## SCHEDULE 1

Regulation 3(1)

### Amendments to the Principal Regulations

1. The principal Regulations shall be amended in accordance with the following paragraphs of this Schedule.

2. In regulation 2—

(a) in paragraph (1)—

(i) after the definition of "activity involving genetic modification" there shall be inserted the following definition—

""the Agreement" means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993 and adopted as respects the United Kingdom by the European Economic Area Act 1993(**1**);",

(ii) after the definition of "the Department" there shall be inserted the following definition—

""the European Economic Area" means the Area referred to in the Agreement;",

(iii) after the definition of "genetic modification safety committee" there shall be inserted the following definition—

""member State" means a State which is a Contracting Party to the Agreement;", and

(iv) for the definition of "organism" there shall be substituted the following definition—

""organism" means a biological entity capable of replication or transferring genetic material and includes a micro-organism, but does not include a human or a human embryo;"; and

(b) for paragraph (2), there shall be substituted the following paragraph—

"(2) Genetically modified organisms shall be classified—

(a) in the case of micro-organisms—

(i) as Group I micro-organisms if they satisfy all of the criteria set out in Part I of Schedule 2, or

(ii) as Group II micro-organisms if they do not satisfy all of the said criteria; or

(b) in the case of genetically modified organisms other than micro-organisms, as satisfying the criteria set out in Part II of Schedule 2 if they so satisfy those criteria.".

3. For sub-paragraph (*a*) of paragraph (2) of regulation 6 there shall be substituted the following sub-paragraph—

"(a) genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of, where such organisms are or are contained in—

(i) a product marketed in pursuance of either—

(aa) a consent granted by the Department of the Environment for Northern Ireland under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991(**2**); or

(**1**) 1993 c. 51
(**2**) S.I.1991/1714 (N.I. 19)

(bb) a written consent given by another competent authority of a member State in accordance with Article 13(4) of Council Directive 90/220/EEC(**3**) on the deliberate release into the environment of genetically modified organisms; and

in either case, the operation is conducted in accordance with any conditions or limitations attached to that consent, or

(ii) a medicinal product for human or veterinary use marketed in accordance with Council Regulation (EEC) No. 2309/93(**4**); or"

4. At the end of paragraph (2) of regulation 8 but before the full stop, there shall be inserted a comma followed by the words—

"except that a separate notification shall not be required—

(a) where a consent has already been given under paragraph (3) for activities involving Group II micro-organisms and the premises are to be used for activities involving Group I micro-organisms; or

(b) where simultaneous notification is being given of an intention to use premises for activities involving both Group I and Group II micro-organisms".

5. In sub-paragraphs (2)(*b*) and (4)(*b*) of regulation 9 for the words "Part III" in each place where they occur there shall be substituted the words "Part II".

6. In paragraph 3(*e*) of Schedule 1 for the words "fulfil the criteria of Part III" there shall be substituted the words "satisfy the criteria of Part II".

(**3**) O.J. No. L117, 8.5.90, p. 15
(**4**) O.J. No. L214, 24.8.93, p. 1