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## EXPLANATORY NOTE

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

These Regulations amend the Genetically Modified Organisms (Contained Use) Regulations 1992 (S.I. 1992/3217) (“the principal Regulations”) in the following ways—

### **Paragraph 2(a) of Schedule 1**

1. Council Directive [90/219/EEC](#) (OJNo. L117, 8.5.90, p.1), on the contained use of genetically modified micro-organisms, implemented by the principal Regulations, now applies to the States of the European Economic Area by virtue of the Agreement on the European Economic Area. A definition of “member State”, which includes those States, is, therefore, inserted into regulation 2(1) of the principal Regulations. Definitions of “the European Economic Area” and “the Agreement” are also inserted into that regulation.

2. The definition of “organism” in regulation 2(1) of the principal Regulations is amended to exclude human and human embryos, which are outside the scope of the above Directive.

### **Paragraphs 2(b), 5 and 7 of Schedule 1; Schedule 2**

3. Regulation 2(2) and Schedule 2 of the principal Regulations are replaced, to implement the new classification criteria for micro-organisms contained in Commission Directive [94/51/EC](#) (OJ No. L297, 18.11.94, p.29), which adapts to technical progress Council Directive [90/219/EEC](#). There are minor consequential amendments to regulation 9 of, and paragraph 3(e) of Schedule 1 to, the principal Regulations.

### **Paragraph 3 of Schedule 1**

4. By Article 5 of Council Directive [90/219/EEC](#), genetically modified micro-organisms marketed in accordance with other Community legislation providing equivalent risk assessment to that required under the said Directive, are excluded from the scope of that Directive as regards storage, transport, destruction and disposal. The exemptions contained in regulation 6(2)(a) of the principal Regulations are extended to exclude from the prohibitions in regulation 6(1) certain medicinal products marketed in accordance with Council Regulation ([EEC](#)) No. [2309/93](#) (OJ No. L214, 24.8.93,p.1).

### **Paragraph 4 of Schedule 1**

5. Regulation 8(2) of the principal Regulations is amended to provide that a separate notification is not required where a consent for Group II micro-organisms has already been granted and it is intended to use the premises for activities involving Group I micro-organisms, or where simultaneous notification is being given for activities involving Group I and II micro-organisms at the same premises.

### **Paragraph 6 of Schedule 1**

6. Regulation 16(4)(b) of the principal Regulations, specifying the location where a copy of the register of notifications is held, is amended to specify the current address for the Health and Safety Executive in London.