

SCHEDULE 4

Regulations 16(2), 16(5) and 28

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, and any specific identification, name or code used by the applicant to identify the genetically modified organism.

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

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

4. A description of how the product and the genetically modified organism as or in the product 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 and types of environment where the product is intended to be used within the Community, including, where possible, an estimate of the scale of use in each area.

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

7. Information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular genetically modified organism products to facilitate post marketing control and inspection. This information should include where appropriate the lodging of samples of the genetically modified organism or its genetic material with the Scottish Ministers, and details of nucleotide sequences or other type of information which is necessary to identify the genetically modified organism product and its progeny, for example the methodology for detecting and identifying the genetically modified organism product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified.

8. Information regarding 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 established in the Community who is responsible for the placing on the market, and how to access the information in the publicly accessible part of the register.

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.

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

11. Specific instructions for carrying out monitoring and reporting to the applicant and, if required, the Scottish Ministers, which are consistent with Part C of Annex VII of the Deliberate Release Directive, so that the Scottish Ministers can be effectively informed of any adverse effect.
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 the Community.
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 The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.

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Changes and effects yet to be applied to :

- Sch. 4 para. 1 substituted by [S.S.I. 2019/86 reg. 19\(a\)](#)
- Sch. 4 para. 7 substituted by [S.S.I. 2019/86 reg. 19\(b\)](#)
- sch. 4 para. 7 word substituted by [S.S.I. 2019/57 reg. 3\(27\)\(d\)](#)
- sch. 4 para. 2 words omitted by [S.S.I. 2019/57 reg. 3\(27\)\(b\)](#)
- sch. 4 para. 5 words omitted by [S.S.I. 2019/57 reg. 3\(27\)\(c\)](#)
- sch. 4 para. 8 words omitted by [S.S.I. 2019/57 reg. 3\(27\)\(e\)](#)
- sch. 4 para. 1 words substituted by [S.S.I. 2019/57 reg. 3\(27\)\(a\)](#)
- sch. 4 para. 11 words substituted by [S.S.I. 2019/57 reg. 3\(27\)\(f\)](#)
- sch. 4 para. 14 words substituted by [S.S.I. 2019/57 reg. 3\(27\)\(g\)](#)

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](#)

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Pt. 6A inserted by [S.S.I. 2019/86 reg. 16](#)
- Sch. 1 para. 6(4)(a)(i) word substituted by [S.S.I. 2023/374 Sch. 2 para. 2\(4\)](#)
- Sch. 1 para. 6(4)(b)(i) word substituted by [S.S.I. 2023/374 Sch. 2 para. 2\(5\)](#)
- sch. 1 para. 6(4)(a)(ii) words inserted by [S.S.I. 2022/361 reg. 14\(2\)\(ii\)](#)
- sch. 1 para. 6(4)(a)(i) words substituted by [S.S.I. 2022/361 reg. 14\(2\)\(i\)](#)
- sch. 2 para. 42 words substituted by [S.S.I. 2019/57 reg. 3\(25\)\(c\)](#)
- sch. 2 para. 43 words substituted by [S.S.I. 2019/57 reg. 3\(25\)\(c\)](#)
- sch. 2 para. 46 words substituted by [S.S.I. 2019/57 reg. 3\(25\)\(c\)](#)
- sch. 2 para. 53 words substituted by [S.S.I. 2019/57 reg. 3\(25\)\(d\)](#)
- sch. 2 para. 54(h)(i) words substituted by [S.S.I. 2019/57 reg. 3\(25\)\(e\)\(i\)](#)
- sch. 2 para. 54(h)(ii) words substituted by [S.S.I. 2019/57 reg. 3\(25\)\(e\)\(ii\)](#)
- sch. 5A inserted by [S.S.I. 2019/57 sch. 2](#)
- reg. 11(1)(a)(aa) substituted for reg. 11(1)(a) by [S.S.I. 2019/86 reg. 4](#)
- reg. 15(1) reg. 15 renumbered as reg. 15(1) by [S.S.I. 2019/86 reg. 7\(a\)](#)
- reg. 15(1) word omitted by [S.S.I. 2019/57 reg. 2\(5\)\(b\)\(ii\)](#)
- reg. 15(1) word substituted by [S.S.I. 2019/57 reg. 2\(5\)\(a\)](#)
- reg. 15(1) words omitted by [S.S.I. 2019/57 reg. 2\(5\)\(b\)\(i\)](#)
- reg. 15(1) words substituted by [S.S.I. 2019/57 reg. 2\(5\)\(c\)](#)
- reg. 15(1)(a) words inserted by [S.S.I. 2019/57 reg. 3\(6\)\(a\)\(i\)](#)
- reg. 15(1)(a) words substituted by [S.S.I. 2019/57 reg. 2\(5\)\(d\)\(i\)](#)
- reg. 15(1)(a) words substituted by [S.S.I. 2019/57 reg. 2\(5\)\(d\)\(ii\)](#)
- reg. 15(1)(b) words substituted by [S.S.I. 2019/57 reg. 3\(6\)\(a\)\(iii\)](#)
- reg. 15(1)(c) omitted by [S.S.I. 2019/57 reg. 3\(6\)\(a\)\(iv\)](#)
- reg. 15(1)(d) word inserted by [S.S.I. 2019/57 reg. 3\(6\)\(a\)\(v\)](#)
- reg. 15(1)(e) substituted by [S.S.I. 2019/57 reg. 3\(6\)\(a\)\(vi\)](#)
- reg. 15(1)(e) word inserted by [S.S.I. 2019/86 reg. 7\(c\)](#)
- reg. 15(1)(e) words substituted by [S.S.I. 2019/86 reg. 7\(b\)](#)
- reg. 15(1)(f) and word omitted by [S.S.I. 2019/86 reg. 7\(d\)](#)
- reg. 15(1)(g) omitted by [S.S.I. 2019/57 reg. 3\(6\)\(a\)\(vii\)](#)
- reg. 15(1)(aa) inserted by [S.S.I. 2019/57 reg. 3\(6\)\(a\)\(ii\)](#)
- reg. 15(2) inserted by [S.S.I. 2019/86 reg. 7\(e\)](#)
- reg. 15(2) substituted by [S.S.I. 2019/57 reg. 3\(6\)\(b\)](#)

- reg. 16(2)(a)-(ab) substituted for reg. 16(2)(a) by S.S.I. 2019/86 reg. 8
- reg. 24(7)-(11) inserted by S.S.I. 2019/86 reg. 10(d)
- reg. 24(7) words substituted by S.S.I. 2019/57 reg. 2(6)(b)
- reg. 24(9) words substituted by S.S.I. 2019/57 reg. 2(6)(c)
- reg. 26(5)-(8) inserted by S.S.I. 2019/86 reg. 11
- reg. 26(5) substituted by S.S.I. 2019/57 reg. 3(13)(b)
- reg. 26(5) words substituted by S.S.I. 2019/57 reg. 2(8)(b)
- reg. 26(6) words substituted by S.S.I. 2019/57 reg. 2(8)(c)
- reg. 26(7) substituted for reg. 26(7)(8) by S.S.I. 2019/57 reg. 3(13)(c)
- reg. 26A26B inserted by S.S.I. 2019/86 reg. 12
- reg. 26A substituted by S.S.I. 2019/57 reg. 3(14)
- reg. 26A(1) words substituted by S.S.I. 2019/57 reg. 2(9)
- reg. 26B substituted by S.S.I. 2019/57 reg. 3(15)
- reg. 26B(1) substituted by S.S.I. 2019/57 reg. 2(10)
- reg. 29A29B inserted by S.S.I. 2019/86 reg. 13
- reg. 29A(1) words omitted by S.S.I. 2019/57 reg. 3(17)(a)(iii)
- reg. 29A(1)(a) word substituted by S.S.I. 2019/57 reg. 2(11)(a)(i)
- reg. 29A(1)(a) words substituted by S.S.I. 2019/57 reg. 2(11)(a)(ii)
- reg. 29A(1)(b) words substituted by S.S.I. 2019/57 reg. 3(17)(a)(i)
- reg. 29A(1)(c) full stop substituted for comma by S.S.I. 2019/57 reg. 3(17)(a)(ii)
- reg. 29A(2) omitted by S.S.I. 2019/57 reg. 3(17)(b)
- reg. 29A(3)(a) words substituted by S.S.I. 2019/57 reg. 2(11)(b)(i)
- reg. 29A(3)(b) word substituted by S.S.I. 2019/57 reg. 2(11)(b)(ii)
- reg. 29A(3)(c) word inserted by S.S.I. 2019/57 reg. 3(17)(c)
- reg. 29A(5) word inserted by S.S.I. 2019/57 reg. 3(17)(d)(ii)
- reg. 29A(5) word substituted by S.S.I. 2019/57 reg. 3(17)(d)(i)
- reg. 29A(6) word substituted by S.S.I. 2019/57 reg. 3(17)(e)
- reg. 29A(6) words inserted by S.S.I. 2019/57 reg. 2(11)(c)
- reg. 29A(7) words inserted by S.S.I. 2019/57 reg. 2(11)(d)
- reg. 29A(7)(a)(v) words omitted by S.S.I. 2019/57 reg. 3(17)(f)(i)
- reg. 29A(7)(b) word inserted by S.S.I. 2019/57 reg. 3(17)(f)(ii)
- reg. 29A(7)(b) word substituted by S.S.I. 2023/374 Sch. 2 para. 2(2)
- reg. 29A(7)(e) word substituted by S.S.I. 2023/374 Sch. 2 para. 2(3)
- reg. 29A(7)(e) words substituted by S.S.I. 2019/57 reg. 3(17)(f)(iii)
- reg. 29A(9)(a) omitted by S.S.I. 2019/57 reg. 3(17)(g)
- reg. 29A(11) words substituted by S.S.I. 2019/57 reg. 2(11)(e)
- reg. 29A(11) words substituted by S.S.I. 2019/57 reg. 3(17)(h)
- reg. 29A(12)(a) word inserted by S.S.I. 2019/57 reg. 2(11)(f)(i)
- reg. 29A(12)(a) words inserted by S.S.I. 2019/57 reg. 2(11)(f)(ii)
- reg. 29A(12)(a) words omitted by S.S.I. 2019/57 reg. 3(17)(i)
- reg. 29B(1)(a) words inserted by S.S.I. 2019/57 reg. 2(12)(a)(i)
- reg. 29B(1)(a) words inserted by S.S.I. 2019/57 reg. 2(12)(a)(ii)
- reg. 29B(1)(a) words substituted by S.S.I. 2019/57 reg. 2(12)(a)(iii)
- reg. 29B(1)(b) words inserted by S.S.I. 2019/57 reg. 2(12)(b)
- reg. 29B(1)(c) words substituted by S.S.I. 2019/57 reg. 3(18)(a)
- reg. 29B(2) words substituted by S.S.I. 2019/57 reg. 3(18)(b)
- reg. 30A inserted by S.S.I. 2019/86 reg. 14
- reg. 30A(1)(a)(i) word omitted by S.S.I. 2019/57 reg. 2(13)(a)(i)(bb)
- reg. 30A(1)(a)(i) word substituted by S.S.I. 2019/57 reg. 2(13)(a)(i)(aa)
- reg. 30A(1)(a)(i) words omitted by S.S.I. 2019/57 reg. 3(19)
- reg. 30A(1)(a)(iii) inserted by S.S.I. 2019/57 reg. 2(13)(a)(iii)
- reg. 30A(1)(a)(ii) word inserted by S.S.I. 2019/57 reg. 2(13)(a)(ii)
- reg. 30A(1)(b) words substituted by S.S.I. 2019/57 reg. 2(13)(b)(i)
- reg. 30A(1)(b) words substituted by S.S.I. 2019/57 reg. 2(13)(b)(ii)
- reg. 30A(1)(c) words substituted by S.S.I. 2019/57 reg. 2(13)(c)
- reg. 30A(1)(d) words substituted by S.S.I. 2019/57 reg. 2(13)(d)
- reg. 32B(1)(d) words substituted by S.S.I. 2019/57 reg. 2(14)(a)(i)
- reg. 32B(1)(d) words substituted by S.S.I. 2019/57 reg. 2(14)(a)(ii)

- reg. 32B(1)(e) words substituted by S.S.I. 2019/57 reg. 2(14)(b)
- reg. 34(3)(i) inserted by S.S.I. 2019/57 reg. 3(22)(a)(iii)
- reg. 34(3A) inserted by S.S.I. 2019/57 reg. 3(22)(b)
- reg. 34(7A) inserted by S.S.I. 2019/57 reg. 3(22)(d)
- reg. 35(3A) inserted by S.S.I. 2019/57 reg. 3(23)(b)
- reg. 35(7A) inserted by S.S.I. 2019/57 reg. 3(23)(c)