



Appendix D - Risk categories of genetically modified organisms

In best practice regulation, excessive compliance costs are avoided by classifying GMOs according to the risk they present and managing them accordingly.¹ Where gene technology extends plant breeding programs by manipulating material within and between plant species, it is utilising 'extremely tried, tested and stable technology' and presents few risks. Greater degrees of manipulation are seen as more risky.²

Under the new legislation, the regulation of risks involved with GMOs will be divided into four components, as indicated below.

Exempt dealings with GMOs

Where the OGTR is confident that a project involves a very low risk, for example contained research involving very well understood processes, no licence is required provided the project remains within specified conditions. While exemptions do not require any regulatory oversight, they will be included in regulations, and subject to review. There are no exemptions for any deliberate release into the environment.³

1 AWB Ltd, Submission no. 66, p. 3; New South Wales government, Submission no. 72, pp. 2, 6-8.

2 AWB Ltd, Submission no. 66, p. 3.

3 *Explanatory Guide to the Draft Commonwealth Gene Technology Bill 2000*, December 1999, p. 39; Interim Office of the Gene Technology Regulator, Exhibit no. 6, p. 6.

Low risk dealings

Notifiable Low Risk Dealings are sufficiently low risk that they do not require licensing on a case by case basis, but do require some regulatory oversight by the OGTR. Low risk dealings must be subject to certain conditions, be independently monitored by the GTR, have penalties for non-compliance and be subject to review. Low risk dealings do not cover deliberate release into the environment.⁴

Licensed dealings

Two classes of licensed dealings are recognised.

Dealings that do not involve deliberate release into the environment

Dealings, such as laboratory research and large scale commercial production in factories are subject to a risk assessment and risk management plan. One licence may cover a range of dealings and persons, and conditions are imposed on persons covered by the licence. These dealings must be on a public register of licences (except commercial-in-confidence), be subject to independent monitoring by the OGTR, and have penalties for non-compliance.⁵

Dealings that do involve deliberate release into the environment.

For dealings such as field trials or commercial release, the OGTR notifies receipt of application in the gazette and newspapers and calls for submissions (except commercial-in-confidence). The OGTR seeks advice and creates a comprehensive risk assessment and risk management plan. This becomes available for public comment. A decision is made and conditions imposed. Details of the licence are made available on a public register of licences (except for commercial-in-confidence material). These dealings are subject to independent monitoring by the OGTR, with penalties for non-compliance.⁶

4 *Explanatory Guide to the Draft Commonwealth Gene Technology Bill 2000*, December 1999, p. 39; Interim Office of the Gene Technology Regulator, Exhibit no. 6, pp. 6-7.

5 *Explanatory Guide to the Draft Commonwealth Gene Technology Bill 2000*, December 1999, pp. 44-5, 49; Interim Office of the Gene Technology Regulator, Exhibit no. 6, pp. 6-7.

6 *Explanatory Guide to the Draft Commonwealth Gene Technology Bill 2000*, December 1999, pp. 44-5, 49; Interim Office of the Gene Technology Regulator, Exhibit no. 6, pp. 6-7.

Register of GMOs

The public register of GMOs contains details of approval and refusal of applications for licensed dealings. A GMO which was previously licensed may also be entered on the register even if licensing is longer necessary. The requirement for licensing may be cancelled because no adverse effects have been reported, and the GMO presents negligible risks which do not require management by a licence holder. When an unlicensed dealing is entered on the register, it may be undertaken by anyone and does not require oversight by a licence holder.⁷

7 *Explanatory Guide to the Draft Commonwealth Gene Technology Bill 2000*, December 1999, pp. 39, 45; Interim Office of the Gene Technology Regulator, Exhibit no. 6, pp. 6, 8.