SCHEDULE 3 Regulation 16(2)(d) and (h) and (5)

Information to be included in applications for consent to market genetically modified organisms

PART I

General information

1. The proposed commercial name of the product and names of the genetically modified organisms in the product, **[**F1the unique identifier assigned in accordance with Regulation 65/2004, and any other**]** name or code used by the applicant to identify the genetically modified organism.

Textual Amendments

F1 Words in Sch. 3 para. 1 substituted (13.2.2019) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(a), **2(4)**

2. The name and address F2... of the person who is responsible for the marketing, whether it be the manufacturer, importer or distributor.

Textual Amendments

F2 Words in Sch. 3 para. 2 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(18)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

3. The name and address of the supplier or suppliers of control samples.

4. A description of how the product and the genetically modified organism are intended to be used, highlighting any differences in use or management of the genetically modified organism compared to similar non-genetically modified products.

5. A description of the geographical area or areas and types of environment where the product is intended to be used F3..., including, where possible, an estimate of the scale of use in each area.

Textual Amendments

F3 Words in Sch. 3 para. 5 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(18)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

6. A description of the intended categories of users of the product, such as industry, agriculture or consumer use by the public.

[F4**7.**—(1) Information on—

(a) methods for the detection, identification and, where appropriate, quantification of the transformation event,

(b) samples of the genetically modified organisms and their control samples,

(c) the place where the reference material can be accessed.

(2) Information under sub-paragraph (1) that cannot be placed on the register for confidentiality reasons, must be identified.**]**

Textual Amendments

F4 Sch. 3 para. 7 substituted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **8**

8. The proposed labelling, which must include, in a label or an accompanying document, at least in summarised form, a commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the genetically modified organism and the name and address of the person **F5**... who is responsible for marketing the product, and how to access the information in the publicly accessible part of the register.

Textual Amendments

F5 Words in Sch. 3 para. 8 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(18)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

PART II

Additional relevant information

9. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.

10. Specific instructions or recommendations for storage and handling of the product.

11. Specific instructions for carrying out monitoring and reporting to the applicant and, if required, the Secretary of State, which are consistent with Part C of Annex VII of the Deliberate Release Directive.

12. The proposed restrictions in the approved use of the genetically modified organism, such as where the product may be used and for what purposes.

13. The proposed packaging.

14. The estimated production in and/or imports to **[**F6England**]**.

Textual Amendments

F6 Word in Sch. 3 para. 14 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88), regs. 1(2)(b), **3(18)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

15. Any proposed additional labelling, which may include, at least in summarised form, the information referred to in paragraphs 4 and 5 of Part I of this Schedule, or paragraphs 9 to 12 of this Part.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to Genetically Modified Organisms (Deliberate Release) Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Sch. 3 para. 7 words omitted by S.I. 2019/88 reg. 3(18)(c) (This amendment not applied to legislation.gov.uk. Reg. 3(18)(c) omitted (29.9.2019) by virtue of S.I. 2019/1252, regs. 1(1), 9)

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

– Blanket amendment words substituted by S.I. 2011/1043 art. 3-68-10