Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

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Operational Policy – Requests for undertaking Notifiable Low Risk Dealings (NLRDs) in alternate facilities

The purpose of this document is to inform researchers undertaking NLRDs about the Gene Technology Regulator's (the Regulator's) operational policy for considering requests to conduct NLRDs in alternate facilities, pursuant to regulation 13(2)(c).

Background

Both the Gene Technology Act 2000 (the Act) and the Gene Technology Regulations 2001 (the Regulations) require that NLRDs do not involve an intentional release of GMOs into the environment.

Prior to amendments in September 2011 the Regulations required NLRDs to be conducted in physical containment facilities, certified by the Regulator, that are appropriate for the dealings.

The normal way containment of NLRDs is achieved is to conduct dealings in a facility certified by the Regulator to the appropriate level of physical containment (eg PC1, PC2, Regulations 13(2)(a) and (b)). In addition, a person may only undertake an NLRD if they do not compromise the containment of the GMO (Regulation 13(1)(h)).

IBCs consider what facilities are appropriate for a dealing when assessing NLRD proposals (Regulation 13B). NLRD proponents should endeavour to foresee facility needs and have them considered by an IBC at this initial stage.

Provision for alternate facilities

Amendments to the Regulations in September 2011 extended the provisions for the physical containment of NLRDs. In addition to certified facilities, regulation 13(2)(c) provides for containment in "a facility that the Regulator has agreed in writing is a facility in which the dealing may be undertaken".

The intent of this change was to provide for the approval of alternate facilities in exceptional circumstances. Examples of exceptional circumstances are:

- emergency treatment of a sick GM animal at an uncertified veterinary clinic;
- temporary removal of GMOs from a certified facility.

Requesting agreement for alternate facilities

Persons or organisations seeking agreement for an alternate facility should provide information and justification to support the request.

In considering a request to use an alternate facility, the Regulator must consider the capacity of the facility to contain the GMO (regulation 13(4)). For example, the Regulator might be satisfied that a

certified facility of a lower physical containment level is appropriate to contain the GMOs. Supporting information should explicitly address how the alternate facility would contain the GMO, why the NLRD cannot be undertaken in a certified facility according to the normal provisions, whether the use of a proposed alternate facility is intended to be temporary or ongoing and information from the IBC that a proposed alternate facility would be appropriate for the NLRD.

It is important to note that all other provisions of the Regulations would apply to NLRDs conducted in alternate facilities – regulations 12, 13(1), 13A, 13B and 13 C. Not undertaking an NLRD in accordance with the Regulations would be an offence under s37 of the Act.