**Information required for the environmental risk assessment according to Annex II of the Royal Decree of 21 February 2005 (art 13§2 e)**

This document describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the environmental risk assessment (e.r.a.) referred to in Articles 5, 13 and 29 of the Royal Decree of 21 February 2005 (see also the explanatory notes given with decision 2002/623/CE of the Commission on 24 July 2002).

With a view to contributing to a common understanding of the terms "direct, indirect, immediate and delayed" when implementing this Annex, without prejudice to further guidance in this respect and in particular as regards the extent to which indirect effects can and should be taken into account, these terms are described as follows:

- "direct effects" refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events;

- "indirect effects" refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management.

Observations of indirect effects are likely to be delayed;

- "immediate effects" refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;

- "delayed effects" refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

A general principle for environmental risk assessment is also that an analysis of the "cumulative long-term effects" relevant to the release and the placing on the market is to be carried out. "Cumulative long-term effects" refers to the accumulated effects of consents on human health and the environment, including inter alia flora and fauna, soil fertility, soil degradation of organic material, the feed/ food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

**A. Objective**

The objective of an e.r.a. is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The e.r.a. should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.

**B. General Principles**

In accordance with the precautionary principle, the following general principles should be followed when performing the e.r.a.:

- identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;

- the e.r.a. should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;

- the e.r.a. should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, i.a., GMOs already in the environment;

- if new information on the GMO and its effects on human health or the environment becomes available, the e.r.a. may need to be readdressed in order to:

- determine whether the risk has changed;

- determine whether there is a need for amending the risk management accordingly.

**C. Methodology**

***C.1. Characteristics of GMOs and releases***

Depending on the case the e.r.a. has to take into account the relevant technical and scientific details regarding characteristics of:

- the recipient or parental organism(s);

- the genetic modification(s), be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;

- the GMO;

- the intended release or use including its scale;

- the potential receiving environment; and

- the interaction between these.

Information from releases of similar organisms and organisms with similar traits and their interaction with similar environments can assist the e.r.a.

***C.2. Steps in the e.r.a.***

In drawing conclusions for the e.r.a. the following points should be addressed:

***1. Identification of characteristics which may cause adverse effects:***

Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. A comparison of the characteristics of the GMO(s) with those of the non-modified organism under corresponding conditions of the release or use, will assist in identifying the particular potential adverse effects arising from the genetic modification. It is important not to discount any potential adverse effect on the basis that it is unlikely to occur.

Potential adverse effects of GMOs will vary from case to case, and may include:

- disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C.2(i) in Annex III A)

- disease to animals and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11. and II.C.2(i) in Annex III A);

- effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see for example items IV B 8, 9 and 12 in Annex III A);

- altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;

- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11(e) and II.C.2(i)(iv) in Annex III A);

- effects on biogeochemistry( biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV.B.15 in Annex III A).

Adverse effects may occur directly or indirectly through mechanisms which may include:

- the spread of the GMO(s) in the environment,

- the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not,

- phenotypic and genetic instability,

- interactions with other organisms,

- changes in management, including, where applicable, in medical practices.

***2. Evaluation of the potential consequences of each adverse effect, if it occurs***

The magnitude of the consequences of each potential adverse effect should be evaluated.

This evaluation should assume that such an adverse effect will occur. The magnitude of the consequences is likely to be influenced by the environment into which the GMO(s) is (are) intended to be released and the manner of the release.

***3. Evaluation of the likelihood of the occurrence of each identified potential adverse effect***

A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which the GMO(s) is intended to be released, and the manner of the release.

***4. Estimation of the risk posed by each identified characteristic of the GMO(s)***

An estimation of the risk to human health or the environment posed by each identified characteristic of the GMO which has the potential to cause adverse effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

***5. Application of management strategies for risks from the deliberate release or marketing of GMO(s)***

The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined.

***6. Determination of the overall risk of the GMO(s)***

An evaluation of the overall risk of the GMO(s) should be made taking into account any risk management strategies which are proposed.

**D. Conclusions on the potential environmental impact from the release or the placing on the market of GMOs**

On the basis of an e.r.a. carried out in accordance with the principles and methodology outlined in sections B and C, information on the points listed in sections D, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental impact from the release or the placing on the market of GMOs:

1. Likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of the proposed release(s).

2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of the proposed release(s).

3. Potential for gene transfer to other species under conditions of the proposed release of the GMO and any selective advantage or disadvantage conferred to those species.

4. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO and target organisms (if applicable).

5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.