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

Regulatory requirements which apply to the supply of research materials which are Genetically Modified Organisms (GMOs) under the *Gene Technology Act 2000* (the Act)

Some businesses in Australia supply research materials which may be GMOs. Businesses engaged in the supply of GMOs can undertake a number of activities which may be subject to the *Gene Technology Act 2000*. In recognition of this, the Office of the Gene Technology Regulator (OGTR) provides the following information.

The OGTR implements the Australian national regulatory system for gene technology. The regulatory system comprises national, state and territory laws providing for:

- the OGTR to identify and manage the risks to human health, safety and the environment arising from dealings with GMOs;
- the restriction of certain forms of dealings with genetically modified organisms unless such dealings are exempt or otherwise authorised; and
- criminal offences for non-compliance.

As a business supplying research materials, your supply of a GMO is regulated under the *Gene Technology Act 2000* if the GMO, is live/viable, is not exempt, and your activities take on any of the following forms. The Act states that, *to **deal with**, in relation to a GMO, means the following:*

a) conduct experiments with the GMO;
b) make, develop, produce or manufacture the GMO;
c) breed the GMO;
d) propagate the GMO;
e) use the GMO in the course of manufacture of a thing that is not the GMO;
f) grow, raise or culture the GMO;
g) import the GMO;
h) transport the GMO;
i) dispose of the GMO;

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).

In some circumstances your participation in a dealing may be authorised through the authorised activities of another entity. For example, this might apply if you are acting as an agent in a client's importation and/or transport of a GMO. In such cases, depending on the GMO, you and your client would need to take account of responsibilities under the legislation and this may include that you:

- keep/provide to your client some documentation if the imported GMO is subject to a *GMO licence* as defined in the Act; or

- provide certain basic information to your client so that they can appropriately manage a proposal to import a GMO belonging to a *notifiable low risk dealing* as defined in the Act and regulations.

However, if you intend to stockpile, make or develop these products and supply them, you would be independently dealing with GMOs. This requires authorisation under our regulatory system. Otherwise you would be acting in contravention of the Act and subject to the offence provisions of the legislation. There are significant criminal and other penalties for offences under the Act. Authorisation for such activities can also be dependent on your business achieving the status of an *accredited organisation* under the regulatory system. You may also need to develop and maintain an *institutional biosafety committee* or have access to one belonging to another accredited organisation.

The regulatory system is further explained at http://www.ogtr.gov.au.

Any person supplying GMOs within Australia should familiarise themselves and comply with these requirements.

For further information email ogtr@health.gov.au or free call 1800 181 030 within Australia.

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