SCHEDULE 1

Regulation 2(1)

HAZARD GROUPS FOR ORGANISMS

GROUP 1	An organism that is most unlikely to cause human disease.
GROUP 2	An organism that may cause human disease and which might be a hazard to laboratory workers but it is unlikely to spread in the community. Laboratory exposure rarely produces infection and effective prophylaxis or effective treatment is usually available.
GROUP 3	An organism that may cause severe human disease and present a serious hazard to laboratory workers. It may present a risk of spread in the community but there is usually effective prophylaxis or treatment available.
GROUP 4	An organism that causes severe human disease and is a serious hazard to laboratory workers. It may present a high risk of spread in the community and there is usually no effective prophylaxis or treatment.

SCHEDULE 2

Regulation 5(2)(a)

PARTICULARS TO BE GIVEN IN A NOTIFICATION OF AN INTENTION TO CARRY OUT ACTIVITIES INVOLVING GENETIC MANIPULATION

1. The name of the person who will carry out activities involving genetic manipulation.

2. The address or location of the premises or site where the work is to be carried out.

3. The name and designation of the person responsible for the work.

4. Into which of the following categories the activities fall—

(a) the construction or modification of a cell or organism by genetic manipulation;

(b) the use of a cell or organism constructed or modified by genetic manipulation; or

(c) intentional introduction into the environment.

5. The arrangements for physical containment (unless the work is assigned to containment level 1 or good large-scale practice).

6. The names and capacities of members of the genetic manipulation safety committee.

7. Comments made by the genetic manipulation safety committee on the local arrangements for risk assessment.

8. The names of the biological and deputy biological safety officers concerned with the work (if any).

9. The name of the supervisory medical officer concerned with the work (if any).

10. The arrangements for health surveillance (if any).

SCHEDULE 3

Regulation 5(2)(b)

PARTICULARS TO BE GIVEN IN A NOTIFICATION OF AN ACTIVITY INVOLVING GENETIC MANIPULATION

1. In all cases—

(a) the name of person carrying out the work;

(b) the address of the premises or site where the work is to be carried out;

(c) particulars of the work to be undertaken;

(d) any variation of the particulars notified in accordance with Schedule 2;

(e) comments by the genetic manipulation safety committee;

(f) the proposals for physical containment (if any);

(g) the subsequent use or distribution of nucleic acid;

(h) the risk assessment and the categorisation data on which it is based.

2. In the case of the construction or modification of a cell or organism by genetic manipulation—

(a) the proposed containment level of the project;

(b) a list of staff to be involved in the project.

3. In the case of the use of a cell or organism constructed or modified by genetic manipulation—

(a) the nature of the gene product;

(b) the host vector system to be used;

(c) the scale of operation proposed;

(d) the safety precautions proposed;

(e) the proposed process containment;

(f) whether any part of the construction involves the use of a pathogen.

4. In the case of intentional introduction into the environment—

(a) the objectives of the project;

(b) the nature of the cell or organism to be released;

(c) the procedure used to introduce the genetic modification;

(d) the nature of any altered nucleic acid and its source, its intended function and the extent to which it has been characterised;

(e) verification of the genetic structure of the novel organism;

(f) the genetic stability of the novel organism;

(g) the ability of the organism to give rise to long-term survival forms and the effect the altered nucleic acid may have on this ability;

(h) in the case of a pest control agent, details of the target biota;

(i) the geographical location, size and nature of the site of release;

(j) the physical and biological proximity of the site to man and other significant biota;

(k) details of the ecosystem into which the organism is to be released;

(l) the method and amount of release, rate, frequency and duration of application;

(m) monitoring capabilities and intentions;

(n) the on-site worker safety procedures and facilities;

(o) the contingency plans in the event of unanticipated effects of the novel organism;

(p) an assessment of the environmental consequences of the release including—

(i) survival and persistence of the novel organism,

(ii) susceptibility to temperature, humidity, desiccation, ultra-violet light and other ecological stresses,

(iii) details of any modification of the organism designed to affect its ability to survive and to transfer genetic material,

(iv) potential for transfer of inserted polynucleotides to other organisms including methods for monitoring survival and transfer,

(v) methods to control or eliminate any superfluous organism or nucleic acid surviving in the environment or possibly in a product,

(vi) an assessment of the effects of the manipulation on the ecological behaviour of the organism in its natural habitat;

(q) details of any local consultation undertaken;

(r) method of termination of the project.

SCHEDULE 4

Regulation 5(4)(b)

PARTICULARS TO BE GIVEN OF ACTIVITIES INVOLVING GENETIC MANIPULATION IN THE ANNUAL RETURN UNDER REGULATION 5(4)

1. The name of person carrying out activities involving genetic manipulation.

2. The address or location of the premises or site where the work was carried out.

3. Any variation in the particulars notified in accordance with Schedule 2.

4. The numbers of all projects assigned to containment levels 1 and 2 respectively.

5. The numbers of projects involving the use of a cell or organism constructed or modified by genetic manipulation warranting only the use of good large-scale practice.