

## **APPLICATION FOR CONSENT TO RELEASE A GMO**

### **PART A2: DATA OR RESULTS FROM ANY PREVIOUS RELEASES OF THE GMO**

**Give information on data or results from any previous releases of this GMO by you either inside or outside the European Community [especially the results of monitoring and the effectiveness of any risk management procedures].**

One of the genotypes included in this application (i.e., Desiree potato plants carrying the *Rpi-vnt1.1* transgene) has been previously released in the UK as part of a successful field trial carried out between 2010 and 2012. None of the other transgenic lines included in this application (i.e., Maris Piper potatoes carrying *Rpi-amr3*, *Rpi-amr1e*, *Rpi-amr1k*, *Rpi-Smira1* or *Rpi-Smira3*) has been previously released.

The results of the previous *Rpi-vnt1.1* field trial have been reported in Jones et al (2014) and showed that this gene conferred effective resistance to the races of the late blight pathogen that circulated in the UK at the time of the trial. No unexpected effects on humans, animals or the environment were observed and thus all risk management procedures in place were deemed to have been effective. The field trial is currently in the post-trial monitoring phase; groundkeepers are still being observed in the plots planted in 2011 and 2012, although only 7 groundkeepers were found in the 2011 plots during 2015 and we expect this number to reduce significantly for 2016.

We plan to use these *Rpi-vnt1.1* transgenic Desiree plants as positive control in the field trial of the *Rpi-amr3*, *Rpi-amr1e*, *Rpi-amr1k*, *Rpi-Smira1* and *Rpi-Smira3* genes, if permission is granted.

### **PART A3: DETAILS OF PREVIOUS APPLICATIONS FOR RELEASE**

**Give details of any previous applications to release the GMO made to the Secretary of State under the 2002 Regulations or to another Member State under the Deliberate Release Directive 2001/18/EC.**

Permission for the previous *Rpi-vnt1.1* transgenic potato trial was granted by the British Department for Environment, Food and Rural Affairs under licence 10/R29/01. The field release ran for three years (2010 – 2012) during which no unexpected effects were observed. This field trial is currently in the post-trial monitoring phase.

None of the other transgenic lines included in this application (i.e., Maris Piper potatoes carrying *Rpi-amr3*, *Rpi-amr1e*, *Rpi-amr1k*, *Rpi-Smira1* or *Rpi-Smira3*) has been the subject of any previous application.

## PART A4: RISK ASSESSMENT AND A STATEMENT ON RISK EVALUATION

### SUMMARY

#### Environmental risks

Four hundred years of cultivation of the potato have established that the potato has limited ability to survive in UK environments except when cultivated. Plants generated from tubers are readily identifiable and easily eliminated either by hand pulling or use of herbicides. Potato plants are not invasive of natural habitats. The pollen of potato normally disperses less than 10 metres, is often infertile and potatoes cannot cross with other crop plants to produce hybrids. A major factor contributing to the lack of pollen dispersal is the fact that flowers of *Solanum* spp produce no nectar, so pollen is the only food reward offered. Consequently, they are not frequently visited by honeybees seeking nectar. In addition, the anthers of these plants require sonication by insects to release pollen, and thus the spectrum of pollinating insects is restricted. Bumblebees typically forage over 70–631 metres (Osborne et al, 1999), but pollen from one flower is usually deposited only across a limited number of flowers that are subsequently visited. This and factors such as residence time in one crop favours highly localized cross-pollination of plants near the pollen source (Cresswell et al, 2002). Estimates of the rates of cross-pollination under field conditions range from 0 to about 20% (Plaisted, 1980). Other studies have shown that the rates of cross-pollination are 2% at a distance of 3 metres from the crop, reducing to 0.017% at a distance of 10 metres (McPartlan and Dale, 1994).

Based on current knowledge, the overall risk to the environment from transgenic potatoes sited at least 20 metres from other plants with which it is cross-fertile is low to effectively zero. The resistance traits to be expressed are predicted to affect only the target pathogen, *Phytophthora infestans*. The expected environmental impact is negligible to effectively zero and will reduce the level of other agricultural inputs such as use of fungicides to control late blight in potato crops.

Any evaluation of biosafety of transgenic potato crops to animals must be set in the context that these plants are a natural hazard to a range of animals. Their tissues naturally contain steroidal glycoalkaloids such as  $\alpha$ -chaconine and  $\alpha$ -solanine that are potent neurotoxins, particularly if administered by an intraperitoneal route. Their levels in leaves are normally higher than safe levels accepted in tubers for food.

#### Human health risks

Resistance (*R*) genes of the NB-LRR class are not new to the human diet, being present in all plants consumed by both humans and animals. The model plant species *Arabidopsis thaliana* is known to possess approximately 200 *R* genes and *R* gene homologues (Meyers et al, 2003), while rice possesses approximately 500 (Zhou et al, 2004). Within the potato genome, a set of 438 NB-LRR-type genes has been predicted (Jupe et al, 2012), and further analysis showed that the doubled monohaploid reference potato genome encodes ~ 750 NB-LRR proteins (Jupe et al, 2013). *R* genes themselves are not toxic even to crop pathogens. They simply serve a recognition function, enabling plants to recognise specific molecules produced by the pathogens, resulting in the triggering of plant defence responses.

These plant defence responses are not specific to late blight resistance. They are triggered upon recognition of any plant pathogen.

The selectable marker gene *nptII* (or *aph(3')*-IIa) is expressed as an enzyme (aminoglycoside 3-phosphotransferase II or neomycin phosphotransferase II) that inactivates the antibiotics neomycin, kanamycin, geneticin (G418), and paromomycin by phosphorylation. The protein encoded by the gene has been shown to be bio-safe, non-toxic and poses no risk to human or animal health. Therefore, the characteristics of the transgenic protein NPTII involve no outstanding safety issues and derived products are no more likely to cause adverse effects on human and animal health than conventional potato (The EFSA Journal, 2006, 323: 1-20).

The marker gene *bar* is expressed as an enzyme (*N*-acetyltransferase) that acetylates the herbicide glufosinate (also known as phosphinothricin), causing its inactivation and detoxification (Thompson et al, 1987; De Block et al, 1987). No toxic or harmful effects on human or animal health have been described for the *bar* gene (Herouet et al, 2005; Wehrman et al, 1996; Wang et al, 2000). This gene has previously been used as plant selectable marker in transgenic lines that were released for field trials in the UK and transgenic events including the *bar* gene have been assessed by the EFSA GMO panel with no concerns being identified (The EFSA Journal, 2013,11(6): 3251).

Any evaluation of biosafety of transgenic potato crops to humans must be set in the context that these plants are a natural hazard as they naturally contain steroidal glycoalkaloids (see above). The total content of such glycoalkaloids in tubers of varieties to be used for food should not exceed 20 mg / 100 g fresh weight (Krits et al, 2007).

## RISK ASSESSMENT

### Conclusions on the Potential Environmental Impact from the Release or the Placing on the Market of GMOs

- i. **Likelihood of the genetically modified higher plant (GMHP) becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.**

Neither the *R* genes *Rpi-amr3*, *Rpi-amr1e*, *Rpi-amr1k*, *Rpi-Smira1*, *Rpi-Smira3* or *Rpi-vnt1.1* nor the kanamycin or glufosinate resistance genes confer characteristics to the GM potato that would increase the competitiveness of plants containing the genes in unmanaged ecosystems. Neither would the genes enable plants carrying them to out-compete plants of similar type for space. None of the transferred genes are anticipated to affect pollen production and fertility, seed dispersal or frost tolerance. Seeds and tubers, which might be spread outside cultivated fields, would have no competitive advantage in this environment. Potatoes are not persistent outside the agricultural environment and feral potato plants do not generally occur in the UK.

The advantage conferred by the resistance genes against the target organism *Phytophthora infestans* will be applicable only in the agricultural environment and only in those cases where no other plant protection measures against *P. infestans* are applied. In addition, the plants carrying *Rpi-Smira1*, *Rpi-Smira3* or *Rpi-vnt1.1* will not benefit from expression of the

*nptII* selectable marker since the antibiotics it confers resistance to are not used in agricultural environments. Finally, the plants carrying *Rpi-amr3*, *Rpi-amr1e* or *Rpi-amr1k* will be resistant to herbicides that have glufosinate as active ingredient. However, these plants can be readily eliminated with other herbicides such as glyphosate (present in Roundup) and glufosinate-containing herbicides won't be used in the context of this trial.

The introduced *R* genes and the kanamycin or glufosinate resistance genes are thus not anticipated to confer any intrinsic advantage compared to conventional potato varieties with respect to persistence in agricultural habitats or invasiveness in natural habitats.

To further minimise any risk, the following risk management measures will be applied: implementation of isolation distances of a minimum of 20 metres from any other potato plants not included in the trial and volunteer management to ensure effective control of volunteers emerging on the field and the immediate surroundings (the plot will be left fallow after potato harvest to enable easy identification and removal of groundkeepers). The overall impact is therefore considered negligible.

## ii. Any selective advantage or disadvantage conferred to the GMHP

The intended effect of the genetic modification described here is to improve the resistance of the recipient plants to *P. infestans*. Under *P. infestans* pressure resistant potatoes are therefore intended to have a selective advantage in comparison to untreated non-resistant conventional potatoes included in the trial. This advantage is only applicable in the agricultural environment and only in those cases where no other plant protection measures against *P. infestans* (such as fungicide treatments) are applied. Conventional agricultural practices as well as volunteer management will ensure effective control of volunteers emerging on the field and the immediate surroundings. Potato plants are never seen established outside the agricultural environment and resistance to *P. infestans* is not a characteristic that would enhance the invasiveness of potatoes.

The introduced kanamycin resistance trait (present in the plants carrying *Rpi-Smira1*, *Rpi-Smira3* or *Rpi-vnt1.1*) is used for selection of transgenic plants during tissue culture and confers improved tolerance to the antibiotics neomycin, kanamycin, geneticin (G418), and paromomycin. These antibiotics are not used in agriculture and hence will not confer any selective advantage to the transgenic plants. The *nptII* gene responsible for the resistance has been approved as safe for use by the European Food Safety Authority.

Plants carrying *Rpi-amr3*, *Rpi-amr1e* and *Rpi-amr1k* will also contain the *bar* gene which confers resistance to herbicides that have glufosinate as active ingredient. This trait will be used only for selection of transgenic plants during tissue culture. Plants carrying the *bar* gene can be readily eliminated with other herbicides such as glyphosate and glufosinate-containing herbicides will not be used in the field during the trial, so no selective advantage will be conferred to these plants. This gene has previously been used as plant selectable marker in transgenic lines that were released for field trials. This includes wheat and barley field trials in the UK (wheat released at John Innes Centre, Consent Date April 1997, and barley released at John Innes Centre in 1998-2000 and 2001-2003). Furthermore, transgenic events including the *bar* gene have been assessed by the EFSA GMO panel and no concerns were identified (The EFSA Journal, 2013, 11(6): 3251). Finally, crop cultivars that carry this gene are commercially available (Green and Owen 2011).

**iii. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.**

Genetic material can be transferred from conventional potatoes as well as genetically-modified potatoes to sexually compatible plants via pollen. Transfer via pollen to other species or wild relatives at or near the release site is very unlikely due to the absence of sexually compatible species. Therefore out-crossing to those species can be excluded. Transfer of genetic material via pollen to conventional potato varieties is possible, however the proposed risk management measures (e.g. isolation distance, monitoring and volunteer management) will prevent any unintended pollination. In the unlikely case that pollen is transferred to non-genetically modified potatoes, the consequences are negligible. No intrinsic selective advantage or disadvantage is being transferred to those potatoes (see point ii) and because potato plants are propagated vegetatively there is no significant risk of introduction of the GM traits into conventional potato material (true potato seed is not saved by growers).

**iv. Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids and pathogens (if applicable).**

The target organism of the introduced disease resistance genes is *Phytophthora infestans*. The intended effect of the genetic modification is to confer tolerance to *P. infestans*, thereby reducing the population in the trial plants. Under conventional agricultural practice *P. infestans* is also controlled by fungicide treatment of potato fields and thus the outcome of the interaction (i.e. a reduction in the population of *P. infestans*) is a desirable one and does not differ from the outcome of these other practices. The overall impact of *P. infestans* tolerant potatoes on target organisms is therefore considered comparable to the impact of fungicide applications on non-genetically modified potatoes conducted according to conventional agricultural practice.

**v. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.**

The resistance genes introduced into the genetically modified potatoes are of the NB-LRR class. Genes of this class recognise specific molecules produced by some plant pathogens (in this case *P. infestans*) and trigger a hypersensitive response, leading to plant cell necrosis, which limits the spread of the pathogen. Due to the specificity of the recognition no effects on other organisms than *P. infestans* are expected other than those that also apply to the interaction with non-genetically modified potatoes under conventional agricultural practice. Pathogens other than the particular races of *P. infestans* to which the introduced genes confer resistance, that are able to infect the non-transgenic plants grown as part of the trial will also be able to infect the transgenic plants. Due to a reduced need for fungal treatments, an increase in the populations of those non-target organisms that respond to

fungal treatments might be expected. Any effects on disease and susceptibility to pests other than *P. infestans* will be monitored during the release. The overall impact on non-target organisms is considered negligible.

**vi. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into direct contact with, or in the vicinity of the GMHP release(s).**

The genetically modified potatoes differ from conventional potato varieties in their tolerance to *P. infestans* conferred by the introduced resistance (*R*) genes. Potato already contains a large number of resistance genes of the same kind: within the potato genome, a set of over 400 NB-LRR-type genes has been predicted (Jupe et al, 2012), and ~750 were found using RenSeq methodology (Jupe et al, 2013). Included in this number are NB-LRR *R* genes that were originally introgressed from other wild potato species, namely *Solanum demissum*, during breeding efforts made during the 20<sup>th</sup> Century. None of the genes are known to exert any toxic or allergenic effects to human health. The *R* genes themselves are not toxic even to *P. infestans*. These *R* genes encode proteins that trigger a hypersensitive response upon recognition of the late blight pathogen, leading to plant cell necrosis. The introduced genes are expressed by their endogenous promoters, thus they are predicted to have extremely low levels of expression, comparable to those from other endogenous resistance genes. Due to the lack of any identified toxic effects of the NB-LRR class of *R* genes (and their protein products) we do not expect there to be any immediate or delayed effects on human health resulting from direct or indirect human interactions with the modified plants.

The introduced selection marker gene *nptII* (present in the plants carrying *Rpi-Smira1*, *Rpi-Smira3* or *Rpi-vnt1.1*) is expressed as the enzyme neomycin phosphotransferase. This selectable marker has been considered safe for use in this context by The European Food Safety Authority (see “Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants”, The EFSA Journal, 2009, 1034: 66-82).

Plants carrying *Rpi-amr3*, *Rpi-amr1e* and *Rpi-amr1k* will also contain the *bar* gene which is expressed as an enzyme (*N*-acetyltransferase) that acetylates the herbicide glufosinate (also known as phosphinothricin), causing its inactivation and detoxification (Thompson et al, 1987; De Block et al, 1987). No toxic or harmful effects on human or animal health have been described for the *bar* gene (Herouet et al, 2005; Wehrman et al, 1996; Wang et al, 2000). This gene has previously been used as plant selectable marker in transgenic lines that were released for field trials in the UK (wheat released at John Innes Centre, Consent Date April 1997, and barley released at John Innes Centre in 1998-2000 and 2001-2003). Transgenic events including the *bar* gene have been assessed by the EFSA GMO panel and no concerns were identified (The EFSA Journal, 2013, 11(6): 3251) and crop cultivars that carry this gene are commercially available (Green and Owen 2011).

In summary, none of the introduced genes encode for products that are known to be toxic to humans either by ingestion or by contact. In any case, the potato plants are not for human consumption and measures taken with regard to planting, harvest, storage and transportation of the plant material will minimize any contact to humans. Therefore the overall impact on human health is negligible.

**vii. Possible immediate and/or delayed effects on animal health and consequences for the food/feed chain resulting from consumption of the GMO and any products derived from it if it is intended to be used as animal feed.**

The GM potatoes will not be used for animal feed. Potatoes are not grazed on by animals due to the toxic nature of alkaloids in the green parts of the plant, which are features of non-transgenic potato plants. Measures to be taken during the proposed trial will in any case protect the trial against damage by wild animals (e.g. fences) and also ensure that potato seed stock and plant material are harvested, stored, transported or disposed of (e.g. cleaning of machinery, packaging) in such a way to prevent contact with animals. Therefore the overall impact on animal health is negligible.

**viii. 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).**

The resistance genes introduced into the genetically modified potatoes confer resistance to *Phytophthora infestans*, which is the target organism. The resistance genes encode receptors that will recognize specific elicitors injected by the pathogen into the plant cell. This recognition will, through a signalling network, trigger both local and systemic defence responses. The local response aims at trapping the pathogen in the cells by localized cell death thus stopping further penetration and spread. Based on this mechanism of response none of the newly expressed proteins are expected to be exuded from the plants to the soil. Thus no effects on biogeochemical processes are anticipated other than those which also apply to non-modified potato varieties under conventional agricultural practise. Due to a reduced need for fungal treatments an increase in the populations of other foliar pathogens and soil organisms might be expected. The overall impact on biogeochemical processes is negligible.

**ix. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.**

The small scale trial will be conducted according to conventional agricultural practice except for a reduction in fungicide treatments in order to evaluate the efficacy of the introduced resistance genes against *Phytophthora infestans*. Differences in the scale of fungicide treatments are also standard practice either in conventional or organic agriculture or in plant protection trials conducted according to applicable agricultural practice. Alterations in fungicide use are likely to have implications on organisms associated with the plants, either present in the soil or on the plant leaves, possibly increasing the populations of both foliar pathogens, other than *P. infestans*, and soil organisms. Therefore overall impact on the environment is negligible and is comparable to the effect of the cultivation of non-genetically modified potatoes with a potentially positive impact on soil and plant-associated microflora.

	<b>Step1: Potential hazards which may be caused by the characteristics of the novel plant</b>	<b>Step 2: Evaluation of how each hazard could be realised in the receiving environments</b>	<b>Step 3: Evaluation of the magnitude of harm caused by each hazard if realised</b>	<b>Step 4: Estimation of how likely/often each hazard will be realised as harm</b>	<b>Step 5: Modification of management strategies to obtain lowest possible risks from the deliberate release</b>	<b>Step 6: Overall estimate of risk of harm caused by the release for each hazard</b>
<b>a</b>	<b>Increased invasiveness in natural habitats or persistence in agricultural habitats.</b>	<i>Negligible.</i> The introduced traits do not confer intrinsic competitive abilities in natural or agricultural habitats. Conventional practice and volunteer management are applied.	<i>Negligible.</i> Neither the <i>R</i> genes nor the <i>nptII</i> or <i>bar</i> genes confer characteristics to the GM potato that add competitive abilities in unmanaged ecosystems or allow the plants to compete against plants of similar type for space. None of the characteristics transferred to the potato plants are anticipated to affect pollen production / fertility, seed dispersal or frost tolerance.	<i>Very unlikely.</i> Surviving, reproductive potato plants are rarely seen outside the field.	Conventional agricultural practice and volunteer management (monitoring for volunteers and removal/destruction of volunteers in the field, isolation distance, crop rotation).	Overall impact is negligible.
<b>b</b>	<b>Selective advantage; improved resistance to <i>P. infestans</i>.</b>	<i>Moderate.</i> The intended effect of the genetic modification is to improve the resistance to <i>P. infestans</i> , therefore a	<i>Likely.</i> The intended effect of the genetic modification is to improve the resistance to <i>P. infestans</i> . Thus under	The advantage is applicable only in the agricultural environment and only in those cases where no other plant protection measures against <i>P. infestans</i> are applied.	Conventional agricultural practice and volunteer management (monitoring for volunteers and	Overall impact is negligible.

		selective advantage is conferred in comparison to untreated non-resistant conventional potatoes.	<i>P. infestans</i> pressure resistant potatoes are intended to have a selective advantage in comparison to untreated non-resistant conventional potatoes in the agricultural environment.	Potato plants are rarely seen outside the field. Resistance to <i>P. infestans</i> is not the key determinant for potential invasiveness of potatoes.	removal/destruction of volunteers).	
<b>c</b>	<b>Selective advantage; resistance to certain antibiotics provided by the antibiotic selectable marker gene <i>nptII</i>. Acquisition of antibiotic resistance by certain other microorganisms.</b>	<i>Negligible</i> . The potato plant will not benefit from expression of this selectable marker as the antibiotics it confers resistance to are not used in agricultural environments. The <i>nptII</i> gene is widely distributed among microorganisms in the environment and it confers resistance to antibiotics that have no / minor use in medicine.	<i>Very unlikely</i> in all aspects.	The chance of a microbe acquiring the gene is negligible given a) the small number of plants in the trial and b) no ecological advantage would be conferred to soil microorganisms. In the very highly unlikely situation that such transfer occurs to microbes occurring in mammals there would be little harm. The antibiotics have only minor therapeutic relevance in human medicine and restricted use in veterinary medicine.	<i>None</i> . This marker has an over 20-year history of safe use in food crops.	Overall impact is negligible.
<b>d</b>	<b>Selective advantage; resistance to glufosinate-containing herbicides provided</b>	<i>Very unlikely</i> . Glufosinate-containing herbicides will not be used in the context of this field	<i>Negligible</i> . Plants containing the <i>bar</i> selectable marker can be readily eliminated by other effective	<i>Very unlikely</i> . Surviving, reproductive potato plants are rarely seen outside the field and plants containing the <i>bar</i> selectable marker can be	<i>None</i> . Glufosinate-containing herbicides will not be used in the context of this field trial.	Overall impact is negligible.

	<b>by the selectable marker gene <i>bar</i>.</b>	trial.	herbicides, such as glyphosate.	readily eliminated by other effective herbicides, such as glyphosate.		
<b>e</b>	<b>Selective advantage or disadvantage conferred to sexually compatible plant species</b>	<i>Negligible.</i> Potato is a vegetatively propagated crop and none of the traits confer an intrinsic selective advantage in the agricultural environment under conventional agricultural practice.	<i>Very unlikely.</i> Neither of the traits confers an intrinsic selective advantage in the agricultural environment under conventional agricultural practice. Pollen transfer to other cultivated potatoes is possible, but unlikely due to short distance of pollen flow. There are two wild <i>Solanum</i> species in the UK but their cross fertilisation with potato crops has not been recorded.	In the unlikely case that pollen is transferred to non-genetically modified potatoes, the consequences are negligible since potato is a vegetatively propagated crop. True potato seed is not saved by growers.	Conventional agricultural practice and volunteer management. Isolation distance to other potato crops.	Overall impact is negligible.
<b>f</b>	<b>Potential environmental impact due to interactions between the novel plant and target organism (<i>P. infestans</i>)</b>	<i>Low.</i> The intended effect of the transferred resistance genes is to reduce the infection and reproductive success of <i>P. infestans</i> , thereby reducing the local population of <i>P. infestans</i> . As <i>P. infestans</i> is a	<i>Very likely.</i> The intended effect of the genetic modification is to confer tolerance against the target organism <i>P. infestans</i> .	The intended effect is a reduced population of <i>P. infestans</i> in the potato field. However, this is acceptable and desired also under conventional agricultural practice and is usually achieved by fungicide-treatment of potato fields.	<i>None</i> but impact on <i>P. infestans</i> populations will be monitored as the main aim of the field trial.	Overall impact is negligible.

		damaging crop disease, this effect is beneficial.				
<b>g</b>	<b>Potential environmental impact due to interactions between the novel plant and non-target organisms</b>	<i>Negligible.</i> Other than carrying an extra resistance gene (in addition to the selectable marker genes previously described), the plants do not differ from non-genetically modified potatoes. Any effect is anticipated to be comparable to that of non-genetically modified potatoes under conventional agricultural practice.	<i>Very unlikely</i> due to the inherent specificity and mode of action of resistance genes.	Any effect on non-target organism due to the introduced trait of <i>P. infestans</i> tolerance is anticipated to be comparable to that of non-genetically modified potatoes under conventional agricultural practice. Due to a reduced need for anti-fungal treatments an increase in the populations of non-target organisms might be expected.	Monitoring plan including observations on disease and pest susceptibility, including any unintended or unexpected effects.	Overall impact is negligible.
<b>h</b>	<b>Potential effect on human or animal health due to the introduced resistance genes</b>	<i>Negligible.</i> Resistance genes of the NB-LRR class are not known to confer toxic or allergenic properties.	<i>Very unlikely.</i> Resistance genes of the NB-LRR class are not known to confer toxic or allergenic properties. The endogenous promoters used are predicted to drive expression of the introduced resistance genes at a very low level, no higher than that at which other	Material from the field trial is not intended for human/animal consumption.	Measures with regard to planting, harvest, storage and transportation minimize the contact to humans and animals.	Overall impact is negligible.

			resistance genes present in non-transgenic potatoes are expressed.			
<b>i</b>	<b>Potential effect on human or animal health due to the introduced <i>nptII</i> gene</b>	<i>Negligible.</i> The <i>nptII</i> gene is not known to confer toxic or allergenic properties. Antibiotics to which the gene confers resistance are not routinely used on humans and have a restricted use in veterinary medicine.	<i>Very unlikely.</i> The <i>nptII</i> gene is not known to confer toxic or allergenic properties. Antibiotics to which the gene confers resistance are not routinely used on humans and have a restricted use in veterinary medicine.	Material from the field trial is not intended for human/animal consumption.	Measures with regard to planting, harvest, storage and transportation minimize the contact with humans and animals.	Overall impact is negligible.
<b>j</b>	<b>Potential effect on human or animal health due to the introduced <i>bar</i> gene</b>	<i>Negligible.</i> No toxic or harmful effects on human or animal health have been described for the <i>bar</i> gene.	<i>Very unlikely.</i> No toxic or harmful effects on human or animal health have been described for the <i>bar</i> gene.	Material from the field trial is not intended for human/animal consumption.	Measures with regard to planting, harvest, storage and transportation minimize the contact with humans and animals.	Overall impact is negligible.
<b>k</b>	<b>Potential effects on biogeochemical processes (changes in soil decomposition of organic material)</b>	<i>Negligible.</i> None of the newly expressed proteins is expected to be exuded from the plants to the soil.	<i>Very unlikely.</i> Soil fertility is not expected to be affected any differently due to the cultivation of the genetically modified potato plants as compared to conventional potatoes. None of the newly expressed	<i>Negligible.</i> Any effect is expected to be comparable to that of non-genetically modified potatoes under conventional agricultural practice. Due to a reduced need for fungicide treatments, an increase in the populations of soil organisms might be expected.	<i>None.</i>	Overall impact is negligible.

			proteins is expected to be exuded from the plants to the soil.			
I	<b>Possible environmental impact due to changes in cultivation practice</b>	<i>Low.</i> Potential positive effects on the population of other foliar pathogens and soil organisms, due to a reduction in fungicide treatments.	<i>Likely.</i> Application of conventional agricultural practice will be as for a conventional, non-transgenic crop, other than a reduction in anti-fungal treatments against <i>P. infestans</i> .	Potential positive effects on the populations of foliar pathogens other than <i>P. infestans</i> also possible on soil organisms.	<i>None.</i>	Overall impact is negligible. Potentially there may be a positive impact on foliar and soil microflora.

**PART A5: ASSESSMENT OF COMMERCIAL OR CONFIDENTIALITY OF INFORMATION CONTAINED IN THIS APPLICATION.**

**Identify clearly any information that is considered to be commercially confidential. A clear justification for keeping information confidential must be given.**

Not applicable.

**PART A6: STATEMENT ON WHETHER DETAILED INFORMATION ON THE DESCRIPTION OF THE GMO AND THE PURPOSE OF RELEASE HAS BEEN PUBLISHED**

**Make a clear statement on whether a detailed description of the GMO and the purpose of the release have been published, and the bibliographic reference for any information so published.**

**This is intended to assist with the protection of the applicant's intellectual property rights, which may be affected by the prior publication of certain detailed information, e.g. by its inclusion on the public register.**

Research detailing the production of the plants containing the resistance gene *Rpi-vnt1.1* has been published (Foster et al, 2009; Pel et al, 2009). In addition, the results of a previous *Rpi-vnt1.1* field trial have been reported in Jones et al (2014). The identification and characterization of the *Rpi-amr3* resistance gene is described in Witek et al (2016). The identification and characterization of *Rpi-amr1e*, *Rpi-amr1k*, *Rpi-Smira1* and *Rpi-Smira3* will be the subject of future manuscripts. This information has also been discussed at scientific conferences and lectures to members of the public.

## REFERENCES

- Cresswell JE, Osborne JL, and Bell SA (2002) A model of pollinator-mediated gene flow between plant populations with numerical solutions for Bumble bees pollinating oilseed rape. *Oikos* 98: 375–384.
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