STATUTORY INSTRUMENTS

1997 No. 1900

ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997

Made - - - -	*30th July 1997*
Laid before Parliament	*4th August 1997*
Coming into force - -	*25th August 1997*

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 Scotland, as respects Scotland, and the Secretary of State for Wales, as respects Wales, in exercise of the powers conferred by sections 108(7) and (10), 111(1), (4) (7) and (11) and 126(1) of the Environmental Protection Act 1990(**a**), and all of those Secretaries of State and that Minister acting jointly as respects Great Britain, in exercise of the powers conferred on them by subsection (2) of section 2 of the European Communities Act 1972(**b**) being designated(**c**) for the purposes of that subsection in relation to the control and regulation of genetically modified organisms, and in each case in exercise of all other powers so enabling them, hereby make the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997 and shall come into force on 25th August 1997.

Amendment of Regulations — Deliberate Release

2.—(1) The Genetically Modified Organisms (Deliberate Release) Regulations 1992(**d**) are amended as follows.

(2) In paragraph (1) of regulation 10 (consent to market products) there is added at the end the following subparagraph—

(a) 1990 c. 43.
(b) 1972 c. 68.
(c) S.I. 1991/755.
(d) 1992/3280; the relevant amending instrument is S.I. 1995/304.

"(e) the marketing of a novel food or novel food ingredient within the scope of Regulation (EC) No 258/97 of the European Parliament and of the Council(**e**)

(3) For Schedule 2 to the Genetically Modified Organisms (Deliberate Release) Regulations 1992(**d**) there is substituted the Schedule 2 set out in the Schedule to these Regulations.

Amendment of Regulations — Risk Assessment

3. In paragraph (2) of regulation 3 of the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996(**f**), there is added at the end the following sub-paragraph—

"(e) are or are contained in a novel food or novel food ingredient which is authorised for marketing in accordance with the provisions of Regulation (EC) No 258/97 of the European Parliament and of the Council(**g**)."

Signed by authority of the Secretary of State for the Environment

Michael Meacher
Minister of State,
Department of the Environment, Transport and the Regions
28th July 1997

Jeff Rooker
Minister of State, Ministry of Agriculture, Fisheries and Food
29th July 1997

Signed by authority of the Secretary of State for the Welsh Office

Win Griffiths
Parliamentary Under-Secretary of State, Welsh Office
30th July 1997

Sewel
Parliamentary Under-Secretary of State, Scottish Office
30th July 1997

(d) 1992/3280; the relevant amending instrument is S.I. 1995/304.
(f) S.I. 1996/1106.

SCHEDULE Regulation 2(3)

SCHEDULE 2 TO THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) REGULATIONS 1992 AS SUBSTITUTED BY THESE REGULATIONS

"SCHEDULE 2 Regulation 11(1)(c)

INFORMATION TO BE CONTAINED IN AN APPLICATION FOR CONSENT TO MARKET GENETICALLY MODIFIED ORGANISMS

PART I

GENERAL INFORMATION

1. The name of the product and the name of the genetically modified organisms in the product.

2. The name and address in the Community of the manufacturer or distributor of the product.

3. The specificity of the product and the exact conditions of use including, where appropriate, the type of environment and/or the geographical areas within the Community for which the product is suited.

4. The type of expected use of the product and the description of the persons who are expected to use the product.

(4a) Information relating to the introduced genetic modification which could be of relevance to the establishment of a possible register of modifications introduced into organisms [species]. This may include nucleotide sequences or any other type of information which is relevant for inclusion in such a register.

(4b) Information regarding proposed labelling which must include, in a label or an accompanying document, an indication that the product contains, or consists of, genetically modified organisms. In the case of products to be placed on the market in mixtures with non-genetically modified organisms, it is sufficient to indicate the possibility that genetically modified organisms may be present.

PART II

ADDITIONAL RELEVANT INFORMATION

5. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.

6. Specific instructions or recommendations for storage and handling of the product.

7. The estimated level and amount of production within the Community and the estimated level and amount of imports of the product into the Community.

8. Information regarding the proposed packaging for the product and its appropriateness so as to avoid the escape of genetically modified organisms during storage or at a later stage.

9. Information regarding proposed labelling including the proposals for stating, in full or summarised form, the information prescribed in paragraphs 1 to 3, 5 and 6 above."

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Commission Directive 97/35/EC (OJ No. L 169, 27.6.97, p. 72) adapting to technical progress for the second time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, by amending the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (SI 1992/3280) (The 1992 Regulations). Regulation 3 substitutes the Schedule to these Regulations for Schedule 2 to the 1992 Regulations.

In addition, these Regulations amend the 1992 Regulations to take account of Regulation (EC) No. 258/97 (OJ No. L 43, 14.2.97, p. 1) concerning novel foods and novel food ingredients (the Novel Foods Regulation), with regard to the cases and circumstances in which a marketing consent is required under the 1992 Regulations.

Finally, these Regulations also amend the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996 (SI 1996/1106) to take account of the Novel Foods Regulation with regard to exemptions from the requirement to carry out risk assessments.