Checklists for Contained Use Inspections

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Checklist for Inspections
(contained use – laboratory activities)

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Overview:

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I. - GENERAL INFORMATION

1) address of the plant

2) location of the laboratory (e.g. is it one part of a larger building?)

3) location of social rooms

4) compliance with the blue print

5) characteristics of each room(s) and their relevant containment category

6) name of the notifier (institution, society, etc), of person(s) responsible for carrying out the contained use including those responsible for supervision, monitoring and safety;
   - name of project leader
   - name of biosafety officer

7) number of plant workers

8) education and experience of the staff

9) outside contractors (cleaning / security / maintenance personnel), visitors

10) description of the activity carried out (research, development, industrial production, etc.)

11) purpose of the activity

12) foreseen duration of contained use activity

II. - Good Microbiological Practice (GMP)

Containment is 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:

The laboratory should be easy to clean. Bench surfaces should be impervious to water and resistant to acids, alkalis, solvents and disinfectants
Benches should be clean and free from clutter
The laboratory door should be closed when work is in progress
To keep workplace and environmental exposure to any GMM to the lowest practicable level
All procedures must be performed so as to minimise the production of aerosols
To test, when necessary, for the presence of viable process organisms outside the primary physical containment
The identity of GMOs should be regularly checked to avoid the culturing of incorrect strains. The time between these checks should depend upon the potential hazard
To exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary
To test adequately and maintain control measures and equipment
To provide appropriate training of personnel
To establish biological safety committees or subcommittees, if required
To formulate and implement local codes of practice for the safety of personnel, as required
Where appropriate to display biohazard signs
To provide washing and decontamination facilities for personnel
Hands must be disinfected or washed immediately when contamination is suspected, after handling viable materials and also before leaving the laboratory
Effective disinfectants should be available for immediate use in the event of spillage
Bench tops should be cleaned after use
Used laboratory glassware and other materials awaiting disinfection must be stored in a safe manner. Pipettes, if placed in disinfectant, must be totally immersed
Use of sharps should be avoided
Contaminated syringes and sharps must be disposed of in a "sharps bin" and incinerated
Materials for disposal must be transported in robust and leakproof containers without spillage
Eating, chewing, drinking, taking medication, smoking, storing of food and applying cosmetics must not take place in the work area
Mouth pipetting must not take place
Laboratory coats or gowns should be worn in the laboratory and removed when leaving the laboratory suite
Personal protective equipment, including protective clothing, must be - stored in a well defined place - checked and cleaned at suitable intervals - when discovered to be defective, repaired or replaced before further use
Personal protective equipment which may be contaminated by biological agents must be - removed on leaving the working area - kept apart from uncontaminated clothing - decontaminated and cleaned, or if necessary, destroyed
To provide written standard operating procedures where appropriate to ensure safety
To keep adequate records
All accidents and incidents should be immediately reported to and recorded by the person responsible for the work or other delegated person

Animals must not be allowed to enter into the laboratory

III. - Physical Control Measures

a) Facility design

	Specification	Containment level			
		1	**2**	**3**	**4**
1	process with viable micro-organisms separated from the environment (closed system)	yes	yes	yes	yes
2	*laboratory suite isolation**	*no*	*no*	*yes*	*yes*
3	*restricted access to the facility (e.g. electronic cards, camera)**	*no*	*yes*	*yes*	*yes*
4	*laboratory sealable for fumigation**	*no*	*no*	*yes*	*yes*
5	acceptability of windows that open	yes	yes	no	no
6	biohazard sign on the door	no	yes	yes	yes
7	signs at laboratory entrance: - special hazard signs if an organism containing rec. DNA needs special provision for persons entering the laboratory - names of occupants who have access to the laboratory	no	yes	yes	yes
8	ventilation system	no	no	yes	yes
9	Outward opening of Laboratory doors	yes	yes	yes	yes
10	Observation window or alternative to enable occupants to be seen	optional	yes	yes	yes
11	Absence of floor drains within the work area	no	yes	yes	yes
12	Installation of safety lighting to facilitate exit from the facility in the case of power failure	no	no	yes	yes
13	*an observation window or alternative is to be present so that occupants can be seen**	*optional*	*optional*	*optional*	*yes*

* *from the annexes of Directive 98/81/EC*

b) Containment equipment

	Specification	Containment level			
		1	**2**	**3**	**4**
1	check the suitability of equipment used for safety purposes	no	yes	yes	yes
2	check the suitability of any chemical disinfectants in use	optional	yes	yes	yes
3	*check position of the autoclave with respect to the GMO installation*[*]	*on site*	*in the building*	*in suite*	*in lab, double closed*
4	check that the autoclave provides a print-out showing the temperature and time of sterilisation	no	no	yes	yes
5	wash hand basin or sink that can be used for hand washing with: - dispenser containing soap - dispenser containing hand disinfectant - paper towels	yes	yes	yes	yes
6	check position and design of biological safety hoods	optional	yes	yes	yes
7	check design of the equipment for the safe storage of GMOs. Storage is not allowed in floors as long it is not part of the facility.	yes	yes	yes	yes
8	check design of waste transport containers	optional	yes	yes	yes
9	check design of containers for the transport of GMOs inside the facility	optional	yes	yes	yes
10	check design of centrifuge buckets	yes	yes	yes	yes
11	*entry to lab via airlock**	*no*	*no*	*optional*	*yes*
12	air lock with two doors which are interlocked	no	no	yes	yes
13	air lock equipped with a hand washing basin (touch free) and hand disinfectant dispenser	no	no	yes	yes
14	*negative pressure relative to the pressure of the immediate surroundings**	*no*	*no*	*optional*	*yes*
15	ventilation system is alarmed to indicate a failure to generate a negative pressure	no	no	yes	yes
16	ventilation system connected to an emergency power supply	no	no	yes	yes
17	switch for ventilation system should be accessible from the outside of the laboratory in case of fumigation	no	no	yes	yes
18	*extract and input air from the laboratory should be HEPA filtered**	*no*	*no*	*extract air*	*input and extract air*
19	filters have to be sterilised on site or instantly sealed in a plastic bag for later sterilisation	no	yes	yes	yes
20	alarm systems for workers working alone	no	no	yes	yes
21	*shower for the occupants before leaving the laboratory**	*no*	*no*	*optional*	*yes*

[*] *from the annexes of Directive 98/81/EC*

22	Provision of eye wash stations / bottles / equipment	yes	yes	yes	yes
23	Provision of intercom system to facilitate communication with persons outside of the laboratory	no	no	yes	yes

IV. – Safety Management

a) Work procedures

	Specification	Containment level			
		1	2	3	4
1	doors and windows closed while working	only doors	yes	yes	yes
2	access to the laboratory must be restricted when experiments are in progress	no	yes	yes	yes
3	workers should be given adequate information on safety matters and be suitably trained. Training should include the following points: a) the existence and application of written work procedures b) the procedures for using particular pieces of equipment c) spillage control and other emergency procedures	yes	yes	yes	yes
4	check at which process steps hazardous quantities of aerosols are formed. Any operation that may involve the formation of aerosols (e.g. sonicating, centrifuging, pipetting) shall be performed in such a way as to ensure that these do not find their way into the working area.	optional	yes	yes	yes
5	GMO's are only to be transported within the facility in closed, robust and leakproof containers	yes	yes	yes	yes
6	work surfaces must be decontaminated daily and after a spillage	yes	yes	yes	yes
7	*inactivation of GMOs in contaminated material and waste*[*]	*optional*	*yes*	*yes*	*yes*
8	*inactivation of GMOs in effluent from the hand washing sinks or drains and showers and similar effluents**	*no*	*no*	*optional*	*yes*
9	corrective actions following the results of the controls and way to register them	yes	yes	yes	yes
10	users should ensure that the performance of safety equipment is validated (e.g. autoclaves and safety hoods) - validation of equipment (e.g. autoclaves, safety hoods) - maintenance of the equipment - markers used to verify the efficiency of autoclaves	yes	yes	yes	yes
11	skin contact with rec. DNA material must be avoided	yes	yes	yes	yes

[*] *from the annexes of Directive 98/81/EC*

12	*change of clothing*[*]	*no*	*no*	*no, optional footwear*	*yes, complete change of clothing and footwear*
13	decontaminate protective clothing before laundering	yes	yes	yes	yes
14	protective clothing and street wear must be kept separate	yes	yes	yes	yes
15	*gloves*	*no*	*optional*	*yes*	*yes*
16	*implementation of an insect and rodent control programme**	*optional*	*yes*	*yes*	*yes*
17	where appropriate make vaccines available	no	yes	yes	yes
18	where appropriate serum samples must be taken from workers and stored to provide baseline information in the event of an unexplained illness	no	optional	optional	optional
19	sample collection, addition of materials to closed system and transfer of viable micro-organisms to another closed system, should be performed as appropriate	yes	yes	yes	yes
20	safe storage of biological agents	yes	yes	yes	yes
21	Regular identification and confirmation of purity of microbial strains	yes	yes	yes	yes
22	Safe storage of contaminated laboratory equipment	yes	yes	yes	yes
23	Personnel to remove protective clothing on leaving the facility	yes	yes	yes	yes
24	Worker required to wear closed shoes	yes	yes	yes	yes
25	Regular maintenance of safety equipment such as safety cabinets	no	yes	yes	yes

[*] *from the annexes of Directive 98/81/EC*

Organisational matters and documentation relating to the safe handling of GMOs

	Specification	Containment level			
		1	2	3	4
1	hygiene plan*	no	yes	yes	yes
2	provide documentation of: - the appointment of the Biological Safety Officer (BSO) by the licensee	yes	yes	yes	yes
3	- the appointment of project leader by the licensee	yes	yes	yes	yes
4	- a description of the tasks of the BSO a.o. with respect to - safety - internal control - accident/incident response and preparedness - internal counselling, advice and education - reporting	yes	yes	yes	yes
5	a description of the tasks of the project leader a.o. with respect to: - everyday management - drawing-up and executing work-protocol	yes	yes	yes	yes
6	a clear description of the separation of responsibilities and tasks between the BSO and the project leader the discretionary powers/mandate that the BSO has received in order to fulfil his duty	yes	yes	yes	yes
7	the status of the BSO should be defined. The job description should include - mechanisms whereby the BSO can report directly to the licensee - instructions that the BSO should hand his function over to a deputy in situations where he is involved in carrying out the practical work himself. - an indication as to the amount of time that the BSO will be allocated to undertake their role	yes	yes	yes	yes
8	there should be written procedures that cover the following: - undertaking risk assessments - the training of new staff - emergency procedures including the treatment of spillages with disinfectants - cleaning and disinfection of equipment - transport of GMOs - operation, testing and maintenance of containment equipment - measures for limiting access to facilities - health surveillance of workers	yes	yes	yes	yes
9	written instructions should be in the language of the	yes	yes	yes	yes

* *from the annexes of Directive 98/81/EC*

	personnel working in the facility				
10	documents that should be centrally held within an institution undertaking GM work: a) records indicating working areas and their containment levels (these records may include plans of buildings) b) all of the documents listed in point 8 above c) a copy of all risk assessments and notifications d) these records should also cover any sites for storage of GMOs outside of containment facilities e) records of internally organised inspections f) records of incidents and accidents, including evaluation and any remedial action g) a list of other data and documents that are held at other locations within the institution	yes	yes	yes	yes
11	examples of documents that can be held separately from the main records: a) records of staff involved in GM work indicating their experience and training and the type of projects in which they have been employed b) results of procedures for checking the purity and identity of the GMOs c) results of the testing of containment equipment (e.g. autoclaves and safety cabinets) d) a list of stored GMOs for each storage facility e) work protocols for particular experimental procedures	yes	yes	yes	yes
12	Implementation of measures to minimise worker exposure, where work with class 1 GMMs with sensitising or toxic properties is being carried out (e.g. safety cabinet, provision of inhalation equipment when working with sporulating fungi)	yes	yes	yes	yes

* *from the annexes of Directive 98/81/EC*

V. - Risk assessment

	Specification	Containment level			
		1	2	3	4
1	check that risk assessments have been undertaken for all projects and that individual risk assessments contain sufficient information and have addressed all relevant issues.	yes	yes	yes	yes
2	Ensure accurate descriptions/ characterisations of GMO's or groups of GMO's	yes	yes	yes	yes
3	description of the host-organism and name of the GMO	yes	yes	yes	yes
4	description of the genetic material used to construct this GMO comprising at least the composition and the donors it was derived from	yes	yes	yes	yes
5	in case of a Class 1 GMMs (requiring only reporting) gene functions should be documented	yes	yes	yes	yes
6	for GMO's requiring notification the number of notification/licence should also be mentioned	yes	yes	yes	yes
7	classification of the micro-organism(s) to be used	yes	yes	yes	yes
8	classification of the operation	yes	yes	yes	yes
9	check that ongoing projects have not diversified into areas of research that were not covered in the original risk assessment (e.g. by the help of a literature search or discussion with other members of staff)	yes	yes	yes	yes
10	check that notifications have been made where necessary	yes	yes	yes	yes
11	check to see that risk assessments are reviewed by a local safety committee, if necessary	yes	yes	yes	yes
12	check that people actually handling a particular GMO are aware of the content of the corresponding risk assessment	yes	yes	yes	yes

VI. – Emergency response

	Specification	Containment level			
		1	**2**	**3**	**4**
1	check emergency plans for protection of the environment and the public outside of the facility	no	no	optional	yes
2	check information on accidents (reporting of accidents and near –misses and records of corrective actions that have been taken)	yes	yes	yes	yes
3	provide written procedures for: - a procedure for internal notification of incidents (e.g. spillages) - a procedure for external notification in case of serious risk - a procedure for incident/accident response (measures, reporting, evaluation) - emergency preparedness actions and counter-measures in case of accidents or incidents	no	yes	yes	yes

VII. – Outlook

information on commercialisation of biotechnological products (present and future prospects)

Information on planned field releases of GMOs

Version. 4.0	Production Facilities			
		Containment level		
	Specification	1	2	3
No.	Facility design			
1	*closed systems should be located within a controlled area*[*]	*no*	*yes*	*yes*
2	*controlled area is constructed in such a way that spillage of the total content of the largest primary closed system will be contained**	*optional*	*optional*	*yes*
3	*the controlled area should be sealable to permit fumigation**	*no*	*optional*	*yes*
4	*biohazard signs at the entrance to controlled areas**	*no*	*yes*	*yes*
5	*access to controlled areas by means of an airlock**	*no*	*no*	*yes*
6	facilities for disinfecting and for washing the hands located in the airlock (without need for manual operation)	no	no	yes
7	airlock for equipment	no	no	yes
8	doors with access to the controlled area are self closing	no	yes	yes
9	installations provided to make it possible to communicate with persons outside the controlled area, alarm system	no	no	yes
10	*the controlled area should be maintained at an air pressure negative to the immediate surroundings**	*no*	*no*	*yes*
11	alarm system installed to detect failure of negative pressure	no	no	yes
12	separate ventilation system installed	no	no	yes
13	measures taken to prevent the air from recirculating to other parts of the building	no	yes	yes
14	*specific measures to adequately ventilate the controlled area in order to minimise air contamination**	*optional*	*optional*	*yes*
15	ventilation system installed to prevent a backflow of air and an overpressure in the production installation in the event of an incident	no	no	yes
16	ventilation system backed up by an emergency generator	no	no	yes
17	*extract and input air from the controlled area should be HEPA-filtered**	*no*	*no*	*yes*

[*] *from the annexes of Directive 98/81/EC*

18	used HEPA filters should be sterilised before changing them, or removed without manual contact, e.g. immediately sealed in a bag and then sterilised	no	yes	yes
19	other installations that depend on electricity and are important for safety must be backed up by an emergency generator	no	no	yes

	Containment Equipment			
20	*surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean*[*]	*yes*	*yes*	*yes*
21	controlled area fully equipped	no	no	yes
22	biological safety cabinet available	no	yes	yes
23	*control of exhaust gases from the closed system like fermenters, autoclaves and pumps which are released to the controlled area e.g. by filtration or handling it thermally**	*optional*	*yes*	*yes*
24	centrifuges fitted with aerosol-proof covers (e. g. an O-ring)	no	yes	yes
25	*seals (O-rings from centrifuges, rotor shafts) should be designed so as to minimise or prevent release**	*no*	*yes minimize dissemination*	*yes prevent dissemination*
26	Autoclave	yes	yes	yes
27	autoclave sterilisation temperature recorded together with the sterilisation time	no	yes	yes
28	shower facilities available	no	no	yes
29	washbasin is equipped with disinfection dispenser	no	yes	yes
30	inoculations should be done by means of closed piping between inoculation vessel and fermenter.	no	yes	yes
31	For taking probes a device is needed which can be disinfected after each probing	no	yes	yes
32	Probing vessels must be transported closed and secured against breakage	no	yes	yes

	Working procedures			
33	*viable micro-organisms should be contained in a system which separates the process from the environment (closed system)**	*optional*	*yes*	*yes*
34	*access to controlled areas is restricted (Access by key, control card / code, list of persons with authorised access, etc.)**	*yes*	*yes*	*yes*

[*] *from the annexes of Directive 98/81/EC*

35	before technical devices are opened, the contaminated parts must be disinfected	no	yes	yes
36	equipment must be regularly checked and properly maintained	yes	yes	yes
37	all persons who have access to the controlled area must be informed about the nature of the activities that take place there	no	yes	yes
38	compliance to Good Large Scale Practice (GLSP)	yes	yes	yes
39	*personnel should wear protective clothing**	*yes*	*yes*	*yes*
40	protective clothing must be kept separate from normal clothing in a suitable storage area	yes	yes	yes
41	clothing and individual protective equipment that may have been contaminated by micro-organisms has to be cleaned and if needed to be disinfected	yes	yes	yes
42	*personnel should shower before leaving the controlled area**	*no*	*no*	*optional*
43	skin contact with micro-organisms should be avoided, e.g. by means of gloves	no	yes	yes
44	spill kit in order to disinfect controlled areas after an accidental spillage	yes	yes	yes
45	*Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system**	*optional*	*yes minimise*	*yes prevent*
46	the controlled area and the adjacent environment has to be monitored for viable organisms used in the production process	no	optional	yes
47	*inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge**	*optional*	*yes*	*yes*
48	*Inactivation of bulk culture fluids before removal from the closed system*	*optional*	*yes*	*yes*
49	*inactivation of GMMs in effluents from handwashing sinks and showers or similar effluents**	*no*	*no*	*optional*
50	waste matter must be suitably labelled (type of waste, biohazard warning sign from Level 2, etc.)	yes	yes	yes
51	transportation within the installation of organisms as well as material and waste containing organisms mustbe carried out in an appropriate manner (sealed, leak-proof and unbreakable container)	yes	yes	yes
52	safe storage of organisms in containers within the installation	yes	yes	yes

[*] *from the annexes of Directive 98/81/EC*

53	safety instructions must include an emergency plan indicating the procedure to follow in the event of an incident (e.g. release of fermentation solution from tanks or other containers)	yes	yes	yes
54	it must be the official company policy that project leaders and the BSO must be notified without delay about any accidents and incidents members of staff must be aware of this policy	yes	yes	yes
55	control program for insects and rodents	no	recommended	yes

Checklist for Inspections
(contained use – Glasshouses and Growth-rooms)

biosafety level 1 - 3

	Specification	Containment level 1	2	3
1	*greenhouse: permanent structure*[*]	*no*	*yes*	*yes*
2	internal walls, ceilings and floors shall be resistant to penetration by liquids and chemicals to facilitate cleaning and decontamination of the area. All penetrations into these structures and surfaces shall be sealed (e.g. cables, pipes)	no	optional	yes
3	*control of contaminated run-off water**	*optional*	*minimise run-off*	*prevent run-off*
4	a suitable program must be worked out to control plant pests, weeds, insects and rodents	yes	yes	yes
5	*measures to control undesired species such as weed, insects, rodents, arthropods**	*yes*	*yes*	*yes*
6	*procedures for transfer of living material between the glasshouse/growth-room, protective structure and laboratory shall control dissemination of genetically modified micro-organisms**	*minimise dissemi-nation*	*minimise dissemi-nation*	*prevent dissemi-nation*
7	transport of GMO's in suitable closed non-breakable containers	no	yes	yes
8	the outside of the container shall be decontaminated e.g. by fumigation	no	no	yes
9	the ground of the greenhouse can be of gravel or other greenhouse-typical material. At least the pavement should be solid, e.g. concrete.	yes	yes	yes
10	the ground of the greenhouse should be of water impermeable material. Gravel and other porous material under the planting tables is suitable if there is only a minor possibility that reproducible biological material can be transmitted through the soil. In this case earth beds are also possible.	no	yes	not applicable
11	if part of the ground consists of gravel, appropriate treatments should be made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel	no	yes	not applicable
12	the ground of the greenhouse is made of water impermeable material with provisions to collect and sterilise waste water.	no	no	yes
13	escape of GMO's	minimised	prevent	prevent
14	windows shall be closed and sealed	no	no, with	yes

[*] *from the annexes of Directive 98/81/EC*

			insect nets	
15	all glazing shall be resistant to breakage	no	no	yes
16	biohazard sign at entry	no	yes	yes
17	a sign shall be posted indicating: - that a restricted experiment is in progress - name of responsible individual - plants (organisms) in use - special requirements for using the area	no	optional	yes
18	access is limited to the project leader and personnel authorised by him	no	yes	yes
19	protective clothing must be sterilised before laundry	no	no	yes
20	gloves shall be worn at work	no	no	yes
21	injuries must be reported immediately to the project leader	yes	yes	yes
22	there must be written instructions for greenhouse practices and procedures	yes	yes	yes
23	hand disinfection apparatus and wash basin	no	yes	yes
24	greenhouse must be entered via a lock with self-closing doors, hand disinfection apparatus and touch-free hand washing basin.	no	no	yes
25	air intake screening and motorised or gravity-driven exhaust fan louvers	yes	yes	not applicable
26	the glasshouse must be held under negative pressure compared to the surrounding area	no	no	yes
27	where there is danger of the dissemination of airborne pathogens, exhaust air must be filtered through HEPA-filters	no	no	yes
28	before disposal genetically modified plants must be made unable to reproduce, e.g. by cutting off blossoms	yes	not applicable	not applicable
29	equipment which was in contact with GMO's must be sterilised before cleaning, if the contact may lead to the transmission of GMO's	no	yes	yes
30	autoclave inside the glasshouse	no	no, but available	yes
31	the glasshouse must be surrounded by a security fence or equal protection system	no	no	yes

Checklist for Inspections
(contained use – animal units)

biosafety level 1 - 3

	Specification	Containment level		
		1	**2**	**3**
1	*isolation of animal unit*[*]	*optional*	*yes*	*yes*
2	*animal facilities separated by lockable doors**	*optional*	*yes*	*yes*
3	*animal facilities designed to facilitate decontamination (waterproof and easily washable material, cages etc.)**	*optional*	*optional*	*yes*
4	*floor and/or walls easily washable**	*optional*	*floor*	*floor and walls*
5	floor to wall, wall to ceiling and wall to wall junctions should be rounded for easy cleaning	yes	yes	yes
6	all joints between door frames and wall should be sealed	yes	yes	yes
7	animal facilities must be cleaned regularly. Sinks must be disinfected regularly.	no	yes	yes
8	surfaces must be disinfected after work	no	yes	yes
9	used cages must be decontaminated	yes	yes	yes
10	material to be sterilised or incinerated as well as used cages must be transported so that the environment is not contaminated	yes	yes	yes
11	hands must be decontaminated and washed if there is the possibility of contamination after handling animals and waste	yes	yes	yes
12	access to animal facilities is restricted	yes	yes	yes
13	an animal unit shall install devices to detect fires, ventilation and heating failures and the intrusion of unauthorised personnel	yes	yes	yes
14	where appropriate, an inspection window should be fitted in the door	yes	yes	yes
15	animal facilities must be aerated appropriate	yes	yes	yes
16	wild forms of animals held inside the facility, occurring in the environment, should not have access to the facility	yes	yes	yes
17	male and female species must be separated in order to avoid reproduction, unless reproductive studies are part of the experiment			
18	measures to control undesired species such as insects and rodents	yes	yes	yes
19	drains and any other services that enter through the walls or floor should prevent the ingress of rodents and insects	yes	yes	yes
20	accidents, bites and scratches caused by animals must be reported to the project leader must record the incident	yes	yes	yes
21	personnel must be trained in the handling of the animals	yes	yes	yes
22	there must be written records about the transfer of foreign	yes	yes	yes

[*] *from the annexes of Directive 98/81/EC*

	genes, about the breeding experiments and the disposal of animals			
23	transgenic animals must be easily identifiable, by using the transgene itself as a marker, or by marking the animal in some way .	yes	yes	yes
24	food and tobacco must be stored so that it does not come into contact with transgenic animals	yes	yes	yes
25	protective clothing and shoes must be worn. They must be changed or cleaned on leaving the facility	yes	yes	yes
26	rodent-barriers should be installed in front of doors, alternatively doors to rooms, where animals are housed and handled should be self-closing to prevent their escape	yes	yes	yes
27	animal species must be housed in appropriate cages, runs, pens suitable for their requirements	yes	yes	yes
28	no animals should be admitted other than for experimental purposes	yes	yes	yes
29	biohazard sign	no	yes	yes
30	doors must be closed if infected animals are held. There must be a sign indicating the kind of work	no	yes	yes
31	the laboratory should contain a washbasin with taps that should be of a type that can be operated without being touched by hand, facilities for hand disinfecting shall be provided	no	yes	yes
32	use of safety cabinets where aerosols are released	no	yes	yes
33	an autoclave should be available when genetically modified micro-organisms are used in experiments	yes	yes	yes
34	in experiments where genetically modified micro-organisms are used contaminated material and waste should be inactivated	yes	yes	yes
35	where GM animals are subject to infection, working tools and equipment must be sterilised	no	yes	yes
36	GMO's must only be transported in breakproof and closed containers	no	yes	yes
37	where the risk assessment indicates, the animal room and contents will need to be fumigated, the room should be capable of being sealed by appropriate means and consideration should be given to the means of removing or extracting the fumigant	no	yes	yes
38	Hygiene plan	no	yes	yes
39	the animal facility has to be entered via a lock equipped with two self closing doors, hand washing basin, disinfection dispenser and shower	no	no	yes
40	acceptability of windows that open	yes	yes	no
41	emergency power supply for safety relevant equipment such as ventilation system	no	no	yes
42	where mechanical ventilation is provided, the airflow should be inwards. Air should not be recirculated to any part of the building.	no	yes	yes
43	the ventilation system should be designed to prevent accidental reverse flow and positive pressure in any part of	no	no	yes

	the animal unit			
44	Areas where work with airborne pathogens is carried out must be under negative pressure relative to the pressure of the immediate surroundings, extract air should be HEPA filtered	no	no	yes
45	HEPA filters should be sited so that they are accessible for testing and allow their safe removal. HEPA filters must be sterilised on site or immediately sealed in an airtight plastic sack for later sterilisation	no	no	yes
46	animals infected with risk group 3 micro-organisms shall be housed in isolator cages with ventilation passing through HEPA filtration to the exterior. Alternatively, animals shall be housed in cages within ventilation units with ventilation exhausts placed behind cages.	no	no	yes
47	Carcasses must be sterilised prior to disposal. If this is not possible inside the facility, carcasses must be trans-ported in closed, leakproof and disinfected containers	no	no	yes
48	waste water must be sterilised	no	no	yes