Vitenskapskomiteen for mat og miljø
Norwegian Scientific Committee for Food and Environment

VKM Report 2026: 08

Guidance on the scientific information required for risk assessment of genetically modified plants intended for field trials in Norway

Johanna Bodin (Chair), Rakel Blaalid, Knut Tomas Dalen, Nur Duale, Siri Lie Olsen, Kristian Prydz, Monica Sanden, Sjur Sandgrind, Ville Erling Sipinen, Hugo de Boer, Anders Bryn, and Kaare Magne Nielsen

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Norwegian Scientific Committee for Food and Environment (VKM)

Postboks 222 Skøyen

0213 Oslo

Norway

Email: vkm@vkm.no

Website: vkm.no

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Preparation of the opinion

The Norwegian Scientific Committee for Food and Environment (Vitenskapskomiteen for mat og miljø, VKM) appointed two separate project groups to draft the opinion. The project group on molecular characterisation consisted of five VKM members, one external expert and one from the VKM staff. The project group on environmental risk assessment consisted of two VKM members, two external experts and one 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 and/or the interdisciplinary VKM approval group, appointed specifically for the assignment.

Members of the project group on molecular characterisation

Johanna Eva Bodin (Chair) – vice chair of the Panel on genetically modified organisms in VKM. Affiliation: 1) VKM; 2) Norwegian Institute of Public Health (NIPH).

Knut Tomas Dalen – member of the Panel on nutrition, dietetic products, novel food, and allergy in VKM. Affiliation: 1) VKM; 2) University of Oslo (UIO).

Nur Duale – member of the Panel on genetically modified organisms in VKM. Affiliation: 1) VKM; 2) Norwegian Institute of Public Health (NIPH).

Kristian Prydz – member of the Panel on genetically modified organisms in VKM Affiliation: 1) VKM; 2) University of Oslo (UIO).

Monica Sanden – member of the Panel on genetically modified organisms in VKM Affiliation: 1) VKM; 2) Institute of Marine Research (HI).

Sjur Sandgrind – external expert. Affiliation: 1) Norwegian Institute of Bioeconomy Research (NIBIO)

Ville Erling Sipinen – Project leader, VKM staff

Members of the project group on environmental risk assessment (ERA)

Johanna Eva Bodin (Chair) – vice chair of the Panel on genetically modified organisms in VKM. Affiliation: 1) VKM; 2) Norwegian Institute of Public Health (NIPH).

Rakel Blaalid – member of the Panel on convention on international trade in endangered species (CITES) in VKM. Affiliation: 1) VKM; 2) Nord University.

Siri Lie Olsen – external expert. Affiliation: 1) Norwegian University of Life Sciences (NMBU); 2) Norwegian Institute for Nature Research (NINA).

Sjur Sandgrind – external expert. Affiliation: 1) Norwegian Institute of Bioeconomy Research (NIBIO)

Ville Erling Sipinen – Project leader, VKM staff

Members of the interdisciplinary approval group

Hugo de Boer – chair of the Panel on convention on international trade in endangered species (CITES) in VKM. Affiliation: 1) VKM; 2) University of Oslo (UIO).

Anders Bryn – member of the Panel on biodiversity in VKM. Affiliation: 1) VKM; 2) University of Oslo (UIO); 3) Norwegian Institute of Bioeconomy Research (NIBIO).

Knut Tomas Dalen – member of the Panel on nutrition, dietetic products, novel food, and allergy in VKM. Affiliation: 1) VKM; 2) University of Oslo (UIO).

Kaare Magne Nielsen – member of the Panel on microbial ecology in VKM. Affiliation: 1) VKM; 2) Oslo Metropolitan University (OsloMet).

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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.

Table of Contents

Summary

The Norwegian Environment Agency has tasked The Norwegian Scientific Committee for Food and Environment (VKM) with developing generic guidance documents for environmental risk assessment of genetically modified organisms (GMOs) to be used in field trials. GMOs used in field trials may have effects on the environment, and human and animal health. All experiments involving the use of GMOs in field trails for research require approval under the Norwegian Gene Technology Act. The Norwegian Environment Agency is the decision-making authority for deliberate release of GM plants in field trials.

VKM performs health and environmental risk assessments (ERAs) of genetically modified plants (GM plants) for the Norwegian Environment Agency. This guidance document is intended as a support for applicants seeking approval for field trials with GM plants under the Gene Technology Act.

The risk assessments conducted by VKM generally follow the step-by-step approach outlined in EU Directive 2001/18/EC on the deliberate release of genetically modified organisms into the environment, starting with hazard identification, hazard characterization, exposure characterization and risk characterization. The Gene Technology Act and the Regulations on impact assessment under the Gene Technology Act implements Directive 2001/18/EC into Norwegian legislation. Appendix 2 of the Regulation contain the principles for environmental risk assessment, which corresponds to the principles of Annex II in the Directive. The European Food Safety Authority (EFSA) has developed further guidance on the risk assessment of genetically modified organisms based on Annex II.

The guidance is based on guidance documents developed by the EFSA on risk assessment of GM plants. The document is divided into four main chapters: molecular characterisation, cross-cutting considerations, specific areas of risk to be addressed in the ERA, and risk-reducing measures. The guidance is intended to support applicants in identifying experimental data and scientific documentation necessary to include in an application to enable an independent risk assessment.

The guidance is intended as a dynamic document to be amended in accordance with future scientific and regulatory developments.

Sammendrag

Vitenskapskomiteen for mat og miljø (VKM) har, på oppdrag fra Miljødirektoratet, utviklet generisk veiledningsmateriell for helse- og miljørisikovurdering av genmodifiserte organismer (GMO) til utsetting i feltforsøk. GMO som brukes i feltforsøk kan ha effekt på miljøet, og på menneskers og dyrs helse. Alle forsøk som innebærer bruk av GMO i feltforsøk, krever godkjenning under den norske genteknologiloven. Miljødirektoratet er beslutningsmyndighet for utsetting av genmodifiserte planter (GM-planter) i feltforsøk.

VKM utfører helse- og miljømessige risikovurderinger av GMO for Miljødirektoratet. Dette veiledningsdokumentet er ment som støtte for søkere som søker om godkjenning av GM-planter til feltforsøk under genteknologiloven.

VKMs risikovurderinger av GMO følger generelt den sak til sak tilnærmingen som er skissert i EUs Direktiv 2001/18/EF (utsettingsdirektivet), som regulerer bevisst utsetting og omsetning av GMO i miljøet. VKMs risikovurderinger identifiserer og karakteriserer fare, karakteriserer eksponering og karakteriserer risiko. Genteknologiloven og forskrift om konsekvensutredning etter genteknologiloven implementerer Direktiv 2001/18/EF i norsk lovgivning. Vedlegg 2 til forskriften inneholder prinsippene for miljørisikovurdering, som samsvarer med prinsippene i Annex II i direktivet. Den europeiske myndighet for næringsmiddeltrygghet (EFSA) har utviklet ytterligere veiledning om risikovurdering av genmodifiserte organismer basert på Annex II.

Veilederen er basert på EFSAs veiledningsdokumenter for GM-planter og er delt inn i fire hovedkapitler: molekylær karakterisering, overordnede hensyn, miljøspesifikk risiko, og risikoreduserende tiltak. Veilederen er ment å hjelpe søkere med å identifisere eksperimentelle data og nødvendig vitenskapelig dokumentasjon som bør inkluderes i en søknad for å muliggjøre en uavhengig risikovurdering.

Veilederen er et dynamisk dokument som kan oppdateres i tråd med framtidig vitenskapelig og regulatorisk utvikling.

Background and Terms of Reference (ToR)

The Norwegian Environment Agency has requested VKM to develop a generic guidance for the health and environmental risk assessment of GMOs intended for deliberate release in field trials and other forms of restricted experimental release under the Gene Technology Act. The request was initiated following two recent applications for field trials with GMOs received by the Norwegian Environment Agency.

The guidance should be applicable to a range of organisms, including plants and animals developed with genome editing techniques.

VKM is requested to use the current legislation, the impact assessment regulations under the Gene Technology Act, together with relevant guidance material available within the EU, as a basis for developing guidance material drawing on VKM's knowledge and experience in the risk assessment of applications for experimental release under the Gene Technology Act.

Introduction

The Norwegian Environment Agency has tasked VKM with developing a generic guidance for environmental risk assessment (ERA) of genetically modified (GM) plants to be used in field trials, or other types of experiments that involve a temporary and restricted release of GM plants into the environment. All experiments involving the use of GMOs in field trails for research require approval under the Norwegian Gene Technology Act. The Norwegian Environment Agency is the decision-making authority for deliberate release of GM plants in field trials.

The guidance is intended as a support for applicants in identifying the scientific documentation and data necessary to include in a field-trial application to enable independent risk assessment. It is based on the comprehensive guidance developed by the European Food Safety Authority (EFSA) for the environmental risk assessment (ERA) of GM plants (EFSA 2010) as well as the EFSA guidance for risk assessment of food and feed from GM plants (EFSA 2011).

The EFSA guidance is based on the requirements and step-by-step approach (step 1-6 described below) for risk assessment outlined in EU Directive 2001/18/EC. Directive 2001/18/EC is implemented in the European Economic Area (EEA) agreement and transposed into the Norwegian Gene Technology Act and underlying regulations. Regulations relating to impact assessment pursuant to the Gene Technology Act describes the requirements for field trial applications of GM plants.

To facilitate an efficient risk assessment, it is important that the submitted documentation is sufficient to complete and conclude the risk assessment. The extent of documentation needed to conclude a risk assessment will vary from case to case depending on e.g. specific characteristics of the GM plant in question, scope of the field trial(s), and characteristics of the receiving environment.

In line with current regulations, VKM structure the risk assessments into six steps:

1. Hazard identification, i.e. identification of characteristics of the GM plant and potential adverse effects that may be caused by the GM plant in a field trial.

2. Hazard characterisation, i.e. evaluation of the potential consequences of each adverse effect, should they occur.

3. Exposure characterisation, i.e. evaluation of the likelihood of the occurrence of each identified potential adverse effect.

4. Risk characterisation, i.e. estimation of the risk posed by each identified characteristic of the GM plant, including likelihood of exposure and the adverse outcome.

5. Risk reducing measures to mitigate identified risks to the environment, such as containment measures to prevent hybridisation with wild species or propagation beyond the trial site.

6. Overall risk evaluation of the use of the GM plant in a field trial including remaining uncertainties and data gaps.

Within the specified areas of risks covered in the guidance, applicants are expected to provide scientific data and documentation regarding points 1-5, as well as describe identified uncertainties that could affect the risk conclusion (**as part of step 6**). Adequate documentation provided by applicants is essential for risk assessors (VKM) to complete the ERA.

The VKM guidance is divided into four main thematic chapters: 1) Molecular characterisation; 2) Cross- cutting considerations; 3) Specific areas of risk to be addressed in the ERA and 4) Risk reducing measures. Each chapter is subdivided to highlight important topics for applicants to consider when gathering general pre-field trial data, as well as data and documentation needed to address the various areas of concerns.

The risk assessment of a field trial focuses on the intended effects but also seeks to exclude unintended effects:

Intended effects are effects that are designed to occur from the introduction of the genetic modification(s) in question, and which fulfil the original objective(s) of the genetic modification(s). Alterations in the phenotype may be identified through a comparative analysis of, for example, growth, development, reproduction, pest or disease resistance with the use of appropriately selected comparator(s). The genetic difference to a comparator is usually characterised in laboratory settings prior to a field trial and the information from such experiments may be essential for addressing the questions in this VKM guidance. Data from other field trials that could be relevant for the ERA of the actual GM plant can be used as supportive information.

Unintended effects are biologically relevant differences between the GM plant and the comparator(s) that go beyond the primary intended effect(s) of the genetic modification. Unintended effect(s) could potentially be linked to genetic rearrangements or metabolic alterations and may be predicted through the comparison of the biological and compositional characteristics of the GM plant with its comparator(s) cultivated and tested, when possible, under the same environmental conditions.

The VKM guidance describes the following areas of risks to be considered for potential effects on the environment by GM plants intended for use in field trials:

- 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, excluding deliberate use of the GM plant as food or feed.

Important notes to applicants:

- All required scientific data necessary for the risk assessment should be presented with sufficient details in the submitted application. Provided experimental data must relate to the specific modified plant intended for use in the field experiment(s).
- References to publications describing similar or parallel experiments (including with the same plant) may be used as supporting documentation but cannot be used as a substitute for the required experimental data described in this guidance.
- The extent of data needed to resolve the areas of risk and conclude a risk assessment will depend on the properties of the tested plant variety and its environmental context and hence will vary from case to case.
- A separate document to this guidance, elaborates on the required data for molecular characterisation and ERA, using an example based on a scientific publication of a GM-oilseed rape. In addition, an assessment performed by VKM (VKM 2025) of a blight-resistant GM potato approved by the Norwegian Environment Agency for use in field trials is also linked to in the document. Note that the application and assessment of the potato was completed prior to the finalisation of this VKM guidance, the structure of the assessment therefore differs somewhat from that of the guidance.
- Unlike more traditional techniques used to develop GMOs, New Genomic Techniques (NGTs) e.g. CRISPR, enable developers to introduce a wide variety of targeted genetic modifications, ranging from subtle mutations (genome editing) to long genetic inserts such as new genes. In June 2026, the EU Commission adopted new regulations for genetically modified plants produced using NGTs. The regulations distinguish between two categories of plants developed by NGTs, NGT-1 and NGT-2. Plants categorised as NGT-1 are considered equivalent to conventional varieties (traits including herbicide tolerance and the production of known insecticidal substances not included), while plants categorised as NGT-2 remain subject to existing EU GMO-legislation. The regulation is under assessment by Norwegian authorities for possible incorporation into the EEA Agreement, and as such, this type of distinction of GM plants is not yet implemented in Norwegian regulations.
- Use of the term ‘should’ in this document may have different interpretations; it can be understood as a suggestion or recommendation, not as a formal requirement. The type/extent of data needed will be case dependent to enable risk characterisation and conclude the risk assessment.
- The VKM guidance is intended as a dynamic document to be amended in accordance with future scientific and regulatory developments and requirements.

1 Molecular characterisation – overview of information related to the genetically modified plant required for a field trial application

Molecular characterisation is at the core of the risk assessment and should provide an in-depth description of all information relevant to the plant that was modified (recipient), method(s) used for the modification(s), intended and resulting actual modifications, introduced traits and properties of the GM plant, including identified unintended effects. The information required is in line with the EFSA guidelines for molecular characteristics of GMOs and follows a case-by case approach regarding relevance and amount of data required (EFSA 2011).

1.1 Information relating to the GM plant

Information regarding the intended use of the GM plant should be described. Innate properties of the plant should also be provided (independent of the genetic modification), such as species and subspecies, known properties of importance e.g., weediness, toxic or allergenic properties, whether it can survive and propagate outside the field trial, is an established cultivar, is known or suspected to have invasive traits or is capable of crossbreeding with wild and/or cultivated plants.

For this information, a descriptive text in the application with referenced literature is usually sufficient.

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

A general description of the introduced trait(s) and its mode of action, the resulting changes in the phenotype and of the intended use of the plant is expected.

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

The application should include a description of all donor organisms (if any) and/or other sources from which genes or other nucleic acid sequences intended for insertion have been isolated or synthesized. The documentation should encompass complete sequences of the intended inserts or modifications, including information on any deliberate alteration(s) to the corresponding sequence(s) in the donor organism(s) or other templates.

The application should include physical maps of all applied plasmids/vectors indicating their size and components. A description of all sequence elements of the vectors should be included, not only the sequences intended for insertion, but also genetic markers and vector backbone sequences (e.g., open reading frames, promoters, origin of replication). Likewise, information should be provided on the nature and source of the reagents used for genome editing, how these were synthesized/produced and whether they were supplied pre-

assembled or expressed endogenously from introduced nucleic acids in the transfected cells/embryos. All nucleotide sequences used should be provided.

Intended and actual modifications may differ. This is further described in section 2.6.

1.4 Techniques used for the genetic modification

The application should include scientific documentation that describes the method(s) used for the genetic modification. All involved techniques used for transfer and integration/editing should be described. This includes reagents, sequences, guide-RNAs, as well as *Agrobacterium*-mediated transformation, biolistics (gene-gun), CRISPR/Cas, TALEN, ZFN, ODM, or other delivery methods. This also includes techniques and vectors used for transient modifications that may not be present in the end product. Applied experimental protocols used should be described.

1.5 Type of intended modification(s)

The applicant should describe the intended modification(s), this includes the intended genetic modifications, resulting biochemical changes and expected new phenotypes (traits).

The European Food Safety Authority (EFSA) has defined GMOs developed by genome editing techniques (e.g. CRISPR/Cas9 and TALEN) into three different categories based on results with the use of site-directed endonucleases (SDN, restriction enzymes): SDN1, SDN2, and SDN3 (EFSA 2012b). This categorisation is included in this document. The SDN1–3 categories of genetic modifications include small, targeted mutations (SDN1 and SDN2), and the insertion of cisgenes or transgenes (SDN3) at specific genomic locations (see Table 1, Box 1, and Figure 1).

Independent of category, an application must include a detailed description of all intended modifications.

1.6 Information on the sequences actually inserted/deleted or altered

The intended modification(s) (described in Section 1.5) and actual modification(s) may differ, and detailed information of the obtained genetic modification(s) must be presented.

For larger insertions such as cis-, intra-, and transgenes, such information includes description of the number of integration sites in the plant, and the size, copy number, and nucleic acid sequence of the insert for each integration site. For other types of genetic modifications, such information includes description of nucleotide alteration(s) and their genomic location(s).

Unintended insertions/sequence(s), deletions or alterations, and their position in the genome, should be described as detailed as possible around the insertion site(s). Information on whether insertions have unintentionally interrupted the regulation/expression of existing genes in the plant should be included.

New open reading frames (ORFs) should be investigated in and around their insertion sites, and analyses of ORFs should consider the possibility of expression of fused protein products.

Certain unintended insertions are of particular concern. E.g. if genetic sequences encoding antibiotic resistance have been part of a vector system used (vector backbone) or inserted and used as a selection marker when generating the plant, the absence of such genetic sequences in the specific GM plant line(s)intended for testing in the field trial should be documented.

For gene edited plants, the absence of plasmid/vector sequences used at intermediate stages in the editing process should be demonstrated.

Method(s) used for the characterization of the genetic modification(s) should be described.

All available experimental data, sequence information and type(s) of modification(s) must be related to the specific plant(s) intended for use in the field trials.

1.7 Information on the expression of insert(s)

If the introduced modification(s) results in expression of new gene product(s) in the plant, information should be available as to whether the inserted or modified sequence(s) results in intended changes at the RNA, protein, and/or metabolite levels. Information on the levels of newly expressed proteins and/or other products and metabolites should be provided when relevant. The modified sequence(s) should be compared to sequences of known toxins, anti-nutrients, and allergens and documented with searches in up-to-date and relevant databases when relevant. This is most relevant for SDN3 modifications and products of new ORFs.

Table 1. Terms and definitions

Genetic modification	The process of inserting novel DNA/genes from the same or another species, altering, or deleting genes with recombinant DNA technology. For detailed definitions and exceptions, we refer to the Norwegian Gene Technology Act: https://lovdata.no/lov/1993-04-02-38
Genome editing	A type of genetic modification limited to the editing of DNA with techniques such as CRISPR, ZFN, and TALEN to target genetic changes to a specific location in a genome. Most often with the aim to change single nucleotides or produce short insertions/deletions (indels).
Site-directed nucleases	Group of enzymes that are capable of targeted cleavage of a double-stranded DNA molecule/genome, based on recognition of a defined nucleotide sequence. The main site-directed nucleases (SDN) are ZFNs, TALENs, and Cas of the CRISPR system. These are usually engineered forms of enzymes found in bacteria. The outcome of their use has been categorised in 3 groups by EFSA (EFSA, 2012a): SDN1, SDN2, and SDN3.
SDN1	Category of genome-edited organisms where the edited genome contains a single or a few base-pair changes after non-homologous end joining (NHEJ) of targeted double-strand breaks in the genome.
SDN2	Category of genome-edited organisms where the edited genome contains single or a few defined base-pair changes after template-based repair of targeted double-strand breaks in the genome.
SDN3	Category of genome-edited organisms where the edited genome contains longer DNA fragments inserted after template-based homologous repair of targeted double-strand breaks in the genome. This use of SDNs enable site-directed insertion of the cis-, intra-, or transgene rather than random insertions as is the case for most commercialized GM plants.
ODM	Oligonucleotide-Directed Mutagenesis (ODM) employs synthetic oligonucleotides (20–100 nucleotides long) that are homologous to a target gene sequence but contain specific mismatches. These oligonucleotides induce point mutations, small insertions, or deletions without introducing foreign DNA sequence(s). The cell's endogenous DNA repair machinery incorporates the desired changes, and the oligonucleotides are subsequently degraded. No double-strand breaks or foreign DNA is involved (Sauer et al., 2016).
Cisgenesis	Cisgenesis is the genetic modification of a recipient organism with a gene from a crossable sexually compatible organism (same species or closely related species). This gene includes its introns and is flanked by its native promoter and terminator in the normal sense orientation (EFSA, 2012b).
Intragenesis	Intragenesis is a genetic modification of a recipient organism that leads to a combination of different gene fragments from donor organism(s) of the same or a sexually compatible species as the recipient. These may be arranged in a sense or antisense orientation compared to their orientation in the donor organism.

Transgenesis	Transgenesis is a genetic modification introducing an exogenous or modified gene (transgene) into a recipient organism of a different species than the organism from which the gene is derived.
New Genomic Techniques (NGTs)	NGTs refer to a collection of modern biotechnological methods that enable targeted modifications of an organism's genetic material. In plants, NGTs are used to develop new crop varieties with improved traits, such as disease resistance, drought tolerance, nutritional enhancements, or reduced allergens/toxins. NGTs include techniques that have emerged or been developed since 2001, and they differ from older genetic modification techniques by offering greater precision, efficiency, and control, often without inserting foreign DNA. Examples of NGTs: ○ Site-Directed Nucleases (SDNs), like CRISPR-Cas, TALENs, ZFNs ○ Oligonucleotide-Directed Mutagenesis (ODM) ○ Base editing and prime editing ○ RNA-dependent DNA methylation ○ Epigenome editing See Box 1. for details.

Box 1. New Genomic Techniques (NGTs) - main categories

- NGTs using Site-Directed Nucleases (SDNs) that create a double-strand break in DNA. These include applications of site-directed nuclease-mediated genome editing (SDNs: endonucleases, zinc finger nucleases, TALEN and CRISPR-Cas), site-specific recombinase-mediated engineering, site-specific DNA transposition.
- NGTs achieving genome editing without breaking the DNA double helix or generating only a single-strand DNA break. These include applications of oligonucleotide-directed mutagenesis (ODM), base editing, prime editing.
- NGTs inducing epigenomic changes or changes affecting DNA transcription into RNA. These NGTs include applications of site-specific modulation of epigenetic state (DNA methylation modifiers, histone modifiers), site-specific activators and repressors (CRISPRa and CRISPRi).
- NGTs acting specifically on RNA. These NGTs include RNA base editing, oligonucleotide-meditated RNA interference, CRISPR-Cas-mediated PAM-independent RNA interference, RNA splice isoform manipulation.

Adopted from Broothaerts et al (2021).

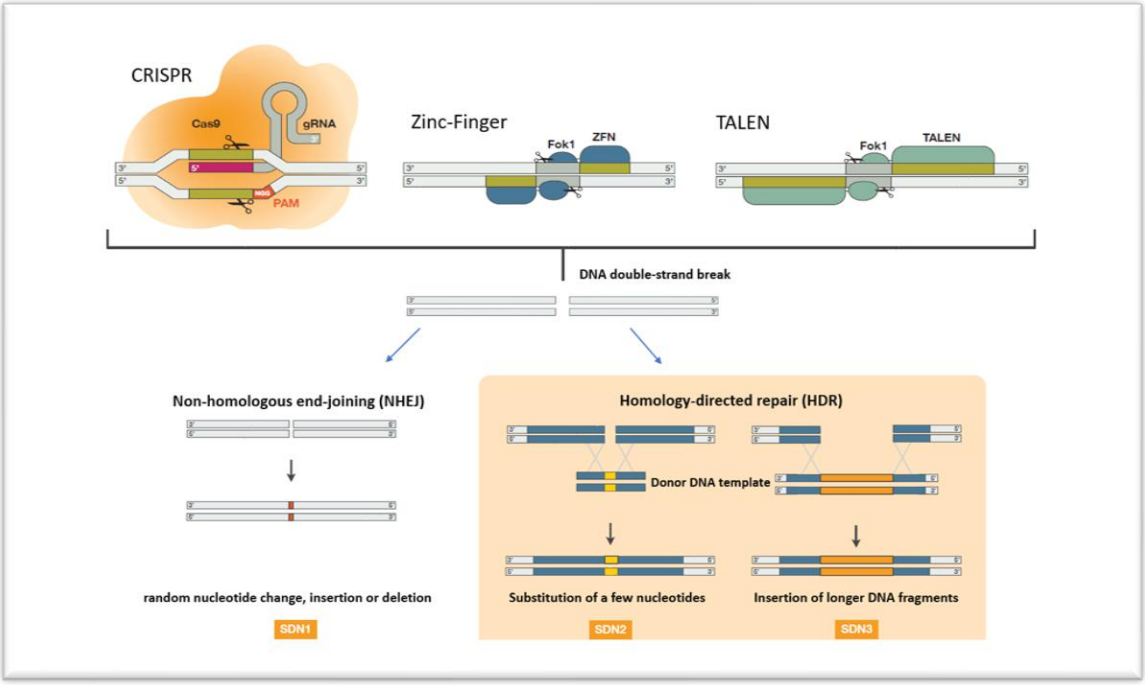

Figure 1. The outcome of genome editing with engineered site-directed nucleases (CRISPR, ZFNs and TALENs). The starting point for each genome editing is that site-directed nucleases (SDN) - "molecular scissors" - cut DNA at specific sites directed by their DNA-binding moiety, introducing a double-strand break (DSB) which triggers cellular DNA repair mechanisms. If no template (donor DNA) is added, the induced break is repaired using NHEJ (non-homologous end joining) pathway leading to gene disruption (SDN1). If a homologous repair template containing one or several single nucleotide variants is added, the break is repaired using HDR (homology directed repair) pathway resulting in gene correction (SDN2). If the added template contains longer DNA insertions flanked by sequences homologous to the target DNA site, the construct is inserted by either HDR or NHEJ (SDN3) (VKM, 2021).

2 Cross-cutting considerations

These are fundamental considerations for the individual parts of an ERA and constitute key information that risk assessors require to perform a sound risk assessment. Cross-cutting considerations as outlined in EFSA (2010), include the choice of comparators, receiving environment(s), statistical considerations, and long-term effects.

2.1 Choice of comparator(s)

A key scientific concept in risk assessment of GMOs is the comparative approach. This approach dictates that the GMO in question should be compared to its nearest conventional non-modified genetic relative - the comparator, throughout all steps of the risk assessment. The assumption is that the use of an appropriate comparator will disclose whether there are elevated risks of adverse effects associated with the GMO in comparison to conventional varieties, for example regarding impacts on the environment.

For field trials, information/data relating to the performance or traits of strictly defined comparators may not always be available to researchers prior to having done the experiment(s). Potential hazards to the environment may therefore instead be assessed for the GM plant as such, with reference to one or more conventional varieties already cultivated in Norway as general comparators.

2.2 Receiving environment(s)

Receiving environment(s) is the environment into which a GM plant is intended for release and into which the genetic modification(s), e.g. a gene edit or a transgene insertion, may spread. Receiving environment(s) is described by EFSA (2010) as characterised by the interaction between the GM plant (e.g. plant species, genetic modification(s) and intended uses(s)); the biogeographical zones and ecosystems (e.g. the climate, altitude, soil, water, flora, fauna, habitats…); and management systems (e.g. land use and production systems, and cultivation practices.).

Intended use in a small-sized field trial will limit the amount of data expected for an ERA. Still, applicants should consider the relevance of the different aspects for their specific trial(s) when composing the application.

If for example the parent plant of the GM plant is native to the Norwegian flora or closely related and may persist or be capable of crossing with plant species, wild or cultivated, at or near the trial site, thorough documentation that can support the risk assessment of such scenarios would be required in an application. The possibilities of the GM plant to spread to protected areas, invade threatened habitat types, hybridise with or replace threatened or key-stone species should be given special attention. If such scenarios are identified, risk reducing measures should be suggested.

2.3 General statistical principles

General statistical principles encompass relevant hypotheses, experimental designs and methodologies in order to generate high quality data. The statistical expectations as outlined

in EFSA (2010) mainly relate to the quality of data presented at later stages of an ERA, i.e., in applications of large-scale cultivation and production of GMOs to be used as food or feed. For the early phase field trials of a GM plant, the statistical principles would mainly concern the applicant's need to ensure that informative data can be collected after repeated field trials.

On this note, the description and soundness of a proposed experimental design of a field trial could be weighted differently (either more, or less stringent) by risk assessors, depending on whether hazards have been identified relating to the plant itself or to the introduced traits of the GM plant. E.g., an application for a field trial with GM plants considered to have a high risk of hybridising with certain plants in Norwegian flora would suggest that a detailed description of a rigorous experimental design is required in the application documentation.

2.4 Long-term effects

Potential for long-term effects, such as genetic homogeneity or loss of key stone species, should be discussed for both annual and perennial species and should in all cases cover the period over which progeny of the GM plant might persist and appear as volunteers or feral plants after the field trial is completed. Potential for spread should be mitigated by predetermined risk-reducing measures.

3 Specific areas of risk to be addressed in the ERA

Several factors should be considered in an ERA, including whether the plant is present in Norwegian flora or 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.

Based on the EFSAs guidance, the areas of concern and cross-cutting considerations addressed in ERAs of GM plants intended for field trials are:

- 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.
- Risk reducing measures.

The following seven sections elaborate on these areas of concern and describe at the general level key information that should be included in an applicant's submitted documentation.

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

GM plants may pose an environmental risk related to the potential of spreading caused by persistence or invasiveness of the plant itself, or via vertical gene transfer (VGT) to compatible cultivated or wild relatives. Enhanced fitness of feral GM plants, or of cultivated relatives with introgressed genetic modifications, may allow for invasion of new communities or occupation of new niches, which may reduce native biodiversity. Moreover, plant-to-plant gene flow from GM plants to compatible wild relatives may result in genetic contamination of wild populations.

In providing the necessary data requested below, the applicant should consider the following. Environmental risks related to persistence and invasiveness, as well as hybridisation and introgression with compatible cultivated or wild relatives, should be described. Information on the following subjects should be addressed regarding the characteristics of the GM plant: reproductive biology, characteristics associated with weediness and invasiveness, factors limiting persistence and invasiveness (e.g. abiotic factors), and potential for hybridisation and introgression with compatible cultivated and wild relatives. Trait-specific information is appropriate to address questions of altered fitness of GM plants. Potential negative effects on identified protection goals such as protected areas, threatened or key-stone species and threatened habitat types should be given special attention.

Data and documentation should be provided to assess:

Step 1. Hazard identification

The applicant should identify characteristics of the GM plant that could affect invasiveness and plant-to plant gene flow (VGT, e.g. plant species that are relevant for hybridization). If a hazard has been identified in step 1, the following steps should be completed.

Step 2. Hazard characterisation

The applicant should describe how characteristics of the GM plant relating to invasiveness and VGT, can induce adverse effects in the environment outside the field trial (e.g. what type of adverse consequences could a possible hybrid or feral population introduce in the environment?).

Step 3. Exposure characterisation

The applicant should consider and discuss the possible exposure routes of the GM plant to adjacent flora and likelihood of these to occur.

Step 4. Risk characterisation

The applicant should estimate the risk based on the identified and characterised hazards, magnitude of consequences and the likelihood of these to occur.

Step 5. Risk reducing measures

If risks are identified adequate risk reducing measures should be described including how they will be implemented and documented during the field trial.

The applicant should discuss an overall risk for the area of concern taking into account the effect of any risk reducing measures and remaining uncertainties.

Step 6. Uncertainties

The applicant should describe encountered uncertainties and/or data gaps of importance for the risk conclusion.

3.2 Plant to microorganism gene transfer

The likelihood of gene transfer into microorganisms, i.e. horizontal gene transfer (HGT), should be assessed. This assessment should include an analysis of the potential transfer of transgenes to initially receiving micro-organisms and the potential for subsequent transfer to other organisms (e.g. microorganisms and plants). The potential environmental consequences of such a gene transfer should be considered. The use of antibiotic resistance marker genes in the GM plant is of special interest in this context.

Factors that may affect the probability of HGT include e.g. presence of microbial recipients with similarities in their DNA sequences compared to the inserted/modified plant sequence, and length and extent of the field trial.

Step 1. Hazard identification

The applicant should assess the presence of possible microbial candidates for HGT in the receiving environment and ideally identify those with similar sequences in their DNA to that of the modified sequence(s) of the GM plant. If a hazard has been identified in step 1., the following steps should be completed.

Step 2. Hazard characterisation

The applicant should discuss whether characteristics of the GM plant could facilitate or increase the possibility for HGT and discuss possible consequences of HGT of the new (GM) trait(s) if introduced into the environment. E.g. via microbes into local microbiota.

Step 3. Exposure characterisation

The applicant should consider and discuss possible factors increasing the risk of HGT, e.g. length and extent of the field trial.

Step 4. Risk characterisation

The applicant should estimate the risk based on the identified and characterised hazards, magnitude of consequences and the likelihood of these to occur.

Step 5. Risk reducing measures

If risks are identified, adequate risk reducing measures should be suggested. Examples of such measures are waste handling and disposal, i.e. high temperature treatment and monitoring of GM spread and removal of feral plants/ volunteers. Manual handling could also minimize the risk of spread of GM plant material and DNA. If applying risk reducing measures, these should be described including how they will be implemented and documented during the field trial.

The applicant should discuss an overall risk for the area of concern taking into account the effect of any risk reducing measures and remaining uncertainties.

Step 6. Uncertainties

The applicant should describe encountered uncertainties and/or data gaps of importance for the risk conclusion.

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

Target organisms (TOs) are organisms on which specifically designed characteristics of a GM plant are intended to act. These are usually pests or pathogens of the plant. The target organisms (if any) should be defined in the application. Data from previous studies may be used as supporting information for the likelihood of interaction with the target organism. The possibility of a target pest to develop resistance should be evaluated with regard to pathogen virulence and selective advantage. The potential for resistance development is based on the pathogen's history of resistance development to conventional pesticides and resistant host plants. The biology (life cycle and known frequency of resistance development) and distribution of the target organisms should be described.

Step 1. Problem formulation including hazard identification

The applicant should define any target organism (TO) and identify potential resistance development of the TO. If a hazard has been identified in step 1., the following steps should be completed.

Step 2. Hazard characterisation

If the applicant has identified hazards in the interaction with the TO due to the modification, the potential consequences and adverse effects in the environment if the TO develops resistance should be discussed.

Step 3. Exposure characterisation

The applicant should discuss the exposure route and likelihood of the TO to develop resistance, considering the exposure period and overall duration of the field trial.

Step 4. Risk characterisation

The applicant should estimate the risk based on the identified and characterised hazards, magnitude of consequences and the likelihood of these to occur.

Step 5. Risk reducing measures

If risks are identified adequate risk reducing measures should be considered.

The applicant should discuss an overall risk for the area of concern taking into account the effect of any risk reducing measures and remaining uncertainties.

Step 6. Uncertainties

The applicant should describe encountered uncertainties and/or data gaps of importance for the risk conclusion.

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

Possible environmental impact resulting from direct and indirect interactions of the GM plant with non-target organisms (NTOs) should be considered. This includes for instance the potential for impact on herbivores, natural competitors, symbionts, pollinators, parasites, pathogens and soil microorganisms that are not the intended or defined as the target organisms, but that could be affected. Results/findings from previous studies can support absence of interactions with defined NTOs.

Step 1. Problem formulation including hazard identification

The applicant should identify hazards and possible adverse effects due to interaction between the GM plant and NTOs in the receiving environment and specifically consider if any of the NTOs are protected or threatened[1] or key-stone species. If a hazard has been identified in step 1., the following steps should be completed.

Step 2. Hazard characterisation

The applicant should characterise the effects on NTO.

Step 3. Exposure characterisation

The applicant should describe possible exposure routes for NTO interactions, and the likelihood of exposure.

Step 4. Risk characterisation

The magnitude of potential adverse effects of the GM plant on NTOs and the likelihood for them to occur should be considered.

Step 5. Risk reducing measures

If risks are identified adequate risk reducing measures should be described. The extent and length of the field trial could be considered if adverse effects on NTOs are identified.

The applicant should discuss an overall risk for the area of concern taking into account the effect of any risk reducing measures and remaining uncertainties.

6. Uncertainties

[1] Norsk-rodliste-for-arter-2021-artsdatabanken.pdf (p. 4)

The applicant should describe encountered uncertainties and/or data gaps of importance for the risk conclusion.

3.5 Impacts of the specific cultivation, management and harvesting techniques

Cultivation of GM plants may require specific management practices and cultivation techniques. The applicant should describe if e.g. herbicide management, soil tillage and use of insecticides will be altered due to the characteristics of the modified plant compared to conventional cultivation of the non-GM counterpart.

Step 1. Problem formulation including hazard identification

The applicant should identify possible hazards related to the altered practices and cultivation techniques if relevant. It is noted that adverse effects of specific cultivation, management and harvesting techniques are generally expected to be transient in most field trials of limited time and scope and considered more relevant for large scale (commercial) cultivation systems.

If a hazard has been identified in step 1., the following steps should be completed.

Step 2. Hazard characterisation

The applicant should discuss any adversity of the effects of altered practices and cultivation techniques.

Step 3. Exposure characterisation

The applicant should describe exposure routes for the adverse effects of altered practices and cultivation techniques if relevant, e.g. time and frequency of herbicide treatment.

Step 4. Risk characterisation

The magnitude of potential adverse effects by altered practices and cultivation techniques and the likelihood for them to occur should be considered/discussed by the applicant.

Step 5. Risk reducing measures

If risks are identified adequate risk reducing measures should be considered.

The applicant should discuss an overall risk for the area of concern taking into account the effect of any risk reducing measures and remaining uncertainties.

Step 6. Uncertainties

The applicant should describe encountered uncertainties and/or data gaps of importance for the risk conclusion.

3.6 Effects on biogeochemical processes

Biogeochemical processes include the movement, transformation, recycling and storage of energy, water, carbon, nitrogen, phosphorous and other elements in ecosystems. Possible

effects of the genetically modified plant on processes like formation of soil organic matter, evaporation of water from fields, altered uptake and cycling of plant nutrients and transformation of nitrogenous compounds related to greenhouse gasses should be described, when relevant.

Step 1. Problem formulation including hazard identification

The applicant should identify possible interactions and adverse effects on biogeochemical processes if relevant. It is noted that adverse effects on biogeochemical processes are generally not expected from field trials of limited time and scope. If a hazard has been identified in step 1., the following steps should be completed.

Step 2. Hazard characterisation

The applicant should discuss adversity of the effects on biogeochemical processes.

Step 3. Exposure characterisation

The applicant should describe exposure routes for the adverse effects on biogeochemical processes and the likelihood of these to occur.

Step 4. Risk characterisation

The magnitude of potential adverse effects on biogeochemical processes and the likelihood for them to occur should be considered/discussed by the applicant.

Step 5. Risk reducing measures

If risks are identified adequate risk reducing measures should be considered.

The applicant should discuss an overall risk for the area of concern taking into account the effect of any risk reducing measures and remaining uncertainties.

6. Uncertainties

The applicant should describe encountered uncertainties and/or data gaps of importance for the risk conclusion.

3.7 Effects on human and animal health

An assessment of potential hazards to human and animal health related to exposure to the plant, e.g. to pollen, dust, or other constituents via handling (occupational exposure) or unintentional consumption should be considered, when relevant.

Step 1. Problem formulation including hazard identification

The applicant should describe if the new characteristics of the GM plant may introduce adverse effects on humans handling the GM plant or animals after undeliberate foraging on the GM plant. It is noted that adverse effects on human and animal health are generally not expected from field trials of limited time and scope. If a hazard has been identified in step 1., the following steps should be completed.

Step 2. Hazard characterisation

The applicant should characterize the adversity of identified effects on human and animal health.

Step 3. Exposure characterisation

The applicant should describe exposure routes for adverse effects on humans and animal health

Step 4. Risk characterisation

The applicant should discuss the likelihood of adverse effects of the GM plant on human and animal health.

Step 5. Risk reducing measures

If risks are identified adequate risk reducing measures should be suggested, like protective clothing or face masks, and enclosures to avoid unintentional foraging by animals.

The applicant should discuss an overall risk for the area of concern taking into account the effect of any risk reducing measures and remaining uncertainties.

6. Uncertainties

The applicant should describe encountered uncertainties and/or data gaps of importance for the risk conclusion.

4 Risk reducing measures

Risk reducing measures may be various containment strategies as well as removal and adequate disposal of GM material, e.g., by autoclavation or incineration when necessary.

This task also includes a description of safeguards in place during and post field experiment. Follow-up measures may include e.g., disposal of feral plants and plant residues, and an extended monitoring period of the cultivated area.

Risk reducing measures should be suggested if risks to the environment have been identified. The following key factors determine the extent of risk reducing measures:

- A hazard of the GM plant is identified (potential of survival, spreading and invasiveness is altered due to the introduced modification).
- Extent of use/cultivation, the size of field trial and proximity to nearby fields and ecosystems, wild flora and fauna, and pollen/propagule dispersal range.
- Proximity and potential corridors to protected areas, threatened or key-stone species or threatened habitat types.
- Presence of sexually compatible relatives.

- Size, location and duration of the field trial could be considered if risks to the receiving environment are identified.

Concluding remarks

The overall risk is assessed by VKM, based on the data provided by the applicant.

The risk analysis is based on the adversity of the risks identified for each area of concern and the sum of overall adverse effects on the environment or human and animal health taking into account risk reducing measures. Transparency regarding encountered uncertainties that may affect the risk conclusion is important. The applicant may address any encountered uncertainties with data from published studies with the same modified plants or other plants having the same characteristics or modification.

Data collected from field trials often form the basis for further and larger scale experiments and applications for commercial production. In this context, it is important that the quality of the experimental design and collected data from the field trial is at the level ensuring proper statistical power for identifying relevant differences to comparator and revealing potential adverse effects.

For all applications, experimental genetic data is necessary that describe the genetic modification introduced into the specific transformation/editing events in the GM plant to be used in the field trial.

Where adverse effects on the environment or human and animal health have been identified, risk reducing measures should be included in the field trial design to minimize the risks associated with the GM plant.

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