Annex G. Biodiversity (Protected Species and Habitats/Ecosystems)

A consideration for the environmental risk/safety assessment of a transgenic plant is the evaluation of the potential for it to have adverse effects on biodiversity of species and habitats/ecosystems explicitly protected by legislation of a country or a region.

Concepts and terms

Protection of biodiversity at genetic, species, and habitat/ecosystem levels is an overarching issue that is integral to environmental risk/safety assessment.

Addressing the potential environmental impact of the release into the environment of a transgenic plant on biodiversity is approached differently in different jurisdictions. For the purpose of this annex, biodiversity or biological diversity focuses on species and/or geographically defined habitats/ecosystems explicitly protected by legislation of a country or region. Biodiversity is also considered in a number of the other environmental consideration annexes relative to potential impacts of a transgenic plant on the biodiversity of species valued (but not explicitly protected) for a variety of reasons including, but not limited to, their contribution to ecological functions. Elements of a number of the environmental considerations described in the other annexes could also be relevant for evaluating the potential of a transgenic plant to adversely affect explicitly protected species and habitats/ecosystems.

However, the conceptual framework for evaluating the potential for a trangenic plant to adversely affect explicitly protected species differs somewhat from the conceptual framework employed in Annexes A-F. For an explicitly protected species, the conservation of every individual of the protected species is important in maintaining the ability of a species to evolve in response to changing environmental variables and avoid extinction. The need to conserve each individual in the species leads assessors, particularly for those species that are low in numbers and could be harmed by testing (e.g. insects), to equate the number of individuals to the genetic diversity of the species. In general, as the number of individuals in a species dwindles, the species loses diversity. For this reason, the conceptual framework generally employed when considering the genetic diversity of an explicitly protected species is the potential effect of the transgenic plant on each individual of an explicitly protected species. Maintaining the numbers of an explicitly protected species is a measure employed to maintain the genetic diversity of the species and thus helps to avoid species extinction.

<u>Biodiversity</u>, or <u>biological diversity</u>, means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part. This includes the diversity within species, between species and of ecosystems (CBD, 1992).

<u>Explicitly protected species or habitats/ecosystems</u> include, for the purpose of this annex, animal or plant species and/or habitats/ecosystems that are explicitly listed as protected due, for example, to their level of endangerment or threatened status (i.e. national endangered species/critical habitat legislation) or their cultural significance because of the responsibility a country has for the given species (e.g. Commonwealth of Australia, 1999).

Protected habitat/ecosystem means a geographically defined area or areas which is/are designated or regulated and managed to achieve specific conservation objectives (see e.g. CBD, 1992). For the sake of simplicity, “explicitly protected species or habitats/ecosystems” are referred to in the text to follow as “protected species or habitats/ecosystems”. In many jurisdictions, species protection is approached in a way that connects the protected species and its habitat/ecosystem, because protected species, in general, are unlikely to survive without the environment that provides the elements necessary for the survival of the species (e.g. the United States’ Endangered Species Act 1973 (USA, 1973), Australia’s Environment Protection and Biodiversity Conservation Act 1999 (Commonwealth of Australia, 1999), and the European Union’s Directive 92/43/EEC 1992 on the Conservation of Natural Habitats and of Wild Fauna and Flora (European Union, 1992)).

Box A G.1. Explicitly protected habitats in the European Union (EU)

In the EU, the Habitats Directive (Council Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora) ensures the conservation of a wide range of rare, threatened or endemic animal and plant species. In addition, some 200 rare and characteristic habitat types are also targeted for conservation in their own right, e.g. ‘Mesophile grasslands’, ‘Forests of temperate Europe’, ‘Sphagnum acid bogs’ or ‘Thermo-Mediterranean and pre-steppe brush’.

Hence, in the EU habitats that are protected due to their function as living area for protected species and/or due to their own rare or endangered habitat composition. In consequence, both aspects are considered during the risk/safety assessment of a transgenic plant for the release into the environment according to Commission Directive (EU) 2018/350 where protected habitats are referred to as ‘protected areas’.

Source: European Union (2018), https://ec.europa.eu/environment/nature/legislation/habitatsdirective/index_en.htm (accessed 12 July 2023).

Box A G.2. Explicitly protected habitats in the United States of America (USA)

During an evaluation of a transgenic plant for experimental testing or commercial use, the protected habitat is considered in the context of designated critical habitat of federally listed threatened and endangered species. Under the USA’s Endangered Species Act 1973, critical habitat is the specific areas within the geographic area occupied by the species at the time it was listed, that contain the physical or biological features that are essential to the conservation of endangered and threatened species and that may need special management or protection. Designated critical habitat of listed species is an important consideration as many protected species in general are unlikely to survive without the environment that provides the elements necessary for the survival of the species.

Source: U.S Fish and Wildlife Service (1973), Endangered Species Act.

Genetic diversity represents both an overall protection aim (e.g. in the CBD, 1992) as well as a factor taken into account when evaluating the potential for a transgenic plant to affect a protected species. This is because the ability to adapt to changing environmental conditions is vital for the survival of wild species and especially, protected species, and the ability to respond to changing environmental conditions is expressed and maintained/conserved at genetic level. As noted above, the number of individuals may serve as a proxy for measuring genetic diversity.

Ecosystem means a dynamic complex of plant, animal, micro-organism communities and their interaction with abiotic features of the environment as a functional unit (see e.g. CBD, 1992). With a focus on individual organisms, habitat means the place or type of site where an organism or population naturally occurs (CBD, 1992). As jurisdictions may use habitat as another term for ecosystem (e.g. natural habitat types in European Union, 1992), we use the term habitat/ecosystem in this annex as a means of capturing all of these meanings. In the context of this annex ecological functions or habitat functions are those functions that an organism, population or community contributes to the habitat/ecosystem in which it resides.

Habitat structure comprises physical components of a habitat which are often formed by species and decomposing matter (e.g. standing or lying dead wood), but can also include abiotic features (e.g. gravel banks for spawning, water resources). Habitat structure is one of the key criterions for the assessment of habitat quality. Further criteria describing the quality of a habitat are habitat functions, typical species, the range and the area of the habitat.

Typical species are those frequently found in a habitat type or at least in a subtype or a variant of a habitat type (e.g. DG Environment, 2017).

Problem formulation

For this consideration, below are simple examples that illustrate the approach for planning an environmental risk/safety assessment. It includes a discussion of assessment endpoints, potential adverse effects, and a linear pathway to harm with corresponding risk hypotheses and information elements to illustrate the approach. As previously indicated in the document (section 1.2.6), the process is often more complex.

(a) Determination of assessment endpoints

A transgenic plant may have impacts on a protected species with which it interacts. At the species level, the attribute of the assessment endpoint is the number of individuals in (a) population(s) of the protected species under assessment, and not the ecological function the species fulfils, distinguishing this annex from the other environmental considerations discussed in this document (e.g. Annex C (Organisms (Animals)) or Annex D (Soil Functions)).

Maintaining the genetic diversity of a species or a population is an overall aim of conservation/protection of a species. Genetic diversity can be a specific, direct assessment endpoint for a species when it is possible to test the genotypes of individuals. This is more likely to be done in relation to conversation programmes. In a risk/safety assessment of a transgenic plant, as explained above, genetic diversity of a protected species can be indirectly assessed, for example, as (1) the abundance (the number of individuals in a given area), (2) the number and the size (number of individuals) of populations, and/or (3) the geographic distribution of the protected species. A transgenic plant may also influence a protected habitat/ecosystem, changing its species composition, structure, and/or quality. For example, if the transgene confers a characteristic that allows the transgenic plant to invade the protected habitat/ ecosystem, it may change the flora of the habitat/ecosystem and thereby, also the fauna of the habitat/ ecosystem, and finally the structure and/or quality of the habitat/ecosystem.

Two examples of assessment endpoints for the protected species and habitats/ecosystems as examples of the biodiversity environmental consideration are: (1) number of individuals in (a) population(s) of protected species under assessment, that as a proxy could correlate with genetic diversity of the protected species; and (2) species composition, structure and/or quality of the protected habitat/ecosystem.

(b) Identification of potential adverse effects on the assessment endpoints

The identification of potential adverse effects of a transgenic plant on biodiversity considers the characteristics of the transgenic plant linked to the genetic modification, including the novel gene product(s) or compounds and the potential receiving environments.

Any interaction of the transgenic plant with species or habitats/ecosystems dealt within the other annexes that has the potential to lead to adverse effects on protected species or habitat/ecosystems is, by nature, also relevant for biodiversity. The transgenic plant may alter the quality of a protected habitat/ecosystem located in the vicinity of a cultivation area by affecting the abundance or ecological functions of typical or vital species of a protected habitat/ecosystem, or by affecting the abiotic conditions of a protected habitat/ecosystem. As a result, the quality of the habitat/ecosystem may change.

Depending on the changed characteristics of the transgenic plant, in relation to the comparator that warrant further consideration, adverse effects on the assessment endpoints related to protected species and habitats/ecosystems may include: (1) reduced number of individuals in (a) population(s) of the protected animal species under assessment, that as a proxy could correlate with decreased/altered level of genetic diversity, of the protected animal species; and (2) changed species composition, structure and/or reduced quality of the protected habitat/ecosystem.

(c) Identification of plausible pathways to harm, formulation of risk hypotheses, and identification of information elements relevant to evaluating the risk hypotheses

In this section, two plausible pathways to harm are postulated. For each step of the postulated pathways to harm, a corresponding risk hypothesis is formulated that will enable the risk assessor to determine whether the pathways are likely to occur. Once it is shown that any part of a pathway is highly unlikely to occur, one does not need to continue evaluating the subsequent steps in the pathway and can conclude that the specific pathway to harm is unlikely to occur. In addition, examples of information elements that can be used to evaluate the risk hypotheses are given along with their rationales.

Because the adverse effects a transgenic plant can potentially have on a protected species, including their genetic diversity or habitat/ecosystem, may, in principle, happen via the same types of interactions as described in some of the other annexes, it follows that some of the same pathways to harm are also relevant. It should be noted that although the pathways and the risk hypotheses may overlap, the information elements may need to be adapted specifically to the protected species or habitat/ecosystem under consideration.

Postulated pathway leading to reduced numbers of individuals and genetic diversity of a protected animal species

Protected animal species occurring in the field or in field margins (i.e. managed ecosystems) and surroundings (e.g. unmanaged ecosystems) can interact with the transgenic plant through feeding. If the transgenic plant has a changed phenotype, this may lead to decreased survival, reproduction, fitness, and thus affect the abundance and genetic diversity of protected animal species. This is in principle the same as for any other species, as described in Annex C (Organisms (Animals)). However, in the case of a protected animal species, the attribute of the assessment endpoint is the number of individuals of the species itself and its genetic diversity and not the ecological function that the species in question provides. Hence, different information elements may be necessary.

One example of a postulated pathway to harm for the reduced numbers of individuals and genetic diversity of a protected animal species is shown in the first column of Table A G.1. Risk hypotheses for each step of the pathway are formulated in the second column and the third column provides examples of information elements for evaluating the hypotheses.

Table A G.1. Postulated pathway leading to reduced numbers of individuals and genetic diversity of a pollen-feeding protected lepidopteran species, corresponding risk hypotheses, and relevant information elements

Pathway steps	Risk hypotheses	Examples of information elements
In relation to the comparator, the transgenic plant produces a novel gene product	In relation to the comparator, the transgenic plant does not produce a novel gene product	Expression of a novel gene product in the transgenic plant
The novel gene product has a potential toxic effect on the protected lepidopteran species	The novel gene product has no potential toxic effect on the protected lepidopteran species	Sequence similarity to known toxic compounds Toxicity lab tests with surrogate species
The expression level of the novel gene product in the pollen of the transgenic plant adversely affects the protected lepidopteran species	The expression level of the novel gene product in the pollen of the transgenic plant does not adversely affect the protected lepidopteran species	Expression level of the novel gene product in pollen of the transgenic plant Comparison of expression level of the novel gene product in pollen and levels tested in toxicity lab tests with surrogate species
The larval food plant of the protected lepidopteran species is found in areas immediately adjacent to the transgenic plant	The larval food plant of the protected lepidopteran species is not found in areas immediately adjacent to the transgenic plant	Protected species location information and location of where the crop that contains the novel gene product will be grown
Pollen containing the novel gene product reaches the food plant of larvae of the protected lepidopteran species at levels that adversely affect the protected lepidopteran species	Pollen containing the novel gene product does not reach the food plant of larvae of the protected lepidopteran species at levels that adversely affect the protected lepidopteran species	Pollen dispersal characteristics of the transgenic plant Comparison of levels of the novel gene product expected to reach the larval food plant and levels tested in toxicity lab tests with surrogate species
There is overlap between the period of pollen shed from the transgenic plant and larval emergence of the protected lepidopteran species	There is not overlap between the period of pollen shed from the transgenic plant and larval emergence of the protected lepidopteran species	Knowledge of the phenology of the transgenic plant and of the protected lepidopteran species
An individual of the protected species ingests the novel gene product leading to decreased survival, reproduction, or fitness of the protected lepidopteran species	An individual of the protected species does not ingest the novel gene product and there is no decrease in the survival, reproduction, or fitness of the protected lepidopteran species	Number of individuals of the protected lepidopteran species
Number of individuals of the protected species decreases, and therefore genetic diversity decreases, due to decreased survival, reproduction, or fitness of the protected lepidopteran species		

It is important to note that examples of information elements in this table are intended to illustrate the types of information that can be used in evaluating a risk hypothesis, i.e. to determine whether particular pathway steps are likely to occur. However, for any step there might be other information that could be relevant. Rationales for how such information elements may be used to evaluate the risk hypotheses include:

- Information on where in the transgenic plant (e.g. pollen or leaves) the novel gene product is expressed and on the level of expression in the plant tissues, is useful in determining potential routes of exposure;
- Sequence similarity to known toxic compounds and toxicity lab tests with surrogate species provide information on potential adverse effects of the transgenic plant to the protected lepidopteran species;
- Toxicity testing of the novel gene product or of the pollen of the transgenic plant containing the novel gene product with surrogate species provide information on potential adverse effects of the transgenic plant to protected lepidopteran species;
- Protected lepidopteran species location information and location of where the crop that contains the novel gene product will be grown provide knowledge as to whether there is overlap between the habitat/ecosystem of the protected lepidopteran species and the area where the transgenic plant is grown;
- Pollen dispersal characteristics of the transgenic plant provides information on the potential for exposure;
- Comparison of levels of the novel gene product expected to reach the larval food plant and levels tested in toxicity lab tests with surrogate species provide information on whether potential adverse effects may result from the degree of exposure;
- Knowledge of the phenology of the transgenic plant and of the protected lepidopteran species provide information as to whether there is temporal overlap, e.g. timing of anthesis and/or larval emergence;
- A change in the number of individuals of the protected lepidopteran species can indicate decreased genetic diversity, survival, reproduction, or fitness of the protected lepidopteran species.

Postulated pathway leading to a changed species composition, structure, and reduced quality of a protected habitat/ecosystem

The cultivation of a transgenic plant may change the species composition, structure and reduce the quality of a neighboring protected habitat/ecosystem by affecting either species that are typical and vital for the specific habitat/ecosystem or by affecting functions and services that are vital for typical species in this protected habitat/ecosystem.

The postulated pathways leading to changes in the species composition, structure and reduced quality of protected habitats/ecosystems are in reality very complex. Many pathways overlap, pathways may have several branches and some information is not easily obtained.

One example of a postulated pathway to harm for changed species composition, structure, and reduced quality of a protected habitat/ecosystem is shown in the first column of Table A G.2. Risk hypotheses for each step of the pathway are formulated in the second column and the third column provides examples of information elements for evaluating the hypotheses.

Table A G.2. Postulated pathway leading to changed species composition, structure, and reduced quality of a protected habitat/ecosystem, corresponding risk hypotheses, and relevant information elements

Pathway steps	Risk hypotheses	Examples of information elements
The transgenic plant is a tree, and the introduced trait confers increased tolerance to drought stress due to water use relative to the comparator	The introduced trait does not confer increased tolerance to drought stress due to water use relative to the comparator	Function of the introduced gene and associated phenotype of the transgenic tree
The transgenic tree is planted in the area of a protected habitat/ecosystem	The transgenic tree is not planted in the area of a protected habitat/ecosystem	Knowledge of locations of protected habitats/ecosystems; Visual observation of protected habitats/ecosystems
Seeds of the transgenic tree are spread in a neighbouring protected habitat/ecosystem.	Seeds of the transgenic tree are not spread in a neighbouring protected habitat/ecosystem	Existence of protected habitats/ecosystems in the area of cultivation; Seed dispersal distance
The transgenic tree has a fitness advantage in a protected habitat/ecosystem compared to the comparator due to water use (e.g. roots extend deeper into the soil and hence access water table better than comparator).	The transgenic tree does not have a fitness advantage in a protected habitat/ecosystem compared to the comparator due to water use	Presence of drought stress in a protected habitat/ecosystem Vegetative and reproductive performance of the transgenic tree and the comparator in the presence of drought stress
The number of self-sustaining populations of the transgenic tree increases in the protected habitat/ecosystem compared to the comparator	The number of self-sustaining populations of the transgenic tree does not increase in the protected habitat/ecosystem compared to the comparator	Establishment and persistence of populations of the transgenic tree in habitat/ecosystem types similar to the protected habitat/ecosystem compared to the comparator
The quality of the protected habitat/ecosystem is reduced through reduction of the water table	The quality of the protected habitat/ecosystem is not reduced through reduction of the water table	Levels to which the water table in areas of cultivation of the transgenic tree is reduced
The abundance of typical plant species of the protected habitat/ecosystem decreases due to the decrease in the water table	The abundance of typical plant species of the protected habitat/ecosystem does not decrease due to the decrease in the water table	Typical plant species of the protected habitat/ecosystem and their ecology particularly with respect to their water consumption needs
Species composition and structure are changed, and quality reduced in the protected habitat/ecosystem		

It is important to note that examples of information elements in this table are intended to illustrate the types of information that can be used in evaluating a risk hypothesis, i.e. to determine whether particular pathway steps are likely to occur. However, for any step there might be other information that could be relevant. Rationales for how such information elements may be used to evaluate the risk hypotheses include:

- Function of the introduced gene and associated phenotype of the transgenic tree provide information on the potential for displaying increased resistance to drought stress due to water use relative to the comparator;

- Existence of protected habitats/ecosystems in the area of cultivation and seed dispersal distance provide information on whether seeds of the transgenic tree may enter in the protected habitats/ecosystems;
- Presence of drought stress in the protected habitat/ecosystem and vegetative and reproductive performance of the transgenic tree and the comparator in the presence of drought stress provide indication of the potential for increased survival and reproduction in the presence of the abiotic stressor;
- Establishment and persistence of populations of the transgenic tree in a habitat/ecosystem types similar to the protected habitat/ecosystem provide information on whether the potential for development of self-sustaining populations of the transgenic tree is increased in the protected habitat/ecosystem;
- Levels to which the water table in areas of cultivation of the transgenic tree is reduced;
- Typical plant species of the protected habitat/ecosystem and their ecology particularly with respect to their water consumption needs;
- Species composition and structure development in comparable habitats/ecosystems if tree populations establish there provide information on the potential that this may happen in the protected habitat/ecosystem as water table falls.

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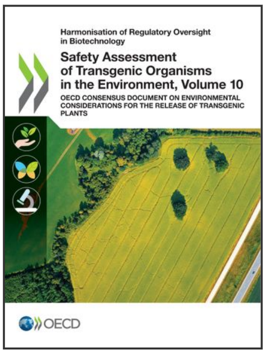

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