

**2004 No. 439**

**ENVIRONMENTAL PROTECTION**

**The Genetically Modified Organisms (Deliberate Release)  
(Scotland) Amendment Regulations 2004**

*Made* - - - - - *6th October 2004*

*Laid before the Scottish Parliament* *7th October 2004*

*Coming into force* - - - *15th November 2004*

The Scottish Ministers, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(a) and of all other powers enabling them in that behalf, hereby make the following Regulations:

**Citation and commencement**

1. These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Scotland) Amendment Regulations 2004 and come into force on 15th November 2004.

**Amendment of the Genetically Modified Organisms (Deliberate Release) Regulations 2002**

2. The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(b) are amended in accordance with the following provisions of these Regulations.

3. In regulation 2–

(a) for the definition of “the Deliberate Release Directive” there is substituted–

““the Deliberate Release Directive” means Directive 2001/18/EC(c) of the European Parliament and the Council on the deliberate release into the environment of genetically modified organisms as amended by the Food and Feed Regulation and Council Regulation (EC) No 1830/2003(d);”; and

(b) after the definition of “the First Simplified Procedure (crop plants) Decision” there is inserted–

““the Food and Feed Regulation” means Council Regulation (EC) No 1829/2003(e) on genetically modified food and feed;

“genetically modified feed” means–

(a) feed containing or consisting of genetically modified organisms;

(b) feed derived in whole or in part from, but not containing or consisting of genetically modified organisms; or

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(a) 1972 c.68. Section 2(2) was amended by the Scotland Act 1998 (c.46), Schedule 8, paragraph 15(3). The function conferred upon the Minister of the Crown under section 2(2) of the 1972 Act, insofar as within developed competence, was transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998.

(b) S.S.I. 2002/541.

(c) O.J. No L 106, 17.4.2001, p.1.

(d) O.J. No L 268, 18.10.2003, p.24.

(e) O.J. No L 258, 18.10.2003, p.1.

(c) genetically modified organisms that may be used as feed or as a source material for the production of feed;

“genetically modified food” means—

- (a) food containing or consisting of genetically modified organisms;
- (b) food, or food containing ingredients, derived in whole or in part from genetically modified organisms, but not containing or consisting of genetically modified organisms; or
- (c) genetically modified organisms that may be used as food or as a source material for the production of food;”.

**4. In regulation 15—**

(a) in paragraph (a), after the words “has approval” there is added—

“and in accordance with the limitations and conditions to which the use of that product is subject”;

(b) for paragraph (f) there is substituted—

“(f) a novel food or novel food ingredient within the meaning of Council Regulation (EC) No. 258/97(a), as amended by the Food and Feed Regulation and Council Regulation 1882/2003(b), is marketed; and”;

(c) after paragraph (f) there is added—

“(g) genetically modified food or feed authorised under the Food and Feed Regulation is marketed.”.

**5. After regulation 17 there is inserted—**

**“Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.**

**17A.**—(1) Subject to paragraph (2), the marketing of traces of a genetically modified organism or combination of genetically modified organisms in products intended for direct use as food or feed or for processing shall be exempted 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) provided that the conditions set out in article 47 of the Food and Feed Regulation are met.

(2) Paragraph (1) shall cease to have effect on 18th April 2007.”.

**6. For paragraph (2) of regulation 21 there is substituted—**

“(2) The Scottish Ministers shall not grant or refuse consent to release genetically modified organisms before the end of the period specified for representations and comments in accordance with regulation 20(b) and (f) and if any comments referred to in regulation 20(f) are received within that period, before they have considered those comments.”.

*ALLAN WILSON*

Authorised to sign by the Scottish Ministers

St Andrew’s House,  
Edinburgh  
6th October 2004

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(a) O.J. No L 43, 14.2.1997, p.1.  
(b) O.J. No L 284, 31.10.2003, p.1.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (S.S.I. 2002/541) (“the 2002 Regulations”).

The amendments to the 2002 Regulations give effect in Scotland to the consequential amendments made to Directive 2001/18/EC of the European Parliament and the Council (O.J. No. L 106, 17.4.02, p.1) on the deliberate release into the environment of genetically modified organisms (the “Deliberate Release Directive”) by Council Regulation (EC) No 1829/2003 (OJ No. L286, 18.10.03, p. 1) on genetically modified food and feed (the “Food and Feed Regulation”).

These amending Regulations—

- (a) update references to relevant EC legislation (*Regulations 3 and 4(b)*);
- (b) provide that, where products have been approved in accordance with legislative provisions other than those contained in the 2002 Regulations, those products are only exempt from the requirements of sections 108(1)(a) and 111(1)(a) of the Environmental Protection Act 1990 if they have been marketed in accordance with any conditions or limitations imposed upon the consent that has been issued in relation to that product (*Regulation 4(a)*);
- (c) provide for the marketing of genetically modified food and feed that has been authorised under the Food and Feed Regulation without the need for a marketing consent under section 111(1)(a) of the Environmental Protection Act 1990 (“the Act”), or an additional risk assessment under section 108(1)(a) of the Act (*Regulation 4(c)*); and
- (d) provide that, until 18<sup>th</sup> April 2007, the placing on the market of traces of a genetically modified organism or a combination of genetically modified organisms in products intended for direct use as food or feed or for processing is exempt from the requirements of section 111(1)(a) of the Act (to obtain a marketing consent) and of section 108(1)(a) of the Act (to carry out a risk assessment) provided the conditions specified in article 47 of the Food and Feed Regulation are met (*Regulation 5*).
- (e) clarify that the Scottish Ministers must not grant or refuse consent to release genetically modified organisms before any comments mentioned in regulation 20(f) of the 2002 Regulations have been considered. (*Regulation 6*).

A Regulatory Impact Assessment for these Regulations has been prepared and a copy has been placed in the Scottish Parliament Information Centre. Copies can be obtained from the Scottish Executive Environment and Rural Affairs Department, GM Team, Victoria Quay, Edinburgh EH6 6QQ.

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