28.3.2001

Checklist for Inspections
(contained use – laboratory activities)

Overview:

I. General Information

II. Good microbiological practice

III. Physical Control Measures
- a) Facility design
- b) Containment equipment

IV. Safety Management
- a) Work procedures
- b) Organisational matters and documentation relating to the safe handling of GMOs

V. Risk Assessment

VI. Emergency Response

VII. Outlook

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 GMOs use

II. - Good microbiological practice

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 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 rDNA 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

1

b) <u>Containment equipment</u>

	Containment level

* from the annexes of Directive 98/81/EC

	Specification	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	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 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*
22	*an observation window or alternative is to be present so that occupants can be seen**	*optional*	*optional*	*optional*	*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 procecures 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	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 rDNA material must be avoided	yes	yes	yes	yes
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	no	optional	optional	optional

	the event of an unexplained illness				
19	sample collection, addition of materials to closed system and transfer of viable micro-organisms to another closed system, should be performed appropriate	yes	yes	yes	yes
20	safe storage of biological agents	yes	yes	yes	yes

b) <u>Organisational matters and documentation relating to the safe handling of GMOs</u>

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	yes	yes	yes	yes

	(BSO) by the licensee				
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 include - mechanisms wherby the BSO can report directly to the licensee - instructions that the BSO should hand their function over to deputy in situations where they are directly involved in a particular piece of work - 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 personnel working in the facility	yes	yes	yes	yes
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 11 above c) a copy of all risk assessments and notifications d) these records should also cover any sites for storage GMO's outside of containment facilities	yes	yes	yes	yes

	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				
11	examples of documents that can be held separately from the main records (see 12 above): 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 expermental procedures	yes	yes	yes	yes

2

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 conain sufficient information and have addressed all relevant issues.	yes	yes	yes	yes
2	check drawing ups (accurate descriptions/	yes	yes	yes	yes

* from the annexes of Directive 98/81/EC

	characterisations of GMO's or groups of GMO's)				
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 group I GMO (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 no deversified into areas of research that were not covered in the original risk assessment (e.g. by the help of a literature search or diskussion with junior 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

		Containment level			
	Specification	**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	no	yes	yes	yes

	(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				

VII. – Outlook

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

Information on planned field releases of GMOs