CHAPTER 6

OTHER ISSUES – LIABILITY, STATE OPT OUT AND MOUNT GAMBIER

6.1 Terms of Reference (i), (j) and (k) deal with other issues not specifically included in the Gene Technology Bill 2000, though the issues are especially relevant to the national regulatory system proposed in the Bill. These issues are discussed in this chapter.

Term of Reference (i): Liability and insurance issues relating to deliberate and accidental contamination of non-genetically modified crops by genetically-modified crops and how those issues are being addressed in international regulatory systems

Contamination

6.2 Contamination is the unintended and/or unwanted presence of a substance, organism or part of an organism in a particular environment, including within organisms. In the context of genetically modified organisms (GMOs), contamination is the unintended/unwanted presence of a GMO, or the genetic material of a GMO or product of a GMO in an organism, environment or product. Contamination is particularly an issue in relation to agricultural crops, for example a GM seed in a non-GM seed sample.

6.3 Contamination can occur in a variety of ways but most commonly through pollen dispersal or cross-pollination, seed dispersal, and inadequate segregation of GM and non-GM crops or products during their processing, transport or distribution. Contamination can thus occur prior to the actual growing of the genetically modified (GM) crop.

6.4 One of the major concerns expressed by opponents of GM products and the reason that excessive caution is required with their use is that neither of the main sources of contamination (pollen or seed) can be entirely eliminated. At best they can be identified and managed. As the Interim Office of the Gene Technology Regulator (IOGTR) conceded:

> Like all crops, once GM crops are released they cannot be completely contained. The same principle is true for spray or fertiliser drift from one farming system to another. There is always the possibility of hybridisation and seed mixing between GM crops and organic or conventional crops, and contamination with chemical residues…
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> Just as there are measures in place for pure seed and organic produce to minimise pollution caused by spray drift, fertilisers and other pollutants,

mechanisms may be put in place to minimise contamination resulting from outcrossing of GMOs.[1]

6.5 The IOGTR noted that during the consultations on the development of the Bill, a range of views were expressed on how the legislation should address the issue of contamination. All considered that it was imperative that the legislation addresses the situation where GMOs have the potential to impact negatively on the natural environment, for example, through outcrossing with native relatives. In respect of the impact on agricultural systems and whether the proposed national system should regulate to minimise contamination, views varied from the advocates of no release of GM crops into the environment, to farmers having the right to choose, to those who believed that a cooperative approach was necessary to comprehensively address the issue of contamination.

6.6 In addressing the risk of contamination, the Bill provides that the Regulator will undertake a comprehensive risk assessment of all applications involving intentional release of a GMO into the environment and must be satisfied that any risks to public health and safety and the environment can be managed before issuing a licence. The Regulator may also impose conditions to limit the dissemination of the GMO or its genetic material in the environment where there may be a risk that the release of the GMO could impact on other farming systems.

6.7 In addition to the capacity to impose conditions limiting the dissemination of a GMO, the Regulator will have the power to enforce these conditions. There are also significant monetary penalties should a licence holder breach the conditions of a licence or if a person deals with a GMO in breach of a condition specified on the GMO Register. The Bill provides for two levels of offences, one that requires the establishment of knowledge or recklessness and one that does not – a strict liability offence. If the breach of a licence condition causes or is likely to cause harm to the environment, the Regulator can direct that remedial action or a clean-up take place either by or at the expense of the person who breached the licence condition, although this does not extend to compensation for third parties who may be affected by the contamination.[2] The role and powers of the Regulator were discussed in detail in Chapter 4.

Liability and insurance

6.8 In relation to liability and insurance, the IOGTR outlined a range of views received during the consultations on the development of the Bill.[3] These views were also reflected in the evidence received by the Committee.

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1 Submission No.77, p.139 (IOGTR).

2 The Bill Part 4 – Regulation of dealings with GMOs and Part 10 – Enforcement. See Explanatory Memorandum pp. 55-8, 90-1 and Explanatory Guide pp.33-6, 61-3.

3 Submission No.77, pp.140-1 (IOGTR).

6.9 While strong support was expressed for the inclusion of the strict liability offences into the Bill, which had not been in the consultation draft, there was concern that the general penalties associated with the strict liability offences and the reckless offences were 'totally inadequate'. It was suggested that they should be increased significantly to reflect the risks associated with GMOs and to ensure that people complied with the provisions of the Bill.[4] The adequacy of penalties was discussed in Chapter 4.

6.10 There was widespread acceptance that any damage to the environment arising from a breach of condition of licence must be 'cleaned-up' and that the Regulator must have the capacity to recover any costs of such a 'clean-up' from the producer of the GMO. However, of concern was that the Bill does not create civil liability provisions for environmental damage, with the potential for persons responsible for environmental damage avoiding liability for the costs of remedying the damage.[5]

6.11 On the issue of liability for contamination of non-GM crops (as opposed to environmental damage) where the resulting damage was economic in nature, it was argued that if a GMO causes any damage to non-GM crops then the producer of the GMO, as opposed to the farmer who used the GMO, should be liable to pay for the damage caused. This should apply even if such damage was only economic in nature, for example, because an organic farmer could not market his/her crop as GM-free.

6.12 A number of suggestions were made about ways to ensure that monies are available to pay such compensation, including the establishment of a compensation fund; requiring that a bond be paid by the producer of the GMO; and requiring the producer of the GMO to hold insurance. The alternative argument was also put that existing legislation (such as State environment protection legislation) and the common law provided adequate recourse for anyone suffering loss as the result of contamination. These issues are discussed below.

Compensation fund

6.13 It has been suggested that the producers of GMOs or the persons dealing with GMOs and GM products should be levied and a compensation fund established. The compensation fund would be accessible to farmers who have suffered as a result of contamination and should also pay for unforseen environmental or public health calamities.[6] However, there were concerns that the establishment of a specialised insurance fund could spread costs unfairly amongst all users of gene technology and diminish the incentive for persons dealing with GMOs to ensure that they are able to remedy any damage associated with their GE dealings.[7]

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4 *Committee Hansard*, 24.8.00, p.309 (ACF).

5 Submission No.25, pp.11, 18 (Mr Andrew Mcintosh).

6 Submission No.85, p.16 (ACF GeneEthics Network).

7 Submission No.25, p.19 (Mr Andrew Mcintosh).

Bond

6.14 An alternative form of compensation funding that has been suggested is for the Regulator to require that a bond be paid by the producer of the GMO at the time that the GMO is approved for release and that the bond should be used to pay compensation to any farmer affected by contamination. Schemes requiring upfront applicant contributions were not supported by industry which considered them as unreasonable in deterring innovation and commercial development.[8]

Insurance

6.15 Many witnesses argued that the Regulator should have the power to require that the producer of the GMO holds insurance before a licence is issued and that in the event of contamination a claim could be made by a third party against the producer's insurance policy.[9]

6.16 Doubts were raised about the availability of specific insurance cover offered by insurance companies. The ACF GeneEthics Network referred to a 1998 report by the Swiss Reinsurance Company which said that the risks to the insurance industry were very unclear at that time and potentially so large that the insurance industry could suffer a serious economic setback if the worst case scenario eventuated.[10]

6.17 The differing views held about insurance were reflected in the submission by the Insurance Council of Australia (ICA). The ICA indicated that it is aware that views amongst its members vary on this topic, and believes that far more research is needed by insurers/reinsurers to gain an appreciation of the risk profile of this relatively new (for Australia) technology.

6.18 In relation to insurability the ICA advised that general insurers in Australia providing product liability and environmental insurance are prepared to accept risks where there is a clear perception of the nature and size of exposures producing losses (which can be quantified drawing on past empirical experience). There is little if any meaningful loss experience available to insurers on genetically engineered risks or products in Australia. The ICA referred to a perception amongst insurers and the community that genetic engineering is dangerous, characterised by an extremely diversified risk profile of a new technology. General insurers are reluctant to accept incalculable risks where it is difficult to predict what loss scenarios will arise.

6.19 Generally most insurers respond to risks involving new technology with great caution even following careful underwriting with the cooperation of scientists and safety engineers. In such circumstances the level of insurance protection offered by insurers may not always meet the full risk exposure presented by genetically

8 Submission No.59, p.5 (Meat and Livestock Australia).

9 For example *Committee Hansard*, 22.8.00, p.61 (Heritage Seed Curators Australia)

10 *Committee Hansard*, 24.8.00, pp.318, 332 (ACF GeneEthics Network).

engineered products. The ICA informed the Committee that the key points of concern to the insurance industry are:

- There is a lack of reliable loss experience history and means for calculation of likely loss patterns. This absence of data inevitably promotes a fundamental doubt over the insurability of such risks.
- For the insurance industry, genetic engineering is potentially one of the most exposed technologies of the future and insurers' experience with pharmaceutical risks could be seen as analogous.
- The less acceptance the public shows towards new risks, the less trust is placed in the means to deal with them. As a consequence there is the likelihood that the possible negative consequences of each new technology will become a financial burden for the insurance industry.
- The risk profile of genetic engineering is extremely diversified and very difficult to quantify. There is no clear perception of the risks involved, making genetic engineering exposures hard to measure and thus insure.
- The insurance industry is happy to open dialogue with all interested parties on the subject of genetic engineering. Risk-related information must however be exchanged openly and honestly and differing values taken seriously.[11]

6.20 Avcare sought to allay concerns expressed during the hearings that farming and related activities involving the use of GMOs may have been inadequately insured. Avcare referred to the suggestion in the ICA submission that appropriately tailored products were not generally available on the market to deal with the risks associated with the escape of GMOs into the environment and informed the Committee that:

> Avcare understands from all of its member companies currently undertaking activities involving GMOs that each and every one of them has taken out appropriate and effective insurance cover in relation to the risks that have been identified in the course of the Senate Committee's hearings.[12]

Application of existing legislation and common law

6.21 The Bill does not contain a provision for a statutory right of action or a compensation fund to compensate those affected by a breach of the legislation, nor is there provision for liability or immunity of GM-free farmers who inadvertently use GM products. The point was made that, in cases involving non-GM contamination where the activities of one farmer affect a neighbour, recourse is to existing statute and common law and that GMOs should not be treated any differently. It was therefore argued by some that persons affected by GMO contamination should

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11 Submission No.1, pp.1-2 (Insurance Council of Australia).

12 Submission No.32 (Avcare), Additional Information dated 8 September 2000. Serve-Ag also noted that in the opinion of the Company and the Company's insurance broker it is adequately insured for any potential liability - Submission No.8 (Serve-Ag), Additional Information dated 21 September 2000.

continue to have recourse to the common law of trespass, public or private nuisance, and negligence. The House of Representatives Committee viewed this 'as an appropriate arrangement'.[13]

6.22 Others have argued that although persons affected by GMO contamination will continue to have recourse to common law actions, these are not optimal remedies and are inadequate for a Bill which has the object of protecting public health and safety. A particular difficulty raised was the capacity to prove, on the balance of probabilities, where the contamination had emanated from. The Australian Conservation Foundation (ACF) commented that reliance on the common law test requiring an applicant to prove harm to personal property is 'totally unacceptable in modern best practice legislation'.[14] The Parliamentary Library has argued:

> Given that the open release of GMOs, particularly GM crops and animals, into the environment is a relatively recent trend, it seems questionable that the issue of potential liability for damage is left solely to the vagaries of the common law. Legal liability for negligently inflicted economic loss is still in a state of uncertainty. In this climate of uncertainty, it is at least arguable that the potential cost of damage from instances of GMO contamination should be incorporated into the regulatory system, perhaps by establishing a statutory compensation scheme or by creating a statutory cause of action specifying in what circumstances and against whom a suit could be brought.[15]

Comparisons with international regulatory systems

6.23 The IOGTR examined the regulatory schemes adopted by the United States of America; New Zealand; Canada; the European Community; the United Kingdom; Germany; and Japan.[16] The comparison of these international regulatory systems is at Appendix 3. In summary, the IOGTR examination found that there are three main ways in which these countries' regulations differ in their coverage of intentional releases of GMOs into the environment, and in particular how liability in relation to such releases is established. The three main ways are outlined below.

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13 *Work in Progress: Proceed with Caution*, Report by the House of Representatives Standing Committee on Primary Industries and Regional Services, June 2000, p.159.

14 *Committee Hansard*, 24.8.00, p.308 (ACF).

15 Department of the Parliamentary Library Bills Digest No. 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, p.31. The Digest notes at Endnote 112 that statutory liability currently exists in areas such as criminal injuries compensation and civil aviation carriers' liability, both in relation to personal injury or death and property damage. The rationale behind such schemes is that it is desirable that persons who suffer loss or damage be compensated for their loss, however, it is also desirable that the level of liability be capped.

16 This section is drawn from Submission No.77, pp.146-151 (IOGTR). A brief summary of the approaches adopted by each of the countries examined by the IOGTR is included in these pages.

Laws of horizontal application vs laws of vertical application

6.24 The terms horizontal and vertical regulation refer to the way in which laws affect different sectors. Horizontal regulation means that general laws will apply to different industries in an equitable way. For example, GMOs released into the environment would be regulated in the same way as any other product proposed to be released into the environment. Vertical regulation entails the creation of specific laws to deal with individual industries.

6.25 While there is some debate regarding whether a horizontal or vertical approach to liability for GMOs, including recovery by third parties for contamination, is preferable, the majority of countries support a horizontal approach (that is the use of existing legislation). Arguments about the advantages of a horizontal approach include efficiency and that it ensures that different types of contamination are dealt with equally and in accordance with the consistent application of general principles, thereby ensuring that damage suffered as the result of different types of contamination can be compared and compensation awarded consistently.

6.26 The IOGTR noted that in the development of the national regulatory framework the Commonwealth-State Consultative Group on Gene Technology (CSCG) recognised that specific legislation was necessary to regulate gene technology and that the legislation should include penalties and enforcement actions in the case of a breach of the legislation. However, in relation to recovery by third parties for any damage or economic loss arising from contamination, it was recognised that there are remedies available under common law and under general environment protection legislation that may be used.

Whether statute law or common law deals with any issues of liability arising from the use of GMOs

6.27 Some international legal systems deal with liability for contamination through legislative enactment, eg Germany. Others allow the common law to deal with liability under general tort or criminal law, eg the USA, the UK, Canada and Japan.

Strict vs fault-based liability

6.28 Some international legal regimes are based around ‘strict liability’ principles, which involve the imposition on the producer of the GMO of liability for contamination by the GMO, regardless of fault. Under such a system, the plaintiff need not demonstrate any wrongdoing in order to affix liability to the defendant, eg Germany. Under a fault-based liability system, compensation is dependent on the ability of the plaintiff to show negligence or some wrongdoing on the part of the producer of the GMO, eg the United States, Canada, the UK, New Zealand and Japan.

6.29 The IOGTR noted that each of the regulatory systems examined varies not only in their approach to the regulation of gene technology but also in how they deal with issues of liability arising from the use of gene technology.

Concluding comments

6.30 The Committee acknowledges that recourse to action under common law through negligence, trespass or nuisance may often be appropriate, though dependent on the facts in particular cases. However, the Committee does accept that the vagaries of common law and burden of proof on a plaintiff may not provide sufficient remedy in all cases.

6.31 The Bill does provide power to the Regulator to order a clean-up and to recover costs if a licence is breached, although this also may not be sufficient remedy in all cases.

6.32 The Committee is not persuaded to recommend the establishment of a compensation fund based on levies, but has preferred to strengthen the link with insurance by amending the Bill to require that in prescribing or imposing conditions of licences, the Regulator may satisfy him or herself that applicants have made provision for suitable insurance coverage to cover the risks associated with the dealings. Recommendations on this area are in Chapter 4. The Committee does note the uncertainty expressed over insurance coverage in this area and believes that the adequacy of insurance policies held by applicants will need to be an issue to be closely monitored by the Regulator.

Term of Reference (j): The validity and practicability of any proposed clause allowing individual States the right to opt out of the scheme and the implications of such an option in the context of Australia's international trade and related obligations

Background

6.33 As noted in the introductory chapter, impetus for the development of the Gene Technology Bill was given in 1997 by the formation of a Commonwealth-State Consultative Group on Gene Technology (CSCG). The CSCG agreed to a set of policy principles to guide the development of the regulatory system. Policy principle 7(d) stated:

> 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.

6.34 The IOGTR advised that in 1997, the thinking behind this policy principle was that a State, Territory or the Commonwealth, regardless of the decision of the central national regulator, might have a health, environment or trade/economic reason for either prohibiting the release of a GMO in a jurisdiction altogether, or for applying more stringent conditions on the GMO's release.[17]

17 Submission No.77, p.155 (IOGTR).

6.35 By August 1999, the CSCG had developed detailed proposals for the new regulatory system and considered that some of the guiding policy principles had become dated. CSCG had now agreed that the regulatory system must focus on protecting the environment and the community – and that trade considerations, or economic or other advantages must not override this fundamental object. However, original policy principle 7(d) envisaged jurisdictions 'opting-out' of applying the regulator's decisions on any ground (health, environment, trade or economic advantage).

6.36 The IOGTR indicated that the CSCG now considered that the new regulator should be established as the authoritative regulator of all risks to the environment and to human health. In making decisions, the regulator must have thoroughly and rigorously assessed all risks. Decisions could not be made until the regulator had sought detailed advice from all States and Territories. The regulator would also be accountable to the States and Territories for how advice received had been taken into account in reaching decisions. The CSCG considered that there would, therefore, be no basis for a State or Territory to veto or opt-out of applying the regulator's decision on environmental or human health grounds. A flawed decision by the regulator would indicate the need to review the regulatory system as a whole, to be addressed on a national basis rather than by fragmenting the national system through the establishment of State-specific regulatory systems.[18]

6.37 This evolving position on the issue of an opt-out on the grounds of protection of human health or safety or the environment was included in the discussion paper 'Proposed national regulatory system for genetically modified organisms – How should it work?' released in October 1999. However, the discussion paper added that a State or Territory could choose to refuse the release on other grounds 'such as local trade considerations'. Even so, the discussion paper noted that there may be difficulties associated with the inclusion of an explicit opt-out provision based on trade and economic considerations, including 'constitutional issues, international trade issues, regulatory uncertainty and the potential for GMOs to move between jurisdictions despite the desires of a particular State or Territory'.

6.38 National consultations using the discussion paper were held during late 1999. The IOGTR advised that four (described as 'sometimes contradictory') messages came through consistently during the consultations. These were:

- that the new regulator must be, and must be seen to be, credible, powerful, expert and accountable;
- that the national regulatory system must be a national system and should not be fragmented by different decisions applying in different jurisdictions;

18 Submission No.77, pp.153, 156-7 (IOGTR).

- that trade and economic considerations must not be included as matters to be considered by the regulator in taking a decision – environment and health concerns must be paramount and exclusive; and
- that there should be a capacity for jurisdictions to opt-out of applying the regulator's decisions.[19]

6.39 Throughout the consultation period, the CSCG continued to explore the options for including an explicit provision allowing individual jurisdictions to opt-out of applying the regulator's decision on trade or economic or other (non-environmental or human health) grounds. In relation to constitutional risks and Australia's international trade obligations, advice was sought from the Australian Government Solicitor, Attorney-General's International Law Division and the Department of Foreign Affairs and Trade. Based on their advice, all jurisdictions (except Tasmania) concluded that there was a 'significant risk that any broad-based opt-out provision in the Commonwealth Bill would, if challenged, be ruled invalid by the High Court' and that there was 'some risk to Australia's international obligations associated with the inclusion of an explicit opt-out provision'. The constitutional and trade arguments are discussed below.

6.40 As a consequence of this perceived combination of risks, the jurisdictions (except Tasmania) agreed that an explicit opt-out should not be included in the Commonwealth Bill.

The Gene Technology Bill 2000

Operation as a national scheme[20]

6.41 The Bill is intended to operate as a national scheme, requiring complementary legislation at Commonwealth, State and Territory levels after all jurisdictions sign the Gene Technology Intergovernmental Agreement. The advantage of a national cooperative scheme is its ability to regulate comprehensively all dealings with GMOs. Any dealings that the Commonwealth is unable to regulate would be covered by identical State legislation.

6.42 Proposed sections 12 and 16 of the Bill deal with 'corresponding State law' and the concurrent operation of State laws. The Explanatory Memorandum notes that the intention of these provisions is to ensure that existing and future State legislation, eg general environmental, fisheries and land management legislation, continues to operate concurrently with the Bill, provided it is capable of doing so. However, where State legislation is enacted that is inconsistent with the national scheme of regulation for GMOs, or effectively establishes a dual licensing regime, there is capacity for such laws to be prescribed as not operating concurrently with the Bill.[21] Tasmania indicated

19 Submission No.77, p.158 (IOGTR).

20 Much of the comment in this section is from the Department of the Parliamentary Library Bills Digest No. 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, pp.9, 26-27.

21 Explanatory Memorandum, p.51.

it would be 'of grave concern' if these provisions were used to overturn State measures taken with constitutional authority to protect their agricultural industries.[22]

6.43 Despite these powers to revoke a declaration in relation to a 'corresponding State law' and to make regulations excluding the operation of non-conforming State laws, the Commonwealth has no ability to ensure that the national scheme is uniformly amended. The continued operation of the national scheme relies on further inter-governmental agreements to approve amendments, and the passage of legislation incorporating those amendments in every jurisdiction. If one or more of the States and Territories choose not to enact complementary legislation, or not to amend the legislation in line with other jurisdictions, the scheme could quickly cease to be uniform and national in its scope.

6.44 The Gene Technology Intergovernmental Agreement on which the scheme is to be based has not yet been signed. The Tasmanian Government has indicated that in the absence of an opt-out clause it will not sign the Agreement.[23] The future of a consistent national scheme appears to rest on uncertain foundations if agreement cannot even be concluded prior to the commencement of the scheme.

6.45 In spite of the difficulties experienced to date in achieving inter-governmental agreement, the Bill does not purport to operate to the full extent of Commonwealth constitutional power. In particular, the Commonwealth has chosen not to rely on its plenary constitutional power to legislate for the territories (section 122 of the Constitution), but is instead relying on complementary legislation being passed by the ACT and Northern Territory. This reflects, so it is argued, the Commonwealth's preference for a cooperative nationally consistent regulatory scheme, rather than Commonwealth legislation relying on every possible head of constitutional power.

Opt-out options under the Bill

6.46 While a specific opt-out provision has not been incorporated into the Gene Technology Bill 2000, the proposed legislation does, nevertheless, provide particular mechanisms that allow the Regulator to take the unique situations of local areas into account. For example, the Bill provides every opportunity for GMOs to be prohibited in any area of Australia where the health or environmental risk warrants such a prohibition. Therefore, if there are unique risks to the environment in Tasmania posed by a particular GMO release application, or a risk to any other particular geographic area, the application could be approved on condition that it not be released in those vulnerable areas.

6.47 The Bill also provides the Ministerial Council with the power to issue policy principles as disallowable instruments on particular matters relating to GMOs, in relation to which the regulator must not act inconsistently. The Council may decide to

22 Submission No.89, p.2 (Tasmanian Government).

23 Submission No.89, p.9 (Tasmanian Government).

issue a principle requiring the regulator to, for example, observe certain GMO free zones established on the basis of the need to protect the sustainability and commercial viability of all agricultural farming systems (including organic and conventional systems). In this case, the regulator must observe such a policy principle in relation to any decisions made under the legislation. The precise nature and content of these principles will be a matter for the Ministerial Council to determine and cannot be pre-empted. The Ministerial Council may also issue policy guidelines and codes of practice.[24]

6.48 The Tasmanian Government referred to correspondence from the Parliamentary Secretary to the Minister for Health and Aged Care which suggested that Ministerial Council policy principles or guidelines could be 'an appropriate vehicle for achieving an opt-out'. The Tasmanian Government expressed concern that the constitution of the Ministerial Council 'would make it uncertain as to whether such a policy guideline would be issued, or would not be changed at a future date'.[25]

6.49 The Organic Federation of Australia (OFA) also expressed reservations about this process, commenting that:

> The way that the legislation is drafted…we are left with the only way we can get buffer zones, protection of organic farming systems or any other genetically engineered free farming system is through the ministerial council making policy principles…Our worry is that to get a principle up through that council we have to go through an enormous process of getting the majority of that council to agree to that.[26]

6.50 The IOGTR noted that all jurisdictions had consistently agreed that, despite the limitations in relation to Commonwealth legislation, if a State or Territory wished to prohibit GM crops on grounds other than health or environmental safety and believed they could do so in a manner that did not breach Australia's international obligations, States should be able to pursue this option under their own legislation. Legal advice prepared by the Departments of Foreign Affairs and Trade, and Attorney-General's, was provided to CSCG participants on the feasibility of such an option as an alternative to achieving an opt-out using the Commonwealth legislation.

6.51 This advice concluded that a range of WTO provisions relevant to Genetic Engineering Free Zones (GEFZ):

> do not, in principle, appear to prevent the creation of GEFZs. However, they do impose a number of disciplines that would apply to the measures used to

24 Submission No.77, p.161 (IOGTR).

25 Submission No.89, p.7 and *Committee Hansard,* 23.8.00, p.230 (Tasmanian Government).

26 *Committee Hansard,* 23.8.00, p.150 (Organic Federation of Australia).

> create any GEFZs. Accordingly, the GEFZ proposals would need to be implemented in a manner consistent with these provisions…[27]

6.52 After considering the advice, CSCG participants from all State and Territory jurisdictions except Tasmania 'determined not to pursue this option and to rely on the strength of the national regulatory scheme and of the Intergovernmental Agreement to appropriately reflect and address any concerns they may have'.[28] However, Premier Bracks from Victoria has advised the Committee that:

> The Victorian Government has an election commitment to investigate the establishment of Gene Modification Free Zones throughout the State. This ongoing work is investigating legislative and other mechanisms which might be available to communities and industry should the need for such a zone be established…I believe this approach is preferable to formal 'opt out' as it maintains the national coverage of the proposed regulatory scheme and allows communities and industry to actively participate in the development of their local areas and economies.[29]

Constitutional issues

6.53 As noted above, the constitutionality of introducing a broad-based opt-put provision was considered by all the jurisdictions and, with the exception of Tasmania, jurisdictions concluded that there was a 'significant risk' that such a provision would, if challenged, be ruled invalid by the High Court. Two sections of the Constitution were especially considered: section 92 – Trade within the Commonwealth to be free and section 99 – Commonwealth not to give preference to any State. However, there was some diversity of opinion at the highest legal levels.

Section 92 - Trade within the Commonwealth to be free

6.54 The first paragraph of section 92 provides:

> On the imposition of uniform duties of customs, trade, commerce, and intercourse among the States, whether by means of internal carriage or ocean navigation, shall be absolutely free.

6.55 The interpretation of this section in relation to the inclusion of an opt-out provision in Commonwealth legislation did not attract much disagreement. The IOGTR submitted that the Australian Government Solicitor (AGS) advised:

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27 Submission No.77, p.207 (IOGTR). The advice 'The establishment of genetic engineering free zones: WTO aspects' is provided in full at Attachment F to the submission.

28 Submission No.77, pp.161-2 (IOGTR). The Tasmanian Government advised the Committee that the advice 'only deals with the WTO implications of GM-free zones on market image grounds, not environment and health and safety as stated in the IOGTR submission. No determination was ever signalled by Tasmania that we would not be pursuing this option'. *Committee Hansard,* 23.8.00, p.221.

29 Submission No.115, p.2 (Victorian Government, Mr Steve Bracks, Premier).

> that a decision by a State or Territory to opt-out would not necessarily impose a discriminatory burden of a protectionist kind, as the decision would apply equally to trade within the State as to interstate trade. As such, a mechanism in the Commonwealth Bill allowing for such a decision should not infringe section 92 of the Constitution.[30]

6.56 The Tasmanian Government indicated that advice from the Tasmanian Solicitor General indicated that an opt-out as had been proposed in policy principle 7(d) 'probably would not offend against Section 92'. This advice argued that:

> In order for a law to discriminate against interstate trade it must be protectionist in the relevant sense, by placing a discriminatory burden on trade in order to protect trade within the State (Cole v Whitfield (1988) 165 CLR 360 is authority for this proposition).
>
> Accordingly, where a State has declined to allow release within its own territory of a GMO, that would apply to trade within the State and trade with other States, therefore the law would not be protectionist in the relevant sense.
>
> In any event, legal authority exists for the principle that laws for the protection from a real danger or threat, or some other legitimate object of a State, will not offend section 92, if the law is appropriate for the achievement of that objective.[31]

6.57 The Committee received comments in a number of submissions favouring similar interpretations as referred to above.[32] The Parliamentary Library made an interesting observation in the Bills Digest relating to the Bill suggesting that while it is difficult to see how an opt-out provision of itself could infringe section 92, a State law attempting to give effect to the provision might infringe this freedom of trade between the States, depending on the nature of the law.[33]

Section 99 - Commonwealth not to give preference to any State

6.58 Section 99 provides that:

> The Commonwealth shall not, by any law or regulation of trade, commerce, or revenue, give preference to one State or any part thereof over another State or any part thereof.

6.59 In relation to this section the AGS argued that:

> Until recently, the scope of the provision appeared restricted to laws which could only be enacted under paragraph 51(i) of the Constitution (law of

30 Submission No.77, pp.158-9 (IOGTR).

31 Submission No.89, pp.12-13 (Tasmanian Government).

32 Submission No.25, pp.23-4 (Mr Andrew Mcintosh).

33 Department of the Parliamentary Library Bills Digest No. 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, p.31.

> trade or commerce). However, there is now ambiguity surrounding the interpretation of this section following recent decisions of the High Court, and it is unclear whether the role of section 99 is to be regarded as still being confined to the sphere of interstate trade, or whether it has taken on a broader role.
>
> Given the tendency of the High Court in recent years to reject formalism in favour of a purposive approach in interpreting provisions of the Constitution, there is a significant risk that the scope of section 99 would be extended to laws affecting trade or commerce made under other heads of power. AGS considered that, were the High Court to go down this route, there was a significant possibility that Commonwealth legislation to regulate GMOs would be regarded as a law of trade and commerce for the purposes of section 99 and the opt-out provision in that legislation would infringe that constitutional limitation.[34]

6.60 The Parliamentary Library similarly noted there have been no cases on section 99 of the Constitution since the 1960s and commented that:

> Accordingly, it is unclear if the narrow interpretation would continue to be applied today, particularly in light of the substantive and purposive interpretation now given to section 92. There have been suggestions that section 99, like section 92, is one of a series of constitutional provisions giving effect to the creation and maintenance of a free trade area throughout the Commonwealth… It may then be seen as a source of an individual right not to be treated differently in matters of trade and commerce merely on the basis of a person's State of residence. If this interpretation were to be adopted, it raises some doubts as to the constitutional validity of a Commonwealth "opt out" clause.[35]

6.61 The Tasmanian Government viewed the situation differently, submitting that:

> In order to offend section 99 of the Constitution, two elements must be made out. Firstly a law or regulation must be one of trade, commerce or revenue. Legal opinion obtained by Tasmania suggests that, as the laws in the Gene Technology Bill 2000 are to regulate the safe release of GMOs within Australia, it is not a law that can be classed as 'trade or commerce' for the purposes of section 99.
>
> Even if the High Court were to uphold the notion that the Gene Technology Bill 2000 is a law for trade and commerce, Tasmania is advised that the opt-out clause could not be interpreted as a law designed to give some commercial advantage or material benefit of a commercial or trading character. The law would apply equally to all jurisdictions, as any State,

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34 Submission No.77, p.159 (IOGTR).

35 Department of the Parliamentary Library Bills Digest No. 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, p.44 Endnote 100.

> Territory, or even the Commonwealth could exercise the right to decline to release the GMO within their territory.
>
> The situation would be different if the opt-out were expressed to apply to only one or more States, rather than all jurisdictions. The opt-out as agreed by policy principle 7(d) does not give preference to one State (or part of a State) over another, and cannot therefore be said to be discriminatory by giving preference. The proposed opt-out provision would be uniform in its application.[36]

6.62 The Committee notes that conflicting legal argument exists over the interpretation of section 99. The jurisdictions other than Tasmania have proposed a constitutionally cautious approach by agreeing not to include an opt-out provision. Ultimately such a provision could only have its constitutionality upheld by determination of the High Court.

International trade obligations

6.63 In addition to the constitutional issues, concerns were raised in relation to Australia's international rights and obligations under the World Trade Organization (WTO) agreements. The IOGTR noted that as a member of the WTO, Australia has agreed to adhere to a number of obligations. Breaching these obligations could lead to the possible imposition of sanctions on Australia.

6.64 The WTO agreements seen as relevant to the establishment of a national regulatory regime under the Gene Technology Bill 2000 are the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Agreement on Technical Barriers to Trade (TBT Agreement) and the General Agreement on Tariffs and Trade 1994 (GATT 1994). These agreements recognise the right of WTO members to adopt measures to protect the health and safety of people, and to protect the environment, as provided for in the Gene Technology Bill 2000.

6.65 Advice to the CSCG from the Departments of Foreign Affairs and Trade, and Attorney-General's on the WTO obligations relevant to gene technology regulation and the Commonwealth's responsibility for State and Territory measures under international law argued that there was some risk to Australia's international obligations associated with the inclusion of an explicit opt-out provision. The IOGTR summarised the advice as follows:

> any measure taken to constrain the release of GMOs in Australia, on the basis that such GMOs might contaminate or damage organic counterparts in a particular State, will only be consistent with Australia's international trade obligations if such damage occurs to the life or health of organic counterparts and that damage is capable of being assessed on the basis of scientific principles. Measures taken purely to respond to consumer

36 Submission No.89, p.14 (Tasmanian Government).

> concerns about the product which do not have a scientific basis will be found to be in breach of Australia's international trade obligation.
>
> …The Commonwealth government may well have an obligation to formulate and implement positive measures and mechanisms to support the observance of the WTO Agreement by local governments making up the Member State…By introducing a clause into the Bill providing for States and Territories to opt-out of the regulatory scheme on other than scientific grounds, there is a risk of contradicting this responsibility.[37]

6.66 Tasmania was again in disagreement with these views, noting that as yet no jurisprudence exists on GMOs in the context of WTO agreements. The Tasmanian Government indicated that it had received advice in relation to the SPS, TBT and GATT Agreements. This advice included:

> …if it were held that the [SPS Agreement] did apply to GMOs, it may be possible for an opt-out where Australia could establish that a particular State or Territory had SPS characteristics different from the rest of Australia. In this case, a proper risk assessment would have to have been completed. Tasmania considers that regional variations in SPS characteristics should be taken into account in the regulation of GMOs.
>
> …should it be found that GMOs are governed by the GATT agreement, then it may be that a particular State or Territory, wishing to opt-out, could do so without offending the agreement on the basis that the refusal to allow the release of a particular GMO was necessary for the protection of human, animal or plant life.
>
> …Assuming that the opt-out is a "technical regulation" and thereby falls within the ambit of the [TBT] Agreement, it is likely that the legitimate objectives of "protection of human health or safety, animal or plant health, or the environment" mentioned in the Agreement are objectives to which the opt-out would apply.

The Tasmanian Government was further advised that, 'even if regional approaches are not possible under the SPS agreement, a GM-free policy or zone based on ensuring the purity and quality of product from the zones to respond to consumer demand or cultivate a certain marketing image, would not offend WTO agreements'.[38]

6.67 Tasmania argued that as the relevant WTO agreements do not apply so as to prohibit restrictions:

> a State wishing to be GM-free or have GM-free zones would then have the following options available under the national regulatory regime:

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37 Submission No.77, p.160 (IOGTR). The advices are provided in full at Attachments D and E to the submission.

38 Submission No.89, p.15 (Tasmanian Government) and Submission No.39 (Department of Primary Industries, Water and Environment).

1. To permit licensed dealings with certain GMOs throughout the entire State, for example if a GMO posed an unacceptable risk to the environment, plant or animal health, purity and quality of produce or market image, the State could decline to have the GMO licence operate within their territory; or
2. To permit licensed dealings with all GMOs in certain parts of the State, for example only in established GM zones; or
3. To permit licensed dealings with certain GMOs in certain parts of the State, for example only those GMOs that the State did not consider imposed an unacceptable risk to the environment, plant or animal health, purity and quality of produce or market image and only within established GM zones; or
4. To permit all licensed dealings with GMOs throughout the entire State; or
5. To refuse to permit any dealings with GMOs throughout the entire State.[39]

6.68 Tasmania concluded that the opt-out arrangements should not, therefore, be considered as an all or nothing approach and should be provided as a measure for giving effect to sovereign States rights to control agricultural industries, including on a commodity by commodity basis. Minister Llewellyn advised the Committee that:

> The points that have been made here have moved from being able to refuse to permit any dealings with GMOs throughout the entire state through to permitting licensed dealings with certain GMOs throughout the entire state, or a regional part within the state. That would be up to states themselves to make those decisions based on their own circumstances. That is the nature of the opt-out provision that I am talking about.[40]

6.69 As noted above, the Victorian Government is now also looking at the possibility of GM-free zones within their State.

6.70 The idea that international obligations under the WTO could be used to bind States to activities that may impact negatively on their economies or environment was criticised in evidence. The OFA commented that:

> There is an international consumer and grassroots reaction to the activities of the WTO in forcing borders open in this way. It is likely that in the future there will be a resurgence of protection of the rights for countries and territories to govern their own affairs.[41]

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39 Submission No.89, p.16 (Tasmanian Government).

40 *Committee Hansard*, 23.8.00, p.232 (Minister David Llewellyn).

41 Submission No.54, p.18 (OFA).

The Tasmanian situation

6.71 While Tasmania dissented from the CSCG decision that an opt-out would not be accommodated in the Commonwealth legislation, based largely on contradictory legal advice on the Constitutional and WTO issues, other arguments were also advanced to support Tasmania's case.

6.72 Tasmania considers, that as a sovereign state, it has a right to decide on the appropriate level of protection for its environment and primary industries, including the right to decide whether GMOs are released in the State and if so on what basis.[42]

6.73 Many submissions were received from Tasmania which, along with their Government, argued that the State has a unique environment and a unique identity. As an island, Tasmania has a range of flora and fauna indigenous and exclusive to the State. The natural barrier of its geographic location and isolation has assisted it to remain relatively pest and disease free, providing a comparative advantage for its primary industry products. The 'clean, green, quality' image this conveys is used extensively to market food and other products. Niche markets are targeted for domestic and international export, which, by using the 'clean, green, quality' image can attract a premium for Tasmanian products.

6.74 Evidence was given that Tasmanian primary producers who may be unable to compete effectively in mass product markets, have a comparative advantage in servicing these premium-priced niche markets. The Committee was advised of international markets where consumer rejection of GE products was rapidly increasing, with a consequent growing demand for organic and certified non-GE products. The ability to compete in these expanding markets relies heavily on marketing and marketing perceptions. It was therefore argued that the release of GMOs into Tasmania would threaten the capacity of Tasmanian food producers to utilise GE free status to compete in both Australian and overseas markets, thereby jeopardising the Tasmanian producers' 'clean, green' market image and undermining consumer confidence in the GE status of their produce.[43]

6.75 The Committee received evidence from and about companies operating in Tasmania which differed dramatically as to the impact the release of GM products and consequent loss of GM free status could have on the viability of their companies in relation to export potential.

6.76 Members from GE-Free Tasmania advised the Committee that they had seen 'major employers and significant companies in Tasmania like Lactos declare that they stand to lose $12 million a year in annual earnings if they forfeit their GE-free status'. In addition, they had seen 'declarations from the pome fruit industry, three of the

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42 *Committee Hansard,* 23.8.00, p.220 (Tasmanian Government).

43 Submission No.25, Appendix A: Reasons for an Opt-Out Clause and a GE-Free Tasmania, p.33 (Mr Andrew Mcintosh). See also Submission No.35, pp.25-6 (GE-Free Tasmania) and Submission No.107, pp.23-6 (Food Industry Council of Tasmania).

largest dairy producers, the salmon industry, the viticulture industry and the apiarists'.[44]

6.77 Serve-Ag, a company covering the whole spectrum of agricultural production, questioned whether Tasmania had to be totally GM free to enhance the 'clean, green' image and suggested that it did not. Serve-Ag argued that the products and markets where GM or GM free would be an advantage needed to be considered on a case-by-case basis.[45] In relation to the Tasmanian agricultural industry, trials have been mainly with canola involving herbicide and disease tolerant strains and poppies involving a strain to produce a greater alkaloid yield.

6.78 The poppy industry is unique in that Tasmania is the only State licensing commercial poppy cultivation for sale to the pharmaceutical industry. Sales are growing rapidly from $23 million in 1996 to an expected $100 million in 2000, of which 95 per cent is export, accounting for about 25 percent of the global market share. While cultivation of GE poppies on a commercial scale is not envisaged for at least five years, the industry would like to explore the technology through limited field trials to ensure overseas competitors do not gain an advantage over the Tasmanian industry. Tasmanian Alkaloids argued that if Tasmania were to opt-out of the Commonwealth regulatory system, an arrangement should be worked out to allow the limited poppy field trials to be conducted on a fully controlled basis.[46]

6.79 The Tasmanian Government has acknowledged that there may be circumstances in which Tasmania's niche markets demand certain products to be either GM or non-GM. In such a rapidly changing climate requiring further research and investigation with few easy answers, a parliamentary inquiry was established in Tasmania to examine issues relating to GMOs, including economic costs and benefits for Tasmania, market opportunities for both GM and non-GM primary products, environmental risks and food safety.

6.80 The establishment of the Tasmanian inquiry followed a declaration made on 26 July 2000 that any genetically modified plant or plant product would be a 'pest' under the Plant Quarantine Act. In conjunction with this declaration a 12-month moratorium was imposed on such products in Tasmania. The declaration and inquiry were made in accord with the current position of the Tasmanian Government 'that the issues surrounding adoption of GMOs is unclear and with such a degree of uncertainty that the Tasmanian Government is unwilling to have GMOs present in our agricultural systems until the issues are resolved'.[47]

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44 *Committee Hansard*, 23.8.00, pp.160-1 (GE-Free Tasmania).

45 *Committee Hansard*, 23.8.00, p.195 and Submission No.8, attached Position Paper – GM in Tasmania (Serve-Ag).

46 Submission No.10, pp.1-3 and *Committee Hansard*, 23.8.00, pp.208-9 (Tasmanian Alkaloids).

47 Submission No.89, p.1 (Tasmanian Government).

6.81 The Food Industry Council of Tasmania has adopted a similar line of argument in making a number of recommendations. The Council believes that there are a number of issues requiring clarification before determining whether Tasmania should refrain from or adopt GM technology. These issues revolve around the impact on Tasmania's export markets and their future acceptance of GM or GM-free produce, and the effects of GMOs in food production. The Council recommends a moratorium while further research is undertaken into these issues, noting that research for GMOs should be contained with no releases into the open environment.[48]

6.82 Minister Llewellyn clarified that the moratorium imposed by the Government is 'currently on the open research and trialing of GM crops in the Tasmanian environment. It is not a moratorium that will stop research in laboratories, in plant houses or in covered cages in the environment'.[49]

6.83 Some companies were critical of the decision in relation to the impact it would have on industry. Indeed, Aventis commented that 'one might almost characterise it as capricious'. Aventis, which has been conducting canola trials in Tasmania since 1998-99, claimed that it now had to reassess conducting 13 trials this spring for which GMAC approvals had already been received and that the growers involved have had their coming season thrown into uncertainty. Aventis provided the Committee with a copy of legal advice by Deacons indicating the legal prospect of having the Declaration ruled invalid was high.[50]

6.84 Concern was expressed at the possibility of a legal challenge by Aventis and the impression this would have on the community.

> They claim to be a corporate citizen and yet the community down here, as reflected and represented by the government, have said that they do not want these field trials at this stage. If they had any integrity they would respect that…They would gain acceptance of this technology by slowing down.[51]

Conclusion

6.85 The Committee has noted the variations in interpretation as to the constitutional and international trade implications of an opt-out clause being inserted into the Commonwealth legislation. Ultimately these variations may only be determined through legal rather than parliamentary decisions.

6.86 The Committee's considerations have led it to conclude that with so much uncertainty over the impact of rapidly developing gene technology, it is imperative that the integrity of a strong national regulatory system remains paramount. The

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48 Submission No.107 (Food Industry Council of Tasmania).

49 *Committee Hansard,* 23.8.00, p.225 (Tasmanian Government, Minister Llewellyn).

50 Submission No.61, p.5 and *Committee Hansard,* 22.8.00, p.123 (Aventis).

51 *Committee Hansard,* 23.8.00, p.151 (OFA).

Committee cannot support States or Territories being permitted to withdraw entirely from a national regulatory system and establishing their own systems, with the inherent problems of duplication and the development of inconsistent systems.

6.87 Nevertheless, the Committee has sympathy with the argument put by many Tasmanians, and others in evidence, and supports the strengthening of State rights and powers within the proposed national regulatory system. With the Regulator having to accept State or Territory viewpoints to prevent the release of GMOs within their jurisdictions and the capacity to establish GM-free zones, the national regulatory system established in the Bill should effectively provide an opt-out. The Committee considers that the relevant provisions of the Bill should be strengthened to ensure that this scenario is entrenched in the Bill so as to achieve an outcome acceptable for the States without undermining the integrity of the national system.

6.88 The Committee also considers that the strengthening of the Commonwealth legislation should also be replicated in the complementary State legislation through the inclusion of a clause reflecting the Commonwealth provisions.

Recommendation

The Committee RECOMMENDS that provisions in the Bill requiring the Regulator to accept State or Territory viewpoints to prevent the release of GMOs within their jurisdictions be strengthened.

Term of Reference (k): The alleged genetically-modified canola contamination in Mount Gambier and the processes followed by the Interim Office of Gene Technology in investigating and reporting on the allegations

Background

6.89 In 1996, the Genetic Manipulation Advisory Committee (GMAC) approved an application to conduct field trials of canola (*Brassica napus*) modified for resistance to the herbicide glufosinate ammonium (PR-62).[52] The gene expressed in the genetically modified canola came from the bacterium *Streptomyces viridochromogenes* and coded for an enzyme phosphinothricin acetyl transferase (*pat*). This enzyme chemically modifies the herbicide glufosinate ammonium and renders it inactive. A plant expressing this enzyme is tolerant to this herbicide.

6.90 In the same year, GMAC approved the field trial of a genetically modified canola with a new hybridization system to ensure cross pollination rather than self pollination to produce higher-yielding hybrid varieties (PR-63).[53]

6.91 To achieve the hybrid, the canola was modified in two ways:

52 PR-62 *Development of glufosinate ammonium tolerant canola cultivars*, GMAC advice notified 25 June 1996.

53 PR-63 *Field evaluation of a genetically modified canola (Brassica napus) with a new hybridization system*, GMAC advice notified 25 June 1996.

- a male sterile line was created by inserting into the canola a gene (barnase) from the bacterium *Bacillus amyloliquefaciens*. The gene codes for an enzyme that inhibits the development of anthers, the pollen producing male parts of the plant. This renders the plant male sterile.
- a second fertility restorer line is created by inserting another gene (barstar) from the same bacterium which produces an enzyme which inhibits the enzyme produced in the male sterile line.

By crossing the male sterile line and the fertility restorer line a fertile hybrid is produced.

6.92 The phosphinothricin acetyl transferase gene from the bacterium *Streptomyces hygroscopicus* was also present in the male sterile and fertility restorer lines to confer tolerance to glufosinate ammonium. Some lines also contained the neomycin phospho transferase gene, from the bacterium *Escherichia coli,* which confers resistance to the antibiotic kanamycin. Both of these genes were used as marker genes to allow identification and selection of transgenic plants.

6.93 In 1997, GMAC also approved a field trial involving a different species of canola (*Brassica rap*a) which contained the new genetic system for making hybrid varieties, and genes for tolerance to the herbicide glufosinate ammonium (PR-85).[54]

6.94 GMAC notified advice and recommendations for a number of extensions to these field trials between April 1997 and September 1998. The extensions for PR-62 and PR-63 evolved from the initial development of glufosinate ammonium tolerant canola cultivars (PR-62), to field evaluations with the new hybridization system (PR-63), to small and large scale seed production (PR-63X(2)) and finally to the release of glufosinate-ammonium tolerant hybrid and open-pollinated canola cultivars (PR-63X(4)). Extensions to PR-85 were aimed at increasing seed stocks of genetically modified canola (*Brassica rapa*).

6.95 Aventis submitted to GMAC proposals for further extensions to these trials on 8 December 1998 (PR-63X(4)) and on 2 March 1999 (PR-85X(2)), with summaries of the two proposals included on the GMAC website and advertised in the *Commonwealth of Australia: Government Notices Gazette* on 24 December 1998 and 25 March 1999 respectively. Public comment in relation to the two proposals was called for and interested persons, including relevant local, state and territory governments, were notified. Thirty days were allowed for comment on the proposals, with only one response received.

6.96 Following consideration of the proposals and on the basis of its risk assessment, GMAC provided advice to Aventis in relation to the trials PR-63X(4) and PR-85X(2) on 25 March 1999 and 17 June 1999 respectively.

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54 PR-85 *Small and large scale seed increase of a genetically modified canola (Brassica rapa) with a new hybridisation system*, GMAC advice notified September 1997.

6.97 GMAC provided the following advice in the form of recommendations to Aventis in relation to the proposals:

- each trial site was surrounded with a 15 metre buffer crop of non-transgenic canola to minimise the escape of pollen;
- the trial sites were separated from other *Brassica* crops by at least 400 metres;
- a 400 metre zone around each site was monitored for the presence of canola (Brassica napus);
- a 50 metre zone around each site was monitored for species that were sexually compatible with the trial species;
- the person responsible for each site should also be responsible for monitoring and clean-up of the site [PR-63X(4) only];
- data was collected on gene transfer [PR-63X(4) only];
- all trial sites would be monitored for 3 years post trial to detect and remove volunteer canola plants;
- harvested seed not required for other field trials was destroyed;
- there was compliance with GMAC guidelines concerning seed transport;
- GMAC was notified of trial site locations prior to planting;
- GMAC was provided with a copy of a press release; and
- GMAC was notified of the procedure for appropriate disposal of field trial trash before these products were utilised.

6.98 PR-63X(4) and PR-85X(2) involved up to 83 trial sites in canola-growing regions of Western Australia, South Australia, Victoria, Tasmania and New South Wales, including Mt Gambier, SA and Wagga Wagga, NSW.

6.99 On 14 March 2000 the IOGTR received information in a letter from a private individual, Ms Leila Huebner, concerning the lack of local canola buffer zones surrounding a GM canola crop at Moorak near Mount Gambier. The IOGTR responded by advising Ms Huebner that the Office intended to investigate the matter but that it required further information, and by writing to the Minister noting that an apparent breach of GMAC conditions had been reported that would be investigated and a report prepared.

6.100 Ms Huebner did not receive the IOGTR letter faxed on 16 March, and, concerned that no response had been made to her earlier letter contacted the IOGTR by phone on 31 March. Ms Huebner finally received a copy of the IOGTR response and provided the requested information on 3 April.

6.101 During this period, on 24 March, a reporter from *The Age* sought background information from the IOGTR relating to a story that was subsequently published on

25 March. The article made allegations relating to GM canola crops at Moorak and the disposal of GM canola plants. The IOGTR identified that the field trials being referred to were PR-63X(4) and PR-85X(2) – the same trials described in the earlier allegations by Ms Huebner.

6.102 When the information provided by Ms Huebner and *The Age* reporter were considered against the GMAC recommendations for these trials, IOGTR considered that some of the recommendations (as highlighted above) may have been breached.

Existing system of administrative controls over genetically modified organisms

6.103 Before outlining the investigation of these possible breaches, it is important to understand the administrative system in place at the time of the possible breaches.

6.104 As has been noted earlier in this report, Australia does not have a system of legislative controls to regulate dealings with genetically modified organisms. It relies on a system of voluntary compliance whereby organisations dealing with GMOs choose to submit information about a GMO to GMAC. GMAC assesses the biosafety risks associated with the GMO and provides recommendations to the organisation about any biosafety risks and how they can be managed. The organisation voluntarily implements and complies with those recommendations.

6.105 Until May 1999, this voluntary system was overseen by GMAC with the support of a small secretariat. Non-compliance with GMAC recommendations were identified primarily through self-reporting by entities dealing with GMOs as required under the GMAC guidelines and notification of possible breaches by third parties. All breaches notified to GMAC were reported in the GMAC Annual Reports between 1985-1999.

6.106 Clearly, such a self-reporting system is inappropriate and unsatisfactory. Even so, up until May 1999 13 breaches of GMAC guidelines and seven incidents involving GMOs had been notified to GMAC.[55] Given that this has been a self-reporting system, one can only speculate as to the extent of other breaches that may have gone unreported.

6.107 The IOGTR was established in May 1999. While the Office's primary function is to develop and implement the new national regulatory system for gene technology, it has also implemented improvements to GMAC's monitoring and investigation systems. These improvements included the development of a new monitoring strategy involving spot checks of field trials by IOGTR officials accompanied by independent experts, the preparation of a protocol for reporting

55 A summary of these breaches/incidents as described in GMAC Annual Reports between 1985-1999 is in Submission No.77, Table K1, p.166 (IOGTR). The ACF GeneEthics Network noted that the Mount Gambier incident was 'only the latest in a long line of releases outside GMAC guidelines and advices over the past decade', Submission No.85, p.17.

breaches, and the implementation of new arrangements for investigating possible breaches of GMAC recommendations and for reporting on these.

6.108 Nevertheless, the IOGTR has conceded that there are continued shortcomings with the current system:

> While considerable administrative improvements have been implemented to underpin the current system of voluntary controls, the IOGTR has no legislative underpinning to conduct investigations into an entity's voluntary compliance with recommendations made by GMAC to manage risks associated with GMOs.
>
> Pending establishment of the new regulatory system, the IOGTR has, therefore, limited capacity to access documents or premises or to investigate matters unless the entity concerned chooses to cooperate. Similarly, the IOGTR has no legislative capacity to enforce compliance with GMAC recommendations or to enforce compliance with risk management plans.[56]

It is within this system with all its shortcomings that the investigation into the alleged breaches at Mount Gambier was undertaken.

The investigation

6.109 The IOGTR provided an overview of the steps taken to investigate Aventis' compliance with GMAC conditions in relation to PR-63X(4) and PR-85X(2). In addition to the particular Moorak site, the IOGTR widened the investigation to include all sites associated with these field trials to establish whether any breaches reflected a problem with overall trial management or whether the problems were confined to the particular site.

6.110 An overview chronology of events during the investigation follows[57]:

13 March 2000: Ms Leila Huebner, a private individual, confirms concerns relating to GE canola trials in the Mount Gambier district with Mr Scott Kinnear from the Organic Federation of Australia, who advises Ms Huebner to raise her concerns with the IOGTR.

14 March 2000: Ms Huebner faxes letter expressing concerns to the IOGTR.

16 March 2000: IOGTR wrote to Ms Huebner requesting further details of the alleged breach. This letter was apparently faxed, though Ms Huebner did not receive it.

IOGTR forwarded advice to the Minister concerning the matters raised in Ms Huebner's letter, the IOGTR's request for additional information from

56 Submission No.77, p.169 (IOGTR).

57 This overview is based on a chronology from Submission No.77, pp.171-5 (IOGTR) with further information added from other submissions and evidence. The Committee notes that there was some dispute in evidence as to the detailed timing of when certain events occurred (see especially Submission No.55, supplementary submission, dated 12 September 2000).

Ms Huebner and the need for the apparent breach of GMAC recommendations to be investigated.

17 March 2000: Prof Rick Roush, a member of GMAC and Head, CRC for Weed Management, provided with copy of Ms Huebner's letter. Shortly after, Prof Roush arranges to meet Ms Huebner on 3 April after meetings in Mount Gambier.

24 March 2000: Mr Geoff Strong, a reporter from *The Age*, contacted the IOGTR by telephone and identified possible breaches of GMAC recommendations, and the location of the offending trial site.

IOGTR provided notification to relevant Departmental officials and the Minister's Office of the further information provided by the reporter in relation to the matters raised by Ms Huebner.

25 March 2000: *The Age* prints article by Mr Strong 'GM crop dumped at tip'.

27 March 2000: IOGTR wrote to Aventis asking for documentation of compliance with GMAC's recommendations and for details of the information Aventis had provided to contracted growers.

IOGTR notified relevant Commonwealth agencies including the Department of Prime Minister and Cabinet, the Department of Agriculture, Fisheries and Forestry and the Department of Industry, Science and Resources of a possible breach and subsequent investigation.

IOGTR determined that the scope of the investigation should be broader than the Yells Road, Moorak site identified thus far. Taking into account the fact that as many as 83 sites were involved in the two trials, it seemed appropriate to determine whether the matters raised in respect of Yells Road, Moorak were isolated incidents, or systemic problems.

IOGTR began identifying an expert to undertake site inspections and put arrangements in train for this inspection.

28 March 2000: IOGTR forwarded advice to the Minister on matters raised in relation to possible breaches in *The Age* article and through discussions with Mr Strong from *The Age*.

IOGTR wrote to the Department of Premier and Cabinet in South Australia.

First response received from Aventis, including a range of documents.

29 March 2000: IOGTR wrote a second letter to Aventis requesting that information provided in Aventis' letter of 28 March 2000 be provided in the form of a statutory declaration. In the absence of a legislative framework for the conduct of the investigation, IOGTR considered that evidence provided in this form would introduce as much rigour as was possible under a voluntary system.

Aventis responded to IOGTR's second letter, providing the requested Statutory Declaration.

Aventis attended a meeting with IOGTR to discuss the alleged breaches.

30 March 2000: IOGTR sought legal advice from the Australian Government Solicitor about relevant matters.

31 March 2000: An expert from the CRC for Weed Management and an IOGTR official carried out unaccompanied (ie. not in the company of Aventis) site inspections in South Australia, visiting several properties growing transgenic canola as part of the field trials under investigation.

Ms Huebner follows-up by phone lack of response by IOGTR to her 14 March letter. A copy of the IOGTR response is finally received.

3 April 2000: Prof Roush investigated sites in the Mt Gambier region in the company of Aventis and attended a public meeting in Mt Gambier.

After meetings, Prof Roush meets Ms Huebner to discuss her observations and concerns and is given copies of her videotapes and photos. IOGTR is provided with further details of alleged breach in response to request to Ms Huebner.

4 April 2000: IOGTR sent a third letter to Aventis, seeking further details and documentation on matters referred to in Aventis' letter of 28 March.

Report of site inspection conducted on 31 March 2000 received by IOGTR. Necessary follow-up actions were identified.

5 April 2000: The alleged breaches was one of the matters raised when the IOGTR appeared before the House of Representatives Standing Committee on Primary Industries and Regional Services. An offer was made by the IOGTR to provide the Committee with a progress report in a fortnight of the hearing. IOGTR stressed that it could not put a timeframe on the completion of the investigation.

6 April 2000: Response received from Aventis to IOGTR's third letter.

11 April 2000: Literature search completed and documents forwarded to relevant GMAC members for review.

13 April 2000: Advice from GMAC re sexually compatible weeds completed.

17 April 2000: File search of relevant GMAC files and document review completed.

19 April 2000: Draft determination completed and forwarded to Aventis in accordance with advice from Australian Government Solicitor. Aventis invited to correct any factual inaccuracies (with supporting documentation) and provide any additional information. Aventis' response was requested by 4 May.

Progress report provided to the House of Representatives Standing Committee on Primary Industries and Regional Services in accordance with the undertaking given on 5 April.

Copies of these documents were provided in electronic form to relevant departmental officials and to the Minister's office.

27 April 2000: Formal advice provided to the Minister asking that the progress report and the draft determination be noted, and informing him that Aventis had been invited to comment on the draft determination by 4 May 2000.

2 May 2000: Aventis advised, by fax, that due to the volume of work involved, and the long Easter break, Aventis would not be in a position to meet the

	IOGTR's deadline of a 4 May response to the draft determination. Aventis advised that it would provide a response on 18 May 2000.
8 May 2000:	Breach and draft determination discussed at GMAC Release Subcommittee meeting.
18 May 2000:	Report received from Professor Roush in respect of the site inspections conducted on 3 April 2000. Oral reports had been previously given to GMAC and IOGTR on 3 and 4 April and 8 May.
19 May 2000:	Aventis' response to the draft determination provided to IOGTR and discussed at a meeting between Aventis representatives and the Office. Aventis subsequently indicated that they wished to provide additional information.
24 May 2000:	The further advice foreshadowed at the meeting of 19 May 2000 was received from Aventis.
30 May 2000:	Further information requested from Aventis concerning fate of seed from field trials and method for dealing with monitoring zones which encroach on neighbouring properties.
2 June 2000:	Aventis advised a delay in replying to the above request.
8 June 2000:	Reply from Aventis to question on fate of seeds received. Aventis were requested to supply information in answer to the second issue (encroachment of monitoring zones).
15 June 2000:	Response received from Aventis on issue of monitoring zone encroachment on neighbouring properties.
	IOGTR staff spoke with a reporter in Mt Gambier from *The Border Watch,* and to a waste contractor in the Mt Gambier area.
16 June:2000:	*The Age* prints article by Geoff Strong 'Seeds of discontent' relating to the investigation's progress.
20 June 2000:	Final determination and summary document for IOGTR Quarterly Report sent to the Chair of GMAC for clearance.
21 June 2000:	Final determination sent to Aventis.
22 June 2000:	Comment on final determination received from Aventis.
29 June 2000:	Report provided to the Minister.
12 July 2000:	Minister approved report.

6.111 The detail of the investigation undertaken is important for the lengthy timeframe involved – from 14 March to 12 July. In particular, this emphasises the lack of power to enforce compliance and delays in the investigative process. These deficiencies were recognised by the IOGTR which commented that in relation to the content and the timing of the completion of the report, it should be noted that:

- while the IOGTR can propose timeframes for matters dealt with in this report, it cannot force third parties to comply with those timeframes;
- the investigation dealt with a large amount of data and required further scientific interpretation from the scientific committee; and

- while recognising there is considerable media interest in this matter, the breaches did not constitute a risk to human health and safety or any significant risk to the environment.[58]

6.112 Even Aventis considered that:

> the IOGTR has faced significant difficulties of process in "investigating" so-called "breaches" of what are in fact "recommendations". There were no statutory provisions to govern their procedures and they faced the common law duty to observe due process (sometimes called natural justice). There was no power to compel witnesses to do anything they wished not to do.[59]

Conclusions and outcomes from the IOGTR's investigation

6.113 The IOGTR investigation identified that Aventis had failed to demonstrate compliance with 5 GMAC recommendations, as follows:

> Breach 1: Aventis failed to demonstrate that a 15metre buffer of non-transgenic canola had been established around summer plantings of field trials under PR-63x(4) and PR-85x(2);
>
> Breach 2: Aventis failed to demonstrate adequate monitoring for the presence of the weed *H. Incana* as a species which is sexually compatible with canola;
>
> Breach 3: Aventis failed to implement appropriate measures, in at least one instance, to give effect to the monitoring for volunteers;
>
> Breach 4: Aventis failed to demonstrate compliance with GMAC's Guidelines for the Deliberate Release of Genetically Manipulated Organisms (April 1998) for transport of transgenic seed to and from trial sites; and
>
> Breach 5: Aventis failed to notify GMAC as required, and did not institute practices that would demonstrate compliance with the requirement to bury trial trash under 1 metre of soil.[60]

6.114 Aventis disagreed with the findings in relation to Breach 1 and Breach 2. Aventis maintained that the 'so-called breaches' were of a technical, administrative or very minor kind. In several cases the 'so-called breach' arose from a lack of certainty as to what GMAC 'recommendations' mean, and how in practice they should be interpreted. Aventis contends that 'there was not enough clarity and certainty in some of the GMAC "recommendations" (and they are that, not rules or orders), for anyone

58 Submission No.77, p.175 (IOGTR).

59 Submission No.61, p.9 (Aventis).

60 Submission No.77, p.176 (IOGTR). The findings in relation to each breach are described in detail on pp.177-8 of the submission.

to characterise the divergences between GMAC's expectations and Aventis' performance as "breaches"'.[61]

6.115 The IOGTR assessed the risks to human health and safety, and the environment, arising from the breaches of the GMAC recommendations as found in their investigation. In summary, the IOGTR reported:

> Risks to human health and safety: GMAC advises that none of the breaches referenced above represent an increased risk to human health and safety because there was negligible risk of transfer of the gene to commercial canola crops (which were not grown in the area during the trial period). Even if such transfer did occur, oil derived from this variety of transgenic canola is approved by ANZFA for human consumption.
>
> Risks to the environment: GMAC advises that the breaches may have resulted in an increased risk to the environment because non-compliance with GMAC recommendations has increased the potential for out-crossing of GM canola, including through uncontrolled seed dispersal.[62]

6.116 After identifying the breaches of GMAC recommendations and assessing the risks arising from them, the IOGTR developed a risk management plan to address environmental problems and technical problems arising from the breaches. The risk management plan forms the basis for a strategy to control further problems that may arise from the current trials and minimise risks in future trials. The main components of the plan are:

- monitoring of sites where a 15 metre buffer zone was not observed;
- monitoring for the presence of sexually compatible species;
- 400 metre zone around trial sites;
- monitoring for volunteers;
- monitoring of transport routes and burial sites; and
- written evidence from farmers and companies that they understood and are adhering to GMAC recommendations.[63]

6.117 The implementation of this plan addresses specific problems associated with the particular breaches of this case. It is imperative that such an approach is adopted for the wider picture.

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61 Submission No.61, pp.9-10 (Aventis).

62 Submission No.77, p.177 (IOGTR).

63 Submission No.77, pp.178-181 (IOGTR).

Monsanto and the release of GM cottonseeds

6.118 While not specifically relating to the Mount Gambier term of reference, the Committee received evidence of a breach by Monsanto that raised issues similar to those addressed in the preceding section. The breach in question related to GM cottonseed from a Roundup ready cotton trial not being segregated, and so becoming mixed with non-GM cottonseed. The GM cottonseed thereby entered normal commerce after being crushed as oil for export or for stock food.[64]

6.119 Under the self-reporting procedure, Monsanto notified GMAC after their monitoring processes discovered the breach and an audit process was instituted. The IOGTR advised that while Monsanto had not fully complied with a GMAC recommendation about how the GM crop should be dealt with, due to the thorough risk assessment of Roundup ready cotton conducted in response to the application, there was no increased risk to human health or safety or to the environment resulting from the breach.[65]

6.120 This incident exemplified, as did Aventis at Mount Gambier, a breakdown in compliance with GMAC recommendations, which continued the line of breached GMAC recommendations referred to earlier in the chapter. The IOGTR commented that the current voluntary system would be improved by the legislation providing a full regulatory system where compliance processes are readily available to the regulator. Monsanto also acknowledged that it did not think the breach would have occurred under the procedures of the new regulatory system.[66]

Issues arising from this case for the future

Approval of trials

6.121 Aventis submitted that difficulty arises out of the informal nature of the present 'approval' processes. The process was described as normally involving:

> a detailed exchange of correspondence, more in the nature of a negotiated arrangement than the issue of an order of determination by duly constituted authority. This exchange of information and advice is a two-way process. The proponent explains their intended action and the GMAC comes to a series of "recommendations" (and that is the word used) about what they believe should be done.[67]

6.122 The Committee considers that, in the light of the breaches and Aventis' response, this process clearly needs strengthening with greater legislative authority required. Licensing of trials and greater certainty in the conditions under which they

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64 *Committee Hansard,* 25.8.00, p.389 (Dr Blowes, Monsanto).

65 *Committee Hansard,* 25.8.00, p.451 (IOGTR).

66 *Committee Hansard,* 25.8.00, pp. 449-51 (IOGTR) and p.390 (Dr Blowes).

67 Submission No.61, pp.7-8 (Aventis).

must take place requires the backing of legal authority. The responsibility of the licensed party in adhering to conditions must be clearly understood with the backing of severe sanctions for any breach of conditions.

Secrecy issues

6.123 It was argued in evidence that while some correspondence was sent to the district council about these trials in their district, the council and local community were not informed of the location of these trials. There was also claimed to be a lack of information among some farmers growing GE canola, who believed they had been deliberately deceived over the status of the canola they were growing. In other situations land had apparently been leased to grow GE canola without the owners' knowledge or consent.[68] Professor Roush disputed these claims, saying that discussions he had with farmers with whom Aventis had worked indicated that they 'knew what was going on'.[69]

6.124 Aventis suggested that in relation to this issue, 'it depends on your definition of secrecy'. They noted that they 'have to convey a lot of information to the farmers' and have contractual obligations that provide minimal requirements. Aventis did concede that in initial contracts there was no reference to genetic modification, though 'we have certainly updated and improved our information flows between our farmers and ourselves and included in the contracts definitions which include that of a GMO'.[70]

6.125 The Committee believes that if the development of GM crops is to receive consumer support and confidence, the apparent levels of secrecy surrounding their trialing, as evidenced at Mount Gambier, must be overcome. The oft-repeated aim of transparency underpinning the current legislation can only be achieved if such trials are conducted in an open fashion. This issue is also discussed in Chapter 3. The Committee considers that the public will only embrace the developing technology if they have understanding and confidence, which can only be accomplished through honesty and information.

Power to enforce recommendations in trials

6.126 The inability of GMAC to enforce adherence to their recommendations is demonstrated by both the Aventis Mount Gambier and Monsanto cottonseed incidents. Aventis proffered the argument that if a transparent and unambiguous regulatory process, with clear rules or codes of practice to follow backed by the force of law had been in place, the Mount Gambier incident 'would not have happened the

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68 Submission No.9, p.17 (Heritage Seed Curators Australia); *Committee Hansard*, 22.8.00, p.76 (Ms Huebner), p.82 (Mr Rankin) and 23.8.00, p.161 (GE-Free Tasmania).

69 *Committee Hansard*, 22.8.00, pp.96, 102 (Professor Roush).

70 *Committee Hansard*, 22.8.00, pp.125, 130 (Aventis). Aventis tabled at the hearing the standard form of licence agreement from September 1999 and June 2000 to show the evolution.

way it did'.[71] The Committee believes that the existence of a regulatory regime in and of itself should not be required to ensure that companies undertake the trialing of GM products in a totally safe and responsible manner.

6.127 The Committee considers that it is perfectly natural for the public to be deeply worried by the apparent willingness of companies to only be concerned at meeting whatever minimal process and procedures may be in place, irrespective of the possible detrimental outcomes to public health and safety, and the environment.

6.128 It is argued that the establishment of the regulatory system proposed in this Bill will impose the absolute necessity of adhering to procedures by companies and provide the Regulator with the powers and sanctions to enforce adherence.

Monitoring of trials

6.129 Deficiencies with the existing system in monitoring trials to ensure recommendations are being adhered to were also demonstrated by the Mount Gambier incident. The Committee was informed that suspicion about the trial crops in question only emerged following 'local gossip' at a TAFE.[72]

6.130 The development of spot checks is an important step in monitoring trials. Such procedures must be further developed and be fully resourced. The legislation should establish a rigorous and funded framework for routine inspections of sites to improve public confidence. Yet again the question of public confidence is paramount. Breaching trial recommendations can be seen as the cardinal sin. To mix metaphors 'the horse has bolted and the genie cannot be put back in the bottle', both in respect of environmental contamination after it has occurred and the resultant community distrust of a system that allows such an incident to occur.

Investigative procedures

6.131 As noted earlier, a period of nearly four months elapsed from the date the IOGTR received allegations of possible breaches to the Minister's final approval of the report. Claims and counter claims have been made in evidence of delays in responding to information, providing assessment reports and commenting on evidence. The Committee notes the advice of the Australian Government Solicitor who stated:

> we have not been able to identify any act or omission by IOGTR or GMAC which would amount to defective administration as defined for the purposes of the scheme… we do not think that the investigation of the alleged breaches can be said to have been carried out in a tardy manner.[73]

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71 Submission No.61, p.10 (Aventis).

72 *Committee Hansard,* 22.8.00, p.8*2* (Ms Huebner).

73 AGS to IOGTR, dated 1 August 2000 (in Submission No.77 additional information provided 25.8.00).

6.132 Nevertheless, the Committee considers the timeframe as unnecessarily long. Whilst the risk assessments concluded that none of the breaches represented an increased risk to human health and safety but may have resulted in an increased risk to the environment, this was only determined after the investigation was concluded. A number of procedures have been identified above that will give the Regulator significantly enhanced powers in conducting such investigations in the future.

Global considerations

6.133 In addition to the issues involving the specifics of a regulatory system, breaches such as occurred at Mount Gambier can also have international ramifications. The AWB Ltd commented (more in the general than the particular):

> These days, it is a global world out there. If our customers overseas see that there are serious breaches here in Australia, for whatever issue, whether it is a GM issue or a food safety issue, they know about it, and they start to raise questions with marketers such as ourselves, such as, "What controls do you have in place there to make sure that you are fully in control of what you are doing there?" So any breaches such as that, whether deliberate or not, are of concern to us.[74]

6.134 While the Committee notes that the IOGTR has commenced an audit of all Aventis trials following the Mount Gambier incident, it believes that in order to reassure the Australian public that no further incidents such as this have or are currently occurring, that all current field trials being conducted in Australia should be audited.

Recommendation

The Committee RECOMMENDS that all field trials currently being conducted in Australia be audited by the IOGTR as soon as possible and the results of the audit be made publicly available.

Concluding comment

6.135 In conclusion, the issues arising from the Mount Gambier trials are exceptionally important and provide pertinent instruction for the future regulatory system. Summary comments from the House of Representatives Primary Industries and Regional Services Committee and the Premier of South Australia are especially apposite:

> The committee is of the view that the alleged breaches would have been much less likely to have occurred if stringent, transparent regulatory processes…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 IOGTR act much more

74 *Committee Hansard*, 24.8.00, p.300 (AWB Ltd).

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.[75]

The incident in question highlights the need for the adoption of a robust legislative regulatory system in order to improve the capacity for enforcement, auditing and monitoring of compliance, and introduce substantial penalties for breaches. The treatment of this incident to date confirms for South Australia the importance of a transparent process and the necessity for the Regulator to be independent and to also be seen to be independent, in its assessment of such cases. Timeliness of reporting and a robust mechanism to ensure full reporting to States and Territories on such cases is important to strengthen community confidence in the treatment of alleged breaches.[76]

Senator the Hon Rosemary Crowley
Chair

75 *Work in Progress: Proceed with Caution*, Report by the House of Representatives Standing Committee on Primary Industries and Regional Services, June 2000, p.129.

76 Submission No.110, p.2 (South Australian Government – Mr John Olsen, Premier).