

## **Environmental Protection Agency**

### **Guidelines for the establishment of a Biological Safety Committee (BSC) and the appointment of a Biological Safety Officer (BSO).**

#### **Introduction**

There is a statutory requirement under Part A of the 5<sup>th</sup> Schedule of the Genetically Modified Organisms (Contained Use) Regulations, 2001 to 2010, to provide *details of any biological committees or subcommittees*. Furthermore, it is a standard condition of consents issued by the EPA in respect of activities for the contained use of Genetically Modified Micro-organisms (GMMs):

- that a Biological Safety Committee (BSC) be established within three months of the date of issue of the consent where there is no BSC in existence; or,
- that a BSC be maintained where a BSC is already in existence.

The following guidelines have been drafted for users of Genetically Modified Micro-organisms (GMMs) / Genetically Modified Organisms (GMOs), who are required to establish a BSC and appoint a Biological Safety Officer (BSO).

#### **1. Functions of a Biological Safety Committee**

It is the overall function of the BSC to review GMM/GMO contained use activities and advise management with regard to the corresponding biological safety procedures that should be put in place.

More specifically the BSC must:

- review applications for the contained use of GMMs/GMOs, provide advice on the Risk Assessment (RA), the classification of the contained use activity and the appropriate containment measures to be applied, in order to avoid any potential adverse effects to human health and the environment;
- review periodically the contained use of GMMs/GMOs ongoing within the facility, in order to ensure that the requirements of the GMO (Contained Use) Regulations and the consent conditions issued in respect of the GMM/GMO activity are fulfilled;
- review any new information which could have significant consequences for the risks posed by the contained use activity, for human health and the environment. Review the RA and the classification and the level of containment applied in order to ensure that it is appropriate;

- provide advice with regard to (where applicable):
  - laboratory design;
  - equipment;
  - control of access to the contained use facility;
  - waste inactivation (validation methods);
  - the training of personnel;
  - the application of good microbiological practices (GMP); and,
  - good occupational safety and hygiene (GOSH);
- provide advice on procedures dealing with the containment and treatment of spillages of GMM material and where required, provide advice in relation to accident and emergency procedures;
- report the minutes of the BSC meetings to the EPA on an annual basis;
- deal with other functions that may arise.

No liability should rest with members of the BSC. Rather, liability should rest with the CEO / president of the company / university. The issue of liability should be discussed and acknowledged by management when a BSC is being established.

## **2. Structure of a Biological Safety Committee**

A BSC should comprise no fewer than three members, and up to five members in the case of larger facilities/activities (e.g. large biotech companies, production facilities). Collectively the membership of the BSC should have sufficient experience and expertise in recombinant DNA (rDNA) technology in order to:

- assess the safety of rDNA research or production involving rDNA molecules;
- provide advice on the points addressed under section 1 of this guidance.

It is recommended that at least 1- 2 members of the BSC should not be GMM users and should not be affiliated with a GMM contained use activity, (apart from their membership on the BSC). Rather they should represent the interests of the surrounding community with respect to health and/or the environment.

## **3. Biological Safety Officer (BSO)**

The BSO should be a member of the BSC.

It is the function of the BSO:

- to ensure that all GMM/GMO users operating within a facility are informed of the legislative requirement *to ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment;*
- to inform the GMM/GMO/ user that a GMM/GMO/ contained use activity shall not be carried out save in compliance with the provisions of the GMO (Contained Use) Regulations, 2001 to 2010;

- to ensure through periodic inspection of the GMM/GMO facility that the requirements of the GMO (Contained Use) Regulations and the consent conditions/letter of agreement issued in respect of the GMM/GMO activity respectively, are adhered to and fulfilled;
- to report all accidents and emergencies relating to GMM/GMO work to the hierarchy, the BSC, and where required under the legislation or consent conditions, to the EPA;
- to investigate the cause of GMM/GMO related laboratory accidents and to put in place measures, preventing their reoccurrence;
- to provide advice on laboratory security;
- to provide technical advice to the BSC on safety procedures;
- to liaise with the EPA particularly during the course of enforcement site inspections carried out by the EPA; and,
- any other duties as they arise.

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