Background

1. This document provides an overview of the development and implementation of Australia’s regulation of facilities used to conduct dealings with genetically modified organisms (GMOs) and highlights a number of challenges encountered throughout this process.

2. The primary driver for the development of Australia’s regulation of facilities used to conduct dealings with GMOs was the introduction of a national scheme for regulating dealings with genetically modified organisms. The scheme regulates research work carried out in laboratories and other containment facilities, field trials and commercial releases of GMOs. It replaces a voluntary scheme which operated for more than 15 years.

3. This paper focuses on the regulation of facilities used to conduct dealings with GMOs.

The Activity/Solution

4. In 2001, the Australian Government, in cooperation with all the State and Territory Governments established a Gene Technology Regulator (‘the Regulator’) to implement national legislation to regulate dealings with GMOs. The Regulator administers the Gene Technology Acts, which have the objective of protecting the health and safety of people and the environment by identifying risks posed by or as a result of gene technology and by managing those risks through regulating certain dealings with GMOs. An Office of the Gene Technology Regulator (OGTR) has been established within the Department of Health and Ageing to support the Regulator.

5. All dealings with GMOs which are defined by the Regulations under the Acts as low risk dealings or higher which are not approved for release into the environment must be conducted in facilities certified by the Regulator. The Regulator has established and issued Requirements for
the facilities, including matters such as the construction of the physical building, the provision of equipment, the work practices employed in the facility, the training of people using the facility and annual inspection of the facility by the organisation managing it. People who seek to have facilities certified must apply to the Regulator and satisfy her that the requirements are being met. For all higher level facilities (ie all but PC1 and PC2 level facilities), the OGTR conducts a physical inspection of the facility before certifying the facility and examines the procedures implemented in the facility. OGTR also meet with the facility manager and staff using the facility and explain the legislative requirements.

6. All certified facilities are also subject to the monitoring powers established under the Gene Technology Acts which means that they can be visited by ‘inspectors’ appointed under the Act at any reasonable time for compliance with the requirements for that facility. These inspections can take place with notice to the facility or may take place as unannounced visits.

The Outcomes

7. The introduction of the Gene Technology Acts and the establishment of the Regulator has led to the formal certification of more than 1700 facilities in Australia which are used to deal with GMOs in Australia. Over 50 of these facilities are PC3, PC4 or PC2 large scale (ie suitable for commercial production of GMOs). All of the these facilities were inspected by OGTR staff in the first year of operation. A program of regular re-inspection of the facilities by OGTR will be established, to complement the annual inspections by the organisations managing the facilities. Since the inception of the Acts, over 110 facilities have been monitored after certification.

8. Some of these facilities do not deal with GMOs but seek certification because the Regulator provides an objective certification that a facility meets accepted scientific requirements for the appropriate containment level.

9. The OGTR also collaborates with other organisations in Australia who provide advice or set requirements for containment facilities. This includes:

- the Australian Quarantine and Inspection Service (AQIS), who approve and inspect facilities used for quarantine purposes,
- Australian Standards who develop the *Australian and New Zealand Standard for Safety in Laboratories Part 3: Microbiological aspects and containment facilities*, a common reference document for containment of microorganisms but which is not required by any Australian law to be followed,
- the Australian Society for Microbiologists and
- the National Association of Testing Authorities, Australia, who test and approve laboratories to conduct certain tests to approved standards.

10. Over time, it is hoped that the requirements these different organisations have for containment facilities will be harmonized and take into account international containment requirements.

11. Some issues have arisen as the legislative system replaced the former voluntary system. One major issue was in making a legal ‘Requirement’ what was ‘Guidelines’. The first obvious issue was in wording, which could be ‘should’ or ‘should consider’ in advisory documents but have to be replaced by ‘must’ if that is the intention in legal requirements.
12. We feel the process has been reasonably successful but requires ongoing contact with organisations and facility managers to ensure that the Requirements continue to be met and requires ongoing outreach.

13. The development and implementation of gene technology legislation has provided valuable experience for Australia for in meeting relevant BWC-related measures in this area. The administrative arrangements serve as a sound model for enhancing related BWC commitments.