Draft guidance document on Risk Assessment and Risk Management of Living Modified Crops with Resistance or Tolerance to Abiotic Stress

General considerations

1. The aim of this document is to provide further guidance for the risk assessment of living modified crops with traits that improve their tolerance or resistance to abiotic stresses.
2. This guidance document should be considered in the context of the Cartagena Protocol on Biosafety. The elements of Articles 15 and 16 and Annex III of the Protocol also apply to LM crops with tolerance to abiotic stress.
3. Because the potential environmental adverse effects of a LM crop with abiotic stress tolerance will depend on the receiving environment and the modified crop and phenotypic changes resulting from the genotypic changes made to the plant, their risk assessment must be performed on a case by case basis following general principle 6 of Annex III.
4. This guidance document complements the Roadmap on Risk Assessment with regard to issues that are of particular relevance to the risk assessment of living modified crops tolerant or resistant to abiotic stress.

Definition

Abiotic stresses are suboptimal environmental conditions caused by non-living factors that are detrimental to growth and reproduction of a living organism. Some types of primary abiotic stresses include drought, salinity, cold and heat.

Risk Assessment

The process of risks assessment associated with abiotic stress tolerance may require some different approaches than have been so far required to assess other types of genetic modifications introduced to living modified organisms.

Potential adverse effects that may be associated with any novel genotypic and phenotypic changes associated with the abiotic stress tolerant LMO should be identified. The first step is to compare the LMO and its closely related conventional counterpart with a history of safe use. Both anticipated and unanticipated or unintended changes associated with the abiotic stress tolerance should be identified, including changes to the biology of the crop plant (e.g., if the genes alter multiple characteristics of the plant) or to its distribution range in relation to the potential receiving environment (e.g., if the plant can grow where it has not grown before). After the adverse effects associated with these changes have been identified, then their likelihood and consequences can be considered together to determine the risk and whether it can be managed.

For instance, an example would be to test whether the hypothesis that the drought- or salinity-tolerant LM crop would be phenotypically different as compared to the non-LM crop when the water or salt stress are minimized.

The second step is to assess the potential for novel changes, anticipated, unanticipated or unintended, to arise under environmental conditions that are not permissive to the conventional comparator. Thus, in the case of abiotic stress, additional molecular and phenotypic characterizations of the LMO may be needed.

For instance, the following issues may be considered when carrying out the phenotypic characterization of a LMO tolerant to an abiotic stress:

a) Phenotypic characteristics of the LMO in the likely potential receiving environment;
b) Phenotypic characteristics of the LMO compared to the counterpart under stressed and non-stress conditions;
c) Phenotypic characteristic of the LMO under different stresses, if necessary.
d) Effects on the frequency or likelihood of gene flow to wild or domestic relatives.

Questions that are of particular relevance to the risk assessment of LM crops with tolerance to abiotic stress in connection with the intended use and receiving environment include:

- Would a plant expressing tolerance to an abiotic stress would have specific advantages in the targeted environment?
- Would the tolerance trait have the potential to cause invasiveness, weediness or damage to other organisms?
- Would the abiotic stress tolerant crop or outcrosses have the potential to colonize an ecosystem beyond the targeted receiving environment?

Some of the potential adverse effects arising from the introduction of crops tolerant to abiotic stress into the environment include, for example: a) increased selective advantage(s) other than the intended tolerance trait; b) increased persistence in agricultural lands and invasiveness of natural habitats; c) adverse effects on organisms exposed to the crop; d) increased gene flow to wild or domestic relatives. While these adverse effects may exist regardless of whether the tolerant crop is a product of modern biotechnology or conventional breeding, some specific issues may be more relevant in the case of stress tolerant LM crops.

The following paragraphs contain points to consider that are particularly relevant for the risk assessment of crops tolerant to abiotic stress for introduction into the environment with a focus on living modified crops tolerant to drought and salinity. These specific points to consider should be taken into consideration with those general points to consider for all risk assessment steps in the Roadmap.

a) Unintended or unanticipated traits

Rationale

The genetic modification or transgene products may confer other unintended or unanticipated traits such as tolerances to other types of biotic and abiotic stresses, which could lead to a selective advantage of these crop plants under conditions other than that related to the modified trait. For instance, crops modified to become resistant to drought or salinity may be able to compete better than their counterparts, at lower and higher growing temperatures.

It is also possible the plants could have increased seed dormancy, viability, and/or improved seedling germination rates under other types of stresses. It is possible that the plants may transfer genes for stress tolerance at higher frequencies than conventional, due to close linkage of the transgenes.

There is a potential crosstalk between abiotic and biotic stress mechanisms in plants. Drought- or salinity-tolerant LM crops may acquire a changed tolerance to biotic stress, which could result in changed interactions with its predators, parasitoids and pathogens, and, therefore, have both direct and indirect impacts on population levels of organisms that interact with them.

Point to consider

Any phenotypic change that may lead to selective advantage or disadvantage acquired by the LM crop under other abiotic or biotic stress conditions that may cause adverse effects.
Any change in the resistance to biotic stresses and how these could affect the population of organisms interacting with the LM crop.
A change in the toxin or nutrient profile of the LMO may be revealed through a combination of appropriate compositional analyses and toxicity and performance studies involving key indicator organisms of the food web.

b) Increased persistency in agricultural lands and invasiveness of natural habitats

Rationale

In environments where water depletion or elevated salt content are the main factors limiting the spread and persistence of a crop, expression of the genes for drought and salinity tolerance, respectively, could result in increased persistence of the modified crop in agricultural lands.
Moreover, the gene(s) inserted for tolerance to drought and salinity might also affect molecular response mechanisms to other forms of abiotic stress, like cold for instance (see “a” above). Therefore, it cannot be excluded that a tolerant crop acquires a potential to persist more than the conventional counterpart under abiotic stress conditions.
In addition, when the genetic modification affects genes that also regulate key processes in seeds, such as the ABA metabolism, physiological characteristics such as dormancy and accumulation of storage lipids may also be altered. In such cases, the seeds of a

tolerant crop may acquire tolerance to cold resulting in an increased winter survivability of the seeds of a crop that has been modified for drought or salinity tolerance.

Points to consider

a) Consequences derived from an increased potential for persistency of the modified crop in agricultural habitats and invasiveness in natural habitats.

b) Need for control measures if the stress-tolerant crop shows a higher potential for persistency in agricultural or natural habitats.

c) Characteristics that are generally associated with weediness such as prolonged seed dormancy, long persistence of seeds in the soil, germination under a broad range of environmental conditions, rapid vegetative growth, short lifecycle, very high seed output, high seed dispersal and long-distance seed dispersal.

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