

# **Checklist**

**For**

**Contained Use (Laboratory Activities)**

**of Genetically Modified Organisms (GMOs) in Kenya**

**Guideline for Inspections**

**June 2004**

## **Overview:**

- I. General Information**
- II. Physical Control Measures**
  - a) Facility design
  - b) Containment equipment
- III. Safety Management**
  - a) Work procedures
  - b) Organisational matters and documentation relating to the safe handling of GMOs
- IV. Risk Assessment**
- V. Emergency Response**
- VI. Outlook**

## **I – GENERAL INFORMATION**

The following basic information must be provided:

- Address of the Laboratory/plant
- Location of the laboratory (e.g. is it one part of a larger building)
- Location of social rooms
- Compliance with the blue print
- Characteristics of each room(s) and their relevant containment category
- 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
- number of laboratory/plant workers
- education and experience of the staff
- outside contractors (cleaning, security maintenance personnel, visitors)
- description of the activity carried out (research, development, industrial production etc.)
- purpose of the activity
- foreseen duration of GMOs use

## II - 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 the laboratory entrance: <ul style="list-style-type: none"><li>• special hazard signs if an organism containing rDNA needs special provision for persons entering the laboratory</li><li>• names of occupants who have access to the laboratory</li></ul>	No	Yes	Yes	Yes
8	Ventilation system	No	No	Yes	yes

## b) Containment equipment

Specification		Containment level			
		1	2	3	4
1	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Yes	Yes	Yes	Yes
2	Check the suitability of equipment used for safety purposes	No	Yes	Yes	Yes
3	Check the suitability of any chemical disinfectants in use	Optional	Yes	Yes	Yes
4	Check position of the autoclave with respect to the GMO installation	On site	In the building	In suite	In lab, double closed
5	Autoclave that the autoclave provides a print-out showing the temperature and time of sterilization	No	No	Yes	Yes
6	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
7	Check position and design of biological safety hoods	Optional	Yes	Yes	Yes
8	Check design of the equipment for the safe storage of GMOs	Yes	Yes	Yes	Yes
9	Check design of waste transport containers	Optional	Yes	Yes	Yes
10	Check design of containers for transport of GMOs inside the facility	Optional	Yes	Yes	Yes
11	Check design for centrifuge buckets	Yes	Yes	Yes	Yes
12	Entry to lab via airlock	No	No	Optional	Yes
13	Air lock with two doors which are interlocked	No	No	Yes	Yes
14	Air lock equipped with a hand washing basin(touch free) and hand disinfectant dispenser	No	No	Yes	Yes
15	Negative pressure relative to the pressure of the immediate surroundings	No	No	Optional	Yes
16	Ventilation system is alarmed to indicate a failure to generate a negative pressure	No	No	Yes	Yes
17	Ventilation system connected to an emergency power supply	No	No	Yes	Yes
18	Switch for ventilation system should be accessible from outside of the laboratory in case of fumigation	No	No	Yes	Yes
19	Extract and input air form the laboratory should be HEPA filtered	No	No	Extract air	Input and extract air
20	Filters have to be sterilized on site or instantly sealed in a plastic bag for later sterilization	No	Yes	Yes	Yes
21	Alarm systems for workers working alone	No	No	Yes	Yes
22	Shower for the occupants before leaving the laboratory	No	No	Optional	Yes
23	An observation window or alternative is to present so that occupants can be seen	Optional	Optional	Optional	Yes

### III – SAFETY MANAGEMENT

#### a) Work procedures

Specification		Containment level			
		1	2	3	4
1	Engineering control measures have to be exercised at source and supplement these with appropriate personal protective clothing and equipment where necessary	Yes	Yes	Yes	Yes
2	Control measures and equipment have to be tested adequately and maintained	Yes	Yes	Yes	Yes
3	Doors and windows closed while working	Only doors	Yes	Yes	Yes
4	Access to the laboratory must be restricted when experiments are in progress	No	Yes	Yes	Yes
5	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
6	Check at which process steps hazards quantities of aerosols are formed	Optional	Yes	Yes	Yes
7	Prevention of aerosol formation	Yes	Yes	Yes	Yes
8	GMO's are only to be transported within the facility in closed, robust and leakproof containers	Yes	Yes	Yes	Yes
9	Work surfaces must be decontaminated daily and after a spillage	Yes	Yes	Yes	Yes
10	Effective disinfectants and specified disinfections procedures in case of spillage of GMOs	Yes	Yes	Yes	Yes
11	Inactivation of GMOs in contaminated material and waste	Optional	Yes	Yes	Yes
12	Inactivation of GMOs in effluent from the hand washing sinks or drains and showers and similar effluents	No	No	Optional	Yes
13	Benches should be free from clutter	Yes	Yes	Yes	Yes
14	The identity of GMOs should be regularly checked to avoid the culturing of incorrect stains. The time between these checks should dependent upon the potential hazard.	Optional	Yes	Yes	Yes
15	Corrective actions following the results of the controls and way to register them	Yes	Yes	Yes	Yes
16	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
17	Prohibition of mouth pipetting	Yes	Yes	Yes	Yes
18	Prohibition of eating , drinking, smoking, applying cosmetics or the storing of food for human consumption in the work area	Yes	Yes	Yes	Yes

Specification		Containment level			
		1	2	3	4
19	Skin contact with rDNA material must be avoided	Yes	Yes	Yes	Yes
20	Hands must be washed after handling rDNA and before leaving the laboratory	Yes	Yes	Yes	yes
21	Protective clothing	Yes	Yes	Yes and optional footwear	Yes, complete change of clothing and footwear
22	Decontaminate protective clothing before laundering	Yes	Yes	Yes	Yes
23	Protective clothing and street wear must be kept separate	Yes	Yes	Yes	Yes
24	Gloves	No	Optional	Yes	Yes
25	Implementation of an insect and rodent control programme	Optional	Yes	Yes	Yes
26	Keep the workplace and environmental exposure to any physical, chemical or biological agent to the lowest practicable level	Yes	Yes	Yes	Yes
27	Tests, when necessary, for the presence of viable GMOs outside the primary physical containment	Yes	Yes	Yes	Yes
28	Use of sharps should be avoided	Yes	Yes	Yes	Yes
29	Contaminated syringes/sharps must be disposed of in a 'Sharps bin' and incinerated	Yes	Yes	Yes	Yes
30	Where appropriate make vaccines available	No	Yes	Yes	Yes
31	Establish Biological Safety Committees or sub-committees as required	Yes	Yes	Yes	Yes
32	Animals must not be allowed to enter into the laboratory	Yes	Yes	Yes	Yes
33	Where appropriate samples must be taken from workers and stored to provide baseline information in event of an unexplained illness	No	Optional	Optional	Optional
34	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
35	Safe storage of biological agents	Yes	Yes	Yes	Yes
36	Safe storage of contaminated laboratory equipment and materials, when appropriate	Yes	Yes	Yes	Yes

**b) Organisational matters and documentation relating to the safe handling of GMOs**

Specification		Containment level			
		1	2	3	4
1	Keep adequate records (drawing ups)	Yes	Yes	Yes	Yes
2	Hygiene plan	No	Yes	Yes	Yes
3	Provide written standard operating procedures where appropriate to ensure safety	Yes	Yes	Yes	Yes
4	Provide documentation of: - the appointment of the Biological Safety Officer (BSO) by the licensee	Yes	Yes	Yes	Yes
5	- the appointment of project leader by the licensee	Yes	Yes	Yes	Yes
6	- a description of the tasks of the BSO a.o. with respect to - safety - internal control - accident/incident response and preparedness - internal counselling, advise and education - reporting	Yes	Yes	Yes	Yes
7	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
8	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
9	The status of the BSO should be defined. The job description include - mechanisms whereby 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
10	There should be written procedures that over 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
11	Written instructions should be in the language of the personnel working in the facility	Yes	Yes	Yes	Yes
12	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 and 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 e) records of internally organized 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
13	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 experimental procedures	Yes	Yes	Yes	Yes

## IV – 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	Check drawing ups (accurate descriptions/characterizations 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 group 1 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 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 junior members of staff)	Yes	Yes	Yes	Yes
10	Check to see that risk assessments are reviewed by a local safety committee, if 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

## V – EMERGENCY RESPONSE

Specification		Containment level			
		1	2	3	4
1	Check emergency plans for protection of the environment and the public outside the facility	No	No	Optional	Yes
2	Check information on accidents (reporting of accidents)	Yes	Yes	Yes	Yes