

The Chair
Cabinet Policy Committee

THE GOVERNMENT'S RESPONSE TO THE REPORT OF THE COMMISSION ON GENETIC MODIFICATION PAPER 5: INTELLECTUAL PROPERTY

PROPOSAL

1. This paper considers the recommendations of the Royal Commission on Genetic Modification ("the Commission") made in chapter 10 of its report, which relate mainly to intellectual property, and recommends how the Government might respond to each recommendation.

EXECUTIVE SUMMARY

2. The recommendations made in chapter 10 of the Commission's report relate mainly to intellectual property rights, are in most cases non-contentious, and can in the main be accommodated within existing work programmes.
3. The recommendations include: amendment to the Plant Variety Rights Act 1987, specific exclusion of patentability of human beings in the Patents Act 1953, the establishment of a Maori Consultative Committee to assist with patent applications, the active promotion of cultural and intellectual property rights of indigenous people internationally, seeking the amendment of the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to allow for exclusions or reservations on the basis of cultural offence, the resolution of the Wai 262 claim, and legislative changes to ensure that all confidential supporting information provided to the Environmental Risk Management Authority (ERMA) is appropriately protected.
4. The first three issues have largely been anticipated by Stage 3 of the Review of the Patents Act 1953 (Cabinet agreed to the 3 Stage Review of the Patents Act on 21 August 2000, CAB (00) M 28/1A refers), and can be addressed by processes already in place.
5. In response to the recommendations concerning Maori 'cultural and intellectual property', it is recommended that the 'active promotion of the cultural and intellectual property rights of indigenous peoples' be adopted as a guiding principle for participation at relevant international fora. It is further recommended that officials be directed to support the concept of 'exclusion or reservation on the basis of cultural offence' through work currently being progressed through the World Intellectual Property Organisation, and the development of new system for the protection of Maori 'cultural and intellectual property'.
6. In response to the final recommendation, amendment of Hazardous Substances and New Organisms Act (HSNO Act) and Agricultural Compounds and Veterinary Medicines Act (ACVM Act) is supported subject to consultation with key stakeholders to determine what

level of protection is 'appropriate' for supporting confidential information provided to the ERMA.

BACKGROUND

7. The Commission was established to look into and report on the issues surrounding genetic modification in New Zealand. The Commission's warrant provided that it could investigate and hear representations on the intellectual property issues involved, or likely to be involved, now and in the future, in relation to the use in New Zealand of genetic modification, genetically modified organisms and products.

COMMENT

8. Some of the Commission's recommendations are very general in nature and address issues not directly related to genetic modification, for example in relation to the protection of the 'cultural and intellectual property rights of Maori'. Nevertheless, work in these areas has in many cases been anticipated. For this reason the Government is in a position to accept the general intention of the recommendations, but not necessarily to implement them immediately or in the exact manner anticipated by the Commission. In some cases further consultation is required to determine how the recommendations might be implemented.
9. In the following paragraphs, brief analysis of each of the recommendations is provided followed by a recommended response. More detailed analysis is provided in a document available from the Office of the Minister for the Environment

Recommendation 10.1 - that the Plant Variety Rights Act 1987 be amended to introduce the concept of essential derivation

10. The Plant Variety Rights Act does not currently provide protection for essentially derived varieties (new varieties predominantly derived from another (protected) variety). Essential derivation may result from a number of methods, one of which is genetic modification.
11. Essential derivation is one of several issues for New Zealand to consider in deciding whether to ratify the 1991 revision of the UPOV (International Union for the Protection of New Plant Varieties) Convention. Among other things, this Convention provides that members shall provide protection for derived varieties.¹ Other issues include farm-saved seed, competition and licensing and the question of whether both patent and plant variety right protection should be provided to plant breeders.
12. The Government has not previously accorded priority to the review of the Plant Variety Rights Act, however in view of the Commission's recommendation, a review could proceed in tandem with Stage 3 of the Review of the Patents Act. Stage 3 will consider the boundaries of patentability, including whether patents should be granted for plant varieties or not, and whether plant breeders should be able to obtain both patent and plant variety right protection for the same genes or species. This would enable consultations to be undertaken in early 2002, policy decisions to be made by September 2002, with a view to introducing any necessary legislation at the beginning of the next parliamentary term.

¹ The Plant Variety Rights Act 1987 is based on the 1978 revision of UPOV, which does not provide protection for derived varieties.

13. It is recommended, therefore, the Government accepts recommendation 10.1 in principle subject to the review of the Plant Variety Rights Act, to be carried out in tandem with Stage 3 of the Review of the Patents Act.

Recommendation 10.2 - that the Patents Act 1953 be amended by adding a specific exclusion of patentability of human beings and the biological processes for their generation, in line with section 18 of the Patents Act 1990 (Commonwealth)

14. As a matter of policy, the Intellectual Property Office of New Zealand (IPONZ - a business unit of the Ministry of Economic Development) does not grant patents for human beings. This policy is based on sections 2 and 17 of the Patents Act (relating to the definition of invention and exclusions where inventions are contrary to morality).
15. While IPONZ would not grant such a patent, a refusal could be challenged in the courts, and there is no guarantee that the decision of IPONZ to refuse the patent would be upheld. Therefore, the only way to ensure that patents are not granted for human beings and biological processes for their generation would be to insert a specific exclusion into the Patents Act. For example, section 18(2) of the Australian Patents Act 1990 provides: "Human beings, and the biological processes for their generation, are not patentable inventions".
16. The Commission also considered the more general question of whether patents should be granted for genes, but did not make a recommendation on the issue. Patents for genes (essentially DNA molecules) can be granted where DNA molecules have been isolated or purified. The applicant must also show that the invention is new and useful. While the Patents Act provides that patents will not be granted for substances found in nature, a DNA molecule which already occurs in nature can still be eligible for a patent because it does not exist in nature in an isolated and purified form. Patents have been granted for genetically modified organisms, which raises the question of whether patents should be granted for them. The grant of such patents, however, only gives the patent owner the right to make, sell and use the patented invention (and exclude others from doing so) - it does not confer ownership of the patented organism itself. The patent owner may also be precluded from actually exploiting the invention commercially as a result of legal or regulatory constraints.
17. The question of whether certain things should be excluded from patentability will be addressed as part of Stage 3 of the Review of the Patents Act. Subject to Cabinet approval, the Ministry of Economic Development anticipates releasing a public discussion document in early 2002, which will seek comment on whether life forms should be excluded from patentability, and refer to the Commission's recommendations.
18. It is therefore recommended that recommendation 10.2 be accepted in principle, and addressed following public consultation in Stage 3 of the Review of the Patents Act.

Recommendation 10.3 - that a Maori Consultative Committee be established by the Intellectual Property Office of New Zealand to develop procedures for assessing applications, and to facilitate consultation with the Maori community where appropriate

19. The intention of recommendation 10.3 is to address Maori concerns about the limits of existing intellectual property mechanisms to protect 'cultural and intellectual property' including traditional knowledge. More particularly, the establishment of a Maori consultative committee would be a first step to address Maori concerns about genetic

modification, and patents and plant varieties. However, the wording of recommendation 10.3 and associated commentary suggest that it is the Commission's intention that a committee would have a role in issues wider than genetic modification.

20. Currently there are no formal consultation requirements. Enhanced consultation with Maori has, however, been identified as one way to limit the inappropriate granting of patents for inventions which are based on Maori traditional knowledge, and are not 'new' and hence not patentable. It is intended (subject to Cabinet approval) that the discussion document being prepared for Stage 3 of the Review of the Patents Act will seek comment on whether there should be specific consultation with Maori during the patent examination process, and if so, how consultation might be facilitated, including the option of establishing a Maori advisory body.
21. In establishing a committee it will be important to define its purpose and functions clearly, so the committee adds value to existing legal process. One useful function would be the provision of expert advice concerning traditional knowledge to assist the Commissioner of Patents to test inventions against the requirements of novelty and inventive step (which are established by comparing the claimed subject matter against relevant 'prior art'). The knowledge base of indigenous peoples is an increasingly relevant source of prior art that often cannot be identified by patent granting authorities such as IPONZ during the examination of a patent application.
22. New Zealand is a party to TRIPS², Article 27 of which provides that member States may only make exclusions from patentability on certain grounds. It is not clear what the Commission envisages when it says a committee would 'develop procedures for assessing applications', and whether the committee itself would have a role in assessing applications. Article 27 would be a factor in determining the parameters in which a committee could operate. This may or may not be an issue depending on the functions of a committee. For example, Article 27 would not present any difficulties in the context of procedures developed (and perhaps applied) by a Maori committee to ensure that patents were not granted for inventions based on traditional knowledge where that knowledge constituted prior art, or for native flora and fauna in its natural state.
23. It is therefore recommended that recommendation 10.3 be accepted in principle, and addressed as part of Stage 3 of the Review of the Patents Act, which will invite public comment on the issue of consultation with Maori, and refer to the Commission's recommendation.

Recommendation 10.4 - that New Zealand be proactive in pursuing cultural and intellectual property rights for indigenous peoples internationally

24. The Commission was concerned that a number of international agreements restrict the ability of member states to change their intellectual property rights systems to meet the concerns of indigenous peoples. The Commission also referred to the Mataatua Declaration on the Cultural and Intellectual Property Rights of Indigenous Peoples, and commented that "members of the New Zealand community showed world leadership in the area of promoting international indigenous rights to intellectual property". It suggested that this initiative be "maintained to pursue progress in this area". Recommendation 10.4 seeks to address these

² Annex IC to the Agreement Establishing the World Trade Organisation

matters by recommending that New Zealand be proactive internationally in pursuing 'cultural and intellectual property rights' for indigenous peoples.

25. The Commission rightly noted that issues of reconciling indigenous and 'Western' intellectual property rights systems are becoming more pressing as rapid advances are made in biotechnology. The vulnerability of traditional knowledge to misappropriation, and repeated calls from indigenous peoples for protection of their cultural and intellectual property rights are also reasons to call for a proactive approach at the international level.
26. While correctly identifying the need for protection at the international level, the Commission did not take account (and perhaps was not aware) of New Zealand's contribution to international standard setting processes relating to indigenous peoples rights in general, and cultural and intellectual property rights in particular. New Zealand has affirmed the need for international protection of indigenous peoples rights, and participates actively in all relevant fora, including: the working group on the draft Declaration on the Rights of Indigenous Peoples, Agenda 21 of the United Nations Conference on Environment and Development (UNCED), the United Nations Educational, Scientific and Cultural Organisation (UNESCO), the Convention on Biological Diversity (CBD), and the World Intellectual Property Organisation (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.
27. It is recommended that recommendation 10.4 be accepted, as it is consistent with existing policy and practice to actively promote the rights of indigenous peoples at international fora. Admittedly, progress has been slow, however these issues are extremely complex, and progress is not assisted by the protracted nature of international processes in general. It is recommended that recommendation 10.4 be implemented as a guiding principle for participation at relevant international fora.

Recommendation 10.5 - that New Zealand pursue the amendment of the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights and associated conventions to include a reference to the avoidance of cultural offence as a specific ground for exclusion or reservation

28. Recommendation 10.5 is a more specific manifestation of the concerns expressed in relation to recommendation 10.4 about the restrictions placed on member states by international agreements, including TRIPS, which limit how far they can amend their intellectual property rights systems to meet the concerns of indigenous peoples.
29. The intention of the recommendation, to allow exclusions or reservations on the specific basis of cultural offence, is consistent with government policy. For example, the Trade Marks Bill currently before Parliament will, if enacted, allow registration of a trade mark to be refused on essentially the same cultural offence grounds as proposed by the Commission. However, the TRIPS provision accommodating this is confined to trade marks.
30. Although expressed in general terms, recommendation 10.5 appears to be driven by a specific concern with patents, namely that patents are being granted in New Zealand or elsewhere for flora and fauna unique to New Zealand, without regard to its special significance to Maori. The Commission noted that a central issue for Maori is that it is not clear that Article 27.2 of TRIPS, allowing exclusions from patentability where necessary to protect "ordre public or morality", permits countries to deny applications on the basis of cultural offence. The Commission seems to assume that Article 27.2 of TRIPS does not

already allow such an exception. However, officials consider that, although untested, a good argument can be made that Article 27.2 as currently drafted already provides scope for exclusions from patentability.

31. While there might be advantages in gaining greater legal certainty that exclusions on the basis of cultural offence are consistent with TRIPS and other related international instruments, direct pursuit of amendments to them offers relatively poor prospects of success.
32. An alternative option not addressed by the Commission rests on the work being carried out by WIPO, in its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. It is possible that in due course this work will result in an international treaty on protection of traditional knowledge and its integration into the international intellectual property rights system. Participation in this forum seems likely to provide a less risky vehicle for addressing the cultural offence issue at this time.
33. It is recommended therefore that in view of the uncertainties and risks associated with an initiative specifically to amend TRIPS, the Government should not pursue that step directly. Instead officials should be directed to achieve the underlying purpose of the recommendation by focusing on work currently being progressed by WIPO, and the development of a new system for the protection of Maori 'cultural and intellectual property'. Officials should also be alert for opportunities in the WTO TRIPS context to pursue the long-term goal of greater legal certainty regarding 'cultural offence' exemptions where this can be done without prejudicing New Zealand's wider trading interests.

Recommendation 10.6 - that all parties concerned work to resolve the Wai 262 and Wai 740³ claims as soon as possible

34. The Wai 262 claim, lodged by 6 iwi, asserts exclusive and comprehensive rights to indigenous flora, fauna and other taonga. It is argued, among other things, that all rights relating to indigenous flora and fauna, and the genetic make-up of those resources, belong to iwi Maori. The claimants have opposed the application of patent rights to lifeforms, and genetically modified products and processes. Some claimants have however acknowledged the benefits of genetic modification as a means of ensuring reliable supplies of valuable medical supplies such as insulin.
35. Officials do not agree with the Commission's contention that there is a critical link between the Wai 262 claim, genetic modification issues, and the Government's intellectual law reform programme. The ownership of flora and fauna and associated intellectual property rights are broader issues than the Commission's terms of reference which related to the intellectual property issues associated with the use of genetic modification, genetically modified organisms and products. Intellectual property rights do not regulate research and development in the field of genetic modification. The ownership of flora and fauna is a separate issue from the regulation of the genetic modification of it. Evidence presented at Wai 262 hearings suggests that existing intellectual property mechanisms cannot provide protections sought for indigenous flora and fauna and associated traditional knowledge. For this reason the option of a new system (*sui generis*) for the protection of 'cultural and

³ The Wai 740 claim was lodged by Frederick C. Allen, of Te Atiawa, and relates to the right to collect fruit, seed and spores from Crown and regional authority land in the Wellington region, and the preservation of native flora and fauna. No hearing date has been set for this claim. The Crown's response to Wai 262 is likely to address issues raised in Wai 740 and Wai 818 - the Wairarapa Intellectual Property and Whakapapa claim.

intellectual property' is being considered domestically (this work is at an early stage of development) and in various international fora.

36. It is important to note that both the Crown and the claimants want to see the claim resolved as soon as possible, but are, to an extent, precluded from doing so due to the complex nature of the claim and the Tribunal process itself. Limits on Tribunal funding affect the speed at which inquiries can be completed, and require the Tribunal to prioritise certain claims over others. The Tribunal has in recent times directed resources to a number of historical claims grouped into substantial regional inquiries. It is currently considering the steps required to complete the Wai 262 inquiry, and intends to issue an interim report on selected issues by October 2002.
37. Despite officials concerns about the Commission's analysis of the Wai 262 claim, it is recommended that recommendation 10.6 be accepted as the Crown is already working to resolve Wai 262 as soon as possible.

Recommendation 10.7 - that the Hazardous Substances and New Organisms Act 1996 and the Agricultural Compounds and Veterinary Medicines Act 1997 be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval

38. The Hazardous Substances and New Organisms Act 1996 provides protection to confidential supporting information supplied to the ERMA but only in relation to approvals for certain hazardous substances, which are also the subject of an innovative medicine application or an innovative agricultural compound application. It does not provide protection for confidential supporting information provided with applications for new organisms whether genetically modified or not (nor for other hazardous substances).
39. The HSNO Act and the ACVM Act also have provisions relating to the release of confidential supporting information under the Official Information Act (OIA). The standard grounds for withholding information apply. When a request is made for information which may be able to be withheld under section 9(2)(b) of the OIA, and the information has been classified commercially sensitive by the person who provided it, the ERMA or the Chief Executive of the Ministry of Agriculture respectively, is required to notify that person of the request. That person has 10 working days to respond with reasons why the information should be withheld. The information may be released if no response is received.
40. Submitters were concerned about the release of confidential supporting information by the ERMA either through its general dealings or through the OIA process. They were particularly concerned about the effect premature disclosure might have on the future patentability of products and the loss of trade secrets to competitors. Officials consider that extending the protection for confidential supporting information would be consistent with the Government's support for the development of innovative industry. Failure to amend the HSNO and ACVM Acts would be a disincentive to development and use of genetically modified organisms in New Zealand. This would result in lost opportunity for New Zealand to exploit the value of such organisms.
41. Officials recommend that the extension of protection for confidential supporting information suggested in recommendation 10.7 be accepted. However it will be necessary to undertake consultation with key stakeholders to determine what level of protection is 'appropriate'. Any changes affecting the current public processes in HSNO Act will be contentious, in

particular the need for sufficient information to be provided to enable submitters to comment on applications. It will also be necessary to consider the current protection for hazardous substances, and the appropriate level of protection for new organisms other than genetically modified organisms.

CONSULTATION

42. The following departments have been involved or consulted in the preparation of this paper and agree with its recommendations: Ministry for the Environment, Ministry of Agriculture and Forestry, Ministry of Fisheries, Ministry of Foreign Affairs and Trade, Treasury, Ministry of Research Science and Technology, Te Puni Kokiri, the Ministry of Economic Development. Amendments were made to this paper at the direction of the office of the Minister for the Environment, by the Ministry for the Environment in consultation with some other agencies. These amendments were required as some matters previously referred to in this paper were considered in Paper 1 at Cabinet on 29 October 2001.

FISCAL IMPLICATIONS

43. Subject to Cabinet's agreement to the proposed recommendations there will be no fiscal implications arising from the response to the Commission's recommendations 10.1, 10.2, 10.3, 10.4, 10.5 or 10.7.

44. In respect of the recommendation 10.6; the Crown's participation in the Wai 262 Waitangi Tribunal inquiry is currently funded through a special appropriation to three departments: Economic Development, Te Puni Kokiri and Conservation. To the extent that acceptance of the recommendation to accelerate the case will result in additional hearings of the Tribunal and increased short term representation costs for the Crown additional funding may be necessary. Any additional funding requirements will be dealt with, as required, through the relevant Budget process.

HUMAN RIGHTS

45. There are no inconsistencies between the proposals made in this paper and the provisions of the Human Rights Act 1993.

TREATY OF WAITANGI

46. This paper has Treaty of Waitangi implications. Further consultation with Maori will be necessary in respect of Commission recommendations 10.1 - 10.3 and the review of the Patents Act and the proposed in tandem review of the Plant Variety Rights Act. The proposed responses to recommendations 10.4 and 10.5 concerning Maori 'cultural and intellectual property' suggest that officials carry on with existing work in that field, which has been identified as necessary to address Maori concerns about the protection of taonga under Article II of the Treaty of Waitangi.

Treaty of Waitangi implications are also discussed further in Paper 6.

LEGISLATIVE IMPLICATIONS

Legislative change will be required to implement recommendations 10.1, 10.2, 10.3, and 10.7 of the Commission. Recommendations 10.1, 10.2, and 10.3 can be implemented by changes to the Patents Act 1953. A new Patents Bill is on the legislative programme.

Recommendation 10.1 will also require changes to the Plant Variety Rights Act 1987, and a legislative bid will need to be prepared in due course. Because of the synergies between patents and plant variety rights issues it is suggested that the bills be considered in tandem.

Legislative change is also required for recommendation 10.7. It is recommended that the amendments to HSNO Act be implemented along with other changes to HSNO Act suggested by the Commission and summarised in Paper 1, considered at Cabinet on 29 October 2001.

REGULATORY IMPACT AND COMPLIANCE COST STATEMENT

47. Some of the recommendations made in this paper have regulatory impact and compliance cost implications, as legislative change to the Patents Act 1953, the Plant Variety Rights Act 1987, HSNO Act and ACVM Act is envisaged. It is not possible to describe or assess the precise regulatory impacts until more detailed proposals are developed, following consultative processes.
48. Following consultations associated with Stage 3 of the Review of the Patents Act 1953, the proposed 'in tandem' review of the Plant Variety Rights Act 1987, and protection for confidential supporting information under HSNO and ACVM Acts, final policy decisions will be sought from Cabinet. At those points regulatory impact and compliance cost statements will be prepared for issues relating to recommendations 10.1, 10.2, 10.3 and 10.7 of the Commission.
49. No regulatory impact or compliance cost issues arise in respect of recommendations 10.4, 10.5, and 10.6.

PUBLICITY

50. A separate communications strategy is being developed for the whole package of Government decisions on the Royal Commission's report. An outline of this strategy is contained in Paper 1 of this suite.

RECOMMENDATIONS

It is recommended that the Committee:

1. **note** that the Royal Commission on Genetic Modification (the Commission) has made a number of recommendations relating to intellectual property which in many respects go beyond the issue of genetic modification, but can in general be accommodated within existing work programmes;
2. **note** that intellectual property rights statutes are not appropriate mechanisms for regulating either ownership and control of, or access to, New Zealand's genetic resources, but do provide some incentive for research and development in that field;

Plant Variety Rights Act 1987 and Patents Act 1953

3. **note** Cabinet has approved a comprehensive review of the Patents Act 1953 [CAB (00) M 28/1A refers] with a view to introducing legislation by the beginning of the next Parliamentary term. Stage 3 of the review will (subject to further Cabinet approval) invite public comment on exclusions from patentability;

4. **agree in principle** the Plant Variety Rights Act 1987 be amended to introduce the concept of essential derivation (Commission recommendation 10.1) subject to a review of the Plant Variety Rights Act 1987, to be undertaken in tandem with Stage 3 of the current review of the Patents Act 1953;
5. **note** it is the current policy of the Commissioner of Patents to refuse to register patents for human beings on the grounds of it being contrary to morality, but to provide certainty it is necessary to legislate to specifically exclude the patentability of human beings;
6. **agree** the Patents Act 1953 be amended by adding a specific exclusion to patentability of human beings and the biological processes for their generation (Commission recommendation 10.2),
7. **agree** that the non-patentability of individual genes be considered further in the course of the review of the Patents Act 1953.

Maori 'cultural and intellectual property rights'

8. **note** the Commission recommended that 'a Maori Consultative Committee be established by the Intellectual Property Office of New Zealand to develop procedures for assessing applications, and to facilitate consultation with the Maori community where appropriate' (Commission recommendation 10.3);
9. **agree** a Maori consultative committee be established, but that its scope and role be confirmed following public consultation as part of Stage 3 of the review of the Patents Act 1953;
10. **agree** New Zealand be proactive in pursuing cultural and intellectual rights for indigenous peoples internationally (Commission recommendation 10.4);
11. **direct** officials to implement recommendation 10.4 of the Commission as a guiding principle for participation in relevant international fora;
12. **note** that the Commission recommended that New Zealand pursue the amendment of the World Trade Organisation Agreement on Trade – Related Aspects of Intellectual Property Rights (TRIPS) and associated conventions to include a reference to cultural offence as a specific ground for exclusion or reservation (Commission recommendation 10.5);
13. **note** that while 'exclusion or reservation on the basis of cultural offence' is consistent with government policy, pursuit of an amendment to TRIPS at this time is unlikely to be successful and could prejudice New Zealand's wider trading interests;
14. **direct** officials (MED, TPK, MFAT) to support the concept of 'exclusion or reservation on the basis of cultural offence' through work currently being progressed through the World Intellectual Property Organisation, and the development of a new system for the protection of Maori 'cultural and intellectual property'. Officials should also be alert for opportunities which may arise in the World Trade Organisation TRIPS context;
15. **agree** with the Commission's recommendation (10.6) that all parties concerned work to resolve the Wai 262 and Wai 740 claims currently before the Waitangi Tribunal as soon as possible;

16. **note** the Crown is working to resolve the Wai 262 claim as soon as possible;

Hazardous Substances and New Organisms Act 1996 and Agricultural Compounds and Veterinary Medicines Act 1997 - confidential information

17. **note** that the Hazardous Substances and New Organisms Act 1996 does not provide protection for confidential supporting information provided with applications for approval of new organisms, whether genetically modified or not;

18. **direct** officials (MAF, MFE) to undertake consultation with key stakeholders to determine what level of protection is appropriate for commercially sensitive or confidential supporting information provided with applications for approval, with a view to amending the Hazardous Substances and New Organisms Act 1996 and the Agricultural Compounds and Veterinary Medicines Act 1997 (Commission recommendation 10.7).

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