STATUTORY INSTRUMENTS

1995 No. 304

The Genetically Modified Organisms (Deliberate Release) Regulations 1995

Amendment of the cases and circumstances in which a marketing consent is required

6.—(1) In regulation 2 of the 1992 Regulations (Interpretation), there shall be inserted immediately after the definition of "the Commission" the following definition—

""the Contained Use Directive" means Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms(1);".

- (2) In paragraph (1) of regulation 10 of the 1992 Regulations (Consent to market products)—
 - (a) between the words "cases and circumstances other than" and "the marketing of a product" there shall be inserted "(a)";
 - (b) after the words "the Deliberate Release Directive" there shall be added the following—

"; (b) the marketing of a product containing genetically modified micro-organisms within the meaning of Article 2 of the Contained Use Directive, the conditions of sale for which specify that it is to be used only in conditions of contained use in accordance with the Contained Use Directive; (c) the marketing of a medicinal product for human or veterinary use within the meaning of Council Regulation (EEC) No. 2309/93(2); (d) the marketing of an additive within the meaning of regulation 2(1) of the Feeding Stuffs Regulations 1991(3) incorporated in or for incorporation in any feeding stuff within the meaning of regulation 2(1) as aforesaid."

⁽¹⁾ OJ No. L117, 8,5,90, p.1

⁽²⁾ OJ No. L214, 24.8.93, p.1. A Council Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products. The Regulation provides for the specific risk assessment of medicinal products containing or consisting of genetically modified organisms.

⁽³⁾ S.I.1991/2840, as amended by S.I. 1993/1442, S.I. 1994/499 and S.I. 1994/2510. These Regulations implement Council Directive 70/524/EEC concerning additives in feedingstuffs (OJ No. L270, 14.12.70, p.1.), as amended from time to time, in particular by Council Directive 93/114/EC (OJ No. L334, 31.12.93, p.24.) which provides for the specific risk assessment of additives containing genetically modified organisms.