

ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

[^{F1}C.Methodology

C.3. *Steps in the e.r.a.*

6. *Overall risk evaluation and conclusions*

A qualitative and, where possible, quantitative evaluation of the overall risk of the GMO shall be made taking into account the results of the risk characterisation, the proposed risk management strategies and the associated levels of uncertainty.

The overall risk evaluation shall include, where applicable, the risk management strategies proposed for each identified risk.

The overall risk evaluation and conclusions shall also propose specific requirements for the monitoring plan of the GMO and, where appropriate, the monitoring of the efficacy of the proposed risk management measures.

For notifications under Part C of the Directive, the overall risk evaluation shall also include an explanation of the assumptions made during the e.r.a. and of the nature and magnitude of uncertainties associated with the risks, and a justification of the risk management measures proposed.]