# 7

# Regulation

## Introduction

7.1 Regulation of GMOs has been established to protect human health and the environment from risks that may arise from the use of GMOs, while at the same time assisting organisations developing and selling GMOs by indicating clearly what is required of these organisations. In terms of primary producer access to gene technology, there are several regulatory processes of significance:

- those that govern their release for commercial use by farmers;
- those that assess food safety and impose labelling requirements, for example, for GM content; and
- international agreements, such as the Biosafety Protocol.

## Regulating GMOs

7.2 Changes are being made to the system that regulates GMOs in Australia. It is expected that the Gene Technology Bill will be introduced into Parliament in the near future with a view to new arrangements coming into force in January 2001. **The committee believes that the bill's provisions must ensure that a more comprehensive, independent and rigorous regulatory system for GMOs is established than exists at present.** The need for an improved regulatory regime stems from three developments as gene technology has expanded:

- an increasing number of GMOs that are not directly regulated by the existing agencies, for example, herbicide tolerant crops;

- more crops reaching the stage at which their proponents are likely to apply for their commercial release; and
- community and industry expectations.[1]

## Current legislative arrangements[2]

7.3 At present, there is no single regulatory body for GMOs; a number of different agencies are involved. The nature of each GMO determines which agency (or agencies) is (are) responsible for regulating it.

- Food is regulated under the *Australia New Zealand Food Authority Act 1991*, which is administered by ANZFA and accompanying state and territory legislation. ANZFA alone among regulatory agencies administers a standard specific to GMOs; the other agencies assess, or would assess, GM products in the same way as any other product.
- Therapeutic goods are controlled by the *Therapeutic Goods Administration Act 1989*, which is administered by the Therapeutic Goods Administration.
- Agricultural and veterinary chemicals fall under the *Agricultural and Veterinary Chemicals Code Act 1994*, which is administered by the NRA and accompanying state and territory legislation. The NRA was involved in regulating the release of Ingard® cotton, on the grounds that the genetic modification of the cotton plants had caused the plants to produce a pesticide. It would also be involved with respect to herbicide tolerant crops in so far as it would need to approve the use of the relevant herbicide to take into account that the crop was modified.[3]
- Industrial chemicals are covered by the *Industrial Chemicals (Notification and Assessment) Act 1989*, which is administered by the National Occupational Health and Safety Commission and accompanying state and territory legislation.
- Imports and exports are regulated by the *Quarantine Act 1908*, the *Imported Food Control Act 1992*, and the *Export Control Act 1982*, which are administered by the Australian Quarantine and Inspection Service (AQIS). Imports and exports are also regulated by wildlife protection legislation administered by EA.

1 *Explanatory Guide to the Draft Commonwealth Gene Technology Bill 2000*, December 1999, p. 5.

2 Information in this and following sections of the chapter draw on Submission no. 78 from the Interim Office of the Gene Technology Regulator.

3 Grains Research and Development Corporation, Submission no. 47, p. 12.

7.4 GMAC oversees all research work in Australia involving the use of GMOs and genetic modification techniques. It scrutinises all stages in the development of GMOs from proposals for research through to their general release into the environment. GMAC's work underpins all the regulatory arrangements described above.

## Interim arrangements

7.5 Since the inquiry was announced at the end of March 1999, changes to the regulatory system have been introduced. In May 1999, interim arrangements were put in place while legislation to change the current system was developed with community and state and territory government input. The IOGTR was established in the Department of Health and Aged Care (DHAC), and GMAC was moved to that department from the Department of Industry, Science and Resources. Until the new legislative controls are in place, the Minister for Health and Aged Care will make decisions, in consultation with other ministers as appropriate, on the general release of GMOs.

7.6 The IOGTR is part of the Therapeutic Goods Administration of DHAC, and is responsible for:

- regulating all aspects of the development, production and use of GMOs and their products, where no existing regulatory body has responsibility;
- working with other regulatory bodies to ensure the consistent application of standards and to harmonise genetic safety assessments across all systems of regulation; and
- undertaking or commissioning research in risk assessment.

IOGTR's position in the health portfolio places it at arms length from industry programs, and reflects the government's view that protecting the environment and the public's health and safety are the paramount concerns.

7.7 Other aspects of the interim arrangements also contribute to making the regulatory process more transparent, accountable and rigorous.

- GMAC's operations are being revised, for example, to include more public input, more publicly available information and a broader basis for GMO risk assessment than at present. Both biosafety and agricultural sustainability must be considered.
- Contracts and agreements will be finalised between the government and proponents of commercial releases of GMOs to provide for greater assurance of compliance with the conditions imposed on releases.

# Regulating agricultural GMOs

## Deficiencies

7.8 This section summarises views expressed in submissions and during public hearings. It should be remembered, however, that most of the input to the inquiry was made before the draft Gene Technology Bill was released in December 1999, and some of it before the interim arrangements were put in place in May 1999.

7.9 There was general agreement that the regulatory regime that was in place in early 1999 was deficient. State governments, industry, and groups engaged in R&D complained that the lack of a clear regulatory pathway was hampering the introduction of GM varieties.[4] Uncertainty was a disincentive both to innovation in Australia, to exporters and to overseas corporations that were considering bringing their products to the Australian market.[5] The Victorian government commented that:

> In the absence of a regulatory system in Australia which provides a clearly defined pathway to the market, gene technology owners face high costs and high risks of failure. …
>
> Until an effective regulatory system is in place, gene technology owners will not be able to invest with any certainty in the infrastructure needed to commercialise GM varieties.[6]

7.10 An example of the difficulties encountered in the face of regulatory deficiencies was provided to the committee by CSIRO. CSIRO's submission described how new regulatory requirements involving the NRA were developed in response to an application for the commercial release of Bt cotton. The submission continued:

> At the time it caused some degree of uncertainty and costs to meet newly developed NRA regulatory requirements but nevertheless provided a pathway by which the entire new cropping system could be introduced, monitored and managed in the field.

In addition, at that time, 'similar arrangements [were] not in place … for introducing new genes to confer resistance to plant diseases such as rust, nematodes, scald, etc or indeed when breeding herbicide tolerant crops'.[7]

4 For example, New South Wales government, Submission no. 72, p. 8.

5 Queensland government, Submission no. 79, p. 4.

6 Victorian government, Submission no. 67, p. 3.

7 CSIRO, Submission no. 56, pp. 3-4.

7.11 Nor are they in place for approving GM livestock.[8] CSIRO recounted its experience with GM pigs:

> Bresagen produced a line of commercially viable pigs with enhanced growth hormone production with the advantage that the pigs grew faster for a given amount of food, putting on more muscle and less fat. Because there was no regulatory agency prepared to approve the use of these animals for human consumption and declare the technology safe, Bunge has slaughtered all the pigs and the germplasm is in existence as semen (and perhaps ova) stored in liquid nitrogen. It is highly likely that this technology will go overseas. It is not the inability of the Australian company that produced the pigs to commercialise them but the lack of a regulatory pathway that has caused the problem.[9]

7.12 Regulatory deficiencies slowed assessment and release of varieties submitted for approval.[10] They were seen as likely to become a more critical issue in the future. The committee is aware that the time taken to gain regulatory approval was among the three most frequently mentioned hurdles in commercialising biotechnology in Australia, according to 90 companies surveyed by Ernst and Young.[11] Regulatory delays increased the cost of bringing GMOs to market and contributed to regulation, along with IP, being key cost items in producing GM varieties. The impact of delays on cost is particularly significant, given that regulatory costs can amount to $50-100 million.[12] The application of gene technology to minor crops was particularly likely to be affected by regulatory costs.[13]

7.13 Others found Australia's regulation of GMOs defective for different reasons.[14]

- Compliance with guidelines developed by GMAC and SCARM[15] is voluntary. Independent verification of compliance with these

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8 Academy of Science, Submission no. 62, p. 3.

9 CSIRO, Submission no. 56, Attachment 2, p. 17.

10 National Farmers' Federation, Submission no. 36, p. 2.

11 Ernst & Young, *Australian Biotechnology Report*, Commonwealth of Australia, 1999, p. 45.

12 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 236.

13 Centre for Legumes in Mediterranean Agriculture, Submission no. 14, p. 4; Cooperative Research Centres Association, Submission no. 40, p. 8; Grain Biotechnology Australia, Submission no. 68, p. 4.

14 Australian GeneEthics Network, Submission no. 71, p. 12; Organic Federation of Australia, Submission no. 24, p. 5; Supplementary submission no. 73, p. 3; Senator Stott-Despoja, Submission no. 28, pp. 6-7.

15 Genetic Manipulation Advisory Committee, *Guidelines for the Deliberate Release of Genetically Manipulated Organisms*, April 1998; Working Group of the Standing Committee on Agriculture

guidelines is not carried out, for example, in relation to refugia among Bt cotton crops. GMAC lacks the statutory power to enforce its decisions, and no penalties are applied to persons who fail to observe the guidelines.

- Both GMAC and the institutional biosafety committees that oversee the implementation of GMAC guidelines in individual companies and institutions are dominated by proponents of gene technology. These groups operate without adequate accountability.
- The buffer zones around GM crops are insufficient to protect organic and GM free crops growing nearby.

7.14 Several witnesses to the inquiry welcomed the establishment of the IOGTR, and supported the changes made under the interim arrangements.[16] Others, while approving the changes, regretted the slow pace at which they were being introduced.[17] The NFF commented that 'we are behind the US and Europe in establishing a regulatory framework'.[18] AAA claimed that:

> … Roundup Ready cotton was about to get its final approval through the previous process; but with the introduction of the Interim Office of the Gene Technology Regulator, that has been set back a year.[19]

7.15 The siting of the OGTR in DHAC was seen as reassuring to those anxious to ensure that the health impacts of GMOs are adequately regulated. However, users of gene technology in agriculture were concerned that their interests might not be given sufficient attention.[20] Mechanisms by which the interests of primary producers could be brought to the regulator's attention were discussed in submissions to the inquiry.[21] For example, regular consultation by DHAC with Commonwealth, state and territory agriculture agencies and CSIRO, among others, was recommended by the New South Wales government.[22]

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and Resource Management, *Good Agricultural Practice Guidelines for the Use of Genetically Modified Plants*, March 1999.

16 Australian Barley Board, Submission no. 60, p. 9; Australian Biotechnology Association, Submission no. 39, p. 8; CSIRO, Submission no. 56, p. 4; industry participants at a private meeting held in Perth in July 1999; Western Australian government, Submission no. 48, p. 5.

17 Agrifood Alliance, Submission no. 37, p. 5.

18 National Farmers' Federation, Submission no. 36, p. 15.

19 Agrifood Alliance Australia, Transcript of evidence, 29 September 1999, p. 192.

20 Grains Council of Australia, Transcript of evidence, 30 August 1999, p. 134.

21 Grains Council of Australia, Submission no. 65, p. 4; CSIRO, Submission no. 56, p. 4.

22 New South Wales government, Submission no. 72, p. 9.

7.16 **The committee believes that it is entirely appropriate for the OGTR to be in the health portfolio, given the level of concern about the possible risks that GMOs pose.** Furthermore, the committee feels that those who suggested meetings between government agricultural agencies and DHAC are missing the point that the GTR is to be an independent statutory office holder. **It is vitally important in establishing public trust in the regulatory system that the regulator is seen to be free of commercial pressures.**

7.17 The committee was very concerned to hear allegations earlier this year that Aventis' (formerly AgrEvo) trials of herbicide tolerant canola in the Mount Gambier area of South Australia had breached GMAC guidelines. It is even more worried by the manner in which the IOGTR has investigated the alleged breaches, in particular its tardiness in completing its investigation. The IOGTR began its examination of the allegations on 24 March 2000[23] and, as at 18 May, the results of this examination had not even been forwarded to the Minister for Health and Aged Care,[24] let alone been publicly released.

7.18 The committee is of the view that the alleged breaches would have been much less likely to have occurred if stringent, transparent regulatory processes, such as those described in the next sections of this chapter, had been in place. The committee is unanimous in believing that rigorous, independent regulatory processes must be instituted as quickly as possible. A more prompt, open, transparent approach must be taken to breaches of guidelines. It is essential that the OGTR act much more efficiently and effectively than the IOGTR has been able to if it is to reassure the Australian people that their interests are being strenuously protected. If this does not happen, public confidence in GMOs and their regulation will be badly prejudiced.

## Characteristics of the ideal regulatory system

7.19 The type of regulatory system that is needed was described in many submissions to the inquiry. The importance of getting it right was also stressed. This was seen as critical to public acceptance of GMOs in agriculture and food, as well as to commercialising new inventions.[25] For example, with respect to cotton, CSIRO emphasised that:

23 Interim Office of the Gene Technology Regulator, Exhibit no. 7, p. p. 1.

24 Interim Office of the Gene Technology Regulator, covering letter to Supplementary submission no. 87.

25 AgrEvo, Submission no. 55, p. 4; CSIRO, Submission, no. 56, p. 1.

> This technology is critically important for the future of the industry, and if it is mismanaged it will go the same way as the chemical insecticides and we will waste it.[26]

7.20 Regulation should be comprehensive, clear, rigorous, impartial, independent, objective, transparent, accountable, and put in place as soon as possible.[27] Clarity depends on having in place such elements as defined and documented processes, accepted standards and codes, clear data requirements, and assessment reports.[28] Independent, impartial assessments could be assured by:

- basing assessments on replicable findings only; and
- requiring the same type of peer review of the research evidence submitted by commercial companies to the regulatory bodies as is applied to published research.[29]

A comprehensive, rigorous regime would also require post approval monitoring of compliance with the conditions imposed on those using GMOs and effective sanctions to maximise compliance.[30]

7.21 The regulatory regime must provide confidence to the community that their health and the environment are being adequately protected while, at the same time, giving industry and farmers certainty about the requirements imposed on them.[31] These requirements should be the minimum to effectively and efficiently ensure health and environmental safety.[32]

7.22 Another view put to the committee was that government also has a clear responsibility to regulate to protect the organic and GM free food industries from 'contamination' by GMOs. Such measures as wider buffer

26 CSIRO, Transcript of evidence, 18 October 1999, pp. 207-8.

27 For example, Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 1; Agrifood Alliance Australia, Submission no. 37, p. 4; Australian Biotechnology Association, Submission no. 39, p. 6; Australian Food and Grocery Council, Submission no. 59, p. 6; Dairy Research and Development Corporation, Submission no. 15, p. 7; Grain Biotechnology Australia, Submission no. 68, p. 5; National Association for Sustainable Agriculture, Australia, Submission no. 74, p. 2; New South Wales government, Submission no. 72, pp. 8, 13; Organic Federation of Australia, Supplementary submission no. 73, p. 3.

28 Environment Australia, Submission no. 82, p. 16.

29 'BMA response to Chief Medical and Scientific Officers' review of GM foods and health', Media release, 21 May 1999; *First Australian Consensus Conference: Gene Technology in the Food Chain: Lay Panel Report*, Canberra, March 1999, p. 4; Environment Australia, Submission no. 82, p. 16; A Kellow, 'Risk assessment and decision-making for genetically modified foods', *IPA Biotechnology Backgrounder*, no. 1, October 1999, p 4.

30 Organic Federation of Australia, Supplementary submission no. 73, p. 3.

31 Australian Food and Grocery Council, Submission no. 59, p. 10; Avcare, Submission no. 61, p. 7.

32 Australian Food and Grocery Council, Submission no. 59, p. 3.

zones and mandatory reporting of GM crops to local farmers and local, state and regional management authorities were supported.[33]

7.23 Consultation with the public is an important element of regulating gene technology.[34] OFA suggested that:

> Decision-making must include representation from all stakeholders, whereby the needs of consumer, government, science, environmental, health, social, ethical and industry interests are all EQUALLY met.[35]

7.24 In addition, a national, coordinated approach is needed, with flexibility to adjust to rapid changes in the fields of plant breeding and gene technology.[36] The separate elements of the regulatory system, which are described at the start of this chapter, must be fully integrated into the regulatory regime and consistency of approach established across these elements. Duplication must be avoided.[37]

7.25 Furthermore, the system should be internationally competitive,[38] and regulatory clearances harmonised at a global level.[39] If Australia's regulations are consistent with our international obligations and recognised internationally, we will not be seen as erecting non trade barriers nor will we encourage other countries to do likewise.[40]

### The case by case, scientifically based approach

7.26 There was one point on which a difference of opinion among witnesses existed in relation to the type of regulatory system needed. It was the extent to which a science-based, case by case approach to regulating GMOs is desirable. Such an approach received support from organisations such as the AFGC, the NFF, representatives of the cotton industry, and the Veterinary Manufacturers and Distributors Association.[41]

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33 Organic Federation of Australia, Supplementary submission no. 73, p. 3.

34 Australian Biotechnology Association, Submission no. 39, p. 6; National Association for Sustainable Agriculture, Australia, Submission no. 74, p. 2; National Genetic Awareness Alliance, Submission no. 54, p. 3.

35 Organic Federation of Australia, Submission no. 24, p. 5.

36 Western Australian government, Submission no. 48, pp. 4-5.

37 Australian Barley Board, Submission no. 60, p. 2; Grains Council of Australia, Submission no. 65, p. 16.

38 Grains Council of Australia, Submission no. 65, p. 16.

39 Avcare, Submission no. 61, p. 7.

40 Australian Barley Board, Submission no. 60, p. 2; National Farmers' Federation, Submission no. 36, p. 15.

41 Representatives of the Australian cotton industry, Transcript of evidence, 18 October 1999, pp. 207, 208; National Farmers' Federation, Submission no. 36, p. 15; The Veterinary Manufacturers and Distributors Association, Submission no. 76, p. 8.

7.27 Others, however, had reservations about it.[42] The consensus conference on gene technology in the food chain held in March 1999 suggested that 'decisions by any regulatory body should take into account more than just science'.[43] Professor Kellow pointed out that risk assessment of GM foods requires 'careful analysis of the best available science, an understanding of the social and psychological factors which will inevitably intrude into the process, and careful policy analysis'. He suggested that, in addition to science, statistics, ethics, economics, sociology, political science and the views of the public must all be involved.[44]

7.28 A British study commented on the narrow remit of regulators and called for broader consideration of the issues relating to the introduction of GM crops and food.[45] This study outlined the limitations of the scientific method and saw it as being ill equipped to tackle the diffuse effects of new technologies. The study also drew attention to the fact that:

> Scientific judgements on risks and uncertainties are underpinned and framed by unavoidably subjective assumptions about the nature, magnitude and relative importance of these uncertainties. These "framing assumptions" can have an overwhelming effect on the results obtained in risk assessments.
>
> … in any given context, more than one set of assumptions may be equally reasonable in appraisal. … The adoption of any particular set of framing assumptions in risk assessment must therefore be justified … in terms of factors such as:
>
> - the legitimacy of the institution making the justification;
> - the degree of democratic accountability to which the institution is subjected; and
> - the ethical acceptability of the assumptions adopted.[46]

7.29 A strong argument was mounted for reliance on a precautionary approach in assessing risks. This is a commonsense attitude to guide action but can be misused. Professor Kellow pointed out that, as everything is capable of

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42 Senator Stott-Despoja, Submission no. 28, p. 7.

43 *First Australian Consensus Conference: Gene Technology in the Food Chain:: Lay Panel Report*, Canberra, March 1999, p. 4.

44 A Kellow, 'Risk assessment and decision-making for genetically modified foods', *IPA Biotechnology Backgrounder*, no. 1, October 1999, pp. 5, 7.

45 *The Politics of GM Food: Risk, Science & Public Trust*, Economic & Social Research Council, Special Briefing No. 5, October 1999, p. 10.

46 *The Politics of GM Food: Risk, Science & Public Trust*, Economic & Social Research Council, Special Briefing No. 5, October 1999, p. 7.

causing harm under some circumstances, it is important that the precautionary principle not be misused. [47] EA suggested that:

> The precautionary principle has particular application to GMOs. Not only could direct damage be serious, but ongoing and extensive because of irreversibility. Once released freely to the environment, a living organism, or a novel gene that has transferred to an unintended host, cannot be 'recalled'. A cautious and conservative approach to risk should be followed where there is insufficient scientific confidence of safety. Successful application of the principle will mean that Australia avoids expensive failures.[48]

7.30 Concerns have been raised that the overall impact of the technology on agriculture and the environment and the long term effects of GMOs may be missed by relying on a case by case approach to regulation. The Royal Society (London) recommended the establishment in the UK of 'an over-arching body or "super-regulator" … to span departmental responsibilities and have an ongoing role to monitor the wider issues associated with the development of GM plants'.[49] The Nuffield Council on Bioethics made a similar recommendation for an independent biotechnology advisory committee 'to consider within a broad remit, the scientific and ethical issues together with the public values associated with GM crops'.[50]

## Gene Technology Bill

7.31 The committee was advised by the IOGTR that the Gene Technology Bill will address many of the points listed above, as well as other concerns about the use of GMOs in agriculture which are covered in Chapter 2. The Bill has been developed on the basis of extensive consultation with state and territory government officials, existing regulators, Commonwealth agencies, and a very broad range of non government stakeholders (industry, primary producers, environmental and consumer groups and the R&D sector). A discussion paper was issued by the Commonwealth and State Consultative Group on Gene Technology in October 1999. Taking account of comments made on this paper, a draft version of the bill and an explanatory guide were circulated in December 1999.

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47 A Kellow, 'Risk assessment and decision-making for genetically modified foods', *IPA Biotechnology Backgrounder*, no. 1, October 1999, p. 6.

48 Environment Australia, Submission no. 82, p. 9.

49 The Royal Society, 'Genetically modified plants for food use', 1998, http://www.royalsoc.ac.uk/st_pol40.htm, accessed 12 July 1999.

50 *Genetically Modified Crops: The Ethical and Social Issues*, Nuffield Council on Bioethics, London, May 1999, p. xv.

Consultations on the draft legislation were held in February and early March 2000.

7.32 The bill has not yet been introduced into Parliament, so the final details are not yet known. However, the policy underpinning the legislation is, as advised by the IOGTR:

- to protect public health and safety and the environment;
- to be based on scientific assessment of risks along with consideration of broader issues of national interest and ethics;
- to operate in conjunction with existing regulators and avoid unnecessary duplication;
- to be nationally consistent, efficient and effective;
- to be characterised by transparent and accountable decision making;
- to rely on extensive stakeholder and community involvement; and
- to provide a streamlined and efficient pathway for industry.[51]

7.33 The IOGTR advised the committee that many of the deficiencies noted above have been addressed. The regulatory regime possesses many of the needed characteristics of a best practice system, as listed above. The IOGTR claimed that the governance structure proposed in the new legislation, which is shown in Figure 7.1, reflects good regulatory practice, as seen in other Australian regulatory bodies.[52]

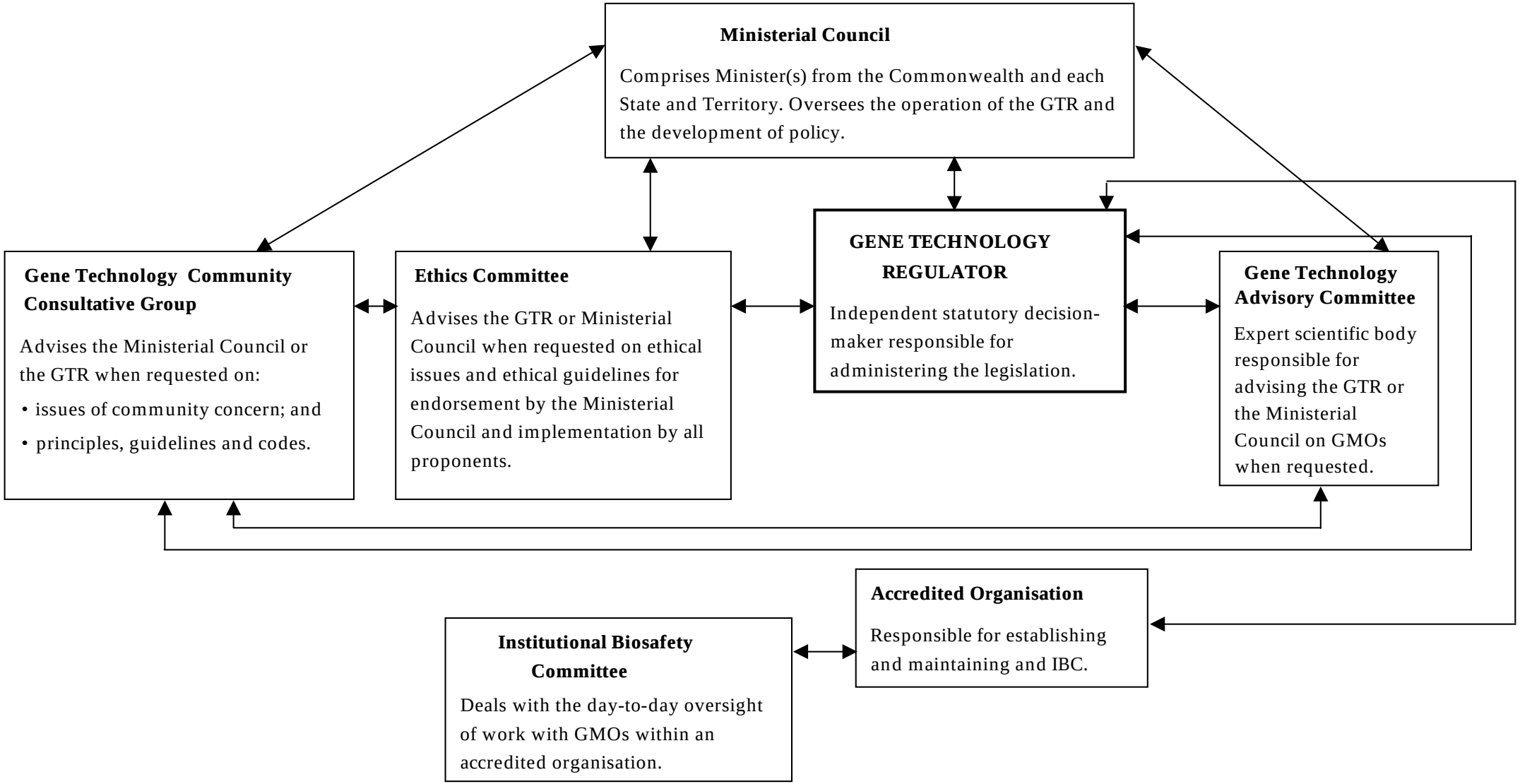
- Comprehensiveness - it covers all GMOs and GM products, from the start of laboratory work onwards, and covers the entire life cycle, including trash and offspring.[53]

51 Office of the Gene Technology Regulator, Exhibit no. 6, p. 2.

52 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, pp. 6-7.

53 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 270.

**Figure 7.1 Proposed governance structure for gene technology regulation***




**Note: it is proposed that all committees and groups have some overlapping membership with the other committees and groups.*

*Source: Department of Health and Aged Care, http://www.health.gov.au/tga/gene/genetech/generegs.pdf, accessed 30 March 2000; Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, pp. 5, 10, 11, 13.*

- Transparency, clarity and accountability:
  - ⇒ notifications about field trials will contain a high level of information, omitting only commercial in confidence material; tight criteria will be applied to assess confidentiality;[54]
  - ⇒ information will be provided in the Gazette, on the internet, in newspapers and by direct mail to interested persons and local governments in affected areas; regulations may require notification or consultation with neighbouring property owners;[55]
  - ⇒ both detailed scientific information and information in plain English will be available;[56]
  - ⇒ applications and draft determinations for the general release of GMOs will be released for public comment;[57]
  - ⇒ guidelines will spell out in detail the requirements for risk assessment;[58] and
  - ⇒ the GTR will report on monitoring activities and suspected breaches of the Act in its annual report to Parliament.[59]
- Independence and impartiality:
  - ⇒ the GTR will be a statutory office holder responsible for the day to day administration of the office; he / she will not be 'subject to direction from anyone in relation to whether or not a particular application for a GMO licence is issued or refused or the condition to which a particular GMO licence is subject';[60]
  - ⇒ the GTR is not inherently pro gene technology; he / she will focus on risks and not on cost / benefit analysis; economic or trade issues could not 'under any circumstances' override environment or human health concerns;[61]

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54 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 271, 276-7.

55 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 276, 278.

56 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 274.

57 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 271.

58 Interim Office of the Gene Technology Regulator Supplementary submission no. 87, p. 23.

59 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 18.

60 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 284; Supplementary submission no. 87, p. 9.

61 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 280; Supplementary submission no. 87, p. 16.

- ⇒ members of GMAC's replacement, the Gene Technology Technical Advisory Committee (GTTAC) will be subject to stringent conflict of interest and disclosure of interest provisions;[62] and
- ⇒ appeals against decisions may be made through reviews carried out internally, by the Administrative Appeals Tribunal, by the Federal Court under the *Administrative Decisions (Judicial Review) Act 1977*, and by the Ombudsman.[63]

- Objectivity - scientific assessment of risk will be continued by GTTAC, which will comprise 20 members with expertise in molecular biology, plant and animal genetics, public health and environmental systems. It will also be able to call on expert advisers.[64]

- Compliance:
  - ⇒ compliance will be encouraged by clean up orders and heavy penalties;[65] and
  - ⇒ a number of monitoring mechanisms will be established: the licence holder will be required to report the results of his/her monitoring activities to the GTR, and the GTR will independently monitor compliance, and appoint inspectors to carry out planned and unplanned inspections, including when breaches of licence conditions are suspected.[66]

- Effectiveness and efficiency:
  - ⇒ by categorising and regulating each GMO according to the level of risk that it presents, the regulatory burden is minimised to an appropriate level (see Appendix D);[67]
  - ⇒ the GTR will, at any time, be able to review any GMO approval and to add or vary conditions of its use;[68]
  - ⇒ evaluating a GMO's risk characteristics after obtaining experience with its use allows for that GMO's reclassification and the removal of

62 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 8.

63 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 21.

64 Interim Office of the Gene Technology Regulator, Exhibit no. 6, p. 5; Supplementary submission no. 87, pp. 10-11.

65 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 266, 270.

66 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 18.

67 Interim Office of the Gene Technology Regulator Proof transcript of evidence, 5 April 2000, pp. 263, 272.

68 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 18.

the requirement to licence, if risks have not been identified; such GMOs will be placed on a register;[69] and

⇒ the IOGTR will lead work on harmonising regulatory processes among existing regulatory agencies.[70]

- Consultation:
  - ⇒ community input will be possible in relation to applications for general release of GMOs, as indicated above;
  - ⇒ the Gene Technology Ethics Committee (GTEC) will conduct public consultations when developing guidelines;[71] and
  - ⇒ the members of the Gene Technology Community Consultative Group (GTCCG), with their experience with gene technology research and community impacts, and consumer, environmental, public health, primary producer, industry and local government issues, will provide advice to the Ministerial Council, as shown in Figure 7.1.[72]
- A nationally coordinated approach - it is expected that an intergovernmental agreement will be reached by the Commonwealth and state and territory governments, and complementary legislation may be enacted.[73]
- Protection for the organic and non GM industries – acting on a broad definition of the environment, the GTR will be able to set conditions to limit contamination of non GM by GM crops and punish breaches. The bill defines the environment as including 'ecosystems and their constituent parts, and natural and physical resources, and the qualities and characteristics of locations, places and areas'.[74]
- Ethical concerns - the 12 members of the GTEC Committee will advise the GTR and the Ministerial Council on ethical issues and guidelines, which will underpin the regulatory scheme. The guidelines 'would come in through the bottom of the system', for implementation by institutional biosafety committees in each institution using GMOs, so that 'any researchers undertaking work would have to observe those

69 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 273.

70 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 265.

71 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 14.

72 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 12.

73 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 266, 268.

74 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 265-6.

ethical guidelines'. The committee will be modelled on the Australian Health Ethics Committee which is established under the National Health and Medical Research Council legislation in relation to human health. Its members will have a range of skills and experience and will be able to access other experts.[75]

7.34 The committee is aware that a requirement for the GTR to report annually to the Parliament has been proposed for the new legislation. The GTR's reports would include, among other matters, information about monitoring activities and suspected breaches of guidelines. The committee believes that the transparency of the regulator's operations would be improved if he/she reported more frequently than annually for the first three years of the OGTR's existence.

### Recommendation 30

7.35 **The committee recommends that the Office of the Gene Technology Regulator report to the Parliament at least quarterly for the first three years of its existence.**

7.36 Other legislation will support the objectives of the gene technology legislation. An amendment to the *Environment Protection and Biodiversity Conservation Act 1999* has been foreshadowed which will allow for environmental impact assessment before GMOs are released into the open environment.[76]

## Issues of concern

### Cost recovery

7.37 The proposal to recover the full costs of regulating GMOs was received with concern by primary producers.[77] In addition, the GRDC argued that industry should not fund the implementation of regulation for GMOs; it suggested that Commonwealth and state government resources should be

75 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 282-3; Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 14.

76 Environment Australia, Submission no. 82, p. 23.

77 Grain Biotechnology Australia, Submission no. 68, p. 4; Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 262.

provided for this task 'commensurate with the potential loss to the competitiveness of Australia's agricultural sector'.[78]

7.38 The IOGTR reported to the committee that it will not be possible to fully cost the regulatory system until:

- the legislation has been passed by the Commonwealth government and regulations developed;
- model state legislation is drafted; and
- the Gene Technology Inter-Governmental Agreement has been signed.

An independent analysis of costs will then be conducted.[79]

7.39 The committee agrees with the view that industry should not fund the setting up of the regulatory system. The committee recognises that adding to regulatory costs by charging users may act as a deterrent to the use of biotechnology.

### Keeping an eye on the wider picture

7.40 Another issue raised earlier in this chapter concerns the limitations of the case by case approach to regulation. The committee feels that such an approach is entirely appropriate for governing the use and release of individual GMOs. As discussed above, however, it has been suggested that this approach may well miss some of the broader impacts of introducing GMOs.

7.41 The committee is aware that the gene technology legislation will establish a community consultative group and an ethics committee, whose members will possess expertise in such matters as:

- health, environmental and applied ethics, law, religious practices, and animal health and welfare for the ethics committee; and
- consumer, environmental, primary producer, industry and local government issues on the consultative group.[80]

In addition, the membership of GTTAC will be wider than GMAC's and will represent 'a balance of reductionist and holistic approaches'.[81] The committee believes that these bodies will be able to provide input to the regulatory process about the more diffuse impacts of introducing GMOs.

78 Grains Research and Development Corporation, Submission no. 47, p. 13.

79 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 20.

80 Interim Office of the Gene Technology Regulator, Exhibit no. 6, p. 5.

81 Interim Office of the Gene Technology Regulator, Exhibit no. 6, p. 5.

7.42 In Chapter 2, the committee referred to proposals in the UK to address this issue by the appointment of a super regulator or an independent biotechnology advisory committee. The Royal Society envisaged that the super regulator's functions would include such activities as:

- review mechanisms by which GM crop plants could be monitored in the environment and make recommendations for long term monitoring of their impact on ecosystems;
- review available methods for minimising gene transfer and make recommendations regarding further research;
- review the appropriateness of current arrangements and recommend changes relating to:
  - ⇒ testing for allergenicity and toxicity of GMOs; and
  - ⇒ managing herbicide tolerant and pest resistant crops; and
- consider the effects of GM crops in comparison with the effects of current agricultural practices in general on ecosystems and the environment as a whole.[82]

7.43 The committee considers that the three advisory committees (GTTAC, GTEC and GTCCG) will possess the expertise to assess the broader impacts of GMOs. As Figure 7.1 shows, these committees' relationships with the GTR and the Ministerial Council provide opportunities for the wider picture to be brought to the attention of ministers and the regulator. The committee believes that the GTR should take account of the more diffuse impacts of GMOs when issuing licences, with responsibility for bringing forward relevant information about these impacts resting with GTTAC, GTEC and GTCCG.

## Regulating GM food safety

7.44 Farmers' decisions about growing GM crops or livestock will be influenced by the domestic and international standards required of the food derived from their produce. In January this year, the European Union approved new rules requiring food companies to label products containing more than one per cent of GM food. These rules came into effect in February and apply to domestically produced and imported food. They are the strictest in the world. Japan and South Korea, among others, are also reported to be moving to introduce GM food labelling.

82 The Royal Society, 'Genetically modified plants for food use', 1998, http://www.royalsoc.ac.uk/st_pol40.htm, accessed 12 July 1999.

7.45 In Australia, the existing standard for labelling for GM content (Standard A18) requires all GM commodities:

- to go through a pre market safety assessment; and
- to be labelled if they contain new and altered genetic material and/or are significantly different from conventionally produced food in terms of nutritional quality, composition, allergenicity or end use

7.46 This standard is under review by the Australia New Zealand Food Standards Council (ANZFSC), which comprises the health ministers of the states and territories and the Australian and New Zealand governments. In August 1999, the council agreed to extend labelling requirements to all foods produced using gene technology, and in October a draft standard was released for public comment. The council will consider the matter at a meeting in July.

7.47 The move to improve the labelling of GM food is being driven by consumer concerns about their safety. Notwithstanding the fact that ANZFA carries out pre market safety assessments on all food released for sale, ANZFSC acknowledges that consumers who do not want to eat GM food should be able to make that choice.

7.48 International food standards are set by the Codex Alimentarius Commission, which is a subsidiary body of the FAO and the WHO. At present there is no Codex Alimentarius standard for labelling the GM content of food which might provide a guide to national food regulators.[83] Furthermore, it is unclear what position the commission will adopt.[84] Once an international standard is in place, however, Australia may be restricted in how stringently it can regulate.

7.49 Under two international agreements to which it is party,[85] Australia may not regulate more stringently in terms of trade restrictions than the standards set down in the Codex Alimentarius. More stringent regulation is allowed only if:

- there is a strong, scientifically based concern that a food product could threaten human, plant or animal health or survival; and

83 I. Lindenmayer, 'Regulating genetically modified food', speech prepared for the APEC Technomart III Conference, Queensland, November 1999, p. 7, http://www.anzfa.gov.au/documents/sp008_99.asp, accessed 11 February 2000.

84 Australia New Zealand Food Authority, Transcript of evidence, 8 March 2000, p. 253.

85 The Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade.

- there are justifiable concerns in relation to national security, environmental protection, or deceptive trade practices.[86]

For this reason, ANZFA brought to the attention of the WTO its Standard A18 which regulates GM foods.[87]

## Costs imposed by labelling

7.50 Mandatory labelling will impose significant additional costs on suppliers of GMOs. It has been estimated, for example, that to identity preserve grain would add 5-15 per cent to delivery costs in world markets.[88]

7.51 A study commissioned last year by ANZFA made preliminary estimates of the cost that might be involved for the entire Australian food industry. Reporting on the basis of a limited analysis that used a highest cost scenario and was carried out within a short time frame, the study found that:

- the cost to industry would be six per cent in the first year and three per cent per annum thereafter;
- prices could rise between 5 and 15 per cent, depending on the content of GM food; and
- regulatory costs would be between $7 million and $150 million per annum, depending on the rigorousness of the regime instituted.[89]

7.52 The study also suggested that, if full mandatory labelling was not required, costs could be reduced. For example, cost reductions of about 80 per cent would be possible if labelling was not required for refined ingredients, minor ingredients, food additives, processing aids and flavourings.[90]

7.53 After considering this study, ANZFSC requested a more thorough analysis of the costs to the food industry of labelling GM food. Press reports indicate that the costs are unlikely to be as high as the first study suggested, and industry could be expected to absorb the full cost without

86 I Lindenmayer, 'Regulating genetically modified food', speech prepared for the APEC Technomart III Conference, Queensland, November 1999, p. 3, http://www.anzfa.gov.au/documents/sp008_99.asp, accessed 11 February 2000.

87 Australia New Zealand Food Authority, *Statement of reasons: Proposal P97 for Recommending Standard A18 - Foods Produced Using Gene Technology*, February 1998.

88 M Foster, 'Market implications: genetically modified crops', *OUTLOOK 2000*, ABARE, Canberra, 2000, p. 186.

89 KPMG, *Report on the Compliance Costs facing Industry and Government Regulators in relation to Labelling Genetically Modified Foods*, October 1999, pp. 20, 27.

90 KPMG, *Report on the Compliance Costs facing Industry and Government Regulators in relation to Labelling Genetically Modified Foods*, October 1999, pp. 26-7.

having to pass it on to consumers.[91] However, it is the view of the committee, based on past experience, that such costs are inevitably passed on.

7.54 The GCA reported to the committee that it was extremely concerned about the decision by the Australian and New Zealand Health Ministers to significantly strengthen the labelling requirements for GM foods. This decision, and the new labelling proposals being considered by ANZFA, 'have the potential to significantly restrict the benefits that the biotechnology revolution can bring to the industry'.[92] AWB felt that the commercial cost impositions of a requirement for grain segregation would prohibit it from trading in GM grain markets.[93]

7.55 The committee recognises that labelling will impose costs on producers and may well deter them from growing GMOs. However, the committee is aware of the public's concern about the introduction of GMOs and the wish of many people to be able to choose to eat non GM food. Labelling the GM content of food provides people with the information they need to make choices; not labelling might be interpreted as an attempt to deny choice and to profit from an unknowing public. The committee believes that, on balance, the public's trust in the regulation of GM food safety is most likely to be engendered by meeting the demand for information. The committee therefore supports a practical regime of labelling for GM foods that provides useful information to the consumer.

7.56 The committee believes that, when a revised standard for the labelling of GM foods is implemented, a survey should be conducted to assess:

- the use made by the public of label information; and
- the public's views on the usefulness of the information provided.

Such a study would allow the information supplied to be adjusted to the public's needs.

91 J Macken, 'GM food labelling talks delayed', *Financial Review*, 10 May 2000, p. 7.

92 Grains Council of Australia, Submission no. 65, p. 14.

93 AWB Ltd, Submission no. 66, p. ii.

### Recommendation 31

7.57 **The committee recommends that, if and when a revised standard for labelling genetically modified foods is instituted, the Australia New Zealand Food Authority evaluate:**

- **the use made by the public of label information; and**
- **the public's views on the usefulness of the information provided.**

## Segregation and identity preservation

7.58 Providing information about the GM content of food for labelling purposes will impose requirements on growers. This will be particularly the case where both GM and non GM crops are grown at the same time and / or in the same place. Growers will need to carefully segregate GM and non GM crops, and track the identity of both from paddock to the market.

7.59 If both GM and non GM crops are grown in close proximity to one another or on the same ground in successive harvests, it will be necessary to establish crop practices that will minimise contamination of the two types of crops and produce from one another. The main sources of contamination of crops are seeds and pollen. Non GM farmers and / or GM crop producers will therefore need to ensure that their crops are isolated from one another by an appropriate distance or barrier to reduce pollen transfer if the crop flowers. To reduce seed mixing, shared equipment will need to be cleaned and enough time allowed for viable seed to disappear from the soil before non GM crops are grown on land previously used for GM crops. Responsibility for isolating crops will need to be decided before appropriate measures can be implemented.[94]

7.60 The requirements for ensuring that non GM crops are not contaminated in the field by foreign genetic material from GM crops will be established and monitored by the GTR.[95] Management practices have long been followed in the seed industry to ensure seed purity, and these provide a model for the type of arrangement that might be established to

94 John Innes Centre, 'Gene transfer from genetically modified crops', http://www.jic.bbsrc.ac.uk, accessed 5 September, 1999.

95 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 265-6.

maintaining the integrity of non GM crops in the field. One of the factors that will influence the exact nature of the management practices needed will be the threshold of GM material that will be allowed in certified non GM produce. In addition, measures must be established to confirm compliance. It should be noted that testing may be difficult and expensive.[96]

7.61 The committee is aware that work is being carried out to establish appropriate management practices for growing and marketing GM crops. For example, a study has been commissioned by the Rural Industries Research and Development Corporation which will produce a guide for farmers, consultants and extension specialists. It will detail farm and resource management issues and strategies associated with growing GM plants and marketing the resulting products.[97]

7.62 Australia already has experience in segregating and preserving the identity of some of its produce.[98] According to AFFA, 'our grain industries, for example, are way ahead of the rest of the world in terms of identity preservation that we are doing with traditional crops'.[99] For such industries, experience with identity preservation could simply be extended to GM and non GM crops. Other industries will need to develop the necessary skills, and there will be costs associated with setting up the necessary infrastructure, management practices and recording systems. AFFA suggested that:

> As more GMO products emerge, both within Australia and overseas, the onus on segregation may well become one of the biggest challenges that not only government but also industry have in order to market.[100]

7.63 The committee was pleased to learn that work is being carried out to establish management strategies for growing GM crops. It is also aware that provision was made in the last budget for an assessment of the requirements and costs involved in segregating GM products and

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96 I Lindenmayer, 'Regulating genetically modified food', speech prepared for the APEC Technomart III Conference, Queensland, November 1999, p. 5, http://www.anzfa.gov.au/documents/sp008_99.asp, accessed 11 February 2000.

97 Rural Industries Research and Development Corporation, 'Management strategies associated with growing and marketing genetically modified plants', http://www.rirdc.gov.au/genplants.html, accessed 14 April 2000.

98 Grains Council of Australia, Transcript of evidence, 30 August 1999, p. 136.

99 Agriculture, Fisheries and Forestry, Transcript of evidence, 20 September 1999, p. 147.

100 Agriculture, Fisheries and Forestry, Transcript of evidence, 20 September 1999, p. 147.

ensuring these products can be traced through to their origins. $3.65 million is being provided over four years for this purpose.[101]

7.64 A system for certifying the GM status of produce for domestic consumption does not exist. With respect to exports, however, AQIS has been able to certify exports as GM free, because very little GM produce is grown commercially in Australia. AQIS told the committee that:

> … we have been approached by a number of countries to ensure that our shipments are free of GMOs. As there had been no commercial releases of GMOs in Australia, we were confident that shipments did not contain GMOs. As things such as canola are commercialised further … AQIS will not be as comfortable doing that.[102]

7.65 AFFA reported to the committee that it is discussing segregation and identity preservation with industry, and could play a role in auditing and certifying the GM status of food for export. However, AQIS will require 'extremely good documentation' to carry out these tasks.[103] With respect to other elements of a system for segregating and certifying the GM content of food, the majority view put to the IOGTR during its consultations on the draft Gene Technology Bill was that:

> … the Gene Technology Regulator should not impose conditions that require segregation, accreditation, and certification of crops for export. People very much saw this as a market issue … [104]

7.66 The committee endorses the role foreshadowed for the GTR in setting conditions to prevent contamination of non GM (and organic) crops and policing compliance with the conditions.[105] There is also a place for government support for the development of some of the broad parameters relating to segregation and certification. However, for any other tasks, the committee believes that the non GM food industry should develop and operate its own standards and systems, as the organic industry has done.

7.67 With respect to certified GM and non GM crops destined for export, the committee believes that AQIS should provide the same type of services to these industries as it does when certifying organic produce for export.

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101 Hon Warren Truss, Minister for Agriculture, Fisheries and Forestry, 'New technologies for Australian agriculture',Media release, 9 May 2000.

102 Agriculture, Fisheries and Forestry, Transcript of evidence, 20 September 1999, p. 146.

103 Agriculture, Fisheries and Forestry, Transcript of evidence, 20 September 1999, p. 147.

104 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 287.

105 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 265-6.

### Recommendation 32

7.68 **The committee recommends that the Australian Quarantine and Inspection Service certify both non genetically modified and genetically modified produce for export.**

## Regulating the international movement of GMOs

7.69 The import of GMOs into Australia is overseen by AQIS. A recent quarantine proclamation provides for the evaluation of novel pest and disease risks posed by imported GMOs. An imported GMO is also controlled under the new interim arrangements of the IOGTR and by other relevant existing regulators in the same way as domestic GMOs.[106]

7.70 The Biosafety Protocol of the Convention on Biological Diversity deals with the international movement of GMOs. Its objective is:

> … the safe transfer, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.[107]

The protocol was agreed to in January 2000 by 130 countries. It is open for signature until 4 June 2001, and will come into force after 50 countries have ratified it.

7.71 The protocol requires exporters to get permission from the importing country before shipping, for the first time, GMOs that are destined to be released into the environment. Nations may bar the import of GMOs on scientific grounds, even if the evidence is incomplete. Permission to import is not required for produce that is intended for food, feed or processing. However, it must be labelled as including, or possibly including, GM material. In addition, an internet based biosafety clearing house will be set up; it will facilitate the sharing of technical data and help to establish the scientific basis for decisions on imports.

106 Evironment Australia, Submission no. 82, p. 25.

107 *Convention on Biodiversity, Draft Cartegena Protocol on Biodiversity*, United Nations Environment Program, 28 January 2000.

7.72 The United Nations Environment Program affirmed that, under the agreement reached over the Biosafety Protocol:

> … the Protocol and the WTO are to be mutually supportive; at the same time, the Protocol is not to affect the rights and obligations of governments under any existing international agreements.[108]

However, the protocol is premised on a precautionary approach, while decisions under trade law require 'sufficient scientific evidence'. It appears that the provisions of the protocol and WTO agreements conflict with one another.

7.73 The NFF's president, Ian Donges, claimed that the Biosafety Protocol had the potential to unduly restrict international trade in GM commodities intended for direct use as food, feed, or for further processing. He suggested that it would be possible for nations to rely on the precautionary principle to cloak politically motivated decisions. In practice, this would introduce uncertainty into international trade and a bias against new products and new technologies which Australian farmers need to remain globally competitive.[109]

7.74 The committee supports the thrust of the Biosafety Protocol in so far as it will contribute to the careful use of GMOs. It is concerned, however, about:

- the apparent lack of clarity introduced by the Biosafety Protocol to the rules of international trade; and
- the potential for its misuse.

Both these features are likely to deter trade in GM produce. The committee believes that Australia must play an active part in negotiating the details of implementing the Biosafety Protocol and help to clarify the apparent contradictions of the protocol and existing WTO arrangements.

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108 United Nations Environment Program, 'Global treaty adopted on genetically modified organisms',Media release, 29 January 2000, http://www.biodiv.org/PRESS/PR-2000-01-28-BIOSAFETY.HTML, accessed 11 April 2000.

109 National Farmers' Federation, 'New gene treaty has hidden dangers for world trade', Media release, 3 February 2000.

### Recommendation 33

7.75 **The committee recommends that the Commonwealth government, together with industry representatives, play an active part in negotiations to implement the Biosafety Protocol in such a way that:**

- **apparent contradictions between the protocol and World Trade Organization arrangements are clarified and addressed; and**
- **Australia's interests in freely trading genetically modified organisms are maximised, without jeopardising public safety.**

## Risk assessment and management

7.76 Concerns about the deficiencies of the current regulatory system were discussed earlier in this chapter. Some of these concerns centred on the rigour of the risk assessment on which approvals are based and management strategies put in place to contain risks. Recognising that assessing and managing risk are the key planks in any regulatory system, EA pointed out that:

> Assessment involves identifying hazards, analysing exposures and probabilities, evaluating impacts, characterising risks, and recommending management measures. Risk management is not only the implementation of management recommendations arising from the risk assessment process, but also the monitoring of implementation and impacts. This monitoring is essential for 'closing the regulatory loop', that is informing subsequent risk assessment and development of management measures. This makes regulation effective and avoids unnecessary regulation.[110]

7.77 Under the interim arrangements currently in place, GMAC examines the risks posed by each application to public health, the environment, or the sustainability of agricultural systems. GMAC takes into account the consequences of any adverse effect, the likelihood of its occurring, and the possibility of reducing the risk to an acceptable level. In the course of developing its view, GMAC draws on many different sources of information, including the applicant, experts, information from overseas and in the literature, environmental assessment, and input from the public

110 Environment Australia, Submission no. 82, p. 15.

and other agencies. GMAC must also address any concerns raised by environmental assessments carried out by EA.[111]

7.78 The committee understands that, under the new legislation, applicants would be required to provide the GTR with information about:

- the GMO's parent organism;
- its characteristics;
- its new traits, including its stability;
- any health impacts it may have;
- details of the proposed release, including information about the receiving environment and the impact of the GMO on that environment;
- potential environmental impacts;
- proposed monitoring techniques;
- methods or procedures to minimise the spread of the GMO; and
- contingency planning in the case of any unexpected effects of the GMO.

With applications for the release of a GMO for commercial production, the applicant would also have to provide information about previous field trials, including any impacts on the native Australian flora and fauna.[112]

7.79 If it appears that the GMO will have a significant environmental impact, the GTR would call for public submissions about the risks and their management, as well as consult other government agencies.
A comprehensive risk assessment and risk management plan would be prepared on the basis of the OGTR's own literature and independent research and advice from GTTAC; state, territory and local governments; EA and state environmental protection agencies; health agencies; and the public. The assessment and plan would be released for further comment before being finalised.[113]

7.80 The arrangements described above are more rigorous than those that were previously in place. It is anticipated that the new legislation will come into effect on 3 January 2001.

111 Interim Office of the Gene Technology Regulator, Submission no. 78, pp. 27-31.

112 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, pp. 22-3.

113 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, pp. 23-4.

7.81 Several submissions to the inquiry commented on the high standard of the work carried out by GMAC. It was EA's view that:

> In Australia, a responsible and professional approach to the development and deployment of agricultural GMOs has always been taken, under the control of the Commonwealth Genetic Manipulation Advisory Committee (GMAC) and existing statutory regulators.[114]

The Western Australian government saw GMAC as comprising 'probably the best set of skill and expertise in the gene technology regulation arena in Australia'.[115] CSIRO told the committee that, without doubt, GMAC's standards 'would be certainly equivalent to the highest standards in the world'.[116]

7.82 The fact that only three GM plant varieties are grown commercially in Australia so far indicates that Australian regulatory authorities have taken a more cautious approach to them than have other countries. Complaints about delays in approving GM crops also suggest that regulators have a careful attitude to their responsibilities.

7.83 The management strategy developed for Bt cotton is an example of the careful approach of both growers and the NRA. The strategy is designed to minimise the likelihood of Bt resistance developing among cotton pests and imposes a 30 per cent limit on the area planted to Ingard® cotton.[117] By contrast:

> In the United States, the introduction of transgenic cotton has been less regulated than we have had. There is no cap and also their resistance management requirements are much less stringent than we have in place. There are parts of the US cotton belt, particularly in the delta and the mid-south states like Mississippi and Alabama, where a very high proportion of the cotton that is grown is transgenic—up to 96 per cent of the cotton area might be transgenic.[118]

The committee is aware that moves are now being made in the USA to introduce more stringent regulation of GMOs than has existed up to this point.

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114 Environment Australia, Submission no. 82, p. 10.

115 Western Australian government, Submission no. 48, p. 5.

116 CSIRO, Transcript of evidence, 18 October 1999, p. 208.

117 Australian Cotton Growers Research Association Inc., Submission no. 80, p. 2.

118 Australian Cotton Cooperative Research Centre, Transcript of evidence, 18 October 1999, p. 217.

7.84 GMAC's performance has been criticised by others because there have been 16 breaches over the last 15 years of the conditions that GMAC had recommended for the conduct of trials.[119] The IOGTR commented that:

> There have been very few recorded breaches of the GMAC Guidelines (or those of GMAC's predecessors) over the past fifteen years (when formal record-keeping commenced) – and none which warranted GMAC's intervention to the extent of causing the research to cease. Most incidents reported to GMAC have involved either minor accidents, such as needle-stick injuries, rather than breaches of the Guidelines, or did not involve a release into the environment. In all cases, appropriate action was taken and there were no significant hazards identified to the environment or the community.[120]

7.85 More recent criticism of GMAC's performance relates to its approval of field trials of GM herbicide tolerant canola. OFA brought these trials to the committee's attention, and claimed that the acreage grown far exceeded that needed for agronomic trials and was being used to bulk up seed for export and commercial gain.[121]

7.86 The committee believes that GMAC's cautious approach to commercial releases is essential and should be continued by it and its successor, GTTAC.

## Recommendation 34

7.87 **The committee recommends that the Genetic Manipulation Advisory Committee and its successor, the Gene Technology Technical Advisory Committee, continue to take a cautious approach to approving the use of genetically modified agricultural organisms.**

119 Australian GeneEthics Network, Submission no. 71, pp. 12-13.

120 Interim Office of the Gene Technology Regulator, Submission no. 78, p. 7.

121 Organic Federation of Australia, Transcript of evidence, 13 August 1999, p. 60.

## Issues in risk assessment and management

### Knowledge and skills base

7.88 From its experience with the introduction of exotic species and their development as noxious weeds and pests, Australian authorities have learnt that:

> The lesson is to manage risks through early detection and improved methods of monitoring. There will be a need to develop and implement the best ways to effectively monitor impacts, and to specify responsibilities and contingency plans.[122]

7.89 Monitoring may need to be widespread and include agricultural and natural ecosystems outside the area in which the GMO is deployed. This is necessary because environmental impacts vary regionally and cannot be predicted from small field trials, as monitoring in the USA has shown. Information gained from monitoring feeds into regular reviews and revision of risk management measures.[123]

7.90 EA suggested that:

> Risk management for GMOs will probably require some new specific methods for detection of impacts, and methodologies for measuring impact. For example, field diagnostic kits or bio-monitoring systems may need to be developed to detect and track transgene flow. Specific adverse effects reporting systems, and perhaps some new infrastructure, will need to be established to monitor for invasiveness, detect novel herbicide tolerance, or detect insects resistant to pesticides.[124]

7.91 The knowledge base on which risk assessment depends is likely to be deficient for many classes of GMOs; data will need to be assembled while the GMOs are being developed. EA suggested that the research needed could be funded by the proponent but:

> … some of the knowledge base needed for adequate risk assessment is not GMO-specific and the information required is more strategic and fundamental (for example basic knowledge about recombination among viruses in co-infected hosts). In other cases, there is market failure for generating the necessary knowledge, for example where the proponent is a government agency developing a GMO for a public good. These are probably

122 Environment Australia, Submission no. 82, p. 18.

123 Environment Australia, Submission no. 82, pp. 18-19.

124 Environment Australia, Submission no. 82, p. 18.

> valid community service obligations, requiring government support.[125]

7.92 In Chapters 2 and 5, the committee discussed the need for Commonwealth assistance for research into gene technology. The committee accepts the argument that the Commonwealth government has a responsibility to support the basic research that underpins effective regulation of GMOs. The committee has already recommended that the Commonwealth government provide more funding for research into the risks associated with the use of GMOs by farmers (see Recommendation 2).

### Arrangements for risk assessment

7.93 According to EA, best practice risk assessment requires two elements. The first is 'access [to] whatever experts and sources best meet the needs of accurately determining the nature and likelihood of impacts arising from the action being assessed'. The second element are the assessors who are:

> … independent persons who have no active interest in promoting gene technology and who do not represent any specific interest group. The need for neutrality is a prime reason for separating provision of expert advice (which will inform risk assessment) from independent risk assessment itself, in the regulatory path. The community expects neutrality.[126]

7.94 The current arrangements for risk assessment are primarily based on a committee of part-time assessors comprising GMAC, and will be continued under the new legislation by GTTAC. EA expressed doubts about:

> … whether such a system will be able to meet all aspects of the risk assessment challenge for the OGTR … There needs, therefore, to be debate about whether the future regulatory scheme for GMOs in Australia should rely on a standing expert committee as the focus for risk assessment.[127]

EA pointed out that 'there are few, if any, developed countries that rely on a standing expert committee as the focus for risk assessment of GMOs'.[128]

125 Environment Australia, Submission no. 82, p. 17.
126 Environment Australia, Submission no. 82, p. 21.
127 Environment Australia, Submission no. 82, p. 22.
128 Environment Australia, Submission no. 82, p. 21.

7.95 EA suggested that:

> … the new OGTR should build on the existing GMAC 'experts committee' system for regulation of agricultural GMOs at the contained research phase. The GTAC could also provide independent expert advice on non-contained proposals, but the OGTR should build primarily on the risk assessment expertise already in the Commonwealth (for existing regulatory systems) for assessment of releases into the open environment (including field trials).[129]

7.96 An AgrEvo employee told the committee in August 1999 that:

> It is my personal belief that the government capacity building needs to happen in a big way in the next 12 months. If you look at the number of people employed in the Canadian government system and the fact that they do all of their evaluations in-house and that expertise has been developed in-house, that is extremely important to the credibility of their system. That would be particularly valuable to the Australian system. I would like to see a lot more experts working within the government departments ... [130]

An alternative, according to EA, would be to use 'accredited, independent, professional risk assessment consultants'.[131]

7.97 CSIRO also pointed out that it is important for Australia to have the capacity to answer the questions raised when they emerge and to build that capacity into its normal risk assessment processes.[132]

7.98 The committee is concerned by suggestions that there may be insufficient in-house capacity in government agencies to deal adequately with the risk assessment task. The committee considers that the arrangements for risk assessment that will be developed under the new legislation must be the best possible. It believes that, if GTTAC's capacity is stretched in the future, it should be augmented, including, where appropriate, by independent risk assessment consultants.

129 Environment Australia, Submission no. 82, p. 22.

130 AgrEvo, Transcript of evidence, 13 August 1999, p. 47.

131 Environment Australia, Submission no. 82, p. 21.

132 CSIRO, Submission no. 56, p. 7.

## Recommendation 35

7.99 **The committee recommends that the Commonwealth government:**

- **ensure that there is sufficient in house capacity in the Gene Technology Technical Advisory Committee to provide timely and effective risk assessment of genetically modified organisms;**
- **give it the authority to coopt independent expertise when required; and**
- **make these assessments public.**

### Regulating all novel and genetically modified organisms

7.100 As EA pointed out, many of the risks posed by GMOs are unrelated to their GM status. For example, all herbicide tolerant crops will tend to pose similar issues for risk management, irrespective of whether they were conventionally bred or genetically engineered (see Box 2.3).[133] The committee's attention was drawn to a canola variety which is highly tolerant to the herbicide triazine that was bred traditionally and is grown in Western Australia. It is not subject to environmental regulations to minimise risks although it could have the same impacts as GM herbicide tolerant varieties which are regulated.

7.101 AgrEvo also pointed out the anomalies of concentrating on GMOs alone, suggesting that it is more appropriate to focus on the product rather than on the process by which it is generated.

> In Australia, GMAC captures only those crops derived by recombinant DNA processes, thereby excluding those crops with novel traits (especially herbicide tolerance) derived by irradiation methods or conventional breeding – and therefore subject to similar environmental management issues. In this context, GMACs requirements for GMOs are restrictive including site selection, management and monitoring.[134]

7.102 The committee considers that it is inappropriate to impose different requirements on crops solely on the basis of the process by which they were derived. In Canada, all herbicide tolerant crops are defined as plants

133 Environment Australia, Submission no. 82, p. 19.

134 AgrEvo, Submission no. 55, pp. 3-4.

with novel traits and as such are evaluated for environmental and feed safety.[135] The committee believes that a similar arrangement should apply in Australia.

**Recommendation 36**

7.103 **The committee recommends that all novel crops, whether bred by conventional means or by gene technology, should be assessed and regulated for their impact on the environment and human and animal health.**

## Liability and insurance

7.104 The definition of organic produce includes a requirement that it not contain GM elements. It is therefore important for organic farmers that, if their crops are contaminated by GM products, they can seek compensation for the damage done. The reverse situation might also occur in the future, for example, if GM crops are developed for specific nutritional qualities; they might be contaminated by neighbouring organic or non GM crops. The organic industry noted that litigation involving GMOs is occurring overseas,[136] and urged the establishment of 'strong enforceable liability regimes'.[137]

7.105 The question of where the liability would rest if GM contamination occurred was debated in several submissions. The National Genetic Awareness Alliance argued for the 'polluter pays' principle.[138] Others suggested that liability could lie with:

- the developer of the GMO, including the owner of plant variety rights;
- government bodies that approved the release of the GMO; and/or
- businesses engaged in producing and growing GMOs, including the farmer and seed supplier.[139]

135 AgrEvo, Submission no. 55, pp 3-4.

136 National Association for Sustainable Agriculture, Australia, Submission no. 74, p. 3.

137 Australian GeneEthics Network, Transcript of evidence, 13 August 1999, p. 77.

138 National Genetic Awareness Alliance, Submission no. 54, p. 4.

139 Heritage Seed Curators Australia, Submission no. 30, p. 2; National Association for Sustainable Agriculture, Australia, Submission no. 74, p. 3; Organic Federation of Australia, Supplementary submission no. 73, p. 2.

7.106 Specific legislation relating to liability for the risks posed by gene technology does not exist, nor has liability been tested in the courts. Common law provides a means for redressing problems arising from GMOs. Remedies might also be sought through environmental protection and pollution control legislation, and legislation relating to wild animals and abnormally dangerous activities. Liability in relation to food would be caught under the Trade Practices Act.[140]

7.107 The AGN suggested that:

> Given clear threats to environment and human health, it would be prudent to require a fidelity bond as the Spanish government has done, or place a tax on GE organisms to fund damage mitigation research and clean-up.[141]

OFA supported the establishment of a compensation fund, to which organic farmers could apply 'immediately they suffer a financial loss as a result of contamination'.[142] Another suggestion was for companies wishing to commercially release GM products to pay 'a substantial licence fee to government to support insurance against risk'.[143]

7.108 The gene technology legislation addresses the issues of liability and compensation. It provides for criminal penalties for breach of the legislation and gives the GTR the power to require that a problem be rectified when the legislation has been breached. A bond can also be imposed under the licence conditions for particular GMOs.[144] However:

> If a third party wanted to bring an action in relation to contamination, their recourse would be through common law trespass, negligence, and nuisance—actions of that nature. The legislation does not establish a compensation fund per se … [145]

It is the committee's view that this is an appropriate arrangement.

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140 Advice provided by the Environmental Defenders Office, Tasmania to the National Association of Sustainable Agriculture Australia, dated 25 October 1999, pp. 2-3; T L'Estrange, T Spender & J Baartz, *GeneCom 98 – Gene technology in the community*, Allen Allen & Hemsley, December 1998, http://www.allens.com.au/wnew/whatscon2.htm, accessed 12 May 1999.

141 Australian GeneEthics Network, Submission no. 71, p. 7.

142 Organic Federation of Australia, Submission no. 73, p. 2.

143 *First Australian Consensus Conference: Gene Technology in the Food Chain:: Lay Panel Report*, Canberra, March 1999, p. 3.

144 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 266, 269.

145 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 266.

7.109 The Insurance Council of Australia reported that most insurers and reinsurers have not yet reached a clearly defined position on insuring gene technology companies because the nature and size of the exposure to losses are not clear. Furthermore, genetic engineering has an extremely diversified risk profile, and any damage or injury may not show up until a lengthy period has elapsed. Class actions for serial and latent claims would present a problem for the insurance industry, as would the substantial costs that might be required to defend politically targeted policy holders.[146]

7.110 Any cover offered is likely to be restricted and leave a large gap between the cover on offer and the level of coverage required. Alternatives to traditional insurance have been sought in tailor made hedging instruments financed jointly by the policy holder and the insurer or reinsurer.[147]

7.111 The committee believes, however, that the best form of insurance is to provide the OGTR with sufficient funding and independence to discharge the duties envisaged for it, as described earlier in this chapter.

## Recommendation 37

7.112 **The committee recommends that the Commonwealth government ensure that:**

- **the independent status of the Gene Technology Regulator is clearly prescribed in the new gene technology legislation;**
- **sufficient funding is provided to enable him/her to fully discharge his/her duties; and**
- **the Gene Technology Regulator is publicly accountable.**

**Fran Bailey, MP**
**Committee Chair**

**7 June 2000**

146 Insurance Council of Australia, Submission no. 83, pp. 1-2.

147 Insurance Council of Australia, Submission no. 83, p. 2.