
STATUTORY INSTRUMENTS

1996 No. 1106

ENVIRONMENTAL PROTECTION

**The Genetically Modified Organisms (Risk Assessment)
(Records and Exemptions) Regulations 1996**

<i>Made</i>	- - - -	<i>12th April 1996</i>
<i>Laid before Parliament</i>		<i>18th April 1996</i>
<i>Coming into force</i>	- -	<i>9th May 1996</i>

The Secretary of State for the Environment and the Minister of Agriculture, Fisheries and Food, acting jointly as respects England, the Secretary of State for Wales, as respects Wales, and the Secretary of State for Scotland, as respects Scotland, in exercise of the powers conferred on them by sections 108(5), (7) and (10) and 126(1) of the Environmental Protection Act 1990⁽¹⁾ and of all other powers enabling them in that behalf, hereby make the following Regulations:—

Citation, commencement, revocation and interpretation

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Risk Assessment)(Records and Exemptions) Regulations 1996 and shall come into force on 9th May 1996.

(2) The Genetically Modified Organisms (Contained Use) Regulations 1993⁽²⁾ are hereby revoked.

(3) In these Regulations—

“the Act” means the Environmental Protection Act 1990, and

“the Contained Use Regulations” means the Genetically Modified Organisms (Contained Use) Regulations 1992⁽³⁾.

Duty to keep records of risk assessments

2. The period for which a person who carries out an assessment under section 108(1)(a) of the Act (Risk assessment and notification requirements) shall keep a record of that assessment shall be ten years.

(1) 1990 c. 43.

(2) S.I. 1993/15.

(3) S.I. 1992/3217, as amended by S.I. 1996/967

Exemptions from requirement to carry out risk assessments

3.—(1) A person who imports or acquires genetically modified organisms shall be exempt from the requirements of section 108(1)(a) of the Act in so far as they relate to the protection of human health.

(2) A person who imports or acquires genetically modified organisms shall be exempt from the requirements of section 108(1)(a) of the Act where the organisms to be imported or acquired—

- (a) are, within the meaning of regulation 2(1) of the Contained Use Regulations, genetically modified micro-organisms;
- (b) are organisms, within the meaning of regulation 2(1) of the Contained Use Regulations, other than micro-organisms within the meaning of regulation 2(1) as aforesaid, which are modified by means of—
 - (i) the application of the techniques which, by virtue of Part II of Schedule 1 to the Contained Use Regulations, are not considered to result in genetic modification for the purposes of the definition of that expression in regulation 2(1) of those Regulations; or
 - (ii) the application of the techniques to which, by virtue of regulation 3(3) of and Part III of Schedule 1 to the Contained Use Regulations, those Regulations do not apply;
- (c) are or are contained in a medicinal product for human or veterinary use which is the subject of a market authorisation under Council Regulation (EEC) No. 2309/93(4);
- (d) consist of, or are included in, an approved product as defined in the Genetically Modified Organisms (Deliberate Release) Regulations 1992(5) which is imported or acquired in accordance with the conditions and limitations to which the use of the product is subject.

Signed by authority of the Secretary of State

Department of the Environment
12th April 1996

James Clappison
Parliamentary Under-Secretary of State,

Signed by authority of the Minister of State for Agriculture, Fisheries and Food

12th April 1996

A. F. Browning
Parliamentary Secretary, Ministry of Agriculture,
Fisheries and Food

(4) OJ No. L214 24.8.93, p. 1.

(5) S.I. 1992/3280 as amended by S.I. 1993/152 and S.I. 1995/304.

Signed by authority of the Secretary of State for Wales

Welsh Office
12th April 1996

Gwilym Jones
Parliamentary Under-Secretary of State,

Scottish Office
12th April 1996

Lindsay
Parliamentary Under-Secretary of State,

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision in relation to section 108(1)(a) of the Environmental Protection Act 1990 (“the Act”), which restricts the import and acquisition of genetically modified organisms (“GMOs”).

They revoke and replace, with certain drafting changes, the Genetically Modified Organisms (Contained Use) Regulations 1993 (S.I.1993/15) and take account of amendments made to Genetically Modified Organisms (Contained Use) Regulations 1992 (S.I. 1992/3217) (“the Contained Use Regulations 1992”) by the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996 (S.I. 1996/967).

Regulation 2 prescribes the period for which records must be kept of risk assessments required to be carried out under section 108(1)(a) of the Act before importing or acquiring GMOs.

Regulation 3 provides for exemptions from the requirement to carry out risk assessments under section 108(1)(a) of the Act. Where a person imports or acquires GMOs, section 108(1)(a) will not apply in relation to micro-organisms within the meaning of the Contained Use Regulations 1992 or to organisms, other than micro-organisms, modified by application of the techniques set out in Parts II and III of Schedule 1 to the Contained Use Regulations 1992.

Regulation 3 provides for an exemption where a person imports or acquires GMOs which are or are contained in a medicinal product which is the subject of a market authorisation under Council Regulation (EEC) No. 2309/93 (OJ No. L241 24.8.93). It is also provided that section 108(1)(a) of the Act will not apply to approved products, as defined in the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (S.I. 1992/3280), which are imported or acquired in accordance with the conditions and limitations to which the use of the product is subject.