

ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

[^{F1}C.Methodology

C.1. *General and specific considerations for 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.]