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Submission No:

FEDERATION OF AUSTRALIAN SCIENTIFIC AND TECHNOLOGICAL SOCIETIES

Science and Technology for the Social, Environmental and Economic Benefit of Australia

Ms Julia Morris Committee Secretary Joint Standing Committee on Treaties Department of the House of Representatives Parliament House CANBERRA ACT 2600

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BY

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Dear Ms Morris

Parliamentary Joint Standing Committee on Treaties inquiry into the Australia-United States Free Trade Agreement

Please find attached the Federation of Australian Scientific and Technological Societies (FASTS) submission to the Committee's inquiry into the AUSFTA.

Yours sincerely

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Introduction

The Federation of Australian Scientific and Technological Societies (FASTS) is the peak representative body for 60,000 sci ists and technologists.

FASTS do not have a formal position on whether Australia should ratify the draft Aus-US Free Trade Agreement.

There are, however, a number of implications for science that we would like to draw to the attention of the committee.

Sanitary and Phytosanitary measures – Ch. 7

FASTS believes that good science is a necessary condition of robust policy, import risk assessment and regulation of sanitary measures.

Invasive species and introduced diseases have had major impacts on the environment and commercial agriculture and aquaculture (eg cane toads and phylloxera). To date, conservative quarantine practices have played an important role in Australia avoiding or minimizing exposure to diseases and pests that have seriously damaged agricultural production in other countries (eg fire blight). Indeed, Australia's reputation for being comparatively clean and low in disease, has given Australian agricultural exporters competitive advantages in many markets.

However, increasing flows of people, goods and services, climate change, reduced investment in relevant education and research disciplines such as parasitology, growing resistance of diseases and parasites to chemical controls and apparent changes in regulatory practices are increasing the risk to Australia's environment, human, plant and animal health and commercial agriculture.¹

In short, the importance of good science informing policy and risk assessment is **increasing**.

Assumptions about risk that may be robust today could well be invalid in the future as a consequence of climate change. Australia exposes itself to great risk if we become complacent, fail to support relevant research and monitoring or allow trade considerations to undermine proper scientific analysis.

The DFAT Guide To The Agreement states:

¹ On this refer An Investment in Human and Animal Health: Parasitology in Australia, FASTS Occasional Paper, Mark Sandeman and Lesley Warner (eds), Canberra, 2002

Nothing in the chapter undermines the right of either party to determine the level of protection it considers appropriate (p. 35).

FASTS is not so confident that this is so. The objectives of Chapter 7 go explicitly to resolving trade issues 'and thereby expand trade opportunities'.

The draft agreement provides for the creation of two bi-lateral Sanitary and Phytosanitary Committees – a general committee and a Standing Technical Working Group on Animal and Plant Health Measures.

The objectives of the general committee include "protecting human, animal, or plant life" and "facilitate trade between the parties" (7.4.3).

The objectives of the technical working group are to "resolve specific bilateral animal and plant health matters with a view to facilitating trade (Annex 7-A 4(a))."

That is, there is an intrinsic conflict in the objectives of both committees. The intent of the objectives suggests Australia has made quite marked concessions to the USA.

Clearly, that is the interpretation of the American Farm Bureau Federation who state in their press release of 10 March 2004:

AFBF's analysis of the proposed free trade agreement forecasts that annual exports of high-value U.S. food products to Australia will grow by \$150 million to \$200 million after that nation removes non-tariff trade barriers, particularly in the area of sanitary/phytosanitary rules.²

FASTS believes scientific analysis of risk must have priority over trade imperatives.

We are concerned that both the objectives of the committees and their character as bureaucratic instruments to facilitate trade, may undermine the fundamental role that proper scientific analysis must have in a sound quarantine system.

Our concern is compounded by the fact that there are no provisions requiring independent scientific expertise on the membership of either committee.

If the draft FTA is ratified then confidence in the two bi-lateral committees will be highly dependent on the capacity and approach of the lead Australian agency, Biosecurity Australia.

FASTS is aware that the confidence of agriculture sectors and relevant scientists in Biosecurity Australia is diminishing over time due to concerns that trade considerations are inappropriately prioritized over scientific analysis of risk. Recent debates and decisions over pineapples, durian, atlantic salmon, apples and pig meat have raised skepticism of Biosecurity Australia's capacity to make good judgments.

More specifically, scientists (and producers) are concerned with

• Biosecurity Australia's increasing emphasis on a 'least trade restrictive' approach that has the potential to undermine the science base of IRA.

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² http://www.fb.com/news/nr/nr2004/nr0310a.html

- Attempts by Biosecurity Australia representatives to 'direct' IRA teams toward facilitating trade,
- Inadequate record keeping of Import Risk Assessment (IRA) committees; and
- scientific errors in Biosecurity Australia's modeling and data;

For some detailed evidence and discussion of such concerns FASTS draws the attention of the Committee to the current Senate Rural and Regional Affairs and Transport Committee inquiry on Import Risk Analysis for Bananas.

Evidence presented to that committee raises serious concerns over Biosecurity Australia's procedures in relation to banana importation and import risk analysis of bananas from The Philippines that is consistent with the concerns noted above.

FASTS believe the arguments for significant reform of Biosecurity Australia's processes and objectives are strong. We recommend the Government initiate reform of Biosecurity Australia with some urgency. This should be done irrespective of Parliament's determination on the draft FTA.

Intellectual Property – Patents (ch. 17.9)

Background

The patent system is crucial to encourage R&D innovation and FASTS are broadly supportive of changes in the Australian patent system in the past few years to lift the threshold of patentability and improve the capacity of patent holders to protect patents.

Patents can, however, be a serious constraint on research.

FASTS believe that patents should not be permissible for factual scientific information including naturally occurring genes and gene sequences.

There is considerable international concern over the issuing of gene patents. The arguments against issuing patents for genes and gene sequences include ethical arguments, constraints on bona fide research and discovery of a gene or gene sequence does not satisfy a fundamental - and internationally recognised criteria for a patent - that it should be an invention.

Such concerns have resulted in major biotechnology research initiatives including the Human Genome Project and the International Haplotype Mapping (HapMap) Project to place their research results in the public domain with no constraints or costs on access for researchers.

No jurisdiction in the world permits patenting of genes or gene sequences *per se*. Debates over what is patentable typically revolve around questions of isolable genes and gene sequences.

It is fair to say that there is a widespread belief internationally that the US Patent system – unquestionably the most powerful patent regime in the world - has not got the balance of interests right and patents have been issued for isolable genes and gene sequences that stretch the criteria of patentability beyond what many scientists,

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ethicists and legislators consider as acceptable. The European Union, for instance, is vigorously opposed to the USA approach.

FTA Provisions

It is not clear what implications there are for the Australian patent system in the draft FTA.

The advice FASTS have received from DFAT is that the patent provisions in the draft FTA are consistent with existing Australian law so presumably there will be no changes at all or no changes of substance.

However, there does appear to be some variance between the proposals in the draft FTA and the current *Patent Act 1990*.

For example, article 17.9.1, seems to imply a broader definition of patents by changing the definition of invention. It makes the USA and Australia provide patents for "any invention ... provided ... (it) ... is new, involves an inventive step, and is capable of industrial application". Presumably, this will replace the current definition in Schedule 1 of the *Patents Act 1990* which defines invention as 'a manner of new manufacture within the meaning of s.6 of the *Statute of Monopolies*'. That statute lists a number of exclusions including that a patent is "not contrary to the law, nor mischievous to the state by raising of the prices of commodities at home or hurt of trade, or generally inconvenient". The scope of this exclusions list is not, however, replicated in 17.9.2(a).

17.9.2(b) does allow for a change in Australian law. It provides that parties *may* exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans and animals'. Under current Australian law exclusions relate to generating a human being (*Patent Act* (1990) s.19(2)). FASTS understand that the Federal Court has allowed that treatments are patentable.³

In addition, article 17.9.3 refers to 'exclusive rights' but these aren't defined elsewhere in the chapter so we are not sure exactly what this might mean.

Accordingly, FASTS are unable to really determine whether there are any substantive implications for science and R&D that are specific to the patent provisions in the draft FTA.

We note that in some of the commentary surrounding the FTA, the Government has stated that "Australians will benefit through closer harmonisation of our already strong intellectual property regime with that of the largest intellectual property market in the world.⁴

It is not clear to FASTS what the scope of 'harmonisation' will mean in practice.

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³ Bristol-Myers Aquibb Co v Faulding (2000).

⁴ http://www.dfat.gov.au/trade/negotiations/us_fta/outcomes/08_intellectual_property.html

As the committee will be aware, law operates at a variety of levels including parliamentary legislation and regulation; judicial, including case law; and administrative and normative practices of agencies.

There is a view that the apparent expansion in the US of what is patentable in respect of genes and gene sequences seems to be driven by interpretations at the officer level in the US patents office as distinct from US legislation.

FASTS does not have the expertise to provide the Committee with the relevant legal analysis of this but if this is, in fact, the case, then this may have some implications to Australian patents if 'harmonisation' is interpreted broadly and acted upon.

ALRC

The Committee will be aware that the Australia Law Reform Commission is currently reviewing gene patenting and human health. An issues paper and a discussion paper have been released and the final report is due in June 2004.⁵

FASTS considers the ALRC to be a highly credible organisation and the processes of their reviews to be genuinely consultative and comprehensive.

FASTS believes public debate over such an important set of issues as gene patents and consequences for research, human health and ethics should not be constrained or pre-empted by a trade agreement.

Government Procurement – Ch. 15

Fasts welcomes the liberalization of access for Australian firms to US Government procurement programs. At face value, this provides opportunities for firms in a variety of advanced technology and the service sectors to benefit. In practice, it is not clear how many Australian firms will benefit due to far to a range of distortions in the procurement process, including US State Government's interventions in support of local firms.

In addition, there will be extensive costs associated with tendering as appeals mechanisms are used extensively and aggressively. Nevertheless, these provisions are a significant improvement on current arrangements and as such are welcome.

Mobility

A defect in the FTA is the failure to resolve the barriers that constrain labour mobility to the US, specifically business people wishing to work in the USA for periods greater than 6 months. This impacts on Australian businesses, notably, given FASTS interests, R&D intensive technology SMEs trying to expand into the US market.

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⁵ http://www.alrc.gov.au/inquiries/current/patenting/index.htm