
SCOTTISH STATUTORY INSTRUMENTS

2002 No. 541

The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002

PART III

MARKETING ORGANISMS

Exempt activities

15. The cases and circumstances prescribed for the purposes of sections 108(7) and 111(7) of the Act in which persons are exempt from the requirements of section 108(1)(a) of the Act (to carry out a risk assessment) and of section 111(1)(a) of the Act (to obtain consent), respectively, insofar as they relate to marketing genetically modified organisms, are all cases and circumstances in which—

- (a) an approved product is marketed for a use for which it has approval [^{F1}and in accordance with the limitations and conditions to which the use of that product is subject];
- (b) genetically modified micro-organisms are made available for activities regulated under the Contained Use Directive (including culture collections);
- (c) genetically modified organisms other than micro-organisms referred to in paragraph (b) are made available to be used exclusively for activities where appropriate stringent containment measures based on the same principles of containment as laid down in the Contained Use Directive are used to limit their contact with and to provide a high level of safety for the general population and the environment;
- (d) genetically modified organisms are made available to be used exclusively for deliberate releases complying with the requirements laid down in Part II;
- (e) a genetically modified organism authorised under Regulation 2309/93 [^{F2}or Regulation (EC) No. 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency] is marketed;
- [^{F3}(f) a novel food or novel food ingredient within the meaning of Council Regulation (EC) No. 258/97, as amended by the Food and Feed Regulation and Council Regulation 1882/2003, is marketed; and]
- [^{F4}(g) genetically modified food or feed authorised under the Food and Feed Regulation is marketed.]

Textual Amendments

- F1** Words in reg. 15(a) added (15.11.2004) by [The Genetically Modified Organisms \(Deliberate Release\) \(Scotland\) Amendment Regulations 2004 \(S.S.I. 2004/439\)](#), regs. 1, **4(a)**
- F2** Words in reg. 15 inserted (20.11.2005) by [The Medicines \(Marketing Authorisations Etc.\) Amendment Regulations 2005 \(S.I. 2005/2759\)](#), reg. 1(b), **Sch. para. 9**

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*

- F3** Reg. 15(f) substituted (15.11.2004) by [The Genetically Modified Organisms \(Deliberate Release\) \(Scotland\) Amendment Regulations 2004 \(S.S.I. 2004/439\)](#), regs. 1, **4(b)**
- F4** Reg. 15(g) added (15.11.2004) by [The Genetically Modified Organisms \(Deliberate Release\) \(Scotland\) Amendment Regulations 2004 \(S.S.I. 2004/439\)](#), regs. 1, **4(c)**

Changes to legislation:

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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)