SCHEDULE 1

Regulation 2(1)

CLASSES OF ACTIVITY INVOLVING GENETIC MODIFICATION

Class	*Description*
1	Activities of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
2	Activities of low risk, for which containment level 2 is appropriate to protect human health and the environment.
3	Activities of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
4	Activities of high risk, for which containment level 4 is appropriate to protect human health and the environment.

SCHEDULE 2

Regulations 2(1) and 3(2)

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 nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

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

(c) cell 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 provided that they do not involve the use of genetically modified organisms made by techniques other than those listed in Part III or the use of recombinant nucleic acid molecules, namely—

(a) in vitro fertilisation;

(b) natural processes including conjugation, transduction or transformation;

(c) polyploidy induction.

PART III

TECHNIQUES TO WHICH THESE REGULATIONS DO NOT APPLY

3. These Regulations (except regulation 17) shall not apply to the following techniques of genetic modification, provided that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms other than those recombinant nucleic acid molecules or genetically modified organisms produced by one or more of the following techniques of genetic modification—

(a) mutagenesis;

(b) cell fusion (including protoplast fusion) of prokaryotic species which can exchange genetic material through homologous recombination;

(c) cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions;

(d) self-cloning, where the resulting organism is unlikely to cause disease or harm to humans, animals or plants.

4. In paragraph 3—

(a) "self-cloning" means the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), whether or not altered by enzymic or mechanical processes, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by homologous recombination; and

(b) self-cloning may include the use of recombinant vectors, with an extended history of safe use in the particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors shall not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.

SCHEDULE 3

Regulations 2(2), 3(5) and 6(2)

PART I

MATTERS TO BE TAKEN INTO ACCOUNT IN CARRYING OUT ANASSESSMENT FOR THE PURPOSES OF REGULATION 6

1. The following matters shall be taken into account in carrying out an assessment for the purposes of regulation 6—

(a) any potentially harmful effects, in particular those associated with—

(i) the recipient micro-organism,

(ii) the inserted genetic material (originating from the donor organism),

(iii) the vector,

(iv) the donor micro-organism (where that donor micro-organism is used during the activity involving genetic modification), and

(v) the resulting genetically modified micro-organism;

(b) the characteristics of the activity;

(c) the severity of the potentially harmful effects; and

(d) the likelihood of the potentially harmful effects being realised.

2. In paragraph 1, "potentially harmful effects" includes—

(a) disease to humans including allergenic or toxic effects;

(b) disease to animals or plants;

(c) adverse effects resulting from the inability to treat disease or offer an effective prophylaxis;

(d) adverse effects resulting from establishment or dissemination of the genetically modified micro-organisms in the environment;

(e) adverse effects resulting from the natural transfer of genetic material to or from other organisms;

(f) adverse effects resulting from the likely interaction of the genetically modified micro-organism with other organisms at the premises where the activity involving genetic modification is to be conducted.

PART II

STEPS TO BE INCLUDED WHEN CARRYING OUT AN ASSESSMENT FOR THE PURPOSES OF REGULATION 6

3. An assessment carried out for the purposes of regulation 6 shall include—

(a) identification of any harmful properties of the recipient and, where appropriate, the donor micro-organism;

(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties;

(c) consideration of relevant Community legislation, including Council Directive 90/679/EEC(**1**) on the protection of workers from risks related to exposure to biological agents at work, other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modifed micro-organisms;

(d) identification of the provisional level of risk associated with the genetically modified micro-organism;

(e) consideration of—

(i) the characteristics of the environment likely to be exposed,

(ii) the characteristics of the activity involving genetic modification of micro-organisms, and

(iii) any activities involving genetic modification of micro-organisms which cannot be adequately controlled by standard laboratory procedures, and which present risks which require controls for each individual case;

(f) adjustment of the provisional level of risk in the light of the matters referred to in sub-paragraph (e) above;

(**1**) OJNo. L 374, 31.12.90, p. 1, as amended by Council Directive 93/88/EEC (OJ No. L 268, 29.10.93, p. 71), Commission Directive 95/30/EC (OJ No. L 155, 6.7.95, p. 41), Commission Directive 97/59/EC (OJ No. L 282, 15.10.1997, p. 33) and Commission Directive 97/65/EC (OJ No. L 335, 6.12.1997, p. 17).

(g) selection of the appropriate containment measures from those specified in the applicable Table in Schedule 8 on the basis of the provisional level of risk as adjusted in accordance with sub-paragraph (f) above;

(h) assignment of the activity involving genetic modification of micro-organisms to the appropriate containment level, in accordance with paragraph 4;

(i) classification of that activity in the class of the same number as that of the appropriate containment level; and

(j) review and reconsideration of that classification in the light of the completed assessment.

4. To assign an activity involving genetic modification of micro-organisms to the appropriate containment level for the purposes of paragraph 3(h), the person carrying out the assessment for the purposes of regulation 6 shall—

(a) first identify for each selected containment measure the column in the applicable Table in Schedule 8 having the lowest number in which that selected containment measure is shown as being required, regardless of whether or not such requirement is subject to any qualification;

(b) then select the highest number of all the columns identified in accordance with sub-paragraph (a) above; and

(c) then assign the activity involving genetic modification in question to the containment level of that highest number.

5. In paragraph 4, "selected containment measure" means an appropriate containment measure selected in accordance with paragraph 3(g).

SCHEDULE 4

Regulation 7(2)

PART I

MATTERS TO BE TAKEN INTO ACCOUNT IN CARRYING OUT AN ASSESSMENT FOR THE PURPOSES OF REGULATION 7

1. The following matters shall be taken into account in carrying out an assessment for the purposes of regulation 7—

(a) the identification of any potentially harmful effects, in particular those associated with—

(i) the recipient organism,

(ii) the inserted genetic material (originating from the donor organism),

(iii) the vector,

(iv) the donor organism, and

(v) the resulting genetically modified organism;

(b) the characteristics of the activity involving genetic modification;

(c) the severity of the potentially harmful effects; and

(d) the likelihood of the potentially harmful effects being realised.

2. In paragraph 1, "potentially harmful effects" includes—

(a) disease to humans including allergenic or toxic effects;

(b) acting as a human disease vector or reservoir;

(c) adverse effects to humans arising from change in behaviour or in physical nature;

(d) adverse effects arising from the inability to treat human disease or offer effective prophylaxis.

PART II

STEPS TO BE INCLUDED WHEN CARRYING OUT AN ASSESSMENT FOR THE PURPOSES OF REGULATION 7

3. An assessment carried out for the purposes of regulation 7 shall include—

(a) identification of the harmful properties of the recipient and, where appropriate, the donor organism;

(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;

(c) identification of the provisional level of risk associated with the genetically modified organisms;

(d) selection of containment and other protective measures on the basis of—

(i) the provisional level of risk, and

(ii) the characteristics of the activity involving genetic modification;

(e) adjustment of the level of risk in the light of the matters referred to in sub-paragraph (d) above; and

(f) review and reconsideration of the containment and other protective measures in the light of the steps required by sub-paragraphs (a) to (e) above.

SCHEDULE 5

Regulations 9(1), 15(2) and 24(3)

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 9(1)

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

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;

(b) the name of the employee of the notifier with specific responsibility for the supervision and safety of activities involving genetic modification;

(c) information on the training and qualifications of that employee;

(d) details of the genetic modification safety committee established pursuant to regulation 16;

(e) the address of the premises where the activity involving genetic modification is to be carried out and a general description of the premises;

(f) the nature of the work to be undertaken;

(g) the class of any activity involving genetic modification of micro-organisms;

(h) where the first activity to be carried out in those premises is an activity involving genetic modification in class 1—

(i) a summary of the assessment of that activity made for the purposes of regulation 6(1),

(ii) any advice received in relation to that assessment from the genetic modification safety committee established pursuant to regulation 16,

(iii) information on waste management, and

(iv) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the emergency plan and of any relevant revisions made in pursuance of regulation 20(3); and

(i) where the first activity to be carried out in those premises involves genetic modification of organisms which are not micro-organisms and that activity is not notifiable under regulation 12(1)—

(i) a copy of the assessment made for the purposes of regulation 7(1), and

(ii) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the plan and of any relevant revisions made in pursuance of regulation 20(3).

SCHEDULE 6 Regulations 10(1), 11(1), 12(1),15(2) and 24(3)

PART I

INFORMATION REQUIRED FOR A NOTIFICATION UNDERREGULATION 10(1)

1. A notification required for the purposes of regulation 10(1) shall contain the following information—

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;

(b) the centre number allocated by the competent authority in respect of the premises at which the activity involving genetic modification of micro-organisms is to be undertaken and the date of the notification required by regulation 9(1) relating to those premises;

(c) the name of the employee of the notifier with specific responsibility for supervision and safety;

(d) information on the training and qualifications of that employee;

(e) the recipient or parental micro-organism to be used;

(f) the donor micro-organism to be used;

(g) where applicable, the host-vector system to be used;

(h) the source and intended function of the genetic material involved in the modification;

(i) the identity and characteristics of the genetically modified micro-organism;

(j) the purpose of the activity involving genetic modification of micro-organisms, including its expected results;

(k) the approximate culture volumes to be used;

(l) a description of the containment and other protective measures to be applied, including—

(i) information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination, and

(ii) justification for not applying any containment measure at containment level 2;

(m) a copy of the assessment carried out pursuant to regulation 6(1);

(n) any advice received in relation to that assessment from the genetic modification safety committee established pursuant to regulation 16;

(o) the information necessary for the competent authority to evaluate any emergency plan; and

(p) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the plan and of any relevant revisions made in pursuance of regulation 20(3).

PART II

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 11(1)

2. A notification required for the purposes of regulation 11(1) shall contain the following information—

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;

(b) the centre number allocated by the competent authority in respect of the premises at which the activity involving genetic modification of micro-organisms is to be undertaken and the date of the notification required by regulation 9(1) relating to those premises;

(c) the name of the employee of the notifier with specific responsibility for supervision and safety;

(d) information on the training and qualifications of that employee;

(e) the recipient or parental micro-organism to be used;

(f) the donor micro-organism to be used;

(g) where applicable, the host-vector system to be used;

(h) the source and intended function of the genetic material involved in the modification;

(i) the identity and characteristics of the genetically modified micro-organism;

(j) the culture volumes to be used;

(k) a description of the containment and other protective measures to be applied, including—

(i) information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination,

(ii) in the case of activities involving genetic modification of micro-organisms in class 3, justification for not applying any containment measure at containment level 3, and

(iii) in the case of activities involving genetic modification of micro-organisms in class 4, justification for not applying any containment measure at containment level 4;

(l) the purpose of the activity involving genetic modification of micro-organisms, including its expected results;

(m) a description of the parts of the installation;

(n) information on any accident prevention and emergency plans, including—

(i) any specific hazards arising from the location of the installation,

(ii) the preventive measures applied, including safety equipment, alarm systems and containment methods,

(iii) procedures and plans for verifying the continuing effectiveness of the containment measures,

(iv) a description of the information provided to workers,

(v) the information necessary for the competent authority to evaluate any emergency plan, and

(vi) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the plan and of any relevant revisions made in pursuance of regulation 20(3); and

(o) a copy of the assessment referred to in regulation 6(1).

PART III

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 12(1)

3. A notification required for the purposes of regulation 12(1) shall contain the following information—

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;

(b) the centre number allocated by the competent authority in respect of the premises at which the activity involving genetic modification of organisms other than micro-organisms is to be undertaken and the date of the notification required by regulation 9(1) relating to those premises;

(c) the name of the employee of the notifier with specific responsibility for supervision and safety;

(d) information on the training and qualifications of that employee;

(e) the recipient or parental organism to be used;

(f) the donor organism to be used;

(g) where applicable, the host-vector system to be used;

(h) the sources and intended functions of the genetic material involved in the modification;

(i) the identity and characteristics of the genetically modified organism;

(j) the purpose of the activity involving genetic modification of organisms other than micro-organisms, including its expected results;

(k) a description of the containment and other protective measures to be applied, including information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination;

(l) a copy of the assessment referred to in regulation 7(1);

(m) the information necessary for the competent authority to evaluate any emergency plan; and

(n) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of that plan and of any relevant revisions made in pursuance of regulation 20(3).

SCHEDULE 7

Regulation 17(2) and (3)

GENERAL PRINCIPLES OF GOOD MICROBIOLOGICAL PRACTICE AND OF GOOD OCCUPATIONAL SAFETY AND HYGIENE

The general principles of good microbiological practice and of good occupational safety and hygiene are as follows—

(a) keeping workplace and environmental exposure to any genetically modified micro-organism to the lowest reasonably practicable level;

(b) exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary;

(c) testing adequately and maintaining control measures and equipment;

(d) testing, where necessary, for the presence of viable process organisms outside the primary physical containment;

(e) providing appropriate training of personnel;

(f) formulating and implementing local codes of practice for the safety of personnel, as required;

(g) displaying biohazard signs where appropriate;

(h) providing washing and decontamination facilities for personnel;

(i) keeping adequate records;

(j) prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption;

(k) prohibiting mouth pipetting;

(l) providing written standard operating procedures where appropriate to ensure safety;

(m) having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms; and

(n) providing safe storage for contaminated laboratory equipment and materials where appropriate.

SCHEDULE 8

Regulations 2(3) and 18(1)

CONTAINMENT MEASURES

PART I

1. In this Schedule—

"GMMs" means genetically modified micro-organisms;

"HEPA" means High Efficiency Particulate Air;

"inactivation" means the complete or partial destruction of GMMs so as to ensure that any contact between the GMMs and humans or the environment is limited to an extent commensurate with the risks identified in the risk assessment and to provide a high level of protection for humans and the environment;

"plant growth facilities" means a structure, whether permanent or impermanent, designed and used principally for growing plants in a controlled and protected environment; and

"risk assessment" means the assessment carried out in accordance with regulation 6.

2. For the purposes of this Schedule, where, in the final column of Table 1b or 1c, a measure is specified as—

(a) a modification, it shall be read in substitution for the relevant measure in Table 1a;

(b) additional, it shall be read as an addition to the measures in Table 1a, subject to the substitution, where appropriate, of an individual measure in Table 1a by a measure specified as a modification in the Table in question.

3. For the purposes of this Schedule—

(a) Table 1a describes containment measures applicable to activities involving genetic modification of micro-organisms in laboratories;

(b) Table 1a, read with Table 1b, describes containment measures applicable to activities involving genetic modification of micro-organisms in plant growth facilities;

(c) Table 1a, read with Table 1c, describes containment measures applicable to activities involving genetic modification of micro-organisms in animal units;

(d) Table 2 describes containment measures applicable to activities involving genetic modification of micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c.

PART II

Table 1a:

Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Laboratories

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
1	Laboratory suite: isolation **(Note 1)**	not required	not required	required	required
2	Laboratory: sealable for fumigation	not required	not required	required	required
	Equipment				

NOTES

1. In the Table above, "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
3	Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for bench	required for bench	required for bench and floor	required for bench, floor ceiling and walls
4	Entry to lab via airlock **(Note 2)**	not required	not required	required where and to extent the risk assessment shows it is required	required
5	Negative pressure relative to the pressure of the immediate surroundings	not required	required where and to extent the risk assessment shows it is required	required	required
6	Extract and input air from the laboratory shall be HEPA filtered	not required	not required	HEPA filters required for extract air	HEPA filters required for input and extract air **(Note 3)**
7	Microbiological safety cabinet/ enclosure	not required	required where and to extent the risk assessment shows it is required	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure	Class III cabinet required

NOTES

1. In the Table above, "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
8	Autoclave	required on site	required in the building	required in the laboratory suite **(Note 4)**	double ended autoclave required in laboratory
	System of work				
9	Access restricted to authorised personnel only	not required	required	required	required (via airlock key procedure)
10	Specific measures to control aerosol dissemination	not required	required so as to minimise	required so as to prevent	required so as to prevent
11	Shower	not required	not required	required where and to extent the risk assessment shows it is required	required
12	Protective clothing	suitable protective clothing required	suitable protective clothing required	suitable protective clothing required; footwear required where and to extent the risk assessment shows it is required	complete change of clothing and footwear required before entry and exit
13	Gloves	not required	required where and to extent the risk assessment shows they are required	required	required

NOTES

1. In the Table above, “isolation” means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
14	Efficient control of disease vectors (eg rodents and insects) which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required	required	required
15	Specified disinfection procedures in place	required where and to extent the risk assessment shows they are required	required	required	required
	Waste				
16	Inactivation of GMMs in effluent from handwashing sinks and showers and similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
17	Inactivation of GMMs in contaminated material and waste	required by validated means	required by validated means	required by validated means	required by validated means
	Other measures				
18	Laboratory to contain its own equipment	not required	not required	required, so far as is reasonably practicable	required
19	An observation window or	required where and to extent the risk	required where and to extent the risk	required	required

NOTES

1. In the Table above, “isolation” means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	alternative is to be present so that occupants can be seen	assessment shows it is required	assessment shows it is required		
20	Safe storage of GMMs	required where and to extent the risk assessment shows it is required	required	required	secure storage required
21	Written records of staff training	not required	required where and to extent the risk assessment shows they are required	required	required

NOTES
1. In the Table above, "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

Table 1b:

Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Plant Growth Facilities (to be read with Table 1a as indicated in paragraph 3)

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	Building					
1	Permanent structure **(Note 1)**	required where and to extent the risk assessment	required	required	required	Modification

NOTE
1. A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure shall also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
		shows it is required				
	Equipment					
2	Entry via a separate room with two interlocking doors	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required (via airlock key procedure)	Additional
3	Control of contaminated run-off water	required where and to extent the risk assessment shows it is required	required so as to prevent run-off	required so as to prevent run-off	required so as to prevent run-off	Additional
	System of work					
4	Effective control of disease vectors such as insects, rodents and arthropods which could disseminate GMMs	required	required	required	required	Additional
5	Effective control of pollen, seeds and other plant material which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	Additional
6	Procedures for transfer of living material between the plant	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	required so as to prevent dissemination	Additional

NOTE
1. A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure shall also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	growth facilities, protective structure and laboratory shall control dissemination of GMMs					

NOTE
1. A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure shall also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

Table 1c:

Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Animal Units (to be read with Table 1a as indicated in paragraph 3)

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	Facilities					
1	Isolation of animal unit **(Note 1)**	required where and to extent the risk assessment shows it is required	required	required	required	Modification
2	Animal facilities **(Note 2)** separated by lockable doors	required where and to extent the risk assessment shows they are required	required	required	required	Additional
3	Animal facilities (cages, etc)	required where and to extent	required where and to extent	required	required	Additional

NOTES
1. In the Table above, “animal unit” means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.
2. In the Table above and in Note 1 above, “animal facility” means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.
3. In the Table above, “isolators” means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	designed to facilitate decontamination (waterproof and easily washable material)	the risk assessment shows they are required	the risk assesment shows they are required			
4	Floor, walls and ceiling easily washable	required where and to extent the risk assessment shows they are required	required for floor	required for floor and walls	required for floor, walls and ceiling	Modification
5	Appropriate filters on isolators or isolated rooms **(Note 3)**	not required	required where and to extent the risk assessment shows they are required	required	required	Additional
6	Incinerator for disposal of animal carcasses	required to be accessible	required to be accessible	required to be accessible	required to be on site	Additional
7	Appropriate barriers at the room exit, and at drains or ventilation duct work	required	required	required	required	Additional
8	Animals kept in appropriate containment facilities, such as cages, pens,	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	Additional

NOTES

1. In the Table above, “animal unit” means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.
2. In the Table above and in Note 1 above, “animal facility” means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.
3. In the Table above, “isolators” means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	tanks or isolators					

NOTES
1. In the Table above, "animal unit" means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.
2. In the Table above and in Note 1 above, "animal facility" means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.
3. In the Table above, "isolators" means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table 2:

Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Premises other than those referred to in Tables 1a, 1b and 1c

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	General				
1	Viable micro-organisms shall be contained in a system which separates the process from the workplace and wider environment (closed system)	required where and to extent the risk assessment shows it is required	required	required	required
2	Closed systems located within a controlled area	not required	required where and to extent the risk assessment shows they are required	required	required and required to be purpose built
3	Control of exhaust gases from the closed system	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
4	Control of aerosols during sample collection, addition of material to a	required where and to extent the risk assessment shows it is required	required so as to minimise release	required so as to prevent release	required so as to prevent release

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	closed system or transfer of material to another closed system				
5	Inactivation of bulk culture fluids before removal from the closed system	required where and to extent the risk assessment shows it is required	required by validated means	required by validated means	required by validated means
6	Seals shall be designed so as to minimise or prevent release	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
7	The controlled area designed to contain spillage of the entire contents of the closed system	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required	required
8	The controlled area sealable to permit fumigation	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
9	Biohazard signs posted	required where and to extent the risk assessment shows it is required	required	required	required
	Equipment				
10	Entry via airlock	not required	not required	required where and to extent the risk assessment shows it is required	required
11	Surfaces resistant to water, acids, alkalis, solvents,	required for any bench	required for any bench	required for floor and any bench	required for bench, floor, ceiling and walls

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	disinfectants and decontamination agents and easy to clean				
12	Specific measures to adequately ventilate the controlled areas in order to minimise air contamination	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required
13	The controlled area maintained at an air pressure negative to the immediate surroundings	not required	not required	required where and to extent the risk assessment shows it is required	required
14	Extract and input air from the controlled area shall be HEPA filtered	not required	not required	required for extract air, optional for input air	required for input and extract air
	System of work				
15	Access restricted to authorised personnel only	not required	required	required	required
16	Decontamination and washing facilities provided for personnel	required	required	required	required
17	Personnel shall shower before leaving the controlled area	not required	not required	required where and to extent the risk assessment shows it is required	required
18	Personnel shall wear protective clothing	work clothing required	work clothing required	required	complete change required

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
					before exit and entry
19	Written procedures and records of staff training	not required	not required	required	required
	Waste				
20	Inactivation of GMMs in effluent from handwashing sinks and showers or similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
21	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	required by validated means	required by validated means	required by validated means	required by validated means

SCHEDULE 9

Regulation 27(1)

FEES FOR NOTIFICATIONS AND APPLICATIONS

Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1).	£200
Notification of an activity involving genetic modification in class 2 under regulation 10(1), except a notification to which paragraph 4(1) or paragraph 5(1) of Schedule 10 applies.	£400
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 2 under regulation 10(1).	£400

Notification of an activity involving genetic modification in class 3 under regulation 11(1), except a notification to which paragraph 4(2) or paragraph 5(2) of Schedule 10 applies.	£430
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 3 under regulation 11(1).	£430
Notification of an activity involving genetic modification in class 4 under regulation 11(1), except a notification to which paragraph 4(2) or paragraph 5(2) of Schedule 10 applies.	£500
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 4 under regulation 11(1).	£500
Notification of an activity involving genetic modification of organisms other than micro-organisms under regulation 12(1).	£400
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification of organisms other than micro-organisms under regulation 12(1).	£400
Notification of additional information under regulation 15(3).	£300
Application for the written agreement of the competent authority under regulation 18(2) where the application is made after a notification has been submitted pursuant to regulation 9(1), 10(1), 11(1) or 12(1).	£300

SCHEDULE 10

Regulation 28

TRANSITIONAL PROVISIONS

Interpretation

1. In this Schedule—

(a) "the 1992 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations 1992(**2**);

(b) "the relevant date" means the date on which these Regulations come into force; and

(c) a reference to a numbered sub-paragraph is a reference to the sub-paragraph so numbered in the paragraph in which that reference occurs.

Risk assessment

2.—(1) Where a person undertakes an activity involving genetic modification of micro-organisms which he commenced before the relevant date, he shall ensure that an assessment is carried out in accordance with regulation 6 as if the date of the commencement of that activity were 15th December 2000.

(2) Where a person undertakes an activity involving genetic modification of organisms other than micro-organisms which he commenced before the relevant date, he shall ensure that an assessment is carried out in accordance with regulation 7 as if the date of the commencement of that activity were 15th December 2000.

Notification of premises

3. Where before the relevant date a person had notified the Executive in accordance with regulation 8(1) of the 1992 Regulations of his intention to undertake an activity involving genetic modification at premises for the first time, the requirements of regulation 9 shall be deemed to be satisfied, provided that, before 15th February 2001, that person submits to the competent authority a notification containing—

(a) the information specified in paragraph (g) of Schedule 5; and

(b) the information specified in paragraph (h)(iii) and (iv) of Schedule 5 where the activity involving genetic modification is a class 1 activity to be undertaken on or after 15th February 2001 at the premises referred to in the notification submitted pursuant to regulation 8(1) of the 1992 Regulations.

Notification of activities involving genetic modification

4.—(1) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations and immediately before the relevant date that person was entitled under the 1992 Regulations to undertake that activity, and where that activity involving genetic modification of micro-organisms is in class 2, the requirements of regulation 10 shall be deemed to be satisfied in relation to that activity, provided that before 15th February 2001 that person submits to the competent authority a notification containing—

(a) in the case of an activity referred to in regulation 9(2)(a) of the 1992 Regulations, the information specified in Part I of Schedule 6;

(b) in the case of an activity referred to in regulation 9(3) or regulation 9(4)(a) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l), (m), (o) and (p) of Part I of Schedule 6; and

(c) in the case of an activity referred to in regulation 9(5) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l)(ii) and (p) of Part I of Schedule 6.

(2) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations

(**2**) S.I.1992/3217, as amended by S.I. 1996/967, 1998/1548.

and immediately before the relevant date that person was entitled under the 1992 Regulations to undertake that activity, and where that activity involving genetic modification of micro-organisms is in class 3 or class 4, the requirements of regulation 11 shall be deemed to be satisfied in relation to that activity, provided that—

(a) before 15th January 2001, that person submits to the competent authority a notification containing the information specified in Part II of Schedule 6; and

(b) before 15th February 2001, the competent authority gives its consent in writing to continue to undertake the activity involving genetic modification of micro-organisms in question.

(3) Where a person had notified the Executive of his intention to undertake an activity involving the genetic modification of organisms other than micro-organisms in accordance with regulation 9(1) of the 1992 Regulations and immediately before the relevant date that person was entitled under the 1992 Regulations to undertake that activity, the requirements of regulation 12 shall be deemed to be satisfied.

(4) Where a person submits a notification in accordance with this paragraph, he shall at the same time provide the competent authority with a short description of the activity involving genetic modification to which the notification relates.

Notification of proposed activities involving genetic modification

5.—(1) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations but immediately before the relevant date that person was not entitled under the 1992 Regulations to undertake that activity for any reason other than the reason mentioned in sub-paragraph (4), and where that activity involving genetic modification of micro-organisms is in class 2, that person may submit to the competent authority a notification containing—

(a) in the case of an activity referred to in regulation 9(2)(a) of the 1992 Regulations, the information specified in Part I of Schedule 6;

(b) in the case of an activity referred to in regulation 9(3) or regulation 9(4)(a) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l), (m), (o) and (p) of Part I of Schedule 6; and

(c) in the case of an activity referred to in regulation 9(5) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l)(ii) and (p) of Part I of Schedule 6,

in which case the provisions of these Regulations shall apply as if that person had submitted a notification pursuant to regulation 10(1) on the date he submitted the notification pursuant to this sub-paragraph, save that regulation 24 shall apply as modified in accordance with paragraph 10.

(2) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations but immediately before the relevant date that person was not entitled under the 1992 Regulations to undertake that activity for any reason other than the reason mentioned in sub-paragraph (4), and where that activity involving genetic modification of micro-organisms is in class 3 or class 4, that person may submit a notification containing the information specified in Part II of Schedule 6, in which case the provisions of these Regulations shall apply as if that person had submitted a notification pursuant to regulation 11(1) on the date he submitted the notification pursuant to this sub-paragraph, save that regulation 24 shall apply as modified in accordance with paragraph 10.

(3) Where a person had notified the Executive of his intention to undertake an activity involving the genetic modification of organisms other than micro-organisms in accordance with regulation 9(1) of the 1992 Regulations but immediately before the relevant date that person was not entitled under the 1992 Regulations to undertake that activity for any reason other than the reason referred to in sub-paragraph (4), the provisions of these Regulations shall apply as if that person had submitted a

notification in accordance with regulation 12 on the relevant date, save that regulation 24 shall apply as modified in accordance with paragraph 10.

(4) The reason referred to in sub-paragraphs (1), (2) and (3) is that the Executive has informed the person who submitted the notification in question that he may not commence the activity involving genetic modification to which the notification relates.

(5) Where a person submits a notification in accordance with this paragraph, he shall at the same time provide the competent authority with a short description of the activity involving genetic modification to which the notification relates.

Duties on receiving notifications and additional information

6. Regulation 14(1) to (5) shall apply to a notification submitted pursuant to the 1992 Regulations which, by virtue of paragraph 4 of this Schedule, is treated as satisfying the requirements of these Regulations as it applies to a notification submitted pursuant to these Regulations.

Additional provisions relating to notification

7. Regulation 15 shall apply in cases where a notification has been submitted pursuant to regulation 8 or 9 of the 1992 Regulations as it applies where a notification has been submitted pursuant to these Regulations.

Emergency Plans

8. Where before the relevant date a person had ensured that a plan had been prepared in accordance with regulation 13 of the 1992 Regulations, that plan shall be treated as satisfying the requirements of regulation 20, provided that, immediately following the assessment to be carried out in accordance with paragraph 2, the plan is reviewed and, where necessary, revised pursuant to regulation 20(3).

Disclosure of information

9. Regulations 22 and 23 shall apply to information notified or provided under the 1992 Regulations as they apply to information provided under these Regulations.

Register of notifications

10.—(1) Subject to sub-paragraph (2), regulation 24 shall apply to a notification submitted in accordance with paragraphs 3, 4 and 5 as it applies to a notification submitted in accordance with regulations 9(1), 10(1), 11(1) and 12(1).

(2) Paragraphs (2), (3) and (4) of regulation 24 shall not apply to a notification submitted in accordance with paragraphs 3, 4 and 5 and shall be replaced by the following provisions, namely—

(a) in relation to a notification submitted in accordance with paragraph 3, the register shall contain the name and address of the person who submitted that notification, and the reference number given by the Executive to the notification under the 1992 Regulations of the premises in question;

(b) in relation to a notification submitted in accordance with paragraph 4, the register shall contain—

(i) the name and address of the person who submitted that notification,

(ii) a short description of the activity involving genetic modification to which the notification relates, and any reference number given by the Executive to the notification of that activity under the 1992 Regulations,

(iii) the date on which any information had been notified under regulation 10(4) of the 1992 Regulations, and

(iv) where appropriate, confirmation that a consent has been granted under paragraph 4(2)(b); and

(c) in relation to a notification submitted in accordance with paragraph 5, the register shall contain—

(i) the name and address of the person who submitted that notification,

(ii) a short description of the activity involving genetic modification to which the notification relates, and any reference number given by the Executive to the notification of that activity under the 1992 Regulations,

(iii) the date on which any information had been notified under regulation 10(4) of the 1992 Regulations, and

(iv) where appropriate, confirmation that a consent has been granted under regulation 11(3) or 11(4).

(3) The competent authority shall include in the register—

(a) by 15th March 2001, the information referred to in sub-paragraph (2)(a);

(b) by 15th April 2001, the information referred to in sub-paragraph (2)(b); and

(c) within fourteen days of the receipt of a notification submitted under paragraph 5, the information referred to in sub-paragraph 2(c).

Reference to previous notification

11. Where a person submits a notification in accordance with paragraph 3, 4 or 5, he shall at the same time provide the competent authority with the following information—

(a) his name, address and telephone number and any fax number and any e-mail address; and either

(b) in the case of a notification submitted in accordance with paragraph 3—

(i) the date of,

(ii) any reference number given by the Executive to, and

(iii) the date of any information notified to the Executive under regulation 10 of the 1992 Regulations relating to,

the notification in question submitted under regulation 8(1) of the 1992 Regulations; or

(c) in the case of a notification submitted in accordance with paragraph 4 or 5—

(i) the date of,

(ii) any reference number given by the Executive to, and

(iii) the date of any information notified to the Executive under regulation 10 of the 1992 Regulations relating to,

the notification in question submitted under regulation 9(1) of the 1992 Regulations.

SCHEDULE 11 Regulation 29

APPEALS

PART I

1. In this Schedule—

(a) "appeal" means an appeal under regulation 29;

"appellant" means a person who has brought an appeal;

"appointed person" means a person appointed in accordance with paragraph 2;

"appropriate person" has the same meaning as in regulation 29;

"authority" means the competent authority in the case of an appeal under regulation 29(1), (2)(c) or (3) and the Executive in the case of an appeal under regulation 29(2)(a) or (b);

"hearing" means a hearing to which Part II of this Schedule applies;

"the parties" means the appellant and the authority;

"site" means premises at which the activity involving genetic modification to which the appeal relates is, or is proposed to be, undertaken; and

(b) a reference to a numbered sub-paragraph is a reference to the sub-paragraph so numbered in the paragraph in which that reference occurs.

2. The appropriate person shall direct that an appeal shall be determined by a person appointed by him for the purpose and the appropriate person shall notify the parties in writing of the name of the appointed person.

3. Before the determination of an appeal, the appointed person shall ask the parties whether they wish to appear and be heard on the appeal and—

(a) the appeal may be determined without a hearing of the parties if both of them express a wish not to be heard as aforesaid;

(b) the appointed person shall, if either of the parties expresses a wish to appear and be heard, afford both of them an opportunity of so doing, in which case the provisions of Part II of this Schedule shall apply.

4. An appointed person may give such directions as he thinks appropriate to give effect to his determination.

5. The appropriate person may pay to an appointed person such remuneration and allowances as the appropriate person may, with the approval of the Minister for the Civil Service, determine.

PART II

6. An appeal brought pursuant to regulation 29(3) shall be heard in private.

7.—(1) Subject to the following sub-paragraphs of this paragraph, a date, time and place for the holding of the hearing shall be fixed, and may be varied, by the appointed person, who shall give not less than 42 days' notice in writing of such date, time and place to the parties.

(2) With the consent of the parties, the appointed person may give such lesser period of notice as shall be agreed with the parties and in that event he may specify a date for service of the statement referred to in paragraph 8(1) later than the date determined in accordance with that paragraph.

(3) Where it becomes necessary or advisable to vary the time or place fixed for the hearing, the appointed person shall give such notice of the variation as may appear to him to be reasonable in the circumstances.

(4) Without prejudice to the foregoing provisions of this paragraph, the appointed person may require the authority to take one or more of the following steps, namely:—

(a) to publish in one or more newspapers circulating in the locality in which the site is situated such notice of the hearing and in such form as he may direct;

(b) to serve such notice of the hearing, in such form and on such persons or classes of persons as he may direct;

(c) to give such other notice of the hearing and in such form as he may direct,

and the requirements as to the period of notice contained in sub-paragraph (1) shall not apply to any such notices.

8.—(1) Not later than 28 days before the date of the hearing, or such later date as the appointed person may specify in accordance with paragraph 7(2), the authority shall serve on the appellant a written statement of any submission which the authority proposes to put forward at the hearing and shall supply a copy of the statement to the appointed person.

(2) Where a government department has expressed in writing to the authority a view in support of the decision of the authority and the authority proposes to rely on such expression of view in its submission at the hearing, the authority shall include the expression of view in its statement and shall supply a copy of the statement to the government department concerned.

(3) Where the authority intends to refer to or put in evidence at the hearing, documents (including photographs, maps and plans), the statement of the authority shall be accompanied by a list of such documents, together with a written notice stating the times and place at which the documents may be inspected by the appellant; and the authority shall afford the appellant a reasonable opportunity to inspect and, where practicable, to take copies of the documents.

(4) If so required by the appointed person, the appellant shall—

(a) serve on the authority and on the appointed person, within such time before the hearing as the appointed person may specify, a written statement of the submissions which he proposes to put forward at the hearing; and such statement shall be accompanied by a list of any documents (including photographs, maps and plans) which the appellant intends to refer to or put in evidence at the hearing; and

(b) afford the authority a reasonable opportunity to inspect and, where practicable, to take copies of such documents as are referred to in the foregoing provision.

9.—(1) The parties shall be entitled to appear at the hearing.

(2) Any other person may appear at the discretion of the appointed person provided that he has, not later than 7 days before the date of the hearing, served on the authority a statement of his proposed submissions.

(3) The authority shall send a copy of every statement served on it in accordance with sub-paragraph (2) to the appointed person and to the appellant.

(4) A body corporate may appear by its clerk or secretary or by any other officer appointed for the purpose by that body, or by counsel or a solicitor.

(5) A person may appear on his own behalf or be represented by counsel, a solicitor or any other person.

(6) Where there are two or more persons having a similar interest in the subject matter of the hearing, the appointed person may allow one or more persons to appear for the benefit of some or all persons so interested.

10.—(1) Where a government department has expressed in writing to the authority a view in support of the decision of the authority and the authority has included this view in the statement referred to in paragraph 8(1), the appellant may apply in writing to the appointed person, not later than 14 days before the date of the hearing, for a representative of the government department concerned to be made available at the hearing.

(2) The appointed person shall send any application made to him under sub-paragraph (1) to the government department concerned who shall make a representative of the department available to attend the hearing.

(3) A representative of a government department who, in pursuance of this paragraph, attends a hearing shall be called as a witness by the authority and shall state the reasons for the view expressed by his department and included in the statement of the authority under paragraph 8(1) and shall give evidence and be subject to cross-examination to the same extent as any other witness.

(4) Nothing in the last foregoing paragraph shall require a representative of a government department to answer any question which in the opinion of the appointed person is directed to the merits of government policy or to matters which affect the safety of the State and the appointed person shall disallow any such question.

11.—(1) Except as otherwise provided in this Part of this Schedule, the procedure at the hearing shall be such as the appointed person shall in his discretion determine and the appointed person shall—

(a) state at the commencement of the hearing the procedure which, subject to consideration of any submission by the parties, he proposes to adopt; and

(b) shall inform the parties what he proposes as regards any site inspection arising out of the hearing.

(2) Unless in any particular case the appointed person with the consent of the appellant otherwise determines—

(a) in the case of an appeal to the Secretary of State, the appellant shall be heard first and shall have the right of final reply; and

(b) in the case of an appeal to the Secretary of State and the Scottish Ministers acting jointly—

(i) the appellant shall be heard first,

(ii) the other persons entitled or permitted to appear shall be heard in such order as the appointed person may determine, and

(iii) any closing statements shall be made in the same order, unless the appointed person otherwise determines.

(3) The parties shall be entitled to make an opening statement, to call evidence and to cross-examine persons giving evidence, but any other person appearing at the hearing may do so only to the extent permitted by the appointed person.

(4) Subject to sub-paragraph (5), any evidence may be admitted at the discretion of the appointed person, who may direct that documents tendered in evidence may be inspected by any person entitled or permitted to appear at the hearing and that facilities be afforded him to take or obtain copies thereof.

(5) The appointed person shall not require or permit the giving or production of any evidence, whether written or oral, which would be contrary to the public interest.

(6) The appointed person may allow the authority or the appellant, or both of them, to alter or add to the submissions contained in any statement served under paragraph 8(1) or (4), or to any list of documents which accompanied such statement, so far as may be necessary for the purpose of determining the questions in controversy between the parties, but shall (if necessary by adjourning

the hearing) give the appellant or the authority, as the case may be, an adequate opportunity of considering any such fresh submission or document.

(7) If any person entitled to appear at the hearing fails to appear, the appointed person may proceed with the hearing at his discretion.

(8) The appointed person shall be entitled (subject to disclosure thereof at the hearing) to take into account any written representations or statements received by him before the hearing from any person.

(9) The appointed person may from time to time adjourn the hearing, and where he does so, shall give reasonable notice to every person entitled or permitted to appear at the hearing of the date, time and place of the adjourned hearing.

12.—(1) The appointed person may make an inspection of the site before or during the hearing after having given notice to the parties of the date and time at which he proposes to do so.

(2) The appointed person may, and shall if so requested by either party before or during the hearing, inspect the site after the close of the hearing and, in all cases where he intends to make such an inspection, shall announce during the hearing the date and time at which he proposes to do so.

(3) The parties shall be entitled to accompany the appointed person on any inspection under this paragraph, but the appointed person shall not be bound to defer his inspection if any person entitled to accompany him is not present at the time appointed.

13.—(1) Where, after the close of the hearing, the appointed person proposes to take into consideration—

(a) any new evidence, including expert opinion on a matter of fact; or

(b) any new issue of fact, not being a matter of government policy or a matter affecting the safety of the State,

which was not raised at the hearing and which he considers to be material to his decision, he shall not come to a decision without first notifying the parties of the substance of the new evidence or of the new issue of fact and affording them an opportunity of making representations thereon in writing within 21 days or of asking within that time for the re-opening of the hearing.

(2) If he thinks fit, the appointed person may cause the hearing to be re-opened and shall cause it to be re-opened if asked to do so in accordance with sub-paragraph (1).

(3) Where the hearing is re-opened, paragraphs 7(1) and 7(4) shall apply as they applied to the original hearing with the substitution in paragraph 7(1) of "28" for "42".

14. The appointed person shall notify the decision on the appeal, and the reasons therefor, in writing to the parties and to any person who, having appeared at the hearing, has asked to be notified of the decision.