Commonwealth Department of Health and Ageing

RESPONSE TO THE PRODUCTIVITY COMMISSION'S DRAFT RESEARCH REPORT:

EVALUATION OF THE MUTUAL RECOGNITION SCHEMES - DRAFT RESEARCH REPORT

August 2003

INTRODUCTION

The Department of Health and Ageing welcomes the opportunity to provide written comments on the Productivity Commission's June 2003 Draft Research Report - *Evaluation of the Mutual Recognition Schemes*. The Department's response follows our submission, in April 2003 (submission No. 104), to the Commission's Review of the Mutual Recognition Arrangement (MRA) and the Trans Tasman Mutual Recognition Agreement (TTMRA).

Comments from the Therapeutic Goods Administration (TGA) on therapeutic goods issues and the Office of Chemical Safety (OCS), on industrial chemicals & domestic poisons scheduling matters, are included in this response. The OCS previously provided a supplementary submission to the review. Comments are also provided on food regulation.

The Department's response provides a number of suggested corrections to slight inaccuracies in the draft report and outlines disagreement with some preliminary findings.

THE RELEVANT RECOMMENDATIONS OF THE SUBMISSION

1. The TGA remains of the view that there should be no mutual recognition of the regulation of any product that were opted out from the joint arrangements, for so long as that opt out applies (preliminary finding 8.1 refers). As the provisions of the Treaty relating to departures from the joint Scheme have not been finalised between Australia and New Zealand, and there is already a process in place to resolve this issue, it would be preferable if the final report did not refer to their possible content.

2. The TGA does not agree that "where the TTMRA applies to New Zealand (NZ) dietary supplements and health care products (sic) if NZ decides to opt out of harmonisation, the requirement for each case to be examined on its merits that is advocated for therapeutic goods in general would better serve mutual recognition objectives than the automatic default position." Such an arrangement is inconsistent with the Australian Government's position that mutual recognition is not an acceptable option.

3. Preliminary finding 8.9 is not supported for two reasons. Firstly, 'complementary medicines' are not outside the TTMRA special exemption arrangements for therapeutic goods at present. Secondly, the finding should preferably read that when a report is next provided to COAG regarding the Therapeutic Goods Cooperation Program, information be provided to COAG regarding how New Zealand's complementary health care products are proposed to be dealt with in the future.

4. Preliminary finding 8.10 is supported - extending the special exemption for therapeutic goods, without the annual roll over requirements, until mid 2006, after which the special exemption could be reduced or eliminated. This would reduce administrative costs.

5. The Department agrees, in-principle, with the draft report's findings and recommendations regarding industrial chemicals and domestic poisons scheduling matters, except as corrected.

6. The OCS considers that the statement on p.138 of the draft report that "the National Drugs and Poisons Schedule Committee's (NDPSC) failure to make a firm commitment to the Globally Harmonised System for the classification and labelling of chemicals (GHS) ……..." is inappropriate. As the GHS document was finalised only recently it has been difficult for the NDPSC to consider its implementation in the consumer sector. In any event, formal adoption of the GHS in the consumer sector is a matter for State and Territory governments and not the NDPSC.

7. Preliminary finding 7.13 that "the *Imported Food Control Act 1992* is no longer needed for blocking risky food imports from New Zealand. We would only support this if certain provisions were met. The Department is concerned that situations may arise whereby Australia wishes to have a particular food risk-listed, but New Zealand does not. The Food Standards Australia New Zealand (FSANZ)/Australian Quarantine and Inspection Service (AQIS)/New Zealand Food Safety Authority (NZFSA) Working Group is currently exploring ways of harmonising the lists of risk categorised food commodities (Joint Risk List Project). We would therefore prefer that this issue be further considered by the Working Group. We would only support the preliminary finding (7.13) following the completion of the Joint Risk List Project.

8. We are also supportive of the recommendation that there needs to be reciprocal treatment of Australian food imported into New Zealand and that the existing and projected third country issues are recognised and dealt with effectively. The Department is not supportive of removing the *Imported Food Control Act 1992* from the list of permanent exemptions until all of these provisions have been met.

9. The Department reiterates it support for its proposal to establish a readily accessible, timely mechanism for TTMRA exemptions that are integrated into the legislation and decision making structures of the Australia New Zealand Joint Food Standards System 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.

COMMENTS ON THE DRAFT REPORT

1. THERAPUETIC GOODS

The comments below relate to the special exemption for therapeutic goods from the operation of the Trans Tasman Mutual Recognition Arrangement. The comments:

- identify some slight inaccuracies regarding the joint agency proposal and the description of the New Zealand dietary supplements/complementary health care products regulatory regime, and suggest some wording changes; and
- provide the Department's views regarding the preliminary findings of the draft report.

The comments are provided in the order in which their subject matter appears in the draft report.

The New Trans Tasman Therapeutic Products Agency

The Agency is not proposed to be "established under a Treaty and incorporated into domestic law in both Australia and New Zealand" (see p142). The Agency is to be established "in accordance with" the Treaty under Australian law, which will also incorporate the Agency. Both Australian and New Zealand legislation will then recognise the Agency as the therapeutic products regulator for that country, and give effect to the regulatory decisions of the Agency.

The wording of the Department's submission regarding the establishment of the Agency (ie, that it will be "established under a Treaty and Australian legislation") is preferable to that currently in the draft report.

Opting out

The draft report states that "the proposed Treaty will contain a narrowly drafted opt out clause to deal with localised threats to public health and safety and differences in cultural attitudes" (see p143). The treaty opt out clause has not, however, been finalised.

The Therapeutic Goods Administration (TGA) would like to discuss with the Commission its Preliminary Finding 8.1 of the draft report that "the different individual circumstances and the inconsistent consequences likely to arise from decisions to opt out of joint arrangements, the merit in including in the Treaty, which will establish the joint therapeutics agency, provisions to prescribe processes where each case is examined on its individual merits, to determine whether mutual recognition should still apply". Upon initial consideration the TGA is still of the view that there should be no mutual recognition of the regulation of any product that is opted out from the joint arrangements, for so long as that opt out applies. As the provisions of the Treaty relating to departures from the joint Scheme have not been finalised between Australia and New Zealand, and there is already a process in place to resolve this issue, it would be preferable if the final Report did not refer to its possible content.

Definition of therapeutic goods

It would be useful if it could be made clear that "the New Zealand Act regulating these products (dietary supplements) is the New Zealand Food Act 1981" (see p144, second last paragraph).

It is not entirely accurate to say that "the decision has been taken to include Australian complementary medicines and New Zealand dietary supplements and, in principle New Zealand dietary supplements and complementary healthcare products within the scope of the new agency." (p145, first para).

This is because New Zealand complementary health care products are New Zealand dietary supplements. The products currently regulated under the NZ Food Act 1981 Dietary Supplement Regulations comprise what New Zealand terms 'food type dietary supplements' and 'therapeutic type dietary supplements'. Only the 'therapeutic type dietary supplements' have been proposed to be regulated as complementary medicines by the joint Agency.

It would therefore be preferable if the first paragraph be amended to state only that: "The decision has been taken to include Australian complementary medicines and, in principle, New Zealand complementary healthcare products (therapeutic type dietary supplements) within the scope of the new agency." This wording could be checked, if necessary, with officials of the Medsafe unit of the New Zealand Ministry of Health.

For the reasons noted above, the inclusion of the rest of the first paragraph is not supported as TGA does not agree that "where the TTMRA applies to New Zealand dietary supplements and health care products (sic) if New Zealand decides to opt out of harmonisation, the requirement for each case to be examined on its merits that is advocated for therapeutic goods in general would better serve mutual recognition objectives than the automatic default position." Such an arrangement would be inconsistent with the Australian Government position that mutual recognition is not an acceptable option.

Preliminary finding 8.9 is not supported for two reasons. Firstly, by referring to 'complementary medicines' and not just to 'New Zealand complementary health care products', it implies that Australian complementary medicines are outside the TTMRA special exemption for therapeutic goods at present, which is not the case. Australian complementary medicines are regulated under the Therapeutic Goods Act 1989, which is listed in Schedule 3 as being exempt from the Trans Tasman Mutual Recognition Act 1997.

Secondly, were such a Cooperation Program Report prepared, and COAG agree that New Zealand complementary health care products be included within the special exemption, this would have to be done by either:

- listing the New Zealand Dietary Supplement Regulations in Schedule 3 to the NZ Trans Tasman Mutual Recognition Act 1997 as a whole in Schedule 3; or
- somehow distinguishing in law between the 'food style' dietary supplements and the 'therapeutic type dietary supplements', something which in the past has been found to be very hard to do.

Should the first approach be taken, as the Dietary Supplement Regulations apply to both 'food style' dietary supplements and 'therapeutic type' dietary supplements, this would make the 'food style' dietary supplements subject to an exemption from the TTMRA, and require reporting regarding them under the therapeutic goods cooperation program.

Even if it should be decided that these products be exempted from the TTMRA, it is not clear why progress towards harmonisation of the regulation of products that are more 'foods' than 'therapeutic goods' should be part of the therapeutic goods cooperation program.

As the New Zealand government has already agreed to review its Dietary Supplement Regulations and has agreed in-principle for the regulation of the New Zealand complementary health care products by the joint Agency it is not clear what would really be achieved by the preparation of such a Report.

Instead, the finding should preferably read that when a report is next provided to COAG regarding the Therapeutic Goods Cooperation Program, information be provided to COAG regarding how New Zealand's complementary health care products are proposed to be dealt with in the future.

Preliminary finding 8.10 is supported. However, it would be useful if the paragraph immediately above clarified that the transition period will be used to enable the Agency to issue new product licences for goods currently on the market, not to 'assess how long it will take" to issue them. The words 'a joint code' should preferably be replaced with the words 'the joint regulatory arrangements'. There is no proposal to develop an actual joint 'Code' with New Zealand.

2. INDUSTRIAL CHEMICALS & DOMESTIC POISONS SCHEDULING

The Department agrees in-principle with the draft report's findings and recommendations to date (re industrial chemicals and domestic poisons scheduling). The Department notes however, that there are a number of factual inaccuracies in the draft report and welcomes the opportunity to provide advice to the Productivity Commission on any further drafts prior to publication. Comments are provided below on the factual errors presented in the draft report under Chapter 8.2 - Hazardous substances, industrial chemicals and dangerous goods.

Inner labelling

The term "inner labelling" is used throughout the draft report and should be defined, as it is not a term used in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) or in related State and Territory legislation. The SUSDP specifies the term "immediate container labelling" instead of "inner labelling". The term "product labelling" may be an appropriate alternative as it refers to both primary pack (immediate packaging or carton) and immediate container labelling.

The existing regulatory framework - p.129

The introductory sentence should clarify if it is referring to chemicals in general or new chemicals specifically. If the former, the second sentence should be:

"Australia's complex regulatory system requires each chemical to be considered for classification and control under a number of different systems while in New Zealand every substance (not just every chemical) must be classified according to the country's unified regulatory regime."

If the latter, the second sentence should be:

"Australia's complex regulatory system requires each new chemical to be notified and assessed under a federal law with classification and control under other regulatory systems, while in New Zealand every new substance (not just every new chemical) must be notified and approved for use according to the country's unified regulatory regime."

Abbreviations - GHS should read: Globally Harmonised System for the classification and labelling of chemicals.

Barriers to trade - p.129

The statement that the divergence in approaches creates significant barriers to trade should be quantified. Australia and New Zealand constitute a very small part of the international

chemicals industry. The current arrangements may provide a barrier to trade, but given the current levels of trade between Australia and New Zealand, it is difficult to determine what the significant increase in chemicals trade would be if mutual recognition existed.

The New Zealand Framework - p.130

Para 3, second to last sentence should read:

"….. all substances which meet the GHS criteria for classification as a hazardous substance (the upper limit for acute toxicity (LD50) is 5000 mg/kg)".

The Australian Framework - p.131

Second para third sentence, reference to EA should be:

"It should be noted that there are no mandatory classification requirements relating to ecotoxicity, one of the properties covered by GHS, though EA assesses chemicals and recommends classification in accordance with GHS guidelines for NICNAS (ref) and APVMA (ref)".

Organisational structures for regulating chemicals in Australia - p.131 Figure 8.1

NICNAS State and territory agencies which have a regulatory relationship with NICNAS should be amended to include in Box 3, Column 1, State/Territory Health Authorities, Environmental Protection Authorities and Workcover Authorities, not consumer affairs.

The National Drugs and Poisons Schedule Committee (NDPSC) - p.132

Abbreviations - Amend to National Drugs and Poisons Schedule Committee (NDPSC).

The paragraph on the NDPSC should be corrected to read:

"is a statutory committee established under the Therapeutic Goods Act 1989, which recommends the appropriate classification or schedule for medicines, agricultural and veterinary chemicals, and domestic chemicals, for inclusion in the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP). The SUSDP contains nine Schedules, although currently Schedule 1 is not used. Substances are scheduled according to the degree of control recommended to be exercised over their availability in order to protect public health and safety. Criteria used for determining the appropriate scheduling of substances include toxicity profile, safety in use, potential for abuse and the need for access to such substances. The Appendices to the SUSDP supplement the Schedules by setting out additional controls or requirements. The NDPSC comprises of representatives from the Therapeutic Goods Administration (TGA), the Australian Pesticides and Veterinary Medicines Authority, State and Territory governments, New Zealand government, industry, consumers, practising pharmacists, and scientific and clinical experts. The Committee's recommendations are included in the SUSDP, which is given legal effect through relevant State and Territory poisons control legislation. While NDPSC recommendations have no force in Australian Government law, the SUSDP forms a template which is used by States and Territories to achieve uniform scheduling throughout Australia."

The National Occupational Health and Safety Commission - p.132

The layout implies that that the National Occupational Health and Safety Commission (NOHSC) is part of the Office of Chemical Safety.

The NOHSC para, last sentence, should be:

"NOHSC classifies chemicals as hazardous substances using the Approved Criteria for Classifying Hazardous Substances, where the upper limit for acute toxicity (LD50) is 2000 mg/kg."

Divergence from TGA Templates - p.134

The Department is not aware of States and Territories adapting NDPSC recommendations instead of adopting them in their entirety. In general, States and Territories adopt NDPSC recommendations but the method of adoption varies.

The following is an extract taken from the NCP Review of Drugs and Poisons & Controlled Substances Legislation (December 2000) – Part A; page 9:

"……..While jurisdictions generally adopt the SUSDP Schedule, some jurisdictions have chosen, in a few cases, not to do so.

The manner in which the NDPSC scheduling decisions are adopted into State and Territory laws also varies. In most jurisdictions they are adopted automatically by reference (unless action is taken not to accept a specific scheduling decision) while other jurisdictions require specific action, such as gazettal of the decisions, before they can come into force.

The Schedules may be adopted into drugs and poisons legislation (variously named by the jurisdictions) or controlled substances legislation (also variously named by the jurisdictions). There is considerable variation in the extent to which the appendixes to the SUSDP are adopted and, while State and Territory legislation may include similar provisions, the extent to which these reflect the SUSDP control level is much more variable than for the Schedules.

The restrictions on the way household chemical products are supplied, which have no national registration scheme, are also determined by the Schedule in which they are included."

The acronym for NOHSC - p. 134 & p.138

The acronym for NOHSC is incorrectly written as NOSCH - pages 134 & 138

Substances versus chemicals - p.135

1st sentence should be:

"In New Zealand, the regulatory system is substance based, whereas in Australia it is principally chemical based."

Overall, this para is too short as a more detailed discussion is required to describe the Australian regulatory system.

2nd para, last sentence is wrong – Europe has a chemical-based system.

Thresholds for requiring approvals – p.135

1st para should be expanded, eg:

"In New Zealand, all hazardous substances according to the GHS require approvals (the upper limit for classification for acute toxicity (LD50) is 5000 mg/kg). In Australia, all new industrial chemicals are notified and assessed under NICNAS (no limit), and industrial chemicals which are hazardous substances according to the NOHSC criteria and dangerous goods according to the ADG Code are regulated for control of use under State and Territory legislation (the upper limit for classification for acute toxicity (LD50) is 2000 mg/kg). Domestic chemicals are regulated under the SUSDP."

Thresholds for requiring approvals - p.135

The statement "……concentration levels below 5000 mg per kg, whereas state regulations coordinated by the NDPSC require applications for the classification and approval of all chemicals destined for domestic use or transportation" is not correct. Not all domestic chemicals are scheduled. As outlined above, there is no national scheme for registration of household chemicals (excluding agricultural and veterinary chemicals).

Agricultural and veterinary chemicals - p.136

The first sentence should be revised to read:

"In Australia, NDPSC classifies agricultural and veterinary chemicals mainly in relation to their toxicological profile."

APVMA is the Australian Pesticides and Veterinary Medicines Authority.

Current Regulatory Structures - p.138

The statement "the NDPSC's failure to make a firm commitment to the GHS ……..." is inappropriate. As the GHS document was finalised only recently it has been difficult for the NDPSC to consider its implementation in the consumer sector. In any event, formal adoption of the GHS in the consumer sector is a matter for State and Territory governments and not the NDPSC.

3. FOOD REGULATION

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's comments on the draft report will focus on two issues:

- The report's preliminary finding (7.13) to remove the *Imported Food Control Act 1992* from the list of TTMRA permanent exemptions provided that there is reciprocal treatment of Australian food imported into New Zealand and the existing and projected third country issues are recognised and dealt with effectively; and
- The Department's proposal 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.

Recommendation to Remove the Imported Food Control Act 1992 from the List of Permanent Exemptions

The 'risk categorisation' process under the *Imported Food Control Act 1992* is the most food-specific TTMRA exemption mechanism currently accessible. The draft report recommends that "the *Imported Food Control Act 1992* is no longer needed for blocking risky food imports from New Zealand. This Act could be removed from the list of TTRMRA permanent exemptions provided that there is reciprocal treatment of Australian food imported into New Zealand and the existing and projected third country issues are recognised and dealt with effectively." (Preliminary Finding 7.13)

The Department is aware of the work currently being undertaken by the FSANZ/AQIS/ NZFSA working group on exploring ways of harmonising the lists of risk categorised food commodities. Although the importance of harmonising the lists of risk categorised foods is recognised, the Department is concerned that situations may arise whereby Australia wishes to have a food risk-listed but New Zealand does not. A current example of this is for herbs and spices treated with ethylene oxide. Another example is in relation to Bovine Spongiform Encephalopathy (BSE) and Australia's unsuccessful efforts to introduce a joint country certification arrangement with New Zealand resulting in New Zealand introducing a separate scheme. This could result in New Zealand classifying countries differently to Australia. The Department therefore requests that this issue be considered by the FSANZ/AQIS/NZFSA working group as part of their discussions on harmonising the lists of risk categorised food commodities.

The Department would be supportive of the draft report's preliminary finding to remove the *Imported Food Control Act 1992* from the list of TTMRA permanent exemptions (preliminary finding 7.13) only following the completion of the joint risk list project. Consistent with this, the Department is also supportive of the recommendation that there needs to be reciprocal treatment of Australian food imported into New Zealand and that the existing and projected third country issues are recognised and dealt with effectively. The Department is not supportive of removing the *Imported Food Control Act 1992* from the list of permanent exemptions until these provisions have been met.

TTMRA Exemption Mechanism for Food Standards

The TTMRA 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 Department recognises that anomalies occur in only a minority of instances 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 acknowledges 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.

However, there are a number of current examples for which there are conflicting standards in Australia and New Zealand which are of regulatory concern including:

- 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 New Zealand in adopting harmonised joint food standards, which would be Australia's preferred outcome in most cases. Local interests or political controversy may influence specific issues, leading to New Zealand's 'opting out' of a harmonised food standard. The New Zealand industry then remains unaffected, and can continue to export to

the Australian market under the TTMRA, with the decision not to harmonise being made at no cost to the New Zealand economy.

If mutual recognition were not the default or assured outcome when New Zealand gave 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 a mechanism to stop these foods coming into Australia. If the *Imported Food Control Act 1992* were removed, no such mechanism would exist.

Options for Integrating TTMRA Exemptions with Food Regulation

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.

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 and in light of the draft report's preliminary finding 7.13, 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 as a whole could be given the power to authorise 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.

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 1997,* the Australian Government 's TTMRA legislation.

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 Australian Government 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.