

## **The FMHS Containment Facility** **Regulation of GMOs and Imported 'Risk Goods'**

### **A. Genetically Modified Organisms**

#### **What is a Genetically Modified Organism?**

1. A Genetically Modified Organism is an organism whose genes have been manipulated using in vitro techniques. Examples of genetically modified organisms include:

- Modified E coli, yeast and cell lines
- Transient and permanently transfected cell lines
- Transgenic and Knockout animals
- Transgenic Plants

Note that animals exposed to viral and some plasmid vectors will be contained as if they were genetically modified.

#### **Regulation of GMOs – HSNO approval**

1. The HSNO Act requires that all development, importation, field trial and release of Genetically Modified Organisms (GMOs) must have prior approval from the Environmental Risk Management Authority (ERMA).

2. ERMA can delegate powers to assess applications to develop or import low risk GMOs

3. The University of Auckland Biological Safety Committee (UABSC) can assess HSNO applications to develop or import low risk GMOs in containment.

4. All research groups working with GMOs have their own approvals which in most cases cover the development of a wide range of GMOs.

5. If you or your supervisor are planning significant changes in your experimentation, check your HSNO approval to ensure that any GMOs that are likely to be developed are approved. The penalties allowed under the HSNO Act are severe, so please check.

## Conditions on GMO approvals

All approvals given by ERMA and IBSCs have containment conditions:

### Laboratories

1. The first set of conditions is that the laboratories and the work conducted in them must meet minimum containment standards.
2. These minimum containment standards are set out in a joint Australian/New Zealand Standard (AS/NZS 2243.3) which classifies laboratories and work practices into one of 4 different levels – PC1 (Physical Containment Level 1) offering the lowest level and PC4 the highest level of containment.
3. GMO work within the University of Auckland is relatively low risk so most laboratories are PC1. There are some PC2 laboratories. The requirements for PC1 laboratories are listed at the end of the module.

### Containment Facilities

The second set of conditions is that all development and importation of GMOs must take place within a MAF approved Containment Facility. (i.e. the PC1 or PC2 laboratories must be within a larger MAF approved Containment Facility).

### Additional Controls

Some ERMA/IBSC approvals have additional controls over and above the two standard conditions above. These additional controls are specific to the experimentation and GMOs and must also be complied with.



### **TASK:**

*You must ask your supervisor what ERMA/UABSC approvals your laboratory operates under, whether the work is approved at PC1 or PC2 and if there are any additional controls*

## **B. Imported Risk Goods**

1. Imported 'Risk Goods' are those items that pose a biosecurity risk if they were to come into New Zealand in an unrestricted manner.
2. Examples of Imported 'Risk Goods' are cell lines, bacterial strains, imported BSA, imported animal sera and unfixed animal or plant tissue.
3. Risk Goods can only be imported on a restricted import permit issued by MAF. The Risk Goods must be imported directly to a 'Transitional Facility' and they must be securely stored in a PC1 laboratory within that facility.
4. A Transitional Facility is much the same as a Containment facility. In fact, University Containment Facilities also function as Transitional Facilities. For the sake of simplicity Containment/Transitional Facilities will just be referred to as 'Containment Facilities'.
5. 'Risk Goods' can only be imported using a Restricted Permit issued by MAF. Once Risk Goods are imported into a Containment Facility they must not leave or be transferred without prior MAF approval.
6. When suppliers such as Sigma import serum, BSA or a cell line, these goods are subject to the same MAF requirements. In many cases the supplier will have a Transitional Facility in NZ and they must obtain a transfer approval to move the Risk Goods from their Quarantine Facility to SBS. You will be notified of transfer and must acknowledge receipt of goods.
7. Store imported risk goods inside labs and keep a clear record of import, storage and use.

## **C. MAF Approved Containment Facilities**

### **What is a Containment Facility?**

A Containment facility is a Building or set of Buildings containing PC1 or PC2 labs which brings these laboratories under a single management structure.

### **What function do Containment Facilities Perform?**

Containment Facilities provide a management structure which documents training, internal audit, special containment provisions, waste treatment, inventory, how emergencies will be dealt with, contingency plans and reporting.



## **Containment Facilities in the University of Auckland**

1. The University has 2 large Containment Facilities - SBS and FMHS with Registrars as Operators (Manager). Note that SBS is a separate Containment Facility so you must obtain prior MAF approval for any transfer between these facilities.
2. Richard Swain is the Operator (Manager) of the FMHS Containment/Transitional Facility

## **Rules relating to Containment Facilities**

1. GMOs and imported risk goods **MUST NOT** leave or be transferred into another Containment facility without prior MAF approval.
2. The definition of transfers includes those transfers to FMHS and export to another country.
3. MAF must be notified of date of transfer and receipt. You must acknowledge date of consignment or receipt – contact David Jenkins.

## **Enforcement**

Containment Facilities (and the laboratories within each Containment Facility) undergo audit by MAF for accreditation and thereafter 6 monthly audits by MAF for continued approval. MAF audits laboratories against AS/NZS 2243.3.

The Containment Facility must also conduct internal audits every 6 months against both AS/NZS 2243.3 and the MAF Containment Standards.

This means your lab will undergo audit every 3 months.

## **D. What is required from you?**

You must:

1. Know what ERMA/IBSC approval your lab is operating under and ensure that it covers the work being contemplated.
2. Know whether work is approved at PC1 or PC2 Containment.
3. Know and comply with any additional controls on these approvals.
4. Ensure that you have prior IBSC approval for any significant changes in experimentation that vary from existing approvals.
5. Ensure that laboratory practices meet PC1 or PC2 at a minimum - this includes:
  - a. wearing laboratory coats,
  - b. keeping under bench areas clear
  - c. keeping benches uncluttered
  - d. not storing cultures long-term on benches.
6. Ensure that waste streams are properly treated - all GMOs, and supporting media must be chemical sterilised or autoclaved before disposal.
7. Store imported risk goods inside labs and keep a clear record of import, storage and use.
8. Not transfer GMOs or risk imported goods from FMHS to other institutions or faculties (e.g. SBS) without prior permission from MAF - see David Jenkins to arrange. David looks after the documentation on behalf of Richard Swain.
9. Not export GMOs without prior permission from MAF. You can arrange permission from MAF by contacting David Jenkins who looks after the documentation on behalf of Richard Swain.
10. If you have received GMOs from another facility and are unsure whether approval has been obtained – contact David Jenkins immediately
11. Report any incident/accident involving potential escape of GMOs immediately to your supervisor and the Operator (Richard Swain).
12. If you are unsure of any compliance issue, ask your supervisor.

*Remember: apart from 6 monthly external and internal audits MAF inspectors have the statutory powers to inspect facilities at any time and ask for ERMA approvals.*

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## **Requirements of PC1 Containment**

### **Laboratory Facilities**

- The laboratory is designed for ease of cleaning. Surfaces are impervious to water and resistant to acid, alkali and organic solvents (this includes coverings on laboratory seating).
- The laboratory is fitted with a sink with hot and cold water for hand-washing. (i.e. soap and hand-towels to be readily available)
- Open spaces between and under benches are accessible for cleaning (i.e. chilli-bins or boxes are not to be left on the floor).
- An autoclave is available.
- Supply of clearly labeled disinfectants are readily available.

### **Personal Protective Clothing**

- Laboratory coats to be worn. Laboratory coats to be removed when leaving laboratory areas.
- Closed footwear to be worn
- Safety glasses or face shields to be used where appropriate.

### **Work Practices**

- No eating or drinking in the laboratory.
- No food or drink to be stored in the laboratory.
- Mouth pipetting is prohibited.
- Hands are to be washed before leaving the laboratory.
- Work surfaces are to be decontaminated regularly and after spills. A cluttered bench indicates this is not being undertaken.
- Laboratory waste is to be decontaminated before disposal –
- Significant spills and accidents to be reported immediately to the supervisor.
- All cultures to be clearly labeled, dated and appropriately stored. Cultures are not to be stored for long periods on the bench.
- Special care taken to reduce hand/mouth contact and to ensure reading/writing materials are not contaminated.