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STATUTORY INSTRUMENTS

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**2004 No. 2411**

**ENVIRONMENTAL PROTECTION**

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

<i>Made</i>	- - - -	<i>14th September 2004</i>
<i>Laid before Parliament</i>		<i>16th September 2004</i>
<i>Coming into force</i>	- -	<i>8th October 2004</i>

The Secretary of State for Environment, Food and Rural Affairs, being designated<sup>(1)</sup> for the purpose of section 2(2) of the European Communities Act<sup>(2)</sup> in relation to the control and regulation of genetically modified organisms, in exercise of the powers conferred on her by that section, makes the following Regulations—

**Title and commencement**

1. These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations 2004 and shall come into force on 8th October 2004.

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

2.—(1) The Genetically Modified Organisms (Deliberate Release) Regulations 2002<sup>(3)</sup> shall be amended in accordance with the following provisions of this Regulation.

(2) In Regulation 2—

(a) for the definition of “the Deliberate Release Directive” there shall be substituted the following definition—

““the Deliberate Release Directive” means Council Directive [2001/18/EC](#)<sup>(4)</sup> 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](#)<sup>(5)</sup>”; and

(b) after the definition of “the First Simplified Procedure (crop plants) Decision” there shall be inserted the following definitions—

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(1) S.I. [1991/755](#).

(2) [1972 c. 68](#).

(3) S.I. [2002/2443](#).

(4) OJ No L106, 17.4.2001, p. 1.

(5) OJ No L268, 18.10.2003, p. 24.

““the Food and Feed Regulation” means Council Regulation (EC) No 1829/2003(6) on genetically modified food and feed;

“genetically modified feed” means—

- (a) feed containing, consisting of or produced from genetically modified organisms; or
- (b) genetically modified organisms for feed use;

“genetically modified food” means—

- (a) food containing or consisting of genetically modified organisms;
- (b) food produced from, or containing ingredients produced from, genetically modified organisms; or
- (c) genetically modified organisms for food use;”.

(3) In regulation 15—

- (a) in paragraph (a), after the words “has approval” there shall be inserted the words “and in accordance with the limitations and conditions to which the use of that product is subject”;
- (b) for paragraph (f) there shall be substituted the following paragraph—

“(f) a genetically modified novel food or genetically modified novel food ingredient within the scope of Council Regulation (EC) No. 258/97(7), as amended by the Food and Feed Regulation and Council Regulation 1882/2003(8), is marketed; and”;

(c) after paragraph (f) there shall be inserted the following paragraph—

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

(4) After regulation 17 there shall be inserted the following regulation—

**“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 18 April 2007.”.

(5) For paragraph (2) of regulation 21 there shall be substituted the following paragraph—

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

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(6) OJ No L258, 18.10.2003, p. 1.

(7) OJ No L43, 14.2.1997, p. 1.

(8) OJ No L284, 31.10.2003, p. 1.

14th September 2004

*Elliot Morley*  
Minister of State  
Department for Environment, Food and Rural  
Affairs

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## EXPLANATORY NOTE

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

These Regulations amend the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (the 2002 Regulations).

The amendments to the 2002 Regulations give effect in England to the consequential amendments made to Council Directive [2001/18/EC](#) (OJ No. L106, 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 1830/2003](#) (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 2(2)(a) and 2(3)(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 2(3)(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 2(3)(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 2(4)*).
- (e) clarify that the Secretary of State must not grant or refuse to consent to release genetically modified organisms before the end of the latest date on which the representations mentioned in regulations 20(c) and (f) of the 2002 Regulations can be made (*Regulation 2(5)*).

A Regulatory Impact Assessment has been prepared for these Regulations and a copy has been placed in the library of each House of Parliament. Copies of the Regulatory Impact Assessment can be obtained from GM Controls Unit, DEFRA, Zone G/9, Ashdown House, 123 Victoria Street, London SW1E 6DE.