Australian Government
Department of the Environment and Heritage

Mr Tony Hinton
Commissioner
MRA Review
Productivity Commission
PO Box 80
BELCONNEN ACT 2616

Dear Mr Hinton

I refer to the draft research report on the Evaluation of the Mutual Recognition Schemes inviting written comments to the Productivity Commission in relation to its Review of Mutual Recognition Arrangements.

Please find the Department of the Environment and Heritage's comments below. The comments focus on a number of areas of the report that relate to the responsibilities of the Department and have been set out on an issues basis.

Should clarification on any aspect of the submission be required, please do not hesitate to contact me, or alternatively, Marc Carter on (02) 6274 1969.

Yours sincerely

Kevin Keeffe
Assistant Secretary
Policy Coordination Branch

September 2003

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**DRAFT REPORT ON EVALUATION OF MUTUAL RECOGNITION SCHEMES – COMMENTS BY DEPARTMENTOF THE ENVIRONMENT AND HERITAGE (DEH)**

**Permanent Exemptions and Exclusions**

*Fish stocks*

Preliminary Finding 7.12

In regard to this finding if the difference for which fish achieved sexual maturity is significant, and regulations in place in other jurisdictions would lead to a clear diminution in the fish stock, DEH would support the grounds for continuing the exemption. On the other hand, if the effect of the application of law has only a marginal effect, then DEH agrees that the continuation of the exemption might not be justified.

*Heritage*

Preliminary Finding 7.15

DEH note that both Schedule 1 of the 'Trans-Tasman Mutual Recognition Agreement' and Schedule 1 of the implementing legislation, the 'Trans-Tasman Mutual Recognition Act 1997', contain provisions excluding the operation of the 'Protection of Movable Cultural Heritage Act 1986'. As the PMCH Act is the legislation that implements in Australian law the 1970 'UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property', to which Australia is a signatory, we would wish that exclusion to continue to apply in any re-negotiated agreement.

*Intellectual Property*

Preliminary Finding 7.18

The integrity of the IP system is the basis for the creation of wealth flowing from the analysis of genetic resources/indigenous knowledge. Accordingly DEH agrees with the conclusion that the TTMRA exclusion for IP should be retained to ensure it does not undermine the patents rights system. The Commission is right about the rapid evolution of patent law and practices and further examination on the TTMRA exclusion in the next review is not unreasonable.

It is likely, however, that in its evolution, the IP systems of both countries will remain in harmony. This applies particularly in relation to IP aspects of genetic resources and traditional indigenous knowledge - other than to the extent that the Treaty of Waitangi may dictate some unique (and as yet unspecified) IP law arrangements.

**Special Exemptions under the TTMRA**

*Chemicals*

While DEH supports moves towards harmonisation where these moves enhance Australia's capacity to efficiently and effectively regulate chemicals, we believe that it would be inappropriate to give away a robust, risk-based assessment methodology for the sake of harmonisation.

We note that the draft report does not necessarily appear to recognise the distinction between the terms "hazard" and "risk". This is crucial to a sound understanding of the issues and preliminary findings, particularly as Australia's registration/notification processes for chemicals are risk-based, whereas New Zealand's are hazard-based. Hazards are issues like mutation, reduced fecundity and death. They are associated with the intrinsic properties of a chemical (or substance). Risks are the likelihoods of hazards being realised. They are products of hazards and exposures (for example, the rate or dose of a chemical application).

Regarding agricultural and veterinary products (substances), the Australian risk-based approach is actually more risk-averse than the NZ system, as the Australian system is able to consider individual chemical products (substances) and design specific risk-mitigation solutions. Instances where we believe the report has used either term erroneously are suggested below.

Preliminary Finding 8.4

Agree, except that the second point should also mention environment. Also, the first dot point indicates: "to address their risks as chemicals". We note that NZ does not assess risk, only hazard.

Preliminary Finding 8.5

Agree, but the word "regulatory" should be inserted in front of agencies as this is the sense intended, rather than the separate agencies conducting risk assessments for those regulatory agencies (re environment, worker safety, human health *etc*). We also suggest that there has already been some progress with the inclusion of NICNAS in TGA, and that further progress could be achieved through cooperation rather than amalgamation.

Preliminary Finding 8.6

Agree, but note use of "risk". ERMA does not assess risk. Thus it seems improbable that NICNAS and ERMA could explore "the feasibility of identifying chemicals … with a low risk profile."

Preliminary Finding 8.7

Agree.

Preliminary Finding 8.8

Agree.

**Scope of Schemes**

*Chemicals*

Preliminary Finding 9.4

Agree, but again note use of "risk". GHS will not reduce risk in the way that chemical/substance-specific labelling can do, as is the current approach of Australia.

**Chapter 8.2 Hazardous substances, industrial chemicals and dangerous goods**

We note several errors in this part of the report:

- p. 129: GHS is inaccurately referred to as "Globally Harmonisation System" – the correct title should be the "Globally Harmonized System of Classification and Labelling of Chemicals" (note the capitals) – also slightly wrong in other places (eg "for" rather than "of");
- pp. 130 and several other pages: All uses of "mgs" should be changed to "mg";
- p. 131: the name cited should be Lee-Steere, not Lee-Street;
- p. 131: while DEH assesses chemicals using GHS classifications for NICNAS (not NOHSC – NICNAS now administered under the TGA) at their specific request (in addition to previous guidelines, which are mainly US EPA classifications), it is yet to adopt GHS classifications for its APVMA assessments (we still use largely the US EPA guidelines in our reports to APVMA, but could simply enough adopt the GHS ones as well as or instead). Note that there clearly <u>are</u> mandatory requirements for provision of ecotoxicity data under both NICNAS and APVMA data requirements for submissions – these data are used for assessments, but not necessarily for MSDSs or labels as yet, and not necessarily using GHS classifications;
- p.132: the OCS's responsibilities have been overstated. While NICNAS is part of OCS, NOHSC is not. Indeed, the OCS is a part of the TGA. The TGA within the health portfolio is analogous to the APVMA within the agriculture portfolio. Further details can be found at <u>http://www.tga.gov.au/docs/html/ocs.htm</u>.

- p. 133: the word “Australian” is omitted before “Pesticides and Veterinary Authority” (i.e. the APVMA). We understand the APVMA’s regulation to be in relation to effects on public health (through dietary and other incidental exposure), occupational health & safety, environment, biosecurity, export trade and effectiveness – as opposed to “food, bio-security and livestock”;

- pp. 133, 136: We understand that the APVMA regulates supply of pesticides and veterinary medicines and that the States regulate use (which is to be in accordance with APVMA approved labels or permits).

- p. 135: it is not correct to state that in Australia classifications and approvals are only required for chemicals. This might be true for industrial chemicals (NICNAS), however the APVMA registers agricultural and veterinary products (substances), while also approving the active constituents (chemicals) contained therein – presumably this is the case for therapeutic goods too;

- p. 136: in the last paragraph, re APVMA replace “Products Management” with “Medicines”;

- p. 136: it is incorrect to state that “the NDPSC classifies agricultural and veterinary products in relation to their chemical properties”. The NDPSC determines whether chemicals should be listed in schedules to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and the APVMA has regard to the SUSDP in determining applications for approval of active constituents (chemicals) and registration of products (substances). See previous comment re Commonwealth/State separation regarding supply and use.