

# **SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE**

**No. 3,005 of 30th October, 1997**

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LEGAL NOTICE NO. 125 OF 1997

## **PUBLIC HEALTH ACT**

### **PUBLIC HEALTH (GENETICALLY MODIFIED ORGANISMS) (CONTAINED USE) REGULATIONS 1995 (AMENDMENT) REGULATIONS 1997**

In exercise of the powers conferred on him by section 180X of the Public Health Act, the Governor has made the following Regulations -

#### **Title.**

1. These Regulations may be cited as the Public Health (Genetically Modified Organisms) (Contained Use) Regulations 1995 (Amendment) Regulations 1997.

#### **Amendment of the Public Health (Genetically Modified Organisms) (Contained Use) Regulations 1995.**

2. The Public Health (Genetically Modified Organisms) (Contained Use) Regulations 1995 shall be amended as follows -

(a) regulation 21 shall be amended in sub-regulation (2) as follows -

(i) the references “£100”, “£130”, “£180” and “£270” shall be deleted; and

(ii) after paragraph (d) the following words shall be inserted -

“on each of the paragraphs of this sub-regulation, such fee as would not reasonably exceed the sum of the costs incurred in dealing with the notification concerned.”; and

(b) Schedule 6 shall be amended by inserting the following table after paragraph (2) -

		Containment Level	Containment Level	Containment Level
	Specifications	B2	B3	B4
1	Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)	Yes	Yes	Yes
2	Exhaust gases from the closed system should be treated so as to -	Minimise release	Prevent release	Prevent release
3	Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to -	Minimise release	Prevent release	Prevent release
4	Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been -	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5	Seals should be designed to -	Minimise release	Prevent release	Prevent release

6	Closed systems should be located within a controlled area,	Optional	Optional	Yes, and purpose built
	(a) Biohazard signs should be posted	Optional	Yes	Yes
	(b) Access should be restricted to nominated personnel only,	Optional	Yes	Yes, via airlock
	(c) Personnel should wear protective clothing,	Yes, work clothing	Yes	Yes, a complete change
	(d) Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
	(e) Personnel should shower before leaving the controlled area	No	Optional	Yes
	(f) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
	(g) The controlled area should be adequately ventilated to minimise air contamination	Optional	Optional	Yes
	(h) The controlled areas	No	Optional	Yes

By Command,  
M J ROBINSON,  
Deputy Governor.

**EXPLANATORY MEMORANDUM**

*(This note does not form part of the Regulations)*

These Regulations amends the Public Health (Genetically Modified Organisms) (Contained Use) Regulations 1995 to achieve the following -

- (a) allow for a more flexible regime for the charging of fees for notifications, and
- (b) to amend Schedule 6, in order to insert the table referred to in that Schedule.

