
Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

[^{F1}ANNEX III

INFORMATION REQUIRED IN THE NOTIFICATION

Textual Amendments

- F1** Substituted by [Commission Directive \(EU\) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms.](#)

Notifications referred to in Parts B and C of this Directive shall, as a rule, include the information set out in Annex III A, for GMOs other than higher plants, or in Annex III B, for genetically modified higher plants.

The provision of a given subset of information listed in Annex III A or in Annex III B shall not be required where it is not relevant or necessary for the purposes of risk assessment in the context of a specific notification, in view especially of the characteristics of the GMO, of the scale and conditions of the release or of its intended conditions of use.

The appropriate level of detail for each subset of information may also vary according to the nature and the scale of the proposed release.

For each required subset of information, the following shall be provided:

- (i) the summaries and results of the studies referred to in the notification, including an explanation about their relevance to e.r.a., where applicable;
- (ii) for notifications referred to in Part C of this Directive, Annexes with detailed information on those studies, including a description of the methods and materials used or the reference to standardised or internationally recognised methods and the name of the body or bodies responsible for carrying out the studies.

Future developments in genetic modification may necessitate adapting this Annex to technical progress or developing guidance notes on this Annex. Further differentiation of information requirements for different types of GMOs, for example perennial plants and trees, single celled organisms, fish or insects, or for particular use of GMOs like the development of vaccines, may be possible once sufficient experience with notifications for the release of particular GMOs has been gained in the Union.]