Commonwealth Department of Health and Ageing

SUBMISSION TO THE

PRODUCTIVITY COMMISSION'S 2003 REVIEW OF THE MUTUAL RECOGNITION ARRANGEMENT (MRA) AND THE TRANS TASMAN MUTUAL RECOGNITION AGREEMENT (TTMRA)

April 2003

INTRODUCTION

The Commonwealth Department of Health and Ageing (the Department) welcomes the opportunity to contribute to the Productivity Commission's 2003 Review of the Mutual Recognition Arrangement (MRA) and the Trans Tasman Mutual Recognition Agreement (TTMRA) [the Review]. The Department has identified specific matters within the Health and Ageing portfolio pertinent to the Review and has presented possible remedies.

This submission is presented within the context of the Department's overall objective of promoting good health and ensuring all Australians have access to key health services. The services provided by the Health and Ageing Portfolio are delivered through nine portfolio outcomes. The Department pursues these in association with other portfolio agencies including Food Standards Australia New Zealand (FSANZ) and the Therapeutic Goods Administration (TGA).

The Health and Ageing portfolio has a diverse set of responsibilities, but throughout there is a common purpose, which is reflected in the mission statement – to lead the development of Australian's Health and Ageing system. The portfolio's responsibilities include to:

- provide expert policy advice, analysis and other services to the Government;
- work with consumers, communities, providers, peak bodies, industry groups, professional organisations, State and Territory Governments and portfolio agencies through consultation and collaboration; and
- safeguard health, safety and equity, in a way that imposes the minimum necessary regulatory burden.

THE PRIMARY RECOMMENDATIONS OF THE SUBMISSION

There are a number of issues within the Department's portfolio responsibilities, which focus primarily on the TTMRA, addressed in this submission. The subject areas are therapeutic goods, food regulation and health occupations.

Therapeutic Goods

Three issues are considered in this section of the submission. Issue 1 identifies the need for some form of continued exemption mechanism to be in place to enable the transitional arrangements for the proposed new joint trans-Tasman therapeutic products agency (the Agency) to operate and be able to:

- allow existing goods legally on the market in either Australia or New Zealand to remain on the market in that country; and
- prevent their supply in the other country, until a dual country product licence has been issued by the Agency.

This would ensure that products supplied in both countries meet the standards of quality and safety that are required by each country.

Issue 2 identifies the need to ensure that the mutual recognition principle does not apply to allow therapeutic products sold in one country to be sold in the other country where one country chooses to depart from the harmonised scheme. Consideration is still being given as to how best to provide for 'opt out' in the Treaty and in the Agency legislation.

At present, therapeutic goods have a special exemption from the operation of the *Trans Tasman Mutual Recognition Act 1997*. Issue 3 identifies the need to limit the considerable administrative resources involved in the annual 'rolling over' of the special exemptions in order to achieve significant administrative savings.

Food Regulation

The ANZ Food Treaty provides a framework for the setting of joint food standards. There are some areas that remain outside the scope of the Food Treaty, for which each country maintains separate standards. The TTMRA allows such products to be traded across the Tasman. Hence, a food product that is illegal in Australia can be legally imported from NZ.

Current examples of where there are conflicting standards in Australia and NZ that present a regulatory problem are:

- NZ's maximum residue limit for ethylene oxide in spices, when Australia's ethylene oxide maximum residue limit is being phased out;
- an NZ regulation permitting the use of hemp seed oil as food;
- an NZ regulation permitting up to 200ppm caffeine in artificial drinks; and
- NZ's Dietary Supplements Regulations.

The submission recognises that anomalies occur in only a minority of instances and those differences in Australian and NZ food standards can arise or already exist for valid reasons. In those cases, mutual recognition continues to be appropriate. The submission sets out to propose a mechanism(s) to ensure that when the Australia and New Zealand Food Regulation Ministerial Council has made a ruling to prohibit or withhold food products or ingredients on health and safety grounds, that these products cannot be made available to the Australian public via the TTMRA.

The preferred mechanism recommended would enable the incorporation of TTMRA exemptions directly into the relevant food standard. This would require integrating consideration of TTMRA issues and their public health and safety and regulatory impacts into the FSANZ standards development process and enable their consideration by the Ministerial Council as part of the standard. A temporary exemption mechanism could also be associated with this mechanism.

Exemption of Doctors from the TTMRA

In developing the TTMRA, the participating parties agreed that medical practitioners be exempted from the arrangement as mutual recognition-type arrangements were already in place in Australia at that time. Australia recognises New Zealand qualifications but NZ trained doctors are still required to register with a State or Territory Medical Board in order to practice in Australia, just like Australian trained doctors.

The Department supports the continued exemption of medical practitioners from the TTMRA as the current arrangements provide a satisfactory means of addressing medical registration issues in keeping with quality concerns. The Department would be concerned to just apply normal mutual recognition arrangements to New Zealand registered medical practitioners as this would not provide the same quality assurance in respect of NZ registered doctors not qualified in NZ.

THE ISSUES

There are a number of issues within the Department's portfolio responsibilities, which focus primarily on the TTMRA, that are addressed in this submission. These fall within the three following subject areas: therapeutic goods, food regulation and health occupations. Under each of the subject headings the issues are identified and explained and recommendations are proposed taking into account the terms of reference of the Review.

I THERAPEUTIC GOODS

Australia and New Zealand propose to harmonise their regulatory schemes for therapeutic products consistent with their obligations under the TTMRA, and establish a single joint agency to administer this harmonised scheme. Therapeutic products (prescription medicines, over the counter medicines, complementary medicines and medical devices) currently have a special exemption under the Trans Tasman Mutual Recognition Arrangement (TTMRA) until 1 May 2003. A further twelve month extension of this special exemption until 1 May 2004 is currently being sought. It is anticipated that the proposed joint trans-Tasman therapeutic products agency (the Agency) will commence operation in mid-2005.

This section of the submission is designed to assist the Productivity Commission address in particular the following aspects of the terms of reference in relation to the current special exemption for therapeutic products:

2(b) Consider whether any changes to the … TTMRA and the related legislation, or the implementation thereof, are required to improve their operation;

5. In relation to the TTMRA, consistent with the intention to minimise exemptions and exclusions from the Arrangement:
(a) assess any amendments or additions to the laws in the Schedules, and comment on their consistency with the principles underpinning the Arrangement; and
(b)(i); Examine the scope for deletions from or amendments to the Schedules, including whether permanent exemptions or exclusions under the scheme and related legislation should be retained.

The Review provides an opportunity to outline two aspects of the harmonised scheme that will have implications for the future operation of the Arrangement:

- the proposed transitional arrangements for the agency; and
- the proposal that each country will have the capacity to depart from the Scheme in respect of a product or class of products in exceptional circumstances.

The Review also provides an opportunity to provide feedback on the impact of TTMRA compliance on agencies already committed to cooperation programs with extended work schedules.

The Trans Tasman Therapeutic Products Agency

The establishment of the joint agency has been agreed in-principle by the Australian and New Zealand Governments and, as mentioned previously, is anticipated to commence operation in mid-2005. The agency would replace the Therapeutic Goods Administration (TGA) in Australia and Medsafe in New Zealand.

The two countries are broadly agreed on the necessary arrangements for legislation, governance, accountability and reporting for the joint agency. It is proposed that the agency would be established under a Treaty and Australian legislation to administer a regulatory scheme to be established in Australian and New Zealand legislation. A Ministerial Council of the Australian and New Zealand Health Ministers would oversee the agency. A Board of five members would be accountable for the agency's efficient operation to the Australian and NZ parliaments through the Health Ministers of each country.

The Agency would regulate the full range of therapeutic products manufactured or supplied in, or exported from, Australia and/or NZ to ensure they met appropriate standards of quality, safety and efficacy. Its functions would include pre-market evaluation and approval, licensing and auditing manufacturers of products, post-market monitoring and surveillance, the oversight of advertising arrangements for therapeutic products, and the setting and monitoring of standards (eg, quality and labelling).

The Agency's regulatory scheme would be based on a risk management approach, in which the degree of regulatory control would be proportional to the risk associated with use of the product. Products would be evaluated and assessed according to their risk, ranging from low risk products (most complementary medicines) to higher risk products (prescription medicines, vaccines and implantable devices).

Consistent with current Australian requirements, the agency would issue product licenses, and have the power to suspend and cancel product licences if sponsors breached compliance requirements. Each product would be uniquely identified, consistent with current practice in Australia, to ensure traceability of products in the event of product failure and the need for recalls, and to ensure that only licensed products (unless specifically exempted) are available for sale in Australia and NZ. The Agency would have sufficient enforcement and monitoring powers, including the power to request information, take samples for testing, search premises and seize goods, impose administrative sanctions and refer offences for prosecution.

The establishment of the trans-Tasman Agency will assist in positioning Australia as a regional centre of excellence for therapeutic products along with the regions of North America and Europe. In the longer term, the establishment of the Agency will provide opportunities for suppliers of therapeutic products to consider Australia and New Zealand as a single market. Over time, this will lead to the greater trans-Tasman integration of business operations and strategies, which is one of the aims of the Australian New Zealand Closer Economic Relations (CER) Trade Agreement. This will serve as a 'blue print' for future cooperation in the Asia Pacific region leading to potential opportunities for increased trade.

Domestically, Australian business that exports to New Zealand will benefit from reduced compliance costs due to single applications rather than dual applications, and faster turnaround of applications seeking marketing approval of therapeutic products. All products currently registered only in Australia will benefit from increased market opportunities. The establishment of the trans-Tasman agency will also provide both Australia and New Zealand with stronger opportunities for influencing global and regional standard setting.

The New Zealand Institute of Economic Research has estimated that adding New Zealand's domestic market to Australia's on the same terms as for the existing Australian domestic market could deliver potential one-off productivity benefits for the therapeutic products

sector of between 2 to 3 per cent, or $180 – 270 million. This has potential benefits of improving trans-Tasman trade that is currently in the order of $300 million.

Implications of the Agency for the TTMRA

The establishment of the harmonised regulatory regime for therapeutic products has implications for the TTMRA. At present, the whole of the *Therapeutic Goods Act 1989* (the TG Act) and the *Therapeutic Goods (Charges) Act 1989* have a special exemption from the operation of the *Trans Tasman Mutual Recognition Act 1997* and hence from the operation of the mutual recognition principle as it applies to goods. This special exemption has to be 'rolled over' each year to remain in operation, which involves considerable administrative resources.

Once the Agency commences operation, and these (therapeutic goods) Acts will be repealed and replaced with new legislation. New arrangements will be needed under the TTMRA to accommodate the transitional arrangements for product licenses, and the capacity for either Australia or New Zealand to depart from the new harmonised arrangements in exceptional circumstances.

Issue 1: the need for some form of continued exemption to enable the transitional arrangements for the new Agency to operate

When the Agency commences operation, a mechanism will be needed to enable existing goods legally on the market in either Australia or New Zealand to remain on the market in that country. This mechanism would also be needed to prevent their supply in the other country, until a dual country product licence has been issued by the agency. This will ensure that products supplied in both countries meet the standards of quality and safety that are required by each country.

Issue 2: the need to ensure the mutual recognition principle does not apply to allow therapeutic products sold in one country to be sold in the other country where one country chooses to depart from the harmonised scheme in exceptional circumstances in respect of a product or class of products

The trans-Tasman regulatory scheme for therapeutic products is designed to deliver common regulatory outcomes in both countries. However, the scheme will also need to enable either country to 'opt out' of the common regulatory scheme in relation to particular products in extraordinary circumstances (eg, to accommodate different public health policy imperatives). This proposal is similar to that of the Food Standards Treaty whereby food standards developed by FSANZ and that have not been rejected by the Australia New Zealand Food Regulation Ministerial Council must be adopted by both Australia and New Zealand unless for certain specified exceptional circumstances different standards are required.

Where one country chooses to depart from the harmonised scheme in relation to particular products, the TTMRA should not operate to allow the supply of those products produced in one country to be sold in the other country, depending upon the nature of the opt-out. In addition, it should also ensure that, where the opt out has been invoked, it does not operate to prevent each country from prohibiting the supply of goods that:

- are produced in other countries; and
- may legally be sold in the other (trans-Tasman) country; and

- do not meet the requirement of the (trans-Tasman) country that wishes to prevent their sale.

Consideration is still being given as to how best to provide for 'opt out' in the Treaty and in the Agency legislation.

Issue 3: the need to limit the administrative resources involved in 'rolling over' special exemptions

Significant administrative resources are expended each year to 'roll over' the therapeutic goods special exemption. These administrative steps include:

- the preparation of, and agreement to, a Report by the TGA and Medsafe in New Zealand;
- attaining approval from Australian and New Zealand Health Ministers for the Report;
- attaining approval from the Prime Minister to forward the report to the Council of Australian Governments for consideration; and
- liaison between the TGA and the Department of Industry, Technology and Resources and the Department of Prime Minister and Cabinet regarding the timely amendment of the regulations.

The TGA would support reform of the special exemption framework to accommodate cooperation programs with extended work schedules. A reduction in the requirements and/or streamlining of the processes necessary to extend the special exemption each year would achieve significant administrative savings.

II FOOD REGULATION

TTMRA, Imported Food and the Australia New Zealand Joint Food Standards System

1. Overview: Food Regulation and the TTMRA

Under the Trans-Tasman Mutual Recognition Arrangement (TTMRA), food that complies with New Zealand food legislation can be freely imported into Australia from New Zealand.

The Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System (ANZ Food Treaty) provides a framework for the setting of joint food standards. There are some areas that remain outside the scope of the Food Treaty, for which each country maintains separate standards. Where these separate standards exist, products can continue to be traded across the Tasman due to the TTMRA. The ANZ Food Treaty also provides for particular circumstances in which New Zealand can opt out of a joint standard, even where this is within the scope of the Treaty.

This has lead in a number of instances to a situation where a food product is illegal to produce in Australia, but can be legally imported from New Zealand and sold in Australia. Furthermore, it allows products to be imported into Australia despite there having been a Ministerial Council policy decision that the products should not be permitted, for instance on public health and safety grounds.

Whilst a number of 'exemption' mechanisms do exist under TTMRA, they are not always appropriate to the food regulation context and are time consuming to implement.

The Department sees the TTMRA Review as an opportunity to provide input into the future of the TTMRA and to address anomalies that are occurring in trans-Tasman food regulation.

The Department recognises that the anomalies are in the minority and that the vast majority of food standards issues are addressed as harmonised food standards under the joint Australia New Zealand Food Standards System. The Department also acknowledge that differences in Australian and New Zealand food standards may arise or already exist for valid reasons and are not necessarily a cause for concern: in those cases, mutual recognition continues to be appropriate.

The Department's goal is to be able to establish a readily accessible, timely mechanism - linked to the joint food standards setting system - that will enable anomalies to be addressed, where the Australia New Zealand Food Regulation Ministerial Council has made a ruling to prohibit or withhold food products or ingredients on health and safety grounds.

2. Food Regulatory Framework

In addition to the TTMRA and its associated legislation, the key instruments that govern the joint Australia New Zealand food standards system are as follows:

- Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System (ANZ Food Treaty)

- COAG Food Regulation Agreement 2002 (Food Regulation Agreement)

- *Food Standards Australia New Zealand Act 1991 (FSANZ Act)*
- Australia New Zealand Food Standards Code

- *Imported Food Control Act 1992*
- Imported Food Control Regulations 1993

3. TTMRA and Food

3.1 Relationship between TTMRA and Joint Food Standards Agreement

The TTMRA applies to goods in general, including food. This means that food may be imported into Australia from New Zealand provided it complies with New Zealand food regulations/standards, even where these are inconsistent with Australian food standards.

The Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System (ANZ Food Treaty) was signed in 1995, came into force in 1996 and was amended in 2002. The review of the Australian Food Standards Code and transition to a complete joint Australia New Zealand Food Standards Code was central to the ANZ Food Treaty. There was a two year transition period from December 2000 to December 2002. On 20 December 2002 the majority of New Zealand Food Standards were repealed and the Australia New Zealand Food Standards Code came into being.

Despite this, the TTMRA continues to underpin the joint food standards system. Article 7 of the ANZ Food Treaty states:

> Member States acknowledge their intention that the provisions of the Trans-Tasman Mutual Recognition Arrangement apply to food, subject to any necessary exemptions determined in accordance with the procedures laid down in that Arrangement.

In practical terms, this means that in cases where a joint standard is not achieved, and different Australian and New Zealand standards or regulations apply for a food, unrestricted trade will still take place. However, where a regulatory difference raises concerns about public health, safety or the environment, the normal TTMRA exemption mechanisms are available.

3.1. How differing food standards may arise

3.1.1. Treaty Scope

The Scope of the ANZ Food Treaty (Article 3) specifically excludes:

- the specification of maximum residue limits for agricultural and veterinary chemicals in food;
- the specification of food hygiene provisions including requirements for food safety programs or other means of demonstrating the safety and compliance of foods; and
- export requirements relating to third country trade.

This means that Australia and New Zealand are free to develop independent standards on these matters.

3.1.2 Opting Out

There are also mechanisms under the ANZ Food Treaty for establishing 'New Zealand only' Standards for issues that are otherwise within the scope (ANZ Food Treaty, Annex C and Annex D).

FSANZ may identify the need for separate Australian and New Zealand food standards during a standards development process. This would be on the grounds of exceptional health and safety or environmental reasons. FSANZ would then approve separate standards for Australia and New Zealand and notify these to the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC).

New Zealand is also entitled to request a review of an approved or existing food standard. This can occur if the New Zealand Minister has concerns that the standard would be:

- inappropriate for New Zealand on the grounds of exceptional health, safety, third country trade, environmental or cultural factors;
- inconsistent with the principles set out in the Treaty or with World Trade Organisation obligations; or
- inconsistent with domestic laws and regulations (of either country).

These are in addition to the standard grounds for seeking a review, which are set out in both the COAG Food Regulation Agreement 2002 and the ANZ Food Treaty.

If the New Zealand Minister still considers that an approved food standard would be inappropriate for New Zealand following the completion of any such reviews, the Minister may inform ANZFRMC that New Zealand needs to vary from the standard. The New Zealand Minister needs to specify the reasons and justification for the variance. This should only be on the grounds of: exceptional health, safety, third country trade, environmental, or cultural factors. In a similar way, New Zealand may also vary from food standards developed under urgency provisions.

New Zealand may then request FSANZ to prepare a separate standard appropriate for New Zealand (subject to agreement on funding arrangements). The standard from which New Zealand has varied would become an 'Australia only' food standard. This would need to be annotated on the New Zealand only standard when it appears in the Australia New Zealand Food Standards Code.

4. Australia and New Zealand Food Regulation Ministerial Council

The Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) was established by the COAG Food Regulation Agreement 2000 (amended in 2002). New Zealand is not a party to the Food Regulation Agreement, but is a member of ANZFRMC by virtue of the ANZ Food Treaty. The FSANZ Act sets up the role of ANZFRMC in relation to food standards.

The ANZFRMC is primarily responsible for the development of food regulatory policy and the development of policy guidelines for setting food standards. It also has the capacity to adopt, amend or reject standards and to request that these be reviewed. There are set grounds on which ANZFRMC may request a review of an existing standard, draft standard or variation, or amend or reject one that has been reviewed.

4.1 Ministerial Councils and TTMRA

The role of Ministerial Councils, the Council of Australian Governments (COAG) Committee on Regulatory Reform (CRR), and TTMRA Heads of Government in making determinations on TTMRA exemptions on standards issues is set out in the ISR/DFAT publication *A User's Guide to the Trans-Tasman Mutual Recognition Arrangement (TTMRA)*.

In practice, the process is quite involved and it would be very time consuming to successfully implement a permanent exemption. This makes this mechanism virtually inaccessible as a means of exempting any particular food standard that has become a concern. Further, as the process currently stands, it does not take into account the unique nature of the joint food standards setting system.

TTMRA was intended as a mechanism to remove unnecessary barriers to trade across the Tasman. The joint food standards setting system prevents barriers to trade by creating harmonised standards. The TTMRA now needs to recognise the existence of the joint food standards setting system and provide a more accessible and timely means of exempting certain standards when Australia and New Zealand are unable to agree on a joint standard. The capacity for a timely response is particularly important when public health and safety is involved in a food standards issue.

Ideally, ANZFRMC would be given the direct authority to exempt particular food standards from TTMRA, at the time the draft standard or amendment was being considered by ANZFRMC. This is particularly important in cases where there is disagreement between Australia and New Zealand regarding a food standard that impacts on public health and safety. In addition, matters of fairness to domestic producers should be able to be taken into account.

5. TTMRA Exemptions

Matters such as health and hygiene requirements, and the protection of health, safety or the environment can generally be excluded from TTMRA.

5.1 Exclusions

The main TTMRA exclusion relevant to food regulation is that of the Customs (Prohibited Imports) Regulations 1956.

5.1.1. Permanent Exemptions

Permanent Exemptions for certain laws apply if the participants in TTMRA agree that mutual recognition principles should not apply. The *Imported Food Control Act 1992*, to the extent that it deals with risk categorised food commodities, is specifically granted a permanent exemption under Schedule 2 of the TTMR Act. This means that risk foods are exempt from TTMRA.

5.1.2 Special Exemptions

Special Exemptions apply in areas where "Cooperation Programs" have been established with a view to developing complementary regulatory arrangements across the Tasman (or deciding whether either mutual recognition or permanent exemption would be more appropriate). A Special Exemption is currently in place for therapeutic goods, subject to ongoing work towards the establishment of a trans Tasman joint therapeutics regulatory agency. This special exemption has a bearing on the debate regarding food-type dietary supplements which fall in between the definition of a therapeutic good and a food.

5.1.3 Temporary Exemptions

The Temporary Exemption mechanism gives participating jurisdictions the right to unilaterally exempt certain goods or laws from TTMRA for 12 months within their jurisdiction, for health, safety or environmental reasons.

In the case of the Commonwealth, a temporary exemption regulation would need to be made under the TTMR Act or the specific legislation that implements the standards for which the exemption is being sought. The regulation making power in the FSANZ Act does not extend to regulations prohibiting food imports and therefore any temporary exemption regulation made for food would need to be made under the TTMR Act.

Temporary Exemptions only apply in the jurisdiction that invokes the exemption. This means goods temporarily exempted in one jurisdiction may still be able to enter that jurisdiction through other jurisdictions via the Australian MRA. However, the

Commonwealth, via the *Imported Food Control Act 1992* has jurisdiction over imported foods at point of entry. Otherwise, for a good that was of concern to all Australian jurisdictions, all would need to simultaneously gazette regulations invoking the Temporary Exemption.

5.2 The Imported Food Control Act and the Customs Act

The *Imported Food Control Act 1992* provides for the inspection and control of food imported into Australia. However, consistent with the TTMR Act, the *Imported Food Control Act 1992* does not apply to food that is imported from New Zealand *and* was made or produced in New Zealand *and* is not risk food (Section 7(1)(aa) and Imported Food Control Regulations 1993, Regulation 3A). However, Schedule 2 of the TTMR Act provides a permanent exemption for risk categorised food commodities under the *Imported Food Control Act 1992*.

Risk food is defined in Regulation 9: Food of a particular kind may be classified as risk food if the Australia New Zealand Food Authority (now FSANZ) advises the Minister under subsection 17 of the *Imported Food Control Act 1992* that the food has the potential to pose a high or medium risk to public health. Section 17 requires the Minister to consult the Australia New Zealand Food Authority before making or varying an order. (The Minister for Agriculture, Fisheries and Forestry administers the *Imported Food Control Act 1992*.)

Under Section 8 it is an offence to knowingly import food into Australia to which the *Imported Food Control Act 1992* applies and which does not meet applicable standards. This is different to 'prohibited food', the importation of which is prohibited under the Customs Act. Section 50 of the Customs Act 1901 allows the Governor-General to make regulations to prohibit the importation of goods into Australia. The Customs (Prohibited Imports) Regulations 1956 are also excluded from TTMRA.

5.2.1 Arrangement on Food Inspection Measures

The 1996 Arrangement on Food Inspection Measures (AFIM) aims to reduce border inspection requirements for food traded between Australia and New Zealand, thus reducing associated costs. The underpinning legislation in Australia is the Commonwealth's TTMR Act.

AFIM allows foods other than "risk classified" foods to be exported without import and export certification and inspection requirements. Only risk classified foods need to be inspected by AQIS – other foods are only subject to domestic surveillance in the same way as locally-produced foods. A food is risk classified if the scientific literature or experience identifies a particular risk for that food.

It was also agreed in AFIM that Australia and New Zealand would develop a joint list of risk classified foods- this has not yet been achieved. The Department understands that a recently formed officials working group with participation from FSANZ, AQIS and the New Zealand Food Safety Authority is now working towards this joint risk list, as well as reviewing trans-Tasman imported food inspection arrangements.

5.3 Limitations of Existing Exemption Mechanisms

The existing TTMRA exemption mechanisms are not always well matched to managing a particular food issue.

The 'risk categorisation' process under the *Imported Food Control Act 1992* is the most food-specific TTMRA exemption mechanism currently accessible. However, as defined in the Act it is only applicable when there is a risk to public health that meets particular criteria. Before FSANZ can advise the Minister regarding a risk categorisation, a further assessment process is required. Also, depending on its outcomes, the FSANZ/AQIS/NZFSA joint risk list project and trans-Tasman imported food Review may reduce or even remove altogether the accessibility of this exemption mechanism.

The Customs (Prohibited Imports) Regulations appear to be broader in scope than the risk food mechanism but the Department is not aware that they have ever been used to manage a TTMRA issue. Amending these regulations may be complicated by the fact that the responsibility for the *Customs Act 1901* is outside the health portfolio. It would be preferable to have a mechanism that could be accessed within the scope of the general food regulatory framework.

Temporary exemption regulations provide another avenue, but the main drawback is that they are temporary and to obtain a permanent exemption after the initial 12 months then requires a further lengthy and resource intensive administrative process.

6. Trade Implications

Increasing the capacity for TTMRA exemptions for food standards may be more trade restrictive than current arrangements. In practice however, the great majority of food items traded across the Tasman comply with the Australia New Zealand Food Standards Code: hence, any measures to facilitate TTMRA exemptions would have a very small impact on the overall volume of trans-Tasman trade.

7. Treaty Review

Article 9 of the ANZ Food Treaty provides that a Review of the ANZ Food Treaty can be conducted at any time mutually agreed by exchange of letters between the Australian and New Zealand Ministers. In addition, a review is required to be conducted and concluded before the conclusion of the review of the Food Regulation Agreement 2000. Clause 36 of the Food Regulation Agreement requires that its review be conducted and concluded no later than five years after its commencement. This would be by November 2005. This means that a Treaty Review should take place during 2004. This timing would provide an opportunity to consider and implement any outcomes of the TTMRA Review.

8. Rationale for Change

Given that trans Tasman food standards are now essentially harmonised, there is a need for food-specific mechanisms for managing TTMRA issues in situations when harmonisation of food standards is not achievable and mutual recognition is not appropriate.

Current examples for which there are conflicting standards in Australia and New Zealand which are of regulatory concern are:

- New Zealand's maximum residue limit for ethylene oxide in spices, when Australia's ethylene oxide maximum residue limit is being phased out for health and safety reasons;
- a New Zealand regulation permitting the use of hemp seed oil as food;
- a New Zealand regulation permitting up to 200ppm caffeine in artificial drinks; and
- New Zealand's Dietary Supplements Regulations.

The major ground for seeking a new food-specific TTMRA exemption mechanism is the protection of public health and safety. It is of concern that some food products that have been prohibited in Australia for public health and safety reasons are able to enter Australia and be legally sold because of TTMRA. The protection of public health and safety is a legitimate ground for exemption from TTMRA.

There are also potential competition issues if Australian producers are subject to restrictions that do not apply to New Zealand imports, as they are not competing on a level playing field. Energy drinks, prior to the introduction of the Formulated Caffeinated Beverages Standard, provided an example of a product that could be legally imported but could not be legally manufactured within Australia, preventing Australian producers from diversifying their product range to compete.

The Department is also concerned that the application of TTMRA to food standards can act as a disincentive to harmonised joint food standards, which would be Australia's preferred outcome in most cases.

If mutual recognition were not the default or assured outcome when giving consideration to 'opting' out of a joint food standard, this would provide substantial additional motivation for favouring standards harmonisation. Continuing progress towards food standards harmonisation is highly desirable from the perspective of good regulatory practice and the protection of public health and safety.

It would be desirable for these factors, along with public health and safety, to be recognised as sufficient rationale for implementing food-specific TTMRA exemptions for food standards.

9. TTMRA Exemptions Mechanism for Food Standards

The Department has considered a number of options for integrating TTMRA exemptions with food regulation. These options are explored below.

Option 1

The current permanent exemption for risk categorised foods under the *Imported Food Control Act 1992* presents a potential platform which could be used to develop a more wide ranging and flexible food-specific TTMRA exemption mechanism.

This might involve broadening the concept of risk food when applied to New Zealand under the *Imported Food Control Act 1992* (and the scope of the 'risk food' TTMRA permanent exemption). Alternatively, it may be preferable to leave the risk food concept untouched and

introduce new, separate, TTMRA powers into the *Imported Food Control Act 1992*. This could involve the ability to make a ruling or declaration that:

- a particular 'New Zealand only' standard either in New Zealand's domestic legislation or the Australia New Zealand Food Standards Code was unacceptable in Australia and exempt from mutual recognition; or
- New Zealand imports must comply with a particular 'Australia only' standard.

The power to make an order concerning risk foods under the *Imported Food Control Act 1992* currently resides with the Minister for Agriculture, Forestry and Fisheries. In order to integrate effectively with the food standards setting system, the power to make orders could be extended to the Minister for Health and Ageing as chair of ANZFRMC. A temporary, emergency power to prevent inappropriate food imports might also be delegated to an appropriate senior official.

The Department notes that FSANZ, AQIS and NZFSA are currently working towards a harmonised imported food risk list, and that this work may impact on the future accessibility or appropriateness of the *Imported Food Control Act 1992* imported food risk categorisation as a permanent exemption mechanism.

Given that there is some doubt about the ongoing appropriateness of the *Imported Food Control Act 1992* as a vehicle for resolving the Department's issues regarding the TTMRA and food regulation, this is not the Department's preferred option.

Option 2

Another option would be to create a blanket permanent exemption from TTMRA for all food standards both within and outside the scope of the ANZ Food Treaty. This would include New Zealand dietary supplements regulations, and remaining New Zealand Food Standards and Food Regulations.

Within the scope of the ANZ Food Treaty, the joint food standards system mostly results in identical standards for Australia and New Zealand; this would naturally limit the extent of this permanent exemption. It would also create real consequences for New Zealand where there is a decision to 'opt out' of a joint standard, and would be an efficient way of preventing public health and safety concerns and eliminating unfair competition arising from incompatible standards.

This option could create an incentive to expand the scope of the ANZ Food Treaty, reducing the number of exceptions to the harmonised food standards system. However, it could also be seen as trade restrictive, potentially blocking mutual recognition and trade of products for which there were no particular health and safety or other concerns.

In particular, for this option to be workable, there may need to be some discretion for areas outside the scope of the treaty, such as primary production standards, where trans-Tasman food standards differences may or may not create concerns.

Option 3 (Preferred Option)

The Department's aim is to move towards a more efficient mechanism for protecting public health and safety on food related TTMRA issues.

Accordingly, the Department's view is that a mechanism for TTMRA exemption should be integrated into the legislation and decision making structures of the Australia New Zealand Joint Food Standards System, rather than requiring action to be taken via separate legislation. This would enable decisions regarding the trans Tasman mutual recognition (or otherwise) of food standards to be made as an integral part of the standards setting process.

The preference would be for exemptions, either temporary or permanent (depending on circumstances), to be incorporated directly into the relevant food standard. The advantage would be that the TTMRA issues and regulatory impacts would be considered during the FSANZ standards development process. TTMRA issues and impacts would be assessed by FSANZ and considered by ANZFRMC at the same time as the standard.

FSANZ and the ANZFRMC should be given the power to specify on a case by case basis in the Australia New Zealand Food Standards Code that mutual recognition is not applicable to a particular standard or part of a standard.

This power would be used when an 'Australia only' standard or a 'New Zealand only' standard (including New Zealand domestic standards or regulations) would create problems with TTMRA. Alternatively, ANZFRMC could be given the power to authorise its members to make their own regulations for permanent exemptions, when a TTMRA concern arose. During the food standards development process, FSANZ would consider whether or not a particular food standard should be subject to TTMRA, and ANZFRMC would make the final determination. Food that had been exempted in this way would automatically be subject to the *Imported Food Control Act 1992.*

From the Department's perspective, it would be preferable if the regulation making power in the FSANZ Act could be extended to make food-specific TTMRA temporary exemptions, rather than needing to rely on the TTMR Act.

Implementing this mechanism would impact on the operation of both TTMRA and food related legislation, and would require amendments. This would require consultation and agreement between the Commonwealth and Australian States and Territories (as Parties to the Food Regulation Agreement 2002) and New Zealand (as Parties to the ANZ Food Treaty). The ANZ Food Treaty would also need to be amended.

III HEALTH OCCUPATIONS

Doctors & MRA

Under Australian Commonwealth and complementary State and Territory laws, there is a process of reciprocal recognition of registration of the qualifications of a medical practitioner who is registered in another jurisdiction. Under the MRA, a doctor who is registered without conditions in one participating state or territory can practise in another participating state. However, in spite of mutual recognition, in order to practice medicine in a particular state or territory, a medical practitioner must apply for registration with the relevant Medical Board and pay a registration fee.

The Australian Medical Council (AMC) is a national standards advisory body for basic medical education. It advises State and Territory Medical Boards on uniform approaches to the registration of medical practitioners and maintains a national network of State and Territory medical registers.

Doctors & TTMRA

The TTMRA covers all occupations for which some form of legislation-based registration, certification, licensing, approval, admission or any other form of authorisation is required by individuals in order to legally practise the occupation. The only exception applies to medical practitioners.

In developing the TTMRA, the participating parties agreed that the medical practitioner occupation be exempted from the arrangement. Mutual recognition-type arrangements for medical practitioners were in place in Australia prior to the introduction of the TTMRA. Australia recognises New Zealand undergraduate qualifications and State and Territories Medical Registration Boards automatically grant medical registration to graduates of AMC-accredited New Zealand medical schools whom have completed an approved period of intern training. These doctors are not required to undergo the AMC examinations, which are a requirement for overseas trained doctors from other countries. However, New Zealand trained doctors are still required to register with a State or Territory Medical Board in order to practice in Australia, just like Australian trained doctors.

The AMC administers the national examinations of overseas trained medical practitioners seeking to practise medicine in Australia. The AMC examinations are designed to assess, for registration purposes, the medical knowledge and clinical skills of overseas trained doctors, whose basic medical qualifications are not recognised by Australia, against Australian and New Zealand standards. The standard of the AMC examinations is defined as the level of attainment of medical knowledge, clinical skills and attitudes required of newly qualified graduates of Australian medical schools who are about to commence intern training. Many overseas trained doctors undertake these examinations each year, including New Zealanders who are registered but were not qualified in New Zealand.

The Department believes that the current arrangements provide a satisfactory means of addressing medical registration issues in keeping with quality concerns for this key health occupation. The Department sees no reason to alter these arrangements and supports the continued exemption of medical practitioners from the TTMRA.

The Department would be concerned to just apply normal mutual recognition arrangements to all New Zealand registered medical practitioners. This is because mutual recognition on its own would not provide the same quality assurance in respect of New Zealand registered doctors who were not qualified in New Zealand. Mutual recognition would extend automatic full registration in Australia to this group without requiring them to meet AMC standards. However, unlike New Zealand trained doctors, there is not assurance that the training of these doctors meets AMC standards.

This is not considered appropriate as it could weaken quality assurance processes for overseas trained doctors and such a change would not be supported by the Department.

Nurses

While the Department has an interest in the issue of the nursing workforce it considers that it is a matter for State and Territory Governments to pursue, as they are both the regulators and significant employers of nurses.

The Commonwealth has a broad policy leadership role in health and an overall interest in the supply, distribution, demand and quality of the health workforce. The Department strives to develop structures and practices that involve health professionals in health policy development, planning and implementation.

The Department supports State and Territory nursing legislation that is underpinned by nationally agreed principles, and which includes the requirement for assessment against the Australian Nursing Council (ANC) competencies for the initial registration of registered and enrolled nurses.

The ANC has in place a Collaborative Advisory Panel which provides advice to the ANC and the nurse regulatory authorities and informs processes for the recognition of overseas qualified nurses, by all Australian and NZ regulatory authorities. This process of collaboration, and the provision of advice, improves the standards for the purpose of mutual recognition, supporting the TTMRA. The ANC, along with State and Territory regulatory authorities is well placed to comment on the application of the MRA and the TTMRA in relation to the registration of nurses.