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Preparation of the opinion

The Norwegian Scientific Committee for Food and Environment (Vitenskapskomiteen for mat og miljø, VKM) appointed a project group to draft the opinion. The project group consisted of 5 VKM members, 1 external expert and 2 from the VKM staff. An interdisciplinary VKM approval group appointed specifically for the assignment, assessed, and approved the final opinion.

Authors of the opinion

The authors have contributed to the opinion in a way that fulfils the authorship principles of VKM (VKM, 2019). The principles reflect the collaborative nature of the work, and the authors have contributed as members of the project group or the interdisciplinary VKM approval group, appointed specifically for the assignment.

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Expertise of VKM experts

Individuals working for VKM, either as appointed members of the Committee or as external experts, do this by virtue of their scientific expertise, not as representatives for their employers or third-party interests. The provisions on impartiality in the Norwegian Public Administration Act apply to all work carried out by VKM.

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Summary

Upon a request from The Norwegian Environment Agency, VKM has assessed potential risks to the environment from genetically modified (GM) late blight resistant potato intended for cultivation in small scale field trials (100 m^2) over several seasons in Norway.

Late blight is the most severe disease affecting potato and tomato plants in Norway, and is caused by the pathogen *Phytophthora infestans,* a fungus-like microorganism. Increased resistance of the GM potato to the pathogen is enabled by expression of three genes acquired from wild potato relatives (*Solanum* spp.). The GM potato is also made resistant to a potato virus (PVY), as well as certain herbicides that were used for selection purposes during plant development.

The application is presented by the Norwegian Institute of Bioeconomy Research (NIBIO) and covers two GM potato breeding lines (SLJ25587_11 and SLJ25587_49) developed by the Sainsbury Laboratory, Norwich, England. The lines were generated from two independent T-DNA transformation events using an *Agrobacterium*-mediated transfer technique.

VKM has assessed risks to the environment, including any effects on human and/or animal health, which may arise from the field trial. The environmental risk assessment (ERA) was structured according to EFSA guidance and included molecular characterisation of the GM potato, effects on the environment, and non-food/feed effects on human and animal health. The specific areas of concern included spread and survival of the GM potato outside of the field area, plant-to-plant gene flow, plant-to-microorganism gene flow, effects on specific potato pathogen target organisms (*Phytophthora infestans* and PVY), and effects on non-target organisms. The assessment also included an evaluation of the risk-reducing measures proposed in the application.

VKM concludes that the applicant's documentation on molecular characterisation is sufficient to demonstrate the presence of the intended target genes (T-DNA) as well as the absence of vector backbone elements in the two GM potato lines intended for use in the field trials. The insertion sites in the plant genome have not been described, but this is not considered critical for the evaluation of the planned field trial.

Available scientific literature suggests that cultivated potato is a biologically contained species in Norway with the following characteristics: plants do not persist or invade natural habitats and have limited capacity of vertical gene transfer including outcrossing with cultivated or wild *Solanum* species. The likelihood of persistence and gene transfer from the GM potato is hence also considered very low as the introduced traits are not considered to affect these characteristics. A specific hazard has not been identified for these characteristics in relation to the GM potato. VKM therefore concludes that the risk of adverse effects from persistence or plant-to-plant gene transfer from the GM potatoes is low.

VKM has not identified specific hazards from horizontal transfer of the inserted genes in the GM potatoes to microorganisms, and as these are derived from *Solanum* spp., microorganisms in the field area might already be naturally exposed to similar genes from local flora. Horizontal gene transfer is also considered very unlikely given that the T-DNA consists of plant derived genes with plant promoters. VKM therefore concludes that the risk of adverse effects from horizontal gene transfer from the GM potatoes is low.

No indications of an increase in toxicity or allergenic potential of the GM potatoes have been identified compared to conventional non-GM potatoes. The target organisms are sufficiently defined, and potential adverse effects on non-target organisms are not expected from the novel traits expressed by the GM potato. As a specific hazard with a defined likelihood has not been identified, VKM concludes there is a low risk of adverse effects from these areas of concern.

VKM concludes that the management proposed for the field trial is sufficient to contain the GM plants within the trial site for the duration of the experiment, which may include repeated planting over several seasons, and that the proposed measures for monitoring, removing, and disposal of GM material, as well as the follow up period of the site, is adequate. The limited field trial area, with a maximum of 200 plants/year, limited invasive and hybridizing potential of potatoes, and low survivability beyond a growing season, further mitigates potential risks.

Sammendrag

På forespørsel fra Miljødirektoratet har VKM vurdert mulig miljørisiko ved dyrking av genmodifisert (GM) potet med resistens mot tørråte til bruk i feltforsøk (100 m²) over flere sesonger i Norge.

Tørråte er den alvorligste sykdommen som rammer potet- og tomatplanter i Norge, og er forårsaket av patogenet *Phytophthora infestans*, en sopplignende mikroorganisme. Økt resistens hos GM-poteten mot *P. infestans* skyldes uttrykk av tre gener hentet fra andre viltvoksende *Solanum*-arter. GM-poteten er også gjort resistent mot et potetvirus (PVY), samt tolerant for enkelte ugressmidler brukt til seleksjonsformål under utviklingen av poteten.

Søknaden er innsendt av Norsk institutt for bioøkonomi (NIBIO) og omfatter to GM-potetlinjer (SLJ25587_11 og SLJ25587_49) utviklet av The Sainsbury Laboratory (TSL) i England. Linjene er generert ut ifra to uavhengige genmodifiseringer hvor ønskede gener (T-DNA) ble overført ved hjelp av en jordbakterie, *Agrobacterium* sp.

VKM har utført en risikovurdering strukturert etter EFSAs veiledning for miljørisikovurdering av GM-planter, som inkluderer en vurdering av molekylær karakterisering, miljøeffekter og mulige helseeffekter etter eksponering hos mennesker og/eller dyr som ikke omfatter bruk av GM-potetene til mat eller fôr. Mer spesifikt ble GM-potetens evne til spredning og overlevelse i miljøet vurdert, samt overføring av gener til andre planter, overføring av gener til mikroorganismer, effekter på målorganismer og effekter på ikke-målorganismer. Vurderingen inkluderte også en evaluering av risikoreduserende tiltak foreslått i søknaden.

VKM konkluderer med at søkers dokumentasjon av molekylær karakterisering er tilstrekkelig til å indikere tilstedeværelse av de ønskede resistensgenene (T-DNA) i de to aktuelle GM-potetlinjene, samt fraværet av uønskede gener (vektorelementer). Hvor genene er satt inn i genomet til GM-potetlinjene er ikke beskrevet i søknaden, men VKM anser ikke informasjonen som nødvendig for omsøkt feltforsøk.

Tilgjengelig vitenskapelig litteratur tilsier at potet er en biologisk avgrenset art i Norge uten evne til overlevelse og spredning utenfor dyrkede områder over tid. Potet har begrenset evne til å krysse seg med både dyrkede poteter og andre *Solanum*-arter (vertikal genoverføring). Sannsynligheten for persistens i miljøet og vertikal genoverføring til andre planter anses derfor som svært lav også for GM-poteten ettersom de introduserte genene ikke påvirker disse egenskapene. VKM konkluderer derfor med at risikoen for persistens og plante-til-plante-genoverføring fra GM-potetene er lav.

VKM har ikke identifisert spesifikke farer ved en eventuell overføring av de introduserte genene i GM-potetene til mikroorganismer (horisontal genoverføring), og ettersom disse genene kommer fra *Solanum*-arter er det mulig mikroorganismer i feltforsøksområdet allerede eksponeres for liknende gener fra lokal flora. Sannsynligheten for at horisontal genoverføring skal skje anses også som svært lav, ettersom T-DNAet består av gener med promotorer tilpasset planter og ikke mikroorganismer. VKM konkluderer dermed at risikoen for negative effekter som følge av horisontal genoverføring fra GM-potetene er lav.

Det er ikke avdekket noe som tilsier økt toksisitet eller allergent potensiale ved GM-potetene sammenlignet med konvensjonelle poteter. Målorganismene er tilstrekkelig definerte, og

negative effekter på ikke-målorganismer forventes ikke ut fra de nye egenskapene til GM-poteten. Ettersom det ikke er identifisert en spesifikk fare med en definert sannsynlighet, konkluderer VKM med at det er lav risiko for negative effekter både når det gjelder helserisiko, målorganismer og ikke-målorganismer.

VKM konkluderer med at den planlagte gjennomføringen av feltforsøket er tilstrekkelig for å unngå spredning av GM-plantene, og at foreslått overvåking, fjerning og destruering av GM-materialet er dekkende. Dette inkluderer også muligheten for gjentatte plantinger over flere sesonger. Det begrensede feltforsøksområdet med maksimalt 200 planter per år, et begrenset potensial for spredning og hybridisering, samt lav overlevelsesevne utover vekstsesongen, reduserer ytterligere eventuell risiko ved utsettingen.

Abbreviations and glossary

Abbreviations

DNA	Deoxyribonucleic acid
EEA	European Economic Area
EFSA	European Food Safety Authority
ERA	Environmental Risk Assessment
GM	Genetically modified
GMO	Genetically modified organism
HGT	Horizontal gene transfer
NIBIO	Norwegian Institute of Bioeconomy Research
NTO	Non-target organism
PCR	Polymerase chain reaction
T-DNA	Transfer DNA
TO	Target organism

Glossary

Agrobacterium-mediated gene transfer	*Agrobacterium tumefaciens* is used as the delivery vehicle. The process uses *Agrobacterium* to transfer a gene of interest into the plant cells, generating recombinant plants.
Case-by-case approach	An approach that allows case-specific assessments to be made and data requirement to depend on the context. The case-specific assessments relate to all aspects regarding the organism, e.g. species, modification/edit, trait, environment etc.
Comparator	The non-modified conventional counterpart used as control to detect characteristic differences due to the modification.
Genetic modification	The process of inserting novel DNA/genes from the same or foreign species or deleting genes. Common to all is the use of recombinant DNA technology.
Herbicide	A chemical or other substance that is toxic to plants, used to destroy unwanted vegetation, e.g. weeds on agricultural land.
Plasmid	A small, extrachromosomal DNA molecule within a cell that is physically separated from chromosomal DNA

	and can replicate independently. Most commonly found in bacteria and archaea. Plasmids often carry useful genes for the organism, such as antibiotic resistance. Artificial plasmids are widely used as vectors in molecular cloning, serving to drive the replication of recombinant DNA sequences within host organisms. In the laboratory, plasmids may be introduced into a cell via transformation.
Replicon	A replicon is a region of DNA or RNA that is replicated from a single origin of replication. It is a discrete unit of the genome that includes the origin of replication and the DNA sequence that is replicated from that origin. Plasmids often function as single replicons.
T-DNA	Part of an *Agrobacterium* plasmid that is transferred to the infected plant. DNA to be intentionally transferred to the plant is placed between specific right (RB) and left border (LB) sequences.
Vector	A vehicle, often a virus or a plasmid carrying desired DNA into a host cell and can also assist in multiplying or expressing the insert.
Volunteers	Plants not intentionally grown or cultivated, but self-sown plants from seeds or crop plants in the same area.

Background

The Norwegian Environment Agency has received an application for the deliberate release of genetically modified potatoes in a field trial in accordance with the Gene Technology Act and has commissioned VKM to assess health and environmental risk of the deliberate release of GMO into the environment.

The Agency received the application on 03.05.2024 from the Norwegian Institute of Bioeconomy Research (NIBIO). VKM received a formal letter of the assignment on 08.05.2024. The assignment letter, elaboration of the assignment with terms of reference and a timeline for the risk assessment can be found in Appendix I.

Terms of reference

The Norwegian Environment Agency has asked VKM to assess:

- Whether the information in the present application is sufficient to assess environmental risk, or whether there is need for more information
- Risk to the environment, including any effects on human and/or animal health, which may arise from the field trial

The risk assessment must include an assessment of, among other things, but not limited to:

- Molecular characterisation of the genetic modification and the genetically modified organism
- Effects on the environment, including, but not limited to:
    - Risk of spread and survival of the GMO in the environment and possible consequences of this
    - Risk of plant-to-plant gene flow
    - Risk of plant-to-microorganism gene flow
    - Effects on target organisms
    - Effects on non-target organisms
- Any adverse effects on human health, as a result of changes caused by the genetic modification, to those in contact with the GMO (does not apply to assessment of the GMO as food).
- Any adverse effects on animal health as a result of changes caused by the genetic modification to animals in contact with the GMO (does not apply to assessment of the GMO as feed).
- Assessment of the risk-reducing measures proposed in the application.

Introduction

The Norwegian Environment Agency has requested VKM to assess potential risks to the environment related to an application for a field trial with a genetically modified (GM) late blight resistant potato. The application is submitted by the Norwegian Institute of Bioeconomy Research (NIBIO).

Late blight is the most severe disease affecting potato and tomato plants in Norway, and is caused by the pathogen *Phytophthora infestans,* a fungus-like microorganism. Increased resistance of the GM potato to the pathogen is achieved by expression of three genes acquired from wild potato relatives (*Solanum* spp.). The GM potato is also made resistant to a potato virus, as well as having increased tolerance to certain herbicides that were used for selection purposes during plant development. The application covers two GM potato breeding lines (named SLJ25587_11 and SLJ25587_49) resulting from two independent T-DNA transformation events. The GM potatoes are to be planted over three seasons at a designated area of 100 m^2 together with other potato cultivars, some of which are naturally resistant and some susceptible to late blight infection. The GM potato is not intended for large-scale cultivation in Norway. The purpose of the field trial is to test the GM plants resistance capacity against the various naturally occurring strains of *P. infestans* in Norwegian soil. The number of GM plants pr. season will not exceed 200, and both planting, harvesting, and post-trial removal of volunteers will be done manually (not using machinery). All GM plant material will ultimately be destroyed. To ensure sufficient infection pressure, artificial inoculation with a mixture of isolates covering the current genetic variation that exists within the Norwegian *P. infestans* population may also be included in the trials. The trial site will be monitored for the duration of the experiment, and for two years following the last cultivation period, to ensure that no GM plant material persists or propagates after the trial has ended. All information relating to the application, including scientific data from the developer was made available to VKM by the applicant via the Norwegian Environment Agency. A project group consisting of 5 VKM members, 1 external expert and 2 VKM staff members, has assessed the application and performed the risk assessment.

The risk assessment follows a semi-quantitative approach in which the hazard and likelihood is determined by the project experts within preset categories (as described in Methodology and data). Together these categories define the level of risk either as low, medium, potentially high, or high. The approach is followed for the various areas of concern throughout the risk assessment.

An interdisciplinary approval group appointed specifically for the assignment reviewed and approved the final risk assessment.

Methodology and data

Methodology for the environmental risk assessment

VKM has used a semi-quantitative approach for the environmental risk assessment. The overall risk is defined as the product of the hazard (magnitude of the consequences of the event) and the likelihood that the event will occur, as assessed by the project-group experts. The resulting risk can be described, structured and presented as shown in Figure 1.

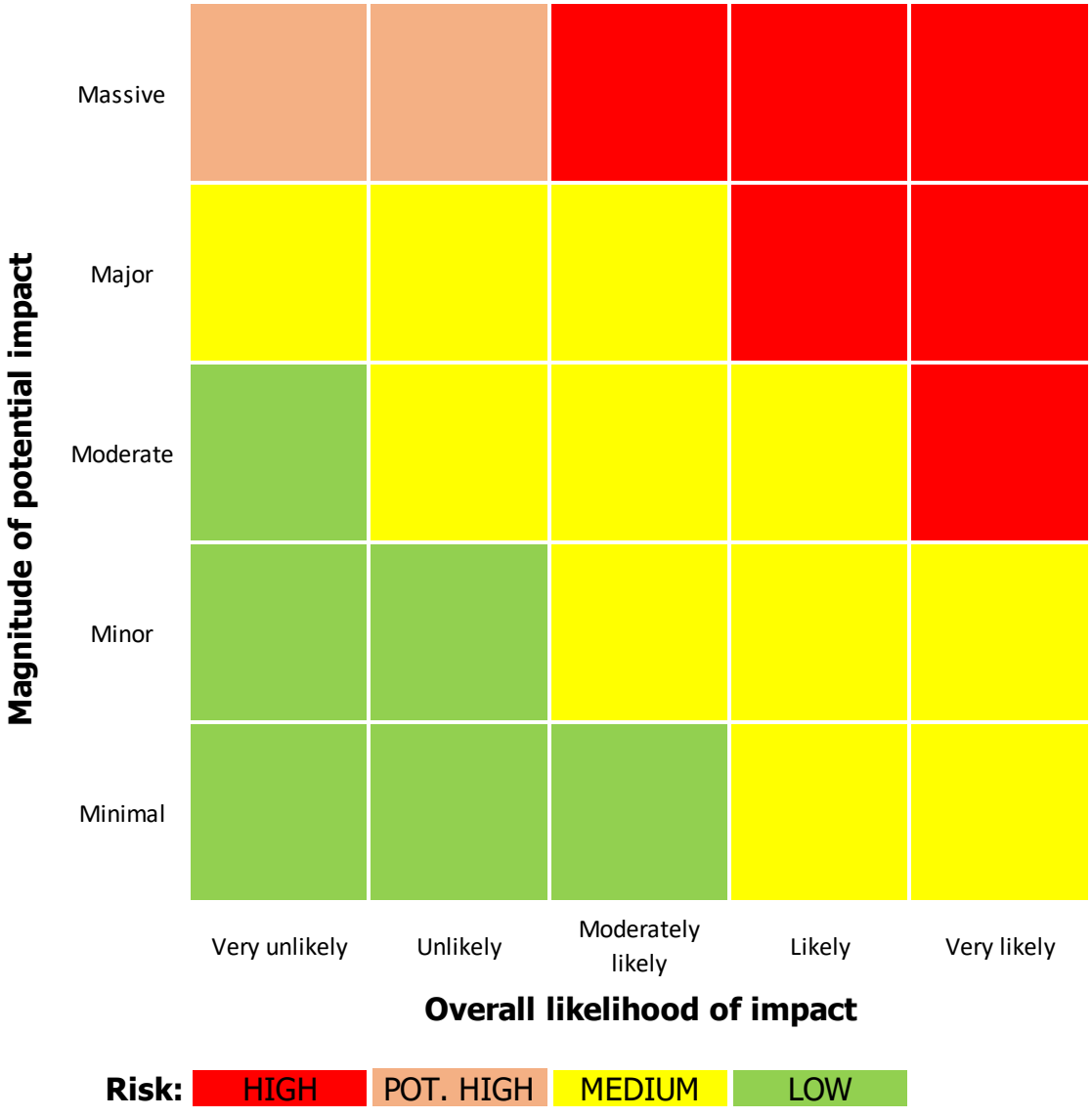

Figure 1. The conclusion of the risk assessment (low, moderate, potentially high, or high) is based on likelihood of occurrence (the overall likelihood of the impact) and the hazard identified (magnitude of the potential consequences of that impact) for the various areas of concern.

Tables 1-3 shows ratings used to describe the likelihood, the impacts and the uncertainty considered in the environmental risk assessments for the field trial of GM potato. The tables are presented at the general level and based on EFSA, 2018 Guidance on uncertainty analysis in scientific assessments, with some modifications.

Table 1. Ratings used for the assessment of the hazard (magnitude of the impact) on the areas of concern as described in the environmental risk assessment.

Rating	Descriptors
Minimal	No known impact
Minor	Potential impact
Moderate	Local impact
Major	Widespread impact
Massive	Widespread, long-term impact

Table 2. Ratings used for the likelihood of impact on the areas of concern as described in the environmental risk assessment.

Rating	Descriptors
Very unlikely	Negative consequences expected to occur with a likelihood of 0-5%
Unlikely	Negative consequences expected to occur with a likelihood of 5-10%
Moderately likely	Negative consequences expected to occur with a likelihood of 10-50%
Likely	Negative consequences expected to occur with a likelihood of 50-75%
Very likely	Negative consequences expected to occur with a likelihood of 75-100%

Table 3. Ratings used for describing the level of uncertainty

Rating	Descriptors
High	Available information on the topic is limited, and mostly expert judgements are used.
Medium	Some published information exists on the topic, but expert judgements are still used.
Low	There is sufficient published information, and expert judgements are in concurrence.

Data and information gathering

Key data used in the risk assessment of the two GM late blight-resistant lines (SLJ25587_11 and SLJ25587_49) of the potato cultivar Charlotte, was the scientific documentation submitted by the applicant and forwarded to VKM by the Norwegian Environment agency.

Additional documentation supporting the risk assessment included previous risk assessments of GM potatoes by VKM (VKM 2011a, VKM 2011b), an assessment by VKM on measures for co-existence of GM and conventional cultivars (VKM 2006), and EFSA guidance documents.

Literature search and selection

Beyond the documentation provided by the applicant, additional references used in the report were acquired through individual searches made by project members. References to any literature used have been inserted where appropriate in the different chapters of the report. E.g. in chapter 2, searches in «Google scholar» with search words including «*Phytophthora infestans,* potato, Norway and late blight» etc., were used to identify relevant literature, in addition to other databases and search strategies when needed.

Risk assessment

1 Molecular characterisation

Molecular characterisation is necessary to provide insight into the genetic material introduced into the genome of GM plants and lays ground for parts of the environmental risk assessment as outlined in the EFSAs Guidance for environmental risk assessment of genetically modified plants (EFSA 2010). The molecular characterisation provides information on e.g., transformation method, the structure and expression of insert(s), and description and stability of new trait(s).

1.1 Information relating to the GM plant

Potato (*Solanum tuberosum* L.) is an important clonally propagated crop, being the third most cultivated food crop globally. It is a staple food in Norway and essential for Norwegian food security. There are no known wild relatives growing in Norway that could successfully hybridise with the modified potato. Potatoes reproduce via vegetative tubers; however, these are frost sensitive and will not survive temperatures below -3°C (Mustonen et al., 2009). The potato plants to be tested in field trials are two breeding lines of the potato cultivar Charlotte (GERMICOPA), that have been genetically modified to resist infection by various strains of the late blight pathogen *Phytophthora infestans* (*P. infestans*), to resist potato virus Y infections, and to have increased tolerance to chlorsulfuron herbicides. The aim of the field trial is to investigate the effectiveness of the introduced resistance genes to prevent infection caused by *P. infestans* when cultivated in Norway.

1.2 Description of the trait(s) and characteristics that have been introduced or modified

The GM potato plants were transformed with the plasmid SLJ25587 containing a T-DNA region including the three genes *Rpi-amr3*, *Rpi-amr1*, and *Rpi-vnt1.1*, which are expected to provide resistance to various isolates of *P. infestans*. The insertion of these three genes renders the cultivated potatoes more efficient in recognizing infection by specific pathogens, thereby triggering a plant defensive reaction and necrosis induction at the site of infection, preventing further disease progression. Stacking of the three different *Rpi* genes was done to enhance the durability and effectiveness of the resistance. The three *Rpi* genes are inserted together with their native promotor/regulatory sequences. The T-DNA region inserted into the potato plant genome also contains two additional genes derived from other species of the *Solanum* genus.

The *Rysto* gene from *Solanum stoloniferum* was included to confer resistance to Potato Virus Y (PVY). PVY is a major aphid-transmitted virus of importance also in Norway.

The *CSR* gene from *Solanum lycopersicum* was included to provide tolerance to certain herbicides (sulfonylureas and imidazolinones). This trait was used for *in vitro* selection of transformed plant cells during tissue culture. No other changes in sensitivity to conventional herbicides are expected from the inserted T-DNA region.

1.3 Information on the nature and source of nucleic acid sequences and/or genes intended for insertion, and use of vectors

The applicant describes the various elements in the plasmid vector that contain the T-DNA intended for insertion into the plant genome: The plasmid SLJ25587 was assembled based on pICSL32281_LacZ (Werner et al., 2012; Engler et al., 2014) and commercially available Golden Gate vector technology. The resultant vector contains the *nptII* gene (for bacterial selection) in its backbone and the *ipt* gene (for counter-selection of plants with vector backbone integration (Richael et al., 2008)). It also carries sequences that function as bacterial origins of replication of the plasmids BR322 and RiA4.

The orientation of the T-DNA boundary/border sequences in the vector means that DNA integrated between the borders can be transferred to the plants through *Agrobacterium*-mediated gene transfer. Table 4. lists genetic elements in the vector backbone of pICSL32281_LacZ.

Table 4. Genetic elements in the backbone of the vector pICSL32281_LacZ.

Abbreviation	Name & Function	Size (bp)	Origin
LB	Left border of T-DNA from a nopaline-type Ti plasmid.	29	*Agrobacterium tumefaciens*
RBO	Right border of T-DNA from a nopaline-type Ti plasmid (with overdrive sequence).	139	*Agrobacterium tumefaciens*
ipt	*Isopentenyl transferase (ipt)* gene.	1640	*Agrobacterium tumefaciens*
p-*bla*	Promoter region of the *beta-lactamase (bla)* gene. Drives the expression of the bacterial selectable marker gene (*nptII)*. Cloned from the pUC19 vector.	108	*Escherichia coli*
nptII	Coding region of the *neomycin phosphotransferase II* (*nptII*) gene.	795	*Escherichia coli*
pBR322 Replicon	Fragment of the plasmid BR325 cloning vector containing the moderate-copy-number replicon pBR322. Functions as origin of replication in *Escherichia coli*.	1863	*Escherichia coli*
pRiA4 Replicon	Plasmid RiA4 replicator region. Functions as origin of replication in *Agrobacterium tumefaciens*.	4604	*Agrobacterium rhizogenes*

The genes intended for transfer into the potato plant genome are those to be inserted/cloned within the left border (LB) and right border (RB) sequences of the T-DNA present in the vector.

According to the applicant, the T-DNA of plasmid SLJ25587 for integration contains the following genetic elements (Table 5):

- Plant selectable marker: a mutated tomato acetolactate synthase (*ALS/CSR*) gene conferring tolerance to the herbicide chlorsulfuron (CS)used for *in vitro* selection of recombinant lines. It is regulated by its native promoter and is located next to the vector's LB.
- An extra LB sequence from an *Agrobacterium tumefaciens* Ti-plasmid inserted between the ALS/CSR gene and the vector LB to reduce the risk of backbone integration during T-DNA transfer.
- A stack of the three late blight resistance (R) genes: *Rpi-vnt1.1* (*Solanum venturii*), *Rpi-amr3* (*Solanum americanum*), *Rpi-amr1* (*Solanum americanum*). These three genes are plant resistance (R) genes that encode coiled-coil nucleotide-binding site leucine-rich repeat (CC-NB-LRR) proteins which confer resistance to a large range of isolates of the late blight pathogen *Phytophthora infestans* (Witek et al., 2021). The expression of these genes is under the control of endogenous regulatory sequences.
- The *Rysto* gene from *Solanum stoloniferum*, which confers resistance to Potato Virus Y (PVY) and related viruses. It encodes a nucleotide-binding leucine-rich repeat (NLR) protein with an N-terminal Toll/Interleukin-1 Receptor (TIR) domain. The expression of this gene is under control of its own regulatory elements.

Table 5. Genetic elements in T-DNAs.

Elements in T-DNA	Name & Function	Size (bp)	Origin
Extra LB	Extra left border sequence derived from an octopine-type Ti plasmid	25	*Agrobacterium tumefaciens*
p-*CSR*	*Acetolactate synthase / chlorsulfuron resistance* gene (*ALS/CS*^{R})	3751	*Solanum lycopersicum*
Rpi-vnt1.1	*Rpi-vnt1.1* gene	3999	*Solanum venturii*
Rpi-amr3	Domesticated *Rpi-amr3* gene	5352	*Solanum americanum*
Rpi-amr1	Domesticated *Rpi-amr1* gene	7201	*Solanum americanum*
Rysto	*Rysto* gene	6790	*Solanum stoloniferum*
End-Linker	Linker sequence required for Golden Gate cloning	36	Synthetic

1.4 Techniques used for the genetic modification

The GM potato lines were developed via *Agrobacterium tumefaciens* (strain AGL1) -mediated gene transfer and transformation of cells from the potato cultivar Charlotte (GERMICOPA). An extra LB sequence from an *A. tumefaciens* Ti-plasmid was inserted between the ALS/CSR gene and the vector LB to reduce the risk of vector backbone integration during T-DNA transfer. The herbicide chlorsulfuron was used to select transformed shoots regenerated from transfected callous tissue, i.e., shoots carrying the inserted T-DNA including the herbicide resistance gene. All GM plants were treated with the antibiotics timentin and cefotaxime to kill any remaining *Agrobacterium* cells

1.5 Type of intended modification(s)

The type of intended modification is one or more genomic integrations of a full-length T-DNA fragment from the plasmid SLJ25587 without insertion of the vector backbone, providing the following functional traits: 1) tolerance to the herbicide chlorsulfuron (CS); 2) late blight resistance; 3) resistance to Potato Virus Y (PVY) and related viruses.

1.6 Information on the sequences actually inserted/deleted or altered

The applicant has not provided scientific data that can confirm the number of complete or potentially partial insertions of T-DNA, nor the genomic locations of the insertions in the transformed potato lines SLJ25587_11 and SLJ25587_49. The applicant has not indicated the ploidy of the GM potato lines, and VKM assumes they are tetraploid. In a statement by the developer, forwarded by NIBIO, it is claimed that all transformed lines are single-copy events, but also stated that they do not have insertion site data for the specific lines.

To support the claim that the transformed potato lines are expected to be single insertion events, the applicant/developer points to the RiA4 replicon in plasmid SLJ25587, a low-copy origin of replication from *Agrobacterium rhizogenes*, which according to the applicant/developer typically results in low numbers of T-DNA inserts, usually 1–2 inserts per plant (ref application Appendix 1, page 6, Table 3). In line with this, plants transformed with constructs based on the pICSL32281_LacZ vector are expected to harbour between 1 and 2 inserts.

The applicant has provided molecular characterisation data for several of the GM potato lines (Charlotte SLJ25587) as gel bands after electrophoresis of PCR products, of which lines 11 and 49 (designated SLJ25587_11 and SLJ25587_49) are confirmed as the field trial candidates that will be used in Norway.

The applicant concludes that the PCR analyses show that these two lines contain the intended genes of interest, i.e., the three *P. infestans* resistance genes *Rpi-vnt1.1, Rpi-amr3, Rpi-amr1*; the Potato Virus Y (PVY) resistance gene *Rysto*, and the acetolactate synthase/chlorsulfuron resistance gene (*ALS/CSR*). A possible minor exception noted by VKM is that a weak PCR amplification in one of the PCR analyses (targeting the junction between the *Rpi-amr1* gene and *Rysto* gene) indicates a possible truncation of the T-DNA around the *Rysto* gene in line SLJ25587_11. This gene is located at the end of the T-DNA near the RB. The PCR gels also

indicate absence of vector backbone and absence of the antibiotic resistance gene *nptII* in the two lines intended for field trials.

1.7 Information on the expression of insert(s)

No gene expression data are available for risk assessment. The initial *in vitro* selection using the herbicide chlorsulfuron provides phenotypic observations that support the presence of T-DNA inserts and expression of the *ALS/CSR* gene in the lines to be tested.

According to the developer, no genetic or phenotypic instability has been observed in the GM potato lines when grown in a greenhouse or in field trials completed in England.

1.8 Conclusions on the molecular characterisation

The applicant has only provided a limited set of molecular characterisation data. For instance, data that reveal the level of expression of the various inserts, or their insertion site(s) in the potato genome have not been provided. On the other hand, molecular data (as PCR analyses) have been presented by the applicant showing the presence of the expected insertion of T-DNA into the two plant lines to be investigated in the proposed field trial. Moreover, PCR-analysis data were presented supporting the absences of vector backbone sequences (including the selectable marker gene *nptII*) in the same plant DNA extracts.

The available molecular characterisation data suggest that the intended genetic changes are as expected from the modification techniques used, and do not indicate unintended changes in the T-DNA inserts in the plant lines. The possible truncation of the insert in one of the lines is not considered to be of importance for the further risk assessment.

VKM considers that the applicant´s PCR analyses data provide a reasonable amount of evidence that the intended genetic changes described in the application have occurred as intended in the produced plants, including an absence of vector backbone sequences. VKM finds that the provided molecular characterisation data are sufficient for the planned field trials of limited scale and scope.

2 Environmental risk assessment (ERA)

Overview

Several factors should be considered in an environmental risk assessment (ERA), including whether the plant has wild or cultivated relatives in the target environment (risk of hybridisation), its adaptability to local climate conditions, and whether it is an annual or perennial species. Potential risks associated with the introduced trait(s) should be identified, including whether it could affect the plant's survivability, fitness, or capacity to spread, and what implications this may have for the surrounding ecosystem and biodiversity.

EFSA (EFSA 2010) provides guidance on how to assess potential effects of GM plants on the environment. The EFSA guidance is comprehensive as its core focus is on the ERA of GM plants/products to be placed on the market. The ERA is based on a stepwise approach and builds on data already collected from contained laboratory studies and contained or open field trials. The relevance of the comprehensive guidance document to the ERA of a field trial of limited size and scope and thereby amount of data required, will hence be variable and case by case based.

The EFSA ERA guidance (2010) is nevertheless of high value to the ERA of a field trial conducted at the national level. It helps to structure the overall risk assessment and specifies the areas of concern as well as cross-cutting considerations to be addressed by applicants and risk assessors.

Based on the EFSA ERA guidance, the areas of concern and cross-cutting considerations addressed in the ERA of the field-released GM potato lines are:

- Cross-cutting considerations.
- Persistence and invasiveness, including plant-to-plant gene flow.
- Plant to microorganism gene transfer.
- Interactions of the genetically modified plant with target organisms.
- Interactions of the genetically modified plant with non-target organisms.
- Impacts of the specific cultivation, management and harvesting techniques.
- Effects on biogeochemical processes.
- Effects on human and animal health.
- Description of environmental monitoring plan.

The following sections address the areas of concern and any identified hazard and likelihood with reference to the applicant's submitted documentation. The risk analyses follow at the general level the step-by-step assessment approach as outlined in EU Directive 2001/18/EC starting with hazard identification, hazard characterization, exposure characterization and risk characterization. Directive 2001/18/EC is implemented in the EEA agreement and transposed into the Norwegian Gene Technology Act. Short risk conclusions are provided for each section, along with considerations of key uncertainty. Section 2.9 considers the applicant´s risk reducing measures while 2.10 provides the overall conclusion on environmental risk.

2.1 Cross-cutting considerations

The cross-cutting considerations as outlined in EFSA (2010), including choice of comparators, receiving environment, statistical considerations, and long-term effects have been addressed by both the applicant and VKM and are part of the assessment of the different areas of concern.

According to the EFSA guidance (EFSA 2010), the ERA of GM plants should include information needed to determine potential impact of the GM plant compared to a non-modified counterpart, a comparator. For the specific field trial, the assessment is based on potential hazards to the environment of the tested potato lines as such. The general comparator is a conventional potato, and more broadly, current potato cultivation in Norway.

The receiving environment for the field trial is an established potato testing site in Southern Norway. The small sized early-phase trial limits the amount of data expected for the ERA, when compared to applications of larger scales and scopes.

The statistical expectations would mainly relate to the quality of data presented at later stages of an ERA. For the early phase field trials of potato, the statistical principles would mainly concern the applicant's need to ensure that informative data can be collected after repeated field trials.

The potential long-term effects have been addressed by the applicant with focus on whether the progeny of the GM plant might persist and appear as volunteers or feral plants after the field experiment has been completed. This is addressed in section 2.2 below.

2.2 Persistence and invasiveness including plant-to-plant gene flow

Cultivated potato (*Solanum tuberosum* subsp*. tuberosum*) belongs to the family *Solanaceae.* The family includes several well-known domesticated species (e.g. tomatoes, eggplant, pepper, tobacco). *Solanum dulcamara* is the only indigenous *Solanum* species in Norway; it is found in South-Eastern Norway and along the coast to Trøndelag. According to the Norwegian Taxonomical Register (Norwegian Biodiversity Information Centre 2025) and Elven et al. (2022), introduced *Solanum* species include (in addition to *S. tuberosum*) *S. americanum, S. chenopodioides, S. decipiens, S. nigrum, S. physalifolium, S. rostratum S. sisymbriifolium* and *S. villosum,* as well as some species with only historical and/or very few observations: *S. capsicoides, S. carolinense, S. hendersonii, S. laciniatum, S. marginatum* and *S. sarrachoides*. Among these, only *S. nigrum* is widely spread in Norway and is found in the South-East and to some extent in South-West and Central Norway. The remaining species are found in few sites and have very limited distribution, although some of them are currently expanding (Elven et al., 2022).

Although gene flow from cultivated to wild potato species has been documented in South America (e.g. Celis et al., 2004; Scurrah et al., 2008; Capurro et al., 2013), potato is biologically contained in Western Europe and does not form fertile progeny after hybridisation with cultivated or wild *Solanum* species. Potato is not sexually compatible with *S. dulcamara* and *S. nigrum* (Eijlander & Stiekema, 1990), the two commonly found wild *Solanum* species in Norway. No pollen-mediated gene flow was observed from GM potatoes to *S. dulcamara* and *S. nigrum* under field conditions (McPartlan & Dale, 1994).

Potato is mainly a self-pollinating plant (OECD 2006) and rate of cross-pollination under field conditions ranges from 0 to 20 % (Plaisted, 1980). Pollen-mediated gene dispersal from GM to conventional potato is limited and very unlikely at distances over 10 m (McPartlan & Dale, 1994). Separation by 20 m is considered adequate to mitigate pollen mediated gene dispersal from transgenic to conventional potatoes (Conner & Dale, 1996; see also Petti et al., 2007). Furthermore, commercial production of potatoes is exclusively vegetative through seed tubers, and cross pollination from GM potatoes will not affect harvested tubers.

Potatoes are generally not competitive outside of cultivated areas and do not establish permanent populations in the wild (Love, 1994). World-wide, there are only two known cases of persistent naturalized populations, in South Africa and Hawaii (Simon et al., 2010). There are no records of potatoes establishing in the wild in Norway, and a recent horizon scanning of alien species indicated that this is unlikely to change in the foreseeable future (Solstad et al., 2023). Therefore, volunteer potato plants would be problematic only in cultivated fields. Volunteer potato plants can grow from potato seeds or from tubers left in the field. Substantial number of tubers can be left behind after harvesting (Phelan et al., 2015; Steiner et al., 2005), and plants arising from these tubers may require active weed management in regions with mild winters (EPPO, 2020; Phelan et al., 2015). However, volunteer potato plants from tubers are not considered to pose significant risks in Northern Europe, due to the cold winters of the region, tubers not surviving temperatures below – 3 °C (Mustonen et al., 2009).

Plants from potato seeds are usually weaker and have low competitive ability compared to plants from tubers. Daughter tubers from plants growing from seeds are smaller and will most likely not survive the frost during winter (Mustonen et al., 2009). Potato seeds can stay viable in the soil for seven to ten years (Askew 1993; Lawson 1983). Production of seeds depends on the type of cultivar and various environmental factors such as photoperiod, temperature, and nitrogen availability (Askew, 1993). Most potato cultivars are sterile or have low fertility due to lack of flowering, limited or sterile pollen production, flower abortion, or poor fruit setting (Ross, 1986; OECD, 2006; Biryukova et al., 2022). Charlotte, the cultivar that will be used in the proposed trial, is characterised to have occasional flowering frequency, low pollen fertility, and very rare fruit setting (The European Cultivated Potato Database, ECPD).

Conclusion

Available literature defines potato as a biologically contained species that does not persist or invade natural habitats and has limited capacity of gene transfer to cultivated potato in Norway, including outcrossing with cultivated or wild *Solanum* species.

VKM concludes that it is **very unlikely** that GM potatoes will be able to spread from the trial site neither vegetatively nor by pollination of neighbouring plants, and that any potential spread would be very limited and have **minimal impact** on the surroundings. A risk of persistence and invasiveness including plant-to-plant gene flow is therefore considered **low.**

2.3 Plant to microorganism gene transfer

The applicant refers to literature that states that field and laboratory studies have shown that horizontal gene transfer (HGT) from transgenic potatoes to soil microorganisms is very rare (Kim et al., 2010; Tae et al., 2005; Schlüter et al., 1995). Kim et al. (2010) investigated the possibility of HGT from GM potatoes containing the (NDPK2) gene to soil microorganisms. The gene was not detected in genomic DNA extracted from rhizosphere soil samples, indicating

that HGT did not occur (Kim et al., 2010). Another study investigated HGT from glufosinate-tolerant GM potato leaf tissue to soil bacteria (Tae et al., 2005). No evidence of HGT was detected over the four-month incubation period (Tae et al., 2005). Schlüter et al. (1995) investigated HGT from GM potato containing an antimicrobial resistance gene and a bacterial plasmid origin of replication to the bacterial pathogen *Erwinia chrysanthemi.* No HGT event was detected under laboratory conditions mimicking natural infection (Schlüter et al., 1995). Advances in next generation sequencing indicates that HGT events may be underestimated in eukaryotes, however, the likelihood for such events are extremely low due to multiple barriers, especially from eukaryotes to prokaryotes (Philips et al., 2022).

Although HGT events might be rare, they do occur, and observations will depend on the timeline and experimental system used. The general conclusions of a broad absence of a transfer potential have been debated (Nielsen & Townsend, 2004). A positive selection for the rate of DNA transfers is likely the most important factor determining HGT potential and rates between unrelated organisms/genomes (Nielsen & Townsend, 2014). The genes in the T-DNA, inserted in the GM potato, are derived from *Solanum* spp., and microorganisms in the field area might already be naturally exposed to similar genes from local flora. VKM has not identified altered characteristics of these genes (structure, composition, and regulatory sequences) when present in T-DNA in the potato lines that would confer a novel selective advantage to bacteria or other microorganisms.

Conclusion

A horizontal gene transfer event from the GM-potato lines to exposed microorganisms in the limited field trial is considered very unlikely. A hazard resulting from potential horizontal transfer of T-DNA from the GM-potato lines to microorganisms has not been identified. VKM concludes that in the **very unlikely** event of horizontal gene transfer to soil microorganisms the impact would be **minimal**, and therefore the overall risk is considered **low**.

2.4 Interactions of the genetically modified plant with target organisms (TOs)

The target organism for the GM-potato is the late blight pathogen *Phytophthora infestans.* The genus *Phytophthora* belongs to oomycetes within the kingdom Stramenopiles and contains over 100 different species that are pathogens of various plant species. *P. infestans* can reproduce both asexually and sexually. Sexual reproduction results in the formation of oospores that can survive prolonged harsh conditions (2-4 years), such as overwintering between seasons. The sexual reproduction is an evolutionary driver important for increasing the diversity and adaptability of the population(s) of *P. infestans* (Ludwiczewska et al 2025).

P. infestans uses certain proteins named effectors that enable the pathogen to infect and colonise host plants. In response, host plants have evolved specific resistance proteins that recognise these effectors and trigger an immune response which involves necrosis at the site of infection halting the pathogen from spreading.

Individual genes encoding resistance proteins from wild *Solanum* species have been introduced into potato cultivars by breeding, however, the achieved resistance in these cultivars is usually overcome by *P. infestans* evolution in the pathogen-host arms race (Coomber et al 2024).

The aim of the field trial is to evaluate the efficacy of the three stacked resistance *(Rpi)* -genes of the GM-potato to the Norwegian *P. infestans* population.

The recombinant lines also carry a Potato virus Y (PVY) resistance gene. The effect of this gene will be assessed if the virus is present at the trial site.

Conclusion

The interaction with the target organism is one of the aims to be investigated in the field trial. The applicant provides information from previous studies supporting the likelihood of the interaction with the target organism.

The risk of adverse effects from increased resistance in the *P. infestans* population as a consequence of altered selection pressure exerted by the GM potato lines is considered to be **not relevant** given the limited scale and duration of the field trial.

2.5 Interactions of the genetically modified plant with non-target organisms (NTOs)

Only a few studies are reported on the effect of GM late blight resistant potatoes on non-target organisms. Lazebnik et al. (2017) investigated the effect of genetically modified potatoes on fitness of non-target aphids (*Myzus persicae*) in greenhouse and climate room experiments. The genetically modified varieties had different numbers and combinations of *Rpi* genes from *S. venturii* and *S. stoloniferum*. The results showed that effects of the genetically modified potatoes were within the range detected for available conventional varieties. Furthermore, aphid performance showed significantly more variation between the different conventional potato cultivars than between the conventional potato cultivar and the GM events (Lazebnik et al., 2017). Another experiment investigated the effect of inoculation of transgenic potatoes by *P. infestans* on oviposition preference of the insect *Spodoptera littoralis* (Abreha, 2015). The plants were transformed by *Rpi* genes from *S. bulbocastanum.* When both conventional and transgenic variants were inoculated by the pathogen, significantly higher oviposition was detected on the conventional cultivar than the transgenic variety. In the absence of the pathogen, however, no difference in oviposition preference was detected. These results suggest that insect behaviour was not affected by the resistance gene itself, but by the change in plant-microbe interaction (Abreha, 2015). In another experiment, the effect of cisgenic potatoes with *Rpi* genes from *S. venturii* on soil microbes was studied under field conditions (Krause et al., 2020). The microbial diversity in the rhizosphere of GM potatoes did not show significant differences compared to conventional varieties. The results demonstrated that cisgenic modification did not have significant effects on soil microbial communities (Krause et al., 2020).

Conclusion

VKM concludes that available data suggest no altered interaction of GM late blight resistant potato variants with known non-target organisms, when compared to conventional potato. VKM has not identified a specific hazard with a defined likelihood, the risk is therefore categorized as **low**.

2.6 Impacts of the specific cultivation, management, and harvesting techniques

The GM potato lines will be grown in a limited field trial at an established experimental field station. No altered impact of the cultivation, management, or harvesting techniques have been identified, beyond those expected for cultivation of conventional potato lines. All harvesting regarding the field trial will be done manually (without use of machinery) as a reduction measure to reduce propagule pressure and thus risk of spread of the GM potatoes.

If naturally occurring infection pressure by *P. infestans* at the trial site is considered too low by the applicant, the plants will be artificially inoculated by isolates of local *P. infestans* to increase infection pressure. VKM has not considered effects of this common practice of artificial *P. infestans* inoculation (Vleeshouwers et al., 1999; Flier et al., 2003; Douches et al., 2004).

If successful modification, the use of GM potatoes with increased resistance to *P. infestans* could be used to reduce or avoid the use of fungicides. Use of fungicides is not relevant for the proposed field trial.

The GM potato is resistant to herbicides (sulfonylureas and imidazolinones) but remains sensitive to other herbicides, such as glyphosate.

Conclusion

VKM has not identified a hazard from cultivation, management, and harvesting techniques applied to the GM potato lines in a field trial when compared to conventional potato variants. VKM concludes that as no specific hazard with a defined likelihood has been identified, the risk is categorized as **low**.

2.7 Effects on biogeochemical processes

The applicant does not expect any differences in biogeochemical processes or soil microbiota when growing the GM potato lines compared to growth of conventional crops, except for the resistance to late blight, a characteristic not expected to alter traits that may affect abiotic factors.

Conclusion

VKM has not identified a hazard related to effects of late blight resistance in the GM potato lines on biogeochemical processes compared to conventional potato variants. VKM concludes that as no specific hazard with a defined likelihood has been identified, the risk is categorized as **low**.

2.8 Effects on human and animal health

An assessment of potential hazards to human and animal health in the context of environmental risk assessment relates to exposure to the plant or its constituents via handling or consumption of plant material by animals that have accessed the trial site. The area for the proposed field trial is used for testing new cultivars with applied biosafety measures, like distance to other cultivated crops and removal of volunteers. The cultivar does not express any new protein with known toxicity or allergenic properties and would therefore not pose any

harm if ingested by animals or humans. Handling of this plant is not expected to be associated with any increased risk of allergy compared to non-modified potato cultivars.

Conclusion

The introduced characteristics are not expected to increase the toxicity or allergenicity of the GM potato or pose new risk from occupational exposure. A hazard caused by ingestion of potato by animals or humans has not been identified. VKM concludes that as no specific hazard with a defined likelihood has been identified, the risk is categorized as **low**.

2.9 Risk reducing measures

Measures taken at the trial site during the experiment

The applicant describes a trial site of ~100 m^2 which is contained within the field experimentation station, with access limited to trained personnel. Standard operating procedures regulate access to the site, site maintenance and monitoring before, during, and after planting, and harvesting.

Approximately 200 GM potatoes will be planted pr season during 2027-2029. The GM potatoes will be separated from other cultivated potato plants, not part of the experiment, by at least 20 m. Harvesting will be done by fork and hand to ensure removal of all GM material. Harvested material (plant tops and tubers) will be placed in sealed bags or containers, removed from site and ultimately destroyed by deep burial, incineration or autoclaving.

Post-experiment management of trial site

The applicant describes that the plot will be left fallow after each experimental season, monitored for volunteers during the remainder of the year and sprayed with a systemic broadleaf herbicide. Identified volunteers will be destroyed by herbicide treatment e.g. glyphosate or removed by hand and destroyed by autoclaving. The monitoring will be maintained at monthly intervals by walking the trial site for a period of two years following every season of the release. Crops that are easy to distinguish from potato may be grown at the site during the monitoring period.

Conclusion

VKM concludes that the likelihood of potato survival and spread from the field trial is mitigated through the proposed risk management measures. Destruction of GM material by autoclaving or incineration is considered the most effective method to ensure complete and rapid destruction of the material.

2.10 Conclusions on the environmental risk assessment

Available literature describes potato as a biologically contained species that neither persists nor invades natural habitats and has very limited potential for gene transfer to cultivated or wild *Solanum* species in Norway. VKM therefore considers it highly unlikely that GM potatoes will spread from the trial site, either vegetatively or through pollination of neighbouring plants. Any potential spread is expected to be limited and have minimal impact on the surroundings.

The risk of adverse effects from persistence, invasiveness, or plant-to-plant gene flow is therefore considered low.

A horizontal gene transfer (HGT) event from the GM-potato lines to exposed microorganisms in the limited field trial is considered very unlikely. A hazard resulting from potential horizontal transfer of T-DNA from the GM-potato lines to microorganisms has not been identified. The risk of adverse effects of rare HGT events is considered low. VKM concludes that in the unlikely event of horizontal gene transfer to soil microorganisms the impact would be minimal, and therefore the overall risk is considered low.

The interaction with the target organism is one of the aims to be investigated in the field trial. The applicant provides information from previous studies supporting the likelihood of the interaction with the target organism. The risk of adverse effects from the development of increased resistance or adaptation to the altered selection pressure in the *P. infestans* population is considered to be not relevant, given the limited scale and duration of the field trial.

VKM concludes that available data suggest no altered interaction of the GM late blight resistant potato variants with known non-target organisms, when compared to conventional potato cultivation. VKM has not identified a specific hazard with a defined likelihood, the risk is therefore categorized as low.

VKM has not identified a hazard from cultivation, management, or harvesting techniques applied to the GM potato lines in a field trial when compared to conventional potato variants. VKM concludes that as no specific hazard with a defined likelihood has been identified, the risk is categorized as low.

VKM has not identified a hazard related to effects of late blight resistance in the GM potato lines on biogeochemical processes compared to conventional potato variants. VKM concludes that as no specific hazard with a defined likelihood has been identified, the risk is categorized as low.

The introduced traits in the GM-potato are not expected to increase the toxicity or allergenicity of the GM potato or pose new risk from occupational exposure. A specific hazard caused by ingestion of plant material by animals or humans has not been identified. VKM concludes that as no specific hazard with a defined likelihood has been identified, the risk is categorized as low.

Finally, VKM concludes that the likelihood of potato survival and spread from the field trial is further mitigated through the proposed risk management measures.

3 Uncertainties[1]

Regarding the molecular characterisation of the GM potato lines, the copy number and exact position(s) of the inserted DNA in the potato genome, is not described. Moreover, stability of inserts and data on the expression levels of the various genes inserted as part of the T-DNA have not been provided. However, VKM considers that the available molecular characterisation is sufficient to inform the ERA of the limited field trial and that the level of uncertainty caused by the limited molecular data is low.

The uncertainty is considered low for all other parts of the risk assessment. I.e., there is sufficient published information, and expert judgements are in concurrence (Table 3.).

[1] Uncertainties described here are those that may influence the conclusions of the case specific risk assessment.

4 Conclusions - with answers to the terms of reference (ToR)

The Norwegian Environment Agency has requested VKM to assess potential risks to the environment related to an application for a field trial with a genetically modified (GM) late blight resistant potato. Below, the ToR from the Agency are reiterated followed by the conclusions of the assessment by VKM.

The Agency has asked VKM to:

- Assess whether the information in the present application is sufficient to assess environmental risk, or whether there is need for more information.

  VKM concludes that the information provided in the application and by the applicant during the risk assessment, including answers to requests for additional data and clarifications, has been **sufficient** to finalise the risk assessment.

- Assess molecular characterisation of the genetic modification and the genetically modified organism.

  VKM concludes that the provided molecular characterisation data are **sufficient**ly detailed to support the ERA of the planned field trial.

- Assess risk of spread and survival of the GMO in the environment and possible consequences of this, including risk of plant-to-plant gene flow.

  VKM concludes that it is **very unlikely** that GM potatoes will be able to survive over time or spread from the trial site neither vegetatively nor by pollination of neighbouring plants, and that potential survival and spread would be very limited and have **minimal impact** on the surroundings. A risk of persistence and invasiveness including plant-to-plant gene flow is therefore considered **low**.

- Assess risk of plant-to-microorganism gene flow.

  VKM concludes that in the **very unlikely** event of horizontal gene transfer to soil microorganisms the impact would be **minimal**, and therefore the overall risk is considered **low**.

- Assess effects on target organisms.

  VKM concludes that the interaction with the target organism is one of the aims to be investigated in the field trial. The applicant provides information from previous studies supporting the likelihood of the interaction with the target organism.

  The risk of an adverse effect caused by increased pathogen resistance as a consequence of altered selection pressure exerted by the GM potato lines has been considered **not relevant**, given the limited scale and duration of the field trial.

- Assess effects on non-target organisms.

  VKM concludes that available data suggest no altered interaction of GM late blight resistant potato variants with known non-target organisms, as compared to

conventional potato. VKM has not identified a specific hazard with a defined likelihood, the risk is therefore categorized as **low**.

- Assess any adverse effects on human and animal health, as a result of changes caused by the genetic modification, to those in contact with the GMO (does not apply to assessment of the GMO as food or feed).

  VKM concludes that the introduced characteristics are not expected to increase the toxicity or allergenicity of the GM potato or pose new risk from occupational exposure or ingestion by animals or humans. VKM concludes that as no specific hazard with a defined likelihood has been identified, the risk is categorized as **low**.

- Assess the risk-reducing measures proposed in the application

  VKM concludes that the very low likelihood of potato survival and spread from the field trial is further mitigated through the proposed risk management measures. Destruction of GM material by autoclaving or incineration is considered the most effective and rapid method to destroy remaining plant material.

5 Data gaps[2]

VKM has not identified data gaps of importance to VKM´s general assessments in the context of the specific ERA of the GM-potato lines for field trials.

[2] Data gaps described here go beyond the case specific risk assessment and addresses a broader perspective, with indication of challenges within the scientific field and/or knowledge gaps.

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Appendix I

Application – risk assessment timeline

3. May 2024	Norwegian Environment Agency (NEA) receives the application from NIBIO, and forwards it to VKM
21. June 2024	VKM requests additional data/information
25. June 2024	NEA forwards VKMs request to NIBIO
12. July 2024	NEA receives answer/new data/information from NIBIO
29. July 2024	NEA forwards answer to VKM
13. August 2024	VKM requests additional data/information, forwarded to NIBIO by NEA
21. October **2025**	NEA receives answer/new data/information from NIBIO and forwards answer to VKM
26. November	Draft ERA sent to interdisciplinary approval group
3 - 5. December	Processing of inputs
8 - 12. December	Report sent to NEA, embargo period
17. December	Final report sent to NEA, and published on vkm.no

Miljø-
direktoratet

Vitenskapskomiteen for mat og miljø
Postboks 222 Skøyen
0213 OSLO

Oslo, 03.11.2025

Deres ref.:	Vår ref. (bes oppgitt ved svar):	Saksbehandler:
	2025/15258	Ingvild Riisberg

Risk assessment of genetically modified potatoes for release in a field trial

Elaboration of the assignment to VKM on risk assessment of genetically modified potatoes for release in a field trial

The Norwegian Environment Agency has received an application for deliberate release of genetically modified potatoes in a field trial in accordance with the Gene Technology Act, and has commissioned VKM to assess health and environmental risk of the deliberate release of GMO into the environment. In the following, the assignment is elaborated.

Background to the case
The Norwegian Environment Agency is the decision-making authority for the release of genetically modified organisms for research purposes (field trials, experimental release) according to the Gene Technology Act and received on 03.05.2024 an application for the experimental deliberate release of genetically modified potatoes from the Norwegian Institute for Bioeconomics (NIBIO). The application was shared with VKM the same day. VKM was notified about the application in advance.

The Norwegian Environment Agency refers to dialogue about the application and assignment letter of 08.05.2024. Furthermore, reference is made to the collaboration agreement between the Norwegian Environment Agency and VKM on 14 .02. 2024, and the authorization for assignments to VKM on risk assessment in 2024. In this letter, we elaborate on the assignment to VKM on risk assessment of genetically modified potatoes for release in field trials in accordance with the Genetic Technology Act.

Briefly about the application:
The experiment with genetically modified potatoes will take place at one location. The purpose of the experiment is to test whether potato plants that have resistance from wild potato relatives can contribute to better control of potato late blight resistance through integrated plant protection, with reduced use of chemicals. The genetically modified potato plants have had various resistance genes inserted against, among other things, potato late blight and potato virus from wild relatives. In addition, the plants contain genes that give tolerance to pesticides, for the

selection of genetically modified plants in the laboratory. It is stated that the genetically modified plants are to be used as a tool for integrated plant protection against potato late blight. There are no intentions to use the genetically modified potatoes in commercial production in Norway. The assignment thus does not include an assessment for use as food and feed.

Elaboration of assignments:
VKM has been given access to the application's part I (information) and part II environmental risk assessment, in addition to the SNIF (summary of the application), for assessment.

The Norwegian Environment Agency asks VKM to assess:
1. Whether the information in the present application is sufficient to be able to assess environmental risk, or whether there is a need for more information:
VKM must assess the submitted information and documentation from the applicant, form questions and point out any deficiencies/needs for additional information in order to carry out a risk assessment of the GMO. Questions and any deficiencies/needs are to be summarized in a document that is sent to the Norwegian Environment Agency, which will forward this to the applicant. If information is required, joint meetings can be held with the applicant. Each round of obtaining new information from the applicant, VKM describes these deficiencies/need for additional information in writing and sends the document to the Norwegian Environment Agency.2.

Risk to the environment, including any effects on human and animal health, which may arise as a result of the field trial:
The risk assessment is based on the information in the application, the applicant's own risk assessment and attached documentation, as well as other relevant scientific literature. The risk assessment must consist of an assessment of, among other things, but not limited to:
• Molecular characterization of the modification and the genetically modified organism
• Effects on the environment, including, but not limited to:
    - Risk of spread and survival of the GMO in the environment and possible consequences of this
    - Risk of plant-to-plant gene flow
    - Risk of plant-to-microorganism gene flow
    - Effects on target organisms
    - Effects on non-target organisms

• Any harmful effects on human health, as a result of changes caused by the genetic modification, which are in contact with the GMO (does not apply to assessment of the GMO for food)
• Any adverse effects on animal health as a result of changes caused by the genetic modification, and which are in contact with the GMO (does not apply to assessment of the GMO for feed)
• Assessment of the effect of risk-reducing measures proposed in the application

Legal background:
Act of 2 April 1993 no. 38 on the production and use of genetically modified organisms, etc. (The Gene Technology Act) regulates the deliberate release of genetically modified organisms (GMO)

into the environment. Regulation of 16 December 2005 no. 1495 relating to impact assessments pursuant to the Gene Technology Act.

Through the EEA agreement, Norway is acceded to the EU regulations for the deliberate release of GMOs into the environment according to Directive 2001/18/EC. The directive is transposed into Norwegian law through the Gene Technology Act.

Conditions:
The assignment may include confidential information. Based on regulation requirements and the applicant's possible request for exemption from publicity, VKM must assess what can be included in the public risk assessment report.
The risk assessment report should be written in English with a Norwegian summary.
The report is published in accordance with the collaboration agreement between the Norwegian Environment Agency and VKM and subject to consultation together with the application. The Norwegian Environment Agency submits the report to the Norwegian Biotechnology Advisory Board as a basis for their assessments of sustainability, social benefit and ethical consideration under the Gene Technology Act.

Further terms and conditions for the assignment are given in the follow-up dialogue.

Deadline for the assignment:
Wednesday 14.08.2024 at day 70 of the proceedings. We would like to emphasize the fact that if there is a need for more information from the applicant, the date will change accordingly. The final date will depend on clock stops that may occur, as new information is obtained.

The Norwegian Environment Agency requests that VKM submit a timeline for the assignment.

Hilsen
Miljødirektoratet

Dette dokumentet er elektronisk godkjent

Inger Mari Eggen	Ingvild Riisberg
seksjonsleder	sjefingeniør

Miljø-
direktoratet

Vitenskapskomiteen for mat og miljø
Postboks 222 Skøyen
0213 OSLO

Oslo, 08.05.2024

Deres ref.:	Vår ref. (bes oppgitt ved svar):	Saksbehandler:
	2024/4913	Ingvild Riisberg

Oppdrag VKM -nye verktøy for IPV – potet med resistensgener fra ville potetarter

Miljødirektoratet mottok 03.05.2024 en søknad om utsetting av genmodifisert potet i feltforsøk etter genteknologiloven fra norsk institutt for bioøkonomi (NIBIO), om forsøksutsetting av GMO med tittel " Nye verktøy for IPV – potet med resistensgener fra ville potetarter ". Søknaden ble delt med VKM fredag 03.05.2024, og VKM ble bedt om å igangsette helse – og miljørisikovurdering av søknaden etter genteknologiloven.

Som avklart i møte mellom Miljødirektoratet og VKM 07.05.2024, vil videre rammer for oppdraget bli spesifisert i eget brev.

Hilsen
Miljødirektoratet

Dette dokumentet er elektronisk godkjent

Janne Øvrebø Bohnhorst
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