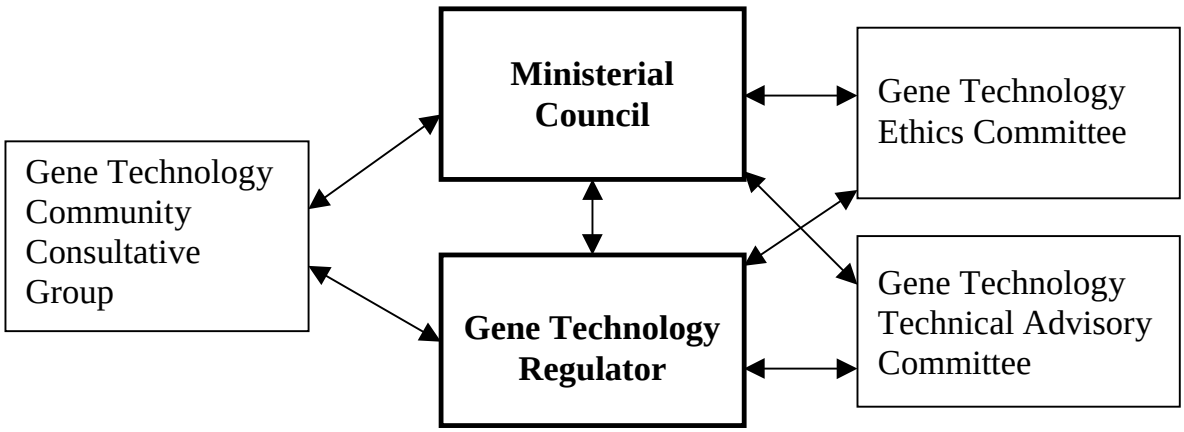
CHAPTER 5

THE EXPERT COMMITTEES AND MINISTERIAL COUNCIL

5.1 This chapter discusses the functions and powers of the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Group and the Gene Technology Ethics Committee; and the role and membership of the proposed Ministerial Council. The chapter also discusses the procedures for review of decisions and, in particular, the rights of third-parties to seek review of decisions of the Regulator.

5.2 The Bill provides for the establishment of a Gene Technology Technical Advisory Committee, a Gene Technology Community Consultative Group and a Gene Technology Ethics Committee to provide expert advice to the Regulator and the Ministerial Council overseeing the national legislative scheme.

Figure 2: Proposed regulatory structure under the Gene Technology Bill



Source: Submission No.77, p.106 (IOGTR).

5.3 The following sections discuss the functions and powers of the three proposed advisory committees.

Gene Technology Technical Advisory Committee

5.4 The function of this committee is to provide scientific and technical advice, at the request of the Regulator, or of the Ministerial Council, on a range of matters including:

- gene technology, genetically modified organisms (GMOs) and genetically modified (GM) products;
- applications made under the Bill;

- the biosafety aspects of gene technology; and
- the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products and the content of such principles, guidelines and codes.[1]

5.5 The committee is to comprise up to 20 part-time members appointed by the Minister. The Minister appoints the chair of the committee, but must not appoint a member to chair the committee unless a majority of the States and Territories agree to the appointment.[2]

5.6 Prior to appointing any members the Minister must consult a range of stakeholders including the States; the Regulator; scientific, consumer, health, environmental and industry groups; and any Ministers considered appropriate. The areas of expertise to be reflected on the committee include molecular biology; ecology; plant, animal or human genetics; virology; entomology; agricultural systems; biosafety engineering; public health; and occupational health and safety; risk assessment; clinical medicine; biochemistry; pharmacology; plant or animal pathology; microbiology; and animal biology. The committee members are subject to conflict of interest and disclosure of interest requirements, which are outlined later in this chapter. The Minister must also appoint a layperson as a member of the committee. The Minister may also appoint one or more 'expert advisers' to the committee. These advisers may be appointed on an ad hoc or continuing basis and will be expected to supplement the expertise of the committee where this is necessary in relation to the consideration of particular applications.[3]

Role of the committee

5.7 Several submissions commented on the limited powers of the committee. Submissions noted that the committee is only able to act on the request of the Regulator or the Ministerial Council. It was argued that the committee should be required to provide advice on all aspects of dealings that may pose a significant risk to human health or the environment.[4] The Australian Conservation Foundation (ACF) argued that the Bill should be amended to ensure that this committee, and the other two advisory committees, are consulted by the Regulator in consideration of all licence applications.[5]

5.8 The Interim Office of the Gene Technology Regulator (IOGTR) noted, however, that the committee 'will consider individual applications and provide

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1 Explanatory Memorandum, Gene Technology Bill 2000, pp.78-9.

2 Explanatory Memorandum, p.78.

3 Explanatory Memorandum, pp.78-9.

4 Submission No.35, p.20 (GE-Free Tasmania); Submission No.25, p.10 (Mr A Macintosh); Submission No.70, p.2 (Professor A Gibbs); *Committee Hansard*, 25.8.00, p.430 (Professor A Gibbs).

5 Submission No.40, p.6 (ACF). See also Submission No.70, p.2 (Professor A Gibbs); Submission No.69, p.3 (Friends of the Earth (Perth, WA Group)).

scientific advice on the possible risks posed by the application to public health and safety and to the environment'.[6] The Regulator will take this advice into account, along with advice received from public submissions, other Commonwealth agencies and the Environment Minister, in preparing risk assessment and risk management plans.[7] The committee has, however, no power to initiate the provision of advice and/or information on a dealing, GMO or GM product. In addition, in most matters the Regulator is under no obligation to seek the advice of the committee on any matter.

5.9 The IOGTR stated that in most overseas regulatory regimes ultimate responsibility for the scientific assessment of risk, and the approval of any applications, lies with an independent decision-maker like the GTR, rather than a committee of experts. Many regulators do, however, seek advice from an expert committee. For example, in Germany, the Federal Ministry of Health seeks advice from the Advisory Committee for Biological Safety. In Canada, the Federal Minister for the Environment seeks advice from the National Advisory Council on the management of toxic substances.[8]

5.10 The Committee considers that the proposed functions of the Gene Technology Technical Advisory Committee as outlined in the Bill are adequate. The Committee believes that the scientific committee in providing scientific and technical advice, at the request of the Regulator, or the Ministerial Council, on a range of matters, including licence applications, will play an important role in the regulatory system.

Composition of the committee

5.11 Several submissions commented on the narrow proposed range of experts on the committee. Submissions argued that the membership of the committee will be dominated by gene technologists.[9] ACF GeneEthics Network argued that 'these people are not independent or impartial. Environmental and other relevant technical and scientific experts must be included. Without a broad range of expertise, this committee will be like GMAC, not a genuinely rounded expert body'.[10]

5.12 One submission argued that the membership of the committee should be reviewed to include experts in the fields of nutrition, agriculture, animal husbandry, veterinary science and environmental science.[11] Another submission argued for the

6 Submission No.77, p.113 (IOGTR).

7 Submission No.77, p.113 (IOGTR).

8 Submission No.77, p.113 (IOGTR).

9 Submission No.70, p.2 (Professor A Gibbs); Submission No.85, p.13 (ACF GeneEthics Network).

10 Submission No.85, p.13 (ACF GeneEthics Network).

11 Submission No.11, p.17 (Canberra Consumers Inc).

addition of economists, ethicists and trade experts to ensure that the impact of GMOs is considered in the 'broadest possible way'.[12]

5.13 It was argued that it was important that this committee not be the captive of 'vested interests' as it is the only committee to view, and advise on, applications for permits for GM work.[13]

5.14 One submission also questioned the effectiveness of having only one layperson in a committee of 20 experts and suggested that the person would be 'overwhelmed'.[14] The IOGTR stated the inclusion of a layperson on the committee was supported by many people during consultations and reflects the current GMAC practice.[15]

5.15 Several submissions also argued that there needs to be cross-membership of the committees with a representative of the community consultative group and the ethics committee on the scientific committee.[16] While the IOGTR stated 'there is actually a requirement in the legislation that there be cross-membership between all three committees'[17], the Committee notes that the proposed legislation only makes it a requirement that:

- the Minister must appoint a layperson as a member of the Gene Technology Technical Advisory Committee;
- the Minister must ensure that the Gene Technology Community Consultative Group includes the following members:
    - a person who is a member of Gene Technology Technical Advisory Committee; and
    - a person who is a member of the Gene Technology Ethics Committee; and
- the Minister must ensure that the Gene Technology Ethics Committee include a member of the Gene Technology Technical Advisory Committee.

Recommendation

The Committee RECOMMENDS that the Bill be amended to require that the Gene Technology Technical Advisory Committee include a member of the Gene Technology Community Consultative Group and a member of the Gene

12 Submission No.54, p.19 (OFA).

13 Submission No.85, p.13 (ACF GeneEthics Network). See also Submission No.70, p.2 (Professor A Gibbs).

14 Submission No.11, p.16 (Canberra Consumers Inc).

15 Submission No.77, p.113 (IOGTR).

16 Submission No.54, p.19 (OFA); Submission No.11, p.17 (Canberra Consumers Inc)..

17 *Committee Hansard,* 14.8.00, pp.45-6 (IOGTR).

Technology Ethics Committee, and preferably that that person should be the Chair of their respective committee.

5.16 The Committee believes that the Gene Technology Technical Advisory Committee should essentially be comprised of members who are able to provide scientific and technical advice to the Regulator and the Ministerial Council but should comprise members with a broad range of scientific and related expertise, including environmental and other relevant technical and scientific experts, and represent a diverse range of scientific views.

Recommendation

The Committee RECOMMENDS that the Bill be amended to require the Minister, in appointing members of the Gene Technology Technical Advisory Committee, appoint members representative of a range of scientific disciplines and a diverse and broad range of scientific views.

Disclosure of interests

5.17 Several groups and individuals argued that there was a need to ensure committee members are subject to strict disclosure of interest provisions. Submissions argued that all members of the committee should be under a statutory obligation to disclose all interests in the development and commercialisation of gene technology. Further, members should be obliged to perform their duties in an independent manner and must be required to excuse themselves from participating in matters where there is a potential for a conflict of interest.[18]

5.18 The draft Regulations, tabled on 25 August 2000, detail the conflict of interest and disclosure of interest requirements. The Committee regrets that the draft Regulations were available so late during the Committee's inquiry. This did not provide witnesses with the opportunity to comment on the adequacy or otherwise of the Regulations during the Committee's hearings into the Bill.

5.19 Under the draft Regulations, committee members, and any expert advisers, will be required to:

- make a declaration setting out all direct or indirect interests, financial or otherwise, that a person is aware that he or she has in any matter of a kind to be considered at a meeting of the committee, before being appointed; and
- a member who is aware that he or she has a direct or indirect interest, pecuniary or otherwise, in a matter being considered, or about to be considered, at a meeting of the committee must disclose the nature of the interest at, or before, the meeting of the committee. Disclosure must include interests of the member, of the member's spouse, of parents of the member and of the spouse, of the

18 Submission No.35, p.20 (GE-Free Tasmania); Submission No.17, p.4 (National Genetic Awareness Alliance); Submission No.25, p.10 (Mr A Macintosh).

children of the member and of any other children of the member's spouse, that provide, or could provide, a substantial source of income or a substantial asset; and could be perceived to represent a possible conflict of interest.

The disclosure must be recorded in the minutes of the meeting and the member must not be present during any deliberation of the committee about the matter; nor must he or she take part in any decision of the committee about that matter.[19]

5.20 The Committee believes that committee members should be subject to strict disclosure of interest provisions. The Committee believes that the proposed disclosure of interest provisions are adequate and appear to meet the concerns expressed in evidence regarding the need for stringent disclosure provisions.

Terms of appointment

5.21 Submissions also argued that there should be fixed and specified terms of tenure for committee members as the positions are potentially very influential given the commercial aspects of the work.[20]

5.22 The Regulations specify that members of the committee are to be appointed for a period of three years, or a lesser period specified in writing. The IOGTR stated that the period of three years was selected because it balances continuity of membership with the need to ensure that membership does not become static. It is anticipated that changes in membership will be staggered to ensure there is not a complete turnover of committee members, with resulting loss of accumulated knowledge, every three years.[21]

Gene Technology Community Consultative Group

5.23 The function of the Consultative Group is to provide advice, at the request of the Regulator or the Ministerial Council, on matters of general concern in relation to GMOs, and on the need for, and content of, policy principles, guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products.[22]

5.24 The IOGTR stated that it is expected that the committee will fulfil this role by ensuring that the Regulator and the Ministerial Council are kept in touch with community views. The Group may do this by:

- providing advice on how it thinks community consultations might most effectively be undertaken;

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19 Draft Regulations, Part 4, Division 1.

20 Submission No.70, p.2 (Professor A Gibbs); *Committee Hansard*, 25.8.00, p.430 (Professor A Gibbs); Submission No.35, p.20 (GE-Free Tasmania).

21 Explanatory Guide to the Draft Commonwealth Gene Technology Regulations 2000, August 2000, p.32.

22 Explanatory Memorandum, p.80.

- providing advice on draft codes of practice developed by the Regulator;
- suggesting that certain policy principles be developed; and
- raising issues of ethical concern that they wish to be examined by the Gene Technology Ethics Committee.[23]

5.25 The Minister is to appoint up to 12 members of the Consultative Group on a part-time basis. Prior to appointing the members the Minister must consult the Regulator; the States; such scientific, consumer, health, environmental and industry groups considered appropriate as well as other Ministers considered appropriate. Appointees to the committee must have skills or experience pertaining to gene technology in one or more of the following areas – environmental issues; consumer issues; the impact of gene technology on the community; issues relevant to the biotechnology industry; issues relevant to gene technology research; public health issues; issues relevant to primary production; and issues relevant to local government.

5.26 The Consultative Group must include a person who is a member of the Gene Technology Technical Advisory Committee (to provide scientific assistance to the Group); and a person who is a member of the Gene Technology Ethics Committee (to assist with advice on ethics issues).[24] The Minister appoints the chair of the committee but may not appoint a chair unless a majority of the States and Territories agree to the appointment.[25]

5.27 The IOGTR stated that it is not intended that the appointees to the Consultative Group be scientific experts in gene technology, rather it is expected that they will be able to speak to certain issues that are relevant to gene technology, such as environmental or consumer issues.[26]

Role of the Consultative Group

5.28 Several groups argued that the role of the Group is too limited and that it should be consulted in relation to all licence applications considered by the Regulator.[27] Submissions noted that the role is only confined to providing advice at the request of the Regulator or the Ministerial Council.[28] GE-Free Tasmania stated that the consultative group needed to have an expanded role so that it can 'take on a more pro-active role, and be able to initiate the advisory process where they feel it is appropriate'.[29] The Australian GeneEthics Network (AGN) concurred with an

23 Submission No.77, p.115 (IOGTR).

24 Explanatory Memorandum, p.80.

25 Explanatory Memorandum, p.81.

26 Submission No.77, p.117 (DHAC). See also Explanatory Memorandum, p.80.

27 Submission No.40, p.6 (ACF); Submission No.54, p.18 (OFA); Submission No.69, p.3 (Friends of the Earth (Perth, WA Group)).

28 Submission No.35, p.20 (GE-Free Tasmania); Submission No.9, pp.13-14 (HSCA).

29 Submission No.35, p.20 (GE-Free Tasmania).

expanded role, suggesting that the Group 'should actively hold roundtables and seek public support for the development of strong policy on broad categories of GE work'.[30]

5.29 As noted previously, only the Gene Technology Technical Advisory Committee will be directly involved in providing advice on GMO licences and other applications (clause 101). The Community Consultative Group (and the Ethics Committee) will be consulted only in relation to general principles or guidelines, not in relation to specific decisions.[31]

5.30 It was argued that the Consultative Group's brief should be broadened and its decisions should have the same weight and standing as GTAC decisions, so that it wins the confidence of the public. As the Organic Federation of Australia (OFA) stated: 'to limit this group to providing advice on policy only does not do justice to concerns in the community about the way regulation is made, and the desire for the community to move beyond the simplistic notion that decisions must be based on science and logic'.[32]

5.31 The IOGTR stated that individual applications for licences are not being referred to the Community Consultative Group:

> …on the basis that, as a result of other mechanisms incorporated into the proposed scheme, there is already extensive opportunity for community input on individual applications...Given this high level of community involvement in decision making (unrivalled in most existing regulatory schemes), the Commonwealth States and Territories did not consider that it was necessary to incur additional expense and resources by duplicating the consultation process and also tasking the GTCCG with examining individual applications.[33]

5.32 The Interim Office also noted that the establishment of a statutory community consultative group advising on matters of policy is itself fairly unique in both the Australian regulatory environment and internationally. The IOGTR stated that most of the existing Australian schemes for regulation of GM products do not have statutory established community committees. The Australian Quarantine and Inspection Service (AQIS), for example, does not have a community advisory committee to assist in its assessment of imports for quarantine risks, although it does involve the community through its consultation process. The Therapeutic Goods Administration (TGA) is,

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30 AGN, Additional Information dated 11 September 2000, p.4.

31 Department of the Parliamentary Library Bills Digest No 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, p.12.

32 Submission No.54, p.19 (OFA).

33 Submission No.77, p.116 (IOGTR). See also *Committee Hansard*, 14.8.00, p.45 (IOGTR); *Committee Hansard*, 25.8.00, p.454 (IOGTR).

however, proposing to establish, through administrative arrangements, a Consumer Health Forum.[34]

5.33 The Interim Office further stated that internationally most countries have not established a community consultative group under legislation and where community groups are utilised they provide advice on policy rather than on individual applications. In the case of the United Kingdom, the Agriculture and Environment Biotechnology Commission has been established to advise the Government on GM foods. While the Commission has strong community representation it will not comment on individual applications.[35]

5.34 Several submissions also argued that meetings of the Community Consultative Group and the technical committee should be held in public, exempting commercial in confidence items, and that they report all proceedings on the Internet. It was also argued that meetings should be convened around Australia to ensure a range of views are heard and evidence is received from a wide-range of interested citizens [36] OFA argued that this would 'ensure there is true transparency in monitoring the workings of these advisory committees'.[37] One submission argued that a local government representative should be a mandatory appointment to the committee.[38]

Terms of appointment/disclosure of interests

5.35 Several groups argued that there needs to be fixed and specified terms of tenure and strict provisions to ensure that members of the consultative group have no conflict of interest relating to their functions.[39]

5.36 The draft Regulations (Part 5) mirror the provisions that apply in relation to the conditions of appointment for the scientific committee. The Regulations provide that the members of the committee will be appointed for three year terms, and must abide by strict disclosure of interest provisions (as discussed in the previous section).

Conclusion

5.37 The Committee believes that Gene Technology Community Consultative Group should have a broader role than merely limited to matters of general concern in relation to GMOs, and on the need for policy principles, guidelines and codes of practice.

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34 Submission No.77, pp.116-17 (IOGTR).

35 Submission No.77, p.117 (IOGTR).

36 Submission No.54, p.20 (OFA); Submission No.9, p.14 (HSCA); AGN, Additional information dated 11 September 2000, p.4.

37 Submission No.54, p.20 (OFA).

38 Submission No.60, p.3 (District Council of Grant).

39 Submission No.70, p.2 (Professor A Gibbs); Submission No.40, p.6 (ACF); Submission No.35, p.20 (GE-Free Tasmania).

5.38 The Committee believes that there needs to be greater community input into the decision-making processes in relation to licence applications especially in light of the potential impact of gene technology on human health and on the environment and the need for effective community involvement in the regulatory processes. The Committee therefore considers that the Bill should provide that the Community Consultative Group provide advice on individual licence applications.

Recommendation

The Committee RECOMMENDS that the Bill be amended to require that the Gene Technology Community Consultative Group provide advice on individual licence applications made under the Bill.

Gene Technology Ethics Committee

5.39 The function of the committee is to provide advice, at the request of the Regulator or of the Ministerial Council, on ethical issues relating to gene technology; the development of codes of practice in relation to ethics in respect of conducting dealings with GMOs; and the development of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.[40]

5.40 As in the case of the community consultative group, before appointing members to the committee, the Minister must consult the States, through the Ministerial Council, the Regulator, appropriate scientific, consumer, health, environmental and industry groups and appropriate Commonwealth Ministers. The Minister must ensure that the composition of the committee includes a member of the Technology Technical Advisory Committee, as well as a member of the Australian Health Ethics Committee with expertise in medical research.[41] The Minister appoints the chair of the committee, but may not appoint a chair without a majority of States and Territories agreeing to the appointment. The Minister may appoint one or more expert advisers to the committee. These advisers may be appointed on an ad hoc or continuing basis and will be expected to supplement the expertise of the committee where this is necessary in relation to the consideration of particular matters.[42]

5.41 There was general support for the establishment of the ethics committee. Heritage Seed Curators Australia (HSCA) stated 'we believe that the moral and ethical dimensions to gene technology are extremely important, However, this aspect goes largely ignored in the general debate on GE [genetic engineering]. We trust that the creation of this committee will bring this aspect of GE more to the fore in future'.[43] CSIRO also welcomed the proposed establishment of the committee but 'attaches urgency to its formation and productive output, particularly the provision of ethical

40 Explanatory Memorandum, p.82. See also DHAC, Additional Information dated 18 September 2000.

41 Submission No.77, pp.120-21 (IOGTR).

42 Explanatory Memorandum, p.82.

43 Submission No.9, pp.14-15 (HSCA). See also Submission No.40, p.6 (ACF); Submission No.50, p.5 (Consumer Food Network).

codes with a strong focus on the practical means by which their tenets are to be applied'.[44]

5.42 The IOGTR stated that the involvement of an independent ethics advisory committee in the regulation of gene technology places Australia ahead of similar regulatory schemes overseas. For example, no statutory ethics committee is involved in providing policy guidance in the United States, New Zealand, Japan or Canada. The IOGTR also noted that neither AQIS, TGA, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the Australia New Zealand Food Authority (ANZFA), or the National Registration Authority (NRA) have established expert ethics committees.[45]

Role of the committee

5.43 Several groups argued that the role of the committee, as with the community consultative group, is too limited and that it should be consulted in relation to all licence applications considered by the Regulator.[46] Submissions noted that the role is only confined to providing advice at the request of the Regulator or the Ministerial Council.[47] HSCA also suggested that the committee's meetings should be public to enhance consumer confidence in the regulatory process.[48]

5.44 As noted previously, under the Bill as it stands, only the scientific committee will be directly involved in providing advice on GMO licences. The ethics committee and the community consultative group will be consulted only in relation to general principles or guidelines, not in relation to specific decisions. The ethics committee, along with the other two committees, may be consulted in relation to the need for, and content of, policy principles guiding the ethical decisions of the Regulator, and codes of practice applicable generally to dealings with GMOs.[49]

5.45 Evidence emphasised the need for an overlap in the membership of the committees. Dr Roush stated that 'if you really want ethics to infuse the whole debate, why not thoroughly integrate the so-called ethics committee, or the ethicists that are involved, in both the technical committee and the community committee. Why have a separate entity? If anything it reinforces the public view that ethics is over here and scientists are over here and the twain never meet.[50]

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44 Submission No.102, p.5 (CSIRO).

45 Submission No.77, p.120 (IOGTR). See also DHAC, Additional Information dated 18 September 2000.

46 Submission No.70, p.2 (Professor A Gibbs); Submission No.40, p.6 (ACF); Submission No.35, p.20 (GE-Free Tasmania).

47 Submission No.35, p.20 (GE-Free Tasmania); Submission No.40, p.6 (ACF).

48 Submission No.9, p.15 (HSCA).

49 Parliamentary Library, p.12.

50 *Committee Hansard*, 22.8.00, p.101 (Dr Roush).

Terms of appointment/disclosure of interests

5.46 Several groups argued that there needs to be fixed and specified terms of tenure and strict provisions to ensure that members of the committee have no conflict of interest relating to their functions.[51]

5.47 The draft Regulations (Part 6) mirror the provisions that apply in relation to the conditions of appointment for the scientific committee and the community consultative group. The Regulations provide that the members of the committee will be appointed for three year terms, and must abide by strict disclosure of interest provisions (as discussed in the previous sections).

Conclusion

5.48 The Committee believes that the Gene Technology Ethics Committee should have a broader role than that envisaged in the Bill and that the moral and ethical dimensions in relation to gene technology should be considered in relation to licence applications.

5.49 The Committee therefore considers that the Bill should provide that the Regulator may, if he or she deems it necessary, refer individual licence applications to the Gene Technology Ethics Committee for advice.

Recommendation

The Committee RECOMMENDS that the Bill be amended to provide that the Regulator may, if he or she deems it necessary, refer individual licence applications to the Gene Technology Ethics Committee for advice.

The Ministerial Council

5.50 The Bill provides that a Ministerial Council comprising Ministers from the Commonwealth and each State and Territory will be established, under an Intergovernmental Agreement on Gene Technology (IGA), to provide broad oversight of the regulatory framework and guidance on matters of policy that underpin the legislation. The Ministerial Council will be responsible for:

- undertaking general oversight of the implementation of the scheme and considering and agreeing any proposed changes to the national scheme;
- issuing 'policy principles,' 'policy guidelines' and 'codes of practice' to underpin the regulatory system (see below);
- seeking advice from each of the statutory committees;

51 Submission No.70, p.2 (Professor A Gibbs); Submission No.40, p.6 (ACF); Submission No.35, p.20 (GE-Free Tasmania).

- ensuring coordination with other Ministerial Councils on matters relating to gene technology; and
- advising on the appointment and termination of the Regulator and the Chairpersons of the three committees to be established (see above).[52]

5.51 'Policy principles' are disallowable instruments and therefore are subject to review by the Parliament. Policy principles deal with ethical issues relating to GMOs or other matters prescribed by regulations (clause 21), and are issued by the Ministerial Council after consultation with relevant Commonwealth, State, industry and community organisations, including the three advisory committees (clause 22). The Regulator must not issue a GMO licence that is inconsistent with a policy principle (clause 57).[53]

5.52 'Policy guidelines' are issued by the Ministerial Council, and may deal with matters relevant to the Regulator's functions. They will be guidance notes to the Regulator, and will not be prohibitive or akin to a direction, but will be advisory. The Regulator must have regard to policy guidelines in deciding whether or not to issue a GMO licence (clause 56), but is not bound to follow them. Unlike policy principles, policy guidelines are not required to be made in consultation with anyone, although the Ministerial Council may choose to consult. Policy guidelines are not disallowable instruments (clause 23), and therefore are not subject to Parliamentary scrutiny.[54]

5.53 'Codes of practice', with which GMO licence-holders may be required to comply, are developed by the Regulator and issued by the Ministerial Council after extensive consultation with each of the committees, relevant Commonwealth and State agencies and industry and consumer groups. They will be disallowable instruments (clause 24), and therefore subject to Parliamentary scrutiny. The Regulator may apply a requirement that a code of practice be complied with as a condition of licence.[55]

Policy guidelines

5.54 Submissions argued that the Bill should be amended to ensure that the three advisory committees are consulted by the Ministerial Council when issuing policy guidelines.[56] As discussed above, unlike policy principles and codes of practice, policy guidelines are not required to be made in consultation with anyone, although the Ministerial Council may choose to consult.

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52 Submission No.77, p.108 (IOGTR).

53 Submission No.77, p.109 (IOGTR).

54 Submission No.77, p.109 (IOGTR).

55 Parliamentary Library, pp.11-12; Submission No.77, p.110 (IOGTR).

56 Submission No.40, p.6 (ACF); Submission No.85, p.14 (ACF GeneEthics Network).

Recommendation

The Committee RECOMMENDS that the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Group and the Gene Technology Ethics Committee be consulted by the Ministerial Council when issuing policy guidelines.

Veto on licence applications

5.55 Some groups proposed that the Ministerial Council should have the power of veto on licences approved by the Regulator or be able to strengthen or include new conditions on a licence granted.[57]

5.56 The IOGTR stated that Commonwealth and State Governments considered that Ministerial direction or a power of veto on individual decisions by the Regulator would undermine the independence of the Regulator and cast aspersions on the Regulator's integrity and freedom from political processes.[58] The Australian Food and Grocery Council (AFGC) also stated that it was important that the Council not be involved in the day-to-day operation and decision making of the Regulator.[59]

5.57 The IOGTR noted that this approach is consistent with other regulatory systems in Australia. For example, in the case of therapeutic goods, the Minister sets policy and standards while the delegate of the Secretary of the Department of Health and Aged Care (DHAC) decides on individual applications for drug approval. Under the system of food regulation, the Australia New Zealand Food Standards Council has the power of veto over food standards, but does not rule on the application of these standards to individual cases – which is the responsibility of ANZFA.[60]

5.58 The Committee does not consider that the Ministerial Council should have the power of veto on licences approved by the Regulator. The Committee believes that Ministerial direction, or a power of veto on individual decisions would undermine the independence of the Regulator.

Membership of the Council

5.59 It is proposed that the Ministerial Council be comprised of one Minister representing each participating jurisdiction. The IOGTR stated that the Minister representing each jurisdiction will be determined by the governments of each jurisdiction. The Commonwealth will be represented by the Minister for Health and Aged Care.[61]

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57 Submission No.17, p.4 (National Genetic Awareness Alliance); Submission No.54, p.6 (OFA).

58 Submission No.77, p.111 (IOGTR).

59 Submission No.71, p.14 (AFGC).

60 Submission No.77, p.111 (IOGTR).

61 Submission No.77, p.111 (IOGTR).

5.60 Consumer and other groups argued that the Ministerial Council should comprise either Health and/or Environment Ministers.[62] OFA, arguing for the inclusion of Health and Environment Ministers on the Council, stated that this was necessary 'to give public confidence in the protection of health and safety and the environment'.[63] The National Farmers' Federation (NFF) argued that the Council should include representation from the Agriculture Minister.[64] NSW Farmers' Association argued for representation from Agriculture and Foreign Affairs and Trade Ministers, noting that it was important that there is representation of affected parties such as the agricultural industry on the Ministerial Council.[65]

5.61 AFGC argued that the Council should include Ministers from a range of portfolios so that the expertise resident in the different areas relevant to gene technology can be brought into the deliberations of the Council. AFGC argued that gene technology impacts on a wide range of portfolios including Health, Environment, Agriculture/Primary Industry, Science and Technology and Trade and Commerce.[66]

5.62 The Committee sought clarification from the IOGTR as to whether Ministers on the Council will comprise the same members or whether a State may elect to send different Ministers to each subsequent meeting of the Council.

5.63 The IOGTR advised the Committee that:

> The expectation that will underpin the intergovernmental agreement is that a consistent minister attends. If it is the agriculture, health, environment or whatever minister, it is envisaged that they consistently attend. There will certainly be flexibility to change the minister, particularly when the legislation may move portfolios within individual jurisdictions.[67]

5.64 DHAC advised the Committee that the Intergovernmental Agreement (IGA) that established ANZFA does not specify that the Health Minister will be the representative on the Council –'the practice of state governments has been to send the health minister, but it is not enshrined as the health minister [in the IGA]'.[68]

5.65 The Committee considers that the Ministerial Council should comprise one Minister representing each participating jurisdiction. The Committee considers that given that gene technology impacts on a wide range of portfolios it is important that the Council should be comprised of Ministers, who, while representing a specific

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62 Submission No.54, p.6 (OFA); Submission No.6, p.4 (Consumers' Association of SA).

63 Submission No.54, p.6 (OFA).

64 Submission No.88, p.3 (NFF).

65 Submission No.76, p.6 (NSW Farmers' Association).

66 Submission No.71, p.15 (AFGC).

67 *Committee Hansard,* 14.8.00, p.44 (IOGTR).

68 *Committee Hansard,* 14.8.00, p.45 (DHAC).

portfolio, have an understanding of broader issues relevant to gene technology and be able to bring a multi-faceted approach to the Council's deliberations.

Rights of third-parties to seek review of decisions

5.66 Several groups argued that third parties should have the right to seek review of a decision by the Regulator.[69]

Review of decisions

5.67 The Bill provides the following procedures for the review of decisions.

- *Internal review*

Division 2 of Part 12 of the Bill provides that certain persons may seek internal review of decisions made under the legislation. Essentially, those people include:

– licence applicants and licence holders;

– applicants for certification and holders of certification (for example, universities or companies who have sought certification to a certain containment level of the facilities owned or operated by them);[70] and

– applicants for accreditation and holders of accreditation (for example, universities and institutions who have sought accreditation, recognising that they have established and maintained an Institutional Biosafety Committee within their institution).

5.68 If the relevant decision has been made by a delegate of the GTR (for example, one of the senior staff members of the GTR) the person seeking a review of the decision would have to apply to the GTR for an initial review of the decision. The GTR would look closely at the delegate's decision and would substitute his/her decision where appropriate.[71]

- *Review by the Administrative Appeals Tribunal*

5.69 If the GTR made the decision personally, or if a person has sought review by the GTR and seeks further review of the decision, those people with standing (detailed above in relation to internal review) may make an application for further review to the Administrative Appeals Tribunal (AAT).[72]

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69 Submission No.6, p.4 (Consumers Association of SA); Submission No.85, p.14 (ACF GeneEthics Network Submission); Submission No.35, p.21 (GE-Free Tasmania); *Committee Hansard,* 25.8.00, pp.360-61 (ACEL).

70 Certification of a facility to a certain containment level is required under the Bill of any organisation who wishes to undertake notifiable low risk dealings, or who holds a licence for dealings with GMOs where the licence includes a condition that the work with the GMO be conducted in a facility certified to a particular containment level. See Explanatory Memorandum, p.74.

71 Submission No.77, p.129 (IOGTR).

72 Submission No.77, p.129 (IOGTR).

- *Review by the Federal Court under the Administrative Decisions (Judical Review) Act 1977*

5.70 The Bill, however, does not include any explicit provisions about who may apply to the Federal Court under the *Administrative Decisions (Judicial Review) Act 1977* – AD(JR) Act. The IOGTR explained that this is because a person may automatically seek review of a decision by the Federal Court provided the person can meet the Court's criteria for determining whether the person is 'aggrieved' by a decision made under the gene technology legislation. Therefore, there is no need, or requirement, for the capacity for review under the AD (JR) Act to be referenced in the Bill.[73]

5.71 Any person wishing to have a decision reviewed by the Federal Court under the AD (JR) Act must establish 'standing' or a 'special interest' as required by the Federal Court. While this is judged on a case-by-case basis, the general position is that an applicant must be able to show an interest above and beyond that of ordinary members of the public.

5.72 For example, an organisation that has as part of its constitution or terms of reference, a reference to gene technology (such as the GeneEthics Network), would be likely to be able to establish standing to seek review under the AD (JR) Act. Similarly, an organic farmer whose property adjoined the property of a farmer growing GM crops would be likely to be able to establish a 'special interest' in the relevant decision of the GTR.[74]

5.73 The IOGTR stated that The *Environment Protection Biodiversity Conservation Act 1999* specifically provides that certain individuals are taken to be aggrieved by a decision for the purposes of seeking review by the Federal Court. For example, an individual who has, in the two years immediately before the decision is made, been engaged in a series of activities in Australia for protection, conservation or research into the environment. This position essentially reflects current 'standing' arrangements under the Federal Court. As such, it was not considered necessary to specifically replicate this in the Bill.[75]

Views on rights of third parties to seek review

5.74 As noted above, several organisations argued that third parties should have the right to seek review of a decision by the Regulator.[76] The Australian Centre for Environmental Law (ACEL) argued that the Bill:

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73 Submission No.77, pp.129-30 (IOGTR).

74 Submission No.77, p.130 (IOGTR).

75 Submission No.77, p.130 (IOGTR).

76 Submission No.6, p.4 (Consumers Association of SA); Submission No.85, p.14 (ACF GeneEthics Network); Submission No.35, p.21 (GE-Free Tasmania).

> …unfairly discriminates against third parties wishing to appeal the grant of licences and incorporates limited standing provisions reminiscent of the 19th century. It certainly does not represent regulatory "best practice" in the nascent 21st century. The right to appeal is limited and exercisable only by applicants for licences. For members of the public that comprise third parties, this limitation is clearly discriminatory, against principles of natural justice, and against the public interest.[77]

5.75 ACEL agued that the Centre's review of environmental standing provisions around the world 'establishes that the "best practice" trend is towards open standing. Indeed, even the Commonwealth's most recent piece of environmental legislation, the EPBC Act, creates limited open standing for any individual or organisation (whether incorporated or not) that has been involved in conservation or environmental issues over the previous two years'.[78]

5.76 GE-Free Tasmania acknowledged that the provision of third party appeal provisions has the potential to place strain on the resources of the Regulator and the AAT. Accordingly, the group argued that it is appropriate that a limit be placed on the persons who should have the right to appeal and that this be limited to third parties who have an ongoing involvement in the GE debate and who seek to represent a significant social interest or concern.[79]

5.77 Industry and primary producer organisations did not support the need to make provision for third parties to appeal the decisions of the Regulator.[80] Industry groups stated that the Bill has extensive provisions which require the Regulator to seek comment and have regard to that comment from the public on risk assessment, risk management and licensing decisions (Division 2 of the Bill).[81] Avcare Ltd commented that:

> Licensing decisions and other actions of the Regulator are open to interlocutory injunctions if a person or community group believes that an inappropriate decision has been made. It is important that the Bill does not facilitate vexatious appeals, with all the delays these involve.[82]

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77 Submission No.34, p.14 (ACEL).

78 Submission No.34, p.15 (ACEL).

79 Submission No.35, p.21 (GE-Free Tasmania). See also Submission No.17, p.5 (NGAA).

80 Submission No.32, p.12 (Avcare Ltd); Submission No.88, p.4 (NFF); *Committee Hansard*, 24.8.00, pp.347-8. (Florigene Ltd).

81 Submission No.32, p.12 (Avcare Ltd); Submission No.59, p.5 (MLA).

82 Submission No.32, p.12 (Avcare Ltd). An interlocutory injunction is an injunction ordered by a court before the court makes a final order in the proceedings. An applicant for an interlocutory injunction must establish that there is a serious question to be tried; that he or she will suffer irreparable injury for which damages will not be an adequate compensation unless an injunction is granted; and that the balance of convenience favours the grant of relief. Interlocutory injunctions are granted to ensure that the purpose of an action is not frustrated by the dissipation of property the subject of the dispute.

5.78 Meat and Livestock Australia (MLA) stated that the proposed processes for review of decisions (Part 12, Division 2) recognise the rights of both applicants and other stakeholders. Applicants and holders of certification and/or accreditation have the opportunity of review and appeal through the AAT – 'which is an appropriate impartial mechanism'.[83] MLA also noted that the Regulator has the discretionary capacity to, at any time, vary, suspend or cancel a licence, and to review decisions relating to exemptions from the need for a licence and notifiable low risk dealings – 'there are adequate opportunities for third parties to raise objections relating to decisions, with the Regulator having extensive discretionary power to act on those objections if there are sufficient grounds'.[84]

5.79 The IOGTR stated that taking into account the open assessment processes described under the Bill, States, Territories and the Commonwealth considered that it would be appropriate to limit the right of review to the AAT to people immediately affected by a decision (such as licence applicants and licence holders). The States and Territories reached this conclusion because:

- the decisions of the Regulator are the product of extensive consultation processes that would be time consuming and costly to repeat on review;
- the details of all decisions are made publicly available on a database of decisions;
- the Bill is drafted to carefully define the people who are able to seek review of decisions. Under a number of other legislative schemes, the class of people who are able to seek review of decisions is not quite so clearly defined. This gives rise to a great deal of uncertainty, not only for the regulator (who must make a decision on whether a complainant has a right of review) but also for the general public, who have to seek interpretation from the AAT as to whether they can seek review of a particular decision;
- the review mechanisms are consistent with similar legislation, including the *Australia New Zealand Food Authority Act 1991* (Cth). Section 63 of this Act restricts applications for AAT review of a decision to reject an application to the applicant. There is no right of review over the decision to accept an application, which would in turn lead to a change in the relevant Standard;
- limiting AAT review to people immediately affected by a decision reduces the capacity for vexatious review of decisions. Without this capacity, certainty of decision-making would be reduced as licence holders, as well as holders of certifications and accreditations, could not truly rely on the decision of the Regulator until all possible avenues of review had been exhausted; and

83 Submission No.59, p.4 (MLA).

84 Submission No.59, p.5 (MLA).

- limiting rights of review to the AAT is consistent with Commonwealth policy. The approach adopted by the States, Territories and the Commonwealth, as reflected in the Bill, has been considered in detail by the Attorney-General's Department, which advised that the approach adopted is appropriate given the extensive consultation processes described in the Bill.[85]

Conclusion

5.80 The Committee considers that third parties should have the right to seek review of a decision by the Regulator. The Committee believes that the Bill as it stands unfairly discriminates against third parties wishing to appeal the grant of licences and as such is discriminatory, against principles of natural justice, and against the public interest and will undermine public confidence in the system.

Recommendation

The Committee RECOMMENDS that the Bill be amended to provide for the right of third parties to apply for review of a decision of the Regulator.

85 Submission No.77, pp.131-32 (IOGTR). See also IOGTR, Additional Information dated 18 September 2000.