Requirements and regulations – a Victorian perspective

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Introduction

In introducing this area it is important first to sketch the scene in Victoria within which requirements and regulations are established. Requirements can be placed on various parties along a product trail, in this case a 'biotechnology' or 'genetically modified organism' product trail. The requirements may be mandatory, through legislation and regulations, or may be voluntary through Codes of Practice, guidelines for operation etc. When to introduce a regulatory requirement entails Government making an assessment of market failure. Market failure occurs when, for example, the price of a product, or service, does not fully reflect the cost of production.

All Government agencies are under public scrutiny and generally operate in an environment of diminishing resources. If market failure exists, Government then examines the cost of intervention. If the costs of intervention are greater than the benefits it is more efficient if no Government activity takes place.

Whilst the basic principles of market failure are relatively simple actual analysis becomes complex especially when factors are taken into consideration which are difficult to cost and describe, e.g. clean air. Clean air is not priced, and how clean is clean?

Regulating genetically modified organisms: international issues

In determining the requirements for controlling biotechnology and genetically modified organisms (GMOs) an essential element will be assessing the scientific data on risks associated with genetically modified products. The extent to which factors other than science form part of this risk assessment is the subject of considerable debate internationally. Australia strongly supports the principles which have been adopted internationally by the CODEX Alimentarius. CODEX is the international standard setting body underpinning the World Trade Organization (WTO) agreements on trade. These principles endorse the utilization of science in assessing risks. It is however important to note that, as a separate exercise, other factors such as social or ethical issues, can be incorporated into the risk management framework that is subsequently adopted.

The role that science plays in the decision making processes of product regulation is a pivotal one. Internationally the role of science in such situations, especially with respect to GMOs, has become somewhat of a political football with complex scientific issues being judged by the media rather than by scientific peer review. Two prime examples have occurred recently, one being the study involving a laboratory assay of Monarch butterfly larvae feeding on milkweed leaves dusted with Bt maize (corn) pollen (Losey 1999). The other being the reported adverse effects on rats following a diet of genetically modified potatoes and the manner in which the information was released (Masood 1999).

The Monarch butterfly larvae study was carried out at Cornell University (New York, USA) and created alarm in the USA because immediate parallels were drawn by the media between the lab study and the field with predicted dire consequences on this 'conservation icon'. The genetically modified potato research carried out by Dr. Arpad Pusztai (Rowett Research Institute Aberdeen, Scotland) served to fuel the debate raging in the UK over public lack of confidence in the Government's ability to manage risk effectively. In response to increasing public concerns the UK Government recently established a special overarching body to bring together the responsibilities of several existing advisory bodies with responsibilities for gene technology controls (Dickson 1999). This public concern about Government and its role in effective risk management extended beyond the UK with the European Union Commissioners forced to resign over public loss of confidence. Food safety is a key issue in Europe, the position that the new EU Commissioner for consumer protection and health takes will be instrumental in shaping the EU and member states approach in this area (Birchard 1999).

The USA is watching developments in Europe very closely, roughly half of all soya and a third of all maize grown in the US is genetically modified to resist either insects or herbicide. As the US becomes more aware of the unwillingness of its trading partners to accept genetically modified produce the market is beginning to respond by segregating GM from non-GM. One of the largest American food processors in the US, Archer Daniels Midland, has recently started requiring its suppliers to segregate genetically modified from non modified crops. (Kleiner 1999)

Controlling genetically modified organisms: Australia

In Australia gene technology (except for use in humans) has been subject to voluntary assessment in Australia since 1975. Development and use of genetic manipulation techniques is currently overseen by the non statutory Genetic Manipulation Advisory Committee (GMAC), which issues guidelines for contained research, and the release of GMOs into the environment. It aims to ensure that any risks associated with genetic manipulation are identified and can be managed, and advises Ministers about matters affecting the control of genetic manipulation technology. GMAC currently has members drawn from fields including biotechnology, biosafety, environmental science and law.

GMAC oversees the development and use of novel genetic manipulation techniques in Australia. It assesses whether such work poses potential hazards to the community and the environment and recommends appropriate safety measures for researchers and institutions working with GMOs. GMAC has developed guidelines which must be followed for genetic manipulation work. Although these guidelines are non-statutory, GMAC does have the ability to impose some funding sanctions in cases of non compliance.

GMAC operates under a system of local supervision, and for this purpose every research institution carrying out genetic manipulation work must establish an Institutional Biosafety Committee (IBC) to certify containment facilities. IBCs are also responsible for carrying out the initial assessments of proposals for genetic manipulation work and are authorized to allow work of low risk to proceed. Research involving a higher level of risk requires advice from GMAC before being permitted to proceed. GMAC also provides advice to government regulatory agencies on proposals for deliberate release of GMOs into the environment.

Whist GMAC's voluntary control system for biotechnology has served Australia well the need for a regulatory framework for gene technology has been recognized in Australia for several years. Statutory regulation of gene technology was first recommended in 1989 by the Victorian Law Reform Commission. In 1992 the House of Representatives Standing Committee on Industry, Science and Technology also examined this area and recommended that legislation be introduced to enable the approval of release of a genetically modified product. Subsequent joint Commonwealth and State discussions in 1992 led to a proposal for an inter-governmental agreement and draft legislation for

the establishment of a statutory authority in 1994.

However, the joint discussions lapsed until late 1997 when the Commonwealth Cabinet agreed in-principle to support renewed consultations with the States and Territories towards an objective of regulating, to be achieved in part through existing legislation and in part through new legislation. The delays in no way suggest a lack of commitment to developing an appropriate regulatory system by governments, but reflects the difficulties and complexity of the task of integrating gene technology into pre-existing regulatory systems.

The Commonwealth favoured the establishment of a Gene Technology Office within a Commonwealth Department to coordinate all applications related to GMOs or GMO products, and to regulate those GMOs and GMO products falling outside the remits of existing regulatory systems and to harmonize risk determinations.

Since then, a new Commonwealth State Consultative Group (CSCG) has been established. Three working groups have been formed to progress the establishment of an appropriate framework that draws upon Commonwealth and State statutory powers. The thrust of the current regulatory proposal is to focus on regulating end-products using existing mechanisms as far as possible. Accordingly, the proposed gene technology regulatory framework will interface with existing Commonwealth and State arrangements for regulating products in the area of food, pharmaceuticals, industrial chemicals, agricultural and veterinary chemicals, quarantine and wildlife protection. Moreover, the framework will provide for statutory control of research, import and post-approval monitoring.

Through the CSCG, Commonwealth, State and Territory Governments have been working together to develop a nationally uniform legislation system to control gene technology and products which are not covered by current regulatory systems. A set of principles have been agreed upon to guide the development of this new system.

Principles for proposed regulatory framework for GMOs

i. Regulation shall be through a nationally agreed framework.

ii. The regulatory framework shall use existing statutory mechanisms as far as possible, and the regulatory burden shall be kept to a minimum.

iii. The legislative and other controls imposed on all organizations and individuals regarding the research, development, release, and use of GMOs and GMO products shall be consistent throughout Australia; and consistency shall be maintained in the event of any relevant legislative change, taking into account Australia's federal system.

iv. The Commonwealth, States and Territories shall act cooperatively on the matters covered by the regulatory framework, the development of policy guidelines, and the way legislation is administered, consistent with mutually agreed roles and responsibilities for the regulation of gene technology. A prime aim must be to foster innovation.

v. The legislation shall establish an effective framework for good decision making on a case by case basis rather than prescriptive laws that attempt to predetermine what activities, technologies or gene modifications should be permitted.

vi. (a) Decisions made on particular proposals for the application of gene technology shall take into account the views of all participating jurisdictions;
(b) Decisions shall be subject to administrative appeal / review and / or judicial review;
(c) Subject to (a) and (b), all participating jurisdictions shall accept the decisions.
(d) If a participating jurisdiction considers that the release of a GMO or a GMO product will pose an unacceptable risk within its territory, then it may decline to allow release within its own territory or impose additional conditions on release within its own territory.

vii. The regulatory framework shall be consistent with Australia's international obligations and, as far as practicable, regulatory oversight shall be harmonized with that of other countries and regulatory measures and standards shall be compatible with relevant international standards and practices.

viii. The regulatory system, including any legislation, shall be framed to minimize the creation of barriers to innovation or the market entry and exit of firms, and to minimize adverse impacts on Australia's international competitiveness.

ix. Legislation shall be designed to ensure that product liability remains the responsibility of the applicant.

Regulatory processes

x. Processes shall be coordinated, efficient, timely, seamless, simple, transparent, regularly audited and evaluated.

xi. There shall be no conflict of interest in the decision-making and risk assessment processes, which shall be at arm's length from specific interest groups.

xii. The decision-making process shall be based on rigorous scientific risk assessment.

xiii. The decision-making process shall also take into account relevant social, economic and ethical issues and pertinent concerns of individual jurisdictions. For transparency, social, economic and ethical considerations shall be separated from safety issues based on scientific risk assessment.

xiv. Processes shall be sufficiently flexible to adjust the degree of regulation according to the potential hazards posed by individual GMOs or products as experience and knowledge are gained.

xv. Regulatory processes shall be designed to minimize the costs of administration to Government, and the costs of compliance to individuals, businesses and organizations. The costs of regulation shall be borne as far as practical by those wishing to release GMOs or to market products made from them.

The new legislation system requires careful drafting to ensure that it dovetails with current systems and does not create duplication or overlap. Currently Australia has four key product regulatory systems and an export control system that must link effectively with the new legislative system for genetically modified products. The relevant systems are:-

- Foods (including GM foods) are regulated under the Australia and New Zealand Food Authority Act 1991 (Commonwealth) administered by the Australia New Zealand Food Authority (ANZFA) and accompanying State / Territory legislation.
- Therapeutic goods (including GM therapeutic goods) are regulated under the Therapeutic Goods Act 1989 (Commonwealth) administered by the Therapeutic Goods Administration (TGA).
- Agricultural and veterinary (agvet) chemicals (including GM agvet chemicals) are regulated under the Agricultural and Veterinary Chemicals Code Act 1994 (Commonwealth) administered by the National Registration Authority (NRA) and accompanying State / Territory legislation.
- Industrial chemicals are regulated through the national Industrial Chemicals Notification and Assessment Scheme under the Industrial Chemicals (Notification and Assessment) Act 1989 (Commonwealth) administered by the National Occupational Health and Safety Commission (NOHSC) and accompanying State / Territory legislation.
- Australia must meet its international trading obligations whilst ensuring that imports / exports are effectively controlled. Imports / exports are regulated under the Quarantine Act 1908 (Commonwealth), the Imported Food Control Act 1992 (Commonwealth) and the Export Control Act 1992

(Commonwealth) administered by the Australian Quarantine and Inspection Service and also under Wildlife Protection legislation administered by Environment Australia.

In May 1999 it was determined that responsibility for the proposed new control system for gene technology would lie with the Federal Minister for Health and Aged Care. An interim Office for the Gene Technology Regulator was established and GMAC, which resided in the Department of Industry Science and Resources, was moved into Health and Aged Care. A web site has been established at www.health.gov.au/tga/genetech/purpose.htm which provides information and updates on developments. The Government has set a target date of 3 January 2001 to have the Office of the Gene Technology Regulator fully operational.

Under the proposed new system the role of GMAC will remain essentially the same i.e. to assess risk. However, as well as risk assessments of the technology, it will also perform risk assessments for products which are not currently covered by other regulatory systems. GMAC will become the Gene Technology Advisory Committee and provide advice to the Gene Technology Regulator. The Gene Technology Regulator will have the statutory power to approve (or otherwise) gene technology products. However, where the intended product is covered by a current regulator, e.g. a food or a therapeutic good, that regulator retains its responsibilities and functions in assessing such products. Establishing these essential linkages with current regulators is a complex issue to be addressed in the proposed new legislation for the Office of the Gene Technology Regulator.

Product regulation systems can be shown diagrammatically (Figure 1). Many interactions exist between current agencies and new interactions will need to be established between them and the Office of the Gene Technology Regulator. In addition, whilst not strictly a product regulator, Environment Australia will provide advice on environmental issues as it does currently for all product regulatory systems in Australia.

References

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Figure 1. Product regulatory pathways.