

Annex E. Plant Health

A consideration for the environmental risk/safety assessment of a transgenic plant is the evaluation of its potential to have adverse effects on plants in the environment. Relative to the comparator, the transgenic plant may have an unintended increased susceptibility to pests, which may impact plant health in agroecosystems.

Concepts and terms

For the purpose of this annex, we refer to managed and areas adjacent to the cultivated field as the agroecosystem. Therefore, the health of cultivated and other valued plants in the agroecosystem is a consideration in the environmental risk/safety assessment of a transgenic plant.

Plant health refers to a plant's capacity to express its full genetic potential as a valued plant in an agroecosystem. Ideal expression of plant health is the result of optimally exhibited desirable phenotypic traits, such as growth and development or vegetative or reproductive yield.

Pest includes any species, strain, or biotype of plant, animal (e.g. insect), or pathogenic agent (e.g. microbe) injurious to plants or plant products; IPPC, 2021). Pests which are a plant (e.g. weed) or vertebrate animal (e.g. rodent) are beyond the scope of this section.

Host plant is a plant that may harbour a specific pest, depending on that plant's susceptibility.

Susceptibility refers to a plant's inability to restrict the growth and development of a given pest.

Problem formulation

For this consideration, below is a simple example that illustrates 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

Plants have an innate ability to resist pests. Cultivated plants tend to have a reduced ability to resist pests relative to wild plants (Whitehead et al., 2017). Plant breeders have successfully developed pest-resistant varieties through conventional breeding and through transgenic approaches. Selection for traits other than pest-resistance, such as low-lignin to increase forage quality, may increase pest susceptibility in the cultivated plant. Depending on the plant, trait, and environment, a transgenic plant may have an unintended increased susceptibility to certain pests, which may impact plant health in the agroecosystem relative to the comparator.

Operational protection goals derived from the general protection goals (e.g. to protect plant health) may be used as an intermediate step to facilitate the selection of assessment endpoints. An example of an operational protection goal could be to minimise or prevent injury to cultivated and other valued plants

in the agroecosystem by pests associated with the transgenic plant. An example of a relevant assessment endpoint for the operational protection goal is the health of cultivated and other valued plants in the agroecosystem.

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

Plant health may be impacted by the introduction of a cultivated plant to the agroecosystem. Whether adverse effects occur depends on the receiving environment and the phenotypic change. Although the presence of a transgene in a plant does not inherently increase the likelihood of adverse effects on the environment, the phenotypic change derived from the transgene may alter the transgenic plant's impacts relative to the comparator. Phenotypic change associated with the transgene may include novel gene products, modified biochemical components (e.g. polyphenols), or alterations in plant protective architecture (e.g. lignin). These changes may affect the transgenic plant's interaction with pests and lead to adverse effects on plant health in the agroecosystem relative to the comparator.

A phenotypic change, whether derived from conventional breeding or a transgene, may increase the plant's susceptibility to pests and even enhance its capacity to harbour pests. Consequently, if the pest load increases in the agroecosystem, pests could spread and adversely affect plants, either in the same growing season as the transgenic plant or in subsequent seasons, even in the absence of the transgenic plant. For example, pests such as cereal rusts, nematodes, and soil-borne pathogens may survive and spread via alternative host plants or volunteers in the agroecosystem (Zeng and Luo, 2006; Baley et al., 2008; CABI and USDA, 2018).

Thus, depending on the changes in phenotype of the transgenic plant relative to a comparator, a potential adverse effect on plant health according to the assessment endpoint identified may include the decreased viability of plants in the ecosystem due to increased susceptibility of the transgenic plant to certain pests.

(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, a plausible pathway to harm is postulated. For each step of a postulated pathway to harm, a corresponding risk hypothesis is formulated that will enable the risk assessor to determine whether the pathway is likely to occur. Once it is shown that any step of the 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.

Postulated pathway leading to decreased viability of a cultivated and/or other valued plant in an agroecosystem

Pests occurring in an agroecosystem may use the transgenic plant, as with any plant, as a host, with or without associated impacts. If the transgenic plant has a changed phenotype (e.g. biochemical composition or plant protective architecture), this change could lead to a new or modified niche for pests, which could lead to an increase in pest abundance and, ultimately, injury to cultivated and/or other valued plants in the agroecosystem in the same and/or subsequent growing season(s) as the transgenic plant.

One example of a postulated pathway to harm for this adverse effect is shown in the first column of Table A E.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 E.1. Postulated pathway leading to decreased viability of a cultivated and/or other valued plant in an agroecosystem due to increased susceptibility of the transgenic plant, corresponding risk hypotheses, and relevant information elements

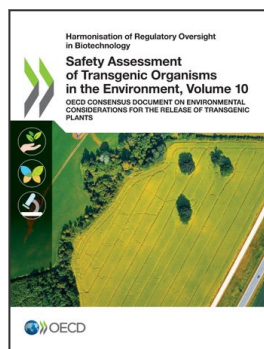
Pathway steps	Risk hypotheses	Examples of information elements
The modified trait in the transgenic plant alters the plant's chemical or structural defence mechanisms	There is no alteration in the plant's chemical or structural defence mechanisms	Expression and nature of the introduced gene product and its function in the transgenic plant
The transgenic plant exhibits pest susceptibility directly in terms of increased disease symptoms or damage and/or indirectly through increased pest numbers (harbouring pests) on the transgenic plant, relative to the comparator	There are no increased disease symptoms or insect damage and/or pest numbers on the transgenic plant relative to the comparator	Changes in pest populations and incidence of pest-damage to the transgenic plant and comparator
The transgenic plant acts as a greater source of pests that spread to plants in the agroecosystem in the same or subsequent growing season(s) relative to the comparator	The transgenic plant does not act as a greater source of pests for plants in the agroecosystem in the same or subsequent growing season(s) relative to the comparator	Plants present in the agroecosystem; known susceptibility of these plants to the pests; and changes in pest populations on plants in the agroecosystem in the same or subsequent growing season(s)
There is an increase in injury to plants in the agroecosystem by pests in the same or subsequent growing season(s) relative to the comparator	There is no increase in injury to plants in the agroecosystem by pests in the same or subsequent growing season(s) relative to the comparator	Injury/damage incidence to plants in the agroecosystem in the same or subsequent growing season(s) relative to the comparator
The viability of a cultivated and/or other valued plant in the agroecosystem is reduced		

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:

- Expression and nature of the introduced gene product and its function in the transgenic plant provide information as to whether a phenotypic change may affect the transgenic plant's defence mechanisms;
- Changes in pest populations and incidence of pest-damage to the transgenic plant and comparator provide information as to whether there is a difference in pest susceptibility between the transgenic plant and the comparator;
- Plants present in the agroecosystem; known susceptibility of these plants to the pests; and changes in pest populations on plants in the agroecosystem in the same or subsequent growing season(s) provide information on whether the transgenic plant may be a source of pests that spread to other plants;
- Injury/damage incidence to plants in the agroecosystem in the same or subsequent growing season(s) relative to the comparator provides information on whether there has been an increase in pest-related damage to plants in the agroecosystem relative to the comparator.

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