

SCHEDULE 5

Regulation 9

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 9

PART I

Information required under regulation 9(3)

1. A notification required for the purposes of regulation 9(3) shall include the following information—

- (a) the name and address of the person responsible for carrying out the activity;
- (b) address of the premises where the activity is to be carried out;
- (c) the date of the notification referred to in regulation 8(1);
- (d) the parental organism used, or where applicable the host-vector system used;
- (e) the source and the intended function of the genetic material involved in the modification;
- (f) the identity and characteristics of the genetically modified organism;
- (g) the purpose of the activity including the expected results;
- (h) where appropriate the culture volumes to be used or the scale of the activity;
- (i) details of waste treatment including levels of live genetically modified micro-organisms in the waste; and
- (j) a summary of the risk assessment required in accordance with regulation 7 and of the comments of the genetic modification safety committee on it.

PART II

Additional information required under regulation 9(4)

2. In addition to the information required under Part I a notification made for the purposes of regulation 9(4) shall contain the following information—

- (a) a description of the sections of the installation involved and the methods for handling the organisms;
- (b) a description of the predominant meteorological conditions and the potential sources of danger arising from the location of the installation;
- (c) a description of the protective and supervisory methods to be applied throughout the duration of the activity; and
- (d) in the case of micro-organisms, the containment level to which the micro-organism has been allocated in accordance with the risk assessment made in accordance with regulation 7(1) and in any case the safety precautions to be observed.

PART III

Additional information required under regulation 9(5)

3. In addition to the information required under Parts I and II a notification made for the purposes of regulation 9(5) shall contain the information specified in paragraph 5.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

4. If it is not technically possible, or if it does not appear necessary to give the information specified in paragraph 5, the reason shall be stated. The level of detail required in response to each subset of considerations is likely to vary according to the nature and scale of the proposed activity. In the case of information already submitted to the Executive by the notifier under these Regulations (or the 1989 Regulations) reference can be made to that information by him.

5. The additional information required is—

- (a) information about the genetically modified micro-organisms—
 - (i) the identity and characteristics of the genetically modified micro-organisms,
 - (ii) the purpose of the contained use or the nature of the product,
 - (iii) the host-vector system to be used where applicable,
 - (iv) the culture volume to be used,
 - (v) behaviour and characteristics of the micro-organisms in the case of changes in the conditions of containment or release into the environment,
 - (vi) overview of the potential hazards associated with the release of the micro-organisms into the environment, and
 - (vii) substances which are or may be produced in the course of use of the microorganisms other than the intended product;
- (b) information about personnel—
 - (i) the maximum number of persons working in the installation, and
 - (ii) the number of persons who will work directly with the micro-organisms;
- (c) information about the installation—
 - (i) the activity in which the micro-organisms are to be used,
 - (ii) the technological processes used,
 - (iii) a description of the sections of the installation involved, and
 - (iv) the predominant meteorological conditions and specific hazards arising from the location of the installation;
- (d) information about waste management—
 - (i) types, quantities and potential hazards arising from the use of the micro-organisms,
 - (ii) waste management techniques used including recovery of liquid or solid wastes and the inactivation techniques used, and
 - (iii) ultimate form and destination of inactivated wastes;
- (e) information about accident prevention and emergency response plans—
 - (i) the sources of hazards and conditions under which accidents might occur,
 - (ii) the preventive measures applied such as safety equipment, alarm systems, containment methods and procedures and available resources,
 - (iii) a description of information given to workers, and
 - (iv) the information necessary for the Executive to evaluate any emergency plan prepared in accordance with regulation 13;
- (f) the full risk assessment referred to in regulation 7; and
- (g) any other information the Executive needs for the purpose of maintaining the register referred to in regulation 16.