption by humans and farm animals is eliminated. The proposed trial protocol provides sufficient security in this respect (see later).

Note coordinator/SBB: This is a statement of expert – not taken up as question as such, only as a note to applicant --> Q 10

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

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

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

3.11. Potential interactions with the abiotic environment

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

Comment 1: see Q3
The concentration of DNA used in the PCR protocol should be indicated.

Comment 2:
Are the protocols and documents demonstrating the efficacy of the detection techniques available for independent assays by the authority?

Note coordinator/SBB: Not relevant for risk assesment, related to monitoring.

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

Comment: see Q4
The last sentence is very brief. Can the notifier provide more precise data concerning for instance the occurrence of volunteer plants e.g. from true potato seed?

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: see Q5
The distance of 150 m to other potato plots is in the line of distances previously recommended. Nevertheless, recent data on bumblebee foraging (Wolf, S. & Moritz, R.F.A. 2008. Foraging distance in *Bombus terrestris* L. (Hymenoptera: Apidae. Apidologie 39: 419-427) reporting mean foraging distances of workers of 267 m (max. 800m) may raise concern about risk of spread beyond the 150 m foreseen in the trial. Kraus et al. 2009 are even reporting male flight distances up to 9.9 km!

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:
happens with the harvest of the non-modified surrounding potato plants? (cv. Bintje).

Comment 2:
The information especially point F4 are scanty and allow various interpretation, e.g. of “the tubers will be harvested thoroughly”. More precise guidelines could minimize the risk of volunteer development.

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: see Q11
The applicant mentions that “ as a safety measure an isolation distance of at least 10 m between the potato lines and commercial potato cultivation will be observed throughout the testing period”. However, the specific trial location seems to impose an isolation distance of 150 m. Ten-meter isolation distance means less than other international standards (see Petti et al., Environ. Biosafety Res. 6 (2007) 223-235 and ref. in the paper) and the applicant should guarantee that 150 meter will be the actual distance, resolving the ambiguity between the two statements. (NB : 150 meter is the distance indicated in the parallel dossier B/BE/10/V1.)

Comment 2:
The fact that incipient variety P880 produces fertile berries represent a greater risk of volunteers.
Mustonen et al. (2009) recommend “accepting only non-berry-producing GM (potato) cultivars for cultivation”. Petti et al. (2007) recommended that a two-tiered system be established in regard to establishing isolation distances for the experimental trial and commercial cultivation of GM potato in Ireland.

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

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

Comment
See comment for point 4.

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

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

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

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

Comment
As it is not the first trial with this material, a more detailed protocol of the agronomical, fungicide treatments could be asked in order to better evaluate the beneficial effect of the inserted new genes.

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

7.1. Precautions taken

Comment 1
The precautions taken (150 m isolation distance, and 4 rows of maize plants around the plot) are more than sufficient to avoid vertical gene flow by pollen. Connor & Dale (1996) summarised available data on cross-pollination, showing that no cross-pollination was detected at 20m. Petti *et al*. (2007) proposed a 30 m isolation distance for potato field trials, based on their data obtained with a high fertile Désirée as pollen donor and a male sterile pollen receptor. Hence an isolation distance of 150 m will be sufficient to avoid vertical gene flow by pollen. In addition, the 4 rows of maize planted around the plot will serve as a buffer and reduce the distance of pollen flow. The other measures taken to minimise and prevent gene dispersal are considered sufficient.

Comment 2
The time frame of the monitoring for volunteers should be precisely specified in order to allow independent inspection by the authority.

Comment Coordinator/SBB: Not relevant for risk assesment, related to monitoring.

7.2. Information on methods for post-release treatment of site

Comment 1: Demeulemeester
The site should be monitored also the second year after the trial, even when no volunteer plants are detected in the first year after the trial.

Comment Coordinator/SBB: Not relevant for risk assesment, related to monitoring.

Q : After plowing, tubers left on the field can be buried into the soil and stay there intact for more than one year. Those tubers can still become volunteer plants in the second succeeding crop after the trial, when they come to the surface by plowing the soil for the second time. Problems with volunteer plants in the second year after potato crop is know in practice, especially for some varieties, for example cv. Asterix.

Comment Coordinator/SBB: Not relevant for risk assesment, related to monitoring.

Additional comment from coordinator - See Q6::
It should be clarified by the notifier what he means with “conventional agriculture practice”.

Comment 2
See comment for Point 7.1.

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

Comment :
Haulm killing of the potato crop is advised. In this way release of the tubers from the stolons will be favoured and the risk of remaining tubers attached to the foliage will be minimised.

Comment 2: See Q7:
The disposal of the waste after the heat treatment is not specified.

Comment Coordinator/SBB: Not relevant for risk assesment, related to monitoring.

7.4 Information related to monitoring plans and the detection techniques

Comment
See comments for 7.1.

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

Comment
In case the trial should be ploughed under, prior application of systemic herbicide at full dose (e.g. ghyphosate) is recommended. This type of herbicides also migrates to the tubers where a rottening process is induced. This method is used by FAVV in the case conventional potato crops should by destroyed during the growing season.

Comment Coordinator/SBB: Not relevant for risk assesment, related to monitoring.

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?

References (not present in notification)

Conner, A.J. and Dale, P.J. (1996) Reconsideration of pollen dispersal data from field trials of transgenic potatoes. Theor. Appl. Genet. 92, 505-508.

EFSA (2004) Opinion of the Scientific Panel on GMOs on the use of antibiotic resistance genes as marker genes in GM plants. The EFSA Journal (2004) 48, 1-18.

Mustonen, L., Peltonen-Saino, P. & Pahkala, K. (2009) Risk assessment for volunteer and seedling GM potatoes in the northernmost European growing areas. Acta Agriculturae Scandinavica Section B – Soil and Plant Science, 59, 552-558.

Petti C, Meade C, Downes M and Mullins E. (2007) Facilitating co-existence by tracking gene dispersal in conventional potato systems with microsatellite markers. Environmental Biosafety Research 6: 223-235.