ANNEX IV

ADDITIONAL INFORMATION

A. The following information shall be provided in the notification for placing on the market of GMOs as or in product in addition to that of Annex III:

1. **[**[F1]proposed commercial names of the products and names of GMOs contained therein, and a proposal for a unique identifier for the GMO, developed in accordance with Commission Regulation (EC) No 65/2004[(1)]. After the consent any new commercial names should be provided to the competent authority,**]**

2. name and full address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor,

3. name and full address of the supplier(s) of control samples,

4. description of how the product and the GMO as or in product are intended to be used. Differences in use or management of the GMO compared to similar non-genetically modified products should be highlighted,

5. description of the geographical area(s) and types of environment where the product is intended to be used within the Community, including, where possible, estimated scale of use in each area,

6. intended categories of users of the product e.g. industry, agriculture and skilled trades, consumer use by public at large,

7. **[**[F1]methods for detection, identification and, where appropriate, quantification of the transformation event; samples of the GMO(s) and their control samples, and information as to the place where the reference material can be accessed. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register(s) referred to in Article 31(2) should be identified,**]**

8. proposed labelling on a label or in an accompanying document. This must include, at least in summarised form, a commercial name of the product, a statement that ‘This product contains genetically modified organisms’, the name of the GMO and the information referred to in point 2, the labelling should indicate how to access the information in the publicly accessible part of the register.

B. The following information shall be provided in the notification, when relevant, in addition to that of point A, in accordance with Article 13 of this Directive:

1. measures to take in case of unintended release or misuse,

2. specific instructions or recommendations for storage and handling,

3. specific instructions for carrying out monitoring and reporting to the notifier and, if required, the competent authority, so that the competent authorities can be effectively informed of any adverse effect. These instructions should be consistent with Annex VII part C,

4. proposed restrictions in the approved use of the GMO, for example where the product may be used and for what purposes,

5. proposed packaging,

6. estimated production in and/or imports to the Community,

7. proposed additional labelling. This may include, at least in summarised form, the information referred to in points A 4, A 5, B 1, B 2, B 3 and B 4.

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.

(1) **[**[F1]Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).**]**

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.