ANNEX I U.K.

PART A U.K.

Techniques of genetic modification referred to in point (b)(i) of Article 2 are, inter alia:

1. 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.

2. Techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism, including micro-injection, macro-injection and micro-encapsulation.

3. Cell fusion or hybridisation 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 B U.K.

Techniques referred to in point (b)(ii) of Article 2 which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs made by techniques/methods other than the techniques/methods excluded by Part A of Annex II:

1. *in vitro* fertilisation;

2. natural processes such as: conjugation, transduction, transformation;

3. polyploidy induction.

ANNEX II U.K.

PART A U.K.

Techniques or methods of genetic modification yielding micro-organisms to be excluded from this Directive on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs other than those produced by one or more of the techniques/methods listed below:

1. Mutagenesis.

2. Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes.

3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.

4. Self-cloning consisting in 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), with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.

Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.

PART B U.K.

Criteria establishing the safety of GMMs for human health and the environment

This Annex describes in general terms the criteria to be met when establishing the safety of types of GMMs for human health and the environment and their suitability for inclusion in Part C. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 20(3) in order to facilitate the implementation and explanation of this Annex.

1. **Introduction** U.K.

Types of GMMs listed in Part C in accordance with the regulatory procedure with scrutiny referred to in Article 20(2) are excluded from the scope of this Directive. GMMs will be added to the list on a case-by-case basis and exclusion will relate only to each clearly identified GMM. This exclusion applies only when the GMM is used under conditions of contained use as defined in point (c) of Article 2. It does not apply to the deliberate release of GMMs. For a GMM to be listed in Part C, it must be proved that it meets the criteria given below.

2. **General criteria** U.K.

2.1. Strain verification/authentication U.K.

Identity of the strain must be precisely established. Modification must be known and verified.

2.2. Documented and established evidence of safety U.K.

Documented evidence of the safety of the organism must be provided.

2.3. Genetic stability U.K.

Where any instability could adversely affect safety, evidence of stability is required.

3. **Specific criteria** U.K.

3.1. Non-pathogenic U.K.

The GMM should not be capable of causing disease or harm to a healthy human, plant or animal. Since pathogenicity includes both toxigenicity and allergenicity, the GMM should therefore be:

3.1.1. Non-toxigenic U.K.

The GMM should not produce increased toxigenicity as a result of the genetic modification nor be noted for its toxigenic properties.

3.1.2. Non-allergenic U.K.

The GMM should not produce increased allergenicity as a result of the genetic modification nor be a noted allergen, having, for example, allergenicity comparable in particular with that of the micro-organisms identified in Directive 2000/54/EC.

3.2. No harmful adventitious agents U.K.

The GMM should not harbour known harmful adventitious agents such as other micro-organisms, active or latent, existing alongside or inside the GMM, that could cause harm to human health and the environment.

3.3. Transfer of genetic material U.K.

The modified genetic material must not give rise to harm if transferred; nor should it be self-transmissible or transferable at a frequency greater than other genes of the recipient or parental micro-organism.

3.4. Safety for the environment in the event of a significant and unintended release U.K.

GMMs must not produce adverse effects on the environment, immediate or delayed, should any incident involving a significant and unintended release occur.

GMMs that do not meet the above criteria may not be included in Part C.

PART C U.K.

Types of GMMs which meet the criteria listed in Part B:

… (to be completed in accordance with the regulatory procedure with scrutiny referred to in Article 20(2))

ANNEX III U.K.

Principles to be followed for the assessment referred to in Article 4(2)

This Annex describes in general terms the elements to be considered and the procedure to be followed to perform the assessment referred to in Article 4(2). Technical guidance notes[(1)] may be developed in accordance with the regulatory procedure referred to in Article 20(3) in order to facilitate the implementation and explanation of this Annex, in particular as regards Section B.

A. **Elements of assessment** U.K.

1. The following should be considered as potentially harmful effects: U.K.

— disease to humans, including allergenic or toxic effects,
— disease to animals or plants,
— deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis,
— deleterious effects due to establishment or dissemination in the environment,
— deleterious effects due to the natural transfer of inserted genetic material to other organisms.

2. The assessment referred to in Article 4(2) should be based on the following: U.K.

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

(i) the recipient micro-organism;

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

(iii) the vector;

(iv) the donor micro-organism (as long as the donor micro-organism is used during the operation);

(v) the resulting GMM;

(b) the characteristics of the activity;

(c) the severity of the potentially harmful effects;

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

B. **Procedure** U.K.

3. The first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, and any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties.

4. In general, only GMMs which show the following characteristics would be considered appropriate for inclusion in class 1 as defined in Article 4(3): U.K.

(i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants[(2)];

(ii) the nature of the vector and the insert is such that they do not endow the GMM with a phenotype likely to cause disease to humans, animals or plants[(2)], or likely to have deleterious effects on the environment;

(iii) the GMM is unlikely to cause disease to humans, animals or plants[(2)] and is unlikely to have deleterious effects on the environment.

5. In order to obtain the necessary information to implement this process the user may firstly take into account relevant Community legislation (in particular Directive 2000/54/EC). International or national classification schemes (e.g. World Health Organisation, National Institutes of Health) and their revisions due to new scientific knowledge and technical progress may also be considered. U.K.

These schemes concern natural micro-organisms and as such are usually based on the ability of micro-organisms to cause disease to humans, animals or plants and on the severity and transmissibility of the disease likely to be caused. Directive 2000/54/EC classifies micro-organisms, as biological agents, into four classes of risk on the basis of potential effects on a healthy human adult. These classes of risk can be used as guidance for the purposes of categorisation of the contained use activities in the four classes of risk referred to in Article 4(3). The user may also take into consideration classification schemes referring to plant and animal pathogens (which are usually established on a national basis). The abovementioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures.

6. The hazard identification process carried out in accordance with points 3 to 5 should lead to the identification of the level of risk associated with the GMM.

7. Selection of the containment and other protective measures should then be made on the basis of the level of risk associated with the GMMs together with consideration of: U.K.

(i) the characteristics of the environment likely to be exposed (e.g. whether in the environment likely to be exposed to the GMMs there are known biota which can be adversely affected by the micro-organisms used in the contained use activity);

(ii) the characteristics of the activity (e.g. its scale and/or nature);

(iii) any non-standard operations (e.g. the inoculation of animals with GMMs; use of equipment likely to generate aerosols).

Consideration of items (i) to (iii) for the particular activity may increase, reduce or leave unaltered the level of risk associated with the GMM as identified under point 6.

8. The analysis carried out as described above will finally lead to the assignment of the activity to one of the classes described in Article 4(3).

9. The final classification of the contained use should be confirmed by reviewing the completed assessment referred to in Article 4(2).

ANNEX IV U.K.

CONTAINMENT AND OTHER PROTECTIVE MEASURESGeneral principles

1. These tables present the normal minimum requirements and measures necessary for each level of containment. U.K.

Containment is also achieved through the use of good work practices, training, containment equipment and special installation design. For all activities involving GMMs the principles of good microbiological practice and the following principles of good occupational safety and hygiene shall apply:

(i) to keep workplace and environmental exposure to any GMM to the lowest practicable level;

(ii) to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary;

(iii) to test adequately and maintain control measures and equipment;

(iv) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;

(v) to provide appropriate training of personnel;

(vi) to establish biological safety committees or subcommittees, if required;

(vii) to formulate and implement local codes of practice for the safety of personnel, as required;

(viii) where appropriate, to display biohazard signs;

(ix) to provide washing and decontamination facilities for personnel;

(x) to keep adequate records;

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

(xii) to prohibit mouth pipetting;

(xiii) to provide written standard operating procedures where appropriate to ensure safety;

(xiv) to have effective disinfectants and specified disinfection procedures available in case of spillage of GMMs;

(xv) to provide safe storage for contaminated laboratory equipment and materials, when appropriate.

2. The titles of the tables are indicative: U.K.

Table I A presents minimum requirements for laboratory activities.

Table I B presents additions to and modifications of Table I A for glasshouse/growth-room activities involving GMMs.

Table I C presents additions to and modifications of Table I A for activities with animals involving GMMs.

Table II presents minimum requirements for activities other than laboratory activities.

In some particular cases, it might be necessary to apply a combination of measures, from Table I A and Table II, of the same level.

In some cases users may, with the agreement of the competent authority, not apply a specification under a particular containment level or combine specifications from two different levels.

In these tables 'optional' means that the user may apply these measures on a case-by-case basis, subject to the assessment referred to in Article 4(2).

3. In implementing this Annex, Member States may in addition incorporate in the following tables the general principles set out in points 1 and 2, with a view to clarifying the requirements.

TABLE I A

Containment and other protective measures for laboratory activities

Specifications		**Containment levels**			
		1	**2**	**3**	**4**
1	Laboratory suite: isolation[a]	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required

a	Isolation	=	the laboratory is separated from other areas in the same building or is in a separate building.
b	Airlock	=	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.
c	Activities where transmission does not occur via airborne route.		
d	HEPA	=	High efficiency particulate air.
e	Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.		
f	With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.		

Equipment					
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents, and easy to clean	Required (bench)	Required (bench)	Required (bench, floor)	Required (bench, floor, ceiling, walls)
4	Entry to lab via airlock[b]	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required except for[c]	Required
6	Extract and input air from the laboratory should be HEPA[d]-filtered	Not required	Not required	Required (HEPA — extract air except for[c])	Required (HEPA— input and extract air[e])
7	Microbiological safety post	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite[f]	In lab = double-ended
System of work					
9	Restricted access	Not required	Required	Required	Required
10	Biohazard sign on the door	Not required	Required	Required	Required

a Isolation = the laboratory is separated from other areas in the same building or is in a separate building.

b Airlock = 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.

c Activities where transmission does not occur via airborne route.

d HEPA = High efficiency particulate air.

e Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.

f With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.

11	Specific measures to control aerosol dissemination	Not required	Required minimise	Required prevent	Required prevent
13	Shower	Not required	Not required	Optional	Required
14	Protective clothing	Suitable protective clothing	Suitable protective clothing	Suitable protective clothing and (optional) footwear	Complete change of clothing and footwear before entry and exit
15	Gloves	Not required	Optional	Required	Required
18	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required
Waste					
19	Inactivation of GMMs in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	Optional	Required
20	Inactivation of GMMs in contaminated material and waste	Optional	Required	Required	Required
Other measures					
21	Laboratory to contain	Not required	Not required	Optional	Required

a Isolation = the laboratory is separated from other areas in the same building or is in a separate building.

b Airlock = 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.

c Activities where transmission does not occur via airborne route.

d HEPA = High efficiency particulate air.

e Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.

f With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.

	its own equipment				
23	An observation window or alternative is to be present so that occupants can be seen	Optional	Optional	Optional	Required

a	Isolation	=	the laboratory is separated from other areas in the same building or is in a separate building.
b	Airlock	=	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.
c	Activities where transmission does not occur via airborne route.		
d	HEPA	=	High efficiency particulate air.
e	Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.		
f	With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.		

TABLE I B

Containment and other protective measures for glasshouses and growth-rooms

The terms ‘glasshouse’ and ‘growth-room’ refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment. All provisions of Table I A shall apply with the following additions/modifications:

Specifications		**Containment levels**			
		1	**2**	**3**	**4**
Building					
1	Glasshouse: permanent structure[a]	Not required	Required	Required	Required
Equipment					
3	Entry via a separate room with two interlocking doors	Not required	Optional	Optional	Required
4	Control of contaminated run-off water	Optional	Minimise[b] run-off	Prevent run-off	Prevent run-off
System of work					

a	The glasshouse shall consist of a permanent structure with a continuous waterproof covering, located on a site graded to prevent entry of surface-water run-off, and with self-closing lockable doors.
b	Where transmission can occur through the ground.

The terms ‘glasshouse’ and ‘growth-room’ refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment. All provisions of Table I A shall apply with the following additions/modifications:

6	Measures to control undesired species such as insects, rodents, arthropods	Required	Required	Required	Required
7	Procedures for transfer of living material between the glasshouse/ growth-room, protective structure and laboratory shall control dissemination of GMMs	Minimise dissemination	Minimise dissemination	Prevent dissemination	Prevent dissemination

a The glasshouse shall consist of a permanent structure with a continuous waterproof covering, located on a site graded to prevent entry of surface-water run-off, and with self-closing lockable doors.

b Where transmission can occur through the ground.

TABLE I C

Containment and other protective measures for activities in animal units

All provisions of Table I A shall apply with the following additions/modifications:

Specifications		**Containment levels**			
		1	**2**	**3**	**4**
Facilities					
1	Isolation of animal unit[a]	Optional	Required	Required	Required
2	Animal facilities[b] separated	Optional	Required	Required	Required

a Animal unit : a building or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves, food storage areas, etc.

b Animal facility : a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures.

c Isolators : transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

All provisions of Table I A shall apply with the following additions/modifications:					
	by lockable doors				
3	Animal facilities designed to facilitate decontamination (waterproof and easily washable material (cages, etc.))	Optional	Optional	Required	Required
4	Floor and/or walls easily washable	Optional	Required (floor)	Required (floor and walls)	Required (floor and walls)
5	Animals kept in appropriate containment facilities such as cages, pens or tanks	Optional	Optional	Optional	Optional
6	Filters on isolators or isolated room[c]	Not required	Optional	Required	Required

a	Animal unit	:	a building or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves, food storage areas, etc.
b	Animal facility	:	a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures.
c	Isolators	:	transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

TABLE II

Containment and other protective measures for other activities

Specifications		**Containment levels**			
		1	**2**	**3**	**4**
General					
1	Viable micro-organisms should be contained in a system which separates the process from the	Optional	Required	Required	Required

	environment (closed system)				
2	Control of exhaust gases from the closed system	Not required	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
4	Inactivation of bulk culture fluids before removal from the closed system	Optional	Required, by validated means	Required, by validated means	Required, by validated means
5	Seals should be designed so as to minimise or prevent release	No specific requirement	Minimise dissemination	Prevent dissemination	Prevent dissemination
6	The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Optional	Required	Required
7	The controlled area should be sealable to permit fumigation	Not required	Optional	Optional	Required
Equipment					

8	Entry via airlock	Not required	Not required	Optional	Required
9	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents, and easy to clean	Required (bench if any)	Required (bench if any)	Required (bench if any, floor)	Required (bench, floor, ceiling, walls)
10	Specific measures to adequately ventilate the controlled area in order to minimise air contamination	Optional	Optional	Optional	Required
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Optional	Required
12	Extract and input air from the controlled area should be HEPA filtered	Not required	Not required	Required (extract air, optional for input air)	Required (input and extract air)
System of work					
13	Closed systems should be located within a controlled area	Not required	Optional	Required	Required
14	Access should be restricted to nominated personnel only	Not required	Required	Required	Required

15	Biohazard signs should be posted	Not required	Required	Required	Required
17	Personnel should shower before leaving the controlled area	Not required	Not required	Optional	Required
18	Personnel should wear protective clothing	Required (work clothing)	Required (work clothing)	Required	Complete change before exit and entry
Waste					
22	Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents	Not required	Not required	Optional	Required
23	Inactivation of GMMs in contaminated material and waste, including those in process effluent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means

ANNEX V U.K.

Information required for the notification referred to in Articles 6, 8 and 9

PART A U.K.

Information required for the notification referred to in Article 6:

— name of user(s), including those responsible for supervision and safety,

— information on the training and qualifications of the persons responsible for supervision and safety,

— details of any biological committees or subcommittees,

— address and general description of the premises,

— a description of the nature of the work which will be undertaken,
— the class of the contained uses,
— only for class 1 contained uses, a summary of the assessment referred to in Article 4(2) and information on waste management.

PART B U.K.

Information required for the notification referred to in Article 8:

— the date of submission of the notification referred to in Article 6,
— the names of the persons responsible for supervision and safety and information on their training and qualification,
— the recipient, donor and/or parental micro-organism(s) used and, where applicable, the host-vector system(s) used,
— the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s),
— the identity and characteristics of the GMM,
— the purpose of the contained use, including the expected results,
— the approximate culture volumes to be used,
— a description of the containment and other protective measures to be applied, including information about waste management, including the wastes to be generated, their treatment, final form and destination,
— a summary of the assessment referred to in Article 4(2),
— the information necessary for the competent authority to evaluate any emergency response plans, if required under Article 13(1).

PART C U.K.

Information required for the notification referred to in Article 9:

(a)
— the date of submission of the notification referred to in Article 6,
— the names of the persons responsible for supervision and safety and information on their training and qualification;

(b)
— the recipient or parental micro-organism(s) to be used,
— the host-vector system(s) to be used (where applicable),
— the source(s) and intended function(s) of the genetic material(s) involved in the modification(s),
— the identity and characteristics of the GMM,
— the culture volumes to be used;

(c)
— a description of the containment and other protective measures to be applied, including information about waste management, including the type and form of wastes to be generated, their treatment, final form and destination,
— the purpose of the contained use, including the expected results,
— a description of the parts of the installation;

(d) information about accident prevention and emergency response plans, if any:
— any specific hazards arising from the location of the installation,

— the preventive measures applied, such as safety equipment, alarm systems and containment methods,
— the procedures and plans for verifying the continuing effectiveness of the containment measures,
— a description of information provided to workers,
— the information necessary for the competent authority to evaluate any emergency response plans, if required under Article 13(1);

(e) a copy of the assessment referred to in Article 4(2).

ANNEX VI U.K.

PART A U.K.

Repealed Directive with list of its successive amendments

(referred to in Article 21)

Council Directive 90/219/EEC (OJ L 117, 8.5.1990, p. 1)	
Commission Directive 94/51/EC (OJ L 297, 18.11.1994, p. 29)	
Council Directive 98/81/EC (OJ L 330, 5.12.1998, p. 13)	
Council Decision 2001/204/EC (OJ L 73, 15.3.2001, p. 32)	
Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)	Annex III, point 19, only

PART B U.K.

Time limits for transposition into national law

(referred to in Article 21)

Directive	Time limit for transposition
90/219/EEC	23 October 1991
94/51/EC	30 April 1995
98/81/EC	5 June 2000

ANNEX VII U.K.

CORRELATION TABLE

Directive 90/219/EEC	**This Directive**
Article 1	Article 1
Article 2	Article 2
Article 3, introductory wording	Article 3(1), introductory wording
Article 3, first indent	Article 3(1), point (a)
Article 3, second indent	Article 3(1), point (b)
Article 4, first paragraph	Article 3(2)
Article 4, second paragraph	Article 3(3)
Article 5	Article 4
Article 6	Article 5
Article 7	Article 6
Article 8	Article 7
Article 9	Article 8
Article 10	Article 9
Article 11(1), (2) and (3)	Article 10(1), (2) and (3)
Article 11(4), introductory wording	Article 10(4), introductory wording
Article 11(4), first indent	Article 10(4), point (a)
Article 11(4), second indent	Article 10(4), point (b)
Article 12, first paragraph	Article 11(1)
Article 12, second paragraph	Article 11(2)
Article 13	Article 12
Article 14, first paragraph	Article 13(1)
Article 14, second paragraph	Article 13(2)
Article 15(1), introductory wording	Article 14(1), introductory wording
Article 15(1), first indent	Article 14(1), point (a)
Article 15(1), second indent	Article 14(1), point (b)
Article 15(1), third indent	Article 14(1), point (c)
Article 15(1), fourth indent	Article 14(1), point (d)
Article 15(2), introductory wording	Article 14(2), introductory wording
Article 15(2), first indent	Article 14(2), point (a)
Article 15(2), second indent	Article 14(2), point (b)
Article 16	Article 15

Article 17	Article 16
Article 18	Article 17
Article 19(1)	Article 18(1), first subparagraph
Article 19(2)	Article 18(1), second subparagraph
Article 19(3), introductory wording	Article 18(2), introductory wording
Article 19(3), first indent	Article 18(2), point (a)
Article 19(3), second indent	Article 18(2), point (b)
Article 19(3), third indent	Article 18(2), point (c)
Article 19(4)	Article 18(3)
Article 19(5)	Article 18(4)
Article 20	Article 19
Article 20a	—
Article 21(1)	Article 20(1)
Article 21(2), first subparagraph	Article 20(2) and (3), first subparagraph
Article 21(2), second subparagraph	Article 20(3), second subparagraph
Article 21(3)	—
Article 22	—
—	Article 21
—	Article 22
Article 23	Article 23
Annexes I-V	Annexes I-V
—	Annex VI
—	Annex VII

(**1**) See Commission Decision 2000/608/EC of 27 September 2000 concerning the guidance notes for risk assessment outlined in Annex III to Directive 90/219/EEC on the contained use of genetically modified micro-organisms (OJ L 258, 12.10.2000, p. 43).

(**2**) This would only apply to animals and plants in the environment likely to be exposed.