SCHEDULE 1 Regulations 2(1) and 3(3)

DEFINITION OF GENETIC MODIFICATION

PART I

Examples of techniques constituting genetic modification

1. Examples of the techniques which constitute genetic modification which are referred to in sub-paragraph (a) of the definition of genetic modification in regulation 2(1) are—

(a) recombinant DNA techniques consisting of the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not occur naturally but in which they are capable of continued propagation;

(b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and microencapsulation; and

(c) cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART II

Techniques which are not considered to result in genetic modification

2. The following techniques are not considered to result in genetic modification if they do not involve the use of recombinant-DNA molecules or genetically modified organisms—

(a) in vitro fertilization;

(b) conjugation, transduction, transformation or any other natural process; and

(c) polyploidy induction.

PART III

Techniques to which these Regulations do not apply

3. These Regulations shall not apply to the following techniques of genetic modification if they do not involve the use of genetically modified organisms as recipient or parental organisms—

(a) mutagenesis;

(b) the construction and use of somatic hybridoma cells (for example for the production of monoclonal antibodies);

(c) cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods;

(d) self-cloning of non-pathogenic naturally occurring micro-organisms which fulfil the criteria of Group I for recipient micro-organisms; and

(e) self-cloning of non-pathogenic naturally occurring organisms other than micro-organisms which fulfil the criteria of Part III of Schedule 2.