Issues for the TTMRA Review

The Issues

There are two areas where the TTMRA impacts on food regulation.

First, the process of harmonising food regulations in Australia and New Zealand is well advanced, but outstanding differences remain which impose costs on industry and may also have implications for public health and safety.

The second issue is the current permanent exemption under the TTMRA of *risk categorised food commodities*.

These issues are examined in detail below and various options are presented to address the outstanding differences in food regulation.

Background

Developing Food Standards

Responsibility for developing and approving new food standards, or variations to food standards, rests with Food Standards Australia New Zealand (FSANZ). FSANZ is an independent statutory authority that develops and amends food standards for composition, labelling and contaminants, including microbiological limits, that apply to all foods produced or imported for sale in Australia and New Zealand. It also develops other food standards that do not apply in New Zealand.

FSANZ is required to notify the Australia and New Zealand Food Regulation Ministerial Council of any amended or new food standard that it approves. The Ministerial Council may then reject, amend or seek a review of these standards.

The Ministerial Council also has responsibility to set policy guidelines for the development of food standards by FSANZ. It does this based on advice from the Food Regulation Standing Committee, which comprises senior government officials from the Commonwealth, New Zealand, the States and Territories.

Implementing Food Standards

New or amended food standards that have been developed by FSANZ are published in the Commonwealth of Australia Gazette, as required by the *FSANZ Act*. From the date of gazettal, the new or amended standards take effect and are adopted into the legislation of the States and Territories by reference, in accordance with the Food Regulation Agreement between the Commonwealth, States and Territories of 3 November 2003. These food standards are then published in the *Australia New Zealand Food Standards Code* (the Code). A gazetted food standard may include special provisions in relation to a State or Territory, if the Ministerial Council is satisfied that the provision is necessary because of exceptional conditions.

A State or Territory may unilaterally adopt or vary a food standard under its legislation, on an urgent issue affecting public health and safety, provided that: (1) the new food standard applies for a period of no longer than twelve months; (2) the jurisdiction immediately notifies FSANZ of its intention to adopt or vary a food standard; and (3) the jurisdiction immediately applies to FSANZ for the new or amended standard to be incorporated into the Code and apply to all jurisdictions.

The arrangements in relation to New Zealand are set out in the *Agreement between the Government of Australia and the Government of New Zealand concerning a joint food standards system*, commonly known as 'the Food Treaty'. The Food Treaty defines the scope for the joint food standards system and specifically excludes food hygiene and provides for New Zealand to opt out or vary a proposed standard at the time it is notified to Ministers. New Zealand also has a different approach to dietary supplements than Australia, regulating these under Dietary Supplements Regulations made under the New Zealand Food Act.

New Zealand follows similar legislative procedures in relation to joint standards as the States and Territories and adopts food standards that are published in the New Zealand Gazette by FSANZ into its legislation by reference. The New Zealand procedures provide for a period (28 days) following gazettal of the adoption to allow New Zealand industry time to adjust to changes should these be immediate and provide forewarning in other cases.

The joint Code is enforced by Governments of the States, Territories and New Zealand.

Objectives of Food Regulation

The objectives of food regulation in Australia and New Zealand are expressed in Commonwealth legislation that establishes the joint food standards setting body, FSANZ.

The first order statutory objectives, in descending priority order, are:

1. the protection of public health and safety;
2. the provision of adequate information relating to food to enable consumers to make informed choices; and
3. the prevention of misleading or deceptive conduct.

There are a number of other factors that must be taken into account.

Harmonising Food Regulations in Australia and New Zealand

In May 1995, Australia and New Zealand signed a Food Treaty that committed both countries to developing harmonised food standards and also established a new joint food regulation authority. The authority undertook a thorough review of all existing food standards, from the perspective of developing 'minimum effective regulation' and, with the exception of a few standards completed this project by December 2000. The Code was implemented with a two-year transition period during which the old standards (and in New Zealand's case, old food regulations) co-existed with the new Code, to facilitate adjustment by industry. Midway through 2002 Australia and New Zealand amended the Food Treaty to reflect changes to the food regulatory system. Both countries repealed their old food standards and regulations at the end of 2002. New Zealand retained some food regulations that were outside the scope of the Food Treaty such as food hygiene related provisions.

New Zealand has its Dietary Supplements Regulations under review including those aspects related to food-type dietary supplements. The New Zealand Government has given in-principle support to repeal the food aspects of these Regulations, and for food-type dietary supplements to be regulated under the Australia New Zealand Food Standards Code. It is holding off further action relating to these regulations until a number of other processes are progressed or concluded. These include:

1. Examination by New Zealand and Australia of the prospect of a Joint Therapeutic Goods Agency that would regulate therapeutic goods in Australia and New Zealand. Many products under the Dietary Supplements Regulations are therapeutic goods according to Australian definition. A joint therapeutics scheme is expected to commence in 2005.

2. Examination of complementary medicines by a New Zealand Select Committee that commenced in the latter part of 2002 and is expected to conclude in the next couple of months.

3. Consideration of the future of 'food-type' dietary supplements' manufactured under the Dietary Supplements Regulations. This requires broad public consultation in New Zealand. It is expected that the implications for food will be clearer by the end of this project.

4. Accommodation of food-type dietary supplements in the Australia New Zealand Food Standards Code. The Code does not currently include a standard for food-type dietary supplements. Work on this will not commence until Ministers finalise policy guidance to issue to FSANZ within which FSANZ can then proceed with developing provisions for the Code.

The new Food Standards Code contains a range of "Australia only" standards, where the matters fall outside the scope of the Food Treaty. New Zealand already has equivalent legislation in place in these areas: food hygiene; food processing standards; maximum residue limits of chemicals in food; and the standards currently under development for primary production and processing. Other 'Australia only' standards address health and safety issues extant in the Australian population. These include the addition of vitamin D to margarine and the addition of thiamine to bread-making flour. Variations such as these are possible in the future for either Australia or New Zealand. As well, the Food Treaty enables New Zealand to "opt out" of new food standards when specified criteria apply (such as health and safety, cultural and third country trade factors) and potentially could lead to further "Australia only" standards. However, the opt out provision is regarded very much as a last resort provision and has not been used to date.

The TTMRA was effective in facilitating trans-Tasman trade in food products when food standards in Australia and New Zealand were different – i.e. from the inception of the TTMRA in May 1997 to December 2002. During this period it would have been recognised as a force supporting the development and implementation of uniform food standards.

At present, the Code would be the major influence on trans-Tasman trade in food products. The TTMRA would impact on trade in only a small group of products, principally where different food regulations exist in the two jurisdictions.

Inspection of Trans-Tasman Imports and Exports

High-risk food imports are accorded a high level of control by both Australia and New Zealand. The lists of foods deemed to be high risk differs between the two countries, as does the approach to import inspection and certification.

New Zealand to Australia

All food produced or manufactured in New Zealand must meet New Zealand safety and suitability standards. In addition, the New Zealand Food Safety Authority operates an export inspection and certification program that covers the majority of food products exported from New Zealand including products defined as high risk by both Australia and New Zealand. Certification of Australian defined high risk products is accepted by the Australian Quarantine and Inspection Service (AQIS) and in these cases AQIS does not require their routine physical inspection. Where New Zealand imports of any foods listed by Australia as high-risk have not been certified by NZFSA, they are subject to physical inspection at a rate of 100% that applies to high-risk imports from all countries. (A supplier that consistently passes the import inspections will be recognised by AQIS and inspected at a lower rate.)

Australia to New Zealand

AQIS requires all exporters of high-risk food products to be registered for export and to comply with AQIS inspection programs. All other food produced in Australia must satisfy all relevant requirements in the Australia New Zealand Food Standards Code. To implement the spirit of the TTMRA, AQIS described the majority of food products as 'prescribed goods' under the Export Control Act, if the destination of the exports was New Zealand. This enabled Australian suppliers to access the New Zealand market without the requirement for export registration and AQIS inspection. Where foods are considered by the New Zealand authorities to be high risk, Australian products are subject to inspection and testing unless accompanied by an AQIS certificate.

New Zealand's inspection of food imports is largely focussed on the list of high-risk commodities. Imports of other food items are presumed safe (unless otherwise notified) or very low risk and not inspected systematically, including imports that are subsequently 're-exported' to Australia.

The Process of obtaining an Exemption under the TTMRA

The TTMRA contains provisions to exempt a product or class of products from the mutual recognition obligations, on either a temporary or permanent basis.

Any jurisdiction can unilaterally invoke a temporary exemption of a product on the basis of a threat to health or safety, enacted through a gazettal under its TTMRA legislation. The temporary exemption only applies to that jurisdiction. In Australia, trans-Tasman trade to other States and Territories is still possible and inter-state trade under the MRA could see the product on sale in the jurisdiction that made the temporary exemption. Where all Australian jurisdictions agree that a particular New Zealand product poses a threat to health or safety then it is open to each jurisdiction to separately invoke a temporary exemption under its TTMRA legislation. Ideally it would be preferable to invoke a temporary exemption under a single, combined process involving the relevant Ministerial Council, which for food regulation would be the Australia and New Zealand Food Regulation Ministerial Council.

Once the Ministerial Council determined that a temporary exemption should apply to a particular product, it would be sufficient for the Commonwealth to gazette a regulation under its own TTRMA legislation.

A temporary exemption suspends the operation of the TTMRA in relation to a product for 12 months. Within that period the relevant Ministerial Council must determine:

1. that the product does not pose a real threat to health or safety and mutual recognition should be allowed to operate; or
2. the regulatory requirements between jurisdictions should be harmonised or in some other way brought into alignment; or
3. the product should be permanently exempted from the TTMRA.

The Ministerial Council determination requires a vote in favour of not less than two-thirds of participating parties. The Ministerial Council must then seek approval from the Heads of Government. For the first two options, if at least one-third of Heads of Government do not disapprove of the determination within three months of its receipt, then jurisdictions must take action to implement the determination as soon as practicable. For the third option of permanent exemption to be successful, the unanimous agreement of all Heads of Government is required.

The TTMRA legislation provides for an additional 12 month period during which the mutual recognition principle would not apply to a temporarily exempt product, so that legislative or other action can be taken to give legal force to a Ministerial Council determination.

Anomalies under the Existing Arrangements

Differences in food regulation between Australia and New Zealand occur where one country does not implement a specific food standard contained in the *Australia New Zealand Food Standards Code*. In these cases each country has a different assessment of a specific health risk or of the strategy to manage that risk. These circumstances have the potential to raise public health and safety concerns for the country adopting the more conservative risk management strategy, because the TTMRA allows food products from the other country, produced under a less conservative regime, to be imported and available for sale.

These circumstances may also impact on industry. Costs may be borne by industry of the country with a more conservative risk management strategy, because it may not be able to respond competitively to imports from the other country that are produced under a less conservative risk management regime.

The full range of food standards that Australia and New Zealand jointly subscribe to is vast, covering composition and labelling requirements of close to all food products on sale in the two countries. Almost all food products traded across the Tasman Sea would be covered by the (joint) *Australia New Zealand Food Standards Code*. In contrast, the specific instances of regulatory anomalies in trans-Tasman trade would be rare and very small in comparison with the total volume of traded food items. Nevertheless differences in food law between the two countries can have a significant impact on a sector of the food industry. An anomaly may also have implications for pubic health and safety. To date the anomalies have not raised any urgent health risks, although the risks have still been considered substantive by the Australia

and New Zealand Food Regulation Ministerial Council and to warrant an active risk management strategy.

Three examples illustrate these issues: beverages produced under New Zealand's Dietary Supplements Regulations; the use of ethylene oxide; and the use of hemp seed oil in food.

1. New Zealand's Dietary Supplements Regulations

The Dietary Supplements Regulations have been used in recent years to accommodate products more closely associated with foods in addition to the range of complementary medicines. These food-type products include a number that are fortified with vitamins and minerals to levels not permitted under the Australia New Zealand Food Standards Code. Some New Zealand manufacturers have chosen to produce food-type items under these regulations, rather than under the Australia New Zealand Food Standards Code, and export them to Australia under the TTMRA.

The prominent examples from recent years are sports drinks and caffeinated beverages.

These products are more highly fortified with vitamins and minerals than other related products and their export to Australia under the TTMRA, according to the decision of the Ministerial Council, potentially exposed the community to public health and safety risks. The principal risks considered by the Ministerial Council concerned consumption by non-target consumers, that is by vulnerable sub-groups in the community, and also from misuse. This situation prompted the development of food standards for both products, where the risks were managed by labelling and advice statements. However the time taken from identification of the risks to the development of new standards was lengthy – a number of years. During this time the Australian community was potentially exposed to public health and safety risks.

Other innovative products permitted under the *Dietary Supplements Regulations*, but inconsistent with the Code, may be produced or imported into New Zealand and exported to Australia under the TTMRA, and potentially expose Australia to new public health and safety risks.

A further potential risk to public health and safety arises from imports of food products into Australia from third countries, via New Zealand. New Zealand's inspection of food imports from all countries is limited to their list of high-risk commodities. Imports of all other food items are not routinely inspected. This means that the perceived easy access to the New Zealand market from third countries is also an easy (and unregulated) route to the Australian market, as Australia inspects only high-risk food exported from New Zealand. The implications of this are that the import controls Australia has implemented for low risk food from other countries can be bypassed.

The regulatory differences also impose costs on the Australian economy. While New Zealand manufacturers may produce food-type items under the *Dietary Supplements Regulations*, Australian manufacturers are not permitted to do so under the Australia New Zealand Food Standards Code and hence cannot respond competitively to an emerging market. For example, Australian soft drinks manufacturers said that the inability to produce sports drinks and caffeinated beverages, prior to the standards being approved, was very costly to the industry and involved forgone export opportunities. There may be a cost, too, to Australian government enforcement agencies in terms of extra time and resources to determine why a product without permissions under the Code is nonetheless legally available for sale.

These issues would be addressed with an alignment of the treatment of complementary medicines and food-type dietary supplements between the two countries.

2. Ethylene Oxide

Ethylene oxide is used primarily to purify herbs and spices. It is a known carcinogen and poses a risk to public health and safety if traces of the substance are contained in food products. It is also dangerous to workers in the food manufacturing industry if they are involved in its applications. These risks will be managed in Australia by banning the substance under the Australia-only provisions of the Code, coming into effect on 1 October 2003. In New Zealand ethylene oxide continues to be permitted for use in food manufacturing under the maximum residue limits regime, which is outside the scope of the Food Treaty.

Consequently the Australian community is potentially at risk from traces of ethylene oxide being contained in food products manufactured or imported into New Zealand, that might be exported to Australia under the TTMRA.

3. Hemp Seed Oil

An application to permit the use of hemp seed oil as an ingredient in food products was disallowed by the Australia and New Zealand Food Regulation Ministerial Council in May 2002. Under a policy agreement between Australian and New Zealand Ministers, when the old food standards were repealed in December 2002, New Zealand continued to allow the sale of food products containing hemp seed oil. This has effectively resulted in an anomaly in the food standards provisions of the two countries.

Options to address Anomalies in the Regulations

The following options reflect different perspectives on the prospects for continuing harmonisation of food standards between Australia and New Zealand and the extent that goodwill on both sides of the Tasman will be sufficient to address food regulation issues.

1. The default option is not to take any action.

   Under this option, we acknowledge that the outstanding differences in regulation affect a very small number of traded food items, compared with all products that are covered under the Code, and consequently the level of risk to the community would be quite small. The risk will fall further with the development of a standard for food type dietary supplements, supported by administrative processes that are occurring now in Australia and New Zealand. Given the progress that has been made to harmonise food standards, the goodwill this engenders, and the commitment of the New Zealand Government, it is reasonable to expect that harmonisation will continue. For matters outside the Food Treaty, such as ethylene oxide, Australia would adopt a strategy of sharing information and generally being cooperative in assisting New Zealand to address these issues.

2. Establish a new permanent exemption under the TTMRA for food items not compliant with the Code. Regulations that are consistent with FSANZ's statutory objectives will be identified by specific criteria and not subject to this exemption.

   Outstanding differences in food regulations will be a permanent feature of the trade and regulatory environment in Australia and New Zealand. There will always be a possibility that food items exported from New Zealand do not comply with the Code. These permanent risks arise from areas outside the scope of the Food Treaty, such as maximum residue limits (as in the case of ethylene oxide), processing standards, and where New Zealand opts out of a new standard. Risks also arise where the harmonisation process is incomplete or has stalled. In particular, it is unclear how the anomaly of food type dietary supplements will be resolved; if New Zealand pursues a policy of 'convergence' rather than 'harmonisation' then the outstanding differences will remain.

   Moreover, the TTMRA is now an impediment to full harmonisation and weakens the incentive for the two parties to complete the process. Under the TTMRA, industry in the exporting country is unaffected by differing regulation between the two countries and will continue to export to the other market. This removes the incentive for further harmonisation. This incentive structure will change with the introduction of a permanent exemption under the TTMRA and encourage completion of the harmonisation process. The result – continuing progress towards full harmonisation – is highly desirable from the perspectives of good regulatory practice and protecting public health and safety.

   The criteria to identify food-related regulation that is consistent with FSANZ's statutory objectives will be developed jointly by Australia and New Zealand.

   The Australia and New Zealand Food Regulation Ministerial Council could take steps to initiate a permanent exemption of food items not compliant with the joint Food Standards Code. The process would be complex and lengthy. Ministers may anticipate that approval of all Heads of Government would not be obtained and therefore would be reluctant to commit resources to an obviously unsuccessful project. The Productivity Commission could address this issue by recommending a permanent exemption for food items not compliant with the Code, in its review of the TTMRA.

   The advantage of addressing this issue through a permanent exemption, as opposed to a temporary exemption on a case-by-case basis (see option 3 below), is that food regulation is clear to all stakeholders on what is required. A permanent exemption provides the incentive for all stakeholders to comply with a single, joint system of food regulation. In contrast, a case-by-case approach could involve a difficult and lengthy decision-making process. In practice it may be confined to addressing the urgent risks, and not deal with the range of more moderate health risks that are considered by FSANZ and the Australia and New Zealand Food Regulation Ministerial Council.

3. Utilise the temporary exemption mechanisms under the TTMRA to facilitate a timely response to emerging public health and safety risks.

   An alternative strategy for managing health and safety risks to the community would be to improve the temporary exceptions mechanisms under the TTMRA and facilitate a timely response to emerging risks on a case-by-case basis.

The strategy would utilise the existing capacity of the Australia and New Zealand Food Regulation Ministerial Council to determine a temporary exemption. The determination must not be disapproved by one-third of the Heads of Governments for it to be enacted in TTMRA legislation. The strategy would also require immediate action to develop harmonised food regulation in all jurisdictions. The difficulty with this process is that the additional temporary exemption period of 12 months to develop a harmonised standard would frequently be insufficient to complete a thorough assessment of the risks and develop an adequate risk management strategy. The Productivity Commission could address this issue by allowing the additional temporary exemption period to extend to whatever time is reasonably required to complete the process.

The permanent exemption for *risk categorised food commodities*

Risk categorised food commodities are goods that inherently pose a high risk to public health and safety and hence their import should be scrutinised and controlled. In relation to trans-Tasman trade, they are controlled through a permanent exemption to the TTMRA, where Australia and New Zealand both have a list of high-risk food imports. This is an adequate form of protection, but it can be enhanced by moving to a harmonised list of high-risk food imports. Such a move, if and when implemented, would remove the need for this permanent exemption.

Regulatory agencies in Australia and New Zealand are currently exploring ways to review and harmonise their lists of risk categorised food commodities. A Working Group comprising the New Zealand Food Safety Authority, AQIS and FSANZ was recently established to progress this initiative and will report back to the respective agencies by July 2003.

Given the commitment on both sides of the Tasman to resolve this issue, the permanent exemption for risk categorised food commodities could be abolished when the regulatory authorities have agreed to a joint high-risk food list.

Recommendations

- Creation of a permanent exemption in the TTMRA for all products not covered in the *Australia New Zealand Food Standards Code*, with criteria to identify food-related regulations that should not be subject to this exemption; and

- Abolition of the permanent exemption for risk categorised food commodities when the regulatory authorities have agreed to a joint high-risk food list.

Food Standards Australia New Zealand
May 2003