ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

[F1C.**Methodology**

C.1. *General and specific considerations for the e.r.a.*

1. *Intended and unintended changes*

As part of the identification and evaluation of the potential adverse effects referred to in Section A, the e.r.a shall identify the intended and unintended changes resulting from the genetic modification and shall evaluate their potential to cause adverse effects on human health and on the environment.

Intended changes resulting from the genetic modification are changes that are designed to occur and which fulfil the original objectives of the genetic modification.

Unintended changes resulting from the genetic modification are consistent changes which go beyond the intended change(s) resulting from the genetic modification.

Intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.

2. *Long-term adverse effects and cumulative long-term adverse effects in the e.r.a. of Part C notifications*

Long-term effects of a GMO are effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a GMO or from an extensive use of a GMO in time and space.

The identification and evaluation of the potential long-term adverse effects of a GMO on human health and on the environment shall take into account the following:

(a) the long-term interactions of the GMO and the receiving environment;

(b) the characteristics of the GMO which become important on a long-term basis;

(c) data obtained from repeated deliberate releases or placings on the market of the GMO over a long period.

The identification and evaluation of the potential cumulative long-term adverse effects referred to in the introductory part of Annex II shall also take into account the GMOs deliberately released or placed on the market in the past.

3. *Quality of the data*

In order to carry out an e.r.a. for a notification under Part C of this Directive, the notifier shall collate already available data from scientific literature or from other sources, including monitoring reports, and shall generate the necessary data by performing, where possible, appropriate studies. Where applicable, the notifier shall justify in the e.r.a. why generating data by studies is not possible.

The e.r.a. for notifications under Part B of the Directive shall be based at least on already available data from scientific literature or from other sources and may be supplemented by additional data generated by the notifier.

Where data generated outside Europe is provided in the e.r.a., its relevance to receiving environment(s) in the Union shall be justified.

Data provided in the e.r.a for notifications under part C of this Directive shall comply with the following requirements:

(a) where toxicological studies carried out to assess risk to human or animal health are provided in the e.ra., the notifier shall provide evidence to demonstrate that they were conducted in facilities which comply with:

  (i) the requirements of Directive 2004/10/EC; or

  (ii) the 'OECD Principles on Good Laboratory Practice' (GLP), if carried out outside the Union;

(b) where studies other than toxicological studies are provided in the e.r.a., they shall:

  (i) comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC, where relevant; or

  (ii) be conducted by organisations accredited under the relevant ISO standard; or

  (iii) in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards;

(c) information on the results obtained from the studies referred to in points (a) and (b) and on the study protocols used shall be reliable and comprehensive and shall include the raw data in an electronic format suitable for carrying out statistical or other analysis;

(d) the notifier shall specify, where possible, the size of effect that each study performed intends to detect and justify it;

(e) the selection of sites for field studies shall be based on relevant receiving environments in view of the potential exposure and impact that would be observed where the GMO may be released. The selection shall be justified in the e.r.a.;

(f) the non-genetically modified comparator shall be appropriate for the relevant receiving environment(s) and shall have a genetic background comparable to the GMO. The choice of the comparator shall be justified in the e.r.a.

4. *Stacked transformation events in Part C notifications*

The following shall apply to the e.r.a. of a GMO containing stacked transformation events in Part C notifications:

(a) the notifier shall provide an e.r.a. for each single transformation event in the GMO or refer to already submitted notifications for those single transformation events;

(b) the notifier shall provide an assessment of the following aspects:

  (i) the stability of the transformation events;

  (ii) the expression of the transformation events;

  (iii) the potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events;

(c) where the progeny of the GMO can contain various subcombinations of the stacked transformation events, the notifier shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned subcombinations, independently of their origin, or, in the absence of such scientific rationale, shall provide the relevant experimental data.**]**